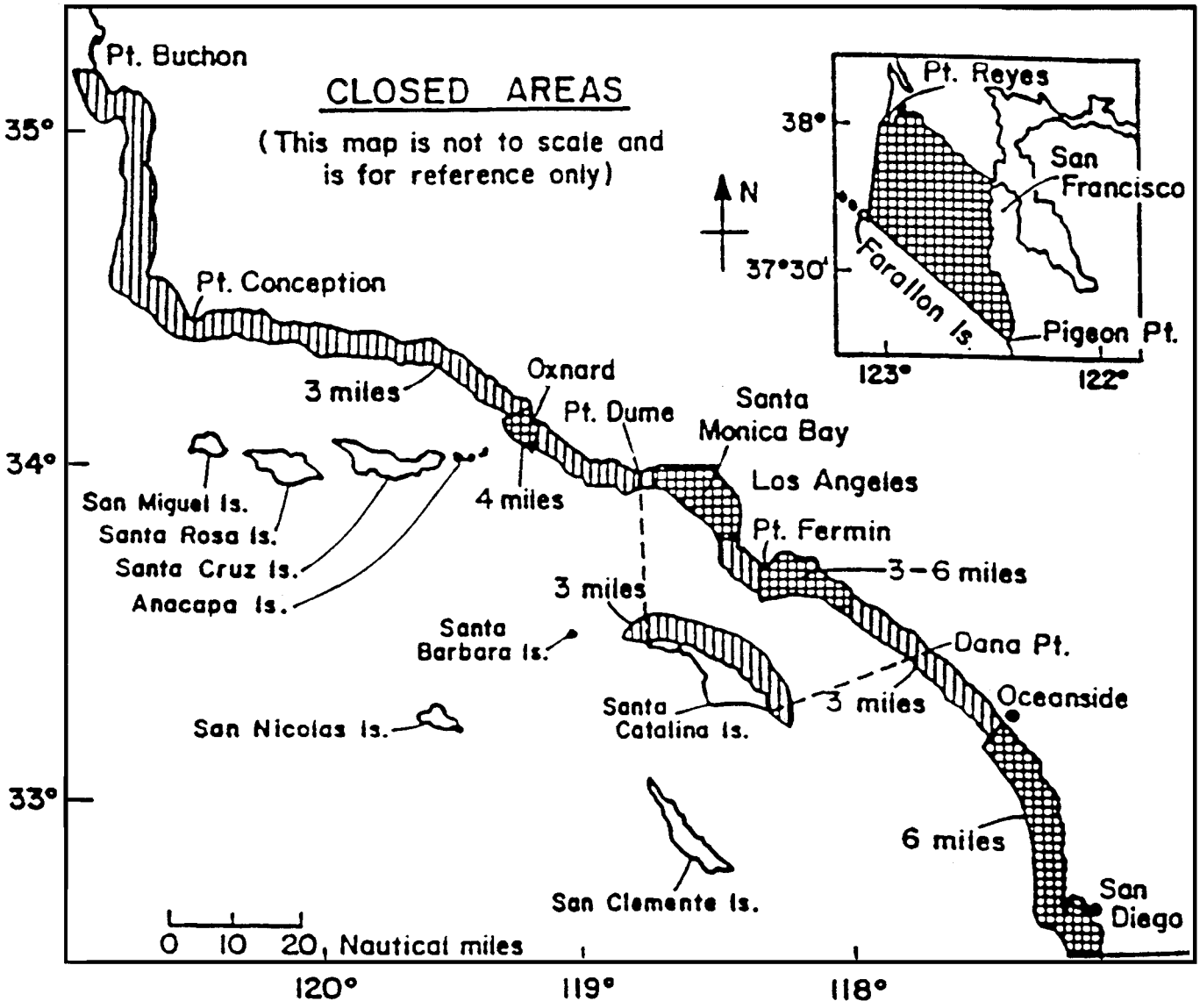

[FR Doc. 99–32320 Filed 12–14–99; 8:45 am]
BILLING CODE 3510–22–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 99F–1423]

Indirect Food Additives: Paper and Paperboard Components

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 4,5-dichloro-1,2-dithiol-3-one (also known as 4,5-dichloro-3H-1,2-dithiol-3-one) as a slimicide in the manufacture of food-contact paper and paperboard. This action is in response to a petition filed by Yoshitomi Fine Chemicals, Ltd.

DATES: The regulation is effective December 15, 1999. Submit written objections and requests for a hearing by January 14, 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: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 27, 1999 (64 FR 28825), FDA announced that a food additive petition (FAP 9B4654) had been filed by Yoshitomi Fine Chemicals, Ltd., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington, DC 20006–1604. The petition proposed to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of 4,5-dichloro-1,2-dithiol-3-one as a slimicide in the manufacture of food-contact paper and paperboard.

In its evaluation of the safety of this additive, FDA has 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 1,2-dichloroethane and tetrachloroethylene, carcinogenic impurities resulting from the manufacture of the additive.

Residual amounts of reactants and manufacturing aids, such as 1,2-dichloroethane and tetrachloroethylene, are commonly found as contaminants in chemical products, including food additives.

I. 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)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, 4,5-dichloro-1,2-dithiol-3-one, will result in exposure to no greater than 0.8 part per billion of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake of 2.4 micrograms per person per day (µg/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 dietary exposure resulting from the petitioned use of the 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 1,2-dichloroethane and tetrachloroethylene, the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of 1,2-dichloroethane and tetrachloroethylene has two aspects: (1) Assessment of the exposure to the impurities 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. 1,2-Dichloroethane

FDA has estimated the exposure to 1,2-dichloroethane from the petitioned use of the additive as a slimicide in the manufacture of food-contact paper and paperboard to be no more than 24 parts per trillion (ppt) in the daily diet (3 kg), or 72 nanograms(ng)/p/d (Ref. 4). The agency used data from a carcinogenesis bioassay on 1,2-dichloroethane, conducted by the National Cancer Institute (Ref. 3), 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 squamous cell carcinomas of the forestomach and hemangiosarcomas of the circulatory system in male rats and adenocarcinomas of the mammary gland in female rats.

Based on the agency's estimate that exposure to 1,2-dichloroethane will not exceed 72 ng/p/d, FDA estimates that the upper-bound limit of lifetime human cancer risk from the petitioned use of the subject additive is 1.3×10^{-8}, or 1.3 in 100 million (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,2-dichloroethane 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 1,2-dichloroethane would result from the petitioned use of the additive.

B. Tetrachloroethylene

FDA has estimated the exposure to tetrachloroethylene from the petitioned use of the additive as a slimicide in the manufacture of food-contact paper and paperboard to be no more than 2.4 ppt in the daily diet (3 kg), or 7.2 ng/p/d (Ref. 4). The agency used data from a carcinogenesis bioassay on tetrachloroethylene, conducted by the National Toxicology Program (Ref. 5), 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 hepatocellular adenomas and carcinomas in male mice and hepatocellular carcinomas in female mice.

Based on the agency's estimate that exposure to tetrachloroethylene will not exceed 7.2 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 3.6×10^{-10}, or 3.6 in 10 billion (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to tetrachloroethylene 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 tetrachloroethylene would result from the petitioned use of the additive.

C. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of 1,2-dichloroethane and tetrachloroethylene as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,2-dichloroethane and tetrachloroethylene may be expected to remain as impurities following production of the additive, the agency would not expect the impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to 1,2-dichloroethane, and tetrachloroethylene are very low, less than 1.3 in 100 million, and 3.6 in 10 billion, respectively.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 176.300 should be amended as set forth below.

The additive, 4,5-dichloro-1,2-dithiol-3-one, intended for use as a slimicide in the manufacture of food-contact paper and paperboard, is regulated under section 409 of the act (21 U.S.C. 348) as a food additive and not as a pesticide chemical under section 408 of the act

(21 U.S.C. 346a). However, this intended use of 4,5-dichloro-1,2-dithiol-3-one may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Therefore, manufacturers intending to use 4,5-dichloro-1,2-dithiol-3-one as a slimicide in the manufacture of food-contact paper and paperboard should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

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.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4654 (64 FR 28825). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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. Objections

Any person who will be adversely affected by this regulation may at any time on or before January 14, 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.

VII. 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 the Chemistry and Environmental Review Team, FDA, to the Division of Petition Control, FDA, ''FAP 9B4654 (MATS # 1039)—SRS International Corp. (on behalf of Yoshitomi Fine Chemicals, Ltd.). 4,5-Dichloro-3H-1,2-Dithiol-3-One (RYH–86) as a Slimicide in the Manufacture of Paper and Paperboard. Division of Petition Control (DPC) E–Mail Request of 9–14–99,'' October 12, 1999.

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

3. ''Bioassay of 1,2-Dichloroethane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–55, 1978.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, ''Third Estimation of the Upper-Bound Lifetime Risk From 1,2-Dichloroethane (DCE) and Tetrachloroethylene (TCE) in 4,5-Dichloro-1,2-Dithiol-3-One for FAP 8B4654,'' October 13, 1999.

5. ''Toxicology and Carcinogenisis Studies of Tetrachloroethylene (Perchloroethylene) in F344/N Rats and B6C3F_1 Mice (Inhalation Studies),'' *National Toxicology Program Technical Report Series No. 311*, 1986.

List of Subjects in 21 CFR Part 176

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

2. Section 176.300 is amended in the table in paragraph (c) by alphabetically adding an entry under the headings ''Lists of substances'' and ''Limitations'' to read as follows:

§ 176.300 Slimicides.

* * * * *

(c) * * *

List of substances	Limitations
* * * * * * *	
4,5-dichloro-1, 2-dithiol-3-one (CAS Reg. No. 1192–52–5).	For use only at levels not to exceed 10 milligrams per kilogram in the pulp slurry.
* * * * * * *	

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Dated: December 7, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–32427 Filed 12–14–99; 8:45 am]

BILLING CODE 4160–01–F

OFFICE OF NATIONAL DRUG CONTROL POLICY

21 CFR Part 1401

RIN 3201–ZA02

Freedom of Information Act

AGENCY: Office of National Drug Control Policy.

ACTION: Final rule.

SUMMARY: The Office of National Drug Control Policy revises this rule to comply with the Electronic Freedom of Information Act. The rule defines records as defined in the Act, establishes an electronic reading room, institutes an expedited process for handling requests and conforms to the statutory time limitations for a response.

DATES: Effective December 15, 1999.

ADDRESSES: Send comments to Executive Office of the President, Office of National Drug Control Policy, Office of Legal Counsel, Attention General Counsel, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Daniel R. Petersen, (202) 395–6745.

SUPPLEMENTARY INFORMATION: This rule is not a major rule for the purposes of Executive Order 12866. As required by the Regulatory Flexibility Act, ONDCP certifies that this proposed rule would not have a significant impact on small business entities.

List of Subjects in 21 CFR Part 1401

Freedom of information, Organization and functions (Government agencies).

For the reasons stated in the preamble, the Office of National Drug Control Policy revises 21 CFR part 1401 to read as follows:

PART 1401—PUBLIC AVAILABILITY OF INFORMATION

Sec.

Authority: 5 U.S.C. 552.

§ 1401.1 Purpose.

The purpose of this part is to prescribe rules, guidelines and procedures to implement the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552.

§ 1401.2 The Office of National Drug Control Policy—organization and functions.

(a) The Office of National Drug Control Policy (ONDCP) was created by the Anti-Drug Abuse Act of 1988, 21 U.S.C. 1501 *et seq.*, and reestablished under 21 U.S.C. 1701 *et seq.* The mission of ONDCP is to coordinate the anti-drug efforts of the various agencies and departments of the Federal government, to consult with States and localities and assist their anti-drug efforts, to conduct a national media campaign, and to annually promulgate the National Drug Control Strategy.

(b) ONDCP is headed by the Director of National Drug Control Policy. The Director is assisted by a Deputy Director of National Drug Control Policy, a Deputy Director for Supply Reduction, a Deputy Director for Demand Reduction, and a Deputy Director for State and Local Affairs.

(c) Offices within ONDCP include Chief of Staff, and the Offices of Legal Counsel, Strategic Planning, Legislative Affairs, Programs Budget and Evaluation, Supply Reduction, Demand Reduction, Public Affairs, State and Local Affairs, and the Financial Management Office.

(d) The Office of Public Affairs is responsible for providing information to the press and to the general public. If members of the public have general questions about ONDCP that can be answered by telephone, they may call the Office of Public Affairs at (202) 395–6618. This number should not be used to make FOIA requests. All oral requests for information under FOIA will be rejected.

§ 1401.3 Definitions.

For the purpose of this part:

(a) All the terms defined in the Freedom of Information Act apply.

(b) *Commercial-use request* means a request from or on behalf of one who seeks information for a cause or purpose that furthers the commercial, trade or profit interests of the requester or the person or institution on whose behalf the request is made. In determining whether a requester properly belongs in this category, ONDCP will consider the intended use of the information.

(c) *Direct costs* means the expense actually expended to search, review, or duplicate in response to a FOIA request. For example, direct costs include 116% of the salary of the employee performing work and the actual costs incurred while operating equipment.

(d) *Duplicate* means the process of making a copy of a document. Such copies may take the form of paper, microform, audio-visual materials, or machine-readable documentation. ONDCP will provide a copy of the material in a form that is usable by the requester.

(e) *Educational institution* means preschool, a public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education that operates a program or programs of scholarly research.

(f) *Noncommercial scientific institution* means an institution that is not operated on a commercial basis as that term is defined in this section, and that is operated solely for the purpose of conducting scientific research not intended to promote any particular product or industry.

(g) *Records* and any other terms used in this part in reference to information includes any information that would be an agency record subject to the requirements of this part when maintained in any format, including electronic format.

(h) *Representative of the news media* means any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. News is information about current events or information that would be of interest to the public. Examples of the news media include television or radio stations that broadcast to the public at large and publishers of news periodicals that make their products available to the general public for purchase or subscription. Freelance journalists may be regarded as working for the news media where they demonstrate a reasonable basis for expecting publication through that organization, even though not actually employed by it.

(i) *Request* means a letter or other written communication seeking records or information under FOIA.

(j) *Review* means the process of examining documents that are located during a search to determine if any portion should lawfully be withheld. It is the processing of determining disclosability.