ENCLOSURE 1

NOPA
NATIONAL OILSEED PROCESSORS ASSOCIATION

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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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