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August 14, 2000

**Docket No. 00N-0504**

**Re: Egg Safety: Current Thinking Papers on the National Standards for Egg Safety**

Attn: Dockets Management Branch (HFA-305)

Food and Drug Administration

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Rockville, MD 20852

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Comments Re: Docket No. 00N-0504. On behalf of our 10,000 members nationwide, we take this opportunity to express our disappointment in and objection to the approach to reducing *Salmonella enteritidis* (SE) summarized in the FDA's "On-Farm Thinking Paper" presented at the Public Meeting on Eggs, July 31, 2000. This "Thinking Paper" does not incorporate or even so much as acknowledge the information and recommendations that have been submitted to the Food and Drug Administration and the Food Safety and Inspection Service regarding the cause and effect relationship between animal welfare and foodborne pathogens in eggs. With citizens' tax dollars the U.S. Department of Agriculture has generated studies and conclusions that are omitted from the "Current On-Farm Thinking Paper on the National Standards for Egg Safety." This omission represents an accommodation of the egg industry at the expense of public health and animal welfare. Therefore, United Poultry Concerns requests that prior to finalization of Egg Safety National Standards, the FDA and FSIS hold a closed door public interest-animal welfare meeting analogous to the closed door meetings that these agencies have been holding with the egg industry. In addition, we renew our request that the Food and Drug Administration prohibit forced molting. FDA can do this, because the agency has regulatory authority for shell eggs throughout the farm-to-table process and "sole federal authority for regulating food safety on egg farms" (GAO, July 1999, p. 31).

Together, animal welfare organizations and consumer advocacy organizations have presented extensive oral and written testimony during the past two years, including a Citizen Petition (**Docket No. 98P-0203/CP1**), documenting the cause and effect relationship between the welfare abuse known as **forced molting** and *Salmonella enteritidis* (SE) in eggs. We have asked the FDA to prohibit the inhumane stress-inducing sustenance withholding practice of forced molting, which has been shown to

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induce cellular immune dysfunction in force-molted hens. Forced molting predisposes the hens and their eggs to *Salmonella enteritidis* infection. A USDA Risk Assessment predicted that human SE infections could be “reduced by 2.1 percent if forced molting were eliminated (USDA Farm Animal Well-Being Task Group Meeting document, July 21, 1998). This would be approximately 6300 cases per year in the United States (Transcript, April 6, 2000, Sacramento, CA, p. 19). USDA’s Farm Animal Well-Being Task Group has acknowledged “serious concerns regarding the practice of forced molting of poultry” with respect to “the humaneness of this practice as well as the food safety issue” (USDA-APHIS, Letter, August 21, 1998). USDA’s Food Safety and Inspection Service wrote: “FSIS recognizes that public health concerns are raised by highly stressful forced molting practices. For example, extended starvation and water deprivation practices lead to increased shedding of *Salmonella enteritidis* by laying hens subjected to these practices” (USDA-FSIS, Letter, August 21, 1998).

Despite these government acknowledgements, the “On-Farm Thinking Paper” of July 31 mentions forced molting only to the extent of suggesting that “environmental testing” may be done 25 weeks after each molting period. This is 5 months and 25 days after the 6–8 week molting period. This is the time when the laying cycle is concluding and the flock is either going to be (a) disposed of or (b) restarved in preparation for the next cycle in which the dwindling survivor population of force-molted hens will be put back into production. These are the “older hens” that, together with “heavy rodent populations,” have been linked with forced molting to increased SE bacterial levels and chicken contamination (GAO, July 1999; Holt, 1993; FDA Docket No. 98P-0203/CP1).

The “On-Farm Thinking Paper” ignores the fact that the USDA, in collaboration with the Pennsylvania Department of Agriculture, conducted field studies of 31 flocks over a two-year period, from May 1, 1992 to May 1, 1994, which showed that “molted flocks produced SE-positive eggs twice as frequently as non-molted flocks for a period up to 140 days [4 ½ months] following molt (Salmonella Enteritidis Risk Assessment-Shell Eggs and Egg Products, 1998, [www.fsis.usda.gov/ophs/risk/pdfrisk2.pdf](http://www.fsis.usda.gov/ophs/risk/pdfrisk2.pdf)).

We wish to point out that the USDA Food Safety and Inspection Service publicly acknowledged the link between stress in farmed animals and human disease. In the February 3, 1995 Federal Register notice of its proposed HACCP rule, FSIS states: “There are major aspects in the production phase that can influence incidence, control, and prevention of potential human pathogens. . . . Management systems addressing increased animal welfare and better husbandry decrease levels of stress, and would be expected to decrease the incidence of pathogens [by reducing] stress-related immune suppression.”

USDA immunologist Peter Holt and his colleagues published a series of Agricultural Research Service studies between 1992 and 1996 in which they are found that depriving hens of sustenance causes immune suppression, thereby predisposing the birds to SE invasion, colonization and migration. As summarized by USDA's Food Safety and Inspection Service:

There is epidemiologic evidence which associates [forced] molting with higher prevalence of SE in flocks. Molted SE-positive flocks also seem to produce SE-positive eggs more frequently than their non-molted counterparts. Experimentally, Holt et al. (1996, 1995, 1994, 1993, 1992) have demonstrated that molting is associated with increased numbers of SE in hens' intestinal tracts, and higher rates of SE-positive eggs are produced following [the forced] molt. (*Salmonella Enteritidis Risk Assessment-Shell Eggs and Egg Products*, 1998).

In study after study, what Holt and his colleagues referred to in 1994 (p. 1268) as the "traumatic physiological impact" of total feed removal resulted in a significant increase in systemic and infectious diseases. Their studies showed that:

Molted birds shed significantly higher numbers of SE during the feed removal period than the unmolted group. Histological examination of cecum and colon from molted infected hens revealed inflammation compared with minimal changes in the intestines of unmolted infected hens. Molting, in combination with an SE infection, created an actual disease state in the alimentary tract of affected hens, whereas, under normal conditions, little SE-induced morbidity occurred in adult birds. (Holt & Porter, 1992:1842).

Holt and his colleagues found that "induced molting has a profound effect on both intestinal and extraintestinal infection by *S. enteritidis*, and these effects occur 24 hr post infection in the intestine and within 48 hr postinfection in the livers and spleens" (Holt et al., 1995:55). In a paper published during the same year of 1995, they observed that "The stress of molting thus appears to result in an increase in intestinal numbers of *S. enteritidis* and the transmission to uninfected hens. . . . Stress has also been shown to cause the reactivation and transmission of infectious laryngotracheitis virus in hens" (Holt, 1995:248).

Holt summarized the causality between the withholding of food, immunosuppression, and diseases in hens including, but not confined to, *Salmonella enteritidis* in a review paper obtained by United Poultry Concerns through a Freedom of Information Act request to the USDA, June 3, 1999. This undated 17-page paper, "Impact of Induced Molting on Immunity and *Salmonella enteritidis* infection in Laying Hens," cites studies showing that deficient diets diminished cell-mediated immunity in mammals and birds (p. 3). Likewise, a concurrency of systemic and infectious disease conditions occurs in force-molted hens:

According to Holt, to cite key points:

“An altered immune response was also observed in birds subjected to induced molting through feed withdrawal” (p. 3).

Total peripheral blood lymphocyte numbers were significantly decreased in molted birds” (p. 3).

“Elevated levels of serum corticosterone were detected during times of stress [in birds and mammals in other studies]. . . . A similar elevation in this stress hormone was noted in hens subjected to feed removal . . . which may be responsible for observed effects on immunity during an induced molt” (pp. 3-4).

“Protection [of internal organs from pathogens] is mediated by effector T cells and by a battery of hormone messages called lymphokines which regulate the intensity of the immune response and define what effector cells will play a role in the protection. Breaching this immunity can dramatically alter its ability to protect the host against infection” (p. 4).

“The discovery [was] that the immune system in molted hens was compromised” (p. 4).

“The potential problems associated with the presence of *S. enteritidis* in the flock environment therefore becomes [sic] exacerbated when birds are exposed to a stress situation such as feed removal” p. 5).

“Stress situations can reactivate a previous infection. . . . and feed withdrawal to induce a molt can also cause the recurrence of a previous *S. enteritidis* infection” (p. 5).

“[R]ecrudescence of infection was observed significantly more often in molted birds. These birds shed significantly more *S. enteritidis* and more readily transmitted the organism to previously uninfected, but contact-exposed hens” (p. 5).

“The molted hens also produced more eggs contaminated with the organism” (p. 5).

Dismissal of the scientific data and public input implies that the government’s purported concern for public health in the case of eggborne contamination is a pretense. Transcripts of Proceedings of the Egg Safety Public Meeting in Columbus, Ohio, March 30, 2000, and the Egg Safety Public Meeting in Sacramento, California, April 6, 2000 reveal the many substantive arguments raised by representatives from both animal protection and consumer advocacy organizations concerning the need for the FDA to prohibit forced

molting in keeping with the agency's authority to regulate, including if need be to prohibit, farming practices that post a significant risk to human health. FDA representative Robert Brackett referred as a matter of course to "forced molting and other stress factors that would lead to enhanced SE in eggs" (Transcript, April 6, 2000, Public Meeting, Sacramento, CA, p. 73).

FDA and FSIS claim they are soliciting public views on whether the agencies are implementing the Egg Safety Plan "in a way that will best achieve its public health goals" (Federal Register, July 11, 2000: 42708). United Poultry Concerns and other public interest organizations have responded to this solicitation in good faith, with relevant facts, and the answer is no, you are not. We have presented to the government its own evidence, which is being ignored in deference to the egg industry. The "On-Farm Thinking Paper" distributed at the July 31 Public Meeting is a nonresponsive paper.

An article in the *Journal of the American Veterinary Medical Association (JAVMA)* says that *Salmonella* is a "major public health problem" in the United States. According to the article, "Eggs are the predominant source of *Salmonella* Enteritidis infection in humans," and many of the egg-associated *Salmonella* outbreaks in the United States "were traced back to the farm of origin and have documentation that infected hens were the source of the outbreak" (Angulo and Swerdlow, 1998, p.1731). The authors concluded that "control of *Salmonella* will require preventing infections in egg-laying and broiler chickens" (p. 1731).

One way to do this is to eliminate forced molting. As Gary D. Butcher, DVM, a poultry veterinarian, and Richard Miles, PhD, a poultry nutritionist at the University of Florida, conclude: "No matter what specific or combination of factors are involved in causing increased susceptibility of laying hens to SE infection, the fact remains that laying hens undergoing a forced molt by feed removal are under stress and are more likely to become salmonella shedders as compared to non-molted hens" (*Salmonella Control and Molting of Egg-Laying Flocks—Are They Compatible*, July 1994).

The bottom line is that *Salmonella* control and forced molting are not compatible. Why is this elementary fact being ignored by the agencies that are claiming to be concerned about, and are charged with protecting, the public's health from "farm to table"?

Mary Evans of the Centers for Disease Control reported at the March 30, 2000 Egg Safety Public Meeting in Columbus, Ohio, that while in terms of outbreaks there have been major declines in SE in certain regions of the United States, "the number of outbreaks have remained relatively unchanged in the most recent years, like, '97, '98, and '99," and that "with outbreaks with a known source, we know that the predominant vehicle remains raw or undercooked eggs" (p. 5). Evans noted, moreover, that every culture-confirmed case actually represents 38 cases in the general population (p. 4). This

information corresponds with the acknowledgement in *Foodborne Pathogens: Risks and Consequences*, published by the Council for Agricultural Science and Technology (CAST) in September 1994 that “[T]he outbreak cases reported to the CDC constitute a small fraction of the actual numbers” (p. 51). In other words, *Salmonella enteritidis* has been and continues to be a significant disease problem in the United States. To suggest that this infectious disease can be meaningfully addressed while ignoring the biological condition and responses of the birds to the treatment they receive and must cope with is nonsense. To call forced molting a Best Management Practice is, as a speaker at the Columbus, Ohio Public Meeting said, absurd (Transcript, March 30, 2000, p. 12).

### CONCLUSION

It is significant that an intestinal microorganism like *Salmonella* has evolved a serotype—*Salmonella enteritidis*—that thrives in the ovaries and oviducts of hens where their eggs are formed, thereby precontaminating the interiors of intact eggs. According to the Centers for Disease Control, “The specific serotype *Salmonella enteritidis* can live in the intestinal tract, but it also can infect the ovaries and oviducts of egg-laying hens. It is not known why this is an increasing problem. It is possible that this bacterial strain has become more invasive, or that hens have less resistance, or that some change in poultry husbandry permitted this strain to become more widespread” (CDC Record, June 8, 1990, p. 2; see also p. 12 of the Transcript of the April 6 Public Meeting in Sacramento, California). This is significant because hens’ eggs, which are intended to hatch healthy chicks in nature, have virtually full-proof, many-layered barriers, from the inside out, against pathogens. In nature, hens’ eggs are formed in a clean protective ovarian environment and they incorporate that environment as they develop from a bundle of cells to shelled egg. Modern farming practices have somehow managed to make the hen’s reproductive system a disease-ridden place. To take the chicken houses themselves, they are so filthy and pathogenic that, according to Rich Dutton of Michael Foods, to wash a typical house holding 70,000 plus caged hens, “takes at least two weeks, eight to ten people, and nearly 24 hours a day washing per day to get it clean” (Transcript, March 30, 2000 Public Meeting, Columbus, Ohio, p. 19). And as Meryl Sosa of Food Animal Concerns Trust (FACT) said at the same meeting, “[R]esearch and studies have shown that even after you’ve cleaned and disinfected, sometimes SE persists in the house and you need to clean and disinfect again” (Transcript, March 30, 2000, Columbus, Ohio, p. 18).

As for the ubiquitous rodents in these filthy houses, according to Ken Klippen of United Egg producers, “One rodent can deposit 100 pellets in the course of one night and each pellet can contain 25,000 different salmonella organisms” (Transcript, March 30, 2000, Columbus, Ohio, p. 19). Many of these *Salmonella*-contaminated rodent pellets are deposited in the food troughs and are therefore unavoidably consumed by the hens. Charles Beard and Richard Gast reported this in *Egg Industry* magazine, citing the work of Drs. Opitz and Henzler: “At night the mice come out of hiding, eat from the feed

trough and deposit an average of a hundred pellets per mouse in the feed trough in a 24-hr. period. Those pellets are the first things that the chickens consume when the lights turn on" (July/August 1992, p. 35). Amplification of the rodent population in the layer buildings has been linked to the practice of forced molting, suggesting that the elimination of forced molting would reduce the pathogen load in the buildings, complexes, hens, and their eggs. Reporting research by Michael Opitz at the University of Maine, Holt concluded in a 1993 study of forced molting and SE, "Because induced molting has been shown to exacerbate concurrent *S. enteritidis* infection, resulting in the shedding of large numbers of the organisms, molted hens could serve as a second amplifier of *S. enteritidis* infection, spreading the organism to other molting hens (and to mice) within a layer operation" (Holt, 1993:416-417).

We find the FDA and FSIS's silence on all this information to be a breach of public trust. The American public wants not only safe food but humanely treated animals, or at least not grossly inhumanely treated animals. As Mary Jo Brooks said at the April 6<sup>th</sup> Public Meeting in Sacramento, "I'm here to represent a growing number of people like myself that are just members of the public who are increasingly concerned about the quality of [the] food supply, and also about the growing amount of cruelty in much of the factory farming industry. . . . The public doesn't want more hormones and antibiotics and drugs in the food they buy. . . . [T]hey're also very concerned about cruelty in the industry. So practices such as forced molting, which seems to be scientifically proven . . . if it were alleviated [sic], would up front cut down on the amount of *Salmonella* and a lot of the other diseases that the birds, and therefore the eggs, develop"(Transcript, p. 97).

United Poultry Concerns perceives that FDA and FSIS show no intention, if the "Thinking Papers" are a reflection of agency intention, of addressing such public concerns except to record them and use them to reinvent the wheel with more chicken starvation studies at taxpayers' expense. We urge the agencies not to do this. We request that prior to finalization of the Egg Safety Plan and Egg Safety Standards, the FDA and FSIS hold a closed door public interest meeting with public interest and animal welfare organizations. In addition, we request that the Food and Drug Administration prohibit the disease-producing inhumane practice of forced molting. The cruelty and the contamination are linked. It doesn't take a highly trained person to see this, but the fact is that highly trained scientists have documented it and the informed public is requesting that forced molting be banned. The next step should be government action. In summarizing the "substantial damage" to both the large and the small intestine of molted hens compared to unmolted hens, Nicholas, Porter, and Holt conclude: "These results are important to the layer industry since they show that a prevalent industry procedure has a substantial effect on the severity of an SE infection and these effects are observed early in the disease process. Also, many organisms infect poultry and if [forced] molting has such rapid effects on an infection by SE, it is very possible that it could have similar effects on infection by other poultry disease agents" (July 2, 1998).

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End. of Comments Presented by United Poultry Concerns re: Egg Safety; Current Thinking Papers. FDA Docket No. 00N-0504. (And FSIS Docket No. 98-045N4.)

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