Paperwork Reduction Act

The collections of information involved in this interim rule have already been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and assigned OMB Control Numbers 1515–0065 (Entry summary and continuation sheet) and 1515–0214 (General recordkeeping and record production requirements). This rule does not propose any substantive changes to the existing approved information collections.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

List of Subjects

19 CFR Part 132

Agriculture and agricultural products, Customs duties and inspection, Quotas, Reporting and recordkeeping requirements.

19 CFR Part 163

Administrative practice and procedure, Customs duties and inspection, Imports, Reporting and recordkeeping requirements.

Amendment to the Regulations

Accordingly, parts 132 and 163, Customs Regulations (19 CFR parts 132 and 163), are amended as set forth below.

PART 132—QUOTAS

1. The general authority citation for part 132 continues to read as follows, and the specific sectional authority under this part is revised to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1623, 1624.

§§ 132.15 and 132.16 also issued under 19 U.S.C. 1202 (additional U.S. Note 3 to Chapter 2, HTSUS; and subchapter III of Chapter 99, HTSUS, respectively), 1484, 1508.

§ 132.15 [Amended]

2. Section 132.15 is amended by removing from paragraph (c)(1) the parenthetical, ''(see § 162.1c of this chapter)'', and by adding, in its place, the parenthetical, ''(see § 163.4(a) of this chapter)''.

3. Part 132 is amended by adding a new § 132.16 to read as follows:

§ 132.16 Export certificate for lamb meat subject to tariff-rate quota.

(a) *Requirement.* For fresh, chilled or frozen lamb meat classified in HTSUS subheading 0204.10.00, 0204.22.20, 0204.23.20, 0204.30.00, 0204.42.20, or 0204.43.20, that is the subject of a tariff-rate quota as provided in subchapter III of Chapter 99, HTSUS, and that is the product of a participating country, as defined in 15 CFR 2014.2(c), the importer must possess a valid export certificate in order to claim the in-quota tariff rate of duty on the lamb meat at the time it is entered or withdrawn from warehouse for consumption. The importer must record the distinct and unique identifying number of the export certificate for the lamb meat on the entry summary or warehouse withdrawal for consumption (Customs Form 7501, column 34), or its electronic equivalent.

(b) *Validity of export certificate.* To be valid, the export certificate must meet the requirements of 15 CFR 2014.3(b), and with respect to the requirement of 15 CFR 2014.3(b)(3), the export certificate covering the lamb meat must have a distinctly and uniquely identifiable number.

(c) *Retention and production of certificate to Customs.* The export certificate is subject to the recordkeeping requirements of part 163 of this chapter (19 CFR part 163). Specifically, the certificate must be retained for a period of 5 years in accordance with § 163.4(a) of this chapter, and must be made available to Customs upon request in accordance with § 163.6(a) of this chapter.

PART 163—RECORDKEEPING

1. The authority citation for part 163 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1484, 1508, 1509, 1510, 1624.

Appendix to Part 163 [Amended]

2. In the Appendix to part 163, under heading ''IV.'', the list of documents/records or information required for entry of special categories of merchandise is amended by adding the following in appropriate numerical order:

§§ 132.15, 132.16 Export certificates, respectively, for beef or lamb meat subject to tariff-rate quota.

Approved: November 18, 1999.

Raymond W. Kelly,

Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–31275 Filed 12–1–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 95F–0150]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

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 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one,2,2,4,4-tetramethyl-,hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized (CAS Reg. No. 202483–55–4) as an antioxidant and/or stabilizer for polyolefins intended for contact with food. This action is in response to a petition filed by Hoechst Aktiengesellschaft.

DATES: The regulation is effective December 2, 1999. Submit written objections and requests for a hearing by January 3, 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: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of July 12, 1995 (60 FR 35914), FDA announced that a food additive petition (FAP 5B4461) had been filed by Hoechst Aktiengesellschaft, c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed that the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of polymeric 2,2,4,4-tetramethyl-7-oxa-3,20-diaza-20-(2,3-epoxypropyl)-dispiro-[5.1.11.2]-heneicosane-21-one (CAS Reg. No. 78301–43–6) as an antioxidant and/or stabilizer for polyolefins intended for contact with food.

Subsequent to the filing of the petition, Hoechst Aktiengesellschaft sold its speciality business, including food additive petition 5B4461, to

Clariant AG, Switzerland. The petitioner also obtained a new Chemical Abstracts Service (CAS) Registry number for the additive under the following name: 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one,2,2,4,4-tetramethyl-,hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized (CAS Reg. No. 202483–55–4).

In FDA's evaluation of the safety of 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one,2,2,4,4-tetramethyl-,hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized 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 minute amounts of epichlorohydrin, a carcinogenic impurity resulting from the manufacture of the additive. 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 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).

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one,2,2,4,4-tetramethyl-,hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized, will result in exposure to no greater than 224 parts per billion (ppb) of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake of 0.67 milligram per person per day (mg/p/d) (Ref.1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of this additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by epichlorohydrin, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of epichlorohydrin has two aspects: (1) Assessment of exposure to the impurity from the petitioned use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. Epichlorohydrin

FDA has estimated the exposure to epichlorohydrin from the petitioned use of the additive as an antioxidant and/or stabilizer for polyolefins to be no more than 0.011 ppb in the daily diet (3 kg) or 33 nanograms (ng)/p/d (Ref.1). The agency used data from a carcinogenesis bioassay on epichlorohydrin conducted by Konishi et al. (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The authors reported that the test material caused significantly increased incidence of stomach papillomas and carcinomas in male rats.

Based on the agency's estimate that exposure to epichlorohydrin will not exceed 33 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.5×10^{-9} or 1.5 in a billion (Ref. 3). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to epichlorohydrin is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to epichlorohydrin would result from the petitioned use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of epichlorohydrin as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which epichlorohydrin may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to epichlorohydrin is very low, 1.5 in a billion.

IV. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive as an antioxidant and/or stabilizer for polyolefins intended for contact with food is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 178.2010 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen

in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before January 3, 2000, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from A. B. Bailey, Chemistry and Environmental Review Team, to D. Harrison, Division of Petition Control, dated August 6, 1998.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in Chemical Safety Regulation and Compliance, edited by F. Homburger, and J. K. Marquis, New York, NY, pp. 24–33, 1985.

3. Memo from Division of Petition Control (HFS–215) to Sara H. Henry, Quantitative Risk Assessment Committee (HFS–308), ''Verification of upper bound risk calculation for epichlorohydrin (ECH) for petition No. FAP 5B4461,'' dated February 10, 1998.

4. Konishi, Y. et al., ''Forestomach Tumors Induced by Orally Administered Epichlorohydin in Male Wistar Rats,'' *Gann*, 71:922–923, 1980.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
7-Oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one,2,2,4,4-tetramethyl-,hydrochloride, reaction products with epichlorohydrin, hydrolyzed, polymerized (CAS Reg. No. 202483–55–4).	For use only: 1. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene; in contact with all types of food described in Table 1 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) when in contact with food of types III, IV–A, V, VII–A, and IX, described in Table 1 of § 176.170 of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 2.1, 2.2, 3.1, and 3.2, having a density of not less than 0.94 gram/milliliter, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from ethylene; in contact with food only under conditions of use C, D, E, F, and G, described in Table 2 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) when in contact with food of types III, IV–A, V, VII–A, and IX, described in Table 1 of § 176.170 of this chapter. 3. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520 of this chapter, items 2.1, 2.2, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 4.0, having a density of less than 0.94 gram/milliliter, in contact with food only under conditions of use D, E, F, and G, described in Table 2 of § 176.170 of this chapter, provided that the finished food-contact article will have a capacity of at least 18.9 liters (5 gallons) except that, films and molded articles containing not more than 0.2 percent by weight of the stabilizer may contact aqueous food of types I, II, IV–B, VI, and VIII, described in Table 1 of § 176.170 of this chapter with no restrictions on the amount of food contacted.
* * *	* * * *

Dated: November 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31228 Filed 12–1–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 2

[Docket No. 99–1020282–9282–01]

RIN 0651–AB08

Clarification of Patent and Trademark Copy Fees

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (PTO) is amending the rules of practice regarding fees for black and white patent and trademark copies by clarifying the meaning of the term ''regular service.'' For black and white patent copies, the term ''regular service'' includes preparation of copies by the PTO normally within 2–3 business days of receipt and delivery by United States Postal Service (USPS), or delivery to a PTO Box. ''Regular service'' also includes preparation of copies within one business day of receipt and delivery to customers by electronic means (e.g., fax, electronic mail). Expedited service for receipt of black and white patent copies by fax is eliminated since this is now done routinely as ''regular service.'' For patent copies, ''expedited service'' is clarified to read preparation of copies by the PTO within one business day and delivery by commercial delivery service within the next business day. For trademark copies, ''regular service'' includes preparation of copies by the PTO within 2–3 business days of receipt and delivery by USPS, fax, or to a PTO Box. The term ''overnight delivery'' is being changed to ''delivery on the next business day'' for clarity.

EFFECTIVE DATE: The effective date for the rules is December 2, 1999.

FOR FURTHER INFORMATION CONTACT: Wesley H. Gewehr by mail addressed to him at Administrator for Information Dissemination, U.S. Patent and Trademark Office, PK3–451, Washington, DC 20231, by telephone at (703) 305–9110, by facsimile at (703) 305–3878, or by e-mail at ''wesley.gewehr@uspto.gov.''

SUPPLEMENTARY INFORMATION: This final rule clarifies PTO fees for providing black and white copies of patents and trademarks.

Background

Patent fees are authorized by 35 U.S.C. 41. Trademark fees are authorized by 15 U.S.C. 1113. Both statutes provide that the Commissioner shall establish fees for processing, services, or materials relating to patents or trademarks to recover the estimated average cost to the Office of such processing, services, or materials. Automated image stores of patent copies and automated system capabilities for electronic delivery are now available for delivery of black and white patent copies under regular service. Full-page images of trademark registrations are not yet available via automated image stores. Therefore, trademark copies cannot yet be delivered electronically, other than by fax.

This final rule clarifies what services are encompassed by the term ''regular service'' for patent copies set forth in 37 CFR 1.19(a)(1), and for trademark copies set forth in 37 CFR 2.6(b)(1).

Other Considerations

This final rule contains no information collection within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* This final rule has been determined to be not significant for purposes of Executive Order 12866.

The PTO for good cause finds that the notice and comment provisions of the Administrative Procedure Act are not required. The notice and public procedure thereon are unnecessary since the PTO is only clarifying the term ''regular service,'' and eliminating as a separate category the delivery of patent copies by fax. 5 U.S.C. 553(b)(B). These are minor technical changes with no substantive effect on the public. 5 U.S.C. 553(b)(B). Prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 (or any other law); therefore, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are inapplicable.

List of Subjects

37 CFR Part 1

Administrative practice and procedures, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

37 CFR Part 2

Administrative practice and procedures, Trademarks.

Accordingly, for the reasons set forth in the preamble, 37 CFR parts 1 and 2 are amended as follows:

PART 1—[AMENDED]

1. The authority citation for part 1 continues to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.19 is amended by revising paragraphs (a)(1)(i) through (iii) to read as follows:

§ 1.19 Document supply fees.

* * * * *

(a) * * *

(1) * * *

(i) Regular service, which includes preparation of copies by the PTO within 2–3 business days and delivery by United States Postal Service or to a PTO Box; and preparation of copies by the PTO within one business day of receipt and delivery by electronic means (e.g., fax, electronic mail)—$3.00.

(ii) Next business day delivery to PTO Box—$6.00.

(iii) Expedited delivery by commercial delivery service—$25.00.

* * * * *

PART 2—[AMENDED]

3. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 1123; 35 U.S.C. 6, unless otherwise noted.

4. Section 2.6 is amended by revising paragraphs (b)(1)(i) through (iii) to read as follows:

§ 2.6 Trademark fees.

* * * * *

(b) * * *

(1) * * *

(i) Regular service, which includes preparation of copies by the PTO within 2–3 business days of receipt and delivery by United States Postal Service, fax, or to a PTO Box—$3.00.

(ii) Delivery on next business day to PTO Box or fax delivery within one business day to U.S./Canada/Mexico—$6.00.

(iii) Expedited delivery by commercial delivery service—$25.00.

* * * * *

Dated: November 22, 1999.

Q. Todd Dickinson,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

[FR Doc. 99–30880 Filed 12–1–99; 8:45 am]

BILLING CODE 3510–16–M