[FR Doc. 98–17853 Filed 7–9–98; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 622

[Docket No. 980513127–8127–01; I.D. 050598A]

RIN 0648–AL15

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Data Collection; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim rule; correction.

SUMMARY: This document contains corrections to the interim rule (I.D. 050598A) that was published in the **Federal Register** on May 19, 1998. That interim rule requires vessels in the shrimp fishery of the Gulf of Mexico to maintain and submit fishing records, to carry a NMFS-approved observer, and/or to carry a vessel monitoring system unit, if selected by NMFS to do so. This document corrects information regarding estimated compliance costs associated with the interim rule and corrects the estimated reporting burden associated with the requirement to maintain and submit fishing records.

DATES: Effective July 10, 1998 through November 16, 1998.

FOR FURTHER INFORMATION CONTACT: Michael E. Justen, phone: 813–570–5305 or fax: 813–570–5583.

SUPPLEMENTARY INFORMATION: The interim rule that is the subject of this correction was published on May 19, 1998 (63 FR 27485). That interim rule requires vessels in the shrimp fishery of the Gulf of Mexico to maintain and submit fishing records, to carry a NMFS-approved observer, and/or to carry a vessel monitoring system unit (VMS unit), if selected by NMFS to do so. That rule also informed the public of the approval by the Office of Management and Budget (OMB) of the collection-of-information requirements contained in that rule and published the OMB control numbers for those collections.

Need for Correction

As published, the preamble to the interim rule contains an incorrect estimate of the cost that shrimpers, in aggregate, would incur to comply with the observer, logbook, and VMS unit requirements and associated vessel safety and sanitation requirements. The preamble, in one instance, also incorrectly attributed costs related to vessel safety and sanitation to U.S. Coast Guard regulations rather than a pending NMFS rule. Finally, the preamble to the interim rule contains an incorrect estimate of the reporting burden associated with the requirement for a vessel owner or operator, if selected by NMFS, to maintain and submit fishing records.

Correction of Publication

Accordingly, the publication on May 19, 1998, of the interim rule (I.D. 050598A), which was the subject of FR Doc. 98–13290, is corrected as follows:

1. On page 27487, in the second column, under the heading ''Classification,'' paragraph 4:

a. In line 23, correct ''$23,770'' to read ''$21,040''.

b. In line 39, correct ''to USCG regulations.'' to read ''to the separate rule, amending regulations at 50 CFR 600.725 and 600.746, that NMFS intends to issue shortly.''

2. On page 27487, in the third column, last paragraph, fifth line from the bottom of the paragraph, correct ''10'' to read ''20''.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 2, 1998.

David L. Evans,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 98–18341 Filed 7–9–98; 8:45 am]
BILLING CODE 3510–22–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 90F–0142]

Indirect Food Additives: Adhesives and Components of Coatings

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 polyurethane resins derived from the reaction of toluene diisocyanate or 4,4′ methylenebis(cyclohexylisocyanate) with fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol, triethylamine, and ethylenediamine as a component of adhesives for articles intended to contact food. This action responds to a petition filed by Olin Corp.

DATES: The regulation is effective July 10, 1998. Submit written objections and requests for a hearing by August 10, 1998.

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: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3084.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of May 10, 1990 (55 FR 19667), FDA announced that a food additive petition (FAP OB4201) had been filed by Olin Corp., 120 Long Ridge Rd., Stamford, CT 06904. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of polyurethane resins derived from the reactions of toluene diisocyanate or 4,4′ methylenebis(cyclohexylisocyanate) with carboxylic acid-modified polypropylene glycol and with triethylamine and ethylenediamine as a component of adhesives for articles intended to contact food. In a notice published in the **Federal Register** of September 5, 1997 (62 FR 46979), FDA amended the May 10, 1990, notice to state that upon further review of the petition, the petitioner specifically requested the approval of the use of polyurethane resins derived from the reaction of toluene diisocyanate or 4,4′ methylenebis(cyclohexylisocyanate) with fumaric acid-modified propylene glycol or fumaric acid-modified tripropylene glycol, triethylamine, and ethylenediamine.

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 may contain minute amounts of toluenediamine (TDA), which is 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 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 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, polyurethane resins derived from the reaction of toluene diisocyanate or 4,4′ methylenebis(cyclohexylisocyanate) with fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol, triethylamine, and ethylenediamine, will result in exposure to the additive that would be virtually nil (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 ''virtually nil'' 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 TDA, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of TDA has two aspects: (1) Assessment of 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 exposure to humans.

A. Toluenediamine

FDA has estimated the cumulative exposure to TDA from all currently regulated uses of the additives where TDA may be present as an impurity and from the petitioned use of the additive in polyurethane adhesive applications to be no more than 0.059 part per billion in the daily diet (3 kilograms) or 0.18 microgram (µg)/person/day (Ref. 3). The agency used data from long-term rodent bioassays on 2,4′ toluenediamine conducted by the National Cancer Institute (Ref. 4) to estimate the upper-bound limit of lifetime human risk from the cumulative exposure to this chemical resulting from the currently regulated food additive uses where TDA may be present as an impurity and the proposed use of the additive. The authors reported that the test material caused significant amounts of hepatocellular carcinomas in both male and female rats and carcinomas of the mammary gland in female rats. The test chemical was also carcinogenic for female mice, causing hepatocellular carcinomas.

Based on the agency's estimate that exposure to TDA will not exceed 0.18 µg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from all regulated uses of the additives where TDA may be present as an impurity and from the proposed use of the subject additive is 6.1×10^{-7}, or 6 in 10 million (Ref. 5). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to TDA 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 TDA 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 TDA as an impurity in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which TDA 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 TDA is very low (6 in 10 million).

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 a component of adhesives for articles intended to contact food is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 175.105 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. No comments were received during the 30-day comment period specified in the May 10, 1990, filing notice for comments on the environmental assessment submitted with the petition.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 10, 1998, 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 the Food and Color Additives Review Section (HFF–415) to the Indirect Additives Branch (HFS–335) entitled ''FAP 0B4201—Olin Corporation: Polyurethane resins from carboxyl-modified polyols as components of adhesives of coatings contacting foods: submission of 3–12–90,'' dated July 18, 1990.

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. Memorandum from the Chemistry Review Branch (HFS–247) to the Indirect Additives Branch (HFS–216) entitled ''FAP 0B4201 MATS# 471): Newly Revised Exposure Estimate for Tolenediamine (TDA) from Polyurethane Adhesive Applications and Cumulative Exposure to TDA,'' dated March 2, 1993.

4. ''Bioassay of 2,4–Diaminotoluene for Possible Carcinogenicity,'' National Cancer Institute. NCI-CG-TR-162, 1979.

5. Report of the Quantitative Risk Assessment Committee entitled ''FAP 0B4201: Upper Bound Lifetime Carcinogenic Risk from Exposure to Toluenediamine (TDA) from Polyurethane Adhesive Applications and Cumulative Exposure to TDA,'' dated June 14, 1996.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

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

2. Section 175.105 is amended in the table in paragraph (c)(5) by revising the entry for ''Polyurethane resins * * *'' under the heading ''Substances'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * *	* * * *
Polyurethane resins produced by: (1) reacting diisocyanates with one or more of the polyols or polyesters named in this paragraph, or (2) reacting the chloroformate derivatives of one or more of the polyols or polyesters named in this paragraph with one or more of the polyamines named in this paragraph, or (3) reacting toluene diisocyanate or 4,4′ methylenebis(cyclohexylisocyanate) (CAS Reg. No. 5124–30–1) with: (i) one or more of the polyols or polyesters named in this paragraph and with either *N*-methyldiethanolamine (CAS Reg. No. 105–59–9) and dimethyl sulfate (CAS Reg. No. 77–78–1) or dimethylolpropionic acid (CAS Reg. No. 4767–03–7) and triethylamine (CAS Reg. No. 121–44–8), or (ii) a fumaric acid-modified polypropylene glycol or fumaric acid-modified tripropylene glycol), triethylamine (CAS Reg. No. 107–15–3), and ethylenediamine (CAS Reg. No. 121–44–8), or (4) reacting *meta*-tetramethylxylene diisocyanate (CAS Reg. No. 2778–42–9) with one or more of the polyols and polyesters listed in this paragraph and with dimethylolpropionic acid (CAS Reg. No. 4767–03–7) and triethylamine (CAS Reg. No. 121–44–8), *N*-methyldiethanolamine (CAS Reg. No. 105–59–9), 2–dimethylaminoethanol (CAS Reg. No. 108–01–0), 2–dimethylamino–2–methyl–1–propanol (CAS Reg. No. 7005–47–2), and/or 2–amino–2–methyl–1–propanol (CAS Reg. No. 124–68–5).	
* * *	* * * *

Dated: June 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18406 Filed 7–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01–96–015]

RIN 2115–AE46

Special Local Regulation: Swim Buzzards Bay Day, New Bedford, MA

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a permanent special local regulation for a swimming event known as Swim Buzzards Bay Day. The event is held annually on a day during the last weekend of July or first weekend in August. This swimming event takes place in Buzzards Bay, on the Acushnet River. The actual date time will be published in a **Federal Register** document. This regulation is needed to protect the participants from vessel traffic during the swimming event.

DATES: This section is effective on July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Lieutenant Timothy J. Carton, Office of Search and Rescue, First Coast Guard District, (617) 223–8460.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was published on May 6, 1996 (61 FR 20196) proposing the establishment of a permanent special local regulation for the annual swimming competition, Swim Buzzards Bay Day, New Bedford, MA. The NPRM proposed to restrict vessels from approaching within 200 feet of any participating swimmer to ensure the safety of participants during the event. No comments were received and no hearing was requested.

Background and Purpose

The annual Swim Buzzards Bay Day is a local, traditional event that has been held for many years on the Acushnet River, New Bedford/Fairhaven, MA. In the past, the Coast Guard has promulgated individual regulations for the event. Given the recurring nature of the event, the Coast Guard is establishing a permanent regulation. This rule establishes a permanent regulation for an annual event to be held during the last week of July or first week in August on the Acushnet River. This rule restricts vessels from approaching within 200 feet of participating swimmers.

The event will consist of approximately 50 swimmers transversing the Acushnet River from Fort Phoenix Beach in Fairhaven, MA, to Billy Woods Wharf in New Bedford, MA. There will be one rowing skiff per participant, along with sponsor provided vessels on scene to augment a Coast Guard patrol to alert boating traffic of the presence of the swimmers. The time period for the event is dictated by tidal conditions. Subject to Coast Guard approval, the sponsor selects a day during the last weekend of July or the first weekend of August that most closely exhibits low tide at a daytime hour reasonable for holding the event. Spectator craft are authorized to watch the race from any area as long as they remain 200 feet away from any participating swimmer. In emergency situations, provisions may be made to establish safe escort by a Coast Guard or Coast Guard designated vessel for vessels requiring transit within 200 feet of participating swimmers.

Good cause exists for providing this rule to become effective in less than 30 days. This rule is being made effective less than 30 days after publication due to the need to publish a notice in the **Federal Register**, which will provide an exact date and time of the annual event. Any delay encountered in effecting this rule would be contrary to the public interest, as the rule is needed to ensure the safety of the boating pubic during this event.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has exempted it from review under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation, under paragraph 10e of the regulatory policies and procedures of DOT, is unnecessary. This conclusion is based on the limited duration of the event, the extensive advisories that will be made to the affected maritime community and the minimal restrictions that the regulation places on vessel traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule would have a significant economic impact on a substantial number of small entities. ''Small entities'' may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000.

For the reasons discussed in the Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and a criterion contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard has considered the environmental impact of this final rule and concluded that under Figure 2–1, paragraph 34(h), of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Final Regulation

For the reasons set out in the preamble, the Coast Guard is amending 33 CFR Part 100 as follows:

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A new section, 100.116, is added to read as follows:

§ 100.116 Swim Buzzards Bay Day, New Bedford, MA.

(a) *Regulated Area.* All waters of the Acushnet River, within 200 feet of participating swimmers.