

directed fishing for golden crab in the South Atlantic EEZ. Golden crab in or from the South Atlantic EEZ may not be retained on board a vessel possessing or using unauthorized gear.

18. In § 622.45, effective September 26, 1996, paragraph (f)(1) is added and, effective October 28, 1996, paragraphs (f)(2) through (4) are added to read as follows:

§ 622.45 Restrictions on sale/purchase.

* * * * *

(f) *South Atlantic golden crab.* (1) A female golden crab in or from the South Atlantic EEZ may not be sold or purchased.

(2) A golden crab harvested in the South Atlantic EEZ on board a vessel that does not have a valid commercial permit for golden crab, as required under § 622.17(a), may not be sold or purchased.

(3) A golden crab harvested on board a vessel that has a valid commercial permit for golden crab may be sold only to a dealer who has a valid permit for golden crab, as required under § 622.4(a)(4).

(4) A golden crab harvested in the South Atlantic EEZ may be purchased by a dealer who has a valid permit for golden crab, as required under § 622.4(a)(4), only from a vessel that has a valid commercial permit for golden crab.

19. In § 622.48, effective September 26, 1996, paragraph (g) is added to read as follows:

§ 622.48 Adjustment of management measures.

* * * * *

(g) *South Atlantic golden crab.* MSY, ABC, TAC, quotas (including quotas equal to zero), trip limits, minimum sizes, gear regulations and restrictions, permit requirements, seasonal or area closures, time frame for recovery of golden crab if overfished, fishing year (adjustment not to exceed 2 months), observer requirements, and authority for the RD to close the fishery when a quota is reached or is projected to be reached.

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 12

[T.D. 96-64]

RIN 1515-AB94

Emissions Standards for Imported Nonroad Engines

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document sets forth amendments to the Customs Regulations which conform to regulations that have already been adopted by the Environmental Protection Agency (EPA), in order to ensure the compliance of imported nonroad engines with applicable EPA emissions standards required by law.

EFFECTIVE DATE: August 27, 1996.

FOR FURTHER INFORMATION CONTACT: Leo Wells, Trade Compliance Division, (202-927-0771).

SUPPLEMENTARY INFORMATION:

Background

The Clean Air Act, as amended, (42 U.S.C. 7401 *et seq.*), which has long authorized the Environmental Protection Agency (EPA) to regulate on-highway motor vehicle and engine emissions, was amended in 1990 to extend EPA's regulatory authority to include as well nonroad engines and related vehicles and 2 equipment (see 42 U.S.C. 7521-7525, 7541-7543, 7547, 7549, 7550, 7601(a)). In brief, EPA was given authority, *inter alia*, to regulate those categories or classes of new nonroad engines and associated vehicles and equipment that contribute to air pollution, if such nonroad emissions have been determined to be significant.

To this end, the EPA has since conducted the requisite studies, and issued regulations in 40 CFR parts 89 and 90, which set emission standards for certain nonroad engines, specifically new nonroad compression-ignition engines at or above 50 horsepower (37 kilowatts) (nonroad large CI engines) as well as new nonroad spark-ignition engines at or below 25 horsepower (19 kilowatts) (nonroad small SI engines). For a complete discussion of the background and development of EPA's regulations concerning emissions standards for nonroad large CI and small SI engines, see 59 FR 31306 (June 17, 1994) and 60 FR 34582 (July 3, 1995), respectively. The Customs Regulations set forth in this document are applicable to all nonroad engines incorporated into

nonroad vehicles or nonroad equipment imported into the United States.

Nonconforming nonroad large CI engines may only be imported by independent commercial importers (ICIs) who hold valid certificates of conformity issued by the EPA (see § 12.74(c)(2), *infra*), unless an exemption or exclusion otherwise applies thereto. The ICI will be responsible for assuring that subsequent to importation, the nonroad engine is properly modified and/or tested to comply with EPA emission and other requirements over its useful life.

By contrast, no ICI program exists for nonconforming nonroad small SI engines. However, an individual may import on a single occasion up to three nonconforming nonroad small SI engines, vehicles or equipment items for personal use (and not for purposes of resale). In fact, with specific exceptions, nonconforming nonroad small SI engines, vehicles and equipment are generally not permitted to be imported for resale. After an individual's limit of three, or after the first importation, additional small SI engines, vehicles, or equipment are not permitted importation, unless an exception or exclusion otherwise so provides.

Exemptions or exclusions to the general restrictions on importing nonconforming nonroad engines are similar to those contained in § 12.73, Customs Regulations (19 CFR 12.73) for nonconforming motor vehicles and their engines, and include exemptions for repair and alteration, testing, precertification, display, national security, hardship, use in competition, and certain nonroad engines proven to be identical, in all material respects, to their corresponding U.S. versions. Furthermore, foreign diplomatic or military personnel on assignment in the U.S. may import a nonconforming nonroad engine exempt from emissions requirements. In addition, nonroad engines greater than 20 original production years old are not subject to EPA emissions requirements.

Accordingly, Customs is amending its regulations to add a new § 12.74 which conforms to the regulations that have already been adopted by EPA, in order to ensure the compliance of imported nonroad engines with applicable EPA emissions standards required by law.

Inapplicability of Public Notice and Comment and Delayed Effective Date Requirements, the Regulatory Flexibility Act, and Executive Order 12866

Inasmuch as these amendments merely conform the Customs Regulations to existing law and

regulation as noted above, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure thereon are unnecessary and pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required. Since this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Nor do these amendments meet the criteria for a "significant regulatory action" under E.O. 12866.

Drafting Information. The principal author of this document was Russell Berger, Regulations Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 12

Customs duties and inspection, Imports, Motor vehicles, Motor vehicle safety, Nonroad engines, Reporting and recordkeeping requirements.

Amendments to the Regulations

Part 12, Customs Regulations (19 CFR part 12), is amended as set forth below.

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general authority citation for part 12 continues to read as follows, and the specific authority for § 12.73 is revised by adding a reference to § 12.74 to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.73 and 12.74 also issued under 19 U.S.C. 1484, 42 U.S.C. 7522, 7601;

* * * * *

2. Part 12 is amended by revising the undesignated centerhead preceding § 12.73, and by adding a new § 12.74 following § 12.73, to read as follows:

Entry of Motor Vehicles, Motor Vehicle Engines and Nonroad Engines Under the Clean Air Act, As Amended

* * * * *

§ 12.74 Nonroad engine compliance with Federal antipollution emission requirements.

(a) *Applicability of EPA requirements.* This section is ancillary to the regulations of the U.S. Environmental Protection Agency (EPA) issued under the Clean Air Act, as amended (42 U.S.C. 7401 *et seq.*), and found in 40 CFR parts 89 and 90. Nothing in this section should be construed as limiting or changing in any way the applicability of the EPA regulations. Those regulations should be consulted for

more detailed information concerning EPA emission requirements. These requirements apply to nonroad combustion-ignition engines at or above 37 kilowatts (kW), and nonroad spark-ignition engines at or below 19 kW. For the purpose of this section, the term "nonroad engine" includes all nonroad engines incorporated into nonroad equipment or nonroad vehicles when imported into the United States.

(b) *Importation of complying nonroad engines.* (1) *Labeled engines.* Nonroad engines which in their condition as imported are covered by an EPA certificate of conformity and which bear the manufacturer's label showing such conformity and other EPA-required information shall be deemed in compliance with applicable emission requirements for the purpose of Customs admissibility and entry liquidation determinations. This paragraph does not apply to importations by independent commercial importers covered by paragraph (c) of this section.

(2) *Pending certification.* Nonroad engines otherwise covered by paragraph (b)(1) of this section which were manufactured for compliance with applicable emission requirements, but for which an application for a certificate of conformity is pending with the EPA may be conditionally released from Customs custody pending production of the certificate of conformity within 120 days of release.

(c) *Importation of nonconforming engines.*

(1) *By other than an independent commercial importer (ICI).* Except for nonroad engines imported in the particular circumstances covered by paragraphs (d)–(m) of this section, an individual or business, other than an independent commercial importer (ICI) holding a currently valid EPA certificate of conformity for the same nonroad engine class and fuel type as the engine being imported, may not enter into the United States a nonconforming nonroad engine to which EPA emissions requirements apply. Individuals and businesses may, however, arrange for the importation of nonconforming nonroad engines through an ICI. In these circumstances, the ICI will not act as an agent or broker for Customs transaction purposes unless otherwise licensed or authorized to do so.

(2) *By an ICI.* (i) *Definition.* Generally, an ICI is an importer that holds a certificate of conformity from EPA, but that lacks a contract with a foreign or domestic nonroad engine manufacturer for distributing nonroad engines into the United States market and cannot therefore export as an original

equipment manufacturer. Further specific discussion of who qualifies as an ICI is set forth in the EPA regulations.

(ii) *Procedure.* An ICI may enter into the United States certain nonroad engines, only if it holds a currently valid EPA certificate of conformity for the same nonroad engine class and fuel type as the nonroad engines being entered. A "certificate of conformity" is the document which is issued by the Administrator, EPA, to the ICI, and which entitles the ICI to import nonconforming nonroad engines into the United States, and ensure that such nonroad engines are brought into conformance with applicable EPA emissions standards. 40 CFR 89.602–96.

(d) *Importation of nonconforming spark-ignition engines at or below 19 kW.* (1) *General.* A nonconforming engine at or below 19 kW may not be imported by any person, business or ICI, except for purposes other than resale under paragraph (d)(2) of this section, or unless an exemption or exclusion applies as provided in paragraphs (e)–(m) of this section.

(2) *Importation for purposes other than resale.* Any individual may import on a one-time basis 3 or fewer nonconforming spark-ignition engines at or below 19 kW for purposes other than resale under 40 CFR 90.611. Such an engine may be conditionally admitted without prior EPA approval and without bond.

(e) *Exemptions and exclusions from emissions requirements based on age of engine.* The following nonroad engines may be imported by any person and do not have to be shown to be in compliance with emissions requirements before being entitled to admissibility:

(1) All spark-ignition engines greater than 19 kW, unless regulated under 19 CFR 12.73;

(2) All compression-ignition engines less than 37 kW;

(3) Spark-ignition engines less than or equal to 19 kW originally manufactured before the 1997 model year;

(4) Compression-ignition engines greater than or equal to 37 kW but less than 75 kW originally manufactured before January 1, 1998;

(5) Compression-ignition engines greater than or equal to 75 kW but less than 130 kW originally manufactured before January 1, 1997;

(6) Compression-ignition engines greater than or equal to 130 kW but less than or equal to 560 kW originally manufactured before January 1, 1996;

(7) Compression-ignition engines greater than 560 kW originally

manufactured before January 1, 2000; and

(8) Engines not otherwise exempt from EPA emission requirements and more than 20 years old. (Age is determined by subtracting the calendar year of production (as opposed to model year) from the calendar year of importation.)

(f) *Exemption for exports.* Nonroad engines which will be used in nonroad vehicles or equipment intended solely for export to a country which does not have in force emissions standards identical to EPA standards are exempt from applicable EPA emissions requirements if both the engine and its container bear a label or tag indicating that it is intended solely for export. 40 CFR 89.909 and 90.909. The EPA publishes in the Federal Register a list of foreign countries that have emissions standards identical to EPA standards.

(g) *Exemptions for diplomats, foreign military personnel and nonresidents.*

Subject to the conditions that they are not resold in the United States and are subsequently exported or destroyed or brought into conformity with EPA emissions requirements, the following nonroad engines are exempt from EPA emission requirements:

(1) A nonroad engine imported solely for the personal use of a nonresident importer or consignee where the use will not exceed one year and the engine subsequently will be exported; and

(2) A nonroad engine of a member of the armed forces of a foreign country on assignment in the United States, or of a member of the personnel of a foreign government on assignment in the United States or other individual who comes within the class of persons for whom free entry of nonroad engines has been authorized by the Department of State. For special documentation requirements, see paragraph (n)(4) of this section.

(h) *Exemption for repairs or alterations.* An engine may be imported by anyone solely for repairs or alterations. Under this exemption, the engine may not be sold or leased in the United States. 40 CFR 89.611-96(b)(1) and 90.612(b)(1).

(i) *Testing exemption.* An engine may be imported by anyone solely for testing. Such engine may only be operated as an integral part of the test. 40 CFR 89.611-96(b)(2) and 90.612(b)(2). This exemption is limited to a period not exceeding one year from the date of importation unless a request is made under 40 CFR 89.905(f) or 90.905(f), as applicable, for a one-year extension.

(j) *Precertification exemption.* An engine may be imported by an

individual as well as by an ICI for use as a prototype in applying for EPA certification, unless otherwise specified. 40 CFR 89.611-96(b)(3) and 89.906. Unless the engine is brought into conformity within 180 days from the date of entry, it shall be exported or otherwise disposed of subject to paragraph (q) of this section.

(k) *Display exemption.* An engine may be imported by anyone solely for display in relation to a business or the public interest, as determined by EPA, if the engine will not be sold in the United States. This exemption is limited to a period of 12 months or for the duration of the display, whichever is shorter. Two extensions are available of up to 12 months each, if approved by EPA, but, in no case may the total extension period exceed 36 months. 40 CFR 89.611-96(b)(4) and 90.612(b)(3).

(l) *Exemption for engines identical to U.S.-certified versions.* An engine may be imported by its owner other than for resale if it is proven to be identical, in all material respects, to an engine certified by the original manufacturer for sale in the United States. 40 CFR 89.611-96(c)(3) and 90.612(c)(3).

(m) *Exemptions and exclusions based on prior EPA approval.* The following exemptions or exclusions from EPA emission standards apply to nonroad engines, if prior approval has been obtained in writing from EPA:

(1) *Competition exemption.* An engine may be imported for use to propel a vehicle or to power equipment used solely for competition. 40 CFR 89.611-96(e) and 90.612(e);

(2) *National security exemption.* An engine that received a national security exemption in writing from EPA may be imported. 40 CFR 89.611-96(c)(1), 89.908, 90.612(c)(1) and 90.908; and

(3) *Hardship exemption.* An engine that received a hardship exemption in writing from EPA may be imported. 40 CFR 89.911-96(c)(2) and 90.612(c)(2).

(n) *Documentation requirements.* (1) *Exception for conforming engines.* The special documentation requirements of paragraphs (n)(2) and (n)(3) of this section do not apply to the entry into the United States of any nonroad engines shown to be in compliance with applicable emission requirements under paragraph (b)(1) of this section relating to labeling.

(2) *Declarations of other importers.* Release from Customs custody shall be refused with respect to all entries of nonconforming nonroad engines into the United States unless there is filed with the entry in duplicate a declaration in which the importer or consignee declares or affirms its status as an original equipment manufacturer, an ICI

holding a relevant certificate of conformity, an individual importer, or other status, and further declares or affirms the status or condition of the imported engines and the circumstances concerning importation including a citation to the specific paragraph in this section upon which application for conditional or final release from Customs custody is made.

(3) *Other documentation and information.* The EPA requires, pursuant to its regulations at 40 CFR 89.604(a) and 40 CFR 90.604(c), that the following information shall be included or submitted with the importer's declaration:

(i) The importer's name, address and telephone number;

(ii) Identification of the engine, including the unique engine number, the engine owner's taxpayer identification number, and his or her current address and telephone number in the United States if different from that provided in paragraph (n)(3)(i) of this section;

(iii) Identification, where applicable, of the place where the engine will be stored until EPA approval of the importer's application to EPA for final admission;

(iv) Authorization for EPA enforcement officers to conduct inspections or testing otherwise permitted by the Clean Air Act and regulations promulgated thereunder;

(v) Identification, in the case of importation by an ICI, of the certificate of conformity by means of which the engine is being imported;

(vi) The date of manufacture of the engine;

(vii) The date of entry;

(viii) Identification of the vessel or carrier on which the merchandise was shipped;

(ix) The entry number, where applicable;

(x) Where prior written approval from EPA is required for an exemption or exclusion, a statement to the effect that such EPA approval has been given; and

(xi) Such other further information as may be required by the EPA.

(4) *Documentation from diplomats or foreign military personnel.* For entries for which an exemption is claimed under paragraph (g)(2) of this section, a statement must also be included with the declaration, identifying and describing the engine importer's official orders, if any, or, giving the name of the embassy to which the importer is accredited if the importer is a qualifying member of the personnel of a foreign government on assignment in the United States.

(5) *Retention and submission of records to Customs.* Documents supporting the information contained in or accompanying the declaration as set forth in paragraphs (n) (2)–(4) of this section must be retained by the importer for a period of at least 5 years from the date of entry, or withdrawal from warehouse, for consumption of the nonroad engine (see § 162.1c of this chapter), and shall be provided to Customs upon request.

(o) *Release under bond.* If a declaration filed in accordance with paragraph (n)(2) of this section states that the entry is being filed under circumstances described in either paragraph (h), (i), (j), or (k) of this section, the entry shall be accepted only if the importer or consignee gives a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter for the production of an EPA statement that the engine is in conformity with Federal emission requirements. Within the period in paragraph (i) or (j) of this section, or in the case of paragraph (h) or (k) of this section, the period specified by EPA in its authorization for an exemption, or such additional period as the port director of Customs may allow for good cause shown, the importer or consignee shall deliver to the port director the prescribed statement. If the statement is not delivered to the director of the port of entry within the specified period, the importer or consignee shall deliver or cause to be delivered to the port director those engines which were released under a bond required by this paragraph. In the event that the engine is not redelivered within 5 days following the specified period, liquidated damages shall be assessed in the full amount of the bond, if it is a single entry bond, or if a continuous bond is used, the amount that would have been taken under a single entry bond. Liquidated damages under the bond generally would be equal to 3 times the value of the merchandise involved in the default (see § 113.62(k) of this chapter).

(p) *Notice of inadmissibility or detention.* If an engine is determined to be inadmissible before release from Customs custody, or inadmissible after release from Customs custody, the importer or consignee shall be notified in writing of the inadmissibility determination and/or redelivery requirement. However, if an engine cannot be released from Customs custody merely because the importer has failed to furnish with the entry the information required by paragraph (n) of this section, the engine shall be held in detention by the port director for a

period not to exceed 30 days after filing of the entry at the risk and expense of the importer pending submission of the missing information. An additional 30-day extension may be granted by the port director upon application for good cause shown. If at the expiration of a period not over 60 days the required documentation has not been filed, a notice of inadmissibility will be issued.

(q) *Disposal of engines not entitled to admission.* An engine denied admission under any provision of this section shall be disposed of in accordance with applicable Customs laws and regulations. However, an engine will not be disposed of in a manner in which it may ultimately either directly or indirectly reach a consumer in a condition in which it is not in conformity with applicable EPA emission requirements.

(r) *Prohibited importations.* The importation of nonroad engines otherwise than in accordance with this section and the regulations of EPA in 40 CFR parts 89 and 90 is prohibited.

George J. Weise,
Commissioner of Customs.

Approved: June 24, 1996.
Dennis M. O'Connell,
Acting Deputy Assistant Secretary of the Treasury.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 105

[Docket No. 95N–310F]

Revocation of Certain Regulations Affecting Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of July 3, 1996, of the final rule published in the Federal Register of June 3, 1996 (61 FR 27771), that revoked regulations on diabetic labeling and on sodium intake labeling. These regulations were among those regulations identified by the agency for revocation as a result of a page-by-page review of its regulations that cover food and cosmetics. This regulatory review was in response to the administration's "Reinventing Government" initiative that seeks to streamline government and

to ease the burden on regulated industry and consumers.

DATES: Effective date confirmed: July 3, 1996. This revocation is applicable for all products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Any labels or labeling that require revision as a result of this revocation shall comply no later than January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 3, 1996 (61 FR 27771), FDA issued a final rule entitled "Revocation of Certain Regulations Affecting Food" that, among other things, revoked regulations on diabetic labeling in § 105.67 (21 CFR 105.67) and on sodium intake labeling in § 105.69 (21 CFR 105.69).

FDA gave interested persons until July 3, 1996, to file written objections to the revocation of these regulations and to request a hearing on the specific provisions to which there were objections. No objections or requests for hearing were received in response to the final regulation.

List of Subjects in 21 CFR Part 105

Dietary foods, Food grades and standards, Food labeling, Infants and children.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 403, 409, 411, 701, 721 of (21 U.S.C. 321, 341, 343, 348, 350, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is hereby given that no objections were received, and that the removal of § 105.67 on diabetic labeling and § 105.69 on sodium intake labeling became effective on July 3, 1996. Any labels or labeling that require revision as a result of this revocation shall comply no later than January 1, 1998.

Dated: August 15, 1996.

William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 96–21528 Filed 8–26–96; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Tablets and Chewable Cubes; Correction

AGENCY: Food and Drug Administration, HHS.