Kraft Foods

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Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
300 12th Street SW
Room 102 Cotton Annex
Washington, DC 20250-3700

97-013P-2706
97-013P
Jean E. Spence

Re: Docket No. 97-013P; Performance Standards for the Production of Processed Meat and Poultry Products; 66 Fed. Reg. 12590 (February 27, 2001)

Dear Sir or Madam:

Kraft Foods (Kraft) is the largest branded food and beverage company headquartered in the United States and the second largest in the world.[1/] Each year, Kraft is responsible for introducing into commerce about 14 billion individual packages of food. Our brands are found in more than 99% of all households in the U.S.[2/] Consumers have trusted our products for many decades. Indeed, the safety of our food products is the essential foundation upon which the success of our business is built. Consequently, food safety regulation is of paramount importance to Kraft.

1/ "Kraft Foods" and "Kraft" both refer to Kraft Foods North America, Inc., including its wholly owned subsidiary Kraft Foods International, Inc. The company's pro forma revenue, including Nabisco, for the year 2000 was roughly $35 billion.

2/ This level of market penetration is based on statistics gathered by A.C. Nielsen. Our well known brands of products containing meat or poultry include Oscar Mayer, Lunchables, Louis Rich, Tombstone, Di Giorno, Jack's, California Pizza Kitchen, and a variety of products sold under the Kraft brand.

Kraft strives to be an industry leader in the development and implementation of science-based programs and technologies designed to enhance food safety. In recent years, we have learned a great deal about food safety programs and techniques that work much more effectively than those previously in place, as well as those that did not prove to be as effective as intended. In these comments on the proposed performance standards for processed meat and poultry products, we are pleased to share what our company has learned. We approach this task realizing that all stakeholders must view food safety as a common, shared goal, if we are to be successful as a nation in preventing foodborne illness.

Introduction

Kraft is convinced that, as a matter of good manufacturing practice, all producers of ready-to-eat (RTE) meat and poultry products should institute *Listeria* control programs that include an environmental testing component. These programs should be designed to identify and sanitize *Listeria* harborage sites in the processing environment and to provide data upon which manufacturers can base corrective actions. Kraft, therefore, shares the Agency's commitment to promoting environmental testing among producers of RTE products.

As structured, however, the Agency's proposal to mandate environmental testing would potentially undermine the very public health objectives it aims to serve. The goal of environmental testing is to reduce the likelihood of finished product contamination. In order to accomplish this objective, testing programs must be designed to meet the unique challenges presented in every plant. The Agency's proposal, however, contemplates a "one size fits all" approach that effectively prevents companies from taking into account their particular manufacturing situation and history, equipment, process and product design, and employee practices in tailoring their programs.

Moreover, the Agency's proposal would punish companies with testing programs that are designed to find and successfully do find *Listeria* on product contact surfaces and in the environment. The goal of an effective testing program must be to locate the organism in order to take the necessary steps to sanitize harborage sites and make corresponding process improvements. Yet, the proposal would treat a single positive test result from a product contact surface as a "regulatory event". This single result could trigger potentially severe regulatory consequences, including the detention of large quantities of finished product for testing and possibly even the interruption of a plant's operations. This type of

regulatory response inevitably would discourage companies from acting aggressively to control *Listeria*, undermining rather than enhancing food safety.

In addition to this serious shortcoming, the proposal fails to identify clearly the products that would be subject to the proposed environmental testing requirement. It appears that the proposal would treat as RTE items meat-topped pizza and other multi-component frozen products that contain a fully cooked meat or poultry component, but that are intended to be cooked by the consumer prior to consumption. This position is inconsistent with prior Agency determinations. The proposal offers no explanation for this apparent departure from past Agency policy, the effect of which would be to divert resources from focusing on truly ready-to-eat products.

Several other aspects of the proposal are troubling as well. The proposed lethality standards are overly conservative and would severely limit the ability of manufacturers to produce products that satisfy the standards but are still palatable and meet consumer expectations. The proposed stabilization standards present similar problems. The effectiveness of historical controls for *Clostridium botulinum* and *C. perfringens* in commercially processed, refrigerated, RTE meat and poultry products is well established. Nevertheless, the Agency proposes to replace these easily understood and widely used controls with resource intensive microbiological testing requirements. Such time consuming, complex, basic research studies should be reserved primarily for validating new processes outside the currently established guidelines, not applied universally, even on processes that have operated sucessfully within the existing guidelines for years. Industry must focus resources on programs that will produce significant food safety improvements, if the country is to show progress toward national food safety goals.

For similar reasons, Kraft disagrees with the Agency's proposal to replace its regulations governing production of thermally processed, commercially sterile products with performance standards. The Agency's regulations, which are consistent with those adopted by the Food and Drug Administration (FDA) for the same product category, have been followed by industry for years and enjoy its full support. Kraft is aware of no scientific reason to eliminate these overwhelmingly successful regulations at this juncture.

Finally, Kraft supports the Agency's tentative decision not to establish a "use by" labeling requirement for processed meat and poultry products. Open dates on the labels of RTE products are intended to serve as quality guidelines, not safety parameters.

Discussion

I. ALL MANUFACTURERS OF RTE MEAT AND POULTRY PRODUCTS SHOULD IMPLEMENT ENVIRONMENTAL TESTING AND CONTROL PROGRAMS FOR *LISTERIA*

Kraft supports the implementation of *Listeria* testing and control programs in all plants producing RTE products, as that product category is properly defined. Given the ubiquitous nature of *Listeria*, eliminating it entirely from the environment is not a realistic goal. It is possible, however, to identify and sanitize harborage sites for the organism. It also is possible to use the data gathered and the subsequent root cause analysis to improve the production operation. Ultimately, all aspects of the *Listeria* control program work synergistically to minimize the risk of contaminating finished product with *L. monocytogenes.*

To accomplish this essential food safety goal, manufacturers must have flexibility to develop programs that are compatible with their particular product and process designs, manufacturing situations, and plant experiences. Manufacturers must also be allowed to monitor their processing environment for sources of the organism, investigate positive findings, and implement corrective actions. Properly designed environmental testing is a critical part of this process; it provides facilities with information that assists them in controlling the risk of post-lethality contamination in a systematic and targeted fashion.

In short, the bedrock of an effective *Listeria* control program is disciplined root cause analysis and corrective action based on a continuous regimen of environmental testing. An effective environmental testing program must include extensive sampling and analysis; sensitive detection methods; appropriate changes in equipment, process, and infrastructure; continuous training; and reassessment based on actual results. Environmental testing by itself, however, is not sufficient. A comprehensive *Listeria* control program is multi-faceted and must include other, broader control measures. Kraft has implemented an extensive *Listeria* control program that has been effective in controlling the risks of post-lethality cross-contamination of RTE products.

Given the common presence of *Listeria* in raw materials and soil, Kraft's program is based on continuous diligence in keeping *Listeria* out of food

processing areas. Thus, the program is designed to seek out and sanitize harborage sites for *Listeria* in processing areas and on equipment. Kraft's years of experience have taught the company that this type of targeted environmental testing and control is far more sensitive and efficient than other control techniques, including finished product testing.

Keeping *Listeria* out of food processing areas requires constant vigilance. Therefore, Kraft combines a number of different control tools including:

1. designing and maintaining equipment so that it can be cleaned effectively;

2. designing production facilities so that employees and portable equipment do not spread bacteria from room to room;

3. teaching employees to use good manufacturing practices without exception;

4. making adjustments as needed to reflect temporary, out-of-the-ordinary situations, such as construction;

5. using sensitive detection programs to monitor the effectiveness of control systems;

6. reassessing detection and control programs based on actual results and evolving science;

7. evaluating and using ingredients that are bacteriostatic or bactericidal to *L. monocytogenes*;

8. continually investigating new technologies that can be applied to packaged product to minimize the presence of *L. monocytogenes*; and

9. monitoring closely the rapidly evolving state of the science, including the availability of new analytical methods.

All of these steps are designed to prevent *L. monocytogenes* from entering and growing in finished product. They are also specifically tailored to a plant's environment and experiences.

There is no scientific basis for tying the frequency of testing a line to plant size, as suggested in the preamble to the proposed rule on page 12609. Plant size only affects the details of each plant's program, which should take into account

factors such as facility age, equipment design, prior control history, and employee practices. Furthermore, changing safety requirements based upon plant size would be at odds with the fundamental goal of reducing food borne disease; and American consumers have the right to expect safe product from all plants regardless of size.

The broad-based approach Kraft has adopted toward *Listeria* control is consistent with prevailing industry and academic thinking.[3] Numerous experts in these fields have acknowledged that, for many products, identifying one or two scientifically sound critical control points that can prevent *L. monocytogenes* contamination is not possible. Rather, control is achieved in processed foods through formulation, process control, equipment design, GMP's and facilities management. Kraft is committed to this approach and has invested more than $100 million dollars to enhance its *Listeria* control programs.

A successful program may also include finished product testing, provided such testing is triggered by a succession of positive environmental monitoring results, for which corrective actions are initiated but are not effective, or is used to verify the effectiveness of corrective actions. Finished product testing alone does not control the presence of the organism. It is only one type of detection tool. Furthermore, as a detection tool, finished product testing has important limitations.

Microorganisms by their very nature are not evenly distributed within a food product or processing environment, so standard statistical techniques, which are based on the premise that the sample represents the entire lot, are unreliable as prediction tools. Our experience has shown that, if *Listeria* were present in a lot of food products, the contamination would likely be sporadic and quite difficult to detect through finished product testing. For example, if a lot of product were contaminated with a level of *Listeria* at 0.5%, and 240 randomly selected samples were analyzed and found to be negative, there would still be a 30% probability that the product contains *Listeria*. Even if the sample size were raised to 460, there still would be a 1% possibility that the organism could be in the product, undetected. Quality professionals have long known the importance of building safety into a product using properly designed process control parameters, because defects cannot

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[3] The attached list of relevant *Listeria* Control References supports the position that environmental monitoring, combined with root cause analysis, and appropriate corrective actions are the most effective way to minimize the possibility that *Listeria* will cause the adulteration of finished RTE food products.

be successfully tested out once the product is manufactured. Indeed, this philosophy is the foundation for the success of the Hazard Analysis Critical Control Point (HACCP) process used to mange food safety today. Undue reliance on finished product testing directly contradicts the principles of HACCP.

If the Agency determines that environmental testing for *Listeria* should be required, testing programs most appropriately should complement, but should stand separate and apart from, a plant's HACCP and SSOP plans. This rulemaking proceeding provides an ideal opportunity, in this regard, for FSIS to recognize the role of good manufacturing practices, and prerequisite programs generally, as the foundation for HACCP. Every other HACCP authority, including the FDA, acknowledges that HACCP programs must be based upon effective prerequisite programs. If FSIS deems formal regulation of *Listeria* testing to be necessary, the regulations that have been part of FDA's regulatory scheme for years (21 CFR part 110) would be a useful model.

II. REGULATORY OVERSIGHT SHOULD ENCOURAGE NOT PENALIZE IMPLEMENTATION OF ENVIRONMENTAL TESTING

Although Kraft shares the Agency's interest in promoting and expanding environmental testing among producers of RTE products, we are concerned about the potential impact of the proposal on the industry's flexibility and willingness to act aggressively to seek out and sanitize *Listeria* harborage sites. Indeed, the manner in which FSIS oversees mandatory environmental testing is just as critical, if not more critical, than mandating testing itself.

As discussed above, the key to an effective *Listeria* control program is the use of aggressive microbiological surveillance as a monitoring and diagnostic tool. If the program is working properly, positive environmental results should be expected. In fact, aggressive monitoring programs rely on focused sampling plans that will result in positive environmental samples. That does not mean, however, that adulterated products are being produced. To the contrary, finding potential harborage sites enables a plant to sanitize them, reducing significantly the risk that products will be affected. If positive findings were to lead automatically to regulatory action, such as detention or suspension of inspection, plants would be penalized for doing a good job. It is especially important to understand that appropriately aggressive sampling plans deliberately concentrate on areas that appear to need special attention, excluding the many other areas of the plant which

are operating in control as expected. Therefore, positive findings should not be misconstrued as a statistically representative measure of plant performance overall.

Of course, Kraft appreciates that, if FSIS were to require environmental testing, plant inspectors would have an obligation to ensure that the testing is being conducted. They also would need to confirm that corrective and preventative actions are being implemented in accordance with the plant's plan. So long as the plant is taking such actions, however, further regulatory intervention (including production shutdowns and/or mandatory finished product testing) is unnecessary and counterproductive.

As drafted, the proposal would mandate that, when a plant finds a single food contact surface positive, it test all finished product produced that day. This would necessitate holding product until the testing is complete, imposing significant costs on the company. In fact, Kraft estimates that the cost to manage a hold and test program of this scope for our retail RTE meat and poultry business alone would exceed $30 million dollars per year in additional storage costs, incremental product distress, and increased inventories. Despite these costs, finished product testing would not provide any statistically reliable evidence that *Listeria* is absent from the product. Finished product testing is beneficial to validate process controls, not to control pathogens.

Other regulatory actions would be similarly unproductive. Stopping a plant from operating if it has a product contact surface positive result for environmental *Listeria*, for example, would not only punish the plant for identifying a potential source of contamination, it would make it impossible to observe personnel practices and equipment in operation, impeding the plant's ability to detect and correct problems.

Unrestricted access to company testing records by Agency inspectors who might not have the training necessary to interpret specific test results from a scientific perspective could also serve as a disincentive for companies to act aggressively in seeking out and sanitizing *Listeria* harborage sites in the processing environment. Positive environmental sampling results, when considered on an individual basis rather than in the context of a plant's experiences over a period of time, can actually be misleading. Documents in which raw data are recorded can be subject to misinterpretation, unless an appropriately trained individual studies them carefully.

If environmental testing for *Listeria* is required, inspectors should not be directed to take action on individual data points. To assure that establishments are operating in compliance, inspectors on a routine basis need only confirm that plants are testing and taking corrective and preventative actions in accordance with their plans. Broader records review should be limited to situations in which there is reason to believe that adulterated product has been distributed or as part of a validation audit by professionals trained for that purpose.

III. ANY RULE GOVERNING *LISTERIA* TESTING SHOULD CLEARLY DEFINE THE PRODUCTS TO WHICH IT APPLIES

In addition to ensuring that any environmental testing requirements encourage rather than discourage companies from acting aggressively to identify and sanitize *Listeria* harborage sites, and to take corrective and preventive actions, it is critical that the Agency clearly identify the products to which the mandatory testing requirement would apply. As written, the proposed testing requirement is extremely broad in scope. It apparently would require environmental testing of all RTE products, defined as "a meat or poultry product that can be safely consumed without cooking or application of some other lethality treatment to destroy pathogens...." The proposal lists numerous products that would fall into this category, including frozen pizzas, and frozen dinners and entrees. Kraft is this country's leading manufacturer of frozen pizzas sold at retail. Our pizzas are sold under the Tombstone, Di Giorno, Jack's, and California Pizza Kitchen brands.

Not all of these products, however, are correctly characterized as RTE, and the Agency's reference to them in the proposal as such is inconsistent with its own prior statements in that regard. For example, in its Directive governing microbiological sampling of RTE products under HACCP and HACCP plan reassessment, FSIS concluded that products such as meat-topped pizza that contain a fully cooked meat or poultry component but that are intended to be cooked by the consumer prior to consumption should not be classified as RTE.[4]

Despite this and other prior statements by the Agency, production of these products apparently would trigger the proposal's mandatory environmental

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[4] Indeed, the preamble's reference to pizza as a product that must be treated as RTE even though the product customarily is cooked, 66 Fed. Reg. 12590, seems inconsistent with the table of examples given on page 12591, which does not include pizza.

testing requirement for *Listeria*. It is unclear why FSIS would depart from its past practice and treat these products, which require further cooking before consumption (and which, by virtue of label directions, consumers are clearly directed to cook), as RTE for purposes of this testing requirement. [5/]

Kraft urges the Agency to resolve this inconsistency in any final rule by adopting the definition of RTE products incorporated into the U.S. Public Health Service Food Code.

Under the Food Code:

> Ready-to-eat food means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form.

The Food Code definition of RTE was developed by FDA, and has been adopted by many states and local regulatory jurisdictions. The definition clearly excludes from the RTE category meat-topped pizzas and other frozen processed meat and poultry products that contain fully cooked meat or poultry components and are meant to be cooked by the consumer.

Adherence to the Food Code definition would be consistent with the Agency's prior policy statements, as well as the policies of other agencies involved in food safety regulation. It would also facilitate clear and consistent communication of product handling information to consumers and would enable manufacturers to focus testing resources more effectively and efficiently, both of which will lead to enhanced food safety.[6/]

5/ It is important to distinguish raw products from products that contain cooked meat or poultry components, but are not ready-to-eat. As the Agency recognized in developing the referenced Directives, products that contain cooked meat or poultry, but are not RTE without additional cooking, do not necessarily have to bear "safe handling instructions" as such, but must be clearly labeled so consumers know they must be cooked prior to consumption.

6/ A comprehensive discussion of the Agency's prior statements with regard to what constitutes a RTE product is contained in comments prepared by the American Frozen Food Institute (AFFI). Kraft concurs fully with that discussion and incorporates it by reference here.

IV. THE PROPOSED LETHALITY PERFORMANCE STANDARD UNNECESSARILY LIMITS PROCESSOR FLEXIBILITY

In addition to an environmental testing program for *Listeria*, the proposal would establish performance standards for lethality. The indicator organisms for these standards would be *Salmonella* (lethality) and *Escherichia coli* O157:H7 (lethality for fermented beef products). Mandating these standards would not offer any meaningful benefit in terms of enhanced food safety. Currently, processors have options to achieve an equivalent lethality using flexible approaches. The rule as proposed may limit or eliminate a processor's ability to use alternative techniques.

The levels of *Salmonella* the Agency cites as possible are highly unlikely to occur in commercial processing environments. Recent USDA surveys show a downward trend in the prevalence of *Salmonella* on raw meat and poultry. Meat or poultry contaminated with such high levels would be regarded as organoleptically unacceptable for use as raw materials and rejected.

Kraft urges the Agency to reconsider carefully the data regarding microbial loads on meat and poultry. More realistic lethality performance standards would allow processors greater flexibility in achieving the target reductions, thereby ensuring the continued palatability of familiar products. Systems that are designed to provide this type of flexibility have worked well for the Agency and industry in the past in other contexts. The current roast beef processing guidelines and requirements to assure the absence of *E. coli* O157:H7 are excellent examples of how flexible approaches can successfully achieve destruction of the target organism.

V. THE PROPOSED STABILIZATION PERFORMANCE STANDARD WOULD ADD UNDUE COMPLEXITY TO PROVEN CONTROLS, IN THE ABSENCE OF AN IDENTIFIED PUBLIC HEALTH BENEFIT

Kraft certainly agrees that preventing illness caused by *C. botulinum* and *C. perfringens* is an essential public health goal. In fact, the goal is so important, that changes to the current, successful regulatory approach should be made judiciously. Only when solid scientific evidence indicates that a new regulatory framework is likely to improve food safety---to produce a measurable public health benefit---should the risk inherent in abandoning the tools that have worked so well for such a long time be accepted.

Today, manufacturers monitor time and temperature routinely as a process control tool during day-to-day production runs, apply the data to scientifically sound cooling curves, and know whether the product is safe to ship. Time and temperature are parameters that can be measured quickly and accurately under actual production conditions. Appropriately trained and qualified experts are able to relate the time and temperature curve data to growth of the pathogenic organism with a high degree of certainty, using a well established body of data published in the scientific literature. Manufacturers typically include the details of the control process in the applicable HACCP plan.

In contrast, the proposal would require companies to predict safety by trying to enumerate the growth of the pathogens in deliberately inoculated media, under artificial production conditions simulated in laboratories. Intentionally introducing a pathogen into a production facility is simply unthinkable, so there is no real world environment available in which a manufacturer could even attempt to enumerate pathogen growth under actual production conditions. Therefore, the proposal in effect would require that food safety decisions be based on models and simulations less well established from a scientific perspective than the cooling curves that are currently in use and have been proven effective. In the absence of an identified food safety benefit, Kraft cannot support adoption of the proposed stabilization performance standard, in place of the cooling guidelines that have worked so well for so many years.

Additionally, the incidence of *C. botulinum* in raw meat and poultry is extremely low. The literature reports one spore per 1 to 7 pounds of meat.[7] Enumerating growth at such low levels is a technical challenge at best. Furthermore, commercially processed, refrigerated, RTE meat and poultry products have been produced and distributed nationwide for decades, without reports of illness attributed to *C. botulinum*. Severe temperature abuse seems to be at least a factor in causing the unusual illness incidents recently reported to be associated with frozen chili. Therefore, establishing a performance standard for zero growth or a tolerance for *C. botulinum* would be unproductive, given the data indicating that the controls currently in use are highly effective and actually better adapted to the realities of production situations than those suggested in the proposed rule.

Similarly, reports of *C. perfringens* causing food borne disease historically have been limited to mishandling of meat products by food service

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7 Lechowich, R.V., *et. al.*, Food Technology (1978).

establishments or in the home. Many of these incidents resulted from gross temperature abuse in the preparation and serving of food service items. Cooling deviations in state or federally-inspected facilities have not been linked to outbreaks, as evidenced by the absence of documented cases of *C. perfringens* illness reported by the Centers for Disease Control and Prevention. The premise that *C. perfringens* presents a food safety risk in commercially processed, RTE meat and poultry products is not supported by scientific data.

Even if such data existed, the proposed performance standard, namely restricting *C. perfringens* multiplication to one log, would be overly restrictive. To cause illness, *C. perfringens* must multiply to levels greater than 100,000 per gram (five logs).[8] The proposed standard is premised on the Agency's worst case scenario that 10,000 *C. perfringens* spores per gram may be present in meat after cooking. Yet the baseline studies USDA relies on to estimate the post-cooking level do not even enumerate spores or confirm that the organisms present were *C. perfringens*. Moreover, the studies assume that raw product counts of *C. perfringens* can be fairly attributed to product after processing. In the absence of more convincing data about the presence of *C. perfringens* in cooked RTE meat and poultry products, Kraft cannot support establishment of a stabilization performance standard for *C. perfringens* that would unnecessarily drain valuable food safety resources from more productive programs.

VI. SPECIFIC REGULATION OF "USE BY" DATE LABELING IS NEITHER NECESSARY NOR MEANINGFUL

Kraft concurs with the Agency's decision to postpone further consideration of a "use by" date labeling requirement until the issue has been reviewed by the National Advisory Committee on Microbiological Criteria for Foods. Establishing "use by" dates would pose substantial legal and practical difficulties given current processing and distribution conditions, as well as prevailing regulatory policy. It would also not enhance food safety, the primary objective of the proposed rule.

Open date labeling is provided to help consumers judge quality, but date labeling never was intended to control product safety. Accepting for a moment

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[8] Control of Communicable Diseases Manual, American Public Health Association (APHA) 2000.

the premise that a product becomes unsafe as of a date specified on the label, we question whether either the government or a company would rely upon labeling alone to assure that consumers do not the eat out of date, *per se* unsafe product. Furthermore, under current law, RTE product is adulterated, if it contains <u>any</u> *L. monocytogenes*, regardless of whether the organism is able to grow in the product. Therefore, the suggestion that "use by" labeling should be established to limit shelf life is not legally relevant.

The development of a science-based, meaningful food safety expiration date is not feasible. Presumably, the date calculation would start with the premise that *L. monocytogenes* is present in the product. Thus, following a typical testing protocol, a researcher would begin by inoculating product with the organism. To assure safety, a responsible manufacturer would need to foresee the possibility of temperature abuse during distribution and direct the researcher to set the shelf life based on the presumption that temperature abuse is likely to occur in some cases. Considering the virtually infinite variety of distribution scenarios as the product moves from the manufacturer, through distributors and retailers to the kitchen, and acknowledging the variable temperatures known to exist in refrigerators, sound analysis could not produce a commercially reasonable shelf life. The flaw in such an analysis, of course, is that the organism should not be present in the product in the first place.

VII. CURRENT REGULATIONS GOVERNING PRODUCTION OF THERMALLY PROCESSED, COMMERCIALLY STERILE PRODUCTS SHOULD NOT BE CONVERTED INTO PERFORMANCE STANDARDS

Although the stated intent of the proposed rule is to enhance food safety, it is unclear how converting the current low acid canning regulations to performance standards would in any way advance that goal. Thermally processed, commercially sterile products produced in accordance with the low acid canning regulations have an exemplary safety record. Industry has successfully implemented and followed these HACCP-based regulations for over thirty years, and they have industry's full support. Changing the current regulations would add complexity for plants producing both FDA and FSIS regulated products, increasing the possibility for human error, without materially advancing the food safety goal. Kraft urges the Agency to retain the regulations in their current format. Doing so

will maintain consistency with FDA's regulatory scheme and ensure the continued production of safe, commercially sterile, shelf stable products.

Summary

Every manufacturer of ready-to-eat meat and poultry products should implement control programs for *Listeria,* consistent with current good manufacturing practices. The programs should begin with an effective lethality step and include aggressive environmental testing as well as the other fundamental components of a broad based *Listeria* control plan, such as systems to assure that the equipment and facilities are designed and maintained for effective sanitation, the use of traffic patterns that limit the ability of bacteria to spread from room to room, careful monitoring of employee practices, use of sensitive detection methods, etc. Broad based, aggressive programs are the most effective way to identify harborage sites for the organism, so that corrective and preventative actions can be implemented to sanitize the environment and reduce the risk of product contamination.

In contrast, the proposed FSIS regulation presumes that a single test is a meaningful measure of plant manufacturing conditions, and that finding *Listeria* in the environment is evidence that the plant is not producing safe food. Neither premise is correct. Plants must have the flexibility to design systems that address their unique production situation, equipment, process and product designs, and employee practices. In addition, finding the organism should be encouraged, not punished; punitive or misguided regulatory action could well undermine, rather than foster, the food safety goals that the proposed rule seeks to achieve.

To ensure that resources are most effectively employed, control and testing programs should focus on foods that are indeed ready-to-eat. Products that contain cooked meat or poultry components, but are intended to be further cooked prior to consumption are not typically classified as RTE by FSIS or any other regulatory body that has considered the question; and they should not be subject to whatever rule FSIS ultimately adopts.

The proposed lethality and stabilization standards offer no meaningful benefit in terms of enhanced food safety, but would replace controls proven effective and significantly complicate production process monitoring, diverting resources from more productive food safety activities and increasing the possibility of human error. Similarly, it would be inappropriate to establish regulations governing "use

by" date labeling. Finally, converting the current regulations for production of thermally processed, commercially sterile products into performance standards would jeopardize a regulatory scheme that has worked very well in its present form.

Kraft is a leader in the development and implementation of programs and techniques that help ensure the safety of America's food supply. The goal of the rulemaking procedure has our full support, but we cannot support the current proposal, due to our concern that the rules would undermine, rather than enhance, food safety. We look forward to working with the Agency and other stakeholders to achieve our shared objective of preventing foodborne illness Thank you for this opportunity to comment.

Very truly yours,

Jean E. Spence

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