



CORNUCOPIA
I N S T I T U T E

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

September 23, 2013

RE: Docket # FDA 2000-N-0190

Dear Ms. Bufano,

Thank you for the opportunity to comment on the Draft Guidance for the prevention of salmonella enteritidis (SE) in shell eggs for egg producers providing outdoor access to their flock.

Definition of poultry house

We appreciate that the guidance document clarifies that the definition of “poultry house” includes only enclosed structures and does not include outdoor runs or pasture.

We had expressed concerns regarding the definition of “poultry house,” because it would have been impossible to apply the testing requirements to the outdoor environment. We appreciate that the FDA considered these specific concerns when drafting the guidance document and specified that testing requirements do not apply to the outdoor space.

However, **we object to the FDA’s and USDA’s determination that an enclosed porch, which is considered part of the poultry house, constitutes acceptable “outdoor access.”**

The USDA’s National Organic Program (NOP) regulations require access to the outdoors for all organic livestock. Enclosed porches, which are considered part of the poultry house, do not constitute “the outdoors.”

By listing “Indoor Area with Porch” as one of four possible organic housing styles, the FDA joins the USDA in inappropriately considering these enclosed structures as outdoor access.

This agreement between regulatory agencies undermines the legal requirement for true outdoor access and the commitment in the FDA's salmonella rule that its implementation would not interfere with the ability for organic farmers to manage their livestock as per federal regulations governing organics. This regulatory sleight-of-hand, if sustained, will likely generate a court challenge.

Most porches adjacent to organic henhouses are not large enough to hold the entire flock, or even an appreciable percentage, generally holding only a very small percentage of the birds. The NOP regulations clearly require outdoor access for all livestock. The NOP regulations 7CFR205.239 state:

- a) The producer of an organic livestock operation must establish and maintain year-round livestock living conditions which accommodate the health and natural behavior of animals, including:
 - (1) Year-round access **for all animals** to the **outdoors**, ... (emphasis added)

We believe that organic egg producers who only provide porches as “outdoor access” to a small percentage of their hens are violating the organic standards.

We object to the FDA’s determination that porches are “outdoor access,” and urge the FDA to delete the “Indoor Area with Porch” as one of the four housing styles acceptable for organic production.

Recommendations to limit contact with salmonella carriers

Some of the recommendations to limit contact with wild animals that are considered salmonella carriers, including rodents and flies, are reasonable and substantiated through experiential data and published research.

We agree that contact with rodents, which is a risk factor, should be minimized. We have no objections to the recommendations in the guidance document to limit contact with rodents, such as maintaining an area of gravel around the entrance to the poultry house, removing debris, removing carcasses and disposing of them properly, minimizing spillage of feed and minimizing access by rodents to feed and water stations.

The scientific literature also clearly points to flies as a risk factor and carrier of SE, and we support the recommendations to decrease fly populations in and near poultry houses. This includes decreasing the amount of fresh manure, removing dead carcasses and disposing of them properly, minimizing spilled feed and broken eggs, keeping grass and weeds low, and removing dead or decaying plants. These are all good management practices.

We are however concerned with the recommended measures to avoid contact between laying hens and wild birds. These are not based on convincing scientific studies showing that wild birds are a risk factor, and they are impractical, burdensome, and in conflict with the goals and federally mandated management practices of organic agriculture.

The scientific literature pointing to wild birds as a significant risk factor is weak. Abundant scientific data show that farms with outdoor access are likely to be the least at risk for salmonella concerns, despite contact with wild birds. Without exception, multiple European studies analyzing SE prevalence rates show that organic farms with outdoor runs are among the safest (see below), while confinement operations with cages are among the most dangerous.

Please consider the following studies, which were not included in the FDA draft guidance, which show hens with outdoor runs are less likely to produce salmonella contaminated eggs than hens in caged systems:

European Union - European Food Safety Authorityⁱ - In 2004-2005, the European Food Safety Authority analyzed more than 5,000 samples from egg farms in all European Union member states for salmonella contamination.

Cage production was found to be associated with a higher risk of salmonella contamination than the other production types, including organic and free range.

Whereas 25% of caged houses tested positive for SE, fewer than 10% of organic houses did. In Europe, organic egg producers are required to have at least 43 ft² of outdoor space per bird, with adequate doors allowing all birds to access the outdoors. There are no requirements for limiting contact with wild birds.

France - French Agency for Food, Environmental and Occupational Health & Safety – French researchers analyzed salmonella rates on 521 French laying-hen farms, and found that the prevalence of salmonella on caged farms was 34%, compared with 9% on alternative farms (including farms with outdoor runs)ⁱⁱ

Germany - Federal Research Institute for Animal Health - Researchers examined 329 flocks of laying hens and found greater prevalence of salmonella infection in flocks housing in caged systems. The share of Salmonella positive flocks was 46.3% in conventional cage systems, compared with 32.996% in organic farming with free-range management systems (“free-range management systems” are defined as systems where chickens have access to an outdoor run), 23.4% in floor management

systems without free range, and 21.9% in floor management systems with free range.ⁱⁱⁱ

Belgium - University of Gent – A total of 292 laying hen farms in five European countries were sampled to determine the prevalence of hens shedding Salmonella and the effect of housing type on Salmonella prevalence. The researchers found housing in conventional battery cages to be a risk factor for the shedding of Salmonella Enteritidis or Typhimurium.^{iv}

Belgium - Hasselt University – Using Belgian data from the 2005 baseline study on the prevalence of Salmonella in laying flocks in the European Union, the main risk factor identified was rearing flocks in cages compared to barns and free-range systems.^v

United Kingdom - Centre for Epidemiology and Risk Analysis - Analysis of 454 commercial layer flock holdings in the UK. The prevalence rate on caged farms for SE was 23.4%, compared with 4.4% on farms with barns without outdoor access and 6.5% on farms with free-range birds.^{vi}

United Kingdom - Veterinary Laboratories Agency - In a study of 74 flocks of laying hens, 19.4% (736/3793) of cage house and 10.2% (85/833) of free-range house samples yielded salmonellas.^{vii}

University of Gent, Belgium - In caged systems, hens are more likely to shed salmonella if they are infected. This study intentionally infected hens to determine the effect of different housing system on colonization of layers of Salmonella. They found that cages are a risk factor: “In contrast, in one study, a faster decline in shedding was noted for layers housed in the alternative cage systems in comparison with the conventional cage system.”^{viii} This study shows that even when birds are intentionally infected, they are less likely to shed salmonella if they were not housed in cages.

Statens Serum Institute, Denmark - This study analyzed people with SE infections, and found that “among persons who had used eggs in the week before disease onset or interview, eggs from battery laying hens were associated with disease.”^{ix}

French Agency for Food, Environmental and Occupational Health & Safety - 519 flocks were studied. Prevalence was significantly higher in caged flocks than in on-floor flocks. In caged flocks (n = 227), the risk of *Salmonella* contamination increased with flock size and when delivery trucks passed near poultry-house entrances.^x **Note:** the “alternative system” in this study does not include an outdoor run, but rather “on-floor flocks.”

Moreover, there are studies that show that wildlife and SE contamination on the farm are not correlated. A study from the UK in 2007 found an association between

the prevalence of SE in wildlife and the prevalence on the farm to be not significant.^{xi}

Another study found that, despite a higher prevalence rate in wildlife in and around the farm, the prevalence rate of SE was **lower** on farms with outdoor runs than on farms without outdoor runs.^{xii}

It appears the FDA was highly selective in the scientific studies that are cited to support its conclusion that contact with wild birds should be minimized. The FDA cited only four studies to justify targeting contact with wild birds (of these four studies, one deals with broilers, not layers).

The FDA also did not cite the studies from Europe that have shown great success in controlling salmonella without requiring netting, noise cannons or other measures to limit contact with wild birds. Without imposing any restrictions on outdoor access or contact with wild birds, European states have dramatically reduced the rates of SE infection over the past couple of years (SE rates fell from 18.3% of laying flocks in 2004-2005 to 3.1% of laying flocks in 2008).^{xiii}

We are concerned that many of the recommendations for avoiding contact with wild birds are logistically and economically impractical, and risk putting undue burdens on organic producers who follow the spirit and the letter of the organic law and regulations, which require meaningful outdoor access for all birds.

Netting the entire outdoor run would be cost-prohibitive and impractical. Noise cannons would presumably scare the hens as well as wild birds, and hens would be discouraged from going outdoors (there is no research presented to suggest otherwise).

There are a number of organic egg marketers whose businesses are built on creating superior quality pastured eggs that will be economically injured, or forced out of business entirely, if these guidance standards are adopted.

We request that the recommendations for limiting contact with wild birds be deleted, especially the suggestion to use netting over the outdoor area and the use of noise cannons should be removed from the final guidance document.

Targeting well-documented risk factors

Rather than placing unnecessary regulatory burdens on producers with outdoor access, the FDA should focus its efforts on addressing the significant risk factors of cages and large flocks.

Multiple scientific studies, in addition to the data from European countries cited above, conclude that the risk of Salmonella Enteritidis contamination is significantly greater when hens are kept in cages.^{xiv, xv, xvi} Many studies also conclude that the risk

of Salmonella Enteritidis contamination increases significantly when flock size increases.^{xvii, xviii, xix, xx}

Conclusion

We repeat our earlier concerns which we shared with you in our April 2012 letter, signed by nearly fifty organic egg producers.

While it is true that wild animals can carry salmonella, scientific studies clearly point to rodents, flies, unsanitary and crowded conditions, caged production and older buildings as the real risk factors. The scientific evidence pointing to wild birds as risk factors is weak, yet the recommendations in the guidance document to limit contact with wild birds would be impractical and cost prohibitive.

Moreover, we are concerned that the FDA guidance, which recommends costly measures to keep wildlife out of the outdoor run, such as fencing and netting, will push organic farmers toward the “Indoor Area with Porch” model that you list as one of four housing styles. Providing only a tiny porch would be a convenient way for a farmer to avoid contact with wild birds, but it would be in violation of both the letter and the spirit of the organic law and regulations and will likely lead to a protracted legal battle.

We see no scientific justification for many of the recommendations to limit contact with wild birds, especially given the preponderance of evidence that contamination of harmful strains of salmonella is **less likely** to occur in eggs produced on farms with well-managed outdoor access.

Thank you for considering our concerns.

Mark Kastel
Codirector
The Cornucopia Institute

Citations

ⁱ European Food Safety Authority. Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline study on the prevalence of Salmonella in holdings of laying hen flocks of *Gallus gallus*. The EFSA Journal (2007) 97. Available online: <http://www.efsa.europa.eu/en/efsajournal/doc/97r.pdf>. Last accessed on August 19, 2013.

ⁱⁱ Mahé, A., Bougeard, S., Huneau-Salaün, A., et al., 2008. Bayesian estimation of flock-level sensitivity of detection of *Salmonella* spp., *Enteritidis* and *Typhimurium* according to the sampling procedure in French laying-hen houses. *Preventive Veterinary Medicine* 84(1-2): 11-26.

iii Methner, U, Diller R, Reiche R and Bohland K (2006) Occurrence of salmonellae in laying hens in different housing systems and inferences for control. *Berl Munch Tierarztl Wochenschr* 119(11-12): 467-73.

iv Van Hoorebeke S, Van Immerseel F, Schulz J, Hartung J, Harisberger M, Barco L, Ricci A, Theodoropolous G, Xylouri E, De Vylder J, Ducatelle R, Haesebrouck F, Pasmans F, De Kruif A, Dewulf J (2010) Determination of the within and between flock prevalence and identification of risk factors for Salmonella infections in laying hen flocks housed in conventional and alternative systems. *Preventive Veterinary Medicine* 94(1-2): 94-100.

v Namata, H., Méroc, E., Aerts, M., et al., 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4): 323-36.

vi Snow, L.C., Davies, R.H., Christiansen, K.H., Carrique-Mas, J.J., Wales, A.D., O'Connor, J.L., Cook, A.J.C., Evans, S.J. (2007) Survey of the prevalence of *Salmonella* species on commercial laying farms in the United Kingdom. *Veterinary Records* 161 (14): 471-6

vii Wales A., Breslin M., Carter B., Sayers R. and Davies R. (2007) A longitudinal study of environmental Salmonella contamination in caged and free-range layer flocks. *Avian Pathology* 36: 187-197

viii J. De Vylder, J. Dewulf, S. Van Hoorebeke, F. Pasmans, F. Haesebrouck, R. Ducatelle, and F. Van Immerseel (2011) Horizontal transmission of Salmonella Enteritidis in groups of experimentally infected laying hens housed in different housing systems *Poultry Science* 90(7): 1391 - 1396.

ix Molbak K and Neimann J (2002) Risk factors for sporadic infection with Salmonella Enteritidis, Denmark, 1997-1999. *American Journal of Epidemiology* 156(7): 654-661.

x Huneau-Salaün, A., Chemaly, M., Le Bouquin, S., Lalande, F., Petetin, I., Rouxel, S., Michel, V., Fravallo, P., and Rose, N. (2009) Risk factors for *Salmonella enterica* subsp. *enterica* contamination in 519 French laying hen flocks at the end of the laying period. *Preventive Veterinary Medicine* 89: 51-58.

xi Wales A., Breslin M., Carter B., Sayers R. and Davies R., 2007. A longitudinal study of environmental Salmonella contamination in caged and free-range layer flocks. *Avian Pathology* 36: 187-197

xii One study found the overall prevalence of salmonella-positive samples from wildlife vectors was 38.6%, more than double the prevalence of positive samples from houses, which was 17.7%. However, overall, this study found the prevalence of salmonella on farms with outdoor runs to be **lower** than on caged farms without outdoor runs (10.2% versus 19.4% on caged farms)

Wales A., Breslin M., Carter B., Sayers R. and Davies R., 2007. A longitudinal study of environmental Salmonella contamination in caged and free-range layer flocks. *Avian Pathology*. 36: 187-197

xiii European Food Safety Commission. EFSA and ECDC issue 2008 report on zoonoses and food-borne outbreaks in the EU. Available online at <http://www.efsa.europa.eu/en/press/news/zoonoses100128.htm>. Last accessed on August 19, 2013.

xiv J. De Vylder, J. Dewulf, S. Van Hoorebeke, F. Pasmans, F. Haesebrouck, R. Ducatelle, and F. Van Immerseel (2011) Horizontal transmission of Salmonella Enteritidis in groups of experimentally infected laying hens housed in different housing systems *Poultry Science* 90(7): 1391 - 1396.

^{xv} Molbak K and Neimann J (2002) Risk factors for sporadic infection with *Salmonella* Enteritidis, Denmark, 1997-1999. *American Journal of Epidemiology* 156(7): 654-661.

^{xvi} Huneau-Salaün, A., Chemaly, M., Le Bouquin, S., Lalande, F., Petetin, I., Rouxel, S., Michel, V., Fravalo, P., and Rose, N. (2009) Risk factors for *Salmonella enterica* subsp. *enterica* contamination in 519 French laying hen flocks at the end of the laying period. *Preventive Veterinary Medicine* 89: 51-58.

^{xvii} Namata, H., Méroc, E., Aerts, M., et al., 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4): 323-36.

^{xviii} Snow, L.C., Davies, R.H., Christiansen, K.H., Carrique-Mas, J.J., Wales, A.D., O'Connor, J.L., Cook, A.J.C., Evans, S.J., 2007. Survey of the prevalence of *Salmonella* species on commercial laying farms in the United Kingdom. *Veterinary Records* 161 (14): 471-6

^{xix} From the Centre for Epidemiology and Risk Analysis in the UK: In an analysis of 454 commercial layer flock holdings in the UK, researchers concluded that the highest prevalence of *Salmonella* (32.4%) occurred in the largest holding size category, 30,000 birds or more.

^{xx} From Hasselt University in Belgium - The results of this study showed a significant increase in risk for *Salmonella* when flock size increased

Namata, H., Méroc, E., Aerts, M., et al., 2008. *Salmonella* in Belgian laying hens: an identification of risk factors. *Preventive Veterinary Medicine* 83(3-4): 323-36.