

DATES: Comments concerning this notice and the interim guidelines must be received by October 6, 1997.

ADDRESSES: Requests for a copy of these documents should be sent to the attention of Ms. Kim E. Jenkins, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE Atlanta, Georgia 30333. Requests for the documents must be in writing.

Comments on this notice should bear the docket control number ATSDR-123 and should be sent to the attention of Dr. Jim Holler, Agency for Toxic Substances and Disease Registry, Division of Toxicology, Emergency Response and Scientific Assessment Branch, 1600 Clifton Road, NE Mailstop E-29, Atlanta, Georgia 30333.

Comments on this notice will be available for public inspection at the Agency for Toxic Substances and Disease Registry, Building 4, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m., Monday through Friday, except for legal holidays. Because all public comments are available for public inspection, no confidential business information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher T. De Rosa, Director, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE Mailstop E-29, Atlanta, Georgia 30333, telephone (404) 639-6300.

SUPPLEMENTARY INFORMATION: This interim policy guideline provides a description of ATSDR's current approaches and judgments regarding hazards posed by the presence of TCDD and its less toxic dioxin-like congeners, the CDDs and CDFs, in residential soils. Likely users of this interim policy guideline include health assessors at ATSDR and in the States, and ATSDR partners including relevant Federal, State, and local health and environmental entities, and concerned community groups who may be involved in a range of health assessment and risk management decisions.

The technical support document is intended to serve as technical background and support for the agency interim policy guideline and, to the extent practicable, harmonize such efforts with those of other Federal agencies and relevant organizations. This document reflects an assessment of current practice within the agency and defines the appropriate roles of professional judgment and emerging scientific principles in ATSDR's public

health assessments of exposures to dioxin and dioxin-like compounds.

These guidelines and procedures apply to human exposure by direct ingestion of soils contaminated with dioxin and dioxin-like compounds in residential areas and may not be appropriate for exposure by other routes or media. This guidance will be evaluated in the future in view of new data that may become available.

Dated: July 31, 1997.

Georgi Jones,

*Director, Office of Policy and External Affairs,
Agency for Toxic Substances and Disease
Registry.*

[FR Doc. 97-20740 Filed 8-6-97; 8:45 am]

BILLING CODE 4163-70-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0040]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Food Safety Practices of Food Processing Firms—New Collection

FDA is evaluating the marginal costs of requiring food processors to use Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is already required for seafood processors, and FDA is considering whether to issue regulations requiring HACCP for processors of other foods under the agency's jurisdiction. The analysis of marginal costs requires information about the prevalence of specific HACCP systems and practices among food manufacturers and repackers. FDA will collect this information through an anonymous voluntary survey of a random sample of food processors. Additionally, through a series of onsite visits to selected processors, a contractor will collect information on the marginal cost of various procedures required to operate a HACCP system. The information will help the Center for Food Safety and Applied Nutrition determine the baseline level of HACCP use from which to estimate the economic costs to the industry of mandatory HACCP regulations for foods other than seafood. FDA will use this information in tailoring any HACCP regulations that may issue so that costs and benefits of such regulations are appropriately considered.

In the **Federal Register** of February 28, 1997 (62 FR 9194), the agency requested comments on the proposed collection of information. FDA received one comment that supported the implementation of HACCP but questioned several aspects associated with the proposed survey. First, the comment questioned whether the survey would yield "reliable" or "practical" data because it was difficult to interpret what "critical control point" means and what the term "hazards" includes. The comment stated "it is difficult to identify costs attributable only to HACCP in facilities where the system has been implemented." This comment is not relevant to the survey because the survey does not ask processors about critical control points, hazards, or costs of HACCP but, instead, seeks information on the processes and controls currently in place.

The comment also stated that FDA should use other sources of data. In fact, FDA is already planning to use multiple sources of information to estimate the marginal costs of requiring HACCP. These sources include interviews with food processing firms and information taken from pilot plants that are already using HACCP, and comments received during other HACCP rulemakings.

Finally, the comment stated that FDA's reporting burden estimate is too low because successful telephone contact typically requires multiple attempts. FDA disagrees with this

comment for two reasons: First, the burden of making multiple attempts to contact a potential survey respondent will fall on FDA, not on the potential respondent. Second, the burden

estimate already includes time to be spent by respondents to set up a subsequent interview.

FDA estimates the burden of this survey as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Part 1—Computer Assisted Telephone Interview (CATI)					
Respond to initial recruitment telephone call	1,231	1	1,231	0.2	246.2
Receive and read introductory letter, key term definitions	1,231	1	1,231	0.25	307.75
Obtain data to prepare for the telephone interview	1,231	1	1,231	0.35	430.85
Respond to telephone interview	1,231	1	1,231	0.5	615.50
Totals		1			1,600.3
Part 2—Onsite Cost Interview					
Receive initial recruitment telephone call	17	1	17	0.2	3.4
Receive and read introductory letter and materials	17	1	17	0.25	4.25
Obtain data to prepare for the site visit	17	1	17	0.5	8.5
Respond to questions during site visit	17	1	17	3.0	51.0
Followup questions	17	1	17	0.25	4.25
Total burden hours, onsite interviews					71.4

There are no capital costs or operating and maintenance costs associated with this collection of information.

The total burden hours for Part 1—CATI and Part 2—Onsite Cost Interview are 1,671.7.

The burden hour estimates are based on a pretest conducted with three focus groups.

Dated: July 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-20754 Filed 8-6-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0317]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealers Certificate—(OMB Control Number 0910-0021)—Reinstatement

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish

industry in the National Shellfish Sanitation Program (NSSP). The NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate." FDA uses this information to publish the "Interstate Certified Shellfish Shippers List," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, the NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.