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Food and Safety Assurance Program; Development of Hazard Analysis Critical Control Points; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 93N-0325]

Development of Hazard Analysis Critical Control Points for the Food Industry; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is asking for public comment about whether and how the agency should develop regulations that would establish requirements for a new comprehensive food safety assurance program for both domestically produced and imported foods. Such regulations, if promulgated, would enhance FDA's ability to ensure the safety of the U.S. food supply. In this document, FDA is proposing that this program be based upon the principles of Hazard Analysis Critical Control Points (HACCP). FDA is requesting comments on a number of specific issues, as well as on all aspects of such a food safety program.

DATES: Written comments by December 2, 1994.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: John E. Kvenberg, Center for Food Safety and Applied Nutrition (HFS-10), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4010.

SUPPLEMENTARY INFORMATION:

I. Background

A. Status of the Food Safety Assurance Program in the United States

FDA's mandate to ensure the safety of the nation's food supply is derived principally from the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq*). Under the act, FDA has authority to ensure that all foods in interstate commerce, or that have been shipped in interstate commerce, are not contaminated or otherwise adulterated, are produced under sanitary conditions, and are not misbranded or deceptively packaged [1]. The agency also has authority to ensure food safety under the Public Health Service Act (the PHS act) (42 U.S.C. 264), which relates to the control of the spread of communicable diseases from one State, territory, or possession to another, or from outside the United States into this country.

To carry out its mandate to ensure the safety of the U.S. food supply, FDA conducts periodic inspections of food processors, shippers, food packers and repackers, food labelers and relabelers, and food warehouses. Some inspections are carried out by the States, under contract with FDA. In addition, although subject to FDA jurisdiction, the many hundreds of thousands of retail food outlets and restaurants in the United States are inspected by State and local health departments with technical assistance and training from FDA. FDA's program to ensure the safety of the U.S. food supply also includes sample analyses of food offered for import, research into rapid detection methodologies for potential hazards, enforcement activities, and education and information sharing programs. The goal of all of these regulatory and enforcement activities is to ensure that the food supply is, and remains, safe.

Although the current food safety assurance program has generally functioned effectively, it currently faces new stresses and challenges. New food processing and packaging technologies, new food distribution and consumption patterns, increasing public health concerns about low levels of certain chemical contaminants, and new microbial pathogens all contribute to today's food safety challenge. For example, the composition of the food supply has changed dramatically in the 55 years since passage of the act. More people consume commercially processed or commercially prepared foods than ever before, and there is increased consumer demand for "fresh" foods in convenient, ready-to-cook forms, which has fostered the development of sophisticated processing and packaging systems that can significantly extend the shelf life of a variety of foods. However, new food safety risks can be associated with these new food products, new packages, and new patterns of distribution and consumption.

One of the most important challenges to FDA's current food safety assurance program is the increasing number of new food pathogens. Although food borne illness has always been a public health problem, such illness appears to be on the rise, and new pathogens are appearing (Ref. 1). In addition, because foods are more extensively processed and handled, there is now a greater opportunity for food to be contaminated.

Food borne illness is a major cause of morbidity in the United States; estimates of the yearly incidence of food borne illness vary greatly, ranging from 6.5 million (Ref. 1) to 12.6 million cases per year (Ref. 2), and from 24 to 81 million cases per year (Ref. 3). In the 15 years between 1973 and 1988, the number of recognized food borne pathogens broadened considerably. During that period, bacteria not previously recognized as important food borne pathogens emerged, including *Campylobacter jejuni, Escherichia coli, Listeria monocytogenes, Yersinia enterocolitica*, and a variety of *Vibrio* spp. During that same period, experts recognized that certain food borne illnesses may be followed by serious complications, such as arthritis, kidney damage, heart disease, and neurological damage (Ref. 3).

Pathogens are not the only potential contaminants of food, however. The extensive use of industrial chemicals, coupled with past failures to deal adequately with chemical waste, have resulted in significant chemical pollution of the environment in some regions. Many of these chemicals have found their way into the food chain. The legal use of pesticides in agriculture may also result in residues in food. Naturally occurring chemicals, such as toxic elements and mycotoxins, can also be found in food at levels of concern. The sheer number of these potential contaminants, the concerns about their toxicity even at very low levels, and the difficulty and expense associated with many of the analytical methods used to quantify their levels in food, make exhaustive endpoint monitoring of the food supply virtually impossible.

The size and diversity of the food industry adds to the stress on the current food safety assurance program. FDA's current inventory lists over 30,000 food manufacturers and processors, and in excess of 20,000 food warehouses. The number of foreign manufacturers and processors shipping food products to the United States continues to increase. In 1992, there were well over 1 million food import entries into the United States. In addition, the diversity of food imports

[1] Two other Federal agencies share with FDA the responsibility for regulating the safety of the food supply. The U.S. Department of Agriculture (USDA) has authority under the Meat Inspection Act (21 U.S.C. 601), the Poultry Inspection Act (21 U.S.C. 451), and the Egg Products Inspection Act (21 U.S.C. 1031) to inspect facilities in which meat, poultry, and eggs, respectively, are processed, and to regulate such products. The U.S. Environmental Protection Agency has authority, under provisions of the act, to establish legal limits (tolerances) for residues of pesticides on foods. FDA and USDA enforce such tolerances.

continues to increase, with a rising volume of foods entering the United States in processed forms.

Finally, the current food safety program is under stress internally. It is unlikely that FDA will ever have sufficient resources to inspect, sample, and analyze more than a small percentage of imported food shipments. State and local governments, on which FDA relies heavily for surveillance of the growing retail food sector, are also under severe resource constraints. Indeed, some States are considering proposals to reduce their food safety programs.

FDA's current regulatory strategy for ensuring food safety, with its emphasis on periodic visual inspection of food facilities and end-product testing, was designed to control the problems that were known to exist when the act was established in 1938. The agency has struggled to keep up with the enormous growth and changes in the food industry and the resulting new food safety challenges. FDA's current regulatory approach is relatively resource intensive and inefficient compared to other ways of ensuring food safety. Inspections that FDA conducts under the current system can determine the adequacy of conditions in a food plant at the time of the inspection but not whether the company has in place a food safety assurance program that is operating reliably and consistently to produce safe food at all times. Furthermore, the current inspectional approach is generally reactive, not preventive. It is effective in detecting and correcting problems after they occur, but, except in certain limited areas such as the regulation of infant formula and low acid canned foods, it is not currently based on a system of preventive controls.

For all of these reasons, FDA believes that it is appropriate at this time for the agency to consider improvements to its food safety assurance program to focus the program on prevention of food safety risks and problems. FDA's goals in establishing additional food safety regulations would be to: (1) Make the food supply safer through prevention of food safety problems; (2) enable FDA and its State and local counterparts to make more efficient use of the existing resources devoted to ensuring food safety, and (3) enhance the ability of the Federal Government to provide consumers with the assurance they seek that the U.S. food supply is safe.

FDA recognizes that risks vary across the food supply and that measures to make food safer should focus on the potential of particular foods or possible contaminants in those foods to cause illness. The agency also recognizes that there is no proven method or approach for ensuring the safety of food that will eliminate risk in all circumstances. Indeed, one purpose of this notice is to seek public comment on the degree of potential risks posed by those microorganisms, chemicals, and physical hazards (e.g., broken glass) that can get into food and be passed on to the consumer, if appropriate care is not exercised. FDA also desires comments on the consequences of these risks if they occur. In addition, the agency seeks comment on how these risks can best be controlled and which systems of quality control can best protect consumers from potentially unsafe food.

Although the agency has reached no final conclusions about how its regulatory programs should be revised to make food as safe as possible, FDA has tentatively concluded that the improvements in the agency's current food safety assurance program should be based on a state-of-the-art, preventive approach known as HACCP. HACCP was developed approximately 30 years ago by the U.S. food industry, and it is currently used in a number of domestic food processing facilities. HACCP is internationally regarded as the most effective system for producing safe food. FDA is considering HACCP as the foundation for revision of the U.S. food safety assurance program because, although simple in its basic concepts, HACCP is a sophisticated and powerful tool for ensuring food safety. HACCP is a science based, systematic approach to preventing food safety problems by anticipating how such problems are most likely to occur and by installing effective measures to prevent them from occurring. HACCP thus requires that the processor and the regulatory authority be aware of the state-of-the-art science relative to food safety and processing technology. HACCP appropriately affirms that the food industry has primary responsibility for producing safe food, and it provides an important opportunity to link the food industry's system for producing safe food with the Government's system of regulatory oversight. A more in-depth discussion of the HACCP concept follows.

B. The HACCP System

The HACCP concept (Ref. 4) is a systematic approach to the identification, assessment of risk (likelihood of occurrence and severity), and control of the biological, chemical, and physical hazards associated with a particular food production process or practice. HACCP is a preventive strategy. It is based on development by the food producer of a plan that anticipates food safety hazards and identifies the points in the production process where a failure would likely result in a hazard being created or allowed to persist; these points are referred to as critical control points (CCP's). Under HACCP, identified CCP's are systematically monitored, and records kept of that monitoring. Corrective actions are taken when control of a CCP is lost, including proper disposition of the food produced during that period, and these actions are documented.

Use of the HACCP system for the food industry will underscore the industry's role in continuous problem prevention and problem solving, rather than relying solely on traditional facility inspections by regulatory agencies to detect loss of control. HACCP provides for real time monitoring procedures to assess the effectiveness of control. Each HACCP plan would reflect the uniqueness of a food, its method of processing, and the facility in which it is prepared.

HACCP has been endorsed by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as an effective and rational means of ensuring food safety from harvest to table. The NACMCF was established in 1988 by USDA in conjunction with FDA to fulfill a recommendation of the National Academy of Sciences, and includes officials from FDA, USDA, the National Oceanic and Atmospheric Administration, and the Department of Defense, as well as experts from academia and the food industry. HACCP is also recognized in the international food safety community as the state-of-the-art means to ensure the safety and integrity of food. In particular, the Committee on Food Hygiene of the United Nations' Codex Alimentarius Commission (Codex) has endorsed the HACCP concept as a world wide guideline. Indeed, the European Union (EU) and other countries around the world have begun to require that foods produced within their borders be processed under HACCP requirements.

The NACMCF has developed the following seven principles that describe the HACCP concept:

1. Hazard Analysis

The first step in the establishment of a HACCP system for a food process or practice is the identification of the hazards associated with the product. The NACMCF defines a hazard as a biological, chemical, or physical property that may cause a food to be unsafe for consumption. The hazard analysis step should include an assessment of both the likelihood that

such a hazard will occur and its severity if it does occur. This analysis should also involve the establishment of preventive measures to control identified hazards.

2. Identification of CCP's

A CCP is a point, step, or procedure at which control can be applied, the result being that a potential food safety hazard can be prevented, eliminated, or reduced to acceptable levels. Points in the manufacturing process that may be CCP's include cooking, chilling, specific sanitation procedures, product formulation control, prevention of cross contamination, and certain aspects of employee and environmental hygiene.

3. Establishment of Critical Limits for Preventive Measures Associated With Each Identified CCP

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, physical dimensions, moisture level, water activity, pH, and available chlorine.

4. Establishment of Procedures to Monitor CCP's

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. Continuous monitoring is possible with many types of physical and chemical methods. When it is not possible to monitor a critical limit on a continuous basis, monitoring intervals must be frequent enough to permit the manufacturer to determine whether the step/process/procedure designed to control the hazard is under control.

5. Establishment of Corrective Actions To Be Taken When Monitoring Shows That a Critical Limit Has Been Exceeded

While the HACCP system is intended to prevent deviations in a planned process from occurring, total prevention can rarely, if ever, be achieved. Therefore, there must be a corrective action plan in place to ensure appropriate disposition of any food produced during a deviation, to fix or correct the cause of noncompliance to ensure that the CCP is once again under control, and to maintain records of corrective actions taken.

6. Establishment of Effective Recordkeeping Systems That Document the HACCP System

This principle requires the preparation and maintenance of a written HACCP plan that lists the hazards, CCP's, and critical limits identified by the firm, as well as the monitoring, recordkeeping, and other procedures that the firm intends to use to implement the plan. This principle also requires the maintenance of records generated during the operation of the plan.

7. Establishment of Procedures to Verify That the HACCP System is Working

This process involves verifying that the critical limits are adequate to control the hazards identified, ensuring that the HACCP plan is working properly and verifying that there is documented, periodic revalidation of the plan to confirm that the plan is still performing its intended function under existing plant conditions at any point in time.

C. FDA's Authority to Mandate HACCP

In the **Federal Register** of January 28, 1994 (59 FR 4142), FDA proposed regulations that would require HACCP controls in the seafood industry. The agency believes that it is now appropriate to explore the application of HACCP to segments of the industry other than seafood. At this time the agency would plan to proceed in a stepwise fashion with those segments of the industry that are suitable candidates for adoption of HACCP principles. This document is intended to explore how the agency should pursue that broader HACCP program. FDA is doing so because the agency believes that such a program would be an effective and efficient way to ensure that food meets the act's safety standards and to implement section 402(a)(4) of the act (21 U.S.C. 342(a)(4)). As explained below, if FDA proceeds with a HACCP proposal covering additional segments of the food industry, such proposal would be made pursuant to the authority of sections 402 and 701(a) of the act (21 U.S.C. 371(a)).

Section 201 of the act defines the term "food" as "articles used for food or drink for man or other animals." Under section 402(a)(4) of the act, a food is deemed adulterated if it has been "prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." Proof that a food is actually contaminated or otherwise hazardous is not required to establish that a food is adulterated under section 402(a)(4) of the act. (See *United States* v. *H. B. Greggory Co.*, 502 F.2d 700, 704 (7th Cir. 1974), cert. denied, 422 U.S. 1007 (1975).) Instead, such adulteration requires only a showing that the conditions under which food is prepared, packed, or held create a "reasonable possibility" of contamination. (See *Berger* v. *United States*, 200 F.2d 818, 821 (8th Cir. 1952).)

In its enforcement of section 402(a)(4) of the act, FDA has considered, among other things, prevailing industry standards and the technical state-of-the-art in determining, on a case-by-case basis, whether the conditions under which a company is processing or otherwise handling food violate the standard of section 402 (a)(4). FDA's current intention is to propose to codify, in a future rulemaking, a state-of-the-art standard based upon HACCP principles. This standard would establish those conditions of food manufacturing, packing, and holding that are consistent with section 402(a)(4) of the act. Such regulations would thus ensure the agency's efficient enforcement of section 402(a)(4) and the other food safety provisions of the act, as authorized by section 701(a) of the act.

At this juncture, the regulations that FDA is considering for proposal would specify the requirements that the agency believes are the minimum necessary to ensure that food products under FDA's jurisdiction are not adulterated under section 402(a)(4) of the act. Under the program that FDA is considering, if a food purveyor covered by the program does not adopt and implement a HACCP plan that complies with the program's requirements or does not operate the plan in accordance with the program, food prepared, packed, or held in that facility would be adulterated under section 402(a) (4) of the act and potentially subject to regulatory action by FDA.

D. Rationale for a HACCP Approach

FDA expects that adoption of HACCP by some or all segments of the food industry, coupled with Government verification through inspections of the HACCP system, will more effectively and efficiently ensure the safety of the American food supply. The agency has tentatively chosen a HACCP approach because HACCP addresses the root causes of food safety problems in production, storage, transportation, etc., and is preventive. Two principal alternatives to HACCP exist; end-product testing and comprehensive current good manufacturing practice (CGMP) regulations. End-product testing does not address the root causes of food

safety problems; it is not preventive by design and requires that a large number of samples be analyzed to ensure product integrity. Similarly, CGMP's are not a practical approach because of the breadth and diversity of the food industry, the limited resources available within FDA to prepare the many specific CGMP regulations that would be needed to cover effectively such a diverse industry, and the time required to implement such regulations. However, FDA may consider the promulgation of CGMP's for certain food processes or types if such regulations would be more effective than a HACCP system for such processes. For example, some of the comments have suggested that sanitation would be better addressed through CGMP's than through a HACCP plan.

A HACCP system for food safety assurance has numerous distinct advantages including the following: (1) HACCP focuses on prevention and is designed to prevent hazards from entering food; (2) HACCP permits more effective and efficient Government oversight; (3) HACCP places primary responsibility for ensuring food safety appropriately on the food manufacturer/distributor; and (4) HACCP assists food companies in competing more effectively in the world market.

The primary purpose of any HACCP system is to prevent problems through the systematic analysis and control of the production system by industry. This analysis and control would be confirmed by Government verification of the industry's monitoring. As such, a HACCP approach provides an appropriate balance between the responsibilities of industry and Government in ensuring food safety. A HACCP based program will also allow FDA and its State and local government counterparts to conduct more efficient and focused inspections of food facilities.

In addition to being preventive in nature and more efficient, a HACCP approach offers two additional benefits over conventional inspection techniques. First, in contrast to FDA's current regulatory approach, a HACCP approach requires industry to analyze, in a rational, scientific manner, its production processes in order to identify CCP's and to establish critical limits and monitoring procedures. An essential part of the industry's role under HACCP is to establish and maintain records to document adherence to the critical limits relating to the identified CCP's, which will result in continuous self inspection.

Second, HACCP allows the regulator to monitor more effectively a firm's compliance with food safety laws. With its current system of inspection, FDA can determine the conditions at a food plant only during the period of inspection. The agency must therefore make assumptions about conditions before and after the inspection based on a snapshot of plant conditions and practices at the time of the inspection.

With an HACCP-based program in place, an investigator can determine and evaluate both current and past conditions critical to ensuring the safety of food produced by the facility. As discussed above, an essential part of a HACCP system is maintenance of monitoring records. By examining such records, the Government inspector can, in effect, look back through time at the conditions of a facility. Under the proposal that FDA currently envisions, the agency would have access to CCP monitoring records to verify that the HACCP plan is working. Government monitoring under a HACCP system would provide assurance that systems of preventive controls are in place and functioning properly and thus afford greater public assurance of food safety.

Current Federal inspection and surveillance strategies attempt to gauge the industry's knowledge of hazards and preventive control measures largely by inference, i.e., whether a company's products are in fact adulterated, or whether conditions in a plant are in compliance with CGMP's. Consequently, the current inspection system places a great deal of responsibility on Government regulators to uncover problems and to take regulatory action to address those problems. Under a HACCP-based inspection system, it would be the responsibility of the company to develop a plan for producing safe food, and the role of Government inspectors would be to verify that the company is carrying out its plan.

Finally, adopting a HACCP system could potentially enhance international trade opportunities for the United States. Although enhancing trade has no direct effect on public health, participation in international trade in food products is critical to the U.S. economy. The United States is by far the world's major food exporter, with exports of raw agricultural and processed food products of over $40 billion per year. The United States also imports a substantial quantity of food products each year from many countries around the world. HACCP will improve FDA's ability to monitor such imports and thus ensure confidence in their safety. Also, HACCP is becoming the world-wide standard to ensure the safety of food and will thus serve as basis for harmonizing U.S. food safety regulations with those of other nations.

The Uruguay Round negotiations under the General Agreement on Tariffs and Trade (GATT) has resulted in further focus on this area. The Agreement on the Application of Sanitary and Phytosanitary Measures states the desire of member countries, including the United States, to further "* * * the use of harmonized sanitary and phytosanitary measures between members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission * * *" (Ref. 5). This trend toward harmonization, coupled with the current recommendations of the Codex Alimentarius Commission encouraging the international use of HACCP, provide further support for FDA's serious consideration of a HACCP program for all or part of the food industry.

E. How the Agency Intends to Proceed

FDA began its initiative to mandate HACCP with a proposal covering the seafood industry due in large part to the fact that a substantial amount of work on the application of HACCP to seafood processing and importation, including the development of specific HACCP models, has already been done by the Federal Government, some States, academia, and by the seafood industry itself. Thus, there is a considerable body of literature and expertise, which can facilitate the development of HACCP systems by seafood processors and importers. Moreover, seafood industry representatives have been urging the Federal Government to adopt a mandatory HACCP program. The National Fisheries Institute, the largest seafood industry trade association, has testified repeatedly at congressional hearings in support of legislation that would mandate such a system. The agency recommends that interested persons refer to the seafood proposal to understand how the HACCP approach might work with respect to one category of food product.

The body of knowledge and experience on the application of HACCP to food production has not, as far as the agency is aware, been developed for other commodities to the extent that it has for seafood. (One possible exception is the low acid canned food industry, where much work has been done in HACCP's application due to FDA's long standing regulatory program for this industry.) Moreover, the food industry is extremely diverse and complex. For these reasons, FDA has decided to issue this advance notice of proposed

rulemaking to request comments on various aspects of the implementation of a mandatory HACCP program for some or all other sectors of the food industry. Those comments may suggest that an industry-wide HACCP requirement is appropriate or may indicate that such a program should be phased-in as data on individual commodities is compiled. FDA is open to any other suggestions. Specific issues on which FDA is particularly interested in receiving comments are set out below.

The agency believes that it could benefit from experience with the application of HACCP to selected commodities outside the seafood area. To gain this experience the agency has announced a voluntary pilot HACCP program and invited interested food producers to participate.

Some of the objectives of this pilot program are to obtain data on the hazards associated with particular types of food, and to develop and implement HACCP plans to control those hazards in conjunction with the participating firms. The pilot program could provide the agency and the industry with the practical knowledge and experience that would assist in the development and implementation of a HACCP program for particular segments of the food industry.

FDA recognizes that an ongoing exchange of scientific, technical, and operational information between the agency, the food industry, trade associations, consumer groups, FDA's State and local counterparts, and other affected parties is essential for the successful implementation of HACCP in the food industry. Consequently, FDA intends to maintain a dialogue with all affected parties during the process of developing its proposed regulations. In particular, FDA will meet with the food industry, consumer groups, and other interested parties during the comment period on this advance notice of proposed rulemaking.

FDA anticipates that it will receive a substantial number of comments in response to this document. The agency will review these comments and have further dialogue with industry and consumer representatives, as well as other groups and organizations knowledgeable in food safety, as part of its process for determining the appropriate regulatory approach prior to publication of a proposed rule.

FDA intends to work closely with USDA, as it considers development of its own HACCP regulations for meat and poultry products, to ensure that the two regulatory bodies have a consistent approach in applying HACCP principles to the food industry, while recognizing that inherent differences may exist between food commodity groups that will necessitate different approaches.

FDA also intends to work closely with its State and local counterparts that regulate the retail segment of the food industry. One principal way FDA conveys its recommended food regulatory policy to the nation's State and local food control agencies is through FDA's model Food Code. A notice of availability of the latest revision of the Food Code, which incorporates certain HACCP principles and terminology, was published in the **Federal Register** of January 28, 1994 (59 FR 4085).

II. Request for Comments

Under the act, the food industry has the primary responsibility for ensuring the safety of the food it produces and distributes. In its simplest terms, the role of Government is to verify that the industry is carrying out its responsibility and to initiate regulatory or other appropriate action when the industry fails to do so. FDA believes that establishing a HACCP program throughout the food industry could enable both the industry and FDA to carry out their respective responsibilities far more efficiently and effectively. FDA invites comments on this point, as well as on specific issues relating to the application of HACCP to foods other than seafood, as set out below.

A. Scope of a HACCP Regulation

NACMCF supports the adoption of HACCP throughout the food industry ((Ref. 4). Additionally, the Codex Ailmentarius Committee on Food Hygiene considers HACCP to be the most efficient and cost effective means to manage food safety (Ref. 4). FDA recognizes, however, that not all foods pose the same inherent risks. The agency intends to work with the Centers for Disease Control and Prevention and other Federal and State agencies as well as health professionals, industry, and consumer groups to access and evaluate data on the relative risks associated with various foods. FDA has concluded that HACCP has great potential to improve food safety and can be successfully used beyond seafood. However, specific HACCP requirements established for the various segments of the industry may be different because of differences in risk as well as differences in processes, etc. The agency encourages the food industry generally to begin using HACCP more widely.

FDA specifically requests comments on the scope of any mandatory HACCP program proposed by the agency. Should FDA mandate HACCP for all segments of the food industry? Or should HACCP be required only for certain segments of the food industry? In deciding whether to cover all or some segments of the food industry by a mandatory HACCP rule, what criteria should FDA use? In particular, should any exclusions from a HACCP requirement be determined on any basis other than the risk presented by the particular activity? Are there categories of activities, such as the warehousing of certain types of foodstuffs, that deserve exclusion?

The agency also requests comment on how a mandatory HACCP rule should apply to those in the chain of distribution of imported foods. How should the agency ensure that imported foods are produced and handled safely? In the seafood proposal, FDA is proposing that all domestic and foreign processors and importers adopt HACCP controls, and FDA is proposing to take steps to ensure that the HACCP controls are in fact implemented by foreign processors. The seafood proposal broadly defines "processor" to include packers, repackers, wholesalers, and warehousers. Should the agency adopt the same approach with respect to foreign processors, handlers, and importers of all other foods?

FDA also solicits comments on whether and how a mandatory HACCP rule should apply to food retailers. The agency's seafood proposal specifically excludes retailers from the definition of "processor." Should a similar exclusion be made for retailers of all other foods as well? The agency notes that its updated Food Code, which serves as guidance to the States as part of an ongoing cooperative program for regulating the retail sector, incorporates several HACCP elements. The agency requests comment on this cooperative program for the retail sector and on how governments at all levels can best collaborate to ensure the safety of food from farm or fishery to the dinner table, including food sold ready-to-eat at the retail level. Should HACCP be required in restaurants and other retail outlets? Should HACCP requirements be applied directly to raw material suppliers and transportation companies? Or should such requirements be imposed indirectly through the HACCP plans of processors and others who receive food (e.g., by using purchase specifications)?

FDA also specifically requests comment on how small firms should be covered by any mandatory HACCP regulations. In the seafood proposal, FDA has made no distinctions in the application of proposed requirements based on firm size. If small firms should

be exempt, on what basis should the exemption be made?

B. Focus of HACCP

NACMCF believes that HACCP and HACCP plans should address food safety, including all biological, chemical, and physical hazards that would affect a particular food. Consistent with this view, FDA has limited the scope of the HACCP requirements in the seafood proposal to safety concerns and has not included food quality and labeling standards and requirements. Although the agency believes that the primary focus of a HACCP program should be safety, FDA is aware that food quality is also important to consumers and is an issue in international trade.

Should FDA's HACCP program for the broader food industry be limited to food safety and the hazards presented by a particular activity? If so, how broadly should hazard be defined? What level of risk warrants HACCP-type control? Should different levels of control be required in HACCP plans for different levels of risk? Or should FDA's proposal mandate that food quality issues be included in HACCP plans? Should sanitation practices within the plant be required to be included in HACCP plans?

C. Implementation of HACCP

FDA recognizes that, because of the size and diversity of the overall food industry, any mandatory HACCP program would likely be costly for some segments of the food industry and need to be phased in gradually. Development of HACCP plans would require at least some segments of the industry to adopt new ways of thinking and operating. Review by FDA of HACCP plans and monitoring records as part of its plant inspections would necessitate additional training of FDA, State, and local investigators.

In view of the scope of the task, what would be a reasonable time period for the implementation of HACCP? In the seafood proposal, FDA is proposing a 1-year period for implementation, measured from the date of the final regulations. This proposed lead time takes into account the fact that a considerable amount of developmental work has already been done on the application of HACCP to seafood processing. Are there special considerations for other types of foods that could affect implementation time? Are there circumstances that would require some industry segments to need an implementation period longer than 1 year after final rule promulgation?

If implementation of HACCP is to be phased in (i.e., certain segments would gradually be subject to the HACCP requirements established), how should this be accomplished? How should firms or segments of the food industry be differentiated for purposes of such a phased in implementation? What would be appropriate time intervals between each implementation phase? What criteria should be used to decide the order of implementation for the various segments of the food industry? For example, should potential food safety risks associated with the product be considered in determining an implementation schedule, and if so, what factors should be used in ranking foods with respect to potential risk? Likewise, for example, should firm size be considered in determining the order of implementation?

The agency is interested in learning about the experiences that food manufacturers have had with the implementation of HACCP and therefore requests comments from firms who have had actual experience in the application of HACCP concepts to food production, both on what has worked and on what has not worked. In particular, FDA seeks information on: (1) How long it took to implement a HACCP program; (2) the start-up and maintenance costs; and (3) the impact of implementing HACCP on the safety of the product, the efficiency of the firm's operation, and any long-term savings (cost effectiveness). The agency is also interested in any measures that have been, or could be, used to measure the effectiveness of HACCP to improve product safety. The agency is particularly interested in the experiences of small food firms on all of the above.

D. Evaluation of the HACCP System

FDA believes that implementation of HACCP beyond the seafood industry, whether voluntary or mandatory, will more effectively and efficiently ensure the safety of the American food supply. The agency recognizes, however, that there may be alternatives to the HACCP approach and invites comment on such alternatives and their effectiveness.

The agency also invites comment on whether there are factors that would limit the effectiveness of the HACCP approach. What information is needed in order to judge the effectiveness of a HACCP program? Should HACCP programs be pilot tested before implementation? Should there be a minimum level of certainty that a HACCP plan would be effective in controlling hazards prior to implementation?

What should be the qualifications of individuals responsible for developing HACCP plans? What should be the qualifications of individuals responsible for verification of HACCP plans? Is the current state of knowledge sufficient to make adequate hazard analyses? Is there a need for microbiological criteria in HACCP plans? Will end-product microbiological testing be necessary?

How should the appropriate frequency of monitoring CCP's be determined? Should a processing plant be required to submit a report to FDA each time a process is found to be out of control? What, if any, circumstances should trigger mandatory reporting to FDA? Is it necessary to require that a food processor have a reliable and well-tested method of recall as part of its HACCP plan?

E. Roles of FDA, the States, and the Food Industry

FDA's interest in institutionalizing HACCP for the food industry is based on the agency's recognition of the need to revise the current regulatory approach and make it more effective and comprehensive. This revision must coordinate and maximize the efforts of all levels of Government and the food industry to provide effective coverage of food from farm or fishery to table. The respective roles of industry, State and local authorities, and FDA must be clearly articulated, and they must be integrated and coordinated. FDA's preliminary thinking on the nature of these respective roles follows.

If FDA decides to make HACCP mandatory for some or all segments of the food industry, firms would be required to develop, implement, and maintain an effective HACCP system in their facility, and to verify that the system is adequate to ensure a safe product. The HACCP system developed by the firm would have to include all relevant critical limits (such as tolerances) contained in existing FDA regulations and guidelines, as well as other CCP's judged necessary by the firm to ensure the safety of the food. Firms would also be responsible for taking appropriate corrective actions whenever a CCP deviation has occurred. The system would be considered out of compliance when a critical limit of a CCP has been exceeded and corrective actions are not taken or are ineffective.

Regulated industry segments would also be responsible for providing appropriate training for personnel involved in implementing HACCP in each facility. Each facility would have to maintain an accurate, up-to-date HACCP plan, which would be available for review by FDA investigators during

an inspection. Records pertinent to the monitoring of the CCP's in the HACCP plan would also have to be available for review by FDA.

FDA is seeking comment on the appropriateness of imposing these obligations on the food industry under a mandatory HACCP system. The agency is especially interested in receiving comments on records access, including:

(1) What records should be considered HACCP records, and therefore be accessible to FDA (and State and local) investigators? Under FDA's proposed HACCP regulations for seafood, HACCP records include the HACCP plan itself, records of the monitoring of critical control points, and records of corrective actions. In the case of seafood, FDA tentatively concluded that the agency should have access to all records deemed to be HACCP records, because without such access, the regulatory requirements would not be meaningful.

(2) How should consumer complaint files relating to CCP failures be utilized in a HACCP system? In FDA's proposed HACCP regulations for seafood, the agency tentatively concluded that each HACCP system should take advantage of consumer complaints as they relate to the operation of CCP's. The agency proposed that procedures for monitoring CCP's include procedures for monitoring relevant consumer complaints, and that consumer complaints that potentially relate to the performance of critical control points be considered HACCP records. FDA invites comment on this approach for foods generally. Should FDA have access to consumer complaint files relating to CCP failures? What criteria should be used to determine whether a consumer complaint is linked to a CCP failure?

(3) How long should HACCP records be kept? The proposed HACCP regulations for seafood mandate 1 year for fresh products and 2 years for frozen and preserved products.

As an additional matter, FDA is aware that there is substantial public interest in the extent to which industry-generated HACCP records could or should be publicly available. FDA invites comment on the general question of public disclosure of HACCP records and on the agency's preliminary analysis of the availability of such records, which follows.

FDA has long had explicit statutory authority to obtain access to certain industry records during inspections involving infant formula, drugs, and devices (21 U.S.C. 374), and has had access by virtue of agency regulations to certain processing records during inspections of low acid canned food processors and manufacturers of infant formula. The agency has the right to copy and take possession of these records, but does not routinely do so. FDA typically copies and takes possession of records only when they may be needed for regulatory purposes. As a preliminary matter, FDA expects to continue this practice with regard to HACCP records.

The public availability of those HACCP documents that would become part of FDA's official records as a result of copying during an inspection would be governed by section 301(j) of the act and by the Freedom of Information Act (FOIA) and regulations issued under the FOIA by the Department of Health and Human Services (HHS) and by FDA. Section 301(j) of the act expressly prohibits any person from disclosing trade secret information obtained during the course of an inspection. The agency's FOIA regulations also state that FDA will not disclose either trade secret or confidential commercial information. FDA's preliminary view is that HACCP plans and monitoring records fall within these two categories of protected records. As a consequence, FDA may have little discretion to disclose such records. Moreover, under HHS FOIA regulations, processors may be entitled to challenge in court a pending disclosure of records on the ground that the records to be disclosed are confidential commercial or trade secret.

Additionally, there are significant legal and practical questions as to whether FDA has the authority to require disclosure of industry records that are not in FDA's possession.

The agency is also seeking comments on whether there should be a standardized format (structure and organization) for written HACCP plans. If so, how should this standard format be developed and who should develop it?

As is the case today, the overall goal of FDA's inspection program would be to ensure that foods are safely prepared, packed, and held. To achieve this goal under a HACCP system, FDA's inspection would seek to verify that a HACCP plan is adequate to ensure food safety and that it is being implemented and maintained properly. The agency is seeking comments on the appropriate frequency of agency inspections under a mandatory HACCP program to achieve its goal of ensuring food safety.

The agency is also interested in receiving comments on the possible role that FDA could play to assist the food industry in developing and establishing HACCP programs. This assistance could take the form of agency guidelines for developing HACCP plans and generic HACCP plans developed in cooperation with the industry. FDA could also promote and participate in educational programs to encourage the use of HACCP and FDA could continue to represent the United States at international meetings on HACCP. The agency could work with interested groups to identify new food safety hazards and to develop new strategies for their control.

The agency expects that the States would play a major role in enhancing FDA's enforcement coverage. State authorities could participate in HACCP inspections both as part of their own enforcement activities and under FDA contract. State and local authorities could also be involved in actively promoting the use of HACCP at the retail level.

The agency is seeking comments on what its role should be relative to the review, verification, monitoring, and certification of HACCP plans. In the seafood proposal, FDA is not proposing to require that HACCP plans be submitted to FDA in advance, or that preapproval by FDA be a condition of the adoption or implementation of these plans. If FDA proposes to make HACCP mandatory for other portions of the food industry, should it adopt this approach? Should FDA indentify CCP's and establish critical limits in its HACCP regulation, or should it defer to firms to develop these themselves? What role should FDA serve in overseeing the corrective actions taken when a deviation has occurred? Can any HACCP oversight function, including review of plans and monitoring, be performed by certified third parties? If so, how should they be certified and by whom?

For implementation of HACCP for fish and fishery products, FDA is developing guidelines for processors. These guidelines inventory and describe the likely hazards associated with both products and processes, and provide advice on how these hazards can be controlled. These guidelines also include a fill-in-the-blank HACCP plan to serve as an example of how a basic HACCP plan could be developed. Are such guidelines necessary for other commodities and, if so, who should develop them? What specifically should be included? What role should the food industry play in the development of these materials? What other forms of assistance should FDA provide? To what extent, if any, should any of this additional guidance be made mandatory?

F. Training and Education

The agency's experience with low acid canned foods established that appropriate training is critical to the successful implementation of HACCP in the food industry. The industry will need training on how to develop HACCP plans, i.e., how to identify hazards and establish critical limits, control measures, corrective actions, and recordkeeping procedures. Investigators employed by regulatory agencies, including FDA, will need training to understand how to review HACCP plans as well as industry records pertaining to implementation and operation of such plans.

Based upon its low acid canned food experience, FDA believes that employee training is an essential element of an effective HACCP program. Should FDA mandate training for plant personnel responsible for developing and maintaining the HACCP program? In the seafood proposal, FDA is proposing to require that each processor and importer employ at least one individual who has successfully completed a training course on the application of HACCP to fish and fishery products processing. Moreover, the regulations propose to require that those at each establishment who have received training be responsible for reviewing records of CCP monitoring, recognizing critical limit deficiencies, and assessing the need for corrective actions relative to the product in question and the HACCP plan itself. FDA seeks comment on the question of training. Are there reasons why such training should not be mandated? If such training is required, as FDA currently believes it should be, who should conduct these training courses? Who should be required to attend? What role, if any, should FDA have regarding course materials and instructors? Should a third party be certified by FDA to review and approve the training courses? Should one, some, or all responsible plant employees be certified?

G. International Harmonization

As the international community moves toward HACCP, FDA believes an opportunity exists to improve the safety of the U.S. food supply by working toward harmonized approaches that would elevate FDA's confidence that food entering the United States meets U.S. safety standards. Such harmonization would also support U.S. exports. For example, after January 1, 1995, unless seafood products for import into the EU are produced under HACCP, the EU will carry out extensive end-product testing, and the competitiveness of importers will be significantly affected. How should FDA approach any effort to harmonize HACCP standards with those of other countries? What role should the Codex play?

H. Potential Costs and Benefits

The agency is also requesting relevant economic information. In particular, FDA seeks estimates of the following costs: (1) The initial costs of developing a HACCP plan and the frequency and costs of altering the plan; (2) costs of monitoring and recordkeeping by type of process, product, and packaging, and the costs of reviewing records before shipment; (3) costs of necessary training of employees, and rate of turnover of employees; (4) administrative costs to oversee all phases of HACCP implementation and operation; (5) the cost of monitoring equipment and other types of equipment needed to implement a HACCP program; (6) the cost and frequency of corrective actions when critical limits are exceeded; (7) the potential cost to the industry of FDA inspections of HACCP programs; (8) cost of testing for chemical and contaminant residues as a component of HACCP; (9) cost of process redesign; (10) cost of new product design; and (11) the costs of any consultants that might be required under a HACCP approach. FDA also seeks comments about the costs of expanding HACCP to elements of the food industry other than manufacturers and processors, such as retail supermarkets and restaurants, food transporters, and raw material suppliers. FDA is particularly interested in the cost experience of small firms who have implemented HACCP, and how HACCP implementation by these firms is different from that of large firms.

FDA is also announcing its intention to survey the food processing industry (except for seafood) to estimate the costs of complying with mandatory HACCP requirements and requests comments on how such a survey should be designed and implemented.

FDA is also interested in receiving comments on benefits of mandating HACCP for particular products, processes, and packaging. Thus, FDA is seeking information about the existing risk levels presented by various foods, including risk from microorganisms, contaminants, and chemical residues from all interested parties, including State and other Federal agencies. FDA is also interested in receiving information concerning any quantitative reductions in risk that have been documented by firms now using HACCP, or other evidence that would document that illness or other food borne risks have been reduced through use of HACCP. FDA also is interested in receiving information that documents savings in production costs or indirect benefits, such as increased quality, that firms using HACCP have experienced. Because many risks are the result of consumer mishandling, FDA requests comments on the extent of this source of illness or other food borne risks, and how this information should be used to target HACCP efforts. Finally, FDA requests comments on the benefits of extending HACCP to the other areas of the food industry that are mentioned above.

I. Potential Environmental Effects

The agency is also requesting relevant environmental information because, under the National Environmental Policy Act, FDA must consider the environmental impact of its actions. The agency does not currently possess the data that would permit detailed analysis of the environmental impact of the action under consideration by the agency, as described in this document.

Therefore, the agency is requesting information on the potential environmental impact including: (1) Potential for increased energy consumption, (2) potential for increased disposal of defective foods, (3) potential for new or increased disposal of sanitizing products, (4) a description of measures that could be taken to avoid or mitigate adverse environmental impacts that might result from this action, and (5) potential for increased paper consumption.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bennett, J. V., S. D., Holmberg, M. F., Rogers, and S. L., Solomon, "Infectious and Parasitic Diseases," in "Closing the Gap: The Burden of Unnecessary Illness," Amlet, R. W. and H. B., Dull, ed., Oxford University Press, pp. 102–114, New York, 1987.

2. Todd, E. C. D., "Preliminary Estimates of the Costs of Food borne Disease in the United States," *Journal of Food Protection*, 52:595–601.

3. Archer, D. L., and J. E., Kvenberg, "Incidence and Cost of Food borne Diarrheal Disease in the United States," *Journal of Food Protection*, 48:887–894.

4. NACMCF, "National Advisory Committee on Microbiological Criteria for Foods, Hazard Analysis and Critical Control Point System Adopted March 20, 1992," "HACCP: Principles and Applications," Van Nostrand Reinhold, 1992.

5. GATT Secretariat, "Final Act Embodying the Results of the Uruguav Round of

Multilateral Trade Negotiations," December 15, 1993.

IV. Comments

Interested persons may, on or before December 2, 1994, submit to the Dockets Management Branch (address above) written comments regarding this document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This document is issued under sections 402, 404, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 344, 371, and 374).

Dated: July 29, 1994

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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