NATIONAL TURKEY FEDERATION
60th Anniversary

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(3)

December 21, 2000

00-014R2
00-014R2-3
Alice L. Johnson

FSIS Docket Room
Docket #00-014R2
Room 102 Cotton Annex Building
300 12th Street, S.W.
Food Safety and Inspection Service
Washington, DC 20250-3700

RE: Announcement of and Request for Comments Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Inspection

Dear Ms. Moore:

The National Turkey Federation (NTF) respectfully submits these comments in response to the Food Safety and Inspection Service's (FSIS) Notice on the Industry Petition to amend certain sections of the agency's HACCP regulations. As a signatory to the petition, NTF strongly urges FSIS to grant the requested relief and amend the existing HACCP regulations as soon as practicable.

NTF represents more than 99 percent of the U.S. turkey industry, including processors, growers, breeders, hatchery owners, and allied industry. It is the only national trade association representing the turkey industry exclusively.

As an initial matter, NTF strongly supports HACCP, the best system to control and eliminate food safety hazards. Importantly, HACCP is a living system, designed to adapt and adjust to better serve its purpose. It is in this spirit that the industry petition was submitted -- to improve implementation of HACCP in a regulatory environment.

The FSIS HACCP regulations, as currently written, are a hazard identification system, requiring establishments to identify all potential food safety hazards. However, the regulations do not provide a meaningful criterion for distinguishing among the potential hazards to ensure that a HACCP plan focuses on true food safety concerns. Therefore, all potential hazards are treated the same, regardless of the severity of the consequences of exposure to the hazard or the likelihood of its occurrence. Since both of these need to be considered in order to assess risk, without them, the HACCP system mandated by current regulations can hardly be described as a "risk-based" system.

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If all hazards are treated in the same regulatory manner regardless of the actual risk they present to consumers, the resources of establishments are often needlessly squandered by addressing "hazards" that do not pose an actual risk. This waste extends to agency resources as well. For example, inspectors will expend resources reviewing HACCP records for controls that do not impact on public health. Likewise, any regulatory action based on alleged noncompliance with unnecessary controls will not improve the public health. Additional resources are typically expended adjudicating these non-compliance situations as disagreements between firms and inspection personnel often drag on for extended periods of time. Squandering resources will restrict everyone's ability to respond effectively to future, unknown hazards.

For these reasons and those discussed below, we respectfully submit that if HACCP remains solely a hazard identification system, the food safety benefits of HACCP will be lost and the system will degenerate into an arbitrary "command and control" regulatory program.

The petition attempts to change the HACCP regulations by moving beyond a hazard identification system to a true risk management program. The petition would accomplish this change by providing establishments and the agency with the criterion necessary to distinguish between true food safety hazards and those that are illusory or merely theoretical. The petition does this through the introduction of "significant risk," a concept that allows for the differentiation of potential hazards based on the severity of the risk posed and the likelihood of its occurrence.

We cannot overemphasize the need to resolve this issue. To be blunt, the question of whether HACCP is a hazard identification or risk management system must be answered if the agency's food safety initiative is to proceed. Unless and until this issue is resolved: (a) training of agency personnel cannot occur; (b) staffing needs cannot be determined; (c) effective communications with industry cannot begin; and (d) the agency's verification activities cannot measure HACCP effectiveness. In short, until the nature of HACCP is resolved, the FSIS: Next Steps initiative will be ineffective.

We have the impression, erroneous as it may be, that the agency may not recognize the need to go beyond mere hazard identification. Our uncertainty is based on the first question posed in the Notice wherein the agency, in effect, seeks evidence that there is a problem with existing regulations. NTF would like to address first the need for change, and then conclude with our responses to the agency's six specific questions.

All Hazards are Not Created Equal but are Treated Equally Under Regulation

In any manufacturing operation, there are a host of potential hazards that may occur. These can range from chemical hazards, such as those posed by unsafe food additives; to biological hazards, such as those created by improper employee hygiene, improper storage, and elevated processing room temperature; to physical hazards which could come from foreign materials.

Under a literal reading of the existing regulations, all of the five potential hazards above would need to be included in a hypothetical establishment's HACCP plan. First, all five meet the definition of a "food safety hazard" since they "may cause the food to be unsafe for human consumption." 9 C.F.R. § 417.1. Second, if totally uncontrolled, we must concede that these five "hazards" may occur; that is why every establishment already has controls for food additives, employee hygiene, storage, temperature, and foreign materials. However, under the hazard analysis required by the regulations, this means that these food safety hazards are "reasonably likely to occur" because they could occur in the absence of controls. 9 C.F.R. □ 417.2(a)(1). Since an establishment must include a CCP for all food safety hazards "reasonably likely to occur," 9 C.F.R. § 417.2(c)(1), the current regulations would mandate that every one of these five hazards must be included in the HACCP plan. Yet, in virtually every case, none of these hazards pose a risk of significant magnitude to warrant inclusion in a HACCP plan.

A Meaningful Criterion is Necessary

As shown above, existing regulations, or at least the prevailing interpretation thereof, do not permit an establishment (or the agency) to distinguish among hazards. Without the ability to distinguish among hazards, HACCP is doomed to failure.

A meaningful criterion provides the framework for reasoned decision making. It identifies the relevant factors to be considered and applied. Without a criterion, there is no uniform, articulated basis for determining whether a particular food safety hazard should be included in a plan; rather the selection would be made arbitrarily. The absence of a criterion invites subjective decision making based on the predilections of the individual; decisions which may be non-uniform across the industry and which sow the seeds of dispute because of the perceived unfairness of any arbitrary, subjective decision.

Even if disputes are minimized, the absence of a criterion will eventually result in hundreds of CCPs being arbitrarily dictated over time by the regulators, often across an entire industry, whether justified or not. For each mandated CCP, the establishment and the agency must dedicate resources to monitor, document and verify. Since there is only a limited, fixed amount of resources, especially inspection resources, an increase in the number of CCPs would dilute the resources that can be spent on any individual CCP. Insignificant hazards therefore will receive the same attention and resources as clearly significant hazards -- not a logical resource allocation. Moreover, if resources are being overtaxed, how can the establishment or the agency respond effectively to any future, unforeseen hazard. In sum, the addition of unnecessary CCPs will fatally weigh the HACCP system down.

For these reasons, a criterion must be adopted to distinguish the important from the minor.

The Criterion Must Be Based on the Principle of Significant Risk

We respectfully submit that the criterion already exists -- that found in the HACCP principles developed and disseminated by the National Advisory Committee on Microbiological Criteria for Food (NACMCF). At its heart, this criterion focuses on significant risk -- risk that is ascertained by focusing on both the severity of consequences associated with exposure to the hazard and the likelihood of its occurrence. If a risk is significant, it must be considered under the HACCP plan. If it is not, then no CCP should be required.

Consideration of Severity of the Possible Health Consequences Allows for a Measured Response to Deviations

The first element deals with the magnitude of the risk posed. This can provide both the agency and establishments with a ready tool to determine which hazards should be covered by a HACCP plan. There is a great difference between the risk posed by handling raw product at 41°F versus the potential for adverse consequences due to failure to meet minimum cooking temperature. The risk associated with the former is virtually non-existent because it is not likely to increase the microbiological "load" of a product that, in any event, is intended to receive a lethality step. On the other hand, the failure to achieve a minimum cooking temperature could result in a product that remains contaminated with pathogens posing a certain probability (risk) of illness.

Moreover, if there is no distinction between hazards based on risk, the agency would end up treating each deviation the same. Returning to the illustration above, it seems draconian to treat a 1° failure of raw product temperature control in the same manner as a failure to properly cook product. Any regulatory action on the former would not have a basis in public health protection, whereas action on the latter would be so justified. *The severity of the regulatory response to a deviation should and must match the potential public health consequences posed by such a deviation.*

It should be noted that FSIS is very familiar with estimating the magnitude of risk posed by a hazard. It's recall procedures assign a risk classification for every recall. In a former regulatory scheme -- PBIS -- the agency had a "Deficiency Classification Guide" to classify deficiencies as "critical," "major," and "minor."

In Determining Likelihood of Occurrence, Control Programs Must be Considered

As noted above, the likelihood of occurrence is the second element to consider in determining whether a particular hazard is significant. The likelihood of occurrence, in turn, depends on the efficacy of any establishment's control programs. As noted above, virtually all establishment control programs, either directly or indirectly, have an impact on the likelihood that a food safety hazard would occur.

Apparently, FSIS has assumed that such programs are beyond the purview of the HACCP regulations and cannot be considered in assessing the adequacy of an establishment's HACCP program. See 63 Fed Reg 4562 (January 30, 1998). Therefore, the agency feels

the need to require that such programs be incorporated in a HACCP plan. We respectfully disagree with this view.

FSIS has authority under the regulations to review and copy all "decisionmaking documents associated with the selection and development of CCPs." 9 C.F.R. § 417.5(a)(1). If an establishment uses a control program to justify the absence of a CCP on the grounds that the food safety hazard is not reasonably likely to occur, the control program **is** a decisionmaking document accessible by the agency. Should FSIS conclude that such program has not demonstrated itself capable of controlling the occurrence of the hazard, FSIS could review the supporting records to determine if the hazard analysis (and the plan itself) is inadequate. This provides FSIS with the regulatory basis to view the programs and to take action, but only when the failure of the control programs requires a reassessment of the hazard analysis.

Since control programs can be regulated by FSIS, establishments should be permitted, if not encouraged, to use such programs to assess the likelihood of the occurrence of any potential food safety hazard.

Responses to Agency Questions

Question 1: Is there Information to Support the Requested Action?

For the reasons discussed above, we respectfully submit that there is more than adequate information to support the requested action. It is the thought process, the approach, which must be revised. Focusing on individual instances is like treating the symptoms instead of the disease. Moreover, these "symptoms" are not limited to industry, there are also incidences of confusion among agency field personnel on what is or is not a "food safety hazard reasonably likely to occur."

In essence, the current regulations are being interpreted in a manner to allow the agency to assert that any potential hazard is a food safety hazard reasonably likely to occur. This requires that the hazard be addressed in the HACCP plan. A meaningful criterion to distinguish hazards must be adopted. In this regard, we note the approach of "significant hazard" that has been recommended by the NACMCF and used by Canada in implementing its HACCP program.

Question 2: Would Amending the Regulations Provide the Level of Public Health Protection Required by the Inspection Acts?

We respectfully suggest the amendments requested would **greatly enhance** the level of public health protection over the current system. The suggested amendments will ensure that principal focus is placed on the true public health concerns raised by each individual establishment's operations. By focusing resources where they are needed, rather than diluting them with insignificant hazards, public health will be enhanced.

Question 3: Should FSIS Consider Regulatory Modifications to Acknowledge Prerequisite Programs?

For the reasons discussed above, NTF respectfully suggests that FSIS already has the regulatory authority to deal with prerequisite programs. No regulatory change would be necessary in this regard. On the general issue of modifications to the HACCP regulations, we do, of course, strongly urge FSIS to adopt the regulatory changes requested by the petition.

Question 4: Should FSIS Consider Implementing GMP Regulations a la FDA?

We do not believe separate GMP regulations are necessary. Virtually all of the FDA GMP regulations deal with sanitation, a topic already covered by FSIS' general sanitation performance standard and SSOP regulations. 9 C.F.R. Part 416. Indeed, there is only one FDA GMP regulation not having a counterpart in FSIS regulations. This FDA regulation deals with process controls (21 C.F.R. § 110.80). On this topic, we believe the establishment control programs can be overseen as discussed in response to question 3 above. Accordingly, there is no need to adopt separate regulations.

Question 5: What Will Be the Effect of Making FSIS and FDA Regulations Dissimilar?

We respectfully submit that there already is some dissimilarity between the two agencies' HACCP regulations. This should not be surprising given that the regulations deal with different products. Moreover, we anticipate that once FDA finalizes its juice proposal, there will be differences between the juice and seafood regulations. Finally, there already is different language being used by both agencies in terms of hazards.

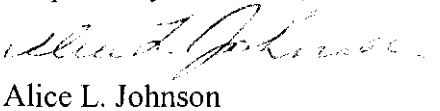
Question 6: Should the Changes be Considered in Light of the Views of Codex and Other Countries?

We submit that FSIS should consider the views of Codex and other countries in connection with the requested changes. We believe that those views will support the requested changes since the changes will improve the operation of HACCP in a regulatory environment.

Conclusion

We appreciate the opportunity to respond to the questions posed by the agency in considering the industry HACCP petition and to reaffirm our support for the petition. Indeed, we respectfully submit that the petition must be adopted before any other activities are undertaken to ensure the viability of HACCP. We look forward to continuing to work with the agency on this important issue.

Respectfully submitted,



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