property to any other depository unless the Dealer has assured itself that all such other separate account depositories will treat such funds in a manner consistent with the procedures described in this paragraph 1 herein; [21] or

2. Must set aside funds constituting the entire secured amount requirement in a separate account as set forth in Commission rule 30.7, 17 CFR § 30.7 (1996), and treat those funds in the manner described by that rule; or

3. Must comply with the terms and procedures of paragraph 1 or 2, with the amount required to be segregated under NZFOE rules and New Zealand laws to be substituted for the secured amount requirement as set forth in such paragraphs.[22]

Upon filing of the notice required under paragraph I. B. as to any such Dealer, the rule 30.10 relief granted by this Order may be suspended immediately as to that Dealer. That suspension will remain in effect pending further notice by the Commission, or the Commission's designee, to the Dealer and the Exchange and/or any applicable regulatory or self-regulatory organization.

Any material changes or omissions in the facts and circumstances pursuant to which this Order is granted might require the Commission to reconsider its finding that the standards for issuance of an order under Commission rule 30.10, including Appendix A of rule 30.10, have generally been satisfied.

Further, if experience demonstrates that the continued effectiveness of this Order in general, or with respect to a particular Dealer, would be contrary to public policy or the public interest, or that the systems in place for the exchange of information or other circumstances do not warrant continuation of the exemptive relief granted herein, the Commission may condition, modify, suspend, terminate, withhold as to a specific Dealer, or otherwise restrict the exemptive relief granted in this Order, as appropriate, on its own motion. If necessary, provisions will be made for servicing existing client positions.

List of Subjects in 17 CFR Part 30

Commodity futures, Commodity options, Foreign futures and options.

Accordingly, 17 CFR Part 30 is amended as set forth below:

PART 30—FOREIGN FUTURES AND FOREIGN OPTIONS TRANSACTIONS

1. The authority citation for part 30 continues to read as follows:

Authority: Secs. 2(a)(1)(A), 4, 4c, and 8a of the Commodity Exchange Act, 7 U.S.C. 2, 6, 6c and 12a.

2. Appendix C to part 30 is amended by adding at the end of the appendix the following entry to read as follows:

Appendix C—Foreign Petitioners Granted Relief From the Application of Certain of the Part 30 Rules Pursuant to § 30.10

* * * * *

Firms designated by the New Zealand Futures and Options Exchange (''NZFOE'')

FR date and citation, _____, 1996, _____ FR _____.

Issued in Washington, D.C., on December 3, 1996.

Jean A. Webb,

Secretary to the Commission.

[FR Doc. 96–31326 Filed 12–9–96; 8:45 am]

BILLING CODE 6351–01–U

[21] This proviso is intended to ensure that the originating Dealer makes reasonable inquiries and understands prior to the initiation of a trade the conditions under which its customers' funds will be held at all subsequent depositories, so that it may determine whether it may count a particular intermediary or clearing house as a good separate account depository for purposes of this Order or must alternatively set aside funds in the manner set forth in paragraph 2. The Dealer initially would discuss with its immediate intermediary broker whether funds will be transferred to any subsequent depositories and determine the conditions under which such funds would be treated. Compliance with this condition would be satisfied by the Dealer obtaining relevant information or assurances from appropriate sources such as, for example, the immediate intermediary broker, exchanges or clearinghouses, exchange regulators, banks, attorneys or regulatory references.

This requirement is intended to ensure that funds provided by U.S. customers for foreign futures and options transactions, whether held at a U.S. FCM under rule 30.7(c) or a firm exempted from registration as an FCM under CFTC rule 30.10, will receive equivalent protection at all intermediaries and exchange clearing organizations. Thus, for example, an exchange that does not segregate customer from firm obligations and firms which trade on such exchanges and which do not arrange to comply otherwise with any of the procedures described in paragraph K would not be deemed an acceptable separate account. Specifically, such exchange or firms could not provide a valid and binding acknowledgement to a rule 30.10 exempted firm.

This provision is not intended to create a duty on a rule 30.10 firm that it audit any intermediaries for continued compliance with the undertakings it has obtained based on discussions with those relevant intermediaries. It is intended to make clear that firms must engage in a due diligence inquiry before customer funds are sent to another intermediary and take appropriate action (*i.e.*, set aside funds) in the event that it becomes aware of facts leading it to conclude that customer funds are not being handled consistent with the requirements of Commission rules or relevant rule 30.10 order by any subsequent intermediary or clearing house.

[22] The Client Funds Regulations permit a Dealer to send client funds to a depository outside New Zealand which cannot or will not provide the acknowledgement required by the Client Funds Regulations, provided that the Dealer has first:

—advised the client that the money may not receive the protection afforded by section 20 of the Client Funds Regulations (*i.e.*, segregation); and

—obtained the written agreement of the client that notwithstanding such notice, the money may be credited to the client funds account. See section 10 of the Client Funds Regulations.

The Commission notes, however, that such waiver is inconsistent with the terms of this Order requiring that the secured amount funds of U.S. foreign futures and options customers (or the segregated amount under New Zealand law) be in appropriate separate account locations and protected for the benefit of such customers.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 94F–0251]

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 1,4-bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione as a colorant in polyethylene phthalate polymers intended for use in food-contact articles. This action is in response to a petition filed by Registration and Consulting Co. AG.

DATES: Effective December 10, 1996; written objections and requests for a hearing January 9, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 2, 1994 (59 FR 39366), FDA announced that a food additive petition (FAP 4B4423) had been filed by Registration and Consulting Co. AG, c/o Bruce A. Schwemmer, Bruce EnviroExcel Group, Inc., 94 Buttermilk Bridge Rd., Washington, NJ 07882 (formerly, c/o Reynaldo A. Gustilo, 125A 18th St., suite 142, Newport Plaza, Jersey City, NJ 07310). The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of 1,4-bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione (C.I. Solvent Blue 104) as a colorant in polyethylene phthalate

polymers complying with 21 CFR 177.1630, intended for use in food-contact articles.

Upon review of information provided by the petitioner, FDA concluded that the use of C.I. Solvent Blue 104 as a synonym for the colorant may cause confusion because it is identified by a different CAS Reg. No. (71872–84–9) than the CAS Reg. No. for the colorant itself (116–75–6). Therefore, this final rule identifies the colorant only by its CAS Reg. name (1,4-bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione) and the corresponding CAS Reg. No. (116–75–6).

In FDA's evaluation of the safety of this food additive, the agency 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 2,4,6-trimethylaniline, which is a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 2,4,6-trimethylaniline, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' 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 additive 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 the 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 clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed 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, 1,4-bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione, will result in exposure to no greater than 0.2 part per billion of the additive in the daily diet (3 kilograms (kg)) or an estimated daily intake (EDI) of 0.6 microgram per person per day (/person/day) (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 to this additive is safe.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by 2,4,6-trimethylaniline, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of 2,4,6-trimethylaniline has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. 2,4,6-Trimethylaniline

FDA has estimated the hypothetical worst-case exposure to 2,4,6-trimethylaniline from the petitioned use of the additive as a colorant in polyethylene phthalate polymers to be 1.3 parts per trillion in the daily diet (3 kg), or 3.9 nanograms (ng)/person/day (Ref. 1). The agency used data from a long-term rodent bioassay on 2,4,6-trimethylaniline conducted by Weisburger et al. (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive. The authors reported that the test material caused significantly increased incidence of liver tumors in male and female mice and female rats and lung tumors in male rats.

Based on the estimated worst-case exposure to 2,4,6-trimethylaniline of 3.9 ng/person/day, FDA's Center for Food Safety and Applied Nutrition estimates that a worst-case upper-bound limit of lifetime human risk from the use of the subject additive is 4.2×10^{-9}, or 4.2 in a billion (Refs. 4, 5, and 6). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 2,4,6-trimethylaniline is likely to be substantially less than the worst-case exposure, and therefore, the upper-bound lifetime human risk would be less. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to 2,4,6-trimethylaniline would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 2,4,6-trimethylaniline present 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 2,4,6-trimethylaniline may be expected to remain as an impurity following production of the additive, 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 the impurity, even under worst-case assumptions, is very low, less than 1.1 in a billion.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed use of the additive as a colorant for polyethylene phthalate polymers in contact with food is safe. Based on this information, the agency has also concluded that the additive will have the intended technical effect. Therefore, the agency concludes that the regulations in § 178.3297 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.

IV. 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.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before January 9, 1997, 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.

VI. 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 Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216) concerning FAP 4B4423: Dietary Concentrations of the Additive and the Impurity (2,4,6-trimethylaniline), August 15, 1994.

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

3. Weisburger, E. K., A. B. Russfield, F. Homburger, J. H. Weisburger, E. Boger, C. G. Van Dongen, and K. C. Chu, ''Testing of Twenty-One Environmental Aromatic Amines or Derivatives for Long-Term Toxicity or Carcinogenicity,'' *Journal of Environmental Pathology and Toxicology*, vol. 2, pp. 325–356, 1978.

4. Memorandum from Executive Secretary, Cancer Assessment Committee (HFS–227) to Chairman, Cancer Assessment Committee, and Chairman, Quantitative Risk Assessment Committee: Worst-case Risk Assessment for 2,4,6-trimethylaniline, December 18, 1995.

5. Memorandum from Executive Secretary, Cancer Assessment Committee (HFS–227) to Chairman, Cancer Assessment Committee, and Chairman, Quantitative Risk Assessment Committee: Correction to December 18, 1995, memorandum: Worst-case Risk Assessment for 2,4,6-trimethylaniline, August 15, 1996.

6. Memorandum from Executive Secretary, Cancer Assessment Committee (HFS–227) to Chairman, Cancer Assessment Committee, and Chairman, Quantitative Risk Assessment Committee: Risk Assessment for 2,4,6-trimethylaniline, August 16, 1996.

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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
1,4-Bis[(2,4,6-trimethylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 116–75–6).	For use at levels not to exceed 0.0004 percent by weight of polyethylene phthalate polymers complying with § 177.1630 of this chapter.
* * *	* * * *

Dated: November 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–31361 Filed 12–9–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–96–068]

RIN 2115–AE46

Special Local Regulations; Rada Fajardo, East of Villa Marina, Fajardo, PR

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special local regulations are being adopted for the AC Delco Offshore Invitational. This event will be held from 1 p.m. AST (Atlantic Standard Time) to 2:30 p.m. AST on December 15, 1996, on the waters of Rada Fajardo, due East of Villa Marine, Fajardo, Puerto Rico. During this event, race boats will be competing at high speeds with numerous spectator craft in the area, creating an extra or unusual hazard on the navigable waterways. Therefore, these regulations are necessary to provide for the safety of life on the navigable waters during the event.

EFFECTIVE DATE: These regulations become effective from 12:30 p.m. AST to 3 p.m. AST, December 15, 1996.