Drafting Information

The principal author of this document was Lee H. Kramer, Regulations and Disclosure Law Branch, Office of Regulations and Rulings, Customs Headquarters. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 10

Customs duties and inspection, Imports, Exports, Oil imports, Petroleum.

Amendment To The Regulations

Part 10, Customs Regulations (19 CFR Part 10), is amended as set forth below:

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for Part 10 and specific relevant authority continues to read as follows:

Authority: 19 U.S.C. 66, 1202, 1481, 1484, 1498, 1623, 1624.

* * * * *

2. Section 10.59 also issued under 19 U.S.C. 1309, 1317.

* * * * *

§ 10.59 [Amended]

2. In the list of countries in § 10.59(f), the listing for Japan is amended by adding ", 88-45" under the column marked "Treasury Decision(s)" and by adding "not applicable to ground support equipment as of August 1, 1986" in the column marked "Exceptions if any, as noted—".

Dated: July 22, 1988.

Kathryn C. Peterson,

Chief, Regulations and Disclosure Law Branch.

[FR Doc. 88-17000 Filed 7-27-88; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 82F-0295]

Food Additives Permitted For Direct Addition To Food For Human Consumption; Acesulfame Potassium

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acesulfame potassium as a nonnutritive sweetener. This action responds to a petition filed by American Hoechst Corp.

DATES: Effective July 28, 1988; objections and requests for hearing by August 29, 1988. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 172.800(b) effective July 28, 1988.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Summary of the Petition

In a notice published in the **Federal Register** of October 15, 1982 (47 FR 46139), FDA announced that a peitition (FAP 2A3659) has been filed by American Hoechst Corp. (now Hoechst Celanese Corp.), Route 202-206 North, Somerville, NJ 08876, proposing that the food additive regulations be amended to provide for the safe use of acesulfame potassium (potassium salt of 6-methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2-dioxide) as a nonnutritive sweetener.

Acesulfame potassium has also been called "acesulfame K" or "acetosulfam," and is a derivative of acetoacetic acid. It can be manufactured by reacting *tert*-butyl acetoacetate with fluorosulfonyl isocyanate. The reaction product is converted to an amide which is then cyclized with concomitant removal of fluoride and formation of the potassium salt. The sweetener is water soluble and is stable at normal temperatures and moderate pH. It is approximately 200 times sweeter than sucrose based on comparison to a 3 percent aqueous solution of sucrose.

This petition has requested the use of acesulfame potassium as a table-top sweetener and as an ingredient in chewing gum, confections, hard candy, soft candy, and dry bases for beverages, instant coffee and tea, gelatins, puddings, pudding desserts, and dairy product analogs. In this final rule, the agency is listing all of the requested uses except confections, hard candy, and soft candy. Before acting on these uses, FDA must first consider further whether acesulfame potassium or other nonnutritive sweeteners can be listed for use in confectionary under section 402(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(d)(3)). Section 402(d)(3) bars the use of any nonnutritive substance in confectionary, unless the subtance is used for some practical functional purpose and does not promote deception of the consumer. In interpreting section 402(d)(3), the agency's position has been that the use of nonnutritive artificial sweeteners in confectionary for the purpose of caloric reduction is not a practical functional purpose. The agency is reexamining this interpretation.

The petitioner submitted a series of toxicity studies concerned with the safety of acesulfame potassium. These include studies on reproduction in rats and rabbits, teratology in rats, and mutagenicity. There are reports on metabolism, kinetics, distribution, and elimination studies using rats, pregnant rats, dogs, pigs, and humans. There are also various pharmacological investigations and a study in rats with artificially induced diabetes. There are reports from studies done concerning acute toxicity, subchronic toxicity, chronic toxicity, and potential carcinogenicity.

Data from four long-term studies were submitted. One is a 2-year toxicity study in beagle dogs in which groups of four male and four female dogs were fed 0, 90, 300, or 900 milligrams per kilogram of acesulfame potassium in their diet. Another is a carcinogenicity study in Swiss mice. Diets containing 0, 0.3, 1.0, or 3.0 percent of the test compound were fed to groups containing 100 male and 100 female mice. There are two long-term studies in rats; both are chronic toxicity and carcinogenicity studies with in utero exposure. In each case, 0, 0.3, 1.0, or 3.0 percent acesulfame potassium in the diet was fed to groups containing 60 females and 60 males. The first rat study was conducted with the CIVO-bred Wistar strain. The second rat study used CPB-WU Wistar rats. The agency discusses its evaluation of these studies below.

II. Evaluation Of The Petition

A. Estimated Daily Intake

In determining whether the proposed use of an additive is safe, FDA considers whether an individual's estimated daily intake of the additive will be less than the acceptable daily intake established from safety data. The

agency determines the estimated daily intake for various age groups by making projections based on the amount of additive proposed for use in particular foods and on data about the consumption levels of each particular food. The use levels of acesulfame potassium considered by the agency to estimate consumer exposure are supported by analytical data and taste panel testing reported in the petition. The petitioner also submitted survey information on the consumption of the food types for which use of acesulfame potassium was requested (Ref. 1).

The agency commonly uses the estimated daily intake for the 90th percentile consumer of a food additive as a measure of high chronic exposure because that level of consumption is significantly above the intake of the average consumer, thus providing an added margin of safety with respect to the acceptable daily intake for those individuals who regularly consume food containing the additive. For the requested food uses of acesulfame potassium, the agency has determined the 90th percentile estimated daily intake to be 1.6 milligrams per kilogram of body weight (for further details on this estmate see Ref. 1).

B. Safety Studies

The metabolism studies of acesulfame potassium revealed no evidence that this substance is metabolized. The reproduction and teratology studies produced no evidence of compound-related teratogenic or adverse reproductive effects. The mutagenicity studies did not indicate any genotoxic effects from acesulfame potassium. None of the various short-term studies showed any untoward adverse effects from acesulfame potassium. The 2-year toxicity study in beagle dogs did not show any toxic effects associated with the consumption of acesulfame potassium.

For the carcinogenicity study in mice, the petitioner had a consulting pathologist, as well as the testing laboratory, review the data and microslides. The testing laboratory, the consulting pathologist, and the agency all concluded that the data did not reveal any association between neoplasms and use of the substance, or between any other adverse effects and use of the substance (Ref. 2). Lymphocytic leukemia was reported as increased in the high-dose female mice, but the incidences were within the range of spontaneous incidences with this strain in the laboratory. The control, low-, and mid-dose groups had incidences of 1 percent and the high-dose group had 4 percent incidence. The historical control groups from eight other studies at this testing laboratory had an overall incidence of 5.2 percent. In rodent studies, lymphocytic leukemia should more properly be considered within the context of the other lymphoreticular neoplasms such as lymphosarcoma and reticulum cell sarcoma (Ref. 3) instead of separately as was done here. The agency concludes that there was no increase in neoplastic disease of the lymphoreticular system in mice due to treatment with acesulfame potassium. FDA also finds that this study met the minimum standards of testing for length of treatment and degree of survival.

For the first of the two long-term rat studies submitted, the testing laboratory stated that the results showed a slightly higher incidence, and a somewhat earlier appearance, of lymphoreticular pulmonary neoplasms (reticulm cell sarcomas) in the mid- and high-dose groups of both male and female rats than in the concurrent control group. The laboratory discussed several reasons to support its conclusion that these effects were not caused by treatment.

The agency concludes that this study, is inadequate to demonstrate safety and does not establish a carcinogenic effect of acesulfame potassium (Refs. 2 and 4). A major deficiency in the study is the fact that only 20 of the 60 rats in the control and high dose groups were subject to a complete histopathological examination, thereby limiting the proper interpretation of the results of the study. Moreover, the presence of extensive, severe chronic respiratory disease in the lungs of rats of all groups confounded diagnosis and interpretation of lung lesions in these animals. Generally, reticulum cell sarcomas in most strains of rats arise from lymph nodes and disseminated to many organs (Ref. 5). However, in the CIVO-bred Wistar rats, the occurrence of reticulum cell sarcomas in the lung seems to be linked with the presence of chronic respiratory disease (Ref. 5). These neoplasms in the CIVO strain are generally localized in the lungs and do not disseminate to other organs or tissues. Reticulum cell sarcomas are known to occur spontaneously in this strain of rat; incidences as high as 32 percent had been reported in untreated CIVO-bred Wistar rats (Ref. 2). These findings on the lymphoreticular neoplasms observed in treated and control rats from this study reinforce the agency's judgment that these neoplasms were not caused by acesulfame potassium treatment and that, therefore, the study is inadequate and does not provide a basis for assessing the carcinogenicity of the compound.

Because the first study was not adequate for the safety evaluation of a prospective food additive, a second long-term rat study was conducted. In the original report by the testing laboratory on this study, submitted with the initial petition, tissues from some of the animals were reviewed by the study pathologist of the performing laboratory and the remainder were reviewed by a consulting pathologist. This division of labor resulted in inconsistencies in the diagnostic criteria applied to the observations reported in the study. Although the data appeared to show treatment-related differences in a few of the observations, these were subsequently found to be due to the different way categories of lesions were summarized. This was shown when the petitioner, in response to the agency's request for more detailed and explicit listings of the results of the study, had all the data and microscopic slides reviewed by a consulting pathologist, who prepared a new report.

After a comprehensive review of the data from this second study, the agency has concluded that it is adequate for the safety evaluation of a food additive and that there is no association between the occurrence of neoplasms and treatment with acesulfame potassium (Ref. 2). Moreover, these rats did not show lymphoreticular neoplasms in the lungs or lymphoreticular disease in any other organs that could be ascribed to treatment. The highest level fed, 3 percent of the diet, produced no adverse toxic effects.

Among the issues in the initial review that received attention were differences in incidence of mammary gland neoplasms in the female rats. Most of the mammary tumors were fibroadenomas; there incidences in the female rats were: Control group—17 of 56 rats examined (30.4 percent); 0.3 percent test compound—26 of 60 (43.3 percent); 1.0 percent test compound—28 of 59 (47.5 percent); 3.0 percent test compound—28 of 59 (47.5 percent) (Ref. 6). The mammary gland neoplasms other than fibroadenomas were few in number and were distributed randomly among the different groups. The incidences of mammary gland hyperplasia were similar and uniformly high in all groups of treated famales and in the control females. Thus, the occurrence of mammary gland hyperplasia was unrelated to treatment with acesulfame potassium.

The agency concludes that there was no association between the occurrence of mammary gland neoplasms and

treatment with acesulfame potassium. This conclusion is based on the following:

(1) Fibroadenomas are a common old age tumor in this strain of rats and their incidence is variable.

(2) The incidence of mammary fibroadenomas in female control rats from seven comparable studies, performed at this testing laboratory around the same time period as the acesulfame potassium study, is 250 of 452 or 55.3 percent (Ref. 6). This incidence is higher than the incidences for any of the treated groups in the acesulfame potassium study and is much higher than that for the concurrent control group. The concurrent control group had an unusually low incidence of these tumors.

(3) In the treated groups, the lack of a dose response in incidences of fibroadenomas, as well as of all mammary tumors and of hyperlasia, is evidence that there is not a treatment-related effect of the sweetener on the incidence of fibroadenomas.

(4) There was no evidence of progressive stages of mammary gland neoplasms (hyperplasia to malignant neoplasms) that would indicate a treatment-related induction of tumors.

The reproduction and teratology studies, and the long-term safety studies did not show any toxic effects due to treatment with acesulfame potassium. From the highest feeding level in the long-term rat study, 3 percent acesulfame potassium, the agency, using a 100-fold safety factor, finds that the acceptable daily intake in 15 milligrams per kilogram body weight. This acceptable daily intake level is well above the expected intake for the food uses requested.

III. Comments

The Center for Science in the Public Interest (CSPI), a consumer advocacy group, wrote to the agency to express its concerns about the testing and safety of this sweetener, and included a copy of a newsletter article it had published on this subject. Several individuals also wrote to the agency echoing the concerns in the newsletter article. CSPI urged that FDA not approve the petition as submitted.

CSPI stated that some of the treated groups in the first long-term rat study showed higher mortality than the controls and this increase was associated with chronic respiratory disease and cancers of lung lymphoid tissue. CSPI also claimed that the occurrence of pulmonary lymphoreticular tumors was relatively high in mid- and high-dose groups of both sexes and was "statistically significant" in high-dose females. The group also mentioned an earlier appearance of these tumors in mid- and high-dose males than in control and low-dose males.

The agency has evaluated this study comprehensively and, as outlined in the proceding Section, finds that deficiencies in the study prevent anyone from drawing any conclusions concerning treatment-related effects. For the reasons described above, the agency found no evidence of a neoplastic effect that is casually associated with acesulfame potassium from this study. Moreover, as noted above, the agency believes that the deficiencies in this study render it inadequate for assessing the carcinogenic potential of the test compound or for any other purposes of a safety evaluation. The second rat study is adequate however, for such purposes and forms a basis for the agency's final conclusion of safety.

On the second long-term rat study, CSPI stated "Although excess pulmonary tumors were not observed in this study, excess mammary gland tumors were found. According to the petitioner, the 'total incidence of mammary gland tumors in each of the test groups was about twice as high as in the controls * * *. In addition, malignant mammary tumors * * * were found only in test animals * * *.'" (Omissions made by CSPI)

The agency disagrees with CSPI's conclusion that this study is not adequate to demonstrate safety. FDA made a detailed evaluation based on the comprehensive reexamination of all the histological slides by the consulting pathologist (see preceding Section). As stated in the previous Section, fibroadenomas are common old-age tumors in female rats of this strain. The quotation of the petitioner's statement omits the fact that no mammary gland tumors were found in any of the male rats of this study. Based on the lack of dose response, the unusually low incidence of tumors in the concurrent control group compared with other contemporary controls, and the other reasons given in the previous Section, the agency concludes that there is no basis to find a causal relationship between acesulfame potassium treatment and development of mammary gland tumors.

In its letter to FDA, CSPI maintained that a positive dose response is not needed to reach a conclusion of carcinogenicity. The group also stated its belief that comparison with historical controls does not excuse the high tumor rates in either rat study. In this regard, they quote the Environmental Protection Agency's "Guidelines for Carcinogen Risk Assessment" as saying, "To evaluate carcinogenicity, the primary comparison is tumor response in dosed animals as compared with that in contemporary matched control animals" (September 24, 1986; 51 FR 33992 at 33995).

FDA disagrees with CSPI's interpretation of these guidelines. CSPI omitted from its quotation the sentences that follow it in the guidelines with respect to consideration of historical controls. The Environmental Protection Agency goes on to state, "Historical control data are often valuable, however, and could be used along with concurrent control data in the evaluation of carcinogenic responses * * *. The review of tumor data at sites with high spontaneous background requires special consideration * * *. For instance, a response that is significant with respect to the experimental control group may become questionable if the historical control data indicate that the experimental control group had an unusually low background incidence" (citations omitted).

FDA has long followed the principles stated in these guidelines, and in the Office of Science and Technology Policy, in reviewing the safety of food and color additives (November 2, 1982; 47 FR 49628 at 49629). The Office of Science and Technology Policy (March 14, 1985; 50 FR 10372 at 10418) stated:

> * * * With such data, the toxicologist may conclude that a study yielding statistical significance is not biologically significant or conversely that an effect is real, even though there is no "significant" difference between test and concurrence controls. Of 27 bioassay study reports issued by the NCI (National Cancer Institute) from 1978–1980, historical controls were used in 14 studies to show that an apparent increase of a specific tumor was not related to treatment. In 13 studies, the use of historical controls showed that an increase in tumors was related to treatment. Historical control data can be valuable when used appropriately, especially when the differences in incidence rates between treated and concurrent negative controls are small and can be shown to be within the anticipated historical incidence.

The agency points out that a determination of whether a compound is carcinogenic should be based on the overall weight of the evidence. The evidence can reasonably include a dose response or a lack of a dose response, consideration of historical controls, associated pathological data, the time to induction tumors, and the multiplicity of tumors. In the second long-term rat study, none of these factors lends weight to a finding of carcinogenicity (Ref. 6).

CSPI also questioned the results in a study the petitioners had volunteered which was conducted for 4 weeks with rats made diabetic by treatment with streptozotocin. CSPI stated that blood cholesterol levels were elevated 15 to 20 percent in groups of rats fed acesulfame potassium and suggested a relation to an increased risk of heart disease for diabetic humans who use this artificial sweetener.

FDA does not agree. The serum cholesterol levels were higher than the controls only in the low- and mid-dose groups but not in the high-dose group. These data do not show a dose-response relationship. In addition, differences in levels were relatively small and well within the normal cholesterol levels for rats (Ref. 7). FDA finds no relation between ingestion of the test compound and the levels of serum cholesterol in this study.

IV. Conclusions

FDA has evaluated the data in the petition and other relevant material and concludes that acesulfame potassium is safe under the conditions of use in a new 21 CFR 172.800 and that the regulations 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 21 CFR 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.

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 prepared under proposed 21 CFR 25.31(b) as published in the **Federal Register** of December 11, 1979 (44 FR 71742) may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's current regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an environmental assessment under § 25.31a(a).

V. Objections

Any person who will be adversly affected by this regulation may at any time on or before August 29, 1988 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 on 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. Kuznesof, P. M., Food and Color Additives Review Section, Memoranda of October 30, 1986, April 9, 1987, and August 5, 1987.

2. Cancer Assessment Committee, Memorandum of Conferences, November 21, 1983, February 21, 1985, December 12, 1985, and June 17, 1986.

3. Della Pora, G., L. Chieco-Bianchi, and N. Pennelli, "Tumors of the Haematopoietic System," *in* IARC Scientific Publications, No. 23, Vol. 2, "Tumors of the Mouse," p. 532, 1979.

4. Taylor, L. L., Additives Evaluation Branch, Memorandum of June 19, 1986.

5. Swaen, G. J. V., and P. Van Heerde, "Tumors of the Haematopoietic System," *in* IARC Scientific Publications, No. 5, Vol. 1, "Tumors of the Rat," Part 1, p. 187, 1973.

6. Hines, F. A., Diagnostic Pathology Branch, Memorandum of June 6, 1986.

7. Irausquin, H., Standards and Monitoring Branch, Memoranda of November 6, 1987, and October 20, 1982.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61

2. A new § 172.800 is added to Subpart I to read as follows:

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589–62–3), also known as acesulfame K, may be safely used as a sweetening agent in food in accordance with the following prescribed conditions:

(a) Acesulfame potassium is the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2-dioxide.

(b) The additive meets the following specifications:

(1) Purity is not less than 99 percent on a dry basis. The purity shall be determined by a method titled "Acesulfame Potassium Assay," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the **Federal Register**, 1100 L St. NW., Washington, DC 20408.

(2) Fluoride content is not more than 30 parts per million, as determined by method III of the Fluoride Limit Test of the Food Chemicals Codex, 3d Ed. (1981), p. 511, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The additive may be used in the following foods when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) Dry, free-flowing sugar substitutes in package units not to exceed the sweetening equivalent of 2 teaspoonsful of sugar.

(2) Sugar substitute tablets.

(3) Chewing gum.

(4) Dry bases for beverages, instant coffee, and instant tea.

(5) Dry bases for gelatins, puddings, and pudding desserts.

(6) Dry bases for dairy product analogs.

(d) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with Part 105 of this chapter.

(e) The additive shall be used in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

Dated: July 19, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-16972 Filed 7-27-88; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 185 and 186

[OPP-00264; FRL-3422-1]

Tolerances for Pesticides in Food and Animal Feeds; Transfer of Regulations; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule that transferred former Parts 193 and 561 of Title 21 of the Code of Federal Regulations (CFR) regarding tolerances for pesticides in food and animal feeds into new Parts 185 and 186, respectively, of Title 40 of the CFR.

EFFECTIVE DATE: July 28, 1988.

FOR FURTHER INFORMATION CONTACT: John A. Richards, Chief, Federal Register Staff (TS-788B), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G009, 401 M St., SW., Washington, DC 20460, (202)-382-2253.

SUPPLEMENTARY INFORMATION: In FR Doc. 88-14718, published in the **Federal Register** of June 29, 1988 (53 FR 24666), EPA transferred former 21 CFR Parts 193 and 561 into new 40 CFR Parts 185 and 186, respectively. The following corrections are made to the document:

1. On page 24666, in the third column under the "old section-new section" table, in the entry for old section 193.80 change the new section entry from 185.375 to 185.410.

2. On page 24667, ir the first column, under the "old section-new section" table, in the entry for old section 193.470 change the new section entry from 185.5500 to 185.5550.

3. On page 24667, in the first column under the "old section-new section" table in the entry for old section 561.51 change the new section entry from 186.400 to 186.375.

4. On page 24667, in the first column, under the "old section-new section" table in the entry for old section 561.53 change the new section entry from 186.5050 to 186.4975.

5. On page 24667, in the first column, under the "old section-new section" table in the entry for old section 561.92 change the new section entry from 186.425 to 186.400.

PART 185—[CORRECTED]

6. On page 24667, in the third column, in the table of contents entry for section 185.375 1,1-Bis(*p*-chlorophenyl)-2,2,2-trichloroethanol, change the section number to 185.410 and reinsert the entry in numeric sequence.

PART 186—[CORRECTED]

7. On page 24668, in the third column, in the table of contents entry for section 186.400 Bentazon, change the section number to 186.375.

8. On page 24668, in the third column, in the table of contents entry for section 186.425 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine, change the section number to 186.400.

9. On page 24668, in the third column, in the table of contents entry for section 186.950, insert a hyphen after the first number 1 so that the entry reads "2-Chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate."

10. On page 24668, in the third column, in the table of contents entry for section 186.1850, remove the hyphen in the word "oxazolidine-dione" so that it reads "oxazolidinedione."

11. On page 26449, in the second column, in the table of contents entry for section 186.5050, change "Propenofos" to read "Profenofos" and change the section number to "186.4975" and reinsert the entry in numeric sequence.

(21 U.S.C. 348)

Dated: July 22, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 88-17105 Filed 7-27-88; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 271

[FRL-3420-9]

Georgia; Final Authorization of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: Georgia has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Georgia's application and has made a decision, subject to public review and comment, that Georgia's hazardous waste program revision for the hazardous components of radioactive mixed wastes and for the closure, post-closure and financial responsibility requirements satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Georgia's hazardous waste program revision for the hazardous components of radioactive mixed wastes and for the closure, post-closure, and financial responsibility requirements. Georgia's application for program revision is available for public review and comment.

DATES: Final authorization for Georgia shall be effective September 26, 1988 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Georgia's program revision application must be received by the close of business August 29, 1988.

ADDRESSES: Copies of Georgia's program revision application are available during 8:00 a.m.-4:00 p.m. at the following addresses for inspection and copying: Georgia Department of Natural Resources, Land Protection Branch, Room 1154, 205 Butler Street SE., Floyd Towers East, Atlanta, Georgia 30334, Phone: 404/656-2833; U.S. EPA Headquarters Library, PM 211A, 401 M Street SW., Washington, DC 20460, Phone: 202/382-5926; U.S. EPA Region IV, Library, 345 Courtland Street NE., Atlanta, Georgia 30365, Phone: 404/347-4216. Written comments on the application should be sent to Otis Johnson, at the address listed below.

FOR FURTHER INFORMATION CONTACT: Otis Johnson, Jr., Chief, Waste Planning Section, U.S. Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365, Phone: 404/347-3016.