

DEPARTMENT OF THE TREASURY**Customs Service**

19 CFR Parts 7, 10, 11, 12, 18, 19, 24, 54, 101, 102, 111, 114, 123, 128, 132, 134, 141, 145, 146, 148, 151, 152, 177, 181, and 191

[T.D. 00-81]

Technical Amendments to the Customs Regulations

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by making certain technical corrections to various authority citations to reflect amendments to the Harmonized Tariff Schedule of the United States made by the President's Proclamation of October 2, 2000, to implement the United States-Caribbean Basin Trade Partnership Act.

EFFECTIVE DATE: November 15, 2000.

FOR FURTHER INFORMATION CONTACT: Gregory R. Vilders, Attorney, Regulations Branch, Office of Regulations and Rulings, (202) 927-1415.

SUPPLEMENTARY INFORMATION:**Background**

In Chapter I of the Customs Regulations (19 CFR chapter I) there are many general and specific authority citations and some sections that reference certain General Note provisions of the Harmonized Tariff Schedule of the United States (HTSUS). See, T.D. 95-29. Due to recent amendments to the HTSUS, many of the General Notes provisions have been renumbered. Thus, those general and specific authority citations and sections in the Customs Regulations that reference certain General Note provisions are no longer accurate.

On May 18, 2000, the United States-Caribbean Basin Trade Partnership Act was enacted. To implement certain provisions of this Act, on October 2, 2000, the President issued Proclamation 7351 (65 FR 59329), the Annex of which modified the HTSUS by, among other things, redesignating certain of the General Notes of the HTSUS. Specifically, HTSUS General Notes 16-21 were redesignated as HTSUS General Notes 18-23, respectively. Some of the former General Notes are referenced in the general or specific authority citations for 24 parts and in 3 sections of the Customs Regulations (19 CFR parts 7, 10, 11, 12, 18, 19, 24, 54, 101, 102, 111, 114, 123, 128, 132, 134, 141, 145, 146, 148, 151, 152, 177, 181, and 191, and §§ 24.23, 141.4, and 152.13).

This document corrects those HTSUS General Note references in the Customs Regulations.

Inapplicability of Public Notice and Comment Requirement and Delayed Effective Date Requirement

Because these amendments merely correct certain authority citation referencing errors in the Customs Regulations, pursuant to 5 U.S.C. 553(b)(B), Customs finds that good cause exists for dispensing with notice and public procedure as unnecessary. For these same reasons, pursuant to 5 U.S.C. 553(d)(3), Customs finds that good cause exists for dispensing with the requirement for a delayed effective date.

The Regulatory Flexibility Act

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. *et seq.*).

Executive Order 12866

These amendments do not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Drafting Information

The principal author of this document was Gregory R. Vilders, Attorney, Regulations Branch, Office of Regulations and Rulings.

Amendments to the Regulations

Chapter I of the Customs Regulations (19 CFR chapter I) is amended as set forth below:

PART 7—CUSTOMS RELATIONS WITH INSULAR POSSESSIONS AND GUANTANAMO BAY NAVAL STATION

1. The authority citation for part 7 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1623, 1624; 48 U.S.C. 1406i.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

2. The general authority citation for part 10 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1321, 1481, 1484, 1498, 1508, 1623, 1624, 3314;

* * * * *

PART 11—PACKING AND STAMPING; MARKING

3. The authority citation for part 11 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Notes 22 and 23, Harmonized Tariff Schedule of the United States), 1624.

PART 12—SPECIAL CLASSES OF MERCHANDISE

4. The general authority citation for part 12 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

PART 18—TRANSPORTATION IN BOND AND MERCHANDISE IN TRANSIT

5. The general authority citation for part 18 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1551, 1552, 1553, 1623, 1624.

* * * * *

PART 19—CUSTOMS WAREHOUSES, CONTAINER STATIONS AND CONTROL OF MERCHANDISE THEREIN

6. The general authority citation for part 19 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624;

* * * * *

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

7. The general authority citation for part 24 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a-58c, 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1505, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 9701.

* * * * *

§ 24.23 [Removed and added]

8. In § 24.23:

a. The parenthetical reference in paragraph (c)(1)(iii) to "(General Note 3(c)(v), HTSUS)" is removed and added, in its place, is the reference "(General Note 7, HTSUS)";

b. The parenthetical reference in paragraph (c)(1)(iv) to "(General Note 20(c)(ii)(B), HTSUS)" is removed and added, in its place, is the reference "(General Note 4(b)(i), HTSUS)"; and

c. The reference in paragraph (c)(1)(v) to "General Note 16, HTSUS" is

removed and added, in its place, is the reference "General Note 18, HTSUS".

PART 54—CERTAIN IMPORTATIONS TEMPORARILY FREE OF DUTY

9. The authority citation for part 54 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22; Section XV, Note 5, Harmonized Tariff Schedule of the United States), 1623, 1624.

PART 101—GENERAL PROVISIONS

10. The general authority citation for part 101 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

* * * * *

PART 102—RULES OF ORIGIN

11. The authority citation for part 102 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624, 3314, 3592.

PART 111—CUSTOMS BROKERS

12. The general authority citation for part 111 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624, 1641.

* * * * *

PART 114—CARNETS

13. The authority citation for part 114 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1623, 1624.

PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO

14. The general authority citation for part 123 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1431, 1433, 1436, 1448, 1624.

* * * * *

PART 128—EXPRESS CONSIGNMENTS

15. The authority citation for part 128 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1321, 1484, 1498, 1551, 1555, 1556, 1565, 1624.

PART 132—QUOTAS

16. The general authority citation for part 132 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

* * * * *

PART 134—COUNTRY OF ORIGIN MARKING

17. The authority citation for part 134 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1304, 1624.

PART 141—ENTRY OF MERCHANDISE

18. The general authority citation for part 141 continues, and the specific authority for § 141.4 is revised, to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

* * * * *

Section 141.4 also issued under 19 U.S.C. 1202 (General Note 18; Chapter 86, Additional U.S. Note 1; Chapter 89, Additional U.S. Note 1; Chapter 98, Subchapter III, U.S. Note 4, Harmonized Tariff Schedule of the United States), 1498;

* * * * *

§ 141.4 [Removed and added]

19. In § 141.4:

a. The reference in paragraph (b)(1) to "General Note 16" is removed and added, in its place, is the reference "General Note 18"; and

b. The reference in the introductory text of paragraph (c) to "General Note 16(e)" is removed and added, in its place, is the reference "General Note 18(e)".

PART 145—MAIL IMPORTATIONS

20. The general authority citation for part 145 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624;

* * * * *

PART 146—FOREIGN TRADE ZONES

21. The authority citation for part 146 is revised to read as follows:

Authority: 19 U.S.C. 66, 81a–81u, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1623, 1624.

PART 148—PERSONAL DECLARATIONS AND EXEMPTIONS

22. The general authority citation for part 148 is revised to read as follows:

Authority: 19 U.S.C. 66, 1496, 1498, 1624. The provisions of this part, except for subpart C, are also issued under 19 U.S.C. 1202 (General Note 22, Harmonized Tariff Schedule of the United States);

* * * * *

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

23. The general authority citation for part 151 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 22 and 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

* * * * *

PART 152—CLASSIFICATION AND APPRAISEMENT OF MERCHANDISE

24. The general authority citation for part 152 continues, and the specific authority for § 152.13 is revised, to read as follows:

Authority: 19 U.S.C. 66, 1401a, 1500, 1502, 1624.

* * * * *

Section 152.13 also issued under 19 U.S.C. 1202 (General Note 19, Harmonized Tariff Schedule of the United States (HTSUS)).

§ 152.13 [Removed and added]

25. In § 152.13:

a. The reference in both paragraphs (b)(1) and (b)(2) to "General Note 17" is removed and added, in its place, is the reference "General Note 19";

b. The reference in the introductory text of paragraph (c) and in paragraphs (c)(1), (c)(2), and (c)(3) to "General Note 17" is removed and added, in its place, is the reference "General Note 19"; and

c. The references in paragraph (d) to "General Note 17" are removed and added, in their place, are the references "General Note 19".

PART 177—ADMINISTRATIVE RULINGS

26. The general authority citation for part 177 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624.

* * * * *

PART 181—NORTH AMERICAN FREE TRADE AGREEMENT

27. The authority citation for part 181 is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1624, 3314.

PART 191—DRAWBACK

28. The general authority citation for part 191 is revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States), 1313, 1624.

* * * * *

Dated: November 8, 2000.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 00-29091 Filed 11-14-00; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 177

[Docket No. 93F-0319]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of hydrogenated butadiene/acrylonitrile copolymers, intended for contact with food in repeated use applications. This action is in response to a petition filed by Zeon Chemicals, Inc.

DATES: This rule is effective November 15, 2000. Submit written objections and requests for a hearing by December 15, 2000. The Director of the Office of the Federal Register approves the incorporations by reference in accordance with 5 U.S.C. 552(a) and 1 CFR 51 of certain publications in § 177.2600(c)(4)(i) (21 CFR 177.2600(c)(4)(ii)), as of November 15, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3095.

SUPPLEMENTARY INFORMATION:
I. Background

In a notice published in the **Federal Register** of October 4, 1993 (58 FR 51632), FDA announced that a food additive petition (FAP 3B4377) had

been filed by Zeon Chemicals, Inc., Three Continental Towers, suite 1012, 1701 Golf Rd., Rolling Meadows, IL 60008 (now 4111 Bells Lane, Louisville, KY 40211). The petition proposed to amend the food additive regulations to provide for the safe use of acrylonitrile-butadiene copolymer, hydrogenated, intended for contact with food in repeated use applications. (The additive is currently listed in the regulation under the nomenclature hydrogenated butadiene/acrylonitrile copolymers, and this nomenclature will be retained.)

In FDA's evaluation of the safety of this food additive, the agency reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain residual amounts of acrylonitrile and butadiene as impurities resulting from its manufacture. These chemicals have been shown to cause cancer in test animals. Residual amounts of impurities are commonly found as constituents of chemical products, including food additives.

II. Determination of Safety

Under the general safety standard of section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the intended use of the additive. (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984).)

In evaluating the safety of a food additive, FDA customarily reviews the available data on each relevant chemical impurity to determine whether the

chemical induces tumors in animals or humans. If FDA concludes that the chemical impurity causes cancer in animals or humans, the agency calculates the unit cancer risk for the chemical and the upper bound limit of lifetime human cancer risk from the chemical's presence in the additive (Ref. 1).

In some instances, the available data and information may not allow the agency to determine whether a particular chemical impurity is a carcinogen. However, the available data may suggest, but not establish definitively, that the impurity poses a human cancer risk. In such circumstances, the agency may perform a risk assessment based upon the assumption that the impurity is carcinogenic. This approach permits the agency to determine whether there is a reasonable certainty that no harm will result from the petitioned use of the additive, even though the carcinogenic status of the impurity is not clearly established.

FDA followed this approach to determine whether there is a reasonable certainty that no harm will result from the use of hydrogenated butadiene/acrylonitrile copolymers; in so doing, FDA assumed that butadiene, an impurity in the additive, is a human carcinogen. In inhalation studies, butadiene has been reported to induce, in mice and rats, tumors at the site of exposure (lungs) as well as a variety of tumors at numerous other sites (Refs. 2 to 4). However, FDA does not believe that these inhalation studies are necessarily determinative of the carcinogenic potential of butadiene when administered orally, the most likely route of human exposure to food additives. Because no long-term studies are available in which butadiene was administered orally, the agency performed a risk assessment for butadiene based on a twofold assumption: That butadiene would induce tumors in animals and humans if administered orally and that its potency by the oral route of exposure would be no greater than its potency by the inhalation route of exposure. In FDA's view, this is a conservative assumption (Ref. 5). Using this procedure, FDA estimated the upper bound limit of lifetime human cancer risk from butadiene under the proposed conditions of use of hydrogenated butadiene/acrylonitrile copolymers.

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, hydrogenated butadiene/acrylonitrile copolymers, will