



Northwest Food Processors Association  
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September 10, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 2004N-0230 Food; Current Good Manufacturing Practice Regulations

Dear Sir or Madam:

NWFPA is the largest regional food industry trade association in the United States. Our organization serves as an advocate and resource for food processing companies in Idaho, Oregon, and Washington. In addition to member processing companies in the Northwest, NWFPA provides membership categories for very small processing companies and for processing companies outside the geographical region of Idaho, Oregon, and Washington. From our unique perspective in representing small processors and working with very small processors, we would like to offer the following comments and suggestions regarding Current Good Manufacturing Practices:

Revision of the Current Good Manufacturing Practices

Northwest Food Processors Association recognizes that much has changed in product formulation and packaging since the last revision 21 CFR Part 110, the Current Good Manufacturing Practices (CGMPs), in the mid 1980s. In spite of these advances in food systems, the framework of FDA regulations and guidance to industry has kept pace. The Eastern Research Group echoes this fact in their report prepared for FDA on CGMPs. All microbiological, chemical, and physical food safety problems identified by experts involved in the ERG report currently have federal regulations associated with them. Additional CGMP regulations are redundant and not needed to cover the range of problems identified.

However, there are provisions of part 110 that need clarification as to the risk of food safety issues versus the risk of wholesomeness issues, particularly for small food processors that may lack the expertise to judge the difference.

#### Small Processor Compliance Challenges

Smaller processors tend to have less in-house food safety and regulatory expertise. Non-compliance is more a factor of lack of understanding and resources, rather than intent. FDA's Small Business Representatives at the recent public meetings on this topic confirmed this point. Here are some reasons why:

- ?? In-house on-going training of line workers by supervision is less available.
- ?? In-house development of labels is more likely, thus creating additional risks as opposed to highly skilled, professional label development specialists.
- ?? Smaller processors are less likely to have capital resources to invest in new, sanitary designed equipment making sanitation more of a challenge. They are also less likely to have the resources to maximize plant design and location for food safety factors such as post-processing cross-contamination. Risk-specific guidance and training, rather than across-the-board restrictions, would assist in channeling resources to problem areas.
- ?? Smaller processors are more likely to obtain raw materials on the open market rather than through contracted sources. This leads to less control on agronomic conditions that reduce contamination of incoming raw materials.
- ?? Smaller processors have less buying power from vendors who provide technical expertise to larger buyers. Thus, they have less access to this resource to solve specific food safety and sanitation problems within their operations.

#### Grass Roots Training and the Culture of Compliance

Food processors in the Northwest range from cottage industry to mid-size companies by national standards. NWFPA member companies, operating along side very small processors, are impacted dramatically and negatively when a food safety incident occurs. NWFPA members have long recognized the overall industry benefit of reaching out with training opportunities to the smallest food processing companies that are unable to afford membership in even low dues regional trade associations, and/or are not represented by regional trade associations in their geographical area and cannot afford national trade association membership.

Over its 90 years of operation, NWFPA has worked aggressively, in partnership with local regulatory and academic organizations, to provide local, low cost food safety training programs to very small processors and those processors in Western states where training is unavailable. We believe these grassroots efforts are the key to education and networking opportunities that strengthen the safety of the food supply by inducting all food processors into a culture of compliance.

A culture of compliance is most effective when based on and incorporated within a competitive atmosphere. Food safety specifications required from the top down through the supply chain are far more stringent and effective than regulatory requirements. FDA needs to use its resources to leverage this culture across the industry. Small processors want to become big processors; they must learn to comply with customer specifications that qualify them for markets and, in turn, grow their businesses. Currently, the agency

stands outside this business culture; it needs to shift towards incorporating its regulatory activities into it. We also believe the FDA should adopt the Northwest model approach to grass roots training and a culture of compliance to strengthen compliance with Current Good Manufacturing Practices at the smallest levels of the food industry.

### FDA Training Opportunities

NWFPA recommends that the focus of FDA's efforts should shift to education and training in these three key areas:

1. Adopt the Codex "Recommendation International Code of Practice: General Principles of Food Hygiene" Section X – Training. Use these requirements to encourage training programs in the food industry. Allow processors to establish their own programs without mandating specific approaches. Work with processors to develop appropriate training programs.
2. Subsidize training partnerships with industry and academia. The primary focus of such training should be to assist small and very small processors in areas of GMP implementation, food safety understanding, and label creation.
3. Improve the training of FDA field staff and their state inspection partners to provide more consistent product-specific food safety guidance during interactions with industry. There are currently frequent inconsistencies from inspection to inspection or between geographical areas. A possible pattern for improving consistency would be to follow the certification process that is currently used for the Interstate Milk Shippers inspectors.

### Additional Observations

In addition, NWFPA would like to offer some specific comments on issues raised at the FDA publications and public meetings on this topic:

#### *ERG Report*

- ?? One of the most frequently mentioned preventive controls by the ERG experts include third party or in-house audits. NWFPA would like to point out that audits should not be increased as their occurrence at most food processing facilities has reached the point of impeding productivity without adding food safety value to the operation. In 1997, NWFPA surveyed members on the number of third party and customer audits conducted per plant per year; on average, the number of audits by outside auditors, not including state and federal regulatory inspections, was eight per year/per plant. By anecdotal account, this number has increased substantially. While a current survey was not possible in the timeframe for comments given by FDA, a casual estimate would increase the 1997 survey estimate by 25-50 percent. With regulatory audits, food processors are audited for CGMPs, on average, more than once a month. More auditing cannot be expected to increase compliance and can only increase the financial burden on food processors through lost staff time and productivity. This financial burden increases as the size of the operation decreases, thus smaller processors are hit hardest.
- ?? Risk scores reported by the ERG vary greatly across and within food sectors. This underscores the need for product-specific guidance based on high risk factors. It

also suggests that factors be broken out by specific causative factors. For instance, “deficient employee training” must be analyzed for product- and process-specific training elements needed. This does not lend itself to the “universal preventive controls” suggested by FDA.

- ?? Smaller processors tend to account for more GMP non-compliance than larger food processors. NWFPA concurs with this observation per the points made above in Small Processor Compliance Challenges. This suggests that the problem does not lie with inadequacies in regulations and guidance, but with the skills and abilities of small processors to comply with them.

#### *Mandatory HACCP, SSOP Programs*

Mandatory HACCP for the general food industry is not necessary, appropriate, or even desirable. Prescriptive programs tend to stifle innovation toward more effective food safety systems. Standards should remain flexible and outcome oriented.

- ?? FDA does not currently have the resources to manage existing mandatory HACCP programs in seafood and juice adequately. Expansion of mandatory HACCP across the industry would be prohibitive.
- ?? Processors have observed that training of inspectors in current mandatory HACCP programs is inadequate and inconsistent, which results in substantial variation from one inspection to the next and poor understanding on the part of inspectors about the need for and the relative importance of control points.
- ?? The FDA changes HACCP policies with inadequate education to industry. The result is high non-compliance rates during inspections because conditions that were non-violative in one inspection become violations in the next.
- ?? Certain CCP policies (e.g., temperature monitor during transport in the seafood HACCP program) fall outside the control of the processor, yet are required by the HACCP regulations. In the example given, large processors may be able to influence transport service providers to provide adequate monitoring during transport, but small processors cannot. In general, the smaller the processor the smaller the sphere of influence for conditions outside their control and the larger the sphere of conditions outside their control.
- ?? Most processors, even small processors, have voluntary HACCP and SSOP programs required by further processing or retail customers.
- ?? Very small processors tend to be the industry sector where good food safety programs (including HACCP and SSOPs) are lacking, hence the sector with the poorest CGMP compliance record. Current regulations are sufficient to produce safe food products. Mandatory HACCP regulations will not solve the problem of non-compliance; they will only add to the over-burdened condition of FDA resources with additional layers of bureaucracy.

#### *Allergen-based recall issues*

- ?? FDA should support improved science on low dose allergen exposure.
  - To facilitate policy development consistent with the level of allergens needed to induce a response in sensitive individuals
  - Reduce recall levels for the presence of undeclared allergens by preventing unneeded recalls for allergens below threshold levels.

?? FDA needs to accelerate approval of test kits for food allergens suitable to a manufacturing environment and within the sensitivity range equal to response levels in sensitive individuals

Conclusion

Revisions to Current Good Manufacturing Practices are not necessary at this time. Current regulations and guidelines cover the range problems that experts have identified, including those issues in the 'pipe line', such as allergens. Training and providing an incentive for a culture of compliance, especially for smaller processors, is the key to reduction of food safety related incidents and recalls.

The Northwest Food Processors Association appreciates the open process that the FDA has created to discuss this issue with stakeholders. The agency has made a strong effort to reach out across the country where small and very small processors are able to be part of the process. Thank you for this opportunity to participate.

Sincerely,

Connie Kirby  
Director, Scientific and Technical Affairs