Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–25–06 British Aerospace Regional Aircraft [Formerly Jetstream Aircraft Limited; British Aerospace (Commercial Aircraft) Limited]: Amendment 39–11449. Docket 98–NM–296–AD.

Applicability: British Aerospace (Jetstream) Model 4101 airplanes, as listed in Jetstream Service Bulletin J41–52–060, dated August 31, 1998; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent sub-frame damage, which, if left undetected, could cause rapid decompression of the airplane and consequent injury to passengers and crew, accomplish the following:

Visual Inspection

(a) Within 1,500 landings or within 5 months after the effective date of this AD, whichever occurs first, perform a one-time general visual inspection of the bottom aft roller of the main baggage bay door structure to check for cracking or damage to the sub-frame in accordance with Jetstream Service Bulletin J41–52–060, dated August 31, 1998. If any cracking or damage is found, prior to further flight, repair in accordance with a method approved by either the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Civil Aviation Authority (or its delegated agent). For a repair method to be approved by the Manager, International Branch, ANM–116, as required by this paragraph, the Manager's approval letter must specifically reference this AD.

Note 2: For the purposes of this AD, a general visual inspection is defined as ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being check.''

Operational Test

(b) Within 30 days after the effective date of this AD, perform an operational test to determine if the counter-balance motor of the main baggage bay door functions properly in accordance with Jetstream Service Bulletin J41–52–060, dated August 31, 1998. Repeat the operational test thereafter at intervals not to exceed 5 days. If the motor fails during any operational test, within 10 flights after accomplishing the test, either replace the motor with a new motor or repair in accordance with the service bulletin, and accomplish the actions specified in paragraph (a) of this AD.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) Except as provided by paragraph (a) of this AD, the actions shall be done in accordance with Jetstream Service Bulletin J41–52–060, dated August 31, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from British Aerospace Regional Aircraft American Support, 13850 Mclearen Road, Herndon, Virginia 20171. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in British airworthiness directive 005–08–98.

(f) This amendment becomes effective on January 12, 2000.

Issued in Renton, Washington, on November 24, 1999.

D. L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–31473 Filed 12–7–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 86F–0312]

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 acrylamide polymer with sodium 2-acrylamido-2-methylpropanesulfonate as a component of paper and paperboard in contact with dry food. This action is in response to a petition filed by American Cyanamid Co. (currently Cytec Industries, Inc.).

DATES: This regulation is effective December 8, 1999; Submit written objections and requests for a hearing by January 7, 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: Edward J. Machuga, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3085.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of August 19, 1986 (51 FR 29612), FDA announced that a food additive petition (FAP 6B3940) had been filed on behalf of American Cyanamid Co., One Cyanamid Plaza, Wayne, NJ 07470 (currently Cytec Industries, Inc., Five Garret Mountain Plaza, West Paterson, NJ 07424). The petition proposed that the food additive regulations in § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) be amended to provide for the safe use of acrylamide polymer with sodium 2-acrylamido-2-

methylpropanesulfonate as a component of paper and paperboard in contact with dry food.

In its evaluation of the safety of acrylamide polymer with sodium 2-acrylamido-2-methylpropanesulfonate, FDA 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 acrylamide as an impurity resulting from its manufacture. This chemical has been shown to cause cancer in test animals. Residual amounts of impurities are commonly found as constituents of chemical products, including food additives.

II. 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)).

III. Safety of the Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, acrylamide polymer with sodium 2-acrylamido-2-methylpropanesulfonate, will result in exposure no greater than 50 parts per billion of the additive in the daily diet (3 kilograms (kg)) or an estimated daily intake of no more than 150 micrograms per person per 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 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 acrylamide, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of acrylamide has two aspects: (1) Assessment of exposure to the impurity 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. Acrylamide

FDA has estimated the exposure to acrylamide from the petitioned use of the additive as a component of paper and paperboard in contact with dry food to be no more than 0.78 part per trillion in the daily diet (3 kg) or 2.3 nanograms per person per day (ng/p/d) (Ref. 3). The agency used data from a long-term rat bioassay on acrylamide, conducted by Johnson et al. (Refs. 4 and 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 incidences of thyroid follicular adenomas and testicular mesotheliomas in male rats, and mammary tumors (adenomas or adenocarcinomas, fibromas or fibroadenomas, adenocarcinomas alone), central nervous system tumors (brain astrocytomas, brain or spinal cord glial tumors), and uterine tumors in female rats.

Based on the agency's estimate that exposure to acrylamide will not exceed 2.3 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 2.7×10^{-8} or 2.7 in 100 million (Refs. 5 and 6). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to acrylamide 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 acrylamide would result from the petitioned use of the additive.

B. Need for Specifications

The agency also has considered whether specifications are necessary to control the amount of acrylamide 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 acrylamide 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 acrylamide is very low, 2.7 in 100 million.

IV. Conclusion

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive as a component of paper and paperboard in contact with dry food is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 176.180 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions 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. Environmental Impact

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. 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.

VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before January 7, 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.

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 Chemistry and Environmental Review Team, FDA, to the Division of Petition Control, FDA, ''DPC Request to Identify and Address Unresolved Issues in the Pending Acrylamide Petitions,'' August 7, 1997.

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

3. Memorandum from the Chemistry and Environmental Review Team, FDA, to the Division of Petition Control, FDA, ''Exposure to Acrylamide From the Use of the Sodium Salt of Copolymers 2-Acrylamido-2-Methylpropanesulfonic Acid and Acrylamide,'' February 3, 1999.

4. Johnson, K. A., Gorzinski, S. J., Bodner, K. M., Campbell, R. A., Wolf, C. H., Friedman, M. A., and Mast, R. W., ''Chronic Toxicity and Oncogenicity Study on Acrylamide Incorporated in the Drinking Water of Fischer 344 Rats,'' *Toxicology and Applied Pharmacology*, 85:154–168, 1986.

5. Memorandum from the Division of Petition Control, FDA, to the Quantitative Risk Assessment Committee, FDA, ''Estimation of Upper-Bound Risk for Acrylamide Exposure Resulting From the Use of Acrylamide Polymer with Sodium 2-Acrylamido-2-Methylpropanesulfonate—FAP 6B3940,'' March 3, 1999.

6. Memorandum of Conference, FDA, CFSAN, Washington, DC, Cancer Assessment Committee Meeting on Acrylamide, February 13 and June 6, 1985, May 31, 1996.

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 176.180 is amended in the table in paragraph (b)(2) by alphabetically adding an entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.180 Components of paper and paperboard in contact with dry food.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
Acrylamide polymer with sodium 2-acrylamido-2-methylpropane-sulfonate (CAS Reg. No. 38193–60–1)	For use at a level not to exceed 0.015 weight percent of dry fiber.
* * *	* * * *

Dated: November 30, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31700 Filed 12–7–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300947; FRL–6390–9]

RIN 2070–AB78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of tebufenozide in or on soybeans. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on soybeans. This regulation establishes a maximum permissible level for residues of benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide in this food commodity. The tolerance will expire and is revoked on December 31, 2001.

DATES: This regulation is effective December 8, 1999. Objections and requests for hearings, identified by docket control number OPP–300947, must be received by EPA on or before February 7, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the ''SUPPLEMENTARY INFORMATION.'' To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–300947 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 308–9367; and e-mail address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially