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Refrigerated Foods and  
Livestock Production Group

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June 19, 2001

FSIS Docket # 97-013p  
U.S. Department of Agriculture  
Food Safety and Inspection Service  
Room 102  
Cotton Annex  
300 12 street, SW  
Washington, DC 20250-3700

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97-013P-2660  
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Katie Hanigan

Farmland Industries, Inc., Kansas City, Mo., ([www.farmland.com](http://www.farmland.com)) is a diversified farmer-owned cooperative focused on meeting the needs of its local cooperative and farmer-owners. Farmland and its joint venture partners supply local cooperatives with agricultural inputs, such as crop nutrients, crop protection products, petroleum products and animal feeds. As part of its farm-to-table mission, Farmland adds value to its farmer-owners' grain and livestock by processing and marketing high-quality grain, pork, beef and catfish products throughout the United States and in more than 60 countries.

Farmland Foods a division of Farmland Industries, has some serious concerns regarding the proposed rule "Performance Standards for the Production of Meat and Poultry Products." Each section of the proposal will be individually addressed. The proposed performance standards for mandatory Listeria testing will be addressed first, as this is particularly troublesome and will create an economic hardship for Farmland Foods.

Proposed Listeria Performance Standards

- ❖ Listeria control is the number one food safety concern facing companies producing "Ready to Eat" (RTE) products. Farmland Foods believes that all companies producing RTE products should be routinely testing their RTE environments for Listeria species and analyzing the data for unfavorable trends. The amount of environmental testing conducted needs to be a decision made by each establishment or company. The amount of testing needed to ensure that Listeria is not a problem is highly dependent on the facility layout, cleaning schedule, and other control systems/programs in place. An establishment and/or company cannot afford to produce product contaminated with Listeria. Clearly producing and distributing product contaminated with Listeria can be devastating to an establishment and/or company. One Listeria incident can ruin a "brand" name, etc.

- ❖ The proposed Listeria performance standards will create a immediate economic hardship for Farmland Foods in many ways.
1. The proposal requires an establishment to prove that product is not adulterated with *Listeria monocytogenes* – if it was packaged on a line which has tested positive for generic Listeria. In order to meet this part of the proposed standard **and** comply with the language in the 1996 Pathogen Reduction; HACCP Final Rule, an establishment would have to implement one of the following three options – all of which would cause an economic hardship.
    - A. All products packed from the beginning of the production day to the end of the production day on the sampled line would need to be held at the establishment until the results are available. Most packaging lines run two shifts per day or approximately 18 hours.
    - B. After the line has been sampled, production on the line would have to stop. The establishment could break a product lot by conducting a full cleanup of the packaging line. This option is not feasible at most facilities because of the equipment layout in the packaging room. One line cannot be completely isolated from all other lines for cleaning.
    - C. After the line has been sampled, packaging on the line would stop for the remainder of the production day.
  - ✓ Each of the three options listed above creates an economic hardship for the establishment. In addition, if a company has multiple plants producing RTE products, the economic hardship grows considerably.
  2. Section 417.6 (e) from the 1996 HACCP Rule states: “A HACCP system may be found to be inadequate if adulterated product is **produced or shipped.**” FSIS has clearly stated that once a product leaves an establishment’s official premises it has “shipped.” FSIS has also stated that product **cannot** be shipped to a “non-company owned” or public warehouse and held in a company’s account. Therefore an establishment must hold all products from a sampled RTE line at the establishment. Farmland Foods does not have the physical ability to hold this amount of product on site, unless the product is held in trailers in the parking lot.
  3. The proposal requires an establishment to sample RTE lines based on the size of the facility. Basing the sampling scheme on the number of establishment employees is a flawed proposal. Many establishments with 500 or more employees are slaughter facilities. These facilities may only have one or two RTE packaging lines. The majority of the 500 employees are working in the slaughter and fresh meat departments.
 

As an example – if an establishment has 600 employees and 5 packaging lines, the proposal requires each packaging line be sampled 4 times per month. If each line packed 5 different lots of products, the amount of product on hold each month would be 100 lots. 5 lines x 5 product lots packed per line x 4 sampling days per month = 100 product lots on hold each month

If an establishment has 100 employees and 8 packaging lines, the proposal requires each packaging line be sampled 2 times per month. If each line packed 5 different lots of products, the amount of product on hold each month would be 80 lots. 8 lines x 5 product lots packed per line x 2 sampling days per month = 80 product lots on hold each month.

If a company has 3 large plants and 3 small plants producing product as shown above, the number of product lots on hold each month = 340 lots.

3 plants x 100 = 300 + 3 plants x 80 lots = 240

- ✓ Why should a smaller establishment with more RTE packaging lines sample less than a large establishment with fewer RTE lines? FSIS is constantly preaching that all sampling schemes must be scientifically valid. Where is the scientific validity of FSIS' proposed environmental sampling scheme? A sampling scheme should be directly related to the number of RTE packaging lines or the pounds of product being packaged at the establishment – not to the number of establishment employees.
- ✓ Additional economic hardship is created by the need to hire additional staff members to physically tag and release product each month.
- 4. The proposal states that mandatory environmental sampling scheme is not required of those establishments which have identified *L. monocytogenes* as a hazard reasonably likely to occur and so have incorporated into their HACCP system one or more controls validated to eliminate it from their products. Although this sounds simple, it is very complex from a scientific viewpoint. It is a known scientific fact that proper lethality treatment will eliminate *Listeria* from a product. It is also a known scientific fact that *Listeria* can be transferred to a product via post cooking contamination. At the FSIS' public meeting in May 2001, various companies presented the "pathogen reduction technology" their company had developed. It is important to note that the majority of these technologies have not been proven in an industry production environment and the cost of such equipment could easily run \$500,000 to \$1 million dollars per establishment.
- ✓ The economic impact on a company with 5 or 6 plants packaging RTE products is huge. How can a small plant ever expect to purchase this type of technology? If a small company does not purchase this equipment – how will they ever compete in the business world?
- ❖ Farmland Foods believes before any further regulatory act on is taken regarding *Listeria* or *Listeria* control, FSIS needs to answer the following questions.
  1. Why was the "Listeria risk assessment" completed using data and processes not pertinent to the USA?
  2. Why does FSIS feel the current micro sampling Directive 10240.2 is not effective?
  3. How many RTE plants are not complying with Directive 10240.2?
  4. What **scientific data** does FSIS have that shows, the current level of food safety is **not** meeting the goals set by former President Clinton

5. What data does the agency have to **scientifically** show the benefits of the proposed Listeria performance standards outweigh the economic hardship to the meat industry.

#### Proposed Stabilization Performance Standards

- ❖ Farmland Foods clearly feels improper product chilling could create a food safety concern. However, in the past 36 months, Farmland is unaware of any recalls relating to improper product chilling and thus allowing the growth of *C. botulinum* or *C. perfringens*.
- ❖ In the proposal, FSIS has failed to properly document or communicate the **scientific** need for the proposed chilling performance standards.
- ❖ Most establishments are following the guidelines in Appendix B of the “Compliance Guidelines For Cooling Heat-Treated Meat and Poultry Products (Stabilization).”
- ❖ Prior to finalizing this portion of the proposed rule, FSIS needs to show how the proposed chilling standards will bring new or added benefit for consumer safety.
- ❖ Before the proposed chilling performance standards are finalized, FSIS needs to provide a method to develop statistically valid sampling plans which are **feasible** – in the event of a product chilling failure. Statistically based sampling programs continue to be a bone of contention between establishments of all sizes and FSIS.
- ❖ In addition, if *C. perfringens* is the organism of concern with improper chilling because of the development of heat resistant spores – what options does an establishment have when product fails to meet the chilling performance standards? Is re-cooking the product an acceptable corrective action?

#### Proposed Lethality Performance Standards

- ❖ Farmland clearly believes that pathogen lethality processes need to be a critical control point in a HACCP program. Industry clearly understands that a finding of any pathogens in RTE products makes the product adulterated. In the proposal, FSIS has failed to properly document or communicate the **scientific** need for the proposed lethality performance standards.
- ❖ Industry is currently operating under the guidelines of Appendix A in the “Compliance Guideline For Meeting Lethality Performance Standards For Certain Meat and Poultry Products.” Prior to finalizing this portion of the proposed rule, FSIS needs to show how the proposed lethality standards will bring new or added benefit for consumer safety.

#### Proposed Trichinae Performance Standards

- ❖ The current lethality guidelines in Appendix A in the “Compliance Guideline For Meeting Lethality Performance Standards For Certain Meat and Poultry Products” will ensure the destruction of Trichinae. Therefore Farmland Foods questions the need for this part of the proposed rule.

## Conclusion

Overall, Farmland feels the agency has failed to show how the proposed rule will enhance food safety. Long ago – FSIS said they were going to move away from command and control. In reality, FSIS is using performance standards as a form of command and control – thus forcing industry to implement CCPs that are not scientifically valid.

When invalid, non-scientific CCPs are mandated and implemented, a vicious circle is created. The establishment cannot scientifically defend their programs – therefore leaving the door open for the agency to find their HACCP system as being inadequate.

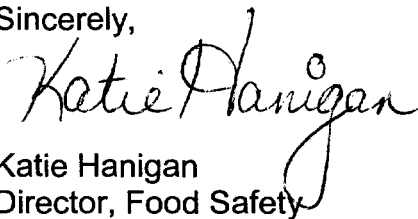
The proposed Listeria performance standards are clearly an economic hardship on establishments and companies of all sizes. The proposal performance standards and the language in the 1996 Pathogen Reduction Act basically conflict with each other. The proposed performance standard forces a company to hold product, yet the 1996 Pathogen Reduction Rule will not allow a company to ship product off-site to a warehouse for holding.

FSIS needs to return to the drawing board and start again. They need to:

1. Complete the “risk assessment” using the most recent USDA processes and data.
2. Study the current level of food safety and determine if the goals set forth by former President Clinton are being met.
3. Clearly communicate “where and why” Directive 10240.2 is failing.
4. Carefully study the economic impact of the Listeria proposal on industry.
5. Scientifically show how the proposed lethality and stabilization performance standards will benefit consumer safety.
6. Scientifically show why *C. perfringens* and *C. botulinum* are the organisms of concern with a chilling failure.

I appreciate the opportunity to express my concerns regarding the proposed “Performance Standards for the Production of Meat and Poultry Products.”

Sincerely,



Katie Hanigan  
Director, Food Safety