



## **Can FloraMax® and Sporulin® help poultry producers comply with the “new” Salmonella rules?**

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### **Description of the Problem**

The United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) began collecting samples for Salmonella testing back in the mid 1990s. Initially, these tests were directed at broilers because there was a generally accepted baseline for this category of poultry. The baseline for Salmonella levels on broiler carcasses was established at 12 or fewer positive carcasses out of 51 sampled. The baseline for ground chicken was established at 26 or fewer positives out of 53 samples. The baseline for ground turkey was established at 29 or fewer positive samples out of 53 samples. No baseline for whole turkeys was established; however, Salmonella testing results for whole turkeys were purported to be analyzed according to statistical process control by USDA FSIS. (Essentially, the plants that have the highest levels would receive more attention than plants that have low levels. More on baselines later in this article.)

The Food and Drug Administration (FDA) regulates table eggs. Accordingly, the FDA has a testing protocol that addresses Salmonella enteritidis (SE). Samples from the environment of table egg flocks must be tested for SE at 14 to 16 weeks of age (pullets) and again at 40 to 45 weeks of age. If these samples are negative, no additional Salmonella testing is required until after the flock molts. If these environmental samples are positive for SE, then a very large number of eggs must be tested (thousands). If any eggs test positive, the eggs from this flock cannot be sold as fresh shell eggs. They must be processed at a breaking plant similarly to pasteurization of milk. (Eggs in the shell receive a much higher price than the liquid egg products, so there is a strong incentive to market eggs in the shell.) It takes a tremendous amount of testing to “prove” that the flock is free of SE and reinstate the authorization to sell shell eggs. In short, the table egg producer with flocks testing positive will receive much lower prices for eggs, with a difficulty re-qualifying for shell egg sales.

In the past, most people have assumed that Salmonella is just part of the normal bacterial population of poultry. Many farmers and production managers have accepted as fact that Salmonella is impossible to control. Recently, the USDA and FDA have asserted that it is feasible for farmers and plants to control, reduce, or prevent Salmonella from setting up residence in poultry flocks. Some information has been communicated through presentations or background statements. However, regulations represent the only “hammer” that government officials have in their “tool belt”. So, the reduction of Salmonella in commercial poultry, from a regulatory perspective, begins to look like a problem that can be solved through stronger regulation.

In defense of USDA-FSIS, the agency has said some things that make sense. USDA has reported the following observations:

- 1) Plants that consistently have low levels of Salmonella tend to continue to have low levels of Salmonella moving forward. The agency interprets this to mean these plants have good process control.
- 2) Plants that have been in and out of compliance with the Salmonella standards tend to continue to have those problems. The agency interprets this to mean that these plants have variable process control.
- 3) Plants that have been in the doghouse when it comes to Salmonella levels tend to stay there. The agency interprets this to mean these plants have poor process control.

The USDA-FSIS has also reported their observations that plants are able to implement corrective actions and reduce their Salmonella levels. The agency recognizes there are both plant and pre-harvest interventions that can help bring a troubled plant below the threshold for regulatory action. The USDA-FSIS asserts the



following: The fact that plants are able to reduce Salmonella levels following a failed test set indicates the general ability to control Salmonella through routine processes.

In short, the USDA-FSIS has taken the “we can’t do anything about it” argument off the table. The bulk of the poultry industry has drastically reduced Salmonella levels, and those who have not are considered to be “bad actors.”

Expectedly, there has been some “standard creep” where USDA-FSIS declares the old standard obsolete and institutes a new, stricter standard. One example of this was the introduction of Salmonella serotyping (identifying specific species like *Salmonella typhimurium*, *Salmonella enteritidis*, etc.) and increased regulatory response based on the presence of species of Salmonella that are commonly found in instances of human illness. Recently, the USDA has announced more stringent performance standards for Salmonella as well as new performance standards for *Campylobacter* sp. These proposed performance standards are described later in this article.

Interestingly, poultry vets have been asking for years that USDA focus on the significant Salmonella serotypes. Regulatory policy has done this, however, as an add-on to the old practices of regulating all Salmonella in poultry, rather than as a replacement to regulations on “generic” Salmonella.

USDA-FSIS currently segregates broiler plants into the following categories as described in the chart below:

Category	Findings
Category 1	6 or fewer Salmonella positives per 51 bird set
Category 2	7 to 12 Salmonella positives per 51 bird set
Category 3	13 or more Salmonella positives per 51 bird set, or the presence of Salmonella serotypes that are commonly found in instances of human illness

### Proposed New Standards - Overview

Shortly after taking office, President Obama created the President’s Food Safety Working Group. This committee is co-chaired by the Secretary of Agriculture and the Secretary of Health and Human Services, giving a broad perspective that includes consideration of both food safety and human illness. Following an initial period of deliberation, this committee recommended a “new, public health-focused approach” based on 1) Prioritizing prevention, 2) Strengthening surveillance and enforcement, and 3) improving response and recovery.

The President’s Food Safety Working Group has charged USDA-FSIS with “cutting Salmonella risk in Poultry Products.” To do this, FSIS has proposed new standards for Salmonella levels in post-chiller carcasses. The stated goal is to have 90% of broiler and turkey plants meeting the new standards (spelled out below) by the end of 2010.

It is worth noting that the FSIS recognized a reduction between rehang and post-chill microbiological loads. This indicates the acceptance that the plant processes are able to lower Salmonella levels, and possibly *Campylobacter* levels, when arriving birds are already contaminated by these regulated bacteria.

### Proposed New Salmonella Standard for Young Chickens

The FSIS has determined that the most recent available data indicates a prevalence of Salmonella in broilers (post chill) at 7.5%.

To reduce illnesses attributed to Broiler Chickens, FSIS proposes to lower the Salmonella Performance Standard to 7.5%, or 5 positive test results out of 51 carcasses sampled. They agency has also proposed to revise the definitions of the Categories as follows:

<b>Category 1</b>	<b>0, 1, or 2 positives on 2 consecutive sets</b>
<b>Category 2T</b>	<b>0, 1, or 2 positives on the last set, 3 or more positives on the previous set</b>
<b>Category 2</b>	<b>Last set with 3, 4, or 5 positives. An results from the previous set</b>
<b>Category 3</b>	<b>Last set with 6 or more positives. Any results from the previous set.</b>



FSIS plans to continue publishing the Category 2 and 3 plants on its website and will base the assessment on the standard in existence when the sample set was begun. If 90% of the broiler plants are in Category 1 and no broiler plants are in Category 3, the Category 2 broiler plants will not be posted. FSIS will continue to target plants that are not meeting the standard with additional testing as well as Food Safety Assessments.

Currently, 82% of broiler plants are in Category 1. If the new standards are implemented, about 57% of the plants will fit into Category 1. The new Category 2 plants will make up 28% of plants and the new Category 3 plants will make up another 15%. FSIS speculates that over half of this 15% who do not meet the performance standard for Salmonella (Category 3) will improve their food safety system and move up to the Category 2 status. This would put the total number of Broiler plants meeting the standard above 90%, reaching the Goal established by the President's Food Safety Working Group.

FSIS speculates that this new set of regulatory standards for Broilers will reduce the number of human illnesses attributable to broiler chickens by 26,000 cases. (There are currently 220,000 cases of human illnesses attributed to Salmonella in Broilers.)

### **Proposed New Campylobacter Performance Standard for Young Chickens**

First and foremost, the FSIS acknowledges that the body of knowledge regarding Campylobacter control is limited compared to what is known about controlling Salmonella. Previous good results in reducing Salmonella levels in broiler chickens do not assure the industry will be able to reduce Campylobacter levels.

Broiler chickens will have Campylobacter samples taken at the same time as the regular Salmonella test set (1 carcass per day for 51 operating days). There will be two Campylobacter sub-samples prepared. One sample will be called the "1 ml" test and it will be (directly) plated out so that the quantity of Campylobacter present can be counted (if there is a high level present). The second sample will be called the "30 ml" test and it will be enriched and then plated. Because the enrichment step selectively amplifies the number of Campylobacter present, this is just a yes/no test and cannot be used to assess the quantity of Campylobacter present. Since the "1ml" test is less sensitive, the "30 ml" test will not be done if the "1 ml" test is positive.

The performance standard for the "1 ml" test will be 10.4%, which is no more than 8 positives out of 51 carcasses tested. The performance standard for the "30 ml" and "1 ml" tests combined will be 46.7% or no more than 27 of 51 carcasses tested.

After 90% of the Broiler Plants have been tested for two, complete 51 carcass sets (estimated to be by 2012), the FSIS will consider setting Category 1, 2, and 3 standards that are separate from the Salmonella Categories.

The FSIS estimates that half of the Broiler Plants that do not meet the new Campylobacter standards will improve their food safety systems to meet the standard during the first 2 years. The agency speculates that 39,000 human illnesses will be prevented each year from this new set of regulations. Currently, Broilers are blamed for causing 400,000 Campylobacter-related illnesses.

### **Proposed New Salmonella Performance Standards for Young Turkeys**

First, it is worth remembering that turkey carcasses, being larger than broiler carcasses, are tested with a different procedure than the "bird rinse" method used in broilers (this is to avoid back injury in the personnel performing the sample collection). Instead, a small portion of the turkey carcass is swabbed with a sponge, and this is used for testing for both Salmonella and Campylobacter. As such, the baseline for turkeys is markedly lower than broilers.

The current baseline level for Salmonella in turkeys is 1.7%, and over 90% of the turkey plants have been in Category 1, with none in Category 3. Because of this, none of the names of Category 2 plants have been published on the FSIS website.

Because the Salmonella levels are so low, it would take a very large number of samples to statistically validate any standards below the existing baseline level. To make resources available for higher priority work (like ground turkey), the FSIS has placed the performance standard at an expectedly easy to reach level of 1.7% or 4 positives out of 56 carcasses.



The FSIS plans to publish the names of plants that do not meet the performance standard on their last set that was begun after finalization of the new standards. However, there will be no names published if more than 90% of the turkey plants meet the performance standard. Like the broilers, FSIS will prioritize additional testing and Food Safety Assessments on plants that cannot meet the standard.

The FSIS expect that 82% of turkey plants will meet the new standard of no more than 4 positives out of 56 carcasses. This is very close to the 90% goal set by the Presidents Food Safety Working Group. They estimate these new standards will reduce the number of human illnesses by 100 cases

(Author's note – Is it possible that the low Salmonella levels in turkeys is attributable to the higher rate of early adoption and higher rate of use - relative to broilers - for direct-fed microbials and probiotics in turkey production?)

### **Proposed New Campylobacter Performance Standards for Young Turkeys**

Again, turkey carcasses are tested with a different procedure than the “bird rinse” method used in broilers. A small portion of the turkey carcass is swabbed with a sponge, and this sample is used for testing for both Salmonella and Campylobacter. Similar to Salmonella, the baseline for Campylobacter in turkeys is markedly lower than broilers.

The estimated prevalence of Campylobacter in turkey is 1.1%. Because this is such a low level, the FSIS has set a single performance standard for the combined “1 ml” and “30 ml” tests at 1.1% or no more than 3 positive samples in a 56 carcass set.

Similar to other regulated bacteria, the FSIS will prioritize new testing and new Food Safety Assessments on Turkey plants not meeting the new standard.

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### **Status of Poultry Producers Regarding Salmonella**

So, what do producers need to reduce Salmonella? Basically, there are two situations in which broiler or turkey producers find themselves:

- 1) “Struggling” producers who need to get from Category 2 or 3 to Category 1. These people have begun pathogen control practices relatively recently, or may have begun the process with a more widespread Salmonella incidence.
- 2) Producers who have figured out how to have low Salmonella levels and are not under intense regulatory scrutiny. Some of these producers are happy with their status, while others are interested in capitalizing on their successes to achieve ultra-low or “zero” levels of Salmonella. In general, the level of knowledge regarding Salmonella control practices is very high in this group.

There is a general level of Salmonella equilibrium in table egg producers. Most are able to control SE levels through biosecurity and vaccination. Vaccination may not prevent gastrointestinal infection of the birds with SE, but it tends to prevent systemic infection – reducing the chances of eggs testing positive for SE. Egg producers, not surprisingly, also fall into two basic categories:

- 1) The first group is represented by farms that have eggs testing positive for SE and are desperate to be able to sell shell eggs again. These people are not unsophisticated, but their program has broken down.
- 2) The other group consists of farms that do not have SE positive eggs, but are looking for a mitigation/intervention that will augment their program and keep them from having to send eggs to the breakers. Arguably, this group of business-as-usual shell egg producers could be divided into two



sub-groups based on the SE status of their environmental samples (positive or negative). As an aside, one issue that makes egg producers nervous is the availability and approval of new Salmonella detection methods that are more sensitive than the established method. It is certain that, over time, regulatory officials or laboratory directors will move to the most sensitive methods. Using methodologies with increased sensitivity could cause a disruption in the equilibrium because Salmonella may be detected in flocks that are currently considered to be negative.

### **Where Do Pacific Vet Group Products Fit in Control of Salmonella?**

Before we discuss the facts, we should discuss the politics. The FDA has determined that competitive exclusion is a “drug effect.” That means anything (other than a very narrowly-defined vaccine) that is intended to displace, reduce, or eliminate Salmonella from animals falls into the same general category as an antibiotic or other drug. Also, products that are non-nutritive and increase growth rate or minimize the effects of disease are also considered to be drugs. These categories of drugs require a lengthy and expensive FDA approval process. Pacific Vet Group products fall into a different category than competitive exclusion products, growth promoting antibiotics, and therapeutic antibiotics. These “direct-fed microbials” contain live organisms, but there is no claim to treat any disease or condition. It is important to remember Pacific Vet Group does not claim its products reduce Salmonella, treat disease, or improve growth rate.

There are two main venues for communicating the effects of direct fed microbials:

- 1) Scientific publications are not restricted, so publishing the positive effects of Pacific Vet Group products in refereed journals (based on actual research) is allowed.
- 2) The other relatively unrestricted type of communication is veterinarian-to-veterinarian professional discussions. Vets are allowed, with restriction, to prescribe products off label if there is not an approved product to treat that condition. These professional discussions are allowed, provided the individuals engaging in the discussion are licensed veterinarians. Some companies promote their products without violating FDA regulations by holding these discussions “offshore” in foreign counties.

Laypersons reading this article should consult with their veterinarian in order to properly apply these recommendations to their existing overall health program. Based on the author’s veterinary experience and substantial available published research, FloraMax® (**often “FM-B11” in the literature**) and Sporulin® can play a role in a poultry Salmonella control program. The application of effective probiotics varies depending on the level of urgency. Broiler plants in Category 2 or 3 and table egg flocks that have SE positive eggs are in similar “critical” situations. These producers will be trying every method of control and intensifying both farm and processing interventions. They will very likely NOT be collecting detailed data on the effects of each intervention. They are just trying to stop the hemorrhaging.

For rapid control (in the urgent situations), use FloraMax® relatively close to the time the Salmonella test samples will be collected. It is advisable to make multiple applications to get maximum saturation of the beneficial bacteria throughout the system. For broilers and turkeys, use FloraMax® at least two times at 14 and 7 days<sup>1</sup> prior to slaughter. For table egg flocks, use FloraMax® every week to 10 days until the flock tests negative for SE according to regulatory interpretations. Other steps that should be recommended to potential customers in the urgent category include 1) use of Optimizer™ in the drinking water during feed withdrawal, 2) litter treatments prior to slaughter, 3) increased rodent control efforts, 4) chiller treatments and/or optimizing pH of the chiller water to fit products being used, 5) reduced feed withdrawal times, and 6) temporary removal of animal byproducts from the diets.

For long term control, FloraMax® should be part of the breeder flock program. These birds should receive FloraMax® at placement or from the primary breeder prior to delivery. Farm applications of FloraMax® to breeding stock could use EarlyBird® perinatal nutritional supplement as a delivery vehicle. EarlyBird® could

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<sup>1</sup> This could be 12 days and 5 days, 10 days and 3 days, etc.





also be used by the primary breeders (broiler or layer breeders, only) by placing this into the chick boxes prior to delivery. The breeder flock should receive FloraMax® about once per month, as it fits into existing coccidia control, vaccination and movement programs. It is especially important that the flocks receive FloraMax® shortly before movement to a new housing situation to minimize transfer of Salmonella from one farm to another. (Typically there is one move from a pullet farm to a laying farm for broiler breeders or laying hens, but turkey breeders may move from a brood specific farm, to a rearing/dark out farm, and then onto the laying farm.) As a course of managing any testing process that has regulatory implications, it makes sense to apply FloraMax® at 14 and 7 days<sup>2</sup> prior to this testing. The supplemental efforts listed in the paragraph above should also be considered for inclusion in a long-term program.

For a more “surgical strike” approach, long term and routine use of FloraMax® can be adjusted to focus on known positive situations. For example, if there is a breeder flock that consistently produces Salmonella-positive chicks, this flock and its progeny can receive additional coverage with FloraMax®. Other flocks known to be Salmonella-negative may receive less frequent applications or may go without FloraMax® in order to free up resources for the problem situations. Testing should include drag swabs of litter and hatchery environment, chick meconium from individual breeder flocks (not a pool of several flocks), rodents, animal byproducts being incorporated into feed, as well as cull chicks and poults from the hatchery or farms.

For producers who are in compliance with Salmonella regulations but would like to reach the ultra-low or negative status, Sporulin® is a viable alternative to FloraMax®. Unpublished research has confirmed the ability of this product to reduce Salmonella levels in laboratory and commercial settings. Because Sporulin® is administered in the feed, compliance at the farm level is not an issue. For best control, Sporulin® should be included in all feeds, including starter and finisher.

Incidentally, Optimizer™ is a mixture of organic acids that has been shown to reduce or eliminate Salmonella in the crop. During feed withdrawal, modern meat strains of broilers and turkeys scratch and peck the litter, consuming fecal material that may be contaminated with Salmonella or other pathogens. The use of Optimizer™ during feed withdrawal is advisable as part of an overall Salmonella control program.

FloraMax® is the most-published beneficial bacterial product on the market. Any objective beneficial bacteria program should start with FloraMax® before considering other products. Distributors should focus their initial sales efforts on producers who are known to have Salmonella (testing) issues. Presentation of research results by sales people, as well as veterinarian to veterinarian discussions and presentations offer the best communication methods for passing on the knowledge of the capabilities of FloraMax®.

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<sup>2</sup> This could be 12 days and 5 days, 10 days and 3 days, etc.



**Appendix – Tables of FloraMax®, Optimizer™, and Sporulin® Applications**  
 Broiler & Meat Turkeys, Category 2 or 3

Breeder Flocks Supplying Hatchery	Apply FloraMax® every 10 to 14 days Water apply Optimizer™ the day before using FloraMax®
Broiler Chicks at Hatchery	Apply FloraMax® to all Chicks via Spray or EarlyBird® <sup>A</sup>
Broiler & Meat Turkey Flocks	Apply FloraMax® 20 to 28 days prior to slaughter Water apply Optimizer™ the day before using FloraMax®
	Apply FloraMax® 10 to 14 days prior to slaughter <sup>A</sup> Water apply Optimizer™ the day before using FloraMax®

A – Most Important Applications

Table Egg Flocks, Egg Tests Positive

Layer Chicks at Hatchery	Apply FloraMax® to all Chicks via Spray or EarlyBird® <sup>A</sup>
Layer Chicks at Farm (Day of Age)	Apply FloraMax® via EarlyBird®
Pullet Flocks (Supplying Positive Farm)	Apply FloraMax® every 28 to 42 days Water apply Optimizer™ the day before using FloraMax®
Layer Flocks	Use FloraMax® 10 to 14 days prior to testing <sup>A</sup> Water apply Optimizer™ the day before using FloraMax®
	Use FloraMax® every 28 to 42 days via the drinking water Water apply Optimizer™ the day before using FloraMax®
	Apply FloraMax® 10 to 14 days prior to testing <sup>A</sup> Water apply Optimizer™ the day before using FloraMax®

A – Most Important Applications

Broiler & Meat Turkeys, Category 1

Breeder Flocks Supplying Hatchery	Use FloraMax® every 28 to 42 days Water apply Optimizer™ the day before using FloraMax®
Broiler Chicks & Turkey Poults at Hatchery	Spray all Chicks with FloraMax® <sup>A</sup>
<i>Broiler &amp; Meat Turkey Flocks</i>	Use FloraMax® 20 to 28 days prior to slaughter Water apply Optimizer™ the day before using FloraMax®
	Use FloraMax® 10 to 14 days prior to slaughter <sup>A</sup> Water apply Optimizer™ the day before using FloraMax®
	Use Sporulin® continuously in feed as an alternative to FloraMax®

A – Most Important Applications

Table Egg Flocks, Environmental Tests Positive (Egg Tests Pending or Negative)

Layer Chicks at Hatchery	Spray all Chicks with FloraMax® <sup>A</sup>
Layer Chicks at Farm (Day of Age)	Apply FloraMax® via EarlyBird®
Pullet Flocks	Use FloraMax® every 28 to 42 days Water apply Optimizer™ the day before using FloraMax®
	Use FloraMax® 10 to 14 days prior to testing <sup>A</sup> Water apply Optimizer™ the day before using FloraMax®

A – Most Important Applications