NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

April 24, 2003

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Dockets Management Branch (HF A-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

RE: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539; Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures- Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

Dear Sir/Madam:

The National Food Processors Association (NFPA) welcomes this opportunity to provide comments on the above referenced Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures- Scope and Application. NFPA is committed to the important goal of promoting and protecting public health and is striving to work closely with the Food and Drug Administration (FDA) as regulations are being developed to respond appropriately to security measures without undue disruption to industry operations.

1350 I Street, NW
Suite 300
Washington, DC 20005
202-639-5900

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA members import ingredients for further processing and export finished processed food products globally and will, consequently, be affected by this rulemaking.

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

The following comments on the above noted draft guidance are submitted on behalf of the NFPA food industry members. NFPA has had numerous discussions with the FDA, via the Industry Coalition and directly with Center for Food Safety and Nutrition (CFSAN) representatives over the past three

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years in order to increase the awareness of issues in compliance within the food industry. This new scope guidance reflects a workable approach to the food industry. NFPA members agree with the risk-based approach to compliance as it reflects the current approach used in the juice and seafood operations that employ Hazard Analysis and Critical Control Points (HACCP). By applying a risk-based approach, the industry can focus its attention on the most critical food safety records/data. This allows different records to be handled according to risk rather than all records being given equal weight. For example, shipping and distribution records versus thermal process records. One way to assign levels of risk would be to first focus on those products that present greatest risk to the consumer (e.g. Low Acid Canned Foods versus cereal products) followed by a focus on those electronic data records that are most associated with assuring the safety of the product. This approach will also allow companies to plan out their capital spending in phases by addressing the high-risk areas first and then moving on down the list. In some cases, there may not be a need to do anything more than what is currently done because there is no risk to food safety or the public health.

Integrating risk based processes into Part 11 and computer system validation, will take time and this reality should be clearly recognized in FDA's plans for future guidance, enforcement and internal training. NFPA strongly supports the open dialogue with FDA and has a vested interest in developing sound approaches to managing and maintaining electronic documents. NFPA is pleased to see that FDA has withdrawn the Compliance Policy Guide and will be exercising discretion on a case-by-case basis prior to taking regulatory action.

NFPA looks forward to the finalization of this draft guidance as a first step towards a reasonable approach to Part 11 Compliance. We look forward to a continuing discussion with FDA on areas of mutual interest.

Sincerely,

Sia Economides
Acting Center Director
Center for the Development of Research
Policy & New Tech.

Allen Matthys
Vice President
State & Federal Regulations