Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

*Paragraph 6004 Class E airspace areas designated as an extension to a Class D or E surface area.*

* * * * *

ASO FL E4 Mayport NS Mayport, FL [Revised]

Mayport NAS, FL
(Lat. 30°23′31″ N, long. 81°25′23″ W)
Mayport (Navy) TACAN
(Lat. 30°23′19″ N, long. 81°25′23″ W)

That airspace extending upward from the surface within 3.2-miles each side of the Mayport (Navy) TACAN 035° radial extending from the 4.2-mile radius of Mayport NAS to 5 miles northeast of the TACAN. This Class E airspace is effective during the days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in College Park, Georgia, on February 10, 1997.

Wade T. Carpenter,

*Acting Manager, Air Traffic Division, Southern Region.*

[FR Doc. 97–5063 Filed 2–23–97; 8:45 am]

**BILLING CODE 4910–13–M**

## DEPARTMENT OF COMMERCE

## Bureau of Export Administration

## 15 CFR Part 746

**[Docket No. 961015286–6286–01]**

**RIN 0694–AB43**

## Exports to Cuba; Support for the Cuban People

**AGENCY:** Bureau of Export Administration.

**ACTION:** Final rule.

**SUMMARY:** On October 6, 1995, President Clinton announced several changes to the administration of the Cuban embargo intended to promote democratic change in Cuba. Accordingly, this final rule amends the Export Administration Regulations by introducing a licensing review policy for the approval, on a case-by-case basis, of certain exports to human rights organizations, news bureaus, and individuals and non-governmental organizations engaged in activities that promote democratic activity in Cuba.

**EFFECTIVE DATE:** March 3, 1997.

**FOR FURTHER INFORMATION CONTACT:** Bruce Cromack, Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, Telephone: (202) 482–5537.

**SUPPLEMENTARY INFORMATION:**

### Background

On October 6, 1995 the President announced new measures designed to improve enforcement of the U.S. embargo against Cuba and to increase support for the Cuban people. The measures would permit U.S. persons to engage in new categories of transactions with eligible Cuban entities, providing increased support for the Cuban people by facilitating communications, and supporting human rights and democratic activities. This rule is consistent with the Cuban Democracy Act of 1992 and the Cuban Liberty and Democratic Solidarity (Libertad) Act of 1996.

Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the EAR in Executive Order 12924 of August 19, 1994, as extended by the President's notice of August 15, 1995 (60 FR 42767) and notice of August 14, 1996 (61 FR 42527).

### Rulemaking Requirements

1. This final rule has been determined to be significant for purposes of E.O. 12866.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694–0021 and 0694–0088. Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553 or by any other law, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Submit comments to Hillary Hess, Office of Exporter Services, Regulatory Policy Division, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

### List of Subjects in 15 CFR Part 746

Embargoes, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, part 746 of the Export Administration Regulations (15 CFR Parts 730–774) is amended as follows:

## PART 746—[AMENDED]

1. The authority citation for 15 CFR part 746 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 6004; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; Notice of August 15, 1995 (60 FR 42767, August 17, 1995); and Notice of August 14, 1996 (61 FR 42527).

2. Section 746.2 is amended by adding paragraph (b)(4) to read as follows:

**§ 746.2 Cuba.**

* * * * *

(b) * * *

(4) Applications for licenses may be approved, on a case-by-case basis, for certain exports to Cuba intended to provide support for the Cuban people, as follows:

(i) Applications for licenses for exports of certain commodities and software may be approved to human rights organizations, or to individuals and non-governmental organizations that promote independent activity intended to strengthen civil society in Cuba when such exports do not give rise to U.S. national security or counter-terrorism concerns. Examples of such commodities include fax machines, copiers, computers (e.g., 486-level/CTP of 24.8 MTOPS or less), business/office software, document scanning equipment, printers, typewriters, and other office or office communications

equipment. Applicants may donate or sell the commodities or software to be exported. Reexport to other end-users or end-uses is not authorized.

(ii) Commodities and software may be approved for export to U.S. news bureaus in Cuba whose primary purpose is the gathering and dissemination of news to the general public. In addition to the examples of commodities and software listed in paragraph (b)(4)(i) of this section, certain telecommunications equipment necessary for the operation of news organizations (e.g., 33M bit/s data signaling rate or less) may be approved for export to U.S. news bureaus.

* * * * *

Dated: February 26, 1997.

Sue E. Eckert,

*Assistant Secretary for Export Administration.*

[FR Doc. 97–5169 Filed 2–28–97; 8:45 am]

**BILLING CODE 3510–33–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 178

**[Docket No. 93F–0028]**

## 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 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

**DATES:** Effective March 3, 1997; written objections and requests for a hearing by April 2, 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:** Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of March 17, 1993 (58 FR 14402), FDA announced that a food additive petition (FAP 3B4349) had been filed by Ciba-Geigy Corp., 315 Water St., Newport, DE 19804–2434 (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). 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 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254) as a colorant in polymers intended for use in contact with food.

In its evaluation of the safety of this food additive, FDA reviewed the safety of the additive 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 may contain minute amounts of polychlorinated biphenyls (PCB's), which are carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants, manufacturing aids, and their constituent impurities, and byproducts, such as PCB's, 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 food 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 to be 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 food additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

### II. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the food additive, 3,6-bis(4-chlorophenyl)-2,5-dihydro-pyrrolo[3,4-c]pyrrole-1,4-dione (C.I. Pigment Red 254), will result in exposure to no greater than 0.2 parts per billion (ppb) of the food additive in the daily diet (3 kilograms (kg)) or an estimated daily intake (EDI) of 0.6 micrograms (µg) per person per day (µg/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 (acute toxicity and mutagenicity studies) on the additive and concludes that the small dietary exposure resulting from the proposed use of the 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 PCB's, carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of PCB's has two aspects: (1) Assessment of the worst-case exposure to these impurities from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of worst-case exposure to humans.

#### *A. PCB's*

FDA has estimated the hypothetical worst-case exposure to PCB's from the petitioned use of the food additive as a colorant in polymers to be less than $1x10^{-4}$ parts per trillion of the daily diet (3 kg), or 0.3 picograms (pg)/person/day (Ref. 3). The agency used data from a carcinogenesis bioassay on PCB's, conducted by Norback and Weltman (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to these chemicals resulting from the proposed use of the food additive (Ref. 5). The results of the bioassay on a PCB mixture (Aroclor 1260) demonstrated that the material was carcinogenic for male and female rats under the conditions of the study. The test material caused significantly increased incidence of hepatocellular tumors in both female and male rats.

Based on the estimated worst-case exposure to PCB's of 0.3 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is less than $7.5x10^{-13}$, or 8 in 10 trillion (Refs. 6 and