CARGILL
CORPORATE FOOD SAFETY

15407 McGinty Road West, MS 63
Wayzata, MN 55391-2399
Mail Address: PO Box 9300, MS 63
Minneapolis, MN 55440-9300
952/742-6095 Fax: 5216

2705

September 7, 2001

97-013P-2705
97-013P
William H. Sperber

FSIS Docket Clerk
Docket No. 97-013P
USDA/FSIS
Room 102, Cotton Annex
300 12th Street, SW
Washington, DC 20250-3700

[Docket No. 97-013P] **Performance Standards for the Production of Processed Meat and Poultry Products; Proposed Rule. 66 *Federal Register* 12590-12636. February 27, 2001.**

Dear Ms. Moore:

Cargill is a global processor, marketer, and distributor of agricultural, food, financial and industrial products and services with 91,000 employees in 60 countries. While we have many meat and poultry operations worldwide, in the United States, Cargill is one of the three largest producers of meat and poultry products, primarily through our Excel, Emmpak, and North America Turkey businesses.

In February of this year the USDA Food Safety and Inspection Service published the proposed rule referenced above and asked for comments regarding this document. Cargill is committed to providing safe and wholesome food to our customers. As part of this commitment we have actively promoted and initiated food safety programs that are firmly grounded in science, and we have encouraged the development and enforcement of food safety regulations that are likewise firmly grounded in science. Therefore, we are grateful for the opportunity to offer comments, which we believe will strengthen the proposed rule and improve its potential effectiveness to further protect the public health.

General Comments
This proposed rule is actually a conglomeration of numerous propos ed rules. These could likely be considered and refined more effectively if they were reorganized and republished as three separate proposed rules as follows:

1. Proposed Performance Standards—Lethality and Stabilizatic n
2. *Listeria monocytogenes*
3. Thermally Processed, Commercially Sterile Products

As written, some requirements in the proposed rule would place a v ry large economic burden on the industry while providing no significant additional public health p rotection.

The proposed rule would encourage the establishment of ineffective critical control points (CCP) in order to avoid the proposed environmental and product testing re uirements. This, of course, is a prescription for continued public health failures. The Agency, r ther, should encourage the industry to adopt effective process controls instead of requiring incr ased environmental and product testing.

In specific matters related to food safety and public health the USD A has been quite reactive. Originating in large part from an external petition, this proposed rul is a case in point. Given its major internal resources (ARS, FSIS, APHIS, etc.), the USDA sh ould be much more proactive in the development of effective science-based regulations.

1. Proposed Performance Standards---Lethality and Stabilizatic n
Proposed Performance Standards—Lethality
The logic used to establish "worst case" numbers of *Salmonella* for his standard is much too conservative, leading to a performance standard that requires a muc more severe heating step than is necessary. This is particularly important for smaller product , which can suffer organoleptic defects from overcooking. It does not apply to larger p roducts in which the integrated lethality ranges from several hundred to several thousand D-values.

Proposed Performance Standards—Stabilization
If adopted, this proposal would require that during cooling after coo king, further handling and distribution that there be no growth of *Clostridium botulinum* and n t more than a one-log increase of *Clostridium perfringens*. We think that these proposed r equirements are not necessary. The *C. botulinum* requirement should be abandoned. Th e *C. perfringens* requirement should either be abandoned or substantially changed.

There is no evidence of a botulism risk in RTE meat and poultry pr ducts. In the many decades since the production of these products began, there has not been an ncident of botulism

attributed to errors in the commercial production of a refrigerated fo od. The industry has a long history of safety on its side.

Similarly, there is no evidence of a *C. perfringens* risk in RTE meat and poultry products. The "worst case" number (10,000 cfu/g) used in this proposed rule was c btained from a raw chicken sample during the mid-1990s baseline study. If this stabilization rec uirement is to be meaningful, the worst case number should be obtained from cooked products. Since vegetative cells are easily killed during cooking, a lower worst case number wc uld be obtained, thereby permitting greater than a one-log increase before the posited hazardc us level (100,000 cfu/g) was reached. As a practical matter, it would be quite impossible to moni or and enforce this stabilization requirement based on a one-log increase of *C. perfringens* during the life of the product. If it is necessary to regulate *C. perfringens* control after co king, which we do not think is the case, it would be far more feasible to establish a maximum all wable level of *C. perfringens* (e.g., 10,000 cfu/g) at all points in the distribution chain after cooking.

In our examination of cooked meat and poultry products that were p oduced under cooling conditions that deviated from the existing regulations, we never dete cted growth of *C. perfringens*. The analysis of some hundreds of samples almost alwa /s yielded a negative result (<10 cfu/g). About 1% of the samples yielded very low *C. perfringens* counts (about 10 cfu/g). This level is vastly lower than the presumptive hazardous level of 1C 0,000 cfu/g.

2. *Listeria monocytogenes*

Listeria monocytogenes*—Proposed Requirements for Controllin g *L. monocytogenes

There is an obvious public health basis for requiring more effective c ontrols of *L. monocytogenes* in RTE foods. However, for truly effective controls to be developed, two important modifications must be made in this part of the proposed rule. These are (1) adopting a realistic and precise definition of RTE foods and (2) placing primary emphas s on process controls to control the listeriosis hazard.

Definition of RTE foods

In the context of the foodborne listeriosis hazard, RTE foods are:

> **those refrigerated foods of extended shelf life (>10 days) t iat can support the growth of *L. monocytogenes* and will be consumed withou : further listericidal treatment.**

In the context of both the foodborne listeriosis hazard and this propo ed rule, all four of the underlined conditions would need to be met for a food to be consider ed RTE and subject to this rule. Different RTE foods would be excluded from the proposed rul by this definition. These foods are frozen, shelf stable, have a very short shelf life, or will not support the growth of *L. monocytogenes*.

It is now generally accepted (refer to recent WHO estimates) that very high levels of *L. monocytogenes* (>100,000 cfu/g) are required to infect even highly susceptible individuals. The continued surveillance and recall of non-RTE foods (by the above definition) is a misuse of government and industry resources that does not provide any public health benefit. Under current federal regulations the entire food industry has borne substantial and unnecessary losses because of the many recalls of products that would not be included in the above RTE definition because they would not support listerial growth (typically frozen products), but were found to be very minimally contaminated with *L. monocytogenes.* This situation would continue under the proposed rule, thereby discouraging the industry from applying effective listeriostatic treatments.

The Agency's own *L. monocytogenes* Risk Assessment supports this argument. Therefore, it would be advisable for the Agency to include in future rules and regulations a limit of about 1,000 cfu *L. monocytogenes*/g for all foods that are not included in the above definition of RTE foods. It would not be "sound science" for the Agency to ignore the conclusions of its own risk assessment.

Place Primary Emphasis on Process Controls

If a food presents a significant listeriosis hazard, the industry should be encouraged to adopt process controls to eliminate the hazard. These should be *bona fide* HACCP controls in which effective CCPs could be implemented. Such CCPs could be established to manage process steps such as heating, irradiation, high pressure, etc. that would be applied to products in the final consumer packages. Alternatively, formulation controls could be managed as CCPs when food additives that killed or prevented the growth of *L. monocytogenes* were used.

One of the maxims of food safety is that if a food cannot be produced and handled safely, that food should not be produced and sold, unless the product or process can be changed so that food safety can be assured. In the context of these comments, if no CCP could be established for a RTE food (as defined above), that food could not be produced and sold unless a logistical change could be made. This hypothetical food, for example, could be distributed frozen instead of refrigerated, or its shelf life could be reduced to less than ten days. Alternatively, additional process step(s) or process control(s) could be implemented to assure the safety of this hypothetical food.

The proposed rule undermines its potential effectiveness by permitting environmental and product testing in place of effective process controls. While product contact surface and finished product testing are useful to monitor the effectiveness of sanitation programs, they are not effective at detecting foodborne hazards, particularly those that occur at a low incidence. In two recent outbreaks of foodborne listeriosis, it was very difficult to detect contaminated products. No contaminated products were detected in one of the outbreaks.

Everyone involved in this discussion understands that the statistics of product testing mitigate against its effectiveness to control microbiological hazards. That is why the industry developed

the HACCP system of food safety to supplant product testing for food safety assurance. HACCP is a food safety system based upon product design and process control. It is not based upon environmental and product surveillance.

We are, of course, not arguing against effective sanitation programs or microbiological monitoring to verify their effectiveness. Sanitation SOPs and GMPs are essential to establish and maintain hygienic environments in which foods can be safely produced. However, SSOPs and GMPs in and of themselves cannot provide effective controls to assure food safety. A logician would say that sanitation is a necessary but insufficient condition for food safety. Experience has proven that sole reliance on SSOPs and GMPs to prevent foodborne listeriosis will eventually result in failure.

As written, this section of the proposed rule will not improve the current situation. In fact, it will quite likely prove to be counterproductive if enacted. Some producers may find it difficult or expensive to install a new process step that could be managed as an effective CCP. All producers will find the increased environmental and product monitoring to be expensive. More significantly, environmental and product monitoring will entail product hold and release programs. These are very costly programs, and the industry estimates that they cannot be accommodated by existing refrigeration capacity. All of these considerations will encourage some producers to establish ineffective control measures, such as documenting employee glove usage or testing sanitizer strength, etc., instead of enduring the expense of product hold and release programs. These ineffective control measures are, of course, smoke screens that will not provide protection against a listeriosis hazard. This situation would not be different from the current regulatory environment.

We expect more from the agency and from this proposed rule. The agency should use its resources to propose science-based recommendations that would encourage the industry to implement effective control measures. It should not permit or encourage alternatives, such as additional product testing, that merely continue past ineffective strategies.

***Listeria monocytogenes*—Shelf-life and Labeling**

If our suggested modifications are implemented, a warning label ("may be contaminated with *Listeria*") will not be necessary. Those RTE foods that fit the revised definition of this proposed rule will be essentially *Listeria*-free because of the process controls that were established and maintained.

RTE foods outside this definition (for example, frozen foods) might contain low levels of *L. monocytogenes*. Regulatory action against these products is unnecessary and, of course, no warning label should be required.

Similarly, shelf-life dates on products of extended shelf life are unnecessary. Fitting the revised RTE definition of this proposed rule, these products would be essentially *Listeria*-free and would present no public health hazard.

"Use-by" dates would be helpful only for those RTE foods whose safety is assured by a short shelf life (<10 days). As explained above, these foods would not be subject to this proposed rule, but such guidance will be beneficial to protect the public health.

3. Thermally Processed, Commercially Sterile Products

Even though we are not producing such products in the United States, we do not think that it is necessary to change the existing canned foods regulations

Thank you for your consideration of our comments.

Sincerely,

William H. Sperber, Ph.D.
Senior Corporate Microbiologist

Timothy A. Freier, Ph.D.
Corporate Microbiologist