ConAgra Foods®

ConAgra Foods, Inc.
Quality Assurance
6 ConAgra Drive, PDL-405
Omaha, NE 68102
TEL: 405-595-6001
FAX: 402-595-7660

September 7, 2001

Docket Clerk
Docket #97-013P
United States Department of Agriculture
Food Safety and Inspection Service
Room 102 Cotton Annex
300 12th Street, S.W.
Washington, D.C. 20250-3700

97-013P-2707
97-013P
Stein Hordvik

2707

Re: Proposed Rule to Establish Performance Standards for the Production of Processed Meat and Poultry Products, 66 Fed. Reg. 12589 (February 27, 2001)

Dear Sir or Madam:

ConAgra Frozen Prepared Foods (CFPF) is a manufacturer and distributor of frozen prepared food products. Principal brands include Banquet, Healthy Choice, Kid Cuisine, Wolfgang Puck, Marie Calendar, Patio, Chun King, LaChoy, and Mama Rosa.

CFPF is dedicated to providing safe products to the consumer, and has adopted numerous procedures to minimize and control the risks associated with environmental and foodborne pathogens. The result is an outstanding safety record for CFPF frozen processed products containing fully cooked meat and poultry components. No dinner, entree or pizza has ever been associated with a public health issue involving *Listeria monocytogenes* (LM).

CFPF fully supports USDA commitment, to provide the U. S. consumer with safe and wholesome foods; and appreciate the opportunity to comment on this proposal. We do, however, have some of the following concerns:

1. The Final Rule Must Adopt Language Which Provides A Clear Definition of Ready To Eat (RTE) Products

2. The Proposed Rule Discourages Manufacturers From Actively Locating *Listeria* in the Plant Environment

3. The Flexibility For Establishing Lethality Performance Standard Is Not Consistent Between the Proposed Rule and Its Preamble.

4. The Flexibility For Establishing Lethality Performance Standard Is Not Consistent Between the Proposed Rule and Its Preamble.

The Final Rule Must Adopt Language Which Provides A Clear Definition of RTE Products

ConAgra Frozen Prepared Foods believes it is critical that the agency clarifies those products that will require testing. It appears that the proposal would apply to all food products, a category defined as "a meat or poultry product that can be safely consumed without cooking or application of some other lethality treatment to destroy pathogens" and which, based on the agency's "examples of RTE products" (see pages 12591-92), would include "entrees/dinners" among others.

The agency's examples are inconsistent with prior agency statements with regard to what constitutes Ready To Eat (RTE) versus Not Ready To Eat (NRTE) products, as well as with the Model Food Code's treatment of that issue. Frozen processed products containing fully cooked meat or poultry component along with raw or partially cooked non-meat or poultry ingredients -- many of which function as "dinners/entrees/pizzas". FSIS, Directive 10.240.2, has determined that it is appropriate to treat these products as NRTE for purposes of microbiological sampling under HACCP, as well as for HACCP plan reassessment to determine if *Listeria monocytogenes* contamination is a food safety hazard reasonably likely to occur.

FSIS's classification of these multi-component products as NRTE is fully consistent with prevailing regulatory policy. In the preamble to its final rule on safe handling instructions, the agency commented:

> Finally, as to whether safe handling instructions need to be on products that include a fully cooked meat filling, but where the total product requires cooking, e.g., a fully cooked meat filling in uncooked dough; the rule does not require safe handling instructions on products where the meat or poultry portion is fully cooked, or otherwise processed to render that portion ready-to-eat. However, while such products do not require safe handling instructions, they are not considered ready-to-eat (59 Fed Reg at 14534).

In addition, the agency has described RTE foo ls elsewhere as "products that may be consumed without any further cooki ıg or other preparation." (64 Fed Reg at28352). FDA's 1999 Model Food Code contir ues to define RTE food as "food that is in a form that is edible without washing, co)king, or additional preparation by the food establishment or the consumer anc that is reasonably expected to be consumed in that form." In meetings and co rrespondence with agency officials regarding these multi-component products, CFPF explained that they are intended to be cooked by the consumer prior to coı sumption, and all packages bear explicit instructions directing the consumer to do so. FSIS acknowledged the point that because products may contair components that have been cooked or thermally processed during manufacturing does not necessarily mean these products are RTE.

The proposed rule ignores these well-establisl ed definitions, including the agency's own prior classification of multi-component pr)ducts as NRTE, and, despite the fact that they require further cooking before co ısumption (and that the package clearly directs consumers to cook them), categoriz s them as RTE. CFPF urges the agency to address this inconsistency in any final rule by adopting a definition of RTE products that closely resembles the Mod l Food Code's and clearly excludes all meat and poultry products meant to be cooked by the consumer. FSIS already considers processed meat and poultry products wit h raw or partially cooked ingredients as NRTE for purposes of microbiological sampl ing and analysis. CFPF believes that all frozen foods, containing processed meat, a ıd poultry products should be treated as NRTE for purposes of a final rule reg rding pathogen performance standards.

A number of fully cooked meat and poultry co nponents are manufactured at one location and are utilized in another l cation exclusively in frozen Not Ready To Eat (NRTE) finished products. Thes components should not be considered Ready To Eat and subjected to microbial san ıpling according to the FSIS routine monitoring program including provisions for monitoring *Listeria monocytogenes* as contained in the 'Proposed Rule...'. Test ng fully cooked components destined to be used in a frozen NRTE final pr duct is a waste of FSIS manpower and laboratory capacities in a time when the a ency could be focusing its resources on several high risk product groups. To the best of our knowledge, no frozen RTE or NRTE product containing a fully cooked me ıt or poultry component has ever been linked to a public health incidence involving *Listeria monocytogenes.*

Frozen meat and poultry processed foods are safe. The fact that these products are frozen drastically lowers the likelihood that they represent a public health risk. The recently released FSIS/FDA *Listeria monocytogenes* draft risk assessment document confirms that freezing lowers the risk of LM contamination substantially by preventing organism growth. The FSIS/FDA *Listeria monocytogenes* draft risk assessment considered the LM risk from the frozen dinner/entrée/pizza so low that they were not even considered candidates for the risk assessment study. This hardly makes this group of products good candidates for *Listeria* monitoring and testing programs given the scarce FSIS manpower and testing budgets.

The protective effects of freezing against LM are compounded by several other important considerations with regard to multi-component frozen products.

1. The meat or poultry in the products is fully cooked, minimizing the potential for pathogens;
2. Finished product is immediately frozen after processing, and remains frozen during distribution and storage, effectively managing the potential for temperature abuse during distribution.
3. Consumers prepare the products directly from the freezer with little or no handling or defrosting, reducing the potential for consumer abuse.
4. The cook step performed by the consumer provides an additional protection against the presence or growth of pathogens. In fact, 100% of the respondents, who participated in a survey regarding how they prepare frozen meals, pies and chicken said that they cooked the product before consuming (see attached National Panel Diary data and diagram).

All of these factors make frozen dinners/entrees/pizzas and other frozen items that consumers are directed to cook prior to consumption far less vulnerable to pathogen contamination than true RTE products. CFPF believes that science and the agency's past policy determinations with regard to what constitutes RTE versus NRTE products fully support excluding multi-component frozen products from the RTE category.

The Proposed Rule Discourages Manufacturers From Actively Locating *Listeria* in the Plant Environment

The agency and CFPF share the goal of enhancing product safety. CFPF fully endorses the adoption of all steps that are necessary to assure the safety of their products, including testing for *Listeria* (species) and *Listeria monocytogenes*. We disagree with the agency's tentative decision to require environmental testing for *Listeria*. A regulatory scheme that mandates testing inevitably undermines at least some of such testing's value in enhancing product safety.

When instituted voluntarily, the goal of environmental testing for *Listeria* is very simple. A Company focuses on finding *Listeria* and, when found, implementing measures to eliminate its source in the environment. The intended effect of finding and eliminating the bacteria is, of course, to reduce the likelihood of product contamination with LM. CFPF believes the testing required in the proposal will be unlikely to achieve its intended goals for the following reasons:

1. Although not mandatory, industry will have to hold all RTE product produced by the establishment on the day that samples are collected because a positive result requires testing product from the implicated line.

2. Most plants have limited capacity to store finished product, and will have to ship product to an outside warehouse to retain control until a report is received from the testing laboratory.

3. The large number of lots on hold will increase the likelihood of errors in maintaining control over all the affected lots until officially released.

4. There will be a substantial financial impact due to double handling and interim storage. This cost was not considered in the proposal, and should be estimated before finalizing the final rule.

5. It is doubtful that the nation's existing storage and distribution system can cope with the volume of product involved.

6. Plants that now aggressively test product contact surfaces on a weekly basis, or more frequently, could not justify shipping product if a positive result for *Listeria*-like or *Listeria* spp is

reported. Thus, even for their own testing programs, all products would have to be placed on hold, and test when a product contact surface is sampled.

7. The necessity to hold product will cause industry to test product contact surfaces at the minimum frequently specified in the regulation instead of the current, aggressive manner adopted by many establishments.

The proposal provides an alternative to testing that consists of including one or more CCPs in the HACCP plan to control *Listeria monocytogenes* between lethality step and packaging.

1. This provision can be used to avoid testing product contact surfaces, a decision that would reduce consumer protection. In fact, the agency predicts that all large plants would establish CCP's in their HACCP plans.

2. It is not possible to control re-contamination through the establishment of one or more CCP's in the HACCP plan.

3. Re-contamination involves a wide variety of factors, all of which fall within the scope of SSOP and GMP (i.e., prerequisite programs). These programs are not amenable to CCP's.

4. The Agency's desire to force control of *L monocytogenes* into HACCP is consistent with prior policies and reinforces the Agency's continued reluctance to recognize the importance of prerequisite programs in pathogen control.

It is assumed by FSIS that increased testing will lead to improved consumer protection.

1. A significant data gap exists in the relationship between a positive product contact surface (i.e., *Listeria*-like, *Listeria* species, and *L. monocytogenes*), whether the product will be positive and risk to consumers.

2. The proposal acknowledges the lack of data on the relationship between a positive surface and the extent to which a product will be a positive product contact surface or product will increase

risk to consumers. No data are provided relating the level of contamination and the probability that multiplication to hazardous levels would occur before the product is consumed. There are no data to demonstrate these relationships that may exist under commercial conditions. Even the information developed from epidemiological investigations is too limited to be of help.

3. The agency has data that can answer some of these questions. Specifically, FSIS laboratory records can be reviewed for the number and percent samples that show blackening in modified Fraser broth, *Listeria*-like colonies on MOX agar, colonies that confirm as *Listeria* species and that confirm as *L. monocytogenes.*

4. There have been numerous changes to FSIS policies since the late 1980's; yet, the data from the FSIS monitoring program through 2000, the latest available, show limited success. It is reasonable to question how this proposal will be more effective, result in lower frequencies of contamination for the different categories of products and result in improved consumer protection.

CFPF proposes the following 3 testing options:

Option 1 – retain the Directive issued in December 2000:

Since 1987, FSIS requirements have continued to be tightened, as new information become available. In December 2000, a new Directive that had been in development for about 2 years provided industry with 3 choices.

During the past several years, industry has been increasing its testing of the environment. This trend has been encouraged by workshops sponsored by larger companies and trade associations that facilitate the transfer of experience and knowledge throughout the industry. There is now more genuine interest in testing correctly and aggressively to assess the level of control, detect and correct problems and, thereby, improve consumer protection.

Option 1 recognizes this favorable trend. By retaining the Directive and encouraging more testing through continued education, further reductions in exposure will occur.

It is evident from the proposed rule that the Agency is not now prepared to evaluate the effectiveness of a sampling program or define the components of an acceptable program. The Directive would enable FSIS to become more familiar with environmental testing programs and determine what would constitute an acceptable, minimum testing program.

Option 1 should involve a re-evaluation of the effectiveness of the Directive and education programs after 1 year to determine whether adjustments should be made to the Directive or if it should be replaced.

Option 2 – This option includes Option 1 and one modification to the Directive.

The Directive species testing product on a monthly or quarterly basis. One of the many data gaps stated in the proposed rule is the relationship between a positive product contact sample and the probability product will be contaminated.

This option would involve sampling the product contact surface and the probability that a product will be contaminated.

Since the industry would place the product on hold, pending the results, this modification would not increase the burden of hold and test beyond the frequency currently specified in the Directive.

Option 3 – Retain the Directive as in Options 1 and 2, and have FSIS sample the environment and/or products from establishments that do not implement a sampling program.

Some establishments can not afford or, for other reasons, will not establish and maintain a sampling program for *Listeria*. The Agency should sample the environment and/or product from these establishments. This has been the policy in Canada for a number of years.

This option would provide the Agency with the data and experience to develop the guidance documents mentioned in the proposal and

promulgate meaningful regulations with a defined public health objective.

The proposal assumes all RTE meat and poultry products are of equal concern and contribute to listeriosis. This is clearly not the case as is evident from the literature, epidemiological investigations, policies of other countries and the FDA/FSIS and FAO/WHO risk assessments.

A large variety of RTE meat and poultry products are of low risk because growth can not occur. For these products, the proposal rule would not yield improved consumer protection.

Policies should reflect the low risk associated with these foods, including change in current policy from a "zero tolerance" to 100/g

A new category should be established for low risk foods in which L. monocytogenes can not multiply due to low pH, low aw, additives, or other reasons. The category should also include products subjected to cook-in-bag or other impervious container, hot fill and hold, or post-packaging pasteurization. These products should be viewed as low risk and not subjected to testing as is now the case For some (e.g., fermented or dried products) in which growth can not occur a tolerance of 100/g should be established.

By establishing a new category of products as described, there would be increased incentive to apply new technologies to shift products from higher risk to lower risk category.

Establish a food safety objective for *L. monocytogenes* of no greater than 100/g in RTE product at the time they are consumed.

The Flexibility For Establishing Lethality Performance Standard Is Not Consistent Between the Proposed Rule and Its Preamble.

As written, the wording of the proposed rule does not allow for the flexibility promoted by the Agency in preamble discussion. To quote Section IV (p. 12594), The Proposed Performance Standards, Paragraph A Lethality: "The Agency acknowledges that it might be possible for producers to demonstrate scientifically that these lethality assumptions or the Agency's defined worst case would not be applicable for their particular processing situation. And establishment could then

design a process with lethality values that are different fro n those provided in this rule, but that would yield a product that meets the final co ıditions equivalent to those achieved by the specific levels of pathogen reduction (ontained in the lethality performance standards."

We agree with the need to allow alternative lethalitie s, but question whether the process defined by the Agency is reasonable or workabl ', or provides the latitude for processors to develop alternative lethalities. Tl e proposed rule states that lethality processes must be validated to achieve specif ed low probabilities that *Salmonella* remain in finished product "assuming the incor ıing product is worse [sic] case". The Agency may have intended the wording of t his provision to indicate solely that it used worst-case product in calculating its prol abilities, but it readily could be interpreted as requiring that a processor who is at :empting to establish an alternative process must assume that his starting product i s worst case product. Since worst case product is codified as having a certain nur ıber of organisms, how can any firm develop an alternative lethality based upon th eir documented ability to start with fewer organisms (as discussed in the preamble – p. 12594)?

The Proposed Performance Standard for *Clostı idium botulinum* Is Unnecessary.

The proposed performance standard for zero ;rowth of *Clostridium botulinum* is both unnecessary and unmeasurable. FSIS i: proposing that processing must prevent the multiplication of *Clostridium botulinum* and limit growth of *C. perfringens* to no more than one log. *C. botuli ıum* is unlikely to be present in meat and poultry, and when it is present, the nı mbers are very low (on the order of 1/1000 g). Furthermore, *C. perfringens* has a r ıuch shorter generation time than *C. botulinum*, and a broader range of growth ten ıperatures. Limiting growth of *C. perfringens* will effectively limit growth of *C. l otulinum*, as well as other sporeformers such as *Bacillus cereus* that might surv ive the process. In addition, it is not clear to us how one would attempt to me: sure growth of this organism.

C. perfringens must grow to approximately 10^{6}/g to cause illness. Given the low levels of spores are generally present in meat and poultry products, and that industry practices do not result in populations of C . *perfringens* of 10^{4}/g after cooking, we believe that a stabilization performance st andard that restricts multiplication to one log is overly conservative. This propos ed performance standard is likely to result in time needlessly expended to e valuate cooling

deviations, and demonstrate product is not adulterated or the destruction of product that is safe and wholesome. Moreover, the performance standard has led to the Agency questioning the safety of product produced under commercial practices with a long history of safety.

CFPF recommends that FSIS establish a Food Safety Objective for cooling that includes an upper limit of *C. perfringens* of 500 – 1000/g in cooled product as an alternative to the performance standard. If the Agency proceeds to set a performance standard for stabilization, we believe that science supports a standard allowing 1.5-log growth of *C. perfringens*.

CFPF is unaware of any instances where meat and poultry products, chilled in a manufacturing facility according to current practices, have resulted in foodborne illness, including illness from *C. perfringens*. To the best of our knowledge, illnesses resulting from improper cooling have been caused by gross temperature abuse, and *C. perfringens* outbreaks have been associated with food service establishments, not food processing establishments.

ConAgra Frozen Prepared Foods appreciates the opportunity to comment on this and future FSIS food safety proposals.

Sincerely,

CONAGRA FROZEN PREPARED FOODS

Stein Hordvik.

Stein Hordvik
Vice President, Quality Assurance