

## **Survey of Food Manufacturers for Year 2000 Compliance**

### **A. Justification**

#### **1. Need for Information**

Emergency clearance is requested for the collection of information from food manufacturers in several high risk food safety areas that have been selected to confirm their operations as being Year 2000 compliant. Emergency clearance is requested because the proposed information collection is required as soon as possible in order to assess their vulnerability to Year 2000 problems and to take corrective actions, if necessary, in advance of January 1, 2000. The existence of a Year 2000 date problem in food industry could pose potentially serious health and safety consequences.

#### **2. How Information Will Be Used**

Through information provided by the contract telephone interviewer, food manufacturers will be asked to provide a status on their Year 2000 readiness. They will also be asked if they have contingency plans. The telephone survey will also ask if they have tested, verified, and certified their systems. The request will also ask for a single point of contact at the manufacturer to discuss the information.

The manufacturer will provide verbal responses during the telephone interview of the information to the FDA contractor. The provision of information will signify that the information provided is true to the best of the manufacturer's knowledge. The information will be used for possible FDA inspectional follow-up, if it indicates potential unsafe food manufacturing situations. It will also provide an opportunity for manufacturers to communicate and better serve customers in a responsible and proactive manner, and avoid the necessity for manufacturers and vendors to field numerous calls and letters from individual organizations.

#### **3. Use of Improved Information Technology**

The information collected will serve as the basis of industry and consumer directed materials that address FDA's food industry findings. These materials will be posted on FDA's web site that contains Y2K information. This use will reduce the burden to the government and industry and consumer groups, since the materials will provide them with a single source of current food industry Y2K status.

#### **4. Efforts to Avoid Duplication**

The telephone interview and the information request for compliant facilities will be sent on behalf of the agency, thus eliminating duplication.

#### **5. Small Businesses**

In the collection of manufacturing information, facilities are asked to identify the Year 2000-compliance status. As part of their preparation for the Year 2000, manufacturers should already have conducted process evaluation and should have this information readily available. They do not need to perform additional testing or assessments to respond to this collection of information. Furthermore, the information requested, along with the compliance status, includes only information needed to adequately identify the facility. The burden reduction is true for all facilities but applies more significantly to small businesses.

#### **6. Consequences if Information is Not Collected**

This information is needed to prevent any potentially adverse health and safety consequences due to unsafe food processing as a result of the Year 2000 date problem. Without this additional information, FDA will not be able to adequately assess the food industry's Year 2000 vulnerability. A single collection will provide the needed information in the most efficient and timely manner and therefore protect the health and safety of the public.

#### **7. Special Circumstances**

Not applicable.

## **8. Consultation**

The Emergency Federal Register Notice will provide an opportunity for public comment.

## **9. Remuneration**

There is no remuneration of respondents.

## **10. Confidentiality**

The letter will inform manufacturers that the information they provide is for Agency assessment purposes only.

## **11. Sensitive Questions**

The survey will not request sensitive information.

## 12. Burden Estimates

Table 1--Estimated Annual Reporting Burden<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
250	1	250	1	250

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents: Manufacturers of food products.

Estimated Processing and Preparation Time for Large Facilities: 1.5 hours.

Estimated Processing and Preparation Time for Small Facilities: 0.5 hours.

Estimated Total Annual Burden: 250 hours.

Estimated Average Burden by Manufacturer: 1 hour

The estimated total annual burden levied on respondents for this collection of information is derived from estimates of the number of manufacturers of Year 2000-vulnerable facilities and the estimated amount of time needed for reporting.

Based on FDA establishment inventory lists the number of food manufacturing facilities in the high risk food safety areas is 2619. A sample of 250 firms will be surveyed.

The manufacturers are already encouraged to assess the Year 2000 compliance of their firms to satisfy business, liability and regulatory concerns. Therefore, the burden estimate assumes that facilities have developed information on the Year 2000 compliance status of their products independent of this request. The burden estimate includes simply the time to provide information, not the time to assess the Year 2000 compliance. Information may be provided to the government as paper record.

Facilities with large number of products will require more effort. This may be estimated by 90 manufacturers requiring 1.5 hours of preparation and 160 manufacturers with smaller product lines requiring 0.5 hours of preparation, for a total of 215 hours.

The average hours per response (one response per facility) is equal to the estimated total hours (215) divided by the number of manufacturers (250), or 0.8 hours per manufacturer. This was rounded up to the next whole hour, or, an estimated 1 hour per response.

At a cost of \$50.00 per hour, the estimated cost to respondents is \$1,250. Note that the actual labor costs incurred by manufacturers for much of this effort will likely be less than \$50.00 per hour.

### **13. Other Costs to Respondents**

No additional costs to the respondents are identified.

### **14. Government Costs**

The estimated contracted cost to the government for this collection and the necessary follow-up is \$30,000.

This includes the random selection of the firms to be surveyed, the preparation of the questionnaire, the telephone interview and recording of the information, the analysis of the responses, and the preparation and delivery of the survey summary.

### **15. Change in Burden**

This is a new information collection resulting in a single time burden increase.

### **16. Plans for Analysis and Publication**

Summary of survey results will be published by FDA in industry and consumer directed materials addressing Y2K concerns.

### **17. Display of Expiration Date**

The expiration date will be displayed.

### **18. Exceptions to Certification**

There are no exceptions to certification.