considered approved as alternative methods of compliance for this AD.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from Small Airplane Directorate.

- (e) All persons affected by this directive may obtain copies of the document referred to herein upon request to Pilatus Britten-Norman, Ltd., Bembridge, Isle of Wight, United Kingdom, PO35 5PR; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.
- (f) This amendment supersedes AD 97-03-03, Amendment 39-9909.

Issued in Kansas City, Missouri, on June 27, 1997.

James E. Jackson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

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DEPARTMENT OF COMMERCE

Bureau of the Census

15 CFR Part 30

[Docket No. 970624153-7153-01]

RIN 0607-AA23

Revision of Section 30.56(b): Conditional Exemptions for Filing Shipper's Export Declarations (SED) for Tools of Trade

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of Proposed Rulemaking and Request for Comments.

SUMMARY: The Bureau of the Census proposes to amend the Foreign Trade Statistics Regulations (FTSR) to include an exemption for exporters who currently must file a Shipper's Export Declaration (SED) for temporary exports of tools of trade. This exemption would apply whenever the tools of trade are company-owned commodities and software, accompany the employees or representatives of the exporting company, and are intended to remain outside of the country for less than one year. The current regulation only allows an exemption for filing an SED when the tools of trade are owned by individuals. This exemption will still apply.

DATES: Written comments must be submitted on or before August 6, 1997. ADDRESSES: Direct all written comments on this proposed rulemaking to the Director, Bureau of the Census, Room 2049, Federal Building 3, Washington, D.C. 20233.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to C. Harvey Monk, Jr., Chief, Foreign Trade Division, Bureau of the Census, Room 2104, Federal Building 3, Washington, D.C. 20233-6700, by telephone on (301) 457-2255 or by fax on (301) 457-2645. SUPPLEMENTARY INFORMATION: The FTSR currently exempts tools of trade that are owned by individuals from the requirement to file an SED. However, for tools of trade owned by a company rather than an individual, the FTSR provides no such exemption. Companies doing business abroad have requested that the Census Bureau review the current regulation to allow an exemption to eliminate the SED filing requirement for company-owned tools of trade that accompany employees or representatives of the

Based upon our evaluation of these customer requests, the Census Bureau is proposing to broaden the current exemption criteria for filing SEDs to include an exemption for companyowned tools of trade.

company for temporary use abroad.

Based upon reviews by the Bureau of Export Administration (BXA) and the U.S. Customs Service, the Census Bureau has determined that, for statistical purposes, it is not necessary to collect information on temporary exports of company-owned tools of trade that do not normally require an export license or that are exported without a license as specified in 15 CFR 740.9 of the BXA Export Administration Regulations (EAR). For SED filing exemption purposes, the Census Bureau will include certain provisions of 15 CFR 740.9 of the EAR in its criteria for exemptions to the SED filing requirements.

Therefore, the Bureau of the Census proposes to amend 15 CFR 30.56(b) to include an exemption to SED filing requirements for exports of companyowned tools of trade, which are reasonable kinds and quantities of commodities and software for use by employees or representatives of the company in its enterprises or undertakings abroad. Commodities and software would be eligible for export under this exemption provided that the commodities and software:

(1) Are owned by the individual or the exporting company:

(2) Accompany the individual exporter, employee or representative of the exporting company;

(3) Åre necessary and appropriate and intended for the personal and/or business use of the individual exporter, employee or representative of the company or business;

- (4) Are not for sale; and
- (5) Are returned to the United States no later than one year from the date of export.

This revision to 15 CFR 30.56(b) is being considered to increase the conditional exemptions for tools of trade owned by individuals, companies and/or businesses and to minimize the reporting burden for filing an SED.

Rulemaking Requirements

This rule is exempt from all requirements of Section 553 of the Administrative Procedure Act because it deals with a foreign affairs function (5 U.S.C. (A)(1)). However, this rule is being published as a proposed rule with an opportunity for public comment because of the importance of the issues raised by this rulemaking.

Because a notice of proposed rulemaking is not required by 5 U.S.C. 553 or any other law, a Regulatory Flexibility Analysis is not required and has not been prepared (5 U.S.C. 603(a)).

This rule has been determined to be not significant for purposes of Executive Order 12866.

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Paperwork Reduction Act

Notwithstanding any other provisions of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number.

This rule covers collections of information subject to the provisions of the Paperwork Reduction Act, which are cleared by the Office of Management Budget under OMB control numbers 0607–0001, 0607–0018, and 0607–0152.

This rule will result in a reduction of reporting-hour burden requirements under provisions of the Paperwork Reduction Act of 1995, Public Law 104– 13.

List of Subjects in 15 CFR Part 30

Economic statistics, Exports, Foreign trade, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, it is proposed that Part 30 be amended as follows:

PART 30—FOREIGN TRADE STATISTICS

1. The authority citation for 15 CFR Part 30 continues to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; Reorganization Plan No. 5 of 1950 (3 CFR 1949–1953 Camp., 1004); Department of Commerce Organization Order No. 35–2A. August 4, 1975, 40 CFR 42765.

Subpart D—Exemptions From the Requirements for the Filing of Shipper's Export Declarations

2. Section 30.56(b); is proposed to be revised to read as follows:

§ 30.56 Conditional exemptions.

* * * * *

- (b) Tools of Trade are usual and reasonable kinds and quantities of commodities and software, and their containers, that are intended for use by individual exporters or by employees or representatives of the exporting company in furthering the enterprises and undertakings of the exporter abroad. Commodities and software eligible for this exemption are those that do not normally require an export license or that are exported without a license as specified in 15 CFR 740.9 of the EAR and are subject to the following provisions:
- (1) Are owned by the individual exporter or exporting company;
- (2) Accompany the individual exporter, employee or representative of the exporting company;
- (3) Are necessary and appropriate and intended for the personal and/or business use of the individual exporter, employee or representative of the company or business;
 - (4) Are not for sale; and
- (5) Are returned to the United States no later than one year from the date of export.

Dated: June 23, 1997.

Bradford R. Huther,

Deputy Director and Chief Operating Officer, Bureau of the Census.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 97N-0218]

RIN 0910-ZA01

Consideration of Codex Alimentarius Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering the amendment of its regulations that establish procedures for review and evaluation of standards adopted by the Codex Alimentarius Commission (Codex). Codex is an international body that establishes food standards under the joint auspices of the United Nations World Health Organization (WHO) and Food and Agriculture Organization (FAO). FDA is considering whether to establish procedures for the systematic review of standards and related texts adopted by Codex. This action has the potential to enhance consumer protection with regard to foods, to promote international harmonization, to enable FDA to better meet its public health mission, and to fulfill U.S. obligations under international agreements. The agency is soliciting comments from interested persons about whether to amend agency regulations to provide procedures for consideration of Codex standards, how to best set priorities and evaluate various Codex standards for possible acceptance by FDA, and how evaluation of each such standard could be accomplished in the most transparent, efficient, and resource-effective manner. FDA also invites comments on the agency's preliminary views on these matters.

DATES: Written comments by October 6, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John W. Jones, Office of Constituent Operations (HFS-550), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4311.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA's Policy Regarding International Standards

Codex is an international food standard-setting organization composed of national Governments that establishes "standards" comparable in scope and intent to certain standards established by FDA. For the purpose of this notice, the term "standard" refers to any numerical limit, such as a tolerance, maximum residue limit or maximum use level; a commodity or food standard of identity or composition; a code of practice; a procedure; a guideline; a labeling requirement; and a method, general recommendation, or other related text that may be adopted by Codex through its formal eight-step procedure (Ref. 1, Codex Procedural Manual, Ninth ed., FAO/WHO Rome, 1995).

In a notice published in the Federal Register of October 11, 1995 (60 FR 53078), FDA articulated its policy regarding the development and use of standards with respect to the harmonization of various national and international regulatory requirements and guidelines. FDA's policy addressed specifically the conditions under which FDA plans to participate in international standard-setting organizations in the development of standards applicable to products regulated by FDA and defined the conditions under which the agency intends to use the resultant standards in fulfilling its statutory mandate to safeguard the public health.

The October 11, 1995, notice stated in part:

It is the intent of this policy to enable FDA to: (1) Continue to participate in international standards activities that assist it in implementing statutory provisions for safeguarding the public health, (2) increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve public health, and (3) respond to laws and policies such as the Trade Agreements Act and OMB Circular No. A–119 that encourage agencies to use international standards that provide the desired degree of protection.

The policy statement concluded that the agency's primary goal in participation in such standard-setting activities and use of resultant standards is to preserve and enhance its ability to accomplish FDA's public health mission, with the aim of enhancing regulatory effectiveness, providing more consumer protection with increasingly scarce government resources, and increasing worldwide consumer access to safe, effective, and high quality products.