

unacceptable. Rather, the agency is leaving it to each firm's discretion to maintain appropriate documentation to demonstrate that the food was so packed or processed.

Examples of documentation which FDA anticipates will serve this purpose consists of documentation associated

with packing codes, batch records, and inventory records. These are types of documents that many food processors routinely generate as part of their basic food-production operations.

Description of Respondents: The likely respondents to this collection of information are firms in the produce

and food-processing industries that handle food products that may contain residues of vinclozolin after the tolerances for this pesticide chemical have been revoked.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN ¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
307	1	307	3	921

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

No. of Recordkeepers	Annual Frequency per Response	Total Annual Records	Hours per Recordkeeper	Total Hours
31	1	31	16	496

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

Estimates for the annual reporting burden were determined by using the maximum number of samples collected throughout a year that FDA believes might be found to contain vinclozolin residues. The estimated annual reporting burden was determined using the total number of samples historically tested for vinclozolin and the number of samples that historically contained vinclozolin residues. These numbers established a rate of samples expected to contain vinclozolin residues. This rate, when applied to the number of potentially affected establishments, was used to calculate the number of expected respondents.

When determining the estimated annual recordkeeping burden, FDA estimated that most firms (at least 90 percent) maintain (or maintain access to) documentation such as packing codes, batch records, and inventory records as part of their basic food production and/or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms which may not currently be maintaining this documentation to develop and maintain (or maintain access to) documentation such as batch records, inventory records, sales records, and distribution records.

III. Comments

Interested persons should submit to the Dockets Management Branch (address above) written comments regarding the draft guidance by September 10, 2001, to ensure adequate consideration of the comments of the comments in the preparation of a revised guidance, if warranted. However, interested persons may

submit written comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Submit to the Dockets Management Branch written comments concerning this collection of information by September 10, 2001. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance is available on the Internet at <http://www.fda.gov>.

Dated: June 29, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-372]

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

AGENCY: Health Care Financing Administration, DHHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the

following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Annual Report on Home and Community Based Services Waivers and Supporting Regulations in 42 CFR 440.181 and 441.300-.305; *Form No.:* HCFA-372 (OMB# 0938-0272); *Use:* States request waivers in order for beneficiaries to have the option of receiving hospital services in their homes. States with an approved waiver under section 1915(c) of the Act are required to submit the HCFA-372 or HCFA-372(S) annually in order for HCFA to: (1) Verify that State assurances regarding waiver cost-neutrality are met, and (2) determine the waiver's impact on the type, amount and cost of services provided under the State plan and health and welfare of recipients; *Frequency:* Annually; *Affected Public:* State, local or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 243; *Total Annual Hours:* 18,225.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 11, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of the Technical/ Agency Draft Florida Manatee Recovery Plan, Third Revision for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability and public comment period.

SUMMARY: We, the Fish and Wildlife Service, announce the availability for second public review of the updated Technical/Agency Draft of the Florida Manatee Recovery Plan, Third Revision. We solicit review and written comments from the public on this draft plan.

DATES: We must receive comments on the draft recovery plan on or before August 9, 2001 to receive consideration by us.

ADDRESSES: You may obtain a copy of the draft recovery plan by contacting Bill Brooks by electronic mail (e-mail) at fw4_es_jacksonville@fws.gov or by calling (904) 232-2580, extension 104 or at Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive, South, Suite 310, Jacksonville, Florida, 32216. If you wish to comment, you may submit your comments by any one of several methods:

1. You may submit written comments and information to the Field Supervisor, at the above address.

2. You may hand-deliver written comments to our Jacksonville Field Office, at the above address, or fax your comments to (904) 232-2404.

3. You may send comments by e-mail to the Field Supervisor at fw4_es_jacksonville@fws.gov. For directions on how to submit electronic filing of comments see the "Public Comments Solicited" section.

Comments and materials received are available on request for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Bill Brooks (see **ADDRESSES** section).

SUPPLEMENTARY INFORMATION:

Background

The West Indian manatee, *Trichechus manatus*, is currently listed as endangered throughout its range for both the Florida and Antillean subspecies (U. S. Fish and Wildlife Service 1967). The Florida manatee lives in freshwater, brackish, and marine habitats. Submerged, emergent, and floating vegetation are their preferred food. During the winter, cold temperatures keep the population concentrated in peninsular Florida and many manatees rely on the warm water from natural springs and power plant outfalls. During the late spring and summer, they expand their range and are seen on infrequent occasions as far north as Rhode Island on the Atlantic Coast and as far west as Texas on the Gulf Coast.

The most significant threat presently facing manatees in Florida is death and serious injury from boat strikes. In the long term, the greatest challenge to manatee recovery is maintaining adequate sources of warm water so the species can survive the cold in winter. The availability of warm-water refuges for manatees is uncertain due to deregulation of the power industry in Florida, and the lack of secure minimum flows at the natural springs on which many manatees depend. Long term survival also depends on maintaining the integrity of ecosystems and habitat sufficient to support a recovered manatee population.

Restoring an endangered or threatened animal or plant to the point where it is again a secure, self-sustaining member of its ecosystem is a primary goal of the endangered species program. To help guide the recovery effort, we are preparing recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for conservation of the species, establish

criteria for downlisting or delisting them, and estimate time and cost for implementing the recovery measures needed.

The Endangered Species Act of 1973, as amended (16 U.S.C. *et seq.*) (Act), requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act, as amended in 1988, requires that public notice and an opportunity for public review and comment be provided during recovery plan development. We will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. We and other Federal agencies will take these comments into account in the course of implementing approved recovery plans.

We developed the initial recovery plan for West Indian manatee in 1980. This plan focused primarily on manatees in Florida, but included Antillean manatees in Puerto Rico and the U.S. Virgin Islands. In 1986, we adopted a separate recovery plan for manatees in Puerto Rico. To reflect new information and planning needs for manatees in Florida, we revised the original plan in 1989 and focused exclusively on the Florida manatee. This first revision covered a 5-year planning period ending in 1994. We revised and updated the plan again in 1996, which again covered a 5-year planning period ending in 2000. In 1999, we initiated the process to revise the plan for a third time. We established an 18-member recovery team made up of the public, agencies, and groups that have an interest in manatee recovery and/or could be affected by proposed recovery actions, to draft this revision. Extensive public comments on the November 30, 2000 Technical/Agency Draft resulted in significant changes to the recovery criteria. We felt these changes were significant enough to warrant another public review of the Technical/Agency Draft as set forth in this Notice.

In the 20 years since approval of the original recovery plan, a tremendous amount of knowledge of manatee biology and ecology has been achieved and significant protection programs have been implemented, through the guidance provided by the recovery planning process. This Technical/Agency Draft of the Florida Manatee Recovery Plan, Third Revision reflects many of those accomplishments, addresses new threats and needs, and specifically addresses the planning requirements of the Act through 2006. The Florida Manatee Recovery Team