3835, 301–436–1165, FAX 301–436–2965, or e-mail: mary.ditto@fda.hhs.gov.
SUPPLEMENTARY INFORMATION:
I. Background
In the Federal Register of August 2, 2002 (67 FR 50578), the U.S. Office of Science and Technology Policy (OSTP) proposed Federal actions to update field test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA’s voluntary consultation procedures for foods derived from new plant varieties (referred to as “biotechnology consultation” in the case of bioengineered plants).1 FDA is issuing this guidance document to address this possibility.

In the Federal Register of November 24, 2004 (69 FR 68381), FDA made available a draft guidance for industry entitled “Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use” and gave interested parties an opportunity to submit comments by January 24, 2005. The agency considered received comments as it finalized this guidance.

This guidance describes the procedure for early food safety evaluation of new proteins produced by new plant varieties that are under development for food use, including, for example, such proteins produced in bioengineered plants. This guidance also provides information to sponsors and developers about submitting their evaluation to FDA.

FDA is issuing this guidance document as a level 1 guidance consistent with FDA’s good guidance practices regulation § 10.115 (21 CFR 10.115). This guidance represents FDA’s current thinking on the early food safety evaluation of new non-pesticidal proteins produced by new plant varieties intended for food use. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see FOR FURTHER INFORMATION CONTACT). If you cannot identify the appropriate FDA staff, call the telephone number listed in the title page of the guidance.

II. Paperwork Reduction Act of 1995
This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the guidance was approved under OMB Control No. 0910–0583.

III. Comments
Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this guidance at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access
Persons with access to the Internet may obtain the guidance document at either http://www.cfsan.fda.gov/guidance.html or http://www.fda.gov/cvm/Guidance/published.htm.

Dated: June 14, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
[FR Doc. E6–9688 Filed 6–20–06; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY
Bureau of Customs and Border Protection
Agency Information Collection Activities: Petroleum Refineries in Foreign Trade Subzones
AGENCY: Customs and Border Protection, Department of Homeland Security.
ACTION: Proposed collection; comments requested.
SUMMARY: Customs and Border Protection (CBP) of the Department of Homeland Security has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995: Petroleum Refineries in Foreign Trade. This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with a change to the burden hours. This document is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the Federal Register (71 FR 12383–12384) on March 10, 2006, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10.
DATES: Written comments should be received on or before July 21, 2006.
ADDRESSES: Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to the Office of Management and Budget Desk Officer at Nathan.Lesser@omb.eop.gov.
SUPPLEMENTARY INFORMATION: The Bureau of Customs and Border Protection (CBP) encourages the general public and affected Federal agencies to submit written comments and suggestions on proposed and/or continuing information collection requests pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Your comments should address one of the following four points:
(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency/component, including whether the information will have practical utility;
(2) Evaluate the accuracy of the agencies/components estimate of the burden of the proposed collection of
information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Petroleum Refineries in Foreign Trade Subzones
OMB Number: 1651–0063.
Form Number: None.
Abstract: The Petroleum Refineries in Foreign Trade Subzones is a rule that amended the regulations by adding special procedures and requirements governing the operations of crude petroleum and refineries approved as foreign trade zones.

Current Actions: This submission is to extend the expiration date with a change to the burden hours.
Type of Review: Extension (with change).

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 81.
Estimated Time Per Respondent: 1000 hours.
Estimated Total Annual Burden Hours: 81,000.
Estimated Total Annualized Cost on the Public: N/A.

If additional information is required contact: Tracey Denning, Bureau of Customs and Border Protection, 1300 Pennsylvania Avenue, NW., Room 3.2.C, Washington, DC 20229, at 202–344–1429.

Tracey Denning, Agency Clearance Officer, Information Services Branch.

[FR Doc. E–9759 Filed 6–20–06; 8:45 am]
BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

Information Collection Renewal To Be Sent to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; OMB Control Number 1018–0124; Migratory Bird Subsistence Harvest Household Survey

AGENCY: Fish and Wildlife Service, Interior.
ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) will ask OMB to renew approval for the information collection associated with our migratory bird subsistence harvest household survey. The current OMB control number for this information collection is 1018–0124, which expires on October 31, 2006. We will request that OMB renew approval of this information collection for a 3-year term. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this information collection.

DATES: You must submit comments on or before August 21, 2006.

ADDRESSES: Send your comments on the information collection to Hope Grey, Information Collection Clearance Officer, Fish and Wildlife Service, MS 222–ARLSQ, 4401 North Fairfax Drive, Arlington, VA 22203 (mail); hope.grey@fws.gov (e-mail); or (703) 358–2269 (fax).

FOR FURTHER INFORMATION CONTACT: To request additional information about this information collection request, contact Hope Grey at one of the addresses above or by telephone at (703) 358–2482.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). Federal agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The Migratory Bird Treaty Act (16 U.S.C. 703–712) and the Fish and Wildlife Act of 1956 (16 U.S.C. 742d) designate the Department of the Interior as the key agency responsible for managing migratory bird populations that frequent the United States and for setting harvest regulations that allow for the conservation of those populations. These responsibilities include gathering accurate geographical and temporal data on various characteristics of migratory bird harvest. We use those data to promulgate harvest regulations. Annually, we adjust harvest regulations as needed to provide a maximum of subsistence harvest opportunity while keeping migratory bird populations at desired levels.

The Migratory Bird Treaty Act Protocol Amendment (1995) (Amendment) provides for the customary and traditional use of migratory birds and their eggs for subsistence use by indigenous inhabitants of Alaska. The Amendment, however, states that its intent is not to cause significant increases in the take of species of migratory birds relative to their continental population sizes. A May 20, 1996, submittal letter from the Department of State to the White House accompanied the Amendment and specified the need for harvest monitoring. The letter stated that the Fish and Wildlife Service, the Alaska Department of Fish and Game, and Native organizations cooperatively would collect harvest estimates within the subsistence eligible areas. Harvest survey data help ensure that customary and traditional use of migratory birds and their eggs for subsistence use by indigenous inhabitants of Alaska does not significantly increase the take of species of migratory birds relative to their continental population sizes.

From 1989 to 2004, we monitored subsistence harvest in Alaska through the use of annual household surveys in the most heavily used subsistence harvest areas; e.g., Yukon–Kuskokwim Delta. In 2004, we began monitoring subsistence harvest in subsistence eligible areas Statewide. We presently rotate survey areas due to budget constraints. This monitoring enables us to track significant changes or trends in levels of harvest and user participation.

We gather information on the annual subsistence harvest of 54 species of birds (including geese, ducks, swans, cranes, loons, seabirds, shorebirds, and upland game birds) through surveys of households in each village and provide survey forms to randomly selected households. We combine the estimates of harvest per household with the complete list of households in the subsistence eligible areas to obtain estimates of the total annual harvest. We use four forms to collect the harvest information. We will aggregate all information collected and use it only for statistical purposes. We do not arrange or retrieve forms by a personal identifier.

Title: List of Occupied Households—Village Harvest Survey Household Enrollment Form
OMB Control Number: 1018–0124.
Form Number: 7–FW–100.
Frequency of Collection: Once per year.