TERMS AND CONDITIONS

Criterion	Applicable CFTC Rule (17 CFR)	Standard	Met by exchange rule number	Justification for not meeting standard, or rule number of identical approved rule
1. Speculative limits	150.5	Combined net position in futures and options on a futures-equivalent basis at the futures position levels, with inter-month spread exemptions that are consistent with those of the futures contracts or consistent with Commission Rule 150.5(e) for underlying future.		
2. Aggregation rule	150.4	Same as Rule 150.5(g) or previously approved language.		
3. Reporting level	15.00(b)(2)	50 contracts or fewer		
4. Strike prices (number listed & increments).	33.4(b)(1)	Procedures for routine listing of strikes are specified and automatic, provisions for listing discretionary strikes are specified.		
5. Option expiration & last trading day.	33.4(b)(2)	Except for options on cash-settled futures contracts, expiration is not less than one business day before the earlier of the last trading day or the first notice day of the underlying future.		
6. Minimum tick	33.4(d)	Equal to, or less than, the underlying futures tick		
7. Daily price limit, if specified.	33.4(d)	Equal to, or greater than, the underlying futures price limit.		

(4) As specifically requested, such additional evidence, information or data relating to whether the contract meets, initially or on a continuing basis, any of the specific requirements of the Act, including the public interest standard contained in Section 5(7) of the Act, or any other requirement for designation under the Act or Commission rules and policies.

3. Part 5 is amended by adding new Appendix E to read as follows:

Appendix E—Information That a Foreign Board of Trade Should Submit When Seeking No-Action Relief to Offer and Sell, to Persons Located in the United States, a Futures Contract on a Foreign Securities Index Traded on That Foreign Board of Trade

A foreign board of trade seeking no-action relief to offer and to sell, to persons located in the U.S., a futures contract on a foreign securities index traded on that foreign board of trade should submit the following in English:

(1) The terms and conditions of the contract and all other relevant rules of the exchange and, if applicable, of the exchange on which the underlying securities are traded, which have an effect on the over-all trading of the contract, including circuit breakers, price limits, position limits or other controls on trading;

(2) Surveillance agreements between the foreign board of trade and the exchange(s) on which the underlying securities are traded;

(3) Information sharing agreements between the host regulator and the Commission or assurances of ability and willingness to share information with the Commission and assurances from the foreign board of trade of its ability and willingness to share information with the Commission, either directly or indirectly.

(4) When applicable, information regarding foreign blocking statutes and their impact on the ability of United States government agencies to obtain information concerning the trading of such contracts; and

(5) Information and data denoted in U.S. dollars relating to:

(i) The method of computation, availability, and timeliness of the index;

(ii) The total capitalization, number of stocks (including the number of unaffiliated issuers if different from the number of stocks), and weighting of the stocks by capitalization and, if applicable, by price in the index;

(iii) Breakdown of the index by industry segment including the capitalization and weight of each industry segment;

(iv) Procedures and criteria for selection of individual securities for inclusion in, or removal from, the index, how often the index is regularly reviewed, and any procedures for changes in the index between regularly scheduled reviews;

(v) Method of calculation of the cash-settlement price and the timing of its public release;

(vi) Average daily volume of trading by calendar month, measured by share turnover and dollar value, in each of the underlying securities for a six month period of time and, separately, the daily volume in each underlying security for six expirations (cash-settlement dates) or for the six days of that period on which cash-settlement would have occurred had each month of the period been an expiration month; and

(vii) If applicable, average daily futures trading volume.

Issued in Washington, D.C. this 25th day of May, 1999, by the Commodity Futures Trading Commission.

Jean Webb,

Secretary of the Commission.

[FR Doc. 99–13780 Filed 5–28–99; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 97F–0450]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Boiler Water Additives

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 sorbitol anhydride esters, an emulsifier blend of sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate (polysorbate 60), and polyoxyethylene (20) sorbitan monolaurate (polysorbate 20) as an anticorrosive agent in boilers where steam may contact food. This action is in response to a petition filed by Nalco Chemical Co.

DATES: This regulation is effective June 1, 1999; written objections and requests for a hearing by July 1, 1999. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in § 173.310 (21 CFR 173.310), effective June 1, 1999.

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: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of November 13, 1997 (62 FR 60903), FDA announced that a food additive petition (FAP 7A4540) had been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60568–1198. The petition proposed to amend the food additive regulations in § 173.310 *Boiler water additives* to provide for the safe use of an emulsifier blend containing sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate, and polyoxyethylene (20) sorbitan monolaurate as an anticorrosive agent in boilers where steam may contact food. The emulsifier blend is a simple mixture of these three substances, each of which is an ester of sorbitol anhydride. For convenience of listing of the mixture, the agency chooses to use the name sorbitol anhydride esters (SAHE) for this additive.

Sorbitan monostearate is currently approved in § 73.1001 (21 CFR 73.1001) as a diluent in color additive mixtures for drug use exempt from certification; in § 172.515 (21 CFR 172.515) as a synthetic flavoring substance and adjuvant; in 21 CFR 172.842 as an emulsifier; and in § 173.340 (21 CFR 173.340) as a defoaming agent. Polyoxyethylene (20) sorbitan monostearate (polysorbate 60) is currently approved in § 73.1001 as a diluent in color additive mixtures for drug use exempt from certification; in § 172.515 as a synthetic flavoring substance and adjuvant; in 21 CFR 172.836 as an emulsifier, foaming agent, dough conditioner, dispersing agent, and surfactant and wetting agent; and in § 173.340 as a defoaming agent. Polyoxyethylene (20) sorbitan monolaurate (polysorbate 20) is currently approved in § 172.515 as a synthetic flavoring substance and adjuvant.

In its evaluation of the safety of SAHE, FDA has reviewed the safety of the three esters and the chemical impurities that may be present in them resulting from their manufacturing process. Because these three esters have similar chemical structures, which do not react with each other, FDA has determined that its safety review for each of the three esters would be the same as that for the SAHE mixture. Therefore, FDA refers to each ester, rather than the additive as a whole, in its evaluation of the safety of SAHE in this final rule.

Although none of the esters have been shown to cause cancer, two of them (polysorbate 20 and polysorbate 60) may contain minute amounts of unreacted 1,4-dioxane (DX) and ethylene oxide (EO), which are carcinogenic impurities resulting from their manufacture. Residual amounts of impurities are commonly found in chemical products, including food additives.

II. Determination of Safety

Under the general safety standard section 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 Petitioned Use of the Additive

FDA estimates that the petitioned use of SAHE will result in a maximum daily dietary exposure to each ester of approximately 0.8 part per million. This corresponds to an estimated daily intake (EDI) of 2.5 milligrams per person per day (/p/d) of each ester (Ref. 1).

The agency has reviewed the available toxicological data on the three sorbitol anhydride esters. Based on the available toxicology data for sorbitan monostearate and polysorbate 60 and the fact that their additional dietary exposure from the proposed use would be small compared to that from their currently regulated uses, the agency concludes that the estimated dietary exposure resulting from the petitioned use of these two esters is safe. The agency also finds that polysorbate 60 and polysorbate 20 would hydrolyze to similar breakdown products under the proposed conditions of use, the only difference being the chain length of the fatty acid residue (C_{12} for polysorbate 20 and C_{16} or C_{18} for polysorbate 60). Based on the chemical similarities between polysorbate 60 and polysorbate 20, the agency concludes that the toxicology data for polysorbate 60 can be used to support the safety of polysorbate 20 under their limited exposure anticipated from the petitioned use of SAHE. Moreover, based on the agency's review of the estimated dietary exposure from all three esters in SAHE, the agency concludes that the estimated small dietary exposure resulting from the proposed use of this additive is safe.

Under the proposed conditions of use, any residual EO will quantitatively react with the boiler water to form ethylene glycol (Ref. 1). Thus, no EO will be present in the steam that contacts food. Consequently, the exposure to EO from the petitioned use of SAHE will be zero. Therefore, 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 DX, a carcinogenic chemical that may be present as an impurity in two of the components of the additive (polysorbate 20 and polysorbate 60). This risk evaluation of DX has two aspects: (1) Assessment of the exposure to the impurity from the petitioned use of the additive, and (2) extrapolation of the risk observed in the animal bioassay to the conditions of exposure to humans.

A. 1,4-Dioxane

FDA has estimated the exposure to DX from the petitioned use of the additive as an anticorrosive agent in boilers where steam may contact food to be no more than 17 parts per trillion in the daily diet (3 kilograms), or 50 nanograms (ng)/p/d (Ref. 1). The agency used data from a carcinogenesis bioassay on DX, conducted by the National Cancer Institute (Ref. 2), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The results of the bioassay on DX demonstrated that the material was carcinogenic for female rats under the conditions of the study. The authors reported that the rodent bioassay showed that the test material caused a significantly increased incidence of

squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the agency's estimate that exposure to DX will not exceed 50 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.8×10^{-9} or 1.8 in a billion (Ref. 3). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to DX 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 DX 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 DX present as an impurity in SAHE. The agency finds that new specifications are not necessary for the following reasons: (1) Because of the low levels at which DX may be expected to remain as an impurity following production of SAHE, the agency would not expect the 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 DX is very low, 1.8 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 anticorrosive agent in boilers where steam may contact food is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 173.310 should be amended as set forth below in this document.

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 previously. 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. 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.

VI. Paperwork Reduction Act of 1995

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

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before July 1, 1999, 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, dated April 20, 1998, from the Division of Product Manufacture and Use (HFS–246) to the Division of Petition Control (HFS–215).

2. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

3. Memorandum, dated June 19, 1998, from the Division of Petition Control (HFS–215) to Executive Secretary, Quantitative Risk Assessment Committee (QRAC) (HFS–308).

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

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

2. Section 173.310 is amended in the table in paragraph (c) by alphabetically adding an entry for ''sorbitol anhydride esters'' under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 173.310 Boiler water additives.

* * * * *

(c) * * *

Substances	Limitations
* * * *	* * *
Sorbitol anhydride esters: a mixture consisting of sorbitan monostearate as defined in § 172.842 of this chapter; polysorbate 60 ((polyoxyethylene (20) sorbitan monostearate)) as defined in § 172.836 of this chapter; and polysorbate 20 ((polyoxyethylene (20) sorbitan monolaurate)), meeting the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 306–307, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055 (Internet http://www.nap.edu), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	The mixture is used as an anticorrosive agent in steam boiler distribution systems, with each component not to exceed 15 parts per million in the steam.
* * * *	* * *

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Dated: May 22, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–13670 Filed 5–28–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Defense Logistics Agency

32 CFR Part 171

RIN 0790–AG68

Implementation of Wildfire Suppression Aircraft Transfer Act of 1996

AGENCY: Defense Logistics Agency (DLA), DoD.

ACTION: Interim final rule.

SUMMARY: The Wildfire Suppression Aircraft Transfer Act of 1996 states that, notwithstanding section 202 of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 483) and subject to subsections (b) and (c), the Secretary of Defense may, during the period beginning on October 1, 1996, and ending on September 30, 2000, sell certain aircraft and aircraft parts to persons or entities that contact with the Federal Government for the delivery of fire retardant by air in order to suppress wildfire. The Act states that, as soon as practicable after the date of the enactment of the Act, the Secretary of Defense shall, in consultation with the Secretary of Agriculture and the Administrator of General Services, prescribe regulations relating to the sale of aircraft and aircraft parts under this section. This interim final rule prescribes regulations to implement the Wildfire Suppression Aircraft Transfer Act of 1996.

DATES: Effective June 1, 1999 through September 30, 2000. Comments are requested by August 2, 1999.

ADDRESSES: Forward comments to: Defense Logistics Agency, Defense Logistics Support Command, ATTN: DLSC–LC, Suite 4222, 8725 John J. Kingman Road, Ft. Belvoir, VA 22060–6221.

FOR FURTHER INFORMATION CONTACT: Michael Stubblebine, (703) 767–1537.

SUPPLEMENTARY INFORMATION:

I. Background

The Wildfire Suppression Aircraft Transfer Act of 1996 states that, notwithstanding section 202 of the Federal Property and Administration Services Act of 1949 (40 U.S.C. 483) and subject to subsections (b) and (c), the Secretary of Defense may, during the period beginning on October 1, 1996, and ending on September 30, 2000, sell certain aircraft and aircraft parts to persons or entities that contract with the Federal Government for the delivery of fire retardant by air in order to suppress wildfire. The Act states that, as soon as practicable after the date of the enactment of the Act, the Secretary of Defense shall, in consultation with the Secretary of Agriculture and the Administrator of General Services, prescribe regulations relating to the sale of aircraft and aircraft parts under this section. This interim rule prescribes such regulations.

II. Administrative Requirements

A. Executive Order 12866

It has been determined that 32 CFR part 171 is not a significant regulatory action. The rule does not (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of the recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

B. Regulatory Flexibility Act

It has been determined that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rule applies only to the sale of certain aircraft and aircraft parts to those entities that contract for the delivery of fire retardant by air in order to suppress wildfire. The U.S. Department of Agriculture provides the list of eligible entities that may bid on aircraft and aircraft parts.

C. Paperwork Reduction Act

It has been certified that 32 CFR part 171 does not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 44).

List of Subjects in 32 CFR Part 171

Aircraft, Fire prevention.

Accordingly, 32 CFR Part 171 is added to read as follows: