Cooling and Chilling Requirements for Raw Meat and Poultry

FSIS proposed that establishments slaughtering livestock be required to chill carcass surfaces and hot-boned meat to 50°F (10°C) within 5 hours and then to 40°F (4.4°C) within 24 hours of slaughter or meat and bone separation. Chilling of meat products such as liver and cheek meat would have been required to begin within one hour of removal from a carcass. The proposed rule also would have changed existing poultry chilling requirements (§ 381.66) to be comparable with those proposed for meat. Chilling would have been required unless the raw product was going directly from slaughter to heat processing.

The proposal also would have required that establishments maintain raw meat and poultry products at an internal temperature of 40°F or below while in the establishment and before release into commerce. Raw products not chilled in accordance with the requirements would have required further processing to kill pathogens or would be condemned.

Lastly, the proposal would have required each establishment handling raw product to have a written plan for temperature controls and monitoring and make monitoring records available to FSIS upon request.

The proposed rule was based on good manufacturing practices generally prevalent in the industry. FSIS's position was that temperature controls, which are known to prevent bacterial growth, are an accepted part of current industry practices, are already required by regulation for poultry carcasses, and should be mandated for all raw product to minimize the possibility that raw products leaving official establishments bear significant levels of pathogenic microorganisms.

Commenters generally supported the concept that establishments should be required to chill raw product as a means of minimizing the growth of harmful bacteria. Some commenters supported the time and temperature requirements as proposed. Others argued that the specific time and temperature combinations in the proposed rule were unduly restrictive and unworkable. A number of commenters advocated ''more realistic'' cooling requirements that take into consideration establishment and product variety, different processing operations, and diverse shipping and receiving operations. These commenters supported the use of independent ''process authorities'' to advise establishments on cooling carcasses and other raw products. Some suggested that the proposed chilling requirements should be recast as guidelines.

Many commenters questioned the need for any regulatory requirements for chilling and asserted that it was conceptually at odds with the proposed HACCP provisions. They recommended that FSIS defer any regulation on chilling because establishments would have to address chilling as part of their HACCP plans.

Some commenters raised concerns about the scientific basis of the proposed time and temperature requirements. They asserted that the cooling requirements would not result in any demonstrable improvement in food safety because they were not based on scientifically valid data. A number of commenters said that the proposed time and temperature requirements were simply not achievable by the beef industry due to the large size of beef carcasses. Also, they said that these carcass cooling requirements might change meat quality attributes such as product texture and palatability.

Many commenters asserted that FSIS's regulatory focus and the economic burdens are placed entirely on establishments when, these commenters argue, a large proportion of foodborne illnesses are caused by temperature abuse and other mishandling of raw products after they leave the establishment.

Many commenters expressed concern about risks to employees' health that could result from employees working continuously in a colder environment. They cited worker safety studies showing many human physical ailments are created or aggravated by cold ambient temperatures. Worker safety was also cited as an issue on the grounds that the difficulty of handling and cutting meat at such cold temperatures increases the potential for accidents and injuries.

Some commenters noted that FSIS did not specify how the equivalence of alternative procedures could be established. In addition, some suggested specific alternative methodologies they thought would provide equivalent procedures, such as cooling with dry ice, CO_2, or nitrogen. Others either did not approve of using any alternative chilling process or wanted them to be included in the final rule.

Some commenters questioned the rationale for proposing identical requirements for meat and poultry. They said that using the same set of requirements for all species fails to take into account the variation in carcass size.

Commenters from small businesses said they did not have the cooling capacity to comply with the proposed requirements, and that the cost of expanding facilities, obtaining the necessary refrigeration equipment, and retaining quantities of carcasses long enough to chill them to 40°F before shipping was prohibitive.

Other commenters said the time and temperature requirements conflicted with religious, cultural, and ethnic practices. For example, there are ethnic markets for ''hot pork,'' whereby hogs are slaughtered and delivered directly to customers for preparation and consumption with little or no intervening chilling. A similar process is used with lamb, goat, and beef for Moslem customers. Some commenters asserted that the proposed requirements also conflict with and preclude the Kosher process of ritual salting of poultry.

Commenters also were concerned that carcasses that are processed in one establishment and shipped to another establishment for immediate further processing or directly to an off-site cooling facility would have to meet carcass cooling requirements.

Questions were raised about the disposition of products that did not meet temperature requirements. Concern was expressed about the possible condemnation of large quantities of product based on slight deviations from temperature requirements that would not by themselves jeopardize food safety.

A number of commenters addressed the proposed shipping temperature requirements. Many asserted that temperature variation during shipping is a significant problem. Several commenters asked about their liability for product after it has left their custody and is found later, e.g., at a warehouse or retail establishment, to have been subjected to temperature abuse or other mishandling. Related comments stated that time and temperature controls were important at all stages of food production, especially at retail, and should be more of a focus of FSIS's regulatory oversight.

A few commenters expressed concern about the burden of preparing a written plan and the proposed recordkeeping requirements.

After reviewing the comments, FSIS agrees that the proposed regulations on this issue should not be promulgated at this time. FSIS is persuaded that the complexity and variety of acceptable chilling practices now in use make the proposed prescriptive time and temperature requirements unduly burdensome and impractical. FSIS

intends to seek an alternative that will not conflict with Kosher or other religious, cultural, or ethnic practices that do not present food safety hazards to consumers. FSIS has concluded that its food safety objectives may be achieved more effectively by regulatory means other than those proposed.

Nevertheless, FSIS continues to believe that prompt, thorough chilling of carcasses and raw meat and poultry products by slaughtering establishments is necessary to minimize consumers' exposure to pathogenic microorganisms. Cooling of carcasses is generally acknowledged to be an essential component of any establishment's processing controls for safe food production.

FSIS agrees with those commenters who stated that keeping raw products cooled after they leave the establishment, during transportation, storage, distribution, and sale to consumers, is essential if growth of pathogenic microorganisms on raw products is to be prevented. This is consistent with FSIS's farm-to-table food safety strategy.

Instead, FSIS believes that the best way to regulate in this area would be by having as a performance standard a maximum temperature for products being shipped into commerce, and at which raw products in commerce must be maintained. This standard would be applicable to all persons who handle such product before the product reaches the consumer. FSIS believes that there are at least two possible temperatures for this purpose.

A mandatory temperature of 41°F would provide a large margin of safety against the multiplication of pathogenic bacteria, which generally will not multiply at temperatures below 50°F. It is similar to the maximum temperature of 40°F originally proposed by FSIS and recommended in Agriculture Handbook No. 412. It is also the same temperature as that specified in the Food and Drug Administration's current model Food Code which is offered for adoption by States and other government entities with jurisdiction over food service, retail food stores and food vending machine operations.

Alternatively, a temperature of 45°F would still provide a margin of safety and also is that required in FDA's current Good Manufacturing Regulations for refrigerated foods generally. It also would comport with the temperature established for raw product in commerce by the European Union. That temperature is increasingly accepted as a standard for raw product storage and transportation by other countries and appears to be an emerging standard for international trade.

FSIS could supplement the shipping/storage temperature regulations with guidelines, including recommended criteria for microorganisms, that would provide purchasers and vendors in commerce additional means by which to determine whether products bear a level of bacteria indicative of temperature abuse and, therefore, are likely to bear levels of pathogenic microorganisms that could be associated with foodborne illnesses.

FSIS has concluded that development of such a performance standard requires that it obtain additional information and engage in further rulemaking. Therefore, FSIS will extend and expand this rulemaking proceeding on the issue of cooling raw meat and poultry products. FSIS will consider alternatives to the specific time and temperature requirements it proposed, including performance standards governing cooling during transportation and storage of raw meat and poultry, probably in the form of a maximum temperature for transporting and holding such product.

As the next step in its proceedings on this topic, FSIS plans to hold a public conference to gather further information on the many technical and practical issues raised in the comments as well as on possible alternatives to the proposal which will be outlined in the Agency's announcement of the conference.

International Trade

The inspection statutes require that meat and poultry products imported into the United States be produced under an inspection system equivalent to the U.S. inspection system.

A large number of commenters requested that FSIS clarify how it will determine the ''equivalence'' of foreign inspection systems following HACCP implementation. Commenters questioned exactly how FSIS will determine foreign system equivalency regarding HACCP systems. Further, some commenters asserted that requiring foreign equivalency with the U.S. HACCP system could create problems in foreign trade if HACCP implementation in the United States causes some foreign inspection programs previously designated ''equivalent'' to lose that designation.

Foreign countries with establishments exporting to the United States must establish inspection system requirements ''equivalent to'' U.S. requirements. This means that all foreign meat and poultry establishments that export meat to the United States must operate HACCP systems or process control systems ''equivalent to'' HACCP. They must also adopt equivalent performance standards.

The components of FSIS's current import inspection system will not change. As part of the evaluation of the laws, policies, and administration of the inspection system of any foreign country eligible to export meat or poultry products into the United States, FSIS will assess the status of HACCP—or equivalent process control system-implementation in that country. This assessment will include on-site reviews of individual establishments, laboratories, and other facilities within the foreign system. The ''equivalency'' of foreign inspection will be determined at this stage.

Further, when these regulations are implemented, the import inspection system will continue to include port-of-entry inspection by FSIS inspectors to verify the effectiveness of foreign inspection systems. All countries exporting raw products to the United States must develop and implement performance standards that are equivalent to the pathogen reduction performance standards for *Salmonella*. They must also be able to demonstrate that they have systems in place to assure compliance with the standards.

As of January 1, 1995, 1,395 establishments in 36 countries were certified to export meat or poultry products to the United States. Canada, with 599 establishments; Denmark, with 125; Australia, with 111 establishments; and New Zealand, with 94 establishments, accounted for two-thirds of those, which were collectively the source of 85 percent of the 2.6 billion pounds of product imported into the United States during 1994. Canada, Denmark, Australia, and New Zealand are currently developing HACCP systems.

Most of the comments concerning the impact on exports dealt with the proposed requirement for antimicrobial treatment of U.S. product and the proposed exemption for exported product. That proposed requirement raised particular concerns because the European Union member states and Canada restrict the use of certain antimicrobials on meat and poultry carcasses.

A number of commenters cited the fact that a proposed exemption would be ineffective because establishments cannot segregate treated product from untreated product. Commenters said this occurs because antimicrobial treatments are performed on whole carcasses, while most meat and poultry is exported in parts. This condition, the commenters argued, would cause

significant operational difficulty to establishments that were required to separate product that had and had not been treated, as well as inventory management problems. This requirement might also result in an artificial trade barrier with countries such as Canada, which restrict use of certain antimicrobial treatments. Suggestions were made that FSIS should obtain Codex support and acceptance for the proposed antimicrobial interventions as a means to overcome international objections to their use. The Agency's decision not to mandate antimicrobial treatments largely negates these concerns. FSIS will continue to work within Codex and in its bilateral relations with major trading partners to ensure that the scientific basis for food safety practices in the U.S. are understood and accepted.

The final rule will affect U.S. exports only if an establishment has difficulty meeting the new microbial performance standards without using an antimicrobial treatment. FSIS is aware that alternative technologies now available can facilitate international trade. For example, public comments indicated that trisodium phosphate is approved for use in Canada and the United Kingdom, and is being considered by the European Union, Australia, and New Zealand. Steam vacuum systems constitute an improved technology for establishments exporting beef and pork products.

Recordkeeping and Record Retention

FSIS notes that recordkeeping requirements and record retention periods for sanitation SOP's, microbiological testing, and HACCP are found in 416.12, 310.25(b)(4), and 381.94(b)(4), and 417.5, respectively. The proposed amendments to sections 320.1, 320.3, 381.175, and 381.177 were intended to continue FSIS' practice of cross-referencing recordkeeping requirements in §§ 320.1, 320.3, 381.175, and 381.177. FSIS has determined that it is unnecessary to amend these sections at this time, especially in view of its ongoing efforts to simplify, consolidate, and streamline the meat and poultry inspection regulations.

Finished Product Standards for Poultry Carcasses

FSIS proposed to remove the feces nonconformance specification from the poultry finished product standards regulations (§ 381.76, Table 1). That change in the poultry products inspection regulations is being effected not in this final rule but in the forthcoming final rule, ''Enhanced Poultry Inspection; Revision of Finished Product Standards with Respect to Fecal Contamination,'' Docket No. 94–016F.

VI. Economic Impact Analysis and Executive Orders

Executive Order 12866

This rule has been determined to be economically significant and was reviewed by OMB under Executive Order 12866.

HACCP-based Regulatory Program Produces Net Benefit to Society

FSIS has prepared a Final Regulatory Impact Assessment (FRIA) that evaluates the costs and benefits of a mandatory HACCP-based program for all meat and poultry establishments under inspection. The FRIA concludes that mandating HACCP systems will lead to potential benefits that far exceed industry implementation and operating costs.

The 20-year industry costs of implementing the HACCP-based regulatory program are estimated to be $968 to $1,156 million. The 20-year costs to the government are estimated at $56.5 million. FSIS estimated that the proposed rule would have 20-year costs of $2.2 billion dollars. The costs from the Preliminary Regulatory Impact Analysis (PRIA) are not directly comparable to costs estimated for the final rule. The proposed rule had a larger number of explicit regulatory requirements. The PRIA focused on estimating the predictable costs of meeting those requirements and included an implicit assumption that compliance with the proposed requirements would assure compliance with pathogen reduction objectives. In contrast, the final rule allows for greater flexibility in meeting the pathogen reduction standards, but also outlines a more rigorous enforcement strategy. Thus for the FRIA, it was necessary to develop separate cost estimates for the potential costs of meeting the new pathogen reduction performance standards for *Salmonella*. Modifications incorporated into the final rule have both reduced the total estimated costs and redistributed costs in a way that reduces the relative burden on smaller establishments.

Both the preliminary and final analysis identify a potential public health benefit of $7.13 to $26.59 billion, tied to eliminating the contamination by four pathogens that now occurs in meat and poultry establishments. These four pathogens include the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* O157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. The potential benefit estimate is tied to the minimization of risk from the 90 percent of these pathogens that are estimated to contaminate meat and poultry during slaughter and dressing procedures. The remaining 10 percent of contamination is estimated to occur after the product leaves the manufacturing sector. The link between regulatory effectiveness, where effectiveness refers to the percentage of pathogens eliminated at the manufacturing stage, and health benefits is the assumption that a reduction in pathogens leads to a proportional reduction in foodborne illness. The high and low range for potential benefits occurs because of the current uncertainty in the estimates of the number of cases of foodborne illness and death attributable to pathogens that enter the meat and poultry supply at the manufacturing stage.

The benefits analysis in the FRIA concludes that there is insufficient knowledge to predict with certainty the effectiveness of the rule, where effectiveness refers to the percentage of pathogens eliminated at the manufacturing stage. Without specific predictions of effectiveness, FSIS has calculated projected health benefits for a range of effectiveness levels. For example, if the HACCP-based program can reduce the four pathogens by 50 percent and that reduction leads to a proportionate reduction in foodborne illness, the projected benefits range from $3.6 to $13.3 billion, which is half the potential benefit estimate of $7.13 to $26.59 billion.

If the low potential benefit estimate is correct, the analysis shows that the new HACCP-based program must reduce pathogens by 15 to 17 percent before benefits outweigh projected costs. If the high estimate is the correct estimate, the new program needs to reduce pathogens by only 4 to 5 percent to generate net societal benefits. While there were a large number of comments relating to the effectiveness estimates in the PRIA, there were no comments that claimed or implied that HACCP would not reduce pathogens at levels necessary to produce net societal benefits. The requirements of the final rule are organized around the following three components:

- The requirement that all inspected establishments develop and implement HACCP programs based on the seven recognized principles of HACCP.
- The requirement that all inspected establishments develop and implement Sanitation SOP's.
- The requirements that all establishments that slaughter cattle, swine, chickens or turkeys implement a microbial sampling

program using *E. coli* (generic) as a measure of control of slaughter and sanitary dressing procedures and that all establishments that slaughter cattle, swine, chickens or turkeys or produce raw ground product from these animals or birds meet new pathogen reduction performance standards for *Salmonella*.

The proposal and final rule can be viewed as two scenarios for implementing a mandatory HACCP-based regulatory program. While it's not possible to compare the benefits of these two options, the FRIA does present a comparison of the costs.

Table 5 summarizes the estimated costs for both the proposal and final rule by individual regulatory component. As mentioned above, the costs are not directly comparable because the regulatory components have changed. Table 5 shows that all costs have been eliminated for the components of time-and-temperature requirements and antimicrobial treatments. However, the discussion of potential costs in the FRIA recognizes that some establishments may use antimicrobial treatments to help meet the pathogen reduction performance standards for *Salmonella*. Other establishments may impose temperature limits to help control *Salmonella* growth.

Table 5 includes the final cost estimate for generic *E. coli* sampling in slaughter establishments under the regulatory component for microbial testing. The costs for required microbial sampling have decreased substantially from the proposal.

In the FRIA, FSIS increased or added a cost estimate for four regulatory components. First, based on comments, FSIS added costs for recurring training to account for the fact that employee turnover will sometimes require establishments to train additional employees. Second, FSIS also added a minimal cost for annual reassessment of HACCP plans, although the Agency believes that reassessment will be negligible for establishments successfully operating HACCP systems. Third, FSIS has increased the estimated cost for HACCP plan development. The estimate for this cost was increased after reviewing public comments and assessing the overall impact on plan development costs of decisions to eliminate time-and-temperature and antimicrobial treatment requirements prior to HACCP implementation. Finally, the Agency recognizes that some establishments will have difficulty meeting the new performance standards for *Salmonella* and that implementing sanitation SOP's and HACCP plans will not always assure sufficient pathogen reduction. The FRIA has developed two scenarios that lead to low and high cost estimates related to potential actions that establishments might undertake. Such actions include both process modifications to reduce pathogens and the implementation of *Salmonella* testing programs to assure compliance with the new performance standards.

As shown in Table 5, the two scenarios developed in the FRIA lead to a range in cost estimates of $55.5 to $243.5 million to comply with the new pathogen reduction standards for *Salmonella*. The FRIA recognizes that the performance criteria for generic *E. coli* also create a set of potential costs for slaughter establishments. A line for these costs is shown in Table 5 along with the entry that these costs were not separately quantified.

As discussed in the FRIA, the anticipated actions to comply with the generic *E. coli* criteria are the same as the anticipated actions to comply with the standards for *Salmonella*. FSIS has concluded that if the low cost scenario for *Salmonella* compliance proves to be more accurate, than the Agency would expect to see some compliance costs for the generic *E. coli* performance criteria. If the high cost scenario is correct, then the compliance actions taken to assure compliance with the *Salmonella* standards should also assure compliance with the generic *E. coli* criteria.

TABLE 5.—COMPARISON OF COSTS—PROPOSAL TO FINAL

[$ Millions—Present value of 20-year costs]

Regulatory component	Proposal	Final
I. Sanitation SOP's	175.9[a]	171.9
II. Time/Temperature Requirements	45.5	0.0
III. Antimicrobial Treatments	51.7	0.0
IV. Micro Testing	1,396.3[b]	174.1
V. Compliance With *Salmonella* Standards	Not Separately Estimated[c]	55.5–243.5
Compliance with generic *E. coli* criteria	Not Applicable	Not Separately Estimated
VI. HACCP		
Plan Development	35.7	54.8
Annual Plan Reassessment	0.0	8.9
Recordkeeping (Recording, Reviewing and Storing Data)	456.4	440.5[d]
Initial Training	24.2	22.7[d]
Recurring Training	0.0	22.1[e]
VII. Additional Overtime	20.9	17.5[d]
Subtotal—Industry Costs	2,206.6	968.0–1,156.0
VIII. FSIS Costs	28.6[f]	56.5
Total	2,235.2	1,024.5–1,212.5

[a] The preliminary analysis included a higher cost estimate for sanitation SOP's ($267.8 million) that resulted because of a programming error. The cost estimate of $175.9 million is based on an effective date of 90 days after publication.

[b] The preliminary analysis was based on the premise that microbial testing would be expanded to cover all meat and poultry processing after HACCP implementation. The proposed rule only required sampling for carcasses and raw ground product. Thus, the cost estimate of $1,396.3 million was higher than the actual cost of the proposed sampling requirements.

[c] The preliminary analysis accounted for some of the cost of complying with the new standards under the regulatory components of micro testing, antimicrobial treatments, and time and temperature requirements.

[d] These costs are slightly different from the proposal because of changes in the implementation schedule.

[e] FSIS added costs for recurring training based on the review of public comments.

[f] Based on current estimates for the cost of training, inspector upgrades, and $0.5 million for annual HACCP verification testing.

Market Failure Justifies Regulation of Pathogens

Since all raw meat and poultry products contain microorganisms that may be pathogens, raw food unavoidably entails some risk to consumers of pathogen-exposure and foodborne illness. The presence and level of this risk cannot be determined by a consumer since pathogens are not visible to the naked eye. The societal impact of this food safety information deficit is a lack of accountability for foodborne illnesses caused by pathogenic microorganisms. Consumers often cannot trace a transitory illness to any particular food or even be certain it was caused by food. Thus, food retailers and restaurateurs are generally not held accountable by their customers for selling pathogen-contaminated products and they, in turn, do not hold their wholesale suppliers accountable either.

This lack of marketplace accountability for foodborne illness means that meat and poultry producers and processors have little incentive to incur extra costs for more than minimal pathogen controls. The widespread lack of information about pathogen sources means that business at every level from farm to final sale can market unsafe products and not suffer legal consequences or a reduced demand for their product.

The science and technology required to reduce meat and poultry pathogens is well established, readily available, and commercially practical. FSIS has concluded that the lack of consumer information about meat and poultry product safety and the absence of adequate incentives for industry to provide more than minimal levels of processing safety represents a market failure requiring Federal regulatory intervention. The present combination of market regulation and industry self-policing has not resolved increasingly apparent problems with meat and poultry pathogens. Documented cases of foodborne illness each year, some of which have resulted in death, represent a public health risk that FSIS has determined to be unacceptable. A comprehensive Federal regulatory program is the only means available to society for lowering foodborne pathogen risks to an acceptable level. FSIS further concludes that a mandatory HACCP regulatory program is the only means to attain this goal.

Regulatory Alternatives

After considering broader regulatory approaches including market incentives and voluntary industry standards, FSIS has determined that effective process control is needed throughout the meat and poultry industry in order to minimize pathogen contamination of food products and lower the risk of subsequent foodborne illness.

FSIS examined the following seven process control approaches before determining that mandatory HACCP was the most effective means for industry to eliminate pathogens in meat and poultry:

- Status quo
- Intensify present inspection
- Voluntary HACCP regulatory program
- Mandatory HACCP regulation with exemption for small businesses
- Mandatory HACCP regulation only for ready-to-eat products
- Modified HACCP—negative records only
- Mandatory HACCP for all establishments

Each of these seven alternatives was assessed using the following five effectiveness factors for process control:

- Controls production safety hazards
- Reduces foodborne illness
- Makes inspection more effective
- Increases consumer confidence
- Provides the opportunity for increased productivity

Only mandatory HACCP for all establishments was determined to meet all five criteria; all of the others were found to be flawed in meeting one or more of the target factors.

The full text of the Final Regulatory Impact Analysis is published as a supplement to this document.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act (P.L. 104–4) requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in annual expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000, (adjusted annually for inflation). The preliminary and final RIA's fulfill this requirement of the Unfunded Mandates Reform Act. FSIS has treated both the proposed rule and this final rule as an economically significant regulatory action, i.e., annual cost to the private sector of more than $100,000,000, under Executive Order 12866 and has prepared a final Regulatory Impact Analysis (RIA) in compliance with the provisions of Executive Order 12866. The final RIA identifies annual recurring private sector costs of from $99.6 to $119.8 million and potential annual public health benefits of $.99 to $3.69 billion.

The Act also requires (in Section 205) that the Agency identify and consider a reasonable number of regulatory alternatives and, from these alternatives, select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule. In the final RIA, FSIS considered several broad regulatory alternatives and selected the one that is both cost-effective and also the least burdensome alternative that achieves the food safety objectives of the rule. FSIS concluded that market incentives will not address the public health risk resulting from microbial pathogens in meat and poultry, primarily because there is rarely feedback to consumers that allows more informed purchase decisions nor is there feedback which would permit consumers who experience a foodborne illness to routinely, and at low cost, seek compensation from responsible parties for losses arising from their foodborne illness. Thus, market solutions would not adequately address the food safety objectives on the rule. FSIS concluded that an industry administered system of voluntary standards is likely to be more expensive and less effective than a governmental one. Finally, FSIS has recognized that public education is essential for assuring food safety, but experience has shown that education alone has limited effectiveness in reducing foodborne illness. Thus, while consumer education may be cost-effective it would not meet the objective of substantially reducing foodborne illness.

Based on a qualitative analysis of broad regulatory strategies, the final RIA concluded that mandatory government standards were needed to achieve a solution that is both cost-effective and meets the objective of reducing the risk of foodborne illness from meat and poultry. Within the framework of a mandatory regulatory program, the final RIA discusses several alternatives to a mandatory HACCP-based program for all inspected establishments including intensified inspection, mandatory HACCP with a small business exemption and mandatory HACCP for only ready-to-eat products. These alternatives were evaluated using several criteria incorporating the goals of effectiveness, efficiency and increased consumer confidence. Using these criteria FSIS concluded that HACCP systems designed to meet microbial performance standards will be both cost-effective and the least burdensome alternative for meeting the foodborne illness reduction objectives of the rule. As the final RIA points out, requiring mandatory process control without microbial performance

standards could lead to processes that are well controlled at unacceptable pathogen levels. FSIS believes that microbial performance standards are necessary to achieve substantial pathogen reduction, encourage industry innovation, and provide the impetus for continuing improvement and increasing effectiveness.

Consistent with the requirements in Section 204 to provide opportunity for input from State, local and tribal government officials, FSIS held a ''Federal-State-Relations Conference,'' August 21–23, 1995, in Washington, D.C. This meeting, in which the National Association of State Departments of Agriculture participated, provided an opportunity for representatives from State government to engage in an open exchange with senior USDA officials on the Pathogen Reduction/HACCP proposal. In addition to Directors of State meat and poultry inspection programs, the meeting included representatives from State Departments of Agriculture, State Health Departments and local food safety enforcement agencies.

Also related to the Section 204 requirements, on May 22, 1995 the Agency held a public meeting for owners and representatives of small meat and poultry establishments and other affected small businesses to discuss the pathogen Reduction/HACCP proposal. Three Directors of State meat and poultry inspection programs provided comments at the meeting.

Section 202 of the Act also requires a summary and evaluation of comments received from State, local, or tribal governments. There were a large number of comments from State and local governments, elected members of State legislatures and associations representing State programs or businesses within States. Collectively, these comments covered most, if not all, of the issues addressed as part of this final rule. This preamble and the final RIA represent a summary and evaluation of these comments.

Most of the comments from State, local, or tribal governments addressed the potential economic impact on small businesses. The Kansas City meeting was intentionally focused on the small business issues. Comments from the State program Directors included recommendations for various forms of exemptions, voluntary programs or financial assistance for small State inspected establishments. The Federal-State-Relations-Conference included a more focused discussion on the cost to the State programs. Attendees stated that FSIS failed to adequately consider the cost of the changes to State programs and that FSIS was increasing the resource demands for State programs without providing adequate funding.

There were also written comments stating that the proposed rule was an unfunded Federal mandate because of the cost to small establishments and the potential impact on State inspection programs. The preliminary RIA did not address the impact on State programs. However, FSIS recognizes that the 27 States operating their own meat and poultry inspection programs will likely have to substantially modify their programs after the HACCP/Pathogen Reduction regulation is finalized to remain ''at least equal to'' Federal inspection programs as required by the FMIA and PPIA. During the regulation's implementation period, FSIS will be using the Agency's State-Federal Program resources to assist the States in bringing the necessary changes to the State inspection programs. Although FSIS has requested some additional funds to implement this rule, FSIS has also acknowledged that implementation of this rule will require eliminating some tasks, conducting other tasks differently and streamlining the organization in order to free up resources to fully address the new requirements. FSIS believes that the same type of restructuring or reprogramming will take place within the State programs. This does guarantee, however, that all States with inspection programs will be able to implement the necessary program changes without additional funds. FSIS believes, however, that with FSIS assistance and with the flexibility provided under the ''equal to'' provisions, most of the States should be able to modify their programs with minimal additional costs. To the extent that there are any additional costs, the State inspection programs are eligible to receive up to 50 percent Federal matching funds.

Regulatory Flexibility Act

The Administrator, FSIS, has determined that this rule will have a significant economic impact on a substantial number of small entities. This final rule uses two size criteria for providing regulatory flexibility for small entities. For livestock and poultry slaughter facilities, the microbial sampling requirements vary depending on the number of animals or birds slaughtered annually. This will significantly reduce the microbial testing costs for smaller establishments which, under the proposed rule, would have been required to test each species they slaughter every day on which slaughter of that species occurred. Under the final rule, establishments that annually slaughter fewer than 6,000 cattle, 20,000 swine (or a combination of such livestock not to exceed a total of 20,000, with a maximum of 6,000 cattle), 60,000 turkeys or 440,000 chickens (or a combination of chickens and turkeys not to exceed 60,000 turkeys or 440,000 birds total) will not be required to operate microbial sampling programs on a continuous basis. Over 78 percent (2,098) of the total 2,682 slaughter establishments meet these criteria. These establishments will be required to annually verify that their slaughter and sanitary dressing processes are under control. However, after an initial period of sampling in each year, these establishments will be required to conduct further sampling in that year only if they make major changes to facilities, equipment, and personnel whereby the slaughter and dressing process is significantly changed.

These low-volume establishments will be required to analyze one sample per week until they have demonstrated compliance with established criteria. At a minimum, low-volume slaughter establishments will be required to collect and analyze one sample per week until they complete a sampling window (13 samples) annually in order to assess whether the performance criteria continue to be met.

Small slaughter establishments that process only minor species (e.g., goats, sheep, ducks, pheasants, etc.) will not be required to conduct any sampling. Small slaughter establishments will also face less burden because the final rule no longer requires that both cattle and swine or chickens and turkeys be sampled in the same establishment, i.e., if a low-volume establishment slaughters both cattle and swine or turkeys and chickens, it will be required to analyze one sample per week from the predominant species until it has demonstrated compliance with established criteria. The costs of small slaughter establishments are also reduced because the carcass cooling and antimicrobial near-term requirements have been eliminated from the final rule. Sampling frequencies for even the larger slaughter establishments will be based on production-volume, thus spreading the cost per pound relatively equally among establishments.

For the purpose of sequencing HACCP implementation FSIS has defined a small entity using the Small Business Administration size standard for a small meat or poultry manufacturing establishment. That is, all establishments with fewer than 500 employees will have additional time to implement HACCP. In addition, in

response to comments that there are hundreds of ''very small'' or ''micro'' establishments, the Agency will classify an establishment as ''very small'' if it has either fewer than 10 employees or annual sales of less than $2.5 million. This sequencing of HACCP responds to a large number of comments requesting that small businesses be given a longer period of time to implement HACCP requirements. Many small businesses stated they did not want to be exempt, but asked for more flexibility in implementing HACCP.

The FRIA is based on 353 large firms implementing HACCP at 18 months, 2,941 small firms implementing HACCP at 30 months and 5,785 very small (2,892 Federal plus 2,893 State) firms implementing HACCP at 42 months.

Table 6 illustrates the costs for a small, single-shift, processing establishment (no TQC or sanitation PQC program) with two distinct production operations other than raw ground product (overall average estimated at 2.29 operations per establishment).

TABLE 6.—COSTS FOR TYPICAL SINGLE-SHIFT PROCESSING ESTABLISHMENT

[Dollars]

Requirement	Development and implementation costs	Recurring annual costs
Sanitation SOP's	190	1,242
HACCP Plan Development	6,958	0
Annual Plan Reassessment ...	0	102
Training	2,514	251
Recordkeeping	0	6,480
Total	9,662	8,075

If one of the two production operations produced a raw ground product, the establishment would have to meet the pathogen reduction performance standard for that product. The FRIA points out that raw ground operations do not have the same opportunities to reduce *Salmonella* levels as do slaughter establishments. They can control growth by avoiding temperature abuse and can limit cross-contamination, but basically they must depend on the *Salmonella* levels of their incoming product in order to meet the performance standards. These establishments may choose to test incoming product in order to eliminate suppliers whose product is found to be positive. The FRIA has assumed that the low volume producers would not test incoming ingredients.

Table 7 illustrates the costs for a small, single-shift, combination (slaughter and further processing) establishment that slaughters cattle or swine, but not both, and has a single further processing operation other than ground product. The establishment is not under TQC inspection.

The cost of meeting the pathogen reduction performance standards assumes that the establishment will use a hot water antimicrobial rinse and have one sample per month analyzed at an outside laboratory ($33.35 per sample-$400 per year). The average number of head slaughtered in a low volume establishment is approximately 5,000 annually. The annual cost for the rinse is $400.

TABLE 7.—COSTS FOR TYPICAL SINGLE-SHIFT COMBINATION ESTABLISHMENT

[Dollars]

Requirement	Development and implementation costs	Recurring annual costs
Sanitation SOP's	190	1,242
Compliance with *Salmonella* Standards	0	800
E. coli Sampling	1,043	653
HACCP Plan Development	6,958	0
Annual Plan Reassessment ...	0	102
Training	5,028	503
Recordkeeping	0	5,434
Total	13,219	8,734

The development costs for *E. coli* sampling in the small establishment includes $640 for developing a sampling plan and $403 to train an individual to conduct aseptic sampling. The recurring costs are based on the assumption that an average low volume slaughter establishment will have to complete two sampling windows (26 samples) before they demonstrate compliance with established criteria.

The cost of HACCP training has doubled for the combination establishment because the FRIA assumed that slaughter and processing operations are significantly different, so that the establishment must either train two employees or send one employee to two separate training courses.

The HACCP recordkeeping costs (monitoring CCPs and recording findings, reviewing records and storing records) in the above two examples assume that the establishments are operating each process continuously over a standard 52-week, 260-day, 2,080-hour work year. Data collected during the preliminary analysis indicates that many low-volume establishments frequently have only a single production line operating at a given time. The final analysis estimates an average annual cost for HACCP monitoring and recording of $4,030 for low-volume establishments.

Executive Order 12778

This rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the FMIA and PPIA from imposing any requirements with respect to federally inspected premises and facilities, and operations of such establishments, that are in addition to, or different from, those imposed under the FMIA and PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements on State-inspected products and establishments that are at least equal to those required under the FMIA and the PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

Paperwork Requirements

The paperwork and recordkeeping for this rule are approved under OMB number 0583–0103, ''Pathogen Reduction, Hazard Analysis and Critical Control Points (HACCP) Systems.'' OMB approved 14,371,901 annual reporting hours. Overall, the burden hours associated with the rule decreased. FSIS determined that the new burden is 8,053,319 hours, a 6,318,582-hour reduction. This reduction resulted from the elimination of proposed requirements and the adjustment of certain burden hour estimations. The following discusses the finalized paperwork and recordkeeping requirements and the changes in the burden estimations.

Sanitation Standard Operating Procedures (Sanitation SOP's)

As part of establishments' sanitation requirements, each establishment must develop and maintain Sanitation SOP's that must, at a minimum, address core

sanitation procedures. As part of the Sanitation SOP's, establishment employees(s) must record results of daily sanitation checks on a checklist at the frequencies stated in the Sanitation SOP's. The checklist must include both preoperational sanitation checks and operational sanitation checks. This checklist must be made available to FSIS upon request.

Agency subject matter experts and private consultants estimate that it will take an average of 5, 10, and 25 hours to develop a sanitation program for low, medium, and high volume establishments, respectively. The burden of documenting the adherence to Sanitation SOP's is based on three factors; recording, reviewing, and storage. Recording encompasses conducting and inscribing the finding from an observation and filing of the document produced. This action is assumed to take 15, 25, and 45 minutes per day in a low-, medium-, and high-volume establishment, respectively. Review of the records generated is estimated to take 5, 10, and 20 minutes per day for a low-, medium-, and high-volume establishment, respectively.

OMB approved 1,243,622 burden hours for Sanitation SOP's plan development, recording and filing, and record review. FSIS determined that the burden estimate for these activities was too high. Based on more accurate data, FSIS reevaluated the burden estimate and calculated the new burden hours to be 1,231,986 hours. This is a 11,636 burden hour decrease.

Time and Temperature

As discussed earlier, the proposed time-and-temperature requirements are eliminated. OMB approved 869,156 burden hours for time-and-temperature requirements. Therefore, elimination of the time-and-temperature requirements, results in a 869,156 burden hour decrease.

Microbiological Testing

As part of microbiological testing, each slaughter establishment must develop written procedures outlining specimen collection and handling. The slaughter establishments will be responsible for entering the results into a statistical process control chart or table. The data and chart will be available for review by FSIS upon request.

Agency subject matter experts estimate that it will take 25 hours for establishments to develop a microbial sampling and analysis plan. It will take an estimated 17.5 minutes to collect samples and 5 minutes per sample to enter data into the chart, review, and file the information.

OMB has approved 1,177,924 burden hours for microbial testing plan development, sample collection, and data entry by meat and poultry establishments. As discussed earlier, the number of meat and poultry establishments required by the Pathogen Reduction/HACCP proposal to perform microbial testing and the number of tests required decreased. FSIS reevaluated this burden estimate and concluded that the burden for microbial testing by meat and poultry establishments is 468,061 burden hours. Therefore, the burden hour decrease associated with microbial testing is 709,863 hours.

HACCP

Establishments will develop written HACCP plans that include: identification of the food safety hazards reasonably likely to occur; identification and description of the critical control point for each identified hazard; specification of the critical limit that may not be exceeded at the CCP; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records that will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Performance standards or limits specified in related FSIS regulations must be accounted for in the critical limits.

Establishments will keep records of measurements taken during slaughter and processing, corrective actions, verification check results, and related activities that contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The record will be signed by the operator or observer.

The HACCP records will be reviewed by an establishment employee other than the one who produced the record, if practicable, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be the second reviewer. The reviewer will sign the records.

Although the amount of time to develop a plan for each process varies based on its difficulty, Agency subject matter experts estimate that low, medium, high volume and state establishments will need an average of 136, 126, 113, and 78 hours to develop each plan. There are an estimated 7.4 CCP's for each processing plan in Federal establishments, 5 CCP's for each slaughter plan in Federal establishments, and 5 CCP's for both types of plans in State slaughter establishments. The recording and filing is assessed to take 5 minutes per CCP and the review should take 2 minutes per CCP.

OMB approved 11,081,199 burden hours for the maintenance of the HACCP-trained individual's resume, plan development, recording, and record review. As discussed earlier, FSIS will not require personnel resumes to be maintained, thus the burden reported for this activity is eliminated. Also, FSIS determined that the burden estimate for plan development, recording, and record review was too high. Based on more accurate data, FSIS reevaluated the burden estimate and calculated the new burden hours to be 6,353,272. This is a 4,727,927 burden hour decrease.

To better illuminate the burden hour changes, the following table is provided.

TABLE 8.—CHANGES IN BURDEN HOURS

Requirement	Burden hours approved by OMB	New burden hours	Reduction in burden hours
SOP's for Sanitation	1,243,622	1,231,986	11,636
Time and Temperature	869,156	0.00	869,156
Microbiological Testing	1,177,924	468,061	709,863
HACCP	11,081,199	6,353,272	4,727,927
Total (Hours)	14,371,901	8,053,319	6,318,582

The changes in the paperwork and recordkeeping requirements contained in this rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq*.).

VII. Final Rules

List of Subjects

9 CFR Part 304

Meat inspection.

9 CFR Part 308

Meat inspection.

9 CFR Part 310

Meat inspection, Microbial testing.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 327

Imports.

9 CFR Part 381

Poultry and Poultry products, Microbial testing.

9 CFR Part 416

Sanitation.

9 CFR Part 417

Hazard Analysis and Critical Control Point (HACCP) Systems.

For reasons set forth in the preamble, 9 CFR chapter III is amended as follows:

PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL OF INSPECTION

1. The authority citation for part 304 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. Section 304.3 is added to read as follows:

§ 304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

PART 308—SANITATION

3. The authority citation for part 308 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

4. Section 308.3 is amended by adding a sentence to the end of paragraph (a) to read as follows:

§ 308.3 Establishments; sanitary condition; requirements.

(a) * * *. The provisions of part 416 of this chapter also apply.

* * * * *

PART 310—POST MORTEM INSPECTION

5. The authority citation for part 310 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

6. Part 310 is amended by adding a new § 310.25 to read as follows:

§ 310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.

(a) Criteria for verifying process control; *E. coli* testing.

(1) Each official establishment that slaughters cattle and/or hogs shall test for *Escherichia coli* Biotype I (*E. coli*) and shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures.* Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* The establishment shall collect random samples from carcasses in the cooler. Samples shall be collected by sponging three sites on the selected carcass. On cattle carcasses, establishments shall take samples from the flank, brisket, and rump; on swine carcasses, establishments shall take samples from the ham, belly, and jowl areas. [1]

(iii) *Sampling frequency.* Samples shall be taken at a frequency proportional to a slaughter establishment's volume of production, at the following rates:

Bovines: 1 test per 300 carcasses
Swine: 1 test per 1,000 carcasses

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume establishments.*

(A) An establishment annually slaughtering no more than 6,000 bovines, 20,000 swine, or a combination of bovines and swine not exceeding 6,000 bovines and 20,000 animals total, shall collect one sample per week starting the first full week of June and continuing through August of each year. An establishment slaughtering both species shall collect samples from the species it slaughters in larger numbers. Weekly samples shall be collected and tested until the establishment has completed and recorded one series of 13 tests that meets the criteria shown in Table 1 of paragraph (a)(5) of this section.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for

[1] A copy of FSIS's ''Guidelines for *E. coli* Testing for Process Control verification in Cattle and Swine Slaughter Establishments'' is available for inspection in the FSIS Docket Room.

analysis of *E. coli* that is approved by the Association of Official Analytic Chemists International [2] or approved by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of cfu/cm^2 of surface area sponged. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by class of livestock slaughtered, permitting evaluation of the laboratory results in accordance with the criteria set forth in paragraph (a)(5) of this section. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for Evaluation of test results.* An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

Slaughter class	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Steers/heifers	Negative [a]	100 cfu/cm^2	13	3
Cows/bulls	Negative [a]	100 cfu/cm^2	13	3
Market hogs	10 cfu/cm^2	10,000 cfu/cm^2	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm^2 carcass surface area.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; *Salmonella.*

(1) *Raw meat product performance standards for Salmonella.* An establishment's raw meat products, when sampled and tested by FSIS for *Salmonella*, as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2.—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for *Salmonella*) [a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	[b]N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) *Enforcement.* FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) *Noncompliance and establishment response.* When FSIS determines that an

[2] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists International,'' 16th edition, 1995, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

7. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

8. Section 320.6 is amended by revising paragraph (a) to read as follows:

§ 320.6 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection, as may be required by the Administrator in special cases.

* * * * *

PART 327—IMPORTED PRODUCTS

9. The authority citation for Part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

10. Section 327.2 is amended by redesignating paragraphs (a)(2)(i) (*a*)–(*g*) as (a)(2)(i) (A)–(G), redesignating paragraphs (a)(2)(ii) (*a*)–(*g*) to (a)(2)(ii) (A)–(G), redesignating paragraph (a)(2)(ii)(*h*) as (a)(2)(ii)(I), and by adding a new paragraph (a)(2)(ii)(H) to read as set forth below, and by redesignating paragraphs (a)(2)(iv) (*a*)–(*c*) as (a)(2)(iv) (A)–(C).

§ 327.2 Eligibility of foreign countries for importation of products into the United States.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

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PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

11. The authority citation for part 381 is revised to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

Subpart D—Application for Inspection; Grant or Refusal of Inspection

12. A new § 381.22 is added to subpart D to read as follows:

§ 381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, in accordance with Part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, in accordance with §§ 417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with § 417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with § 417.4 of this chapter.

Subpart H—Sanitation

13. Section 381.45 is amended to read as follows:

§ 381.45 Minimum standards for sanitation, facilities, and operating procedures in official establishments.

The provisions of §§ 381.46 and 381.61, inclusive, and part 416 of this chapter shall apply with respect to all official establishments.

Subpart K—Post Mortem Inspection: Disposition of Carcasses and Parts

14. Section 381.94 is added to subpart K to read as follows:

§ 381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; *E. coli* testing.

(1) Each official establishment that slaughters poultry shall test for *Escherichia coli* Biotype I (*E. coli*) and shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures.* Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* The establishment shall collect random samples from carcasses. Carcasses to be sampled will be selected randomly. Samples shall be collected by taking a whole bird from the end of the chilling process, after the drip line, and rinsing it in an amount of buffer appropriate for the type of bird being tested. [1]

(iii) *Sampling frequency.* Samples will be taken at a frequency proportional to a slaughter establishment's volume of production, at the following rates:

Chickens: 1 sample per 22,000 carcasses
Turkeys: 1 sample per 3,000 carcasses

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that

[1] A copy of FSIS's guideline, ''Sampling Technique for *E. coli* in Raw Meat and Poultry for Process Control Verification,'' is available in the FSIS Docket Room for inspection.

the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume establishments.*

(A) An establishment annually slaughtering no more than 440,000 chickens, 60,000 turkeys, or a combination of chickens and turkeys not exceeding 60,000 turkeys and 440,000 birds total, shall collect one sample per week starting the first full week of June through August of each year. An establishment slaughtering both chickens and turkeys shall collect samples from the species it slaughters in larger numbers. Weekly samples shall be collected and tested until the establishment has completed and recorded one series of 13 tests that meets the criteria shown in Table 1 of paragraph (a)(5) of this section.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is sensitive to 5 or fewer cfu/ml of rinse fluid and is approved by the Association of Official Analytic Chemists International [2] or approved by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of cfu/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by kind of poultry slaughtered, permitting evaluation of the laboratory results in accordance with the criteria set forth in paragraph (a)(5) of this section. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for Evaluation of test results.* An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1.—EVALUATION OF E. COLI TEST RESULTS

Slaughter class	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Broilers	100 cfu/ml	1,000 cfu/ml	13	3
Turkeys	[a] N.A.	N.A.	N.A.	N.A.

[a] Not available; values for turkeys will be added upon completion of data collection program for turkeys.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; *Salmonella.*

(1) *Raw poultry product performance standards for Salmonella.* (i) An establishment's raw poultry products, when sampled and tested by FSIS for *Salmonella* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2.—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for *Salmonella*) [a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Broilers	[b] 20.0%	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are avialable in the FSIS Docket Room.)

[b] Standard is based on partial analysis of baseline survey data; subject to confirmation upon publication of baseline survey report.

[d] Not available; baseline targets for turkeys will be added upon completion of the data collection programs for that product.

[2] A copy of the ''Official Methods of Analysis of the Association of Official Analytical Chemists International,'' 16th edition, 1995, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

(2) *Enforcement.* FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

Subpart Q—Records, Registration, and Reports

15. Section 381.180 is amended by revising paragraph (a) to read as follows:

§ 381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

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Subpart T—Imported Poultry Products

16. Section 381.196 is amended by redesignating paragraphs (a)(2)(i) (*a*)–(*g*) as paragraphs (a)(2)(i) (A)–(G), redesignating paragraphs (a)(2)(ii) (*a*)–(*g*) to (a)(2)(ii) (A)–(G), redesignating paragraph (a)(2)(ii)(*h*) as (a)(2)(ii)(I), and by adding a new paragraph (a)(2)(ii)(H) to read as set forth below, and redesignating paragraphs (a)(2)(iv) (*a*)–(*c*) as (a)(2)(iv)(A)–(c).

§ 381.196 Eligibility of foreign countries for importation of products into the United States.

* * * * *

(a) * * *

(2) * * *

(ii) * * *

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

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17. A new subchapter E, consisting of Parts 416 and 417 is added to chapter III—Food Safety and Inspection Service, Meat and Poultry Inspection, Department of Agriculture to read as follows:

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

Part

416 Sanitation

417 Hazard Analysis and Critical Control Point (HACCP) Systems

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

PART 416—SANITATION

Sec.

Authority: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein.

§ 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accesable available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 U.S.C. 1901–1906; 7 CFR 2.18, 2.53.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE *Food Safety Hazard.*

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) *Hazard analysis.* (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) *The HACCP plan.* (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

(ii) Raw product—ground.

(iii) Raw product—not ground.

(iv) Thermally processed—commercially sterile.

(v) Not heat treated—shelf stable.

(vi) Heat treated—shelf stable.

(vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 608 and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) *Initial validation.* Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) *Reassessment of the HACCP plan.* Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§ 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;

(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.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual

times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers*. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention*. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(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.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by § 417.3 of this part;

(d) HACCP records are not being maintained as required in § 417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

Done at Washington, DC, on: July 5, 1996.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

The following are appendices to the preamble of the Final Rule.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A—Guidelines for Developing a Standard Operating Procedure for Sanitation (Sanitation SOP's) in Federally Inspected Meat and Poultry Establishments

I. Introduction

Foodborne illness is a significant public health problem in the United States. While data on illness associated with meat and poultry products are limited, data from various sources suggest that foodborne microbial pathogens may cause up to 7 million cases of illness each year, and 7,000 deaths. Of these, nearly 5 million cases of illness and more than 4,000 deaths may be associated with meat and poultry products.

FSIS is pursuing a broad and long-term science-based strategy to improve the safety of meat and poultry products to better protect public health. FSIS is undertaking steps to improve the safety of meat and poultry throughout the food production, processing, distribution, and marketing chain. The Agency's goal is to reduce the risk to public health of consuming meat and poultry products by reducing pathogenic microbial contamination. The FSIS strategy relies heavily on building the principle of prevention into production processes.

Sections 308.7, 381.57 and 381.58 of the Meat and Poultry Inspection Regulations require that rooms, compartments, equipment, and utensils used for processing or handling meat or poultry in a federally inspected establishment must be kept clean and in a sanitary condition. Establishments are responsible for sanitation of facilities, equipment and utensils.

Sanitation maintains or restores a state of cleanliness, and promotes hygiene for the prevention of foodborne illness. Sanitation encompasses many areas and functions of an establishment, even when not in production. However, there are certain sanitary procedures that must be addressed and maintained on a daily basis to prevent direct product contamination or adulteration. Good sanitation is essential in these areas to maintaining a safe food production process.

FSIS is requiring meat and poultry establishments to develop and implement a written Standard Operating Procedure for sanitation (Sanitation SOP's) which addresses these areas. An establishment's adherence to its written Sanitation SOP will demonstrate knowledge of and commitment to sanitation and production of safe meat and poultry products.

New part 416 to the Meat and Poultry Inspection Regulations requires that a written Sanitation SOP contain

established procedures to be followed routinely to maintain a sanitary environment for producing safe and unadulterated food products. Plant management must develop a Sanitation SOP that describes daily sanitation procedures to be performed by the establishment. A designated establishment employee(s) must monitor the Sanitation SOP and document adherence to the SOP and any corrective actions taken to prevent direct product contamination or adulteration. This written documentation must be available to FSIS program employees.

These FSIS guidelines should help federally inspected meat or poultry establishments develop, implement and monitor written Sanitation SOPs.

The Sanitation SOP developed by the establishment must detail daily sanitation procedures it will use before (pre-operational sanitation) and during (operational sanitation) operation to prevent direct product contamination or adulteration. FSIS program employees will verify an establishment's adherence to its Sanitation SOP and will take appropriate action when there is noncompliance.

These guidelines, where applicable, are for:

- Livestock Slaughter and/or Processing Establishments
- Poultry Slaughter and/or Processing Establishments
- Import Inspection Establishments
- Identification Warehouses

The establishment should update the Sanitation SOP to reflect changes in equipment and facilities, processes, new technology, or designated establishment employees.

II. Pre-operational Sanitation

Established procedures of pre-operational sanitation must result in clean facilities, equipment and utensils prior to starting production. Clean facilities, equipment, and utensils are free of any soil, tissue debris, chemical or other injurious substance that could contaminate a meat or poultry food product. Pre-operational sanitation established procedures shall describe the daily, routine sanitary procedures to prevent direct product contamination or adulteration. The sanitary procedures must include the cleaning of product contact surfaces of facilities, equipment and utensils to prevent direct product contamination or adulteration. The following additional sanitary procedures for pre-operational sanitation might include:

- Descriptions of equipment disassembly, reassembly after cleaning, use of acceptable chemicals according to label directions, and cleaning techniques.
- The application of sanitizers to product contact surfaces after cleaning. Sanitizers are used to reduce or destroy bacteria that may have survived the cleaning process.

III. Operational Sanitation

All federally inspected establishments must describe daily, routine sanitary procedures that the establishment will conduct during operations to prevent direct product contamination or adulteration. Established procedures for operational sanitation must result in a sanitary environment for preparing, storing, or handling any meat or poultry food product in accordance with sections 308/381 of the Meat and Poultry Inspection Regulations. Established procedures during operations might include, where applicable:

- Equipment and utensil cleaning—sanitizing—disinfecting during production, as appropriate, at breaks, between shifts, and at midshift cleanup.
- Employee hygiene: includes personal hygiene, cleanliness of outer garments and gloves, hair restraints, hand washing, health, etc.
- Product handling in raw and in cooked product areas.

The established sanitary procedures for operational sanitation will vary with the establishment. Establishments with complex processing need additional sanitary procedures to ensure a sanitary environment and to prevent cross contamination. Establishments that do not slaughter or process (such as an Import Inspection facility) should develop established sanitary procedures specific to that facility.

IV. Implementing and Monitoring of the Sanitation SOP

The Sanitation SOP shall identify establishment employee(s) (positions rather than specific names of employees) responsible for the implementation and maintenance of the Sanitation SOP. Employee(s) are to be identified to monitor and evaluate the effectiveness of the Sanitation SOP and make corrections when needed. The evaluation can be performed by using one or more of the following methods: (1) organoleptic (sensory—e.g., sight, feel, smell); (2) chemical (e.g., checking the chlorine level); (3) microbiological (e.g., microbial swabbing and culturing of product contact surfaces of equipment or utensils).

Establishments might specify the method, frequency, and recordkeeping processes associated with monitoring. Pre-operational sanitation monitoring should, at a minimum, evaluate and document the effective cleaning of all direct product contact facilities, equipment, and/or utensils that are to be used at the start of production. Operational sanitation monitoring should, at a minimum, document adherence to the SOP, including actions that identify and correct instances or circumstances of direct product contamination which occur from environmental sources (facilities, equipment, pests, etc.) or employee practices (personal hygiene, product handling, etc.). All establishment records of pre-operational and operational sanitation monitoring, including corrective actions to prevent direct product contamination or adulteration, must be maintained by the establishment for at least six months, and be made available to FSIS program employees. After 48 hours, they may be maintained off-site.

V. Corrective Actions

When deviations occur from the established sanitary procedures within the Sanitation SOP, the establishment must take corrective actions to prevent direct product contamination or adulteration. Instructions should be provided to employees and management officials for documenting corrective actions. The actions must be recorded.

Appendix B—Model of a Standard Operating Procedure for Sanitation

Hill-Top Meats has prepared a written Standard Operating Procedure (SOP) for Sanitation. Let's look at the Sanitation SOP and discuss its attributes (guidance and advice are inside the boxes).

Hill-Top Meats, Est. 38, Anytown, U.S.A. is a slaughter and medium processing establishment. This plant receives live cattle for slaughter and dressing and processes the carcasses into chubs of ground beef, roast beef, and ready to eat beef products.

> This introductory information is not a regulatory requirement but identifies the type of establishment and its production. The information will help FSIS personnel, who are not familiar with the establishment, review the Sanitation SOP.

Management structure is as follows:

President—Joe Doe
Slaughter Manager—Ken Smith
Processing Manager—Susan Jones
Quality Control (QC) Manager—Gwen Summers
Sanitation Manager—Carl Anderson

The QC Manager is responsible for implementing and daily monitoring of the Sanitation SOP and recording the findings and any corrective actions. The

Slaughter, Processing and Sanitation Managers are responsible for training and assigning specific duties to other employees and monitoring their performance within the Sanitation SOP.

All records, data, checklists and other information pertaining to the Sanitation SOP will be maintained on file and made available to FSIS program employees.

> The identification of establishment personnel (positions rather than specific names of employees) responsible for implementing, maintaining, monitoring and records associated with the Sanitation SOP is a regulatory requirement. All records pertaining to the Sanitation SOP must be kept on file and made available to FSIS personnel, but it is not necessary to make that statement.

Sanitation SOP for EST. 38

I. Preoperational Sanitation—Equipment and Facility Cleaning Objective

All equipment will be cleaned and sanitized prior to starting production.

A. General Equipment Cleaning. (Simple equipment and hand tools are cleaned and sanitized in the same manner but they do not require disassembly and reassembly.)

1. Established Sanitary Procedures for Cleaning and Sanitizing Equipment:

a. The equipment is disassembled. Parts are placed in the designated tubs, racks, etc.

b. Product debris is removed.

c. Equipment parts are rinsed with water to remove remaining debris.

d. An approved cleaner is applied to parts and they are cleaned according to manufacturers' directions.

e. Equipment parts are rinsed with potable water.

f. Equipment is sanitized with an approved sanitizer, and rinsed with potable water if required.

g. The equipment is reassembled.

h. The equipment is resanitized with an approved sanitizer, and rinsed with potable water if required.

> The established sanitary procedures are daily routine sanitary procedures to prevent direct product contamination or adulteration. Daily routine sanitary procedures to prevent direct product contamination or adulteration are required in the Sanitation SOP; FSIS personnel use them to verify compliance with the Sanitation SOP. The procedures shall be specific for each establishment; however, they can be as detailed as the establishment wants to make them.

2. Implementing, Monitoring and Recordkeeping. The QC Manager performs daily organoleptic sanitation inspection after preoperational equipment cleaning and sanitizing. The results of the inspection are recorded on Establishment Form E–1. If everything is acceptable, the appropriate box is initialed. If corrective actions are needed, such actions are to be documented (see below).

The QC Manager performs daily microbial monitoring for Total Plate Counts (TPCs) after preoperational equipment cleaning and sanitizing. The QC Manager swabs one square inch of a food contact surface on a piece of equipment or hand tool within one hour prior to production. The samples are plated and incubated at 35° C. for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Daily microbial counts are documented on Establishment Form M–1.

3. Corrective Actions.

a. When the QC Manager determines that the equipment or hand tools do not pass organoleptic examination, the cleaning procedure and reinspection are repeated. The Sanitation Manager monitors the cleaning of the equipment or hand tools and retrains sanitation crew employees, if necessary. Corrective actions are recorded on Establishment Form E–1.

b. If microbial counts exceed ____ CFUs/sq. in., the QC Manager notifies the Sanitation Manager and attempts to determine the cause of the high count (for example, cleaning procedures varied, new people cleaned the equipment, sanitizer not applied). If microbial counts remain high for several days, the QC Manager will confer with the Sanitation Manager. The Sanitation Manager notifies sanitation crew employees and reviews all cleaning and sanitizing procedures and personal hygiene. Microbial counts are recorded on Establishment Form M–1. Corrective actions to prevent direct product contamination or adulteration are documented on Establishment Form E–1.

> The establishment is required to monitor daily routine sanitation activities as described in the Sanitation SOP, the establishment determines the methods and frequency of monitoring. Microbiological sampling is not required, but Hill-Top Meats wants to monitor the effectiveness of the cleaning by daily microbial sampling, in addition to organoleptic monitoring, and has set limits to enable them to take appropriate action when those limits are exceeded. Establishment Forms E–1 and M–1 are used only as examples; no specific forms or form numbers are required. However, establishments must record the daily completion or adherence to the established procedures in the Sanitation SOP, any deviations from regulatory requirements, and corrective actions.

B. Cleaning of Facilities—including floors, walls and ceilings.

1. Cleaning Procedures.

a. Debris is swept up and discarded.

b. Facilities are rinsed with potable water.

c. Facilities are cleaned with an approved cleaner, according to manufacturer's directions.

d. Facilities are rinsed with potable water.

2. Cleaning Frequency.

Floors and walls are cleaned at the end of each production day. Ceilings are cleaned as needed, but at least once a week.

> There is no specific requirement to include facility cleaning in the Sanitation SOP, unless part of the facility could directly contaminate or adulterate product.

3. Establishment Monitoring.

The QC Manager performs daily organoleptic inspection prior to the start of operations. Results are recorded on Establishment Form E–1.

4. Corrective Actions.

When the QC Manager determines that the facilities do not pass organoleptic inspection, the cleaning procedure and reinspection are repeated. The Sanitation Manager monitors the cleaning of facilities and retrains sanitation crew employees if necessary. Corrective actions to prevent direct product contamination or adulteration are recorded on Establishment Form E–1.

II. Operational Sanitation

Objective: Carcass dressing will be performed under sanitary conditions and in a manner to prevent contamination of the carcass.

A. Slaughter Operations.

1. Established Methods for Carcass Dressing—

a. Employees will clean hands, arms, gloves, aprons, boots, etc., as often as

necessary during the dressing procedures.

b. Employees will clean and then sanitize with 180° F. water, knives and other hand tools, saws and other equipment, as often as necessary during the dressing procedures to prevent contamination of the skinned carcass.

c. The brisket saw is sanitized between carcasses using 180° F. water.

d. Eviscerating employees will maintain clean hands, arms, clothes, aprons, boots and knives during the evisceration process. If contamination occurs, the employee is required to step away from the evisceration table onto a side platform to clean and sanitize apron, boots and knives. It may be necessary to clean hands and arms with soap and water. In cases of contamination from an abscess or other extensive contamination, the employee may need to shower and change clothes before resuming work.

e. The carcass splitting saw is sanitized with 180° F. water after each carcass.

The above methods for carcass dressing are specific for Hill-Top Meats. The establishment considers them to be Good Manufacturing Practices for their type of operation, to prevent direct contamination or adulteration of carcasses. Each establishment determines the sanitary procedures and any requirements they want to detail in their Sanitation SOP.

2. Monitoring and Recordkeeping.

a. The Slaughter Manager is responsible for ensuring that employee hygiene practices, sanitary conditions and cleaning procedures are maintained during a production shift. The QC Manager monitors the sanitation procedures twice during a production shift. Results are recorded on Establishment Form E–1.

b. A Microbiological Control and Monitoring Program is used to determine the level of bacteria on product contact surfaces of equipment (e.g., knives, hand tools, evisceration table, etc.) and outer garments (such as aprons and gloves) during production. The QC Manager performs daily microbial monitoring for Total Plate Counts (TPCs). The samples are plated and incubated at 35°C. for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Daily microbial counts are documented on Establishment Form M–1.

3. Corrective Actions.

a. When equipment is visibly contaminated, contaminants are removed by cleaning and sanitizing equipment prior to resuming production. The Slaughter Manager attempts to determine the cause of the contamination and takes corrective action. This may require adjusting equipment, retraining employees, temporarily stopping or slowing the line speed, etc. Corrective actions are recorded on Establishment Form E–1.

b. If microbial counts from equipment swabbing exceed the action level set, the QC Manager notifies the Slaughter Manager. The Slaughter Manager attempts to determine the cause (for example, new people not adequately trained, equipment not adjusted properly) and takes corrective action. If microbial counts remain above established limits for several days, the QC Manager confers with the Slaughter Manager and all slaughter operations are reviewed. The Slaughter Manager notifies the slaughter employees and reviews personal hygiene, equipment adjustment, and sanitary handling procedures. Corrective actions to prevent direct product contamination or adulteration are recorded on Establishment Form E–1.

The establishment is required to monitor the regulatory daily sanitation activities as described in its Sanitation SOP, but each establishment determines its own methods for monitoring, the frequency of monitoring, and the corrective actions to include in the Sanitation SOP. Records must be kept on daily completion of the established procedures, deviations, and corrective actions.

B. Processing Operations.

Objective: Processing is performed under sanitary conditions to prevent direct and cross contamination of food products.

1. Established Sanitary Procedures for Processing—

a. Employees clean and sanitize hands, gloves, knives, wizard knives, other hand tools, cutting boards, etc., as necessary during processing to prevent contamination of food products.

b. All equipment, belt conveyors, tables, and other product contact surfaces are cleaned and sanitized throughout the day as needed.

c. Employees take appropriate precautions when going from a raw product area to a cooked product area, to prevent cross contamination of cooked products. Employees change outer garments, wash hands and sanitize hands with an approved hand sanitizer (sanitizer is equivalent to 50 ppm chlorine), put on clean gloves for that room and step into a boot sanitizing bath on leaving and entering the respective rooms.

d. Raw and cooked processing areas are separate. There is no cross utilization of equipment between raw and cooked products.

e. Outer garments, such as aprons, smocks and gloves, are identified and designated specifically for either the raw processing rooms or the cooked processing rooms. Blue is designated for raw processing rooms and orange for cooked processing rooms. The outer garments are hung in designated locations when an employee leaves each room. Outer garments are maintained in a clean and sanitary manner and are changed at least daily and, if necessary, more often.

Establishments with processing will determine their own established sanitary procedures in the Sanitation SOP and any establishment requirements. Hill-Top Meats considers its established procedures for processing to be Good Manufacturing Practices.

2. Monitoring and Recordkeeping.

a. The Processing Manager is responsible for ensuring that employee hygiene practices, employee and product traffic patterns, sanitary product handling procedures, and cleaning procedures are maintained during a production shift. The QC Manager monitors the sanitation procedures twice during a production shift. Results are recorded on Establishment Form P–1.

b. A Microbiological Control and Monitoring Program is used to determine and control the level of bacteria on both raw and cooked product contact surfaces during production. Once a day, the QC Manager performs Microbial Monitoring for Total Plate Counts (TPCs). The QC Manager swabs one square inch on a product contact surface from each of three randomly selected pieces of equipment in each raw product room and cooked product room.

Note: The samples are taken from the *cooked product rooms first* and then from the raw product rooms. The samples are plated and incubated at 35° C. for 48 hours. Colonies are counted and recorded as number of colony forming units (CFU) per square inch of surface swabbed. Microbial counts are documented on Establishment Form M–1.

3. Corrective Actions.

a. When the QC Manager identifies sanitation problems, the QC Manager notifies the Processing Manager. The Processing Manager stops production, if necessary, and notifies processing employees to take appropriate action to correct the sanitation problems. If necessary, processing employees are retrained. Corrective actions are recorded on Establishment Form P–1.

If microbial counts exceed the action level set for each piece of equipment for the specific product in that production line, the QC Manager notifies the Processing Manager. The Processing Manager attempts to determine the cause (for example, new people going back and forth between the raw and cooked rooms, gloves not being changed regularly) and takes corrective action. Additional daily microbial sampling is done on any equipment that showed high microbial counts, until the counts fall below the action level. If microbial counts remain high for several days, the QC Manager confers with the Processing Manager and Sanitation Manager to review all operations that impact that equipment. The Processing Manager notifies the processing employees and reviews personal hygiene and sanitary product handling procedures. Corrective actions are recorded on Establishment Form P–1.

The monitoring and corrective actions are specific for Hill-Top Meats only. Microbial sampling and monitoring are not required for product contact surfaces. Each establishment determines its own procedures for monitoring and the frequency of monitoring to include in its Sanitation SOP.

Appendix C—Guidebook for the Preparation of HACCP Plans

Preface

The Hazard Analysis Critical Control Points (HACCP) system is a logical, scientific system that can control safety problems in food production. HACCP is now being adopted worldwide. It works with any type of food production system and with any food. It works by controlling food safety hazards throughout the process. The hazards can be biological, chemical, or physical.

This guidebook was developed to help meat and poultry establishments prepare HACCP plans. The steps to developing a HACCP plan can be used by all establishments, large or small, complex or simple. The guidebook identifies additional sources of information, so that small operators won't have to ''go it alone.''

The forms shown in this guidebook are examples only. Think of this as a self-help guide or a do-it-yourself manual. There are many ways to get to the final product—a good HACCP plan. So, choose the examples that work best in your establishment.

The guidebook can be used to complement HACCP training. You may also wish to use it in conjunction with a video about HACCP. The guidebook will provide the basics. When you are ready to move on, there are more specialized documents. FSIS is also publishing the *Meat and Poultry Products Hazards and Controls Guide*. It explains in detail the biological, chemical, and physical hazards that can occur at different steps of meat and poultry slaughter and processing and provides some examples of controls for those hazards. In addition, there will be a series of Generic Models for different meat and poultry processes, to be used as examples. You will probably want to look at the models for processes that you use in your establishment. There will be model plans for the following 13 processes:

Raw, Ground
Raw, Other
All Other Shelf-Stable, Heat Treated
Fully Cooked, Non-Shelf Stable
All Other Shelf-Stable, Not Heat Treated
All Non-Shelf Stable, Heat Treated, Not Fully Cooked
Non-Shelf Stable with Secondary Inhibitors
Thermally Processed/Commercially Sterile
Swine Slaughter
Poultry Slaughter
Beef Slaughter
Irradiation
Mechanically Separated Species

Developing a HACCP Plan

The Hazard Analysis and Critical Control Points (HACCP) System is a logical, scientific approach to controlling safety problems in food production. When a company adopts HACCP, it puts controls in place at each point in the production system where safety problems could occur from biological, chemical, or physical hazards. To start a HACCP system, a company must first write a HACCP plan. This guidebook explains how to write a HACCP plan in five preparatory steps and then the seven HACCP principles.

The five ''pre-HACCP'' steps in this guidebook are:

1. Bring together your HACCP resources.
2. Describe the product and its method of distribution.
3. Develop a complete list of ingredients and raw materials used in the product.
4. Develop a process flow diagram.
5. Meet the regulatory requirements for Sanitation Standard Operating Procedures (SOPs).

Applying the seven HACCP principles makes up the major steps to writing a HACCP plan. They are:

1. Conduct a hazard analysis.
2. Identify critical control points.
3. Establish critical limits for each critical control point.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish recordkeeping procedures.
7. Establish verification procedures.

As you read this guidebook and look at the examples, the process for writing a HACCP plan should become clearer. This first section of the guidebook explains the five ''pre-HACCP'' steps. The next seven sections cover each of the HACCP principles that you will need to follow to develop a HACCP plan.

Pre-HACCP Step 1—Bring Together Your HACCP Resources

The first step is to assemble your HACCP resources. When a company develops a HACCP plan, it is important to bring as much knowledge to the table as possible. Actually, you probably have access to more HACCP resources than you think! With a small establishment, this might mean bringing together one or two employees, one of whom has had HACCP training. Your HACCP resources may include outside expertise. You can get this expertise through your local Extension Office, a trade or professional association, or a contractor of your choice. A larger plant may wish to bring in employees from a number of departments, such as production, sanitation, quality control, and engineering, as well as employees directly involved in daily processing activities. There is no magic number of employees needed to write a HACCP plan. It could be one employee or, in a very large company, it could be seven or eight people.

Your employee or employees writing the HACCP plan should understand some basic things about your establishment: The technology and equipment used in your processing lines; the practical aspects of food operations; and the flow of the process in your plant. It will be a bonus for your HACCP plan if those employees have some knowledge of the applied aspects of food microbiology and of HACCP principles and techniques, although this knowledge can be supplemented by outside experts.

Pre-HACCP Step 2—Describe the Product and Its Method of Distribution

The second step is to describe completely each food product that your plant makes. This will help identify hazards that may exist either in the ingredients or in the packaging materials.

To describe your product, you might ask the following questions about the product:

1. Common name?

For example, a cooked sausage could be called franks/hot dogs/wieners.

2. How is it to be used?

Categories might include: Ready-to-eat, to be heated prior to consumption, or for further processing.

3. The type of package?

For example, is it modified atmosphere packaging?

4. Length of shelf life?

In the cooked sausage example, the length of shelf life might be 30 to 50 days for modified atmospheric packaging.

5. Where will it be sold?

For example, will it be sold to wholesale, retail or institutions?

6. Labeling instructions?

''Keep Refrigerated'' would be a common labeling instruction for meat and poultry products.

7. Is special distribution control needed?

For instance, should the product be kept refrigerated at or below 40°F? Below is a blank Product Description Form. It is an example. You may take it and tailor it to your own establishment.

Below is an example of a Product Description Form filled in for cooked sausage. The HACCP Generic Models developed for 13 different processes will give you more samples of product descriptions.

Pre-HACCP Step 3—Develop a Complete List of Ingredients and Raw Materials

The third step is to develop a written list of ingredients and raw materials for each process/product. You can write this on a very simple form, as shown below. You may wish to divide the ingredients into just two categories: Meat (meat such as boneless beef or chicken parts with skin) and Other Ingredients (such as spices and preservatives). Below is a sample Product and Ingredients Form for chunked and formed, breaded chicken patties. Again, these forms are only examples to get you started. You may wish to have more elaborate forms for your establishment. The important thing is to list all ingredients that go into each product!

Pre-HACCP Step 4—Develop a Process Flow Diagram

The next step is to construct a process flow diagram that identifies all the steps used to prepare the product, from receiving through final shipment. The diagram should not be so complex that it is difficult to follow and understand, but must be complete from the beginning of your process to the end.

You will want to verify the process flow diagram. You do this by actually walking through the plant to make sure that the steps listed on the diagram describe what really occurs in producing the product.

A blank process flow diagram is shown below. It is a very simple form on which you may want to draw the flow freehand. If you have a computer, you can make a fancier form, with arrows leading from step to step.

BILLING CODE 3410–DM–P

PRODUCT(S) DESCRIPTION

PRODUCT:

THE FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE PRODUCT DESCRIPTION:

1. **COMMON NAME?**

2. **HOW IS IT TO BE USED?**

3. **TYPE OF PACKAGE?**

4. **LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?**

5. **WHERE WILL IT BE SOLD?**

6. **LABELING INSTRUCTIONS?**

7. **IS SPECIAL DISTRIBUTION CONTROL NEEDED?**

DATE:_____ **APPROVED BY:**_____

PRODUCT(S) DESCRIPTION

PRODUCT: Cooked sausage

THE FOLLOWING QUESTIONS NEED TO BE ANSWERED WHEN DEVELOPING THE PRODUCT DESCRIPTION:

1.	**COMMON NAME?**	Franks, Hot dogs, Wieners
2.	**HOW IS IT TO BE USED?**	Heat and eat, Ready-to-eat
3.	**TYPE OF PACKAGE?**	Atmospheric packed, Vacuum packed; Modified Atmospheric packed
4.	**LENGTH OF SHELF LIFE, AT WHAT TEMPERATURE?**	Atmospheric - 12 to 20 days, Vacuum - 30-60 days, Modified atmosphere - 30-50 days
5.	**WHERE WILL IT BE SOLD?**	Retail; HRI
6.	**LABELING INSTRUCTIONS?**	Keep Refrigered, Fully Cooked Code Date
7.	**IS SPECIAL DISTRIBUTION CONTROL NEEDED?**	Keep Refrigerated at or below 40°F.

DATE: April 15, 1996 **APPROVED BY:** J. M. MacIntosh

PRODUCT AND INGREDIENTS
PRODUCT:

DATE: _____ APPROVED BY: _____

PRODUCT AND INGREDIENTS

PRODUCT: CHUNKED AND FORMED, BREADED CHICKEN PATTIE

MEAT

CHICKEN

OTHER INGREDIENTS

SPICES
PHOSPHATES
BROTH
SALT
BREADING

DATE: June 21, 1996 **APPROVED BY:** Jean Dumouchel

An example of a Process Flow Diagram for cooked sausage is shown below. The employees in this case chose to construct a flow diagram for the meat and poultry ingredients, another one for the non-meat ingredients, and a third flow diagram for supplies such as packaging materials. You will find more examples of process flow diagrams for specific products in the HACCP Generic Models.

Remember, the purpose of this diagram is to find any places in your specific establishment where hazards could occur. As with all HACCP planning forms, the approving employee should sign and date the form, for your records.

Pre-HACCP Step 5—Meet the Regulatory Requirements for Sanitation Standard Operating Procedures

Good sanitation is one of the most basic ways to ensure that you produce safe products. Maintaining good sanitation serves as an excellent and necessary foundation for building your HACCP plan. It also demonstrates that you have the commitment and resources to successfully implement your HACCP plan. Because it is so important, meeting the regulatory requirements for Sanitation Standard Operating Procedures (SOPs) is a pre-HACCP requirement that must be carried out in all establishments. A separate guide and a model Sanitation SOP have been prepared and are available to help you with this activity.

Now you are ready to apply the seven principles that will produce a HACCP plan suited to your plant and your products. Those principles and how to carry them out will be discussed in detail in the next seven sections of this guidebook.

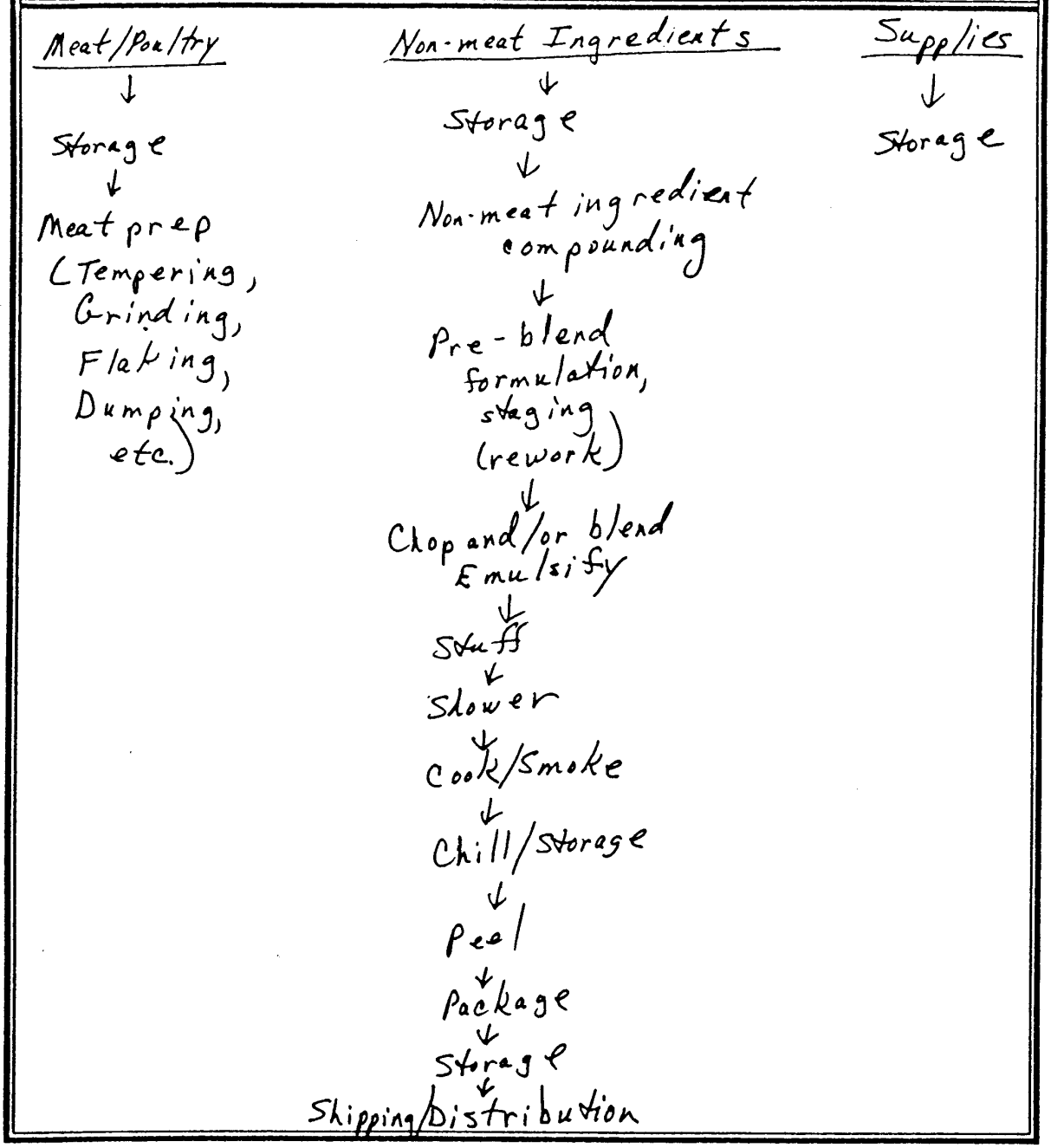
PROCESS FLOW DIAGRAM

PRODUCT(S):

DATE:_____ **APPROVED BY:**_____

PROCESS FLOW DIAGRAM

PRODUCT(S): Cooked sausage



DATE: April 17, 1996 **APPROVED BY:** J. D. MacIntosh

BILLING CODE 3410–DM–C

Principle 1—Conduct a Hazard Analysis

HACCP Principle No. 1 states:

''Conduct a hazard analysis. Prepare a list of steps in the process where significant hazards occur and describe the preventive measures.''

The regulation defines a food safety hazard as ''Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.''

This section will define the hazards and discuss in general where they may occur in meat and poultry production. It will then talk about identifying hazards in your establishment.

Finally, this section will explain how you can apply preventive measures to the hazards you have identified, to ensure that the products are safe for consumers. A preventive measure is defined, in the regulation, as ''Physical, chemical, or other means that can be used to control an identified food safety hazard.''

You will find a far more detailed listing of and discussion of hazards in the *Meat and Poultry Products Hazards and Controls Guide*. The generic HACCP models discuss the hazards specific to various meat and poultry processes, such as raw, ground product or swine slaughter. In addition, the References section of this guidebook lists publications which can help you identify hazards.

To identify biological, chemical, or physical hazards likely to occur, you need to know about the chemical, physical, and microbiological characteristics of meat, poultry, and other ingredients, as well as how various processes affect those characteristics. You also need to understand the interactions among ingredients.

You need to evaluate each step in the process flow diagram to determine whether a biological, chemical and/or physical hazard may be introduced at that step and whether preventive measures are available.

Biological Hazards

Biological hazards are living organisms, including microorganisms, that can put human health at risk. Biological hazards include bacteria, parasites, protozoa, viruses, and the like.

Agricultural products and food animals carry a wide range of bacteria. From a public health standpoint, most bacteria are harmless. Others—the pathogenic microorganisms—can cause illness or even death in humans. The numbers and types of bacteria vary from one food or animal species to another, from one geographic region to another, and with production and slaughter or harvesting methods. During production, processing, packaging, transportation, preparation, storage and service, any food may be exposed to bacterial contamination. The most common biological hazards in meat and poultry are microbiological.

Some of the major pathogenic bacterial organisms that can cause foodborne illness from eating meat or poultry are: *Salmonella, Clostridium perfringens, Listeria monocytogenes, Staphylococcus aureus, Campylobacter jejuni, Yersinia enterocolitica, Bacillus cereus, Clostridium botulinum,* and *Escherichia coli* O157:H7.

In the *Meat and Poultry Products Hazards and Controls Guide*, you will find a brief description of the major microorganisms of concern in meat and poultry. Table 1 in that guide describes the temperature and pH ranges and the minimum water activity needed for each organism to grow. Table 4 lists some preventive measures for biological hazards. To thoroughly identify significant biological hazards in your establishment, you need to evaluate each specific ingredient and processing step in your operation.

Chemical Hazards

Chemical hazards may also cause foodborne illnesses.

Chemical hazards fall into two categories:

1. Naturally occurring poisons or deleterious substances are those that are natural constituents of foods and are not the result of environmental, agricultural, industrial, or other contamination. Examples include aflatoxins, mycotoxins, and shellfish toxins.

2. Added poisonous or deleterious substances are those which are intentionally or unintentionally added to foods at some point in growing, harvesting, storage, processing, packing, or distribution. This group of chemicals can include pesticides, fungicides, insecticides, fertilizers, and antibiotics, as well as direct and indirect food additives. This group can also include chemicals such as lubricants, cleaners, paints, and coatings.

To identify any chemical hazards, you first need to identify any chemical residues that might be in the animal. To do this, think about the following:

- The types of drugs and pesticides routinely used in raising the animals which are the source of your meat and poultry ingredients.
- Feeds and supplements fed to the animals.
- Environmental contaminants the animals may have come into contact with. This includes both naturally occurring contaminants and added contaminants.
- Pesticides used on plants that may end up as residues in the animal.
- The source of the water the animals were allowed to drink. You can use the following preventive measures to help ensure that animals entering your establishment are free of harmful residues:
- Require that the animals have been raised in conjunction with the January 1994 FDA Compliance Policy Guidelines.
- Require written assurances from suppliers for each lot of animals, stating that the animals are free of illegal residues.
- Set your own maximum allowable residue limits for specific drugs, pesticides, and environmental contaminants in animal urine or tissues as targets to ensure that FDA and EPA tolerances are met.
- Ensure that trucks used to ship the animals do not have chemical hazards that could contaminate the animals.

Most establishments use chemicals during processing and to keep their operations sanitary. Yet you need to be aware that chemical hazards can occur at any of the following points:

- Prior to receiving chemicals at your establishment.
- Upon receiving chemicals.
- At any point where a chemical is used during processing.
- During storage of chemicals.
- During the use of any cleaning agents, sanitizers, lubricants, or other maintenance chemicals.
- Prior to shipment of the finished product.
- In trucks used to ship finished product.

Some of the measures you can use to prevent chemical hazards are:

- Use only approved chemicals.
- Have detailed product specifications for chemicals entering your plant.
- Maintain letters of guarantee from suppliers.
- Inspect trucks used to ship finished product.
- Properly label and store all chemicals.
- Properly train employees who handle chemicals.

In the *Meat and Poultry Products Hazards and Controls Guide*, Table 5 lists some preventive measures for chemical hazards. For still more information, see the publication *HACCP—Establishing Hazard Analysis Critical Control Point Program*, Food Processors Institute, 1993.

Physical Hazards

A physical hazard is any physical material not normally found in a food which causes illness or injury to the individual using the product. Physical hazards include a variety of foreign materials or objects, such as glass, metal, and plastic. However, foreign objects which cannot cause illness or injury are not hazards, even though they may not be aesthetically pleasing to your customers.

A number of situations can result in physical hazards in finished products. They include, but are not limited to:

- Contaminated raw materials.
- Poorly designed or poorly maintained facilities and equipment. An example would be rust particles and paint chips falling from overhead structures onto exposed product.
- Improper procedures or improper employee training and practices. For example, by using the wrong cutting technique during the cut-up/prefabrication process, employees could cut off and leave pieces of their rubber gloves in the product.

Measures you can take to prevent physical hazards include, but are not limited to:

- Make sure your plant specifications for building design and operation are accurate and updated regularly.
- Make sure your letters of guarantee for ingredients and product supplies are accurate and updated regularly.
- Perform random visual examinations of incoming product and materials.
- Use magnets and metal detectors to help find metal fragments that would be a physical hazard.
- Use stone traps and bone separators to remove these potential physical hazards.
- Keep equipment well maintained.
- Train employees to identify potential problems.

To identify some preventive measures for physical hazards, see Table 6 in the *Meat and Poultry Products Hazards and Controls Guide*.

Conducting a Hazard Analysis

Now that you have some understanding of the types of hazards that can occur and how to identify and prevent them, you are ready to conduct a hazard analysis for each process or product covered in your HACCP plan.

A hazard analysis is the identification of any hazardous biological, chemical, or physical properties in raw materials and processing steps, and an assessment of their likely occurrence and potential to cause food to be unsafe for consumption.

Your hazard analysis needs to be very specific to your establishment and how you make your product, since hazards may vary greatly from one establishment to another. This is due to differences in: sources of ingredients, product formulations, processing equipment, processing methods, duration of the processes and storage, and employee experiences, knowledge, and attitudes.

You also need to review—and perhaps revise—your hazard analysis whenever you make any changes in: raw materials suppliers, product formulation, preparation procedures, processing steps, packaging materials or procedures, distribution or intended use of the product.

Below is a blank Hazard Identification/Preventive Measures form that you may wish to use for your hazard analysis. Below is an example of that form filled in for hazards that might exist in a specific establishment's ground beef process. The form contains space for the process step in which the hazards could occur, the specific hazards, and preventive measures to keep that hazard from occurring. Remember, HACCP is a preventive system.

Steps in Conducting a Hazard Analysis

To conduct a hazard analysis, you need to do the following:

First—Evaluate Your Operation for Hazards

1. Review the product description developed in Pre-HACCP Step 2 and determine how this information could influence your hazard analysis.

2. Look at all product ingredients and incoming materials for the product. You developed this list in Pre-HACCP Step 3.

3. For each processing step identified in the process flow diagram, determine if a biological, chemical or physical hazard(s) could exist at that step.

BILLING CODE 3410–DM–P

HAZARD IDENTIFICATION/PREVENTIVE MEASURES

PRODUCT/PROCESS:

PROCESS STEP	HAZARD	PREVENTIVE MEASURE(S)

DATE: _____ **APPROVED BY:** _____

Biological - B
Chemical - C
Physical - P
Hazard Description

HAZARD IDENTIFICATION/PREVENTIVE MEASURES

PRODUCT/PROCESS: Ground Beef

PROCESS STEP	HAZARD	PREVENTIVE MEASURE(S)
Receiving - Meat	B (Microbial Growth) Insufficient temp. control will result in unacceptable microbial proliferation	Maintain product temperature within specified limits.
	B (Mishandling) Integrity of immediate container compromised such that microbial growth could occur.	Visual inspection to ensure immediate container is not compromised.
	P (Foreign Material) Visible foreign material could compromise product	Visual inspection to ensure no foreign material.
Receiving - Non-meat	C (Deleterious Chemicals) Chemicals/non-meat ingredients/packaging materials are acceptable for this use. Food grade for intended use.	Verify letter of guarantee is on file and appropriate for product use.
	P (Foreign Material) Visible foreign material that could compromise product safety; insects, etc.	Visual inspection to ensure no foreign material is present.

DATE: July 10, 1996 **APPROVED BY:** Jerry Flores

Biological - B
Chemical - C
Physical - P
Hazard Description

[Note: This page represents only the first two process steps; there are several more.]

BILLING CODE 3410–DM–C

4. To help identify hazards, you can ask the following questions at each processing step:

Could contaminants reach the product during this processing step? Possibilities include: worker handling, contaminated equipment or materials, cross-contamination from raw materials, leaking valves or pipes, dead ends, splashing, etc.

Could any pathogens multiply during this process step to the point where they became a hazard? Consider product temperature, hold time, etc.

Could this step create a situation where an ingredient, work in process, or finished product became contaminated with pathogens?

Could this step introduce a chemical hazard into the product?

Could this step introduce a physical hazard into the product?

5. Fully describe the hazards identified for each step.

6. For each incoming ingredient and material, indicate if a biological, chemical and/or physical hazard exists.

7. To help identify hazards, you can ask the following questions about each ingredient:

Could this ingredient contain any pathogenic microorganisms, toxins, chemicals or physical objects?

If it became contaminated or were mishandled, could this ingredient support the growth of pathogenic microorganisms?

Are any hazardous chemicals used in growing, harvesting, processing or packaging the ingredient?

Is this ingredient hazardous if used in excessive amounts?

If this ingredient were left out or used in amounts lower than recommended, could it result in microbial growth?

Are any chemical or physical hazards associated with this ingredient?

8. You can ask the following questions about the product in general:

Have any livestock entering the slaughter establishment been subjected to hazardous chemicals?

Are any returned/reworked products used as ingredients?

If so, could they cause a hazard?

Are preservatives or additives used in the product formulation to kill or inhibit the growth of microorganisms?

Do the amount and type of acid ingredients, and the resulting product pH, affect the growth/survival of microorganisms?

Does the water activity of the finished product affect microbial growth?

Should refrigeration be maintained for products during transit or in storage?

Are any chemical or physical hazards associated with any packaging materials?

9. Fully describe the hazards identified.

Second—Observe the Actual Operating Practices in Your Operation

After describing the hazards you've identified with each step, you should:

1. Observe the actual operation in your establishment and be sure that it is the usual process or practice.

2. Observe employee practices where raw or contaminated product could cross-contaminate workers' hands, gloves or equipment used for finished/post-process products.

3. Observe product handling past any kill step for potential cross-contamination.

For additional information about potential biological, chemical, and physical hazards, you may wish to consult tables 8 through 12 in the *Meat and Poultry Products Hazards and Controls Guide.* They can serve as a guide for identifying potential hazards in ingredients and at various steps in slaughter and processing. However, they do not address every ingredient and every processing step used in the meat and poultry industry.

Preventive Measures

You have identified all significant biological, chemical and physical hazards for each processing step and each ingredient. Now, it is time to identify measures to prevent hazards from compromising the safety of your finished product. Remember, you may not be able to identify a preventive measure for every hazard that you identified. You are ready to fill in the preventive measure(s) column of the Hazard Identification/Preventive Measures Form.

Remember, HACCP defines a preventive measure as ''Physical, chemical, or other means that can be used to control an identified food safety hazard.''

Some examples of preventive measures are:

In beef slaughter, a chemical hazard could result from animals having high levels of drug residues. As a preventive measure, you could test the animals or require letters of guarantee from producers that the animals are free of harmful residues.

In poultry slaughter, the venting, opening and evisceration process could result in a biological hazard from cross contamination by pathogenic microorganisms. Preventive measures for this hazard would be: use Good Manufacturing Practices (GMP's) at all times; properly maintain and operate equipment used to perform these tasks; and rinse food contact surfaces on equipment with chlorinated water between each carcass.

In the grinding step for cooked sausage, a physical hazard could be metal fragments from the grinding equipment. There could be three different preventive measures for this hazard. You could inspect the grinding equipment daily to ensure that it is assembled and operated correctly, is functioning properly, and is not worn or damaged. You could have an employee visually examine the product at the packaging step. Or you could use a metal detector at the packaging step.

In many operations, the packaging step could pose chemical hazards from the packaging materials. A preventive measure could be a letter of guarantee from the supplier that the packaging materials are all food grade.

Once you have identified your preventive measures and written them on your form, you are ready to go on to the next step in developing your HACCP plan. See blank and filled-in forms for preventive measures below.

Principle 2—Identify Critical Control Points

HACCP Principle No. 2 states:

''Identify the Critical Control Points (CCPs) in the process.''

A critical control point (CCP) is defined as ''A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.''

So far, in developing your HACCP plan, you have identified biological, chemical, and physical hazards in the raw materials and ingredients you use and in the steps of your process. You've also identified preventive measures, if they exist, for each hazard that you identified. With this information, your next step is to identify the points in the process at which the preventive measures can be applied to prevent, eliminate, or reduce the hazard. Then you can use the CCP Decision Tree to assess each step in the process to determine whether it is a *critical* control point. (Many control points may not be *critical*; often, companies starting out in HACCP identify too many control points.)

Fortunately, a great deal of work has already been done for you in identifying CCPs. Many CCPs are already recognized in various food processing and production systems. Some common CCPs are:

- Chilling.
- Cooking that must occur for a specific time and temperature in order to destroy microbiological pathogens.

- Product formulation controls, such as mixing ground beef and spices to form a meatball.
- Certain processing procedures, such as filling and sealing cans.
- Prevention of cross contamination between raw and cooked product.
- Certain slaughter procedures, such as evisceration.

These are just a few examples of measures that may be CCPs.

There are many more possibilities. Different facilities, preparing the same food, can differ in the number and location of hazards and the points, steps or procedures which are critical control points. This is due, in part, to differences in plant layouts, equipment used, selection and sources of raw materials and ingredients, or the process that is used.

Steps in Identifying Critical Control Points

A good tool for identifying Critical Control Points is the CCP Decision Tree, shown below. The CCP Decision Tree was developed to help companies separate CCPs from other controls. You will get the best results if you use the Decision Tree very methodically and use simple, descriptive, and familiar wording. You should apply the Decision Tree at each step in the process where you have identified a hazard.

You can use the blank Critical Control Point Determination Form, to record the results from your CCP Decision Tree work. Or, you may wish to design your own form. An example of a filled-in Critical Control Point Determination Form for poultry slaughter at one establishment is shown below.

Determining whether a process step is a CCP is really a basic exercise of answering four questions. To use the form and the Decision Tree, follow the next six steps:

1. In Column 1 of the Critical Control Point Determination Form, write in each step in the process where you have identified a hazard.

2. In Column 2, write in the identified hazard(s), indicating whether it is biological, chemical or physical. Then take the information you wrote on your Hazard Identification/Preventive Measures form and answer the following questions for each hazard you identified.

3. Question #1—Do preventive measures exist for the identified hazard?

Note: From a regulatory standpoint, no further action is necessary if the hazard is *not* reasonably likely to occur.

If the answer is yes, write YES and proceed to the next question.

If the answer is no, ask the question ''Is control at this step necessary for safety?''

If control is not necessary at this step in the process, this process step is not a CCP. Write NO in Column 3 and write how and where this hazard will be controlled. Proceed to the next process step and identified hazard you have entered in Columns 1 and 2.

If control is necessary, in Column 3 explain how the step, process or product will be modified to ensure safety.

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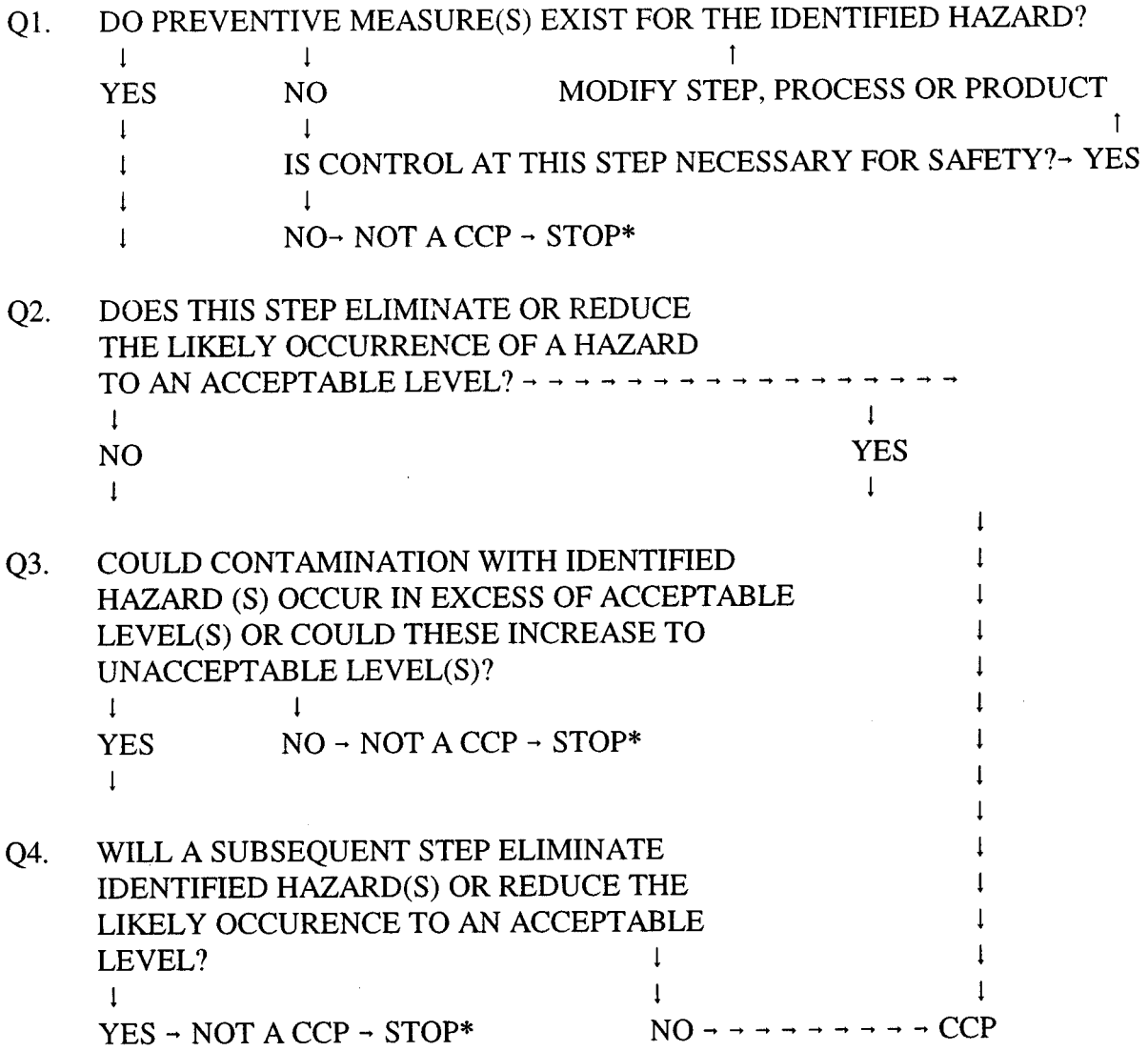
CCP DECISION TREE

(Apply at each step of the process with an identified hazard.)



* Proceed to the next step in the described process

CCP DETERMINATION

(A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)

PROCESS STEP	HAZARD(S) Biological - B Chemical - C Physical - P Hazard Description	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP

DATE: _____ **APPROVED BY:** _____

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CCP DETERMINATION

(A CRITICAL CONTROL POINT IS DEFINED AS A POINT, STEP OR PROCEDURE AT WHICH CONTROL CAN BE APPLIED AND A FOOD SAFETY HAZARD CAN BE PREVENTED, ELIMINATED, OR REDUCED TO ACCEPTABLE LEVELS)

PROCESS STEP	HAZARD(S) Biological - B Chemical - C Physical - P Hazard Description	Q1. DO PREVENTIVE MEASURES EXIST FOR THE IDENTIFIED HAZARD(S)? *If no=not a CCP-Identify how and where this hazard will be controlled. * If yes= move to next question.	Q2. DOES THIS STEP ELIMINATE OR REDUCE THE LIKELY OCCURRENCE OF A HAZARD(S) TO AN ACCEPTABLE LEVEL? *If no=move to the next question. *If yes=CCP	Q3. COULD CONTAMINATION WITH IDENTIFIED HAZARD(S) OCCUR IN EXCESS OF ACCEPTABLE LEVELS OR COULD THESE INCREASE TO UNACCEPTABLE LEVELS? *If no=not a CCP. *If yes=move to the next question.	Q4. WILL A SUBSEQUENT STEP ELIMINATE HAZARD(S) OR REDUCE THE LIKELY OCCURRENCE TO AN ACCEPTABLE LEVEL? *If no=CCP. *If yes=not a CCP.	#CCP
Scalding	B-Cross Contamination	Yes	Yes			CCP #3B
	C-None					
	B-None					
Venting Opening Evisceration	B-Cross Contamination. Exposure of opened carcass to enteric pathogens.	Yes	Yes			CCP#4B
	C-None					
	P-None					
Presentation	B-Cross Contamination	Addressed in SOP's				
	C-None					
	P-None					
Off Line Procedures	B-Cross Contamination	Yes	Yes			CCP#5B
	C-None					
	P-None					
Gizzard Harvest	B-Cross Contamination	No - Controlled at giblet rework/chilling				
	C-None					
	B-None					

DATE: June 10, 1996 APPROVED BY: Clem Lee

[Note: This page shows 5 intermediate process steps in a poultry slaughter establishment; this establishment has 16 process steps, from receiving through shipment.]

Once the step, process, or product has been modified, return to Question #1.

4. Question #2—Does this step eliminate or reduce the likely occurrence of the hazard(s) to an acceptable level?

If the answer is yes, write YES in Column 4 and identify the step as a CCP in Column 7.

If the answer is no, write NO in Column 4 and proceed to the next question.

5. Question #3—Could contamination with identified hazard(s) occur in excess of acceptable levels or could these increase to unacceptable levels?

If the answer is yes, write YES in Column 5 and proceed to the next question.

If the answer is no, write NO in Column 5, indicating that the step is not a CCP. Then proceed to the next process step and hazard.

6. Question #4—Will a subsequent step eliminate identified hazard(s) or reduce the likely occurrence to an acceptable level?

If the answer is yes, write YES in Column 6, indicating that the step is not a CCP. Then write down which processing step, which occurs later, will reduce the hazard to acceptable levels. Then proceed to the next process step and hazard.

If the answer is no, write NO in Column 6 and identify the step as a CCP in Column 7.

Principle 3—Establish Critical Limits for Each Critical Control Point

HACCP Principle No. 3 states:

''Establish critical limits for preventive measures associated with each identified CCP.''

The regulation defines critical limit as ''The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.''

- Critical limits are expressed as numbers, such as:
- Time/temperature
- Humidity
- Water activity
- pH
- Salt concentration
- Chlorine level

You will find that many critical limits for your identified CCPs have already been established. You can find these limits in sources such as regulatory requirements, scientific literature, experimental studies, and through consultation with experts. Some examples of regulatory critical limits for CCPs in meat and poultry production are shown in Table 7 of the *Meat and Poultry Products Hazards and Controls Guide.*

You may wish to establish critical limits that are stricter than regulatory requirements. However, your critical limits must never be less stringent than the requirements.

In some cases, you will need more than one critical limit to control a particular hazard. For example, the critical limits for cooked beef patties are time/temperature, pattie thickness, and conveyor speed.

Below you will find an example of a Critical Limits, Monitoring and Corrective Actions Form. You can use that form, or develop your own, to use in this and the following two sections. You will find an example of that form filled in for swine slaughter in one establishment below. You can find examples of critical limits for specific processes in the HACCP Generic Models.

Steps in Establishing Critical Limits

1. For each identified CCP, determine if there is a regulatory critical limit. If so, write that critical limit—or a more stringent one—into the critical limit column of your form.

For example, the regulatory critical limit for chilled poultry is 40 degrees F. So, for the chilling CCP in poultry slaughter, you would write, in the Critical Limit column of your form: ''Deep breast muscle temperature of ≤40 degrees F. as the carcasses exit the chiller.''

2. If there are no regulatory critical limits for a CCP, you need to establish critical limits for the CCP that are adequate to maintain control and prevent a food safety hazard. That is the responsibility of each establishment. You may wish to obtain the assistance of outside HACCP experts to help you determine critical limits for your CCPs. Once you have identified critical limits, enter them into the critical limit column of your form.

3. You should also file, for future reference, any documentation such as letters from outside HACCP experts or scientific reports supporting the critical limits you have identified. This documentation will help validate that the limits have been properly established. In addition, you should keep on file any test results that show your early experience in implementing the HACCP plan, to demonstrate you can implement what is written and make it work.

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CRITICAL LIMITS, MONITORING AND CORRECTIVE ACTIONS

PRODUCT:

PROCESS STEP/CCP	CRITICAL LIMITS	MONITORING PROCEDURES (WHO/WHAT/WHEN/HOW)	CORRECTIVE ACTIONS

DATE:_____ **APPROVED BY:**_____

CRITICAL LIMITS, MONITORING AND CORRECTIVE ACTIONS

PRODUCT: SWINE SLAUGHTER

PROCESS STEP/CCP	CRITICAL LIMITS	MONITORING PROCEDURES (WHO/WHAT/WHEN/HOW)	CORRECTIVE ACTIONS
SCALDING	USE APPROVED CHEMICAL PER 9CFR318.7 NOT TO EXCEED 2%. SCALD TEMPERATURE RANGE 138°-140°F. CARCASS DWELL TIME SUFFICIENT TO LOOSEN HAIR.	OBSERVE LEVELS OF SUBSTANCES AT TIME OF MIX/ VERIFY TYPE AND SPECIFIC AMOUNT OF CHEMICAL UPON ADDITION TO SCALDER AT DESIGNATED TIME/ PLANT-SPECIFIC PROCEDURE FOR SCALDER (TIME/TEMP) QC SUPERVISOR	AT TIME OF MIX: IDENTIFY/CONTROL PROBLEM WITH FORMULATION/ REFORMULATE, ADJUST AS NECESSARY; AT TIME OF ADDITION TO SCALDER: DRAIN, CLEAN, REFILL SCALDER, ADD PROPER MIX OF CHEMICALS/ CORRECT OR ADJUST PROCEDURE/RECONDITION AFFECTED PRODUCT/ DOCUMENT ACTIONS TAKEN, SIGN RECORD
DEHAIRING/ GAMBRELLING/ SINGEING/ POLISHING/ WASH/ SHAVING	TIME IN DEHAIRER AND EXPOSURE TO SINGEING DETERMINED BY PLANT-SPECIFIC TESTING RESULTS TO REMOVE VISIBLE HAIR TO AN ACCEPTABLE LEVEL WITHOUT BREAKING SKIN.	RANDOM TIME SAMPLING OF EXPOSURE TO DEHAIRER AND SINGEING FLAME UNITS/ MONITORING OF PLANT-SPECIFIC PROCEDURES FLOOR SUPERVISOR	IDENTIFY/CONTROL AFFECTED PRODUCT OR ADJUST PROCEDURE/ RECONDITION PRODUCT/ DOCUMENT ACTIONS TAKEN AND SIGN RECORD.

DATE: May 17, 1996 APPROVED BY: Pat Johnson

[Note: This page represents only two steps in this establishment's swine slaughter process.]

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Principle 4—Establish Monitoring Procedures

HACCP Principle No. 4 states:

''Establish CCP monitoring requirements. Establish procedures for using the results of monitoring to adjust the process and maintain control.''

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

Monitoring is essential to a HACCP system. Monitoring can warn you if there is a trend towards loss of control, so that you can take action to bring your process back into control before a critical limit is exceeded. For example, say that an establishment tests the pH of a batch of product at 6 a.m., 7 a.m., and 8 a.m. Each time, the pH is within acceptable limits, but it is steadily climbing towards the high end of the range. This information is showing a trend and the establishment should take action to prevent the pH from exceeding the critical limits.

The monitoring procedures you will establish at CCPs will generally relate to on-line processes. Monitoring may be continuous or non-continuous. Continuous monitoring at a CCP usually is done with measuring equipment, such as automatic time-temperature equipment used at a cooking step. Continuous monitoring is better because it results in a permanent record that you can review and evaluate to ensure that the CCP is under control. However, you should regularly check continuous monitoring equipment for accuracy.

You should use non-continuous monitoring procedures when continuous monitoring is not feasible. Non-continuous monitoring can include: visual examinations; monitoring of ingredient specifications; measurements of pH, water activity (Aw), and product temperatures; attribute sampling; and the like. When you use non-continuous monitoring, you need to ensure that the frequency of monitoring is enough to ensure that the hazard is under control and that the monitoring is performed at random times. For instance, each plant needs to set its own times and frequency for checking the cooking time/temperature of products. This may vary from one establishment to another because of differences in plant size, plant layout, the type of product, the length of time for processing, and the product flow.

Each establishment has the responsibility to establish a frequency that ensures that the CCP is under control. In some cases, you may have to perform tests at a CCP or use statistically based sampling.

Monitoring will go much more smoothly if you:

- Clearly identify the employee(s) responsible for monitoring.
- Train the employee(s) monitoring the CCPs in the testing procedures, the critical limits established, the methods of recording test results, and actions to be taken when critical limits are exceeded.
- Ensure that the employee(s) understand the purpose and importance of monitoring.

You can use the Critical Limits, Monitoring and Corrective Actions Form shown below, or you can develop your own form. Below is an example of a form filled in for swine slaughter in one establishment.

Steps in Establishing Monitoring Procedures

You can identify monitoring procedures for your HACCP plan by doing the following:

1. For each CCP, identify the best monitoring procedure.
2. Determine the frequency of monitoring for each CCP.
3. Determine if the monitoring activity needs to be done randomly to get a good representation of the product throughout the day's production. If it does, decide how the random monitoring will be done.
4. Determine what testing procedures need to be done for each monitoring function. For example, will you need to do a chlorine check or a temperature measurement?
5. Identify and train the employee(s) responsible for monitoring.
6. Make sure that the employee doing the monitoring signs all records and documents associated with CCP monitoring. Also make sure that the monitoring results are documented or recorded at the time the monitoring takes place.
7. Enter the above information in the monitoring column of your form.

Principle 5—Establish Corrective Actions

HACCP Principle No. 5 states:

''Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.''

The regulation defines corrective action as ''Procedures to be followed when a deviation occurs.''

A deviation is a failure to meet a critical limit.

Since HACCP is a preventive system to correct problems before they affect the safety of the food, you have to plan in advance to correct potential deviations from established critical limits. Once your HACCP plan is in place, any time a critical limit is not met, you will need to take corrective actions. Those corrective actions should include:

1. Determining the disposition of non-complying product;
2. Correcting the cause of the non-compliance to prevent a recurrence;
3. Demonstrating that the CCP is once again under control (this means examining the process or product again at that CCP and getting results that are within the critical limits);
4. Maintaining records of the corrective actions.

Under HACCP, you determine in advance what you will do when a critical limit is not met at a CCP. The employee(s) monitoring CCPs should understand this process and be trained to perform the appropriate corrective actions. It is important that an establishment record all corrective actions and that the employee responsible for taking the corrective actions sign all the documentation.

In some cases, the product in question will be held for further investigation of the deviation. This investigation may require a thorough record review, product testing, or consultation with a processing authority.

Some examples of corrective actions are:

- Immediately adjust the process and hold product for further evaluation and disposition.
- Empower employees to stop the line when a deviation occurs, hold all product not in compliance, and call in the plant's quality control manager.
- Rely on an approved alternate process that can be substituted for the one that is out of control at the specific critical control point. For example, if the in-line eviscerators in a poultry slaughter plant are malfunctioning, evisceration can be done by hand as long as Good Manufacturing Practices (GMPs) are followed.

Regardless of the corrective actions you take, you need to keep records that include:

- The deviation that was identified.
- The reason for holding the product; the time and date of the hold; the amount of product involved; the disposition and/or release of product; and the individual who made the disposition decision.
- Actions to prevent the deviation from recurring.

You can use the Critical Limits, Monitoring and Corrective Actions form below or you can develop your own

form. A sample form, filled in for swine slaughter, appears below.

Steps in Establishing Corrective Actions

1. For each CCP, determine the corrective action to take if the critical limits are exceeded. Determine what should be done with the product if a deviation occurs at this step. You may need more than one corrective action for a CCP.

2. Develop the record form to capture all the necessary information on the deviation, and identify the employee responsible for maintaining and signing the record.

3. Ensure that employees conducting the monitoring at each CCP are fully trained and know the corrective actions to take if a deviation occurs.

4. Enter the appropriate corrective action(s) for each CCP in the corrective action column of the Critical Limits, Monitoring and Corrective Actions form and identify the record that will be maintained.

Principle 6—Establish Recordkeeping Procedures

HACCP Principle No. 6 states:

''*Establish effective recordkeeping procedures that document the HACCP system.*''

Maintaining proper HACCP records is an essential part of the HACCP system. Good HACCP records—meaning that they are accurate and complete—can be very helpful to you for the following reasons:

- Records serve as written documentation of your establishment's compliance with its HACCP plan.
- Records allow you to trace the history of an ingredient, in-process operations, or a finished product, should problems arise.
- Records help you identify trends in a particular operation that could result in a deviation if not corrected.
- If you were ever faced with a product recall, HACCP records could help you identify and narrow the scope of such a recall.
- Well-maintained records are good evidence in potential legal actions against an establishment.

In accordance with the HACCP principles, your HACCP system should include records for CCPs, establishment of critical limits, handling of deviations, and your HACCP plan. Examples of these and other HACCP forms that may be useful in assembling the HACCP plan are located in the appropriate sections of this guidebook. For your review, these forms are:

Product(s) Description Form
Product and Ingredients Form
Process Flow Diagram Form
Hazard Identification/Preventive Measures Form
CCP Determination Form
Critical Limits, Monitoring and Corrective Actions Form
Recordkeeping and Verification Form (Verification will be explained in the next section of this guidebook)
HACCP Plan Form

In many cases, the records you currently maintain may be sufficient to document your HACCP system. Records must contain at least the following information: title and date of record; product identification; critical criteria or limits; a line for the monitor's signature; a place for the reviewer's signature; and, an orderly manner for entering the required data.

An example of a blank Recordkeeping and Verification Form is found below. Also below is an example of the form filled in for cooked sausage in one establishment.

Steps in Establishing Recordkeeping Procedures

1. Review the records you currently maintain and determine which ones adequately address the monitoring of the CCPs you have identified, or develop forms for this information.

2. Develop any forms necessary to fully record corrective actions taken when deviations occur.

3. Develop forms to document your HACCP system. (This will be explained in the next section, on verification).

4. Identify the monitoring employees responsible for entering data into the records and ensure that they understand their roles and responsibilities.

5. Enter the record form name(s) on the Recordkeeping and Verification Form under the records column adjacent to the appropriate CCP. (Verification will be explained in the next section).

6. Enter the appropriate record form name(s) on the Recordkeeping and Verification Form under the verification procedures column adjacent to the appropriate CCP. (Verification will be explained in the next section).

Principle 7—Establish Verification Procedures

HACCP Principle No. 7 states:

''*Establish procedures to verify that the HACCP system is working correctly.*''

After a HACCP plan has been put into place, verification activities occur on an ongoing basis. Verification entails the use of methods, procedures, or tests in addition to those used in monitoring, to determine whether the HACCP system is operating as intended.

Simply stated, you need to verify that your HACCP system is working the way you expected it to work. There are several areas that warrant checking. You will probably first want to review your HACCP plan to determine whether the CCPs and critical limits that you established are really the right ones and that you are controlling and monitoring them adequately. You should also make sure that employees are following your procedures for taking corrective actions when a critical limit is exceeded. Finally, you should check to see that your employees are keeping good HACCP records.

By doing these things, you will evaluate the day-to-day operation of your HACCP system. Don't be surprised if you find that you need to fine-tune your HACCP plan.

Some things you can do to verify your HACCP system are:

- Analytically test or audit your monitoring procedures;
- Calibrate your temperature equipment;
- Sample your product, including microbiological sampling;
- Review your monitoring records;
- Review your records of deviations and product dispositions;
- Inspect and audit your establishment's operations;
- Sample for environmental and other concerns.

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RECORDKEEPING AND VERIFICATION

PRODUCT:

PROCESS STEP/CCP	RECORDS	VERIFICATION PROCEDURES

DATE:_____ **APPROVED BY:**_____

RECORDKEEPING AND VERIFICATION

PRODUCT: Cooked sausage

PROCESS STEP/CCP	RECORDS	VERIFICATION PROCEDURES
Receiving Non-meat ingredients	Receiving Record	Review Daily Receiving Record against approved supplies Quarterly collect audit sample for lab analysis
Cook/Smoke CCP	Handwritten smokehouse log and smokehouse temperature recording chart	Review daily smokehouse logs & charts. Calibrate temperature measuring devices weekly & temperature recording charts quarterly Quarterly, collect samples for micro. analysis.
Packaging CCP	Metal Detection Log	Review log daily & corrective action records. Calibrate equipment daily against known standard. Conduct spot checks of equipment weekly.

DATE: April 23, 1996 **APPROVED BY:** J. D. MacIntosh

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You can use the Recordkeeping and Verification Form to record your verification procedures. A sample blank form appears below. An example filled in for cooked sausage in one establishment appears below.

Steps in Establishing Verification Procedures

1. Determine the appropriate verification procedure to ensure that each CCP and critical limit is adequately controlled and monitored.
2. For each CCP, determine procedures to ensure that employees are following your established procedures for handling product deviations and for recordkeeping.
3. Identify the frequencies for conducting any verification checks and the records where the results will be recorded.
4. Enter the appropriate details on the Recordkeeping and Verification Form for future reference.

Validate Your HACCP Plan

It is very important to validate your HACCP plan. The regulation defines validation as ''the scientific and technical process for determining that the CCPs and associated critical limits are adequate and sufficient to control likely hazards.''

Simply put, when you validate your HACCP plan, you demonstrate that what you have written and put into place can actually prevent, eliminate, or reduce the levels of hazards that you have identified.

To validate your HACCP plan, you need to assemble information to show that your HACCP plan will work to control the process and to prevent food safety hazards. There are two types of information that you will probably collect. First, you will likely gather supporting scientific information, such as studies that establish the time and temperatures necessary to kill certain harmful bacteria. Second, you may wish to gather practical information, such as test results from products produced under your HACCP plan. An example of a test might be microbiological analysis of your finished, ready-to-eat products. There are many sources of information to validate your HACCP plan, including: the scientific literature, product testing results, experimental research results, scientifically-based regulatory requirements, official FSIS guidelines, or information developed by process authorities.

You have a great deal of flexibility in assembling the information to validate your plan, in terms of both source and quantity of information. For example, a slaughter plant should validate that its plan ensures residue control, to prevent violative levels of chemicals, animal drugs or pesticides in carcasses. A slaughter plant might choose to purchase animals only from suppliers who provide veterinary certifications that the animals have been raised under a program that assures that all animal drugs, pesticides, and other chemicals are properly used. In this situation, the establishment could validate this critical control point with the following information: a copy of the residue prevention program under which the producer is certified; a report of an on-site visit to the feedlot; and results of analyses of carcasses for compounds of concern.

Validation is simpler for HACCP plans for products such as cooked beef, roast beef, or cooked corned beef. Current regulatory requirements for these products include scientifically-based processing times, temperatures, and handling requirements. Your HACCP plan would need only to reflect these regulatory requirements; additional information would be unnecessary. In this case, you could do a minimal number of product analyses to demonstrate that hazards of concern, such as *Salmonella*, were not found in the products produced under the HACCP plan.

It is important that you reassess your HACCP plan at least once a year and whenever any of the following occurs:

1. Potential new hazards are identified that may be introduced into the process for the product.
2. You add new ingredients.
3. You change the process steps or procedures.
4. You introduce new or different processing equipment.

Finishing Your HACCP Plan

Now you are ready to assemble all your information into one HACCP Plan. A sample HACCP Plan blank form is provided below. An example of a form filled in for one establishment's canned beef stew process is shown below. It is important for your records that you assemble all your information into a final HACCP plan. To make sure that your HACCP Plan is complete, you may want to check it against the checklist provided in the next section of this guidebook.

Now you are ready to put your HACCP Plan into action and make HACCP a reality in your establishment.

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HACCP PLAN

PRODUCT:

PROCESS STEP	BIOLOGICAL - B CHEMICAL - C PHYSICAL - P HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURES/PERSON RESPONSIBLE

DATE:_____ **APPROVED BY:**_____

BILLING CODE 3410-DM-C

HACCP PLAN

PRODUCT: Canned Beef Stew

PROCESS STEP	BIOLOGICAL - B CHEMICAL - C PHYSICAL - P HAZARD DESCRIPTION	CCP	CRITICAL LIMITS	MONITORING PROCEDURES/FREQUENCY/ PERSON RESPONSIBLE	CORRECTIVE/PREVENTIVE ACTION/PERSON RESPONSIBLE	HACCP RECORDS	VERIFICATION PROCEDURES/PERSON RESPONSIBLE
Formulation	B - Microbial Growth (C. botulinum)	6B	Product formulated using quantities of ingredients specified in the formula	Monitor formulation of product as each Component is added. Record all findings in HACCP record log and sign record/ Formulation supervisor	Identify and control affected product; correct procedure; evaluate operation for cause of deficiency take corrective action; document action in HACCP records logs and sign. Formulation supervisor	Record all results and corrective actions in specific record and sign	Audit to verify accuracy of records; Check if Critical Limit is correct and adequate for hazard; assure corrective actions are adequate; document findings. QC Manager
Filling	B- Microbial Growth	7B	Container filled to required fill weight as specified in recommended process schedule	Monitor operational Filling procedures. Recorded all findings in HACCP records log and sign./ Filling Machine operator	Identify and control affected product; empty all rejected containers and rework contents; correct or adjust procedure; evaluate operator for cause of deficrency; take corrective	Record all results and corrective actions in HACCP records	Audit to verify calibration of metering devices and accuracy of records; review records to assure accuracy; check to see if Critical Limit is adequate for hazard and comparable to
					action; document actions in HACCP records log and sign/ Filling Machine Operator	log and sign.	plant records; assure corrective actions are adequate; document findings/ QC manager

DATE: August 5, 1996 **APPROVED BY:** R. S. Winston-Jones

[Note: This page represents only two steps in this establishment's process for canned beef stew]

HACCP Plan Checklist

You can use the HACCP Plan Checklist provided in this section to ensure that your HACCP plan adequately addresses all seven HACCP principles.

When completing the checklist, if you answer ''NO'' to any question, you reevaluate that section of the HACCP plan and make whatever modifications are necessary. Some modifications may require the assistance of recognized HACCP experts.

Any time you make major changes to the HACCP plan based upon product or process modifications, it would be advisable to review the checklist to ensure that the revisions are acceptable.

You can keep the HACCP Plan Checklist as part of your HACCP plan for future reference and to provide documented evidence that your HACCP plan addresses all seven HACCP principles.

ESTABLISHMENT NO. _____
PRODUCT/PROCESS _____
DATE _____

HACCP PLAN CHECKLIST

A. DESCRIBE THE PRODUCT	YES	NO
1. Does the HACCP plan include:		
a. The producer/establishment and the product name?		
b. The ingredients and raw materials used along with the product receipt or formulation?		
c. The packaging used?		
d. The temperature at which the product is intended to be held, distributed and sold?		
e. The manner in which the product will be prepared for consumption?		
2. Has a flow diagram for the production of the product been developed that is clear, simple, and descriptive of the steps in the process?		
3. Has the flow diagram been verified for accuracy and completeness against the actual operating process?		
B. CONDUCT A HAZARD ANALYSIS	YES	NO
1. Have all steps in the process been identified and listed where hazards of potential significance occur?		
2. Have all hazards associated with each identified step been listed?		
3. Have safety concerns been differentiated from quality concerns?		
4. Have preventive measures to control the identified hazard been identified, if they exist, and listed?		
C. IDENTIFY CRITICAL CONTROL POINTS	YES	NO
1. Has the CCP Decision Tree been used to help determine if a particular step is a CCP for a previously identified hazard?		
2. Have the CCPs been entered on the forms?		
3. Have all significant hazards identified during the hazard analysis been addressed?		
D. ESTABLISH CRITICAL LIMITS	YES	NO
1. Have critical limits been established for each preventive measure at each CCP?		
2. Has the validity of the critical limits to control the identified hazard been established?		
3. Were critical limits obtained from the regulations, processing authority, etc?		
4. Is documentation attesting to the adequacy of the critical limits maintained on file at the establishment?		
E. ESTABLISH MONITORING PROCEDURES	YES	NO
1. Have monitoring procedures been developed to assure that preventive measures necessary for control at each CCP are maintained within the established critical limits?		
2. Are the monitoring procedures continuous or, where continuous monitoring is not possible, is the frequency of monitoring sufficiently reliable to indicate that the hazard is under control?		
3. Have procedures been developed for systematically recording the monitoring data?		
4. Have employees responsible for monitoring been identified and trained?		
5. Have employees responsible for reviewing monitoring records been identified and trained?		
6. Have signatures of responsible individuals been required on the monitoring records?		
7. Have procedures been developed for using the results of monitoring to adjust the process and maintain control?		
F. ESTABLISH CORRECTIVE ACTIONS	YES	NO
1. Have specific corrective actions been developed for each CCP?		
2. Do the corrective actions address:		
a. Reestablishment of process control?		
b. Disposition of affected product?		
c. Procedures to correct the cause of non-compliance and to prevent the deviation from recurring?		
3. Have procedures been established to record the corrective actions?		
4. Have procedures been established for reviewing the corrective action records?		
G. ESTABLISH RECORDKEEPING PROCEDURES	YES	NO
1. Have procedures been established to maintain the HACCP plan on file at the establishment?		
2. Do the HACCP records include:		
Description of the product and its intended use?		
Flow diagram for the process, indicating CCPs?		
Preventive measures?		
Critical limits?		
Monitoring system:		
Corrective action plans for deviations from critical limits?		
Recordkeeping procedures for monitoring?		
Procedures for verification of the HACCP system?		
H. ESTABLISH VERIFICATION PROCEDURES	YES	NO
1. Have procedures been included to verify that all significant hazards were identified in the HACCP plan when it was developed?		
2. Have procedures been included to verify that the critical limits are adequate to control the identified hazards?		
3. Are procedures in place to verify that the HACCP system is functioning properly?		

HACCP PLAN CHECKLIST—Continued

4. Are procedures in place to reassess the HACCP plan and system on a regular basis or whenever significant product, process or packaging changes occur?		

References

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Internet Home Pages

Agriculture Canada
http://aceis.agr.ca

Center for Disease Control
http://fftp.cdc.gov/pub/mmwr/MMWRweekly

Food Law Sites
http://www.fsci.umn.edu/FoodLaw/foodlaw.html

HACCP95
http://www.cvm.uiuc.edu/announcements/haccp95/haccp95.html

International Meat and Poultry HACCP Alliance
http://ifse.tamv.edu./haccpall.html

Material Safety Data Sheets
http://listeria.nwfsc.noaa.gov/msds.html

U.S. Department of Agriculture
http://www.usda.gov

U.S. Food and Drug Administration/Bad Bug Book
http://vm.cfsan.fda.gov/list.html

Appendix D—Hazards and Preventive Measures Guide

Preface

This Guide is designed to help a plant's HACCP team conduct a hazard analysis (HACCP Principle 1) by providing both general and detailed information on hazards associated with meat and poultry products and by listing some of the controls that can be used to prevent or manage those hazards. When using this Guide it is very important to remember that it is not all-inclusive: There may be other hazards associated with ingredients or processes; there may be other control measures. The examples assembled here are to help plant HACCP teams think through all the hazards that could affect their product and know about various controls that can be used.

Section I describes some of the biological (including microbiological), chemical, and physical hazards generally recognized and associated with meat and poultry products. This section can serve as a resource when the HACCP team begins the hazard analysis. It is probably useful to read through this general information early in the process of developing the HACCP plan. This will help the team form an idea of what is meant by a given hazard.

Section II provides information on generally recognized preventive measures used in the meat and poultry industry to control biological, chemical, and physical hazards. This section also has examples of regulatory critical limits associated with some preventive measures.

Sections III, IV, and V list processing steps, hazards, and controls for beef, poultry, and swine slaughter. This section should be used with the process flow diagram developed by the HACCP team.

Section VI presents hazards and controls organized according to ingredients, including both meat and poultry ingredients and other ingredients used in meat and poultry production. This section should be used with the list of ingredients developed by the HACCP team.

Section VII contains a set of tables identifying potential hazards at various processing steps used to produce meat and poultry products. This section should be used with the process flow diagram developed by the plant's HACCP team.

Section VIII contains a list of valuable references that will help the plant's HACCP team further develop the HACCP plan.

Section I

Overview of Biological, Chemical, and Physical Hazards

In a HACCP system, a hazard is defined as a biological, chemical, or physical property that may cause a food

to be unsafe for human consumption. This guide is a reference for plant HACCP teams to use in their hazard identification and analysis. It is not intended to be totally inclusive; the team may have other information or may rely on additional references.

Biological Hazards

Biological hazards, which are mainly bacterial, can cause either foodborne infections or intoxications. A foodborne infection is caused by a person ingesting a number of pathogenic microorganisms sufficient to cause infection as a result of their multiplication, e.g., salmonellosis. A foodborne intoxication is caused by the ingestion of already formed toxins produced by some bacteria when they multiply in food, e.g., staphylococcal enterotoxin.

When assessing bacterial hazards to human health in meat and poultry products, nine pathogenic bacteria must be considered. The following identifies and discusses the nine pathogenic microorganisms of concern.

Bacillus cereus

B. cereus foodborne intoxication includes two recognized types of illness—diarrheal and emetic (vomiting).

Foods associated with illness include: Boiled and fried rice, custards, cecal products meats, vegetables, and fish; food mixtures such as sauces, puddings, soups, casseroles, pastries, and salads.

Campylobacter jejuni

Campylobacteriosis is the illness caused by *C. jejuni*. It is also often known as campylobacter enteritis or gastroenteritis.

Food associated with illness include: raw and undercooked chicken, raw milk, non-chlorinated water.

Clostridium botulinum

Foodborne botulism (as distinct from wound botulism and infant botulism) is a severe foodborne disease caused by the ingestion of foods containing the potent neurotoxin formed during growth of the organism. Botulism has a high mortality rate if not treated immediately and properly.

Foods associated with disease include: sausages, meat products, and seafood products, improperly canned foods, vegetable products.

Clostridium perfringens

Perfringens foodborne illness is the term used to describe the common foodborne disease caused by the release of enterotoxin during sporulation of *C. perfringens* in the gut.

Foods associated with illness include: meat and poultry products and gravy.

Escherichia coli O157:H7

Hemorrhagic colitis is the name of the acute disease caused by *E. coli* O157:H7.

Foods associated with illness: undercooked or raw hamburger (ground beef) has been implicated in many documented outbreaks and in other sporadic cases; other meat products, raw milk, untreated water.

Listeria monocytogenes

Listeriosis is the name of the general group of disorders caused by *L. monocytogenes*.

Foods associated with illness: cole slaw, cooked poultry, cooked meat, and raw milk, supposedly pasteurized fluid milk, cheeses (particularly soft-ripened varieties). Its ability to grow at temperatures as low as 3 °C permits multiplication in refrigerated foods.

Salmonella spp

S. typhi and the paratyphoid bacteria are normally septicemic and produce typhoid or typhoid-like fever in humans and are pathogenic only for humans. Other forms of salmonellosis generally produce milder symptoms. The organism is found in the intestinal tracts of warm blooded animals.

Foods associated with illness: raw and cooked meats, poultry, eggs (and exterior of egg shells), untreated water, raw milk and dairy products, fish, shrimp, frog legs, yeast, sauces and salad dressing, etc.

Staphylococcus aureus

Staphylococcal food poisoning (staphylococcal enterotoxicosis; staphylococcal enterotoxemia) is the name of the condition caused by the enterotoxins that some strains of *S. aureus* produce.

Foods associated with illness: meat and meat products; poultry and egg products; egg, tuna, ham, chicken, potato, and macaroni salads; sandwich fillings; milk and dairy products; etc.

Yersinia enterocolitica

Yersiniosis is the name of the disease caused by pathogenic species in the genus *Yersinia*. The disease is a gastroenteritis with diarrhea and/or vomiting, and fever and abdominal pain.

Foods associated with illness: meats, oysters, fish, milk, and chitterlings.

TABLE 1.—CHARACTERISTICS OF GROWTH FOR NINE PATHOGENS ASSOCIATED WITH MEAT AND POULTRY PRODUCTS

Pathogens	Temperature of growth	pH	Minimum A_w
Bacillus cereus	10–48 °C	4.9–9.3	0.95
Campylobacter jejuni	30–47 °C	6.5–7.5	.....
Clostridium botulinum	3.3–46 °C	>4.6	0.94
(Types A,B,E)	.....	.....	.....
Clostridium perfringens	15–50 °C	5.5–8.0	0.95
Escherichia coli O157:H7	10–42 °C	4.5–9.0	.....
Listeria monocytogenes	2.5–44 °C	5.2–9.6	.....
Salmonella	5–46 °C	.....	4–9 0.94
Staphylococcus aureus	6.5–46 °C	5.2–9	0.86
Yersinis enterocolitica	2–45 °C	4.6–9.6	.....

Zoonotic agents are biological hazards that cause disease in animals and can be transmitted and cause disease in humans. The following lists some zoonotic hazards:

Trichinella spiralis is a nematode parasite whose larval from encysts primarily in the striated muscle of pigs, horses, rats, bears and other mammals. Infection in humans results in ''flu-like symptoms'' (diarrhea, fever, stiffness, muscle pain, respiratory distress, etc.) And heavy infection may lead to death.

Foods associated with illness include: raw and undercooked pork, bear and equine meat.

Taenia saginata is a human tapeworm whose larval form (*Cysticercus bovis*) encysts in the tissues of cattle.

Foods associated with illness include: raw or undercooked beef.

Taenia solium is a human tapeworm whose larval form (*Cysticercus cellulosae*) encysts in the tissues of pigs,

dogs, and humans. Cysts in humans are most common in the subcutaneous tissues, eye and the brain.

Foods associated with illness include: raw or undercooked pork.

Toxoplasma gondii is a protozoan parasite that encysts in the tissues of a variety of mammalian hosts including pigs. Human infection may result in ''flu like'' symptoms in adults, late term abortions in pregnant women or serious congenial infections in children.

Foods associated with illness include: raw or undercooked pork.

Balantidium coli is a protozoal organism.

Foods associated with illness include: raw, undercooked pork (fecal contamination)

Cryptosporidium spp.

Foods associated with illness include: inadequately treated water, raw or undercooked veal or beef.

Chemical Hazards

While biological hazards are of great concern because contaminated foods can cause widespread illness outbreaks, chemical hazards may also cause foodborne illnesses, although generally affecting fewer people.

Chemical hazards can originate from four general sources:

(1) Agriculture chemicals: pesticides, herbicides, animal drugs, fertilizers, etc.

(2) Plant chemicals: cleaners, sanitizers, oils, lubricants, paints, pesticides, etc.

(3) Naturally-occurring toxicants: products of plant, animal, or microbial metabolisms such as aflatoxins, etc.

(4) Food chemicals: preservatives, acids, food additives, sulfiting agents, processing aids, etc.

(5) Environmental contaminants: lead, cadmium, mercury, arsenic, PCBs.

For many years the Food Safety and Inspection Service has conducted a National Residue Program to monitor the occurrence of residues from hazardous chemicals in meat and poultry products. Under a HACCP regime, frontline responsibility for control of residues from animal drugs or environmental contaminants will move from the government to the industry, although the agency will continue to verify that these controls and preventive measures are effective. Companies that slaughter livestock and poultry will probably find the FSIS National Residue Program Plan to be a useful document. The plan contains lists of compounds that might leave residues in the tissues of animals or birds, and provides some information on their relative risk through the rankings in the Compound Evaluation System. It provides information on which compounds FSIS has included in its annual testing program. It also provides information on the methods that are used to test for the compounds. Another FSIS document, the Domestic Residue Data Book, presents the results of FSIS testing. These data can help a HACCP team understand the overall hazard presented by various residues, although each company should gather information about the residue control performance of its own suppliers.

Another useful reference about hazardous chemicals is the FSIS List of Proprietary Substances and Nonfood Compounds. This publication lists substances used in the preparation of product and nonfood compounds used in the plant environment that have been authorized by FSIS.

Table 2 identifies some additional sources of chemical hazards. References listed in Section VIII can be used by the HACCP team in evaluating the potential chemical hazards associated with their product or process.

TABLE 2.—TYPES OF CHEMICAL HAZARDS

Location	Hazard
Raw Materials	Pesticides, antibiotics, hormones, toxins, fertilizers, fungicides, heavy metals, PCBs. Color additives, inks, indirect additives, packaging materials.
Processing	Direct food additives—preservatives (nitrite), flavor enhancers, color additives. Indirect food additives—boiler water additives, peeling aids, defoaming agents.
Building and Equipment Maintenance	Lubricants, paints, coatings.
Sanitation	Pesticides, cleaners, sanitizers.
Storage and Shipping	All types of chemicals, cross contamination.

Physical Hazards

Physical hazards include a variety of materials referred to as extraneous materials or foreign particles or objects. A physical hazard can be defined as any physical material not normally found in a food that can cause illness or injury to a person consuming the product.

Physical hazards in finished products can arise from several sources, such as contaminated raw materials, poorly designed or maintained facilities and equipment, faulty procedures during processing, and improper employee training and practices. Table 3 identifies some common physical hazards and their causes or sources.

TABLE 3.—TYPES OF PHYSICAL HAZARDS

Hazard	Source or cause
Glass	Bottles, jars, light fixtures, utensils, gauge covers, thermometers.
Metal	Nuts, bolts, screws, steel wool, wire, meat hooks.
Stones	Raw materials.
Plastics	Packaging materials, raw materials.
Bone	Raw material, improper plant processing.
Bullet/BB Shot/Needles	Animals shot in field, hypodermic needles used for infections.
Jewelry	Pens/pencils, buttons, careless employee practices.