ENCLOSURE 2

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December 2, 1994

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Advance Notice of Proposed Rulemaking
Hazard Analysis Critical Control Point Systems
For the Food Industry
Docket No. 93N-0325
59 Fed. Reg. 39888 (August 4, 1994)

The National Oilseed Processors Association (NOPA) is a national trade association comprised of 12 regular and 27 associate member companies that process oilseeds to produce edible oils and vegetable protein products used for human food and animal feed. The NOPA regular member firms process an estimated 1.1 billion bushels of oilseeds annually at 65 plants located in 22 states and employ approximately 1,900 workers.

Because of its strong interest in food good manufacturing practices (GMP) in general, and hazard analysis and critical control point (HACCP) systems in particular, NOPA submitted comments regarding the seafood HACCP proposal, 59 Fed. Reg. 4142 (January 28, 1994), to FDA on May 31, 1994. A copy of those comments is attached. These NOPA comments, submitted in response to the August 4, 1994, advance notice of proposed rulemaking, reiterate a number of the important points made by the Association in those earlier comments.

These comments focus on the issues raised in the advanced rulemaking insofar as they relate to the use of oilseed products in

human food and animal feed. NOPA endorses and supports the views of the packaged food industry as expressed in the comments submitted by the Grocery Manufacturers of America and the National Food Processors Association.

DISCUSSION

NOPA strongly supports the present voluntary HACCP system incorporated in the existing food GMP regulations, 21 C.F.R. 110.3(e) and 110.80(b)(13)(i). This voluntary system, proposed in 1979 and promulgated in 1986, is sufficient as part of the general food GMP requirements to ensure an adequate level of safety in the food supply.

It may well be helpful for FDA to make publicly available -- either through general background materials or through a specific Federal Register notice -- additional information regarding the principles and procedures that have become accepted for implementation of a HACCP system. This could help ensure that the entire food industry -- from farm to table -- is fully aware of the voluntary HACCP system available for implementing good manufacturing practices in the manufacture and processing of food products.

We strongly oppose any mandatory system, on several grounds.

1. Oilseed Products Used In Human Food and Animal Feed Do Not Represent a Serious Human Health Hazard.

Animal feed and their components, including oilseed meals, are at the early end of the food chain. Many are used in non-food-producing animals, and thus bear no relationship to human health. Those that are used for feed for human food-producing animals must first be consumed by the specific animal species involved and then converted into the resulting human food. Thus, different considerations apply to the safety of animal feed as contrasted with the safety of human food.

It is widely accepted that HACCP is properly directed only to serious human health hazards. NOPA is satisfied that the regulatory concerns that can arise with respect to animal feed cannot properly be considered a serious human health risk.

Pathogenic microorganisms such as those that may occur in animal feed are ubiquitous in our environment, and particularly on the farm. Targeting pathogens in animal feed for eradication would make no discernible impact on the overall level of pathogens in this environment. Nor would such a program result in any discernible reduction in food borne illness. If FDA truly intends to eradicate pathogenic microorganisms from all farms in the United States, animal feed would constitute an extremely small and insignificant part of the effort.

Nor are there any other categories of human health hazards associated with

oilseed meals used in animal feed. Food additives, color additives, pesticide residues, and environmental contaminants -- to name just a few potential components of oilseed meals -- raise no significant human health risks from animal feed. Any occasional excess of these ingredients which might result in a level somewhat above an established tolerance, could not possibly raise a serious human health hazard. First, it is extremely unlikely that any such over-tolerance amount of these substances would result in a correspondingly higher level in the food produced from the animal. Second, even if that were to occur, current tolerance levels incorporate such a high safety factor that human health would not in any way be endangered.

The use of oilseed products in human food similarly reflects a long history of human safety. These products, used as ingredients in the manufacture of packaged food, have not been a source of serious human risk. A mandatory HACCP system for these products therefore simply cannot be justified on public health grounds.

The current food GMP regulations, including the voluntary HACCP approach in Section 110.80(b)(13)(i), have been shown quite sufficient in providing adequate public protection with respect to oilseed products used in human food and animal feed. Imposing a mandatory HACCP program would therefore raise the cost of food production (and thus the retail cost of food) substantially, with no potential public health benefits, and thus cannot be cost-justified.

2. HACCP Must Be Retained As a Flexible Part of Food GMP.

The voluntary HACCP program set forth in Sections 110.3(e) and 110.80(b)(13)(i) of the existing food GMP regulations is stated in broad, general, and flexible terms. When FDA proposed this program in 1979 and promulgated it in 1986, the Agency made no attempt to set forth specific detailed requirements for any HACCP system. NOPA agrees with this approach. HACCP is a set of principles and a process or system for their implementation. It cannot be reduced to a set of rigid requirements.

There are numerous reports and documents readily available to the food industry that establish the HACCP principles and concepts. Nonetheless, NOPA encourages FDA to prepare another version of these existing documents, either as general background materials that could be helpful to companies that wish to undertake a voluntary HACCP system in accordance with Section 110.80(b)(13)(i) of the FDA food GMP regulations, or even as a separate notice in the Federal Register that would incorporate this information. If FDA concludes that this would be appropriate, however, NOPA urges that the original intent of HACCP -- that it is a general set of principles, addressing clearly identified safety hazards, the implementation of which must be tailored to each individual food manufacturing process -- be retained. HACCP properly fixes the responsibility for food safety squarely on the food manufacturing industry, through such programs as HACCP. NOPA and its member companies agree that it is in fact the responsibility of the industry to

provide a safe food supply, and thus opposes any form of mandatory HACCP regulations.

If FDA is able to demonstrate that oilseed products used in human food and animal feed do present a serious human health risk that could substantially be reduced through a mandatory HACCP system, NOPA urges that any such requirement be limited to whatever hazards are identified by FDA as resulting in these human health risks. To the extent that any such risks result from the potential presence of pathogenic microorganisms, the appropriate way for FDA to proceed would be under the authority granted FDA in Section 404 of the Federal Food, Drug, and Cosmetic Act. In accordance with these narrow statutory provisions, FDA would potentially have the authority to require access to records that demonstrate a company's adherence to its HACCP plan, but would not have the right to copy these records or otherwise take them away.

CONCLUSION

NOPA supports the current existing voluntary HACCP system under the present food GMP regulations, and opposes making any aspect of this program mandatory for oilseed products used in human food or animal feed. If FDA concludes otherwise, however, any resulting mandatory HACCP system must be limited to particular hazards that result in a serious human health risk and must be formulated in such a way that individual oilseed processing plants have sufficient flexibility to adapt

general HACCP principles to their specific manufacturing and processing operations.

Respectfully submitted,

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ATTACHMENT

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May 31, 1994

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Seafood HACCP Proposal,
Dockets 90N-0199 & 93N-0195,
59 Fed. Reg. 4142 (January 28, 1994)

The National Oilseed Processors Association ("NOPA") is a national trade association comprised of 13 regular and 26 associate member companies that process oilseeds to produce edible oils and vegetable protein products used primarily for feed. NOPA's 13 regular member firms process an estimated 1.1 billion bushels of oilseeds annually, at 59 plants located in 19 states. These companies employ an estimated 1,900 workers and each year produce approximately 6.2 million metric tons of vegetable oils, valued at approximately $2.8 billion.

NOPA appreciates this opportunity to submit comments in response to the above-captioned notice of proposed rulemaking. As explained at length in the discussion that follows, the proposed HACCP seafood requirements are overly broad in their application, excessively rigid, and unnecessarily burdensome in requiring access to records.

DISCUSSION

Food safety is and must remain the primary responsibility of the food industry. Although FDA has played an important role in implementing the statute and defining good manufacturing practices (GMPs), the impressive record of food safety in the United States primarily reflects the conscientious efforts of this country's food processors to ensure the quality of their products. The food industry routinely cooperates with FDA to assure the safety of food. Regulated companies are fundamentally committed, as is the agency, to ensuring the quality of all food products and maintaining public faith in the wholesomeness of the nation's food supply. The industry has therefore worked with FDA over the last two decades to enhance implementation of the agency's food GMP requirements. Although seafood may raise special questions, it would be incorrect to generalize and assume that other industry sectors want or need the intrusive agency oversight envisioned in this proposal.

A. HACCP Should Only Apply To High Risk Products

NOPA believes that primary emphasis should be placed on serious health risks. The proposed regulations should be

revised to ensure that HACCP plans focus just on truly serious hazards. In limited instances, namely acidified foods and thermally processed low acid foods, adherence to HACCP principles already has been mandated by the agency. 21 C.F.R. pts. 108, 113, 114. It must be remembered, however, that the detailed requirements for acidified foods and low acid canned foods represent conditions that must be met in order to avoid application of the emergency permit control requirements for microbiological hazards under Section 404 of the FD&C Act and FDA's implementing regulations. The agency's general authority to regulate sanitary conditions under Section 402(a)(4) of the Act is substantially more limited.

In the preamble to the proposed HACCP regulations, FDA properly suggests excluding "low risk" and "remote" hazards (59 Fed. Reg. at 4156), but this intent is not reflected in the proposed regulations. Although most microbiological problems that consumers experience arise from food mishandling at retail or in the home, the National Academy of Sciences has repeatedly recommended the use of HACCP principles in the food process-

ing industry.[1] Microbiological contamination is universally regarded as presenting the most serious risk to food safety. It is important to minimize the number of critical control points so that HACCP plans remain workable. This can only be done by focusing on truly serious hazards, namely those that would meet the criteria for a Class I recall.

FDA should not, for example, require the use of HACCP plans as a mechanism for assuring conformity with food additive or pesticide residue tolerances or with action levels for environmental contaminants. Unless one is likely to encounter serious health effects if the regulatory limits have been exceeded, it would be inappropriate to require that HACCP plans anticipate and control for such matters. Compliance with tolerances is already achieved through normal quality controls.

Finally, HACCP efforts should not be diluted by their extension to concerns that have no relation to serious safety issues, such as economic or esthetic adulteration. Thus,

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[1] NAS, AN EVALUATION OF THE ROLE OF MICROBIOLOGICAL CRITERIA FOR FOODS AND FOOD INGREDIENTS 308-35 (1985); NAS, PREVENTION OF MICROBIAL AND PARASITIC HAZARDS ASSOCIATED WITH PROCESSED FOODS: A GUIDE FOR THE FOOD PROCESSOR 29 (1975).

proposed Section 123.6(c), which would encourage the application of HACCP to issues admittedly "not related to the safety of the product," should be deleted.

B. Overly Detailed HACCP Requirements Must Be Avoided

HACCP is an approach to implementing good manufacturing practices rather than a single, generally applicable set of rules to prevent contamination problems. HACCP regulations must provide for ample flexibility so that the principles can be applied to the critical control points most relevant to a particular product or process. Processes under HACCP are simply extensions of basic GMPs that have been subjected to systematic analysis to obtain the most effective and efficient safety controls. HACCP plans reflect the uniqueness of each particular food, its method of processing, and the facility in which it is prepared. Thus, food processors must bear primary responsibility for the development and implementation of HACCP plans.

The overly rigid application of HACCP principles would be counterproductive. FDA should not, for instance, have proposed detailed sanitation controls for seafood products. Perhaps certain seafood products should be governed by prescriptive

GMP rules like those applicable to slaughterhouses, but it would be a mistake to suggest that such detailed requirements should be an integral part of a mandatory HACCP system that might be extended in the future to other classes of products. Sanitation requirements related to the control of serious pathogens may be appropriate, but routine sanitation issues are not properly part of HACCP.

FDA also should not formalize its draft HACCP guidelines. Each facility or operation is different is some respects, and each food processor must perform a particularized hazard assessment, geared toward specific products and processes and based on the special expertise that resides in a company. FDA must not allow its guidelines to become a *de facto* checklist for inspectors because companies would then be hesitant to deviate from the guidelines even if a different HACCP plan would be better tailored to their operations. Experience with HACCP efforts demonstrates the need to provide flexibility so that safety assurance plans are tailored to those truly critical control points in a particular manufacturing process. Overly detailed and prescriptive regulatory requirements, or extension to issues beyond serious food safety issues, will undermine this goal.

C. HACCP Oversight Requires Only Limited Records Access

Although a HACCP oversight role may require limited access by certain FDA personnel to certain processing records pertaining to critical control points, deviations, and validation of process controls, the agency must ensure that records access not lead to burdensome "fishing" expeditions. The proposed authority to copy records (§ 123.8(d)) should, therefore, be deleted, and any other access to processors' records must be coupled with assurances that such records will be treated as confidential information.

For more than half a century, FDA has been extraordinarily effective in using this factory inspection authority to make certain that food manufacturers comply with both the adulteration and the misbranding provisions of the law. FDA also has imposed specific access requirements for processing records in its regulations applicable to acidified and thermally processed low acid foods where a need to do so was demonstrated as required by Section 404 of the Act (21 C.F.R. §§ 108.25(g), 108.35(h)). The agency has taken the position in other contexts that it has implicit authority to demand access to records (59 Fed. Reg. at 4160). In order to justify this position, however,

FDA must limit access only to those records which relate directly to the specific critical control points relevant to a documented, serious hazard in each case.

Customer complaints represent one category of records that have no useful place in a HACCP system. Complaints about food products typically relate to taste, color, or other quality parameters which have nothing to do with safety. Serious complaints are brought to FDA's attention in any event, and an undue emphasis on complaint records could do a disservice to HACCP efforts. Although FDA inspectors would be able (under the regulations as proposed) to verify that HACCP plans include adequate steps for handling complaints, the proposal to give inspectors access to the actual complaint files should be deleted. Requiring access to such records would be unduly burdensome for industry, divert inspectors' time and attention from serious questions related to microbiological hazards, and exceed the agency's statutory authority. Agency access to such records would penalize conscientious manufacturers for good record-keeping.

CONCLUSION

NOPA commends FDA for undertaking the difficult task of attempting to apply HACCP principles to seafood products, and we appreciate the opportunity to provide comments to the agency on these important issues. The agency should take care to ensure that its effort to mandate HACCP does not contravene the original principles and rationales underlying this innovative approach to good manufacturing practices. For HACCP plans to function as intended, the agency must ensure that the regulations give food processors sufficient flexibility to respond to any serious hazards encountered with their specific products and processes.

Respectfully submitted,

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