NFPA
The Food Safety People

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

July 2, 2001

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

[Docket No.01N-0174] Agency Information Collection Activities; Proposed Collection; Comment Request; Recall Regulations
66 *Federal Register* 21767-21768, May 1, 2001

Dear Sir or Madam:

NFPA is the voice of the $460 billion food processing industry on scientific and public policy issues involving food safety, 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's 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 has been a leading food industry advocate on issues dealing with food safety, including crisis management matters related to the recall of food products from the marketplace in order to protect against foodborne illnesses. NFPA provides assistance to our members in those infrequent instances when problems resulting in the potential for a recall occur.

In the May 1 *Federal Register* (66 FR 21767) FDA published a notice soliciting comments on FDA's recall regulations (guidelines) with respect to requirements for submission of recall information to FDA. The request was related to the Paperwork Reduction Act and the requirement that agencies obtain approval from OMB for each collection of information.

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Under 21 CFR 7, which sets forth guidelines on recalls of FDA-regulated products, manufacturers are required to undertake the following activities that require reports or records:

- Developing a recall strategy (actions or procedures required to manage the recall) (Sec. 7.42);
- Providing FDA with complete details of the recall including reasons for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, copy of any recall communication(s), and a contact official (Sec. 7.46);
- Notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (Sec. 7.49);
- Submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluating return reply cards, effectiveness checks and product returns (Sec. 7.53); and
- Providing the opportunity for a firm to request in writing that FDA terminate the recall (Sec. 7.55).

Using the 1,933 recalls in 2000, FDA estimated the total annual industry burden to collect and provide the above information is 84,665 hours. The breakdown for the hours was given as follows:

TASK (21 CFR SECTION)	HOURS PER RESPONSE	TOTAL HOURS
RECALL STRATEGY (7.42)	1.8	3,479
DETAILS OF RECALL (7.46, 7.49)	4.0	7,732
STATUS REPORTS (7.53)	36.0	69,588
TERMINATION REQUEST (7.55b)	2.0	3,866
TOTAL	**43.8**	**84,665**

With respect to the above collection of information, FDA invited comments on several questions (see below).

NFPA submits the following comments on the docket referenced above.

GENERAL COMMENTS

The requirements and guidelines set forth by FDA for recalls are generally fair and appropriate. However, we believe there are changes that can make the recall reporting process more efficient, as indicated below and in our response to the specific questions.

FDA is too slow in determining the recall classification and notifying the firm. We find that our members' consignees, when contacted about the need to recall a product, immediately want to know how the recall has been classified by the regulatory agency. A Class I recall warrants a more urgent response than a Class II or Class III recall.

FDA's estimate of time expended was low (see #2 below).

For recalls other than Class I, summaries rather than the detail should be sufficient. Moreover, we do not believe the requirement for periodic status reports is essential – in most instances a final report after the recall has been completed should suffice.

RESPONSE TO QUESTIONS

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

The proposed collection of information is probably necessary for FDA to do its job. However, for recalls that are not Class I, summaries of the categories of information rather than detailed lists would be just as effective, especially in cases where the firm is cooperating fully, which is most of the time. It is our understanding that in some recalls, NFPA members have been providing the district with such summaries instead of massive printouts of each account. This has worked well.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

NFPA recognizes that each recall is a unique situation, and that some companies may be more efficient than others in gathering the required information. Thus there are likely to be a wide range of experiences with regard to the time involved in obtaining the required information. However, based on our experience with companies conducting recalls, we believe that the time required to collect the data has been underestimated.
The minimum estimated time based on our experiences with past recalls is as follows:
Recall Strategy: 15 hours
Details of recall: 20 hours
Status reports: 40 hours
Termination request: 10 hours
Again, these are minimum estimates. The actual number of hours is influenced by other circumstances such as product return/destruction/reconditioning decisions. This does not include meeting time to investigate and trouble-shoot.

Accordingly, we request that the Agency reissue its estimates in the chart for FY2000 as follows:

TASK (21 CFR SECTION)	HOURS PER RESPONSE	TOTAL HOURS
RECALL STRATEGY (7.42)	15	28,995
DETAILS OF RECALL (7.46, 7.49)	20	38,660
STATUS REPORTS (7.53)	40	77,320
TERMINATION REQUEST (7.55b)	10	19,330
TOTAL	**85**	**164,305**

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; Establish a process to submit reports via email. This might involve the use of pre-developed questionnaires that would outline the specific information desired. However, in order for effective electronic submission of information, plants should not be restricted to use of the questionnaire, as they may have generated spreadsheets of data that would easily be submitted electronically; having to transfer the data to a questionnaire could result in errors.

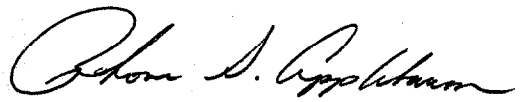
(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

- As noted in 3, electronic submission of information to FDA would minimize the burden of data collection and submission. Companies are already collecting the data that FDA requires in order to track the progress and effectiveness of the recall.
- Provide email addresses of recall coordinators and their back-ups to provide additional communication line.
- The FDA Website should clearly provide Recall Coordinator contact information; this information should be kept up to date.
- Allow Processing Authorities to authorize reconditioning/destruction of thermally processed low acid and acidified foods in hermetically sealed containers with a summary to FDA. As stated above, in most recall situations, summaries and progress reports to FDA should be satisfactory.

CONCLUSIONS

In summary, NFPA believes that the information collected during a recall is necessary to effectively track the recall. However, in most instances a summary of the data would provide FDA with sufficient information to verify the company's recall is effective. Data submission should be less frequent for Class II and Class III recalls. Electronic data submission could reduce the burden on both industry and the FDA, and provide more timely and legible information.

Sincerely,



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