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November 19, 2004

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

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

Dear Sir or Madam:

I am writing to comment on the Food and Drug Administration's proposed rule on *Salmonella* Enteritidis in shell eggs. My company, Hy-Line International, employs 430 workers at its operations in Iowa, Indiana, Pennsylvania, Georgia, Texas, California and Washington. We are keenly interested in the egg industry because we supply the egg industry with the genetic products used in the production of eggs. Approximately 80% of the industry's laying hens originate from our genetics. Thus we are extremely interested in the well being of the egg industry and our collective responsibility to supply a safe and wholesome product to the consumer.

I know many egg producers, and am confident that they want to deliver a safe product to their customers. The Centers for Disease Control and Prevention has just published a study that documents how Salmonellosis rates have declined when producers have initiated quality assurance programs. These producers are 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:

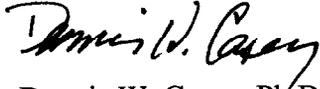
1. **Recognize and reward what states and the industry are already doing.** FDA should thoroughly review all existing state and private egg quality assurance programs to see if they already provide protection equivalent to what FDA is seeking. If so, then producers who are in compliance with one of these 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.

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Producers will always comply with the law and regulations to the best of their ability. But the industry needs regulations that are flexible, reasonably applied, and scientifically based in order to survive as a business. I strongly urge you to make the changes that producers are asking, so that this regulation can be workable for our industry.

Respectfully,

A handwritten signature in black ink that reads "Dennis W. Casey". The signature is written in a cursive style with a large, stylized initial "D".

Dennis W. Casey, Ph.D.
President