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FSIS Docket Clerk Docket No. 00-014R2 Room 102, Cotton Annex

300 12th Street, SW

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NATIONAL.

Food

[Docket No. 00-014R2]

Washington, DC 20250-3700

Announcement of and Request for Comment Regarding Industry Petition on Hazard Analysis and Critical Control Point (HACCP) Petition; 65 Federal Register 63229; October 23, 2000

PROCESSORS

ASSOCIATION

Dear Ms. Moore:

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks, and juices, or provide supplies and services to food manufacturers.

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NFPA appreciates the opportunity to provide additional insight into our reasoning for co-signing a petition to the Agency requesting certain changes in the Pathogen Reduction/HACCP rule. NFPA agreed to submit the petition as we have become concerned that much of the potential benefit that could be derived from HACCP will be unrealized in the absence of some midcourse refinements to the rule and/or its interpretation. The purpose of the industry HACCP petition was to set forth certain current provisions that we believe to be most problematic and to suggest remedial measures that will enhance the long-term effectiveness of HACCP. In this regard, we appreciate the additional time granted by the Agency for preparation and submission of substantive information that we believe bolsters the case for change; either by amendment of the rule, or, by some other means if equally effective in producing essential policy changes.

WASHINGTON, DC

DUBLIN, CA

SEATTLE, WA

In these comments, NFPA focuses on Agency authority for oversight of industry production operations, or data generated by such operations, when these lead an establishment to determine that a potential hazard is not "reasonably likely to occur." In addition, we address potential hazards that do not warrant inclusion in a firm's HACCP program because they do not represent a significant level of risk to consumers. We are also responding to a series of questions posed by the Agency in its initial *Federal Register* announcement on this issue.

As a related matter, NFPA strongly supports the initiative by the Agency to arrange and host another HACCP technical conference that could provide a valuable opportunity for in-depth discussion of these and related matters. In anticipation of such a meaningful dialogue, we expect to submit additional comments on this important matter following the conference, as well as on the Agency's "FSIS: The Next Steps" initiative.

SUMMARY OF KEY POINTS

- ♦ To maximize the positive impact on public health, HACCP should focus meat and poultry inspection activities on those hazards that present significant risk to consumers. It is for this reason that NFPA feels the Agency should seriously consider the adoption of the NACMCF 1997 definition of "hazard," as requested in the petition.
- ♦ Prerequisite programs provide a solid foundation for effective HACCP implementation. Wider recognition of the role of prerequisite programs in addition to SSOPs is essential for optimal benefit from the HACCP system.
- ◆ NFPA believes that FSIS has authority, under the HACCP record keeping provisions outlined in 417.5(a)(2), to access industry validation data and/or integrated production programs when such data or programs are integral decision-making documents for a firm's hazard analysis. This specific access to decision-making documents must be distinct from access to other company production records. Such decision-making documents should only need to be accessed by Agency personnel when an In-Depth Verification is performed or when specifically evaluating the accuracy of the hazard analysis, as opposed to during the Agency's routine daily verification procedures.
- ♦ NFPA suggests that FSIS issue a new directive describing inspector actions in review of HACCP plans when an establishment concludes in its hazard analysis that routine production activities document that a potential hazard does not represent a significant public health risk or is not reasonably likely to occur.

DISCUSSION OF KEY POINTS

To maximize the positive impact on public health, HACCP should focus meat and poultry inspection activities on those hazards that present significant risk to consumers. It is for this reason that NFPA feels the Agency should seriously consider the adoption of the NACMCF 1997 definition of "hazard," as requested in the petition.

In the preamble discussion for the HACCP/Pathogen Reduction final rule, the Agency expressed an expectation that under HACCP "(T)he number of inspection tasks will be reduced, so that inspectors can focus more attention on areas of greatest risk in the meat or poultry production system within each establishment" (61 FR 38808, Column 2). At another point in the preamble, it is stated that under HACCP "... FSIS will be better able to allocate its resources to areas of greatest risk" (61 FR 38818, Column 2). In addition, the preamble states, "HACCP also focuses FSIS inspection on the most significant hazards and controls" (61 FR 38808, Column 1). Based upon these declarations, it is clear that a primary intent of the Agency when drafting the PR/HACCP rule was to concentrate inspection resources on issues that directly relate to risks to consumers and to prioritize activities utilizing risk as the primary criterion. Recent pronouncements by the Agency during public meetings on "FSIS: The Next Steps" reiterate a desire to continue evolution to a riskbased/public health-based regulatory agency. Thus, it appears that the Agency has again realized the importance of the concept of using risk as the overarching principle to guide industry and Agency actions. In fact, we believe that Agency actions "pre-HACCP" were governed by such thinking, as evidenced by the normal use of the "Deficiency Classification Guide," which facilitated Agency actions based on likelihood of adverse effects on consumers. We feel it is vital to recapture this concept under the HACCP system.

Under HACCP, the vehicle for identifying those activities necessary for controlling risk is the hazard analysis. In order to provide greater focus on those areas where control is necessary to address risk, it follows that day-to-day production activities that do not have a direct bearing on food safety should not receive the same degree of emphasis. In addition, the effort devoted by the Agency for non-conformance in the area of true food safety issues should be the highest priority and should be followed with the greatest stringency, with more severe consequences. For example, a food safety HACCP non-compliance was issued in one facility for failure of the operator to initial the monitoring action entered in the log and for the verification review to catch the missing initials. This carries the same weight as a non-conformance issued for failure to conduct monitoring at a CCP. While we recognize the importance of proper record keeping, it was clear in the first instance that the CCP had been monitored and that potentially unsafe product had not been produced. This should not be considered as serious a non-conformance as the failure to monitor a CCP. The Agency may wish to consider the use of different terminology for "critical" HACCP non-compliances, such as failure to monitor, versus those of a less serious nature, such as failure to initial an entry.

Likewise, measures taken by the Agency for non-conformance on non-safety issues should be distinct from measures taken for non-conformance on HACCP issues. Such a stance will reinforce the concept of the importance of HACCP. The following is an example of the problem presented when the Agency gives undue attention to non-conformance on non-safety issues. A food safety HACCP non-compliance record (NR) was issued to one of our members due to the occurrence of a block of wood in a large kettle of soup, despite the fact that the firm found the problem and took corrective actions (disposed of implicated product and cleaned equipment) that prevented adulterated product from leaving the plant. Not only did the firm receive an NR, but also inspection personnel insisted that this was an unforeseen hazard that the firm must address as a critical control point (CCP) in its HACCP plan. Though this incident had no relevance to food safety (the size of the object was much larger than that considered to be a risk to consumers), several months of effort were required by the firm to convince the Agency that adding a CCP for this matter was inappropriate.

Prerequisite programs provide a solid foundation for effective HACCP implementation. Wider recognition of the role of prerequisite programs in addition to SSOPs is essential for optimal benefit from the HACCP system.

The authoritative body that developed the tenets of HACCP referenced by FSIS in its final rule - the National Advisory Committee on Microbiological Criteria for Foods¹ (NACMCF) - the Canadian government² and others, including the Codex Alimentarius Commission,³ have embraced the proposition that successful HACCP is dependent upon a solid foundation of basic programs for control of production operations. The introduction to the NACMCF guidelines for application of HACCP principles states, "Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food." Similarly, the Codex Alimentarius document on "HACCP principles and guidelines for their application" is an annex to the Codex General Principles of Food Hygiene, which implies that Codex also intends that firms should be in basic compliance with GMPs as a foundation for HACCP.

While many people find some difficulty in readily distinguishing between matters best covered in prerequisite programs and other matters that should be incorporated into HACCP, we believe there are certain characteristics or parameters of programs that can help properly categorize issues. Primarily, the decision should hinge on the degree of risk presented to consumers by the potential hazard under consideration. Secondarily, the decision can be judged by consideration of the level of control and oversight needed to assure adequate consumer protection. Simply put, if violation of a control limit clearly represents an inappropriate food safety risk that should lead to action against product, then inclusion of the potential hazard within a HACCP program is generally warranted. However, if non-conformance with a control limit is undesirable, but unlikely to have health implications and therefore unlikely to require action against product, then we believe that inclusion

of such a potential hazard in a HACCP plan is not generally appropriate and certainly should not be mandated by government.

In addition to minimizing complexity and permitting a proper focus on significant food safety concerns, another primary reason for dealing with some issues via production programs rather than in HACCP plans is the difficulty in setting science-based critical limits and the consequences of failure to meet specified limits. HACCP CCPs require "bright line" critical limits (CLs) that, when violated, demand specific actions to deal with implicated product. The consequences of failure to meet CLs at HACCP CCPs are clearly spelled out in 417.3. As such, these CLs should have a solid basis in science. Failure to meet the critical limit should suggest a reasonable likelihood of health hazard consequences. In contrast to this, limits set in most production programs are based upon desirable operational parameters rather than relevance to immediate food safety concerns.

A good example (further illustrated below) is temperature control. Virtually all firms in the meat industry find it desirable to specify a relatively low receiving temperature for raw meat ingredients in their production program. While we recognize that at some point, temperature control does become a significant risk control factor, in most cases these conditions are well above that specified in production programs. If a processor chooses to receive product at a temperature of "X" or less and a load arrives at one degree above that desired limit, the likelihood of health hazard consequences is virtually nil. The temperature can be noted and a determination made that the deviation from the desired temperature did not require further action other than determining why it occurred and taking some reasonable measures to assure better control on future shipments. This however, is primarily a business matter, not a food safety issue. Regulatory involvement in this matter should be reflective of this fact.

Were this a HACCP CL, then all the requirements of 417.3 would need to be met, including actions taken on product, even though the product does not pose a safety risk. Furthermore, under these circumstances, repeat non-conformance with the temperature stipulation may raise questions regarding the adequacy of the HACCP plan itself. This would typically result in considerable time being expended by both the plant and the inspection staff to resolve a non-health issue. We are not advocating inattention in such situations. Rather, we believe that outside of HACCP this matter can be resolved much more simply and via less punitive measures than would be appropriate for violations of CLs that are important for consumer safety.

Wider recognition by FSIS of industry-managed production control programs and/or data generated by such programs should facilitate an appropriate level of attention by regulators and industry to those activities that may be broadly related to food safety, but clearly do not warrant a high degree of oversight. Employee practices might be a good example. Hairnets, handwashing, and exclusion of ill employees are all important parts of GMP prerequisite programs. None can be effectively managed at a single "step" in the process and all require judgment to assess risk. Discrepancies

from a desired control limit within a production control program would generally not lead to increased public health risk for consumers and, thus, inspector reactions to such non-conformance should be appropriate to the situation but distinct from a requirement under 417.3. We assume it is for these reasons that the Agency agreed with industry that these programs are more effectively addressed as SSOPs rather than HACCP CCPs. Likewise, there are other program issues that are better left to prerequisite programs.

We strongly believe that without proper recognition of the role of prerequisite programs, more and more issues that are not directly related to consumer safety will be expected by the Agency to be included in establishments' HACCP plans. As this occurs we can envision that HACCP plans will become more and more complex, and that, of necessity, critical limits (CLs) that have no direct scientific meaning will have to be adopted, (e.g., a minimum receiving temperature of "X" degrees, when "X + 1" degrees would not represent a marked increase in risk to consumers). Of significant further concern is the fact that setting CLs that are not "critical" is counter-intuitive to both industry and inspectors. Over time this practice will undermine confidence in the integrity of the system. While the management practice of "Just do it because we say so" may have been acceptable at one time, we believe this strategy to be self-defeating in the long term. Such actions may result in inspectors that selectively enforce such requirements because they themselves don't agree with them. Such actions would also tempt establishment employees to overlook or ignore a minor deviation from a non-critical CL, a practice that would not be tolerated for a true CCP.

NFPA believes that FSIS has authority, under the HACCP record keeping provisions outlined in 417.5(a)(2), to access industry validation data and/or integrated production programs when such data or programs are integral decision-making documents for a firm's hazard analysis. This specific access to decision-making documents must be distinct from access to other company production records. Such decision-making documents should only need to be accessed by Agency personnel when an In-Depth Verification is performed or when specifically evaluating the accuracy of the hazard analysis, as opposed to during the Agency's routine daily verification procedures.

As noted above, meat and poultry establishments implement and operate a wide variety of manufacturing activities that are essential to the production of wholesome, quality products that meet the desires of their customers. Most of these activities are of great importance to the company, but are not particularly relevant within the scope of a HACCP-based FSIS inspection program. In certain cases however, we recognize that some of these programs do impact food safety. Some establishments may elect to rely upon validation data from such programs or rely on on-going operation of such programs as a documentary basis for a finding that a potential hazard is not reasonably likely to occur. In such cases, the Agency should consider the results of this assessment when evaluating the efficacy of a firm's HACCP program. In order to facilitate

thorough review of such a hazard analysis by the Agency, these records may be accessed under the record keeping provisions of 417.5(a)(2).

The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures [9 CFR 417.5(a)(2)].

Furthermore, Agency access to these records is clearly stated in 9 CFR 417.5(f)

Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

NFPA suggests that FSIS issue a new directive describing inspector actions in review of HACCP plans when an establishment concludes in its hazard analysis that routine production activities document that a potential hazard does not represent a significant public health risk or is not reasonably likely to occur.

NFPA suggests that the Agency issue a new FSIS directive describing inspector actions in review of HACCP plans when an establishment concludes in its hazard analysis that routine production activities document that a potential hazard does not represent a significant public health risk or is not reasonably likely to occur. We have attached a draft of such a document for Agency consideration.

EXAMPLES OF CURRENT AND ANTICIPATED PROBLEMS

In response to the Agency request for specific examples of problems that the industry faces and that the HACCP petition is intended to remedy, NFPA provides the following information. In each example below, we attempt to define a scenario and describe the problem presented to the establishment, as well as the element of the FSIS HACCP regulation or Agency policy interpretation that contributes to the problem. Following the three examples, we identify a mechanism we believe may be effective for handling these issues, and we describe how inspection program staff can retain adequate oversight authority over public health elements of the issues.

Scenario One – Metal Objects

A firm has determined in its hazard analysis that this is a hazard that is not reasonably likely to occur. The history of this plant shows the overall incidence of metal in product is low and that,

while the firm has occasionally observed foreign objects, including metal, they have never observed metal of sufficient size or hardness to present a public health risk. The firm has metal detectors that are of sufficient sensitivity that ferrous objects of a nominal size are detected and segregated for appropriate disposition.

Problem Presented

FSIS field staff have often demonstrated an expectation that if the firm's metal detectors have ever detected metal, then a food safety hazard has occurred and now must be addressed in the firm's HACCP plan.

Perceived Source of Disagreement

- ♦ In this case, the interpretation of the HACCP regulation does not provide adequate weighting for the two independent elements for a determination of public health risk likelihood of occurrence and severity of consequences. This results in the classification of relatively inconsequential matters as food safety hazards, thus requiring the same level of activity by inspection and plant personnel as for activities devoted to control of more significant hazards, such as control of *E. coli* O157:H7.
- Also the current FSIS rule and its policy interpretation fail to provide for routine company production activities that manage low risk concerns such that potential hazards never rise to a level where they may impact public health. This policy doesn't fully recognize the important role that industry prerequisite programs play in setting the solid foundation required for successful HACCP implementation.
- Situations like this are too often responsible for the expenditure of considerable Agency and industry time and talent in an attempt to adjudicate such disagreements. These matters often result in appeals that take considerable resources to resolve.

Scenario Two -Temperature Control

A firm manufactures a frozen meat patty product. The physical setup of the firm's manufacturing operating system dictates that product is frozen to a rigid state within a few minutes. The frozen patties are then individually wrapped. In order for the wrapping machinery to operate properly, the patties must be solidly frozen at the time of packaging. If product is not solid, the patties crumble, resulting in an obvious and immediate problem that can only be resolved by stopping the line and cleaning up the equipment.

Problem Presented

The Agency's performance standard regulation for cooked beef patties identifies growth of Clostridium perfringens as a hazard reasonably likely to occur, leading to mandatory identification of stabilization (cooling rate and time) as a CCP. However, in this case, there is no likelihood that the sporeformers can grow given the extremely rapid cooling (below 10° F within 25 minutes). Moreover, the establishment, which took literally thousands of temperature readings over the years for quality control reasons, demonstrated that this process operated as designed. Indeed, the process would not work unless the patties were sufficiently frozen. Additionally, tests for C. perfringens have seldom revealed the presence of the organism in product and, when it does occur, it is always in low number. Nevertheless, the in-plant inspector, with the concurrence of the District Office, required the addition of a CCP for stabilization. FSIS has made clear its expectation that temperature control should be included in industry HACCP plans. As a result, one firm was threatened with the possibility of having its inspection withdrawn for failure of its HACCP system. It experienced a lengthy exercise to appeal an inspector's assertion that the firm's HACCP plan was inadequate since it did not include temperature control as a CCP. This situation took four months of discussion and appeals to finally have the Agency recognize that temperature is not a critical control point for this firm.

Perceived Source of Disagreement

- FSIS policy interpretation in this case did not provide for an interpretation of the likelihood of occurrence of the potential hazard in light of company operational programs.
- ♦ Also, as with scenario one, the current FSIS rule and its policy interpretation allow for little or no distinction between routine company production activities that manage potential hazards at a level far below that which could create a public health risk versus those more rigorous controls designed specifically to prevent a public health risk to consumers. Thus current policy doesn't fully recognize the important role that industry prerequisite programs play in setting the solid foundation required for successful HACCP implementation.

Scenario Three - Residue Controls

A hypothetical firm slaughters 300,000 head of cattle annually. Periodically, Agency monitoring for residues indicates a positive test result for an antibiotic or a sulfa drug. Drug residues of a type that might present an acute health risk have never been associated with animals presented for slaughter at this facility. As required by the FSIS HACCP regulations, the firm considered chemical residues as a potential hazard when it conducted its hazard analysis. The firm determined that residues at the levels and with the frequency found in Agency monitoring do not constitute a hazard to public health. Nevertheless, the firm has initiated a prerequisite program

for residue avoidance under which it notifies the supplier of all cattle that yield positive test results, (whether violative or not), about the finding and advises that recurrence of positive results could lead to a refusal to accept additional animals for slaughter in the future. This program in its year of operation has contributed to a further drop in the already low frequency of positive test results to a level well below one percent.

Problem Presented

FSIS has issued a *Federal Register* notice expressing a strong intent to have establishments include residue controls in HACCP plans. Clearly, violative residue levels render product adulterated and therefore require some form of control by slaughter establishments. However, with extremely rare exception, residues are not found at a level which would represent an acute health hazard nor at a frequency that would present a chronic health risk to consumers and therefore do not represent a hazard to the public that needs to be controlled in a HACCP program.

Tolerances are based on very conservative assumptions about elevated ADIs over a lifetime of consumption. FSIS National Residue Program (NRP) data show that residue violations occur in only a very small percentage of samples.

Perceived Source of Disagreement

- ◆ There appears to be disagreement that most residues should be considered a health hazard or a food safety hazard, regardless of the discussion that follows as to whether the residues are reasonably likely to occur.
- Also as with scenario one, the current FSIS rule and its policy interpretation allow for little or no distinction between routine company production activities that manage potential hazards at a level far below that which could create a public health risk versus those more rigorous controls designed specifically to prevent a public health risk to consumers. Thus, current policy doesn't fully recognize the important role that industry prerequisite programs play in setting the solid foundation required for successful HACCP implementation.

Possible Avenues for Resolution

- ◆ Adopt a definition of hazard that more closely matches that proposed in the industry HACCP petition and that is in line with the intent of the NACMCF.
- ♦ Issue an Agency Directive that comports with the draft Directive attached to these comments. This will provide Agency recognition of such company production programs and will define the conditions for Agency review of these programs or of data generated by these programs,

when used as the scientific basis for determining that a potential hazard need not be addressed in the firm's HACCP plan.

How FSIS Retains Oversight

In accord with the record-keeping and records access provisions of the FSIS HACCP rule, inspection personnel may request to review decision-making documents used to determine that a potential hazard need not be covered in a HACCP program.

As discussed above in our comments, we envision inspection personnel access to these production operation programs or data as a periodic rather than a routine activity. In the absence of any substantial indication to the contrary, we expect that Agency access would be limited to the occasion of the firm's annual review of its HACCP plan or upon some other event that triggers the need for a reassessment of the firm's HACCP plan.

RESPONSES TO QUESTIONS IN FR NOTICE

1. The industry petition relies mainly on the NACMCF document and does not provide any data or examples to support its request. Is there any information that would support taking any of the actions requested in the petition?

The NACMCF is this country's most preeminently qualified body to advise on how HACCP should work. The guidelines developed by this group are well supported by scientific data.

HACCP is most successful when managed with an integrated approach to food safety management using science to select CCPs and supported by SSOPs and GMPs as prerequisite programs.⁴

Several examples of problems that have occurred and that we foresee continuing to arise in the absence of adjustments to the FSIS HACCP regulation were discussed above.

2. Would amending 9 CFR 417.2(a) in the manner suggested in the petition result in regulations that provide the level of public health protection required by the Federal Meat Inspection Act and the Poultry Products Inspection Act?

Yes, we are confident that the proposed actions would not only maintain, but would in fact improve, the level of public health protection inherent in products manufactured under the regulatory jurisdiction of FSIS. A regulatory policy that permits the industry to focus its

greatest attention on CCPs associated with control of public health risks would not only be effective for the industry, but would also enable the Agency to allocate its limited inspection resources more effectively on those plant operations most critical to public health.

3. Should FSIS consider regulatory modifications that would acknowledge the prerequisite programs concept of NACMCF?

It is important to note that the term "prerequisite program" was not developed within the NACMCF. This term was already in use by others, including the Canadian government in its Food Safety Enhancement Program (FSEP)². In addition, because of the importance of prerequisite programs as an integral component of a process/food safety control system, the NACMCF undertook the re-write of its advisory document at the request of FSIS Administrator Tom Billy, in part, to provide contemporary guidance on the role of prerequisite programs. In the preamble to the PR/HACCP final rule, the Agency in fact refers to Sanitation Standard Operating Procedures (SSOPs) as a prerequisite program. Thus the issue is not to recognize prerequisite programs but how and to what extent they should be considered. In our opinion, FSIS should acknowledge the role of prerequisite programs and incorporate the concept as described by the NACMCF into its HACCP program. There are probably a number of mechanisms through which this can be accomplished. It is conceivable that such a change could be made through an administrative policy change. If such a change in policy can be effected by publication of the new policy in a Federal Register notice, then that avenue would surely be the most expeditious and efficient. Otherwise, we encourage the Agency to pursue whatever avenue is available to make this change.

4. Do FDA regulations, such as the GMP regulations, offer an approach that FSIS should consider? How would such an approach fit within the HACCP concept? How would FSIS implement such an approach?

It is interesting to note that the FSIS sanitation performance standards touch on most of the elements addressed in the FDA GMPs. Furthermore, the sanitation performance standards regulation had not been published when the previously discussed FSIS policy pronouncement limiting consideration of GMPs was published on January 30, 1998. While promulgation of GMP regulations may eventually be desirable, we would like to explore existing vehicles for accomplishing this objective.

5. What will be the effects of making FSIS and FDA HACCP regulatory requirements dissimilar?

We do not believe the requested changes would result in any functional dissimilarity. There already exist several differences between the FDA rule for Seafood HACCP⁵ and the FSIS

HACCP rule. Considering that FDA will (eventually) publish a final rule on HACCP for juice products, there are likely to be more, not fewer differences. Since FDA and FSIS are not currently harmonious in their approaches and interpretations of HACCP, we do not believe that the changes requested in the petition will create any new burden for the regulated industry.

6. Should the changes suggested in the industry petition be considered in light of the views expressed on HACCP by Codex and by other countries?

It clearly is appropriate for FSIS to consider the position of Codex and other countries on activities it undertakes. At this formative stage it is not only appropriate to consider these changes, but, in our view, it is imperative that these concepts be addressed. Especially as other countries are considering or advancing the HACCP concept on a mandatory basis, delay in making needed adjustments will only slow the progress of HACCP and of food safety in general.

As noted in FSIS Administrator Tom Billy's presentation at the September 7, 2000 National Conference on Animal Production Food Safety in St. Louis, food safety has become central to negotiations with respect to international trade over the last decade. He added that the US "...must ensure that science guides international food safety policies...." In our opinion, if the US continues to refuse to acknowledge that GMPs must play a role in food control programs as general control measures, a pattern will be perpetuated that will ultimately result in the failure of HACCP programs and will make it more difficult to assess equivalence between two countries.

CONCLUSION

NFPA appreciates this opportunity to comment on this important rulemaking activity. We welcome any opportunity to work with the Agency to assure that HACCP reaches its full potential as a mechanism for assuring the safety of our nation's meat and poultry products.

Sincerely,

Rhona Applebaum, PhD

Executive Vice President, Scientific and Regulatory Affairs

Attachment

References

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