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September 13, 2000

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Via Messenger

FSIS Docket Clerk
Docket 00-027N
U.S. Department of Agriculture
Food Safety and Inspection Service
300 12th Street, SW, Room 102
Washington, DC 20250-3700

Re: Comments on In-Distribution Program Materials from June, 2000 Meeting; Docket No. 00-027N

Dear Sir or Madam:

The purpose of this letter is to respond to the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service's (FSIS's) request for comments on the materials provided at the June 9, 2000 public meeting on the Department's in-distribution (ID) activities. 65 Fed. Reg. 49534 (Aug. 14, 2000). FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of \$300 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

FMI and its members have a longstanding commitment to food safety. FMI is a founding member of the Partnership for Food Safety Education, which unites government, consumer and industry resources toward the development and implementation of a national, broad-based food safety education program to reduce foodborne illness. We have also created the FMI Foundation, a supporting organization dedicated to food safety education. FMI is pleased to provide financial and technical support for the "National Food Processors Association Research Foundation Listeria Project," a study to sample ready-to-eat products at retail to determine the incidence of *Listeria monocytogenes*. FMI members have also developed six generic HACCP-based models and are pilot testing them in retail stores.

FMI and its members are active participants with multiple representations in the Conference for Food Protection (CFP), the advisory body for the model Food Code. We have also been selected by the Food and Drug Administration (FDA) as instructors for the agency's Food Code course ("Train-the-Trainer"), which educates state regulators on the Food Code. FMI co-sponsors two retail food safety manager certification programs and has developed extensive food safety training materials – in both English and Spanish – for store associates. We also serve on key regulatory and technical bodies, such as the Association of Food and Drug Officials, the National Sanitation Foundation, and the International HACCP Alliance. FMI hosts an annual food safety conference dedicated to educating industry, regulators and academia on food safety issues at retail. We have also been pleased to serve as speakers and technical consultants for food safety education programs conducted by USDA's Cooperative State Research, Education and Extension Service.

FMI commitment to food safety is predicated on the need for a strong overall food safety system. However, we are concerned that the in-distribution plan that USDA discussed at the June 9 public meeting will not be an efficient or effective use of valuable food safety resources. First, although the agency's public policy rationale supports the conclusion that food safety programs are appropriate for the complete farm-to-table continuum – a conclusion with which FMI strongly agrees – the rationale does not support the need for the program proposed by USDA. Substantial federal, state, local and private resources are already committed to ensuring the safety of food at the distribution stage. Indeed, according to the materials USDA presented in June, the ID inspectors that the agency has already redeployed to this program are only duplicating work currently performed by USDA compliance officers, as well as state and local inspectors.

Moreover, each of the states has programs in place to oversee supermarkets and grocery stores and, according to USDA, these state programs would remain in place, even following the advent of the federal in-distribution program. Given the agency's candid acknowledgements regarding the status of the additional work that USDA may develop in the future for ID inspectors – verification of plant HACCP plans, hazard identification, or other consumer protection (OCP) activities – it will be a long time before these programs will be available for implementation. Furthermore, the food safety system would be far better served by performing these functions earlier in the production system where they will best protect consumers. Thus, the in-distribution program described by USDA will not strengthen the overall food safety system.

Second, the program represents a shift away from preventing food safety hazards at meat and poultry processing establishments in favor of trying to detect problems later in the distribution chain when the product has been shipped to multiple locations and corrective action is more difficult to implement. Given the agency's assertion that the size of the overall inspection workforce will remain the same and that some of the in-plant inspectors will be re-deployed to the in-distribution program, we are concerned that a shift away from prevention and toward detection will result in a food safety system that is less effective overall.

Finally, despite the fact that USDA is far from completing the development of the in-distribution program design, the agency has allocated precious food safety inspection resources to begin its implementation. We submit, based on the foregoing, that the program is unnecessary; but, even if the agency determines that it is needed, the agency should complete the design through a continuation of the public process before further resources are used on this experimental program.

I. Factual Background

USDA ties the development of the in-distribution program to the agency's commitment to enhancing the safety of the overall meat and poultry supply. One of the agency's achievements in this regard was the promulgation of the "Pathogen Reduction; Hazard Analysis and Critical Control Point" (PR/HACCP) final regulation in 1996. 61 Fed. Reg. 38806 (July 25, 1996). The following year, the agency announced its HACCP-Based Meat and Poultry Inspection Concepts, which was the forerunner of the agency's HACCP Inspection Models Project (HIMP) and jointly outlined new inspection models for both meat processing plants and the distribution chain. 62 Fed. Reg. 31553 (June 10, 1997).

On January 25, 1999, the agency announced the availability of a November 1998 report entitled, "Report on the In-Distribution Inspection Pilot Test Project" (hereinafter "November 1998 Report"), and requested comments on the document.¹ FMI and at least fifteen others filed comments, most of which expressed reservations about the proposed program.

USDA held a public meeting on June 9, 2000 to advise the public of the status of the in-distribution pilot project. 65 Fed. Reg. 34653 (May 31, 2000). At the meeting, USDA advised that, from January through February, 2000, USDA trained eleven in-distribution inspectors to perform activities currently conducted by compliance officers, such as planned and random product reviews, recall effectiveness checks, consumer complaint investigations, and sampling for *E. coli* O157:H7. These inspectors are currently in the field and are deployed in the same locations as the HIMP plants. In the future, USDA is considering adding further duties to the ID inspector job description, such as HACCP plan verification and hazard identification, as well as other so-called consumer protection activities (OCP's).

¹ The November 1998 Report is no longer available on the agency's website.

II. Comments on In-Distribution Pilot Project

A. **FMI Agrees with USDA that a Sound Food Safety System Requires “Adequate Public Health Protection Measures” throughout the System, Including the Distribution Chain; FMI Disagrees that USDA’s Proposed ID Program Will Enhance Overall Food Safety**

Several times during the June 9 meeting, USDA officials quoted the following passage from a 1985 National Research Council (NRC) report as justification for the ID program:

An ideal meat and poultry inspection system will ensure that adequate public health protection measures are located throughout the food system, from animal production to the sale of the food product.

NRC, “Meat and Poultry Inspection: The Scientific Basis for the Agency’s Program,” as quoted in Transcript at, *e.g.*, 31. As further support for the necessity of the in-distribution program, USDA cited three HACCP principles:

- Hazards that may result in foodborne illness can arise at each stage of the farm-to-table continuum;
- Those in control of the stage bear responsibility for identifying and preventing or reducing food safety hazards under their control; and
- USDA must implement preventive strategies to improve the whole system.

Transcript at 32-33. USDA cited two additional food safety reasons that “point to the need to deploy agency personnel to scrutinize the condition of product as it moves in distribution:” (1) ensuring that product that bears the mark of inspection is not mishandled and (2) verifying that in-plant HACCP plans are adequate. Transcript at 34.

FMI agrees with many of USDA’s statements regarding the importance of a farm-to-table food safety system and the need for adequate public health protection measures throughout each stage of the continuum, including the distribution segment.² We further agree that hazards may arise at various points in the production chain and that those in control of each stage should be responsible for identifying and preventing or reducing those hazards that are under their control.

² Indeed, grocery stores and supermarkets are subject to substantial oversight from state and local regulatory programs, as well as federal oversight from both FDA and USDA. As noted at the meeting, USDA has been involved in the oversight of the food distribution system for thirty years. Transcript at 7. In the preamble to the proposed HACCP rule, USDA “pointed out that it was exercising regulatory oversight of meat and poultry products in transportation, storage, and distribution channels through the work of its compliance officers and by working with the Food and Drug Administration.” Transcript at 32. In contrast, meat and poultry processing plants are generally subject only to federal inspection or state inspection under a program that is “equal to” the federal standards.

We disagree, however, that the foregoing rationale supports the conclusion that USDA's in-distribution pilot program will strengthen the food safety program or that it is a necessary or desirable component of the current food safety system. USDA implies that, simply because the program relates to the distribution chain, it will be an appropriate use of food safety resources and will enhance the overall food safety system.

As discussed more fully below, the agency has not provided any information to support the conclusion that the implementation of USDA's in-distribution program will, in fact, improve the food safety system. Rather, we present our conclusion that it may actually reduce food hazard prevention and increase risk to consumers. The tasks now assigned to USDA's ID inspectors under the pilot program are the same tasks that are currently being performed by state and local inspection personnel, *as well as by USDA's own compliance officers*; consequently, the ID program as currently implemented does not enhance the food safety system. Although the agency provided some general information on possible additional information collection duties that USDA is now developing for ID inspectors to perform in the future, we are concerned about the need, desirability or benefit of conducting these in distribution, as well. In short, valuable food safety resources should be allocated wisely and carefully so that they will provide the most meaningful enhancement to the food safety system and, ultimately, the greatest benefit to consumers; the in-distribution project discussed at the June 9 meeting does not meet this standard.

1. ID Inspectors Applying Same Standards and Performing Same Functions in Same Establishments at Same Frequency as USDA Compliance Officers

According to the agency's remarks and the description USDA provided of the training program for the in-distribution inspectors, the ID inspectors are essentially performing the same functions and applying the same standards in the same facilities and at the same frequency as USDA compliance officers. Specifically, the ID inspectors were trained to perform planned and random compliance reviews, recall effectiveness checks, investigating consumer complaints, collecting *E. coli* O157:H7 samples and liaison activities. Transcript at 57-58. These are functions currently performed by USDA's compliance officers. Moreover, USDA stated:

The initial concept for in-distribution was the in-distribution inspectors would do the same in-distribution work as compliance officers. We've followed the concept to date and as a result in-distribution inspectors are visiting warehouses, distribution centers, and retail stores.

Transcript at 39. *See, also*, Transcript at 81. ("Right now we have in-distribution inspectors who are doing work that is similar to the work traditionally done by compliance officers.") Furthermore, USDA stated that the ID inspectors are applying the

same standards and performing these duties at the same frequency as compliance officers.³ Transcript at 41, 83.

During the meeting, USDA tried to explain why the agency felt that it was more appropriate for ID inspectors to perform these tasks than compliance officers. The agency asserted that their “tentative view is that reliance on inspectors to assess the condition of product as it moves in distribution is consistent with a fundamental shift effected by the implementation of HACCP.” Transcript at 35. The actual meaning of the statement is difficult to understand and the following elaboration does not provide meaningful insight:

Before HACCP, the prime focus of the agency’s efforts in distribution was *to find noncompliant product*... Now, however, . . . the agency’s emphasis in distribution is *to verify that product that is moving in commerce is not adulterated*.

Transcript at 35-36 (emphasis added). The difference between “find[ing] noncompliant product” and “verify[ing] . . . that product . . . is not adulterated” seems elusive at best,⁴ particularly when the personnel are performing the same activities and applying the same standards in the same facilities. The in-distribution program’s benefits in this regard to the food safety are, therefore, difficult to understand.

One possible explanation mentioned by USDA during the meeting is that ID inspectors will “free up time at some locations so compliance officers can concentrate on the more complex investigation and enforcement work.” Transcript at 20. Indeed, USDA states that compliance officers conduct “randomly scheduled reviews in distribution channels . . . when time and travel funds permit compliance officers to visit a firm or location not covered by the planned compliance program.” Transcript at 17. However, as USDA’s 179 compliance officers and supervisors last year were able to perform 34,000 random reviews, see Transcript at 17, it would seem that they had ample time to perform their “more complex investigation and enforcement work.”

³ USDA’s remarks regarding the frequency at which ID inspection tasks will be performed are particularly troubling and further undermine the agency’s claim that the ID work is related to food safety. In response to a question regarding the frequency of performance, USDA stated as follows:

To the extent that we have our in-distribution inspectors doing it, then it’s [frequency of inspection] *going to be dependent on the number of inspectors we have*, the nature of the task that we’ve defined for them – those sort of things.

Transcript at 83 (emphasis added). The need to perform the tasks, then, is dependant on the availability of inspectors and not on an overall assessment of risk or a need to improve food safety. If the ID tasks were needed to ensure food safety, the agency would be impelled to ensure that sufficient resources were available to perform the work; if less is sufficient for food safety purposes, then adding extra tests or inspectors to the area is truly an unnecessary and, therefore, wasteful expenditure of food safety resources.

⁴ The most effective, and HACCP-supported, way to verify that product in commerce is not adulterated is to assure it meets this standard *before* it enters the distribution chain. Once in commerce, the agency’s only option is to fall back into detection, *i.e.*, “finding noncompliant product.”

In contrast, however, USDA has had substantial difficulty recruiting and retaining in-plant inspectors, the very pool of personnel from which the agency intends to recruit in-distribution inspectors. *See, e.g.*, USDA, “FSIS Workforce of the Future” (presentation to National Advisory Committee on Meat and Poultry Inspection, May 2000); FSIS, “Staffing Report” (Communications to Congress, August 15, 2000). In fact, USDA stated that the agency does not plan to expand the inspection work force beyond its current size. Transcript at 84. Given the expense involved in re-training and re-locating in-plant inspectors to perform the same activities that are currently being well-handled by compliance officers, we fail to understand the justification for re-deploying scarce in-plant inspectors to the in-distribution program.

2. ID Inspector Tasks Encompassed within State Inspection Programs

Not only are the in-distribution inspectors performing the same tasks as USDA compliance officers, the functions are also encompassed by state retail inspection and enforcement programs. At the June meeting, USDA insisted that the federal ID program is not redundant to state programs “because of the differences in the focus of the two programs.” Transcript at 40. The agency’s assertion is that USDA personnel focus only on the handling of the product, while state programs focus on the entire facility. Transcript at 40.

The distinction being drawn by the agency is dubious at best. First, in focusing on the entire facility, states are necessarily (and importantly) including the product and the conditions under which it is held. The ultimate purpose of the state inspection is to ensure the safety of the food, not the conditions of the facility. In this regard, Jim Rutger, with the Minnesota Department of Agriculture provided the following remarks during the meeting:

Indeed, if we go into a food establishment and find uninspected product or a misuse of a federal inspection seal, the state of Minnesota also feels that it’s a violation. And through concurrent jurisdiction, it’s not only a federal violation, it’s a state violation.

Transcript at 96.

Second, unless the agency considers some aspects of the facility,⁵ it is unclear what the agency will rely upon to determine that the product is out of compliance. The

⁵ USDA specifically cited several factors listed by the NRC as relevant to the safety of meat and poultry products after they leave the inspected establishment. Transcript at 31. These included the microbial load in the product at the time of shipment, temperature during transportation and storage, loading of walk-in refrigerators and display cases, and the cleanliness of items used to handle meat and poultry products. Transcript at 31. Other than the “load of microbes in the product at the time of shipment,” (which can only be addressed by the plant), the remaining factors primarily relate to the

agency currently does not have any performance standards, such as storage temperature requirements, for product at retail. These standards are established and enforced by state and local regulators. Accordingly, and in light of recent judicial guidance, we would expect the agency to look to the facility to determine whether the product was adulterated on the basis that it had been held under unsanitary conditions.⁶ Therefore, we expect that the agency would find it difficult to adhere to a policy in which it only considered the product.⁷

Furthermore, USDA was not able to identify any activities that an in-distribution inspector would conduct that are not already being performed by state or local governments.⁸ Transcript at 48. Although the agency later asserted that “listeria grow out” is an area that the ID program would cover that is not being addressed by the states (see Transcript at 50), states are, in fact, sampling both product and the environment for Lm at retail and taking appropriate enforcement action, including recalls.

As members of the food production and delivery system, we have an active interest in the strength and integrity of the food safety system. We expect the agency to identify an actual gap or food safety need before allocating valuable food safety resources

facilities and conditions under which the product is held. Moreover, these factors are already covered by state regulations.

⁶ See *Supreme Beef Processors v. USDA*, Civ. Action No. 3:99-CV-2713-G (N.D. Tex. May 25, 2000) (agency may conclude that meat is adulterated based on finding of an adulterant in the meat or finding that facility itself is unsanitary, but agency cannot rely on performance standards for non-adulterants in meat to conclude that facility is unsanitary).

⁷ One attendee at the meeting expressed concern that different state and local jurisdictions provided different standards and the agency responsible for retail food safety was sometimes difficult to discern. See Transcript at 51. However, neither of these issues would be addressed by adding an additional layer of federal inspection, particularly in the absence of federal standards.

⁸ Q: Can you clarify for us, is there anything that an in-distribution inspector would inspect or monitor that a state inspector does not already do.

A: Well, I think I acknowledged that there is some overlap, and that’s why we’re working with Minnesota to see how that works out. The state inspector may well look at the conditions under which the meat is being held. And that’s what we’re trying to work out with Minnesota.

Transcript at 48. (Indeed, determining whether there would be overlap between the federal ID program and the state program, and, thus, whether it would be necessary to post ID inspectors in the states, is one of the stated goals of the ID program. Transcript at 41.) First, we submit that this evaluation should be performed *before* the start of the federal program. The handful of inspectors that USDA has deployed in four states certainly will not be sufficient for this purpose since they will only be able to review a relatively small number of retail stores. A true evaluation of the food safety need would require a more substantial investigation of the issue, which again would necessitate the allocation of substantial resources that might better serve food safety in a different capacity. For the assessment of each state’s capability to be truly meaningful, FSIS will need to develop criteria and a valid evaluation system to assess state programs to determine which states are incapable of regulating the retail segment of the farm-to-table continuum. We would expect such a program might be similar to the evaluation currently conducted by FSIS to determine whether state establishment inspection programs are “equal to” the federal establishment inspection program. Given the Food and Drug Administration’s jurisdiction over retail food stores generally, we would expect the process to involve FDA as well. Perhaps in future proposals regarding the in-distribution program, USDA might share its thinking on the evaluation system that the agency intends to use.

that might otherwise be used for a purpose that would truly serve the goal of enhancing the food safety system.⁹

3. Additional Tasks Being Developed by USDA Do Not Provide Sufficient Justification for Use of Food Safety Resources in ID Pilot Program

During the course of the meeting, USDA identified additional activities that the agency may assign to in-distribution inspectors in the future. These include information gathering to verify the effectiveness of plant HACCP plans, hazard identification, and other consumer protection (OCP) activities. As discussed more fully below, none of these will enhance the strength of the current system to ensure the safety and overall integrity of product; some of USDA's proposals will, in fact, weaken the system and reduce consumer protections. Moreover, as the agency has not determined the scope or the substance of any of these programs as they might be conducted at retail,¹⁰ they certainly cannot be used to justify the pilot that is already underway.

a. Verification of HACCP Plan Effectiveness Should Be Conducted In-Plant, Not In-Distribution

USDA stated that the agency wants to use information collected through the in-distribution program "to help evaluate whether in-plant HACCP plans are working to place safe products in the consumer's hands." Transcript at 9; see, also, Transcript at 49, 63. *Listeria* and shelf life are cited as examples of "the kinds of things that we can make both verifications and collect information on in federally inspected product in distribution that can allow us to look at the efficacy and adequacy of in-plant HACCP plans that are addressing hazards as they do not relate to in the plant but, as the regulation says, after the product has left the plant." Transcript at 67-68. This approach will jeopardize the safety of the food supply and is antithetical to HACCP.

The specific examples cited – determination of *Listeria* load and proper shelf life – need not and should not be determined in the distribution chain. As USDA noted during the meeting, "those in control of the stage bear responsibility for identifying and preventing or reducing food safety hazards under their control." Transcript at 32-33. If a plant's HACCP plan is insufficient to ensure that the product does not contain *Listeria* or that it will retain quality through its shelf life, the agency should not place its

⁹ For example, food safety resources would be more effectively directed toward enhancing the oversight of imported foods, in-plant inspection, on-farm activities, research or consumer education. See, e.g., "Food Safety: Opportunities to Redirect Federal Resources and Funds Can Enhance Effectiveness" at 8 (GAO/RCED-92-224, August 1998).

¹⁰ With respect to the HACCP plan verification activities, USDA stated that "we plan to develop a system to be able to look at this information, *although at this time we are not sure exactly what the system will look like. . .*" Transcript at 67 (emphasis added). See, also, Transcript at 69 ("How are we talking about doing some of these verifications and collecting information? *After we determine who and where and when would perform these verifications, we also want to look at how those verifications would be performed.*" (emphasis added)).

mark of inspection on the product. These are issues that should be addressed *before* the product is shipped to food retailers who will sell the product directly to consumers.

Moreover, a proper in-plant HACCP plan is intended to be a self-contained program that includes all of the elements necessary to ensure that the product is produced as safely as possible. Proper plan validation and pre-shipment reviews are part of every HACCP plan. The purpose of pre-shipment reviews is to ensure that non-compliant product does not leave the plant and to allow processors to implement immediate corrective action. In-plant verification, therefore, is an essential component of HACCP. To replace in-plant verification checks with in-distribution checks will decrease food safety since production verification will occur after product has been shipped and purchased by consumers and will not cover all products. The alternative, repeating verification checks in-distribution, is unnecessarily redundant.

Furthermore, in-distribution inspectors will not have access to the plant HACCP plans that this program would purportedly verify. Connecting information gathered in distribution would require traceback procedures to determine the origin of the product and to verify the HACCP plan. As is the case in many recall situations, product cannot always be traced back to its origin; in those cases, verification of a HACCP plan will not be accomplished and resources will have been expended on activities that have served no food safety purpose. In-distribution verification of in-plant HACCP plans is, thus, an inefficient expenditure of resources and effort.

b. Retail Hazard Identification Does Not Need Development of Ongoing Bureaucracy and Has Been Completed by FDA Baseline Study

The second future program that USDA identified as prospective in-distribution work involved gathering information on “where the hazards most likely to affect food safety occur in this continuum.” Transcript at 65. More specifically, USDA proposes to determine the “conditions that exist in the distribution chain under which inspected products are held that may constitute food safety hazards and how to address them, using the resources available to us at FSIS, the federal levels, state levels and local levels.” Transcript at 62.

We agree that hazard identification has some merit, and note that we are supporting the National Food Processors Association *Listeria* Retail Testing Program, a study to which the Food and Drug Administration is also providing substantial financial support. However, we disagree that USDA’s proposed in-distribution program is an appropriate forum for this purpose.

First, USDA has not yet designed a hazard identification information gathering program, thus, this function will not be performed in the pilot.¹¹ Second, hazard identification information need not be collected on an on-going basis, but may be the subject of a more discrete study. In this regard, we note that FDA has just released its “Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors.” The baseline data provided in the report suggest that some food safety areas are being handled well at retail and others warrant improvement. In this regard, FMI and our members look forward to working with the appropriate regulatory bodies to develop strategies to strengthen the food safety deficiencies identified.

c. OCP’s Cannot Be Corrected at Retail; Only Meaningful Remedy for Consumers Can Be Obtained Through In-Plant OCP Activities

Other consumer protection (OCP) activities constitute the third specific area of prospective in-distribution work that USDA identified at the June meeting. OCP issues generally concern economic adulteration, such as accuracy of net weight, species identification and nutrition labeling statements. Although USDA suggested that the distribution chain was the appropriate place to conduct OCP activities, the agency was unable to articulate any reasoning to support this approach. Indeed, in response to a question on why it would be more effective to look at OCP in the distribution stream than before the product left the plant, USDA replied, “I don’t think any of us really know the answer to that question and that’s why we’d like to explore it.” Transcript at 78. Although the agency might not know for certain, sound scientific methodology suggests that USDA should at least have a hypothesis that they intend to test before embarking on an experiment.

We submit that the consumer is best protected if the Agency follows the most fundamental HACCP principle: prevention. That is, resources to detect OCP’s should be focused as close to the source of the problem as possible to prevent its occurrence and provide the opportunity for immediate corrective action. Accordingly, USDA should continue to focus its OCP activities in plants, rather than in the distribution chain.

In fact, waiting until the distribution channels to detect economic adulteration will deprive consumers of a meaningful remedy. In many cases, the harm (*i.e.*, consumer purchase of economically adulterated product) would occur long before it is detected by ID OCP testing. Costly investigative and traceback procedures would be required, which would not have been necessary if the problem had simply been ameliorated at the plant.

As USDA noted during the meeting, OCP’s were the subject of a recent advance notice of proposed rulemaking that had been published by the agency to request guidance on the need and desirability of revising the agency’s approach with respect to OCP’s. 65

¹¹ Indeed, we doubt that USDA could obtain meaningful hazard identification data from the handful of inspectors that are currently deployed in four states under the pilot program.

Fed. Reg. 14486 (March 17, 2000). FMI filed comments fully explaining our recommendations to the agency in this regard. Our comments are attached hereto and fully incorporated herein.

In addition to the comments that we filed within the original comment period, FMI participated in the development of comments submitted to the agency from several members of the regulated industry during the comment period extension. These comments – which stress the importance of targeting resources to the area of the food chain in which the resources will be most effective – also support the conclusion that OCP's are properly controlled in-plant and not in-distribution. A copy of these comments is also enclosed for inclusion and consideration in this docket.

4. History of ID Program Suggests Its Basis Is Retention of Inspector Jobs, Rather than Food Safety

In response to inquiries, USDA stated during the meeting that it is not the purpose of the in-distribution inspection project to find a place for inspectors displaced by the models project (HIMP) or displaced from model plants even though, as the agency notes, the two projects were initially handled together and “the institution of the implementation phase of the HACCP implementation models project *provided the occasion for FSIS to select and train inspectors to work in distribution and to institute the in-distribution project.*”¹² Transcript at 36-38 (emphasis added). According to USDA, the agency’s memorandum of understanding with the union linked the two projects because it “provided that there could be up to 30 models plants [and] also provided for the selection and deployment of 11 in-distribution inspectors.” Transcript at 38. The November 1998 Report stated that, “The three locations [for the ID pilots] were selected *because they are also the locations of four of the in-plant models* and because [they] are examples of an urban area, a rural area and a combination of an urban and rural area.” November 1998 Report at 10.

Although the projects were obviously conceived together and linked as a joint initiative, the agency later decided to separate them because “there was no reason to keep them connected” because “they focus on completely different aspects of the agency’s work.” Transcript at 38. As the core substance of the projects did not change over time, the only conclusion that can be drawn is that they have always focused on completely different aspects of the agency’s work and the only connection between them was the employment element. Thus, the ID program was not motivated by a food safety need; rather, the impetus was employment.¹³

¹² Indeed, the “Vacancy Announcement” for the position, which was only issued once in a district-wide job announcement (see November 1998 Report at 5), states that “displaced or surplus USDA employees in the local commuting area . . . will be given special selection priority consideration.” Vacancy Announcement No. FSIS-MM-99-0379 (Sept. 7, 1999).

¹³ We should also note that USDA has not offered criteria the agency will use to remove inspectors from federal plants and shift them into distribution, nor has the agency provided a plan regarding the evaluation of the need for in-distribution inspectors or criteria for new positions. While the projects were

B. USDA Must First Ensure the Safety of Food before It Enters the Distribution Chain, Where It Is Ultimately Destined for Consumers

A sound food safety system depends on the prevention of food safety hazards, rather than on trying to detect pathogens in food products. Indeed, one of the fundamental tenets of HACCP is that the public is better served by the prevention of food safety hazards that cause adulteration of meat and poultry products than by efforts to detect adulterated product after it has been produced for consumption. *See, e.g.*, Transcript at 6. The principle is based on the fact that foodborne pathogens may present significant health risks, but may be difficult to detect because of their overall low frequency of occurrence and their random distribution. Therefore, it is better to prevent foodborne pathogens than to try to detect them in food following production.

FMI strongly supports the “prevention” philosophy. Under USDA’s HACCP program, meat and poultry processing establishments are required to establish HACCP plans to identify hazards and the critical control points and limits necessary to ensure that the hazards are controlled. USDA is responsible for inspecting both the product and the system in the plant to ensure that the HACCP plan is effective and that product manufactured under the plan is not adulterated. Thus, well-implemented HACCP programs are the most effective means of preventing, eliminating, reducing and controlling potential hazards in meat and poultry products before they are shipped from plants to grocery stores.

We are concerned, therefore, that USDA’s plan to redeploy inspectors from their current positions in the establishments that process meat and poultry to the distribution chain to perform tasks that are already being performed by other federal, state and local inspectors will weaken food safety. USDA stated at the June 9 public meeting that the agency did not plan to expand the inspection workforce beyond its current size. Transcript at 84. Therefore, to the extent that inspectors are being moved into distribution channels, they are necessarily being moved out of plants. Inspectors in plants can assure that HACCP systems are operating as designed to produce safe food; however, inspectors in distribution can only detect that – somewhere – the system failed. The point of failure cannot be identified nor can immediate action be taken to correct the system when the failure is detected in distribution. As the agency shifts its finite resources from prevention to detection, the potential for food safety problems will only increase. FMI cannot support a program that increases the likelihood of food safety problems.

linked together, these issues were addressed simply by the availability of inspectors displaced by the HIMP project; however, now that USDA has officially separated them, the agency would also need to develop criteria to determine the need for inspectors in the ID program.

C. **USDA Should Complete ID Plan *Before* Allocating Food Safety Resources**

At the outset of and throughout the public meeting, USDA was admirably candid about the development status of the in-distribution project. Tom Billy, the FSIS Administrator, began the meeting by stating that the agency does “not have an approach in a system already designed to present to you today.” Transcript at 9. Moreover, the agency has yet to decide on the facilities that will be inspected, the standards that will be applied, the frequency of inspection or the “who, where, when or how” that will be used for performance verification activities.¹⁴ Transcript at 39, 68-69, 83. Mention was made of the possible development of performance standards for handling meat and poultry products as they move through distribution, although the attendees were assured that any such standards would “go through the public process.” Transcript at 10, 42. As the agency has yet to issue a proposal, we can only assume that performance standards will not be available for enforcement in the near future.

USDA stated at one point during the meeting that the agency’s goal was “to configure our in-distribution resources in a way that will increase their effectiveness in ensuring the product remains safe after it leaves an inspected facility.” Transcript at 39. However, with all due respect, it is difficult to see how the in-distribution plan presented in June – which essentially amounts to (1) taking in-plant inspection personnel from jobs at which they are qualified and needed (2) to re-train them (a) to do the same work and (b) apply the same standards currently used by compliance officers (3) in establishments that have not been fully identified (4) at a frequency that has not been decided and (5) before an assessment of where the hazards are in distribution – is an effective reconfiguration of the agency’s in-distribution resources. Given these circumstances it is also unclear how the agency will be able to conduct the “formative evaluations” that USDA pledged to perform to determine, among other things, if the “program is working as intended.” Transcript at 58. Without a well-defined program, we do not understand how the agency will be able to determine whether it is “working as intended.”

Although we appreciate the Department’s candor and the opportunity to provide input on the formulation of the in-distribution project, it is premature to assign valuable food safety resources to implement the project at this point. We submit that the agency would be better advised to ensure the necessity and complete development of the plan *before* taxpayer dollars are used to support it. At a minimum, we hope that the agency will develop a new written plan – to replace the November 1998 Report, which no longer

¹⁴ See Transcript at 39 (“I don’t really have a definitive answer to this question [of which establishments the ID inspectors would visit] today.”); see Transcript at 68 (“There are a number of different types of businesses that we *will be considering* for verification activity.”) (emphasis added); see Transcript at 69 (“After we determine who and where and when would perform these verifications, we also want to look at how these verifications would be performed.”); see Transcript at 83 (Q: “Do you have any feel for [the frequency of inspections] at all?” A: “I think the answer is, not at this point.”)

reflects the agency's current thinking and has apparently been withdrawn – before proceeding any further.

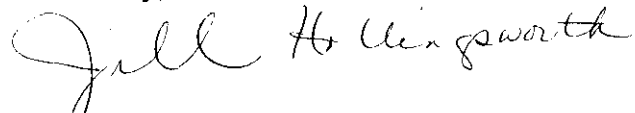
III. Conclusion

Given the foregoing, we respectfully submit that continuation of the in-distribution proposal is an unnecessary and inefficient use of valuable food safety resources. As noted above, the agency has not fully defined the plan's purpose or the activities of the inspectors. The work that is currently being performed is already being performed by both state officials and USDA's own compliance officers. The additional tasks that USDA is considering assigning to ID inspectors would be inefficient, at best, and would certainly not be a wise or careful use of food safety resources. If the agency does have a surplus of resources (financial or labor) that are available as a result of HIMP, we recommend that the agency apply them to a more effective food safety program.

* * *

We appreciate the opportunity to provide feedback to the agency on the in-distribution plan currently under development. If you would like to discuss the foregoing, or if we may be of assistance in any other way, please do not hesitate to call on us.

Sincerely,



Jill Hollingsworth
Vice President, Food Safety Programs

Enclosures