

Stoller

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Division of Documents Management
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville Md 20852

Docket Nos. 1996P=0418, 1997P=0197, 1998P-0203, and 2000M-0504

Dear Sir or Madam:

We at Stoller Farms are forth generation family egg producers in Van Wert Ohio. Currently it is my son and I that own and operate the business. In an industry which has consolidated and grown, (as have many other industries), we are of the smallest group in terms of numbers of egg layers in production. To illustrate our relative size, I commonly say that we are about one third the size of our industry average.

That being prefaced, we want you to know, that we feel very threatened and endangered by FDA's proposed entry into agricultural regulation. We have been increasingly regulated over the past fifteen years, and the possibility of our becoming unable to comply at some time soon is always on our horizon. Currently, we in Ohio are governed by the following agencies:

1. The Ohio Department of Agriculture
2. The "Ohio Egg Quality Assurance Program," which meets requirements of USDA and ODA, and includes testing and documentation.
3. The United Egg Producer "Animal Care Certified Program," which includes USDA audit and inspection.
4. USEPA and/or the Ohio EPA (some conflict currently)
5. Van Wert County Health Department
6. Ohio Department of Natural Resources

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While some of these regulators are billed as voluntary, virtually all of them have governmental involvement at the county, state, or federal level. This multi-level regulation gives rise to duplication, overlap of authority, confusing and sometimes contradictory requirements, overburden of documentation, and excessive costs for compliance. The areas of oversight covered by these entities include:

1. Insect and pest control
2. Manure storage, management, and disposal
3. Production equipment maintenance
4. Grounds maintenance
5. Water usage and ground water testing.
6. Housekeeping and cleaning.
7. Salmonella testing, monitoring and documentation
8. Bird housing space, bird handling, bird feeding, lighting, ventilation, medication.
9. Production farm egg handling and storage.
10. Agronomy analysis and management
11. Construction and expansion permitting of cropland
12. Recurrent operating permission.
13. Production facility capacities and limits
14. Employee certification for specified responsibilities.
15. Standards for transportation of eggs
16. Processing, cleaning, grading, storage and packaging of eggs.
17. Farm proximity to neighbors.
18. Waste water treatment.

Suffice it to say at this point, that the list is undoubtedly incomplete, and that each item therein engenders additional labor, documentation, and cost which is beyond the norm of good animal husbandry and reasonable responsibility for the production of high quality food at fair prices.

Thus, is the threat to my livelihood and occupation, of which I spoke at the beginning of this letter.

I am enclosing a copy of a letter which was drafted by the United Egg Producers regarding FDA's proposed regulation of food production farms. I do so because it has several valid and important points of which I cannot improve, and are well stated.

However, I would like to summarize my thoughts with the statements following:

1. FDA has not the experience or expertise to enter the agricultural regulation business. While FDA may insist that they do have some knowledge of farm production, it has been true many times, that a little knowledge can be very dangerous.
2. The stated intent of FDA is to reduce the incidence of egg born SE Salmonella Enteriditis illness. The magnitude of the problem seems to be greatly exaggerated by FDA. It seems to be based upon old information that is further extrapolated by flawed reasoning based on unknown information, rather than upon sound fact. Their estimates of the problem are not consistent with CDC reports, and do not take into account the progress that has been made in recent years by agencies of regulation which already are involved in egg born SE reduction.
3. FDA either has no idea of the cost and impact otherwise on the agricultural sector, or is not sensitive to it. Their proposal represents duplicity and will not reduce the real problem of egg borne SE as is their intention. Simply, the cost is not worth the investment.
4. FDA should abandon this effort to regulate agriculture. USDA is already involved in the very problem that FDA is citing as their purpose. Experience and knowledge are invaluable for effective solutions, and FDA should defer to the states and to the USDA.

I submit the above respectfully in light of FDA's valuable service of the past to the people of our great nation. May they not tarnish their record and image with an experimental venture so ill advised.

Sincerely yours,



Gary Stoller
Stoller Farms

Comment Letter by United Egg Producers of Alpharett, Georgia concerning FDA proposal enter the SE regulation at the farm level.

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Dear Sir or Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on *Salmonella* Enteritidis in shell eggs. I am an egg producer with operations in (city, state). As an egg producer, I take pride in delivering a safe product to my customers. Food safety is in my interest as a farmer and small business operator. FDA should review medical information from the Centers for Disease Control, which finds egg quality assurance programs have already made a difference wherever they have been used. Producers and states have been implementing these plans voluntarily, with no federal mandate.

I am already regulated by many different federal and state agencies. Even when the aim of regulation is good, the burden of complying can be heavy, especially on farms and other small businesses. I respectfully urge FDA to minimize the additional burden:

1. **Recognize and reward what states and the industry are already doing.** FDA should thoroughly review all existing state and private egg quality assurance programs to see if they already provide protection equivalent to what FDA is seeking. If so, then producers who are in compliance with one of these plans should be considered to be in compliance with FDA's regulations.
2. **Carry out inspections and enforcement through federal and state agencies that already regulate our industry.** The Agricultural Marketing Service already inspects egg packing facilities four times a year under the Shell Egg Surveillance Program, often in cooperation with state agencies. AMS and the states are knowledgeable of the egg industry, and using them will avoid diverting FDA employees away from homeland security, import inspections and other work.

I would also suggest that FDA needs more input from scientists who are experts in egg and poultry science. Several parts of the proposal should be changed because they are either impractical, unnecessarily costly or in conflict with sound science.

- **The proposed rule does nothing to encourage vaccination,** even though it is a highly effective means of controlling SE. I suggest that producers have the ability to demonstrate the effectiveness of a vaccination program,

and if they can do so, then they should be able to follow a protocol of a single environmental test shortly before depopulation.

- **FDA does not give any indication whether it has surveyed existing laboratories to find out whether they can handle the increased testing workload** as a result of this proposed rule. Before implementing the rule, FDA should survey public and private laboratories to assess whether lab capacity is adequate, especially in case of an outbreak of avian influenza, exotic Newcastle disease, or another serious animal illness.
- **FDA's requirement for a wet cleaning is unrealistic.** In winter months, it is not practical to do this in large parts of the United States. FDA should not impose a requirement that producers cannot carry out. FDA says in the proposed rule that some studies show an increase in SE after a wet cleaning – and yet the agency is still proposing to require wet cleaning! FDA should make the wet cleaning optional, and require only a dry cleaning after an environmental positive.
- **FDA's requirement that eggs held more than 36 hours be refrigerated at 45° F is also unrealistic and unnecessary.** This would mean new refrigeration requirements *every weekend and holiday* for further processors who have production capacity – and yet the eggs will immediately be pasteurized, killing the bacteria! In addition, this requirement could actually be detrimental to food safety for eggs that go into the table market. When the eggs are washed, there will be a higher incidence of checks and cracks if they have previously been refrigerated, simply because of the sudden change in temperature. FDA should lengthen the 36-hour limit to something more realistic, like 72 hours. FDA should then require refrigeration at 55° F unless the eggs are held more than a week, and then impose the 45° F requirement if necessary.
- **FDA's biosecurity requirements should be more flexible.** Biosecurity is important, but the extensive steps the agency lists will be extremely burdensome on smaller farms, especially off-line contract farms. Along with other costs, these requirements could cause further consolidation in our industry, with some smaller operations unable to afford the additional labor and compliance costs. Yet our government always professes to be concerned about increasing concentration in agriculture.
- **Has FDA surveyed processors to see whether they are willing to accept eggs from SE-positive flocks?** In the years since FDA first began working on egg safety, more and more egg processors have arranged for dedicated sources of egg production, on-site or off-site, so their need to buy eggs on the open market is less to begin with. If eggs from SE-positive flocks could not be sold at any price, then the loss to producers would be much more than FDA has estimated and might require the regulation to be submitted to Congress under the unfunded mandates law. One way for FDA to address this problem would be through an indemnity system, payable if producers have fully complied with the regulatory requirements.

In closing, I repeat that my farm is dedicated to delivering a safe product to our customers. We will always comply with the law and regulations to the best of our ability. But we need regulations that are flexible, reasonably applied, and scientifically based if we are to survive as a business. In agriculture, we usually cannot pass on increased costs to our customers. The producer ends up absorbing the cost of regulations. I strongly urge you to make the changes that producers are asking, so that this regulation can be workable for our industry.

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