FACT

FOOD ANIMAL CONCERNS TRUST
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December 17, 2004

Food and Drug Administration
Division of Dockets Management
Food And Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Nos.1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504

(RIN) 0910-AC14

Dear Docket Manager:

Please find enclosed the comments of Food Animal Concerns Trust on the proposed rule to prevent *Salmonella* Enteritidis in shell eggs during production.

Sincerely,

Richard R. Wood
Executive Director

00N-0504 C 205

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(RIN) 0910-AC14

Comments from Food Animal Concerns Trust (FACT) in response to the
Food and Drug Administration's (FDA)
Proposed Rule
Prevention of *Salmonella* Enteritidis in Shell Eggs During Production

Comments submitted by
Richard Wood, Executive Director and Steven Roach, Food Safety Program Manager

December 17, 2004

FACT is a non-profit organization that advocates for better farming practices to improve the safety of meat, milk, and eggs. For the last 20 years, FACT worked with 14 smaller egg farms in Pennsylvania and in the Midwest, marketing eggs from uncaged hens to major grocery chains. Beginning in 1991, our Pennsylvania farms were required to participate in a SE control program that included extensive environmental sampling.

When this egg safety proposal was first being fashioned, FACT, based on its dual role as an egg producer and consumer advocate, worked closely with the FDA, the egg industry, and a coalition of consumer groups to arrive at an agreement with all parties on the basic tenants of an on-farm egg safety plan. FACT believes that the current proposed rule is consistent with that agreement made between the stakeholders at that time.

The proposed rule acknowledges the seriousness of the public health risk created by SE contaminated shell eggs and recognizes that on farm controls are necessary for managing this risk. FACT is strongly supportive of the requirement for environmental testing, as this is the most reliable means to verify that control measures are working. Requiring environmental testing followed by diversion if contaminated eggs are detected

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also provides a public health benefit in that the eggs most likely to be SE contaminated will be required to undergo further processing to reduce the likelihood that infectious doses of bacteria will reach the consumer.

In addition to supporting the environmental testing, FACT supports requirements in the proposed rule that replacement chicks be sourced from SE monitored flocks, that buildings with positive SE tests be cleaned and disinfected before new chickens are introduced, and that all farms implement biosecurity and pest control programs.

FACT has already commented twice on the proposed rule at the public meetings in Rockville and Chicago. These written comments are intended to reiterate our concerns and to provide greater detail to those comments made orally. As we stressed in our earlier comments, FACT strongly supports the proposed rule and hopes to see it quickly moved forward. At the same time, FACT has some concerns about specific provisions in the proposed rule that we feel should be modified before the final rule is published.

FACT's concerns regarding the Proposed SE Rule

- The timing for the post molt environmental test occurs after the period when there is the greatest risk of shell egg contamination.
- The definition of "poultry house" in the proposed rule does not address the risk of airborne transmission of SE.
- The proposed rule does not require an environmental test after cleaning and disinfection of SE positive houses to ensure that cleaning was effective.
- The biosecurity provision in the proposed rule may be interpreted as disallowing free-range layer production.
- The proposed rule does not address the risk from farms with less than 3,000 hens.
- The proposed rule does not consider the benefits of maintaining state programs that have established track records and more stringent requirement than the proposed rule.
- The proposed rule does not require farms to have written protocols for their biosecurity program.

Detailed Comments

The timing for the post molt environmental test occurs after the period when there is the greatest risk of shell egg contamination. While there is some uncertainty to the extent that induced molting impacts the contamination of eggs by SE, there is an abundance of evidence that molting does increase the risk of infected eggs during the first 20 weeks post-molt. The consensus of the scientific community that molting does increase the risk of infected eggs was reflected in the joint Food Safety Inspection Service (FSIS) and FDA risk assessment which included an increased risk of finding positive eggs in infected molted flocks (*Salmonella* Enteritidis Risk Assessment Team, 1998.) The FSIS just completed another draft risk assessment that again reflects the abundance of data showing that there is a greater risk of contaminated eggs in the first 20 weeks post molt (FSIS 2004).

Based on the findings of the two SE risk assessments, FACT recommends that the post molt test be moved from 20 weeks as is currently proposed in the rule to a 4 to 6 weeks range post molt. The 2004 FSIS Draft Risk Assessment (Draft RA) finds the greatest risk of infected eggs immediately after molt, but at this time hens are laying few eggs. If the increased risk used in the Draft RA is multiplied by expected lay post molt, the greatest number of infected eggs from infected molted flocks will occur between 4 to 6 weeks post molt (See Appendix A).

Given the increased risk of infected eggs from molted infected flocks, FACT recommends that molting be prohibited in positive poultry houses unless a method of molt is used that has been shown not to increase the risk of contaminated eggs.

The definition of a "poultry house" in the proposed rule does not address the risk of airborne transmission of SE. There is considerable evidence that SE can be transmitted through dust and other airborne particles (Baskerville et al., 1992; Holt et al., 1998; Nakamura et al., 1997). The proposed definition of a "poultry house" requires that different sections of a single building separated by walls be considered as separate

houses. However, the proposed rule does not require that these separate sections have separate ventilation systems. The proposed rule does state that there must be "biosecurity procedures in place to ensure that there is no introduction or transfer of SE from one section to another." The definition of a poultry house should clarify that this includes transfer through airborne particles. FACT is particularly concerned that the proposed rule may allow for multi-aged flocks to share a structure that even though divided by walls, has air flowing from one flock to another.

The proposed rule does not require an environmental test after cleaning and disinfection of SE positive houses to ensure that cleaning was effective. FACT supports the provision that positive poultry houses be cleaned and disinfected before new hens are placed on the premises. In addition, from our experience with the Nest Eggs flocks, FACT strongly recommends that the rule require an environmental test of a previously positive house after cleaning and disinfection and before new hens are introduced. In the Nest Eggs flocks we rarely had positive results from our SE environmental tests. However, one test immediately after clean out and disinfection was SE positive. The proposed rule itself notes that cleaning and disinfection resulted in no further positive samples only 50 percent of the time. FACT recommends that the rule prohibit the placement of new hens in a positive house until that house tests negative for SE after cleaning and disinfection. A house may need to be cleaned and re-tested several times before SE is cleared. Finally, we are aware of the controversy over wet versus dry clean out and do not feel that there is a consensus on whether wet cleaning is necessary.

The biosecurity provision in the proposed rule may be interpreted as disallowing free-range layer production. FACT supports the provision in the proposed rule that egg producers must develop and implement a biosecurity program that includes restricting contact with wild birds and animals. However, FACT opposes any interpretation of biosecurity that is inconsistent with allowing outdoor access to laying hens. There is widespread consumer support for raising livestock using more humane and natural methods than caged hen production. While there are theoretical risks from contact

between wild birds and free-range poultry, we are aware of no studies showing that this has resulted in a higher SE prevalence in flocks with access to the outdoors. This is in contrast to epidemiological studies that have shown poultry houses with greater than 100,000 hens to be at a greater risk of SE (NAHMS, 2000).

As the proposed rule acknowledges biosecurity procedures must be tailored to the individual facility. Biosecurity for flocks with outdoor access should be designed to exclude wild birds and other animals from hen nesting areas and feeders. The proposed rule includes the impractical provision that wild birds be prevented from entering the "grounds." Given that all laying operations have grounds, this provision will be impossible to fulfill for any type of housing, not just those allowing outdoor access. Since wild birds will inevitably enter the grounds of any type of laying facility, the challenge is how to prevent these birds from spreading SE. This provision should be modified to acknowledge the great diversity of laying facilities and the different risks involved with different types of hen housing.

The proposed rule does not address the risk from farms with less than 3,000 hens. FACT recognizes that applying the proposed rule to the 65,000 small farms would be very costly both to the government and to the regulated farms. At the same time, mishandled eggs from a single small farm could result in a SE outbreak affecting dozens of people.

FACT proposes that small farms selling directly to consumers not be regulated. For example, this would include small farms that sell eggs at roadside stands and farmers markets. However, FACT proposes that producers with less than 3,000 hens selling eggs to wholesalers, retailers, or restaurants be required to environmentally test all nesting and laying facilities once each year, following the testing based scheme described on page 56838 of the Federal Register notice. While being required to test their flocks, FACT recommends that they would not need to meet the other requirements of the proposed rule unless positive environmental samples were found. FDA would not need to inspect

regulated small farms unless there was a complaint or traceback implicating one of these farms as a source of SE contaminated eggs. FDA would need to use some resources to reach out to small farms to educate them on the requirements of the proposed rule and on steps they could take to reduce the risk of SE to their customers.

The proposed rule does not consider the benefits of maintaining state programs that have established track records and more stringent requirement than the proposed rule. FACT supports the creation of a mandatory Federal egg safety regulation as the only method for assuring public safety and providing a level playing field for egg producers. At the same time, FACT acknowledges the value of existing state quality assurance programs like the Pennsylvania Egg Quality Assurance Program (PEQAP) that are equal to, or go beyond the requirements in the proposed rule. In addition, FACT recognizes that FDA resources and staffing limitations will almost certainly require the Agency to rely on state officials for compliance inspections.

Given these realities, FACT would support a federal-state partnership where FDA establishes the requirements for a national SE control program and is responsible for seeing that the program is enforced. Then in states having a SE control program equal to or stronger than the federal rule, the FDA could certify the state program as such and use it as the structure for implementing the federal rule in that state. This arrangement would protect the viability of already existing strong state programs, would facilitate the implementation of the federal program, and would not burden egg producers in those states with two sets of requirements and inspections.

In this arrangement all qualifying state programs must meet the Federal requirements, all covered egg producers must participate in either the state or Federal program, and the FDA must maintain its authority to enforce the provisions of the rule.

The proposed rule does not require farms to have written protocols for their biosecurity program. FACT supports adding to the proposed rule a requirement that

farms maintain a written SE prevention plan. FACT believes that writing the plan down is a necessary step in developing the plan. A written plan can be an essential tool for educating current and future employees about steps they need to take to prevent SE. FACT also supports requiring farms to maintain records on rodent control programs. Keeping careful written records is an essential aspect of farm management and this is equally true for SE control.

Conclusion

FACT has long advocated that poultry and livestock producers take greater responsibility for the safety of the food they produce. Previously, federal food safety controls have focused on processing plants and retail establishments. Now this proposed rule addresses the missing link in the food safety continuum by including the farm as a critical control point in reducing the risk of SE in shell eggs.

FACT hopes that a final rule based on this proposal will be published soon. A final egg safety rule will level the playing field so that all producers will meet the same high standards that many farmers have voluntarily followed over the years. Even more importantly, a final rule will reduce the risk of SE related illness for consumers and can help avert illness and even death for thousands of people in the US. FACT hopes that the FDA will move expeditiously to publish a final rule, and once published will devote sufficient resources to ensure high levels of compliance among egg producers. With these steps accomplished FACT believes that by 2010 the public health goal of a 50% reduction in all salmonellosis with a similar reduction in outbreaks will be achieved.

References

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Appendix A – Calculation of period of greatest risk for infected eggs from molted infected flock. Weeks with highest numbers of infect eggs are underlined

W Week post molt	M(W) Multiplier	eM Fraction of infected eggs	% lay	%infected
1	8.734190321	75.11403676	0.03	2.253421
2	7.147320924	61.46695994	0.21	12.90806
3	5.885672355	50.61678225	0.5	25.30839
4	4.882727314	41.9914549	0.76	31.91351
5	4.085523474	35.13550188	0.8	28.1084
6	3.451909603	29.68642259	0.83	24.63973
7	2.948350326	25.35581281	0.84	21.29888
8	2.54817235	21.91428221	0.83	18.18885
9	2.230164956	19.17941862	0.83	15.91892
10	1.977464218	17.00619228	0.81	13.77502
11	1.776664043	15.27931077	0.8	12.22345
12	1.617108329	13.90713163	0.8	11.12571
13	1.490327604	12.81681739	0.79	10.12529
14	1.389590785	11.95048075	0.79	9.44088
15	1.309548669	11.26211855	0.78	8.784452
16	1.245950417	10.71517358	0.77	8.250684
17	1.195418142	10.28059602	0.77	7.916059
18	1.155267714	9.935302343	0.77	7.650183
19	1.123366322	9.660950365	0.77	7.438932
20	1.098019259	9.44296563	0.76	7.176654

Values for M(W) and eM calculated from FSIS 2004 Table 3-1 page 34.
Values for percent lay from Hyline Variety W98 Commercial Management Guide 2004-2006.