

**§ 11.3 Scar rule.**

The scar rule applies to all horses born on or after October 1, 1975. \* \* \*

Done in Washington, DC, this 25th day of July, 1988.

Larry B. Slagle,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 88-17024 Filed 7-27-88; 8:45 am]

BILLING CODE 3410-34-M

**DEPARTMENT OF THE TREASURY****Comptroller of the Currency****12 CFR Part 35**

[Docket No. 88-11]

**Agricultural Loan Loss Amortization**

**AGENCY:** Office of the Comptroller of the Currency, Treasury.

**ACTION:** Final rule.

**SUMMARY:** The Office of the Comptroller of the Currency ("OCC") is issuing this final rule to implement Title VIII of the Competitive Equality Banking Act of 1987 ("CEBA"). CEBA permits national agricultural banks to amortize losses on qualified agricultural loans. This final rule describes the procedures and standards applicable to national banks desiring to amortize those losses. It also describes the manner in which amortizations are to be done.

This final rule is intended to benefit small, agricultural banks by providing a form of capital relief and, thereby, added time to work out problems brought about by the extended downturn in the agricultural industry.

This action is needed to make final the temporary rule issued on November 2, 1987. After consideration of comments received, the OCC is making one substantive change and several technical changes to its temporary rule. The substantive change allows eligible national banks to amortize losses on the reappraisal or sale of real or personal property acquired in connection with a qualified agricultural loan and that the bank owned on January 1, 1983, or acquires prior to January 1, 1992, whether or not that property is "currently owned." Under the temporary rule, property had to be currently owned for the loss to qualify for deferral. The technical changes: (1) Amend the definition of "qualified agricultural loan" and "qualified agricultural bank" to clarify that the OCC intends to construe the phrases broadly; (2) add a definition of "agriculturally related other property"; (3) clarify the relationship between 12 CFR Part 35 and the

alternative legal lending limit in 12 CFR 32.8; and (4) include various minor wording changes intended to enhance clarity.

**EFFECTIVE DATE:** August 29, 1988.

**FOR FURTHER INFORMATION CONTACT:** James F.E. Gillespie, Jr., Senior Attorney, Legal Advisory Services Division (202) 447-1880; Jon A. Nagy, National Bank Examiner, Commercial Activities Division (202) 447-1164; or Lance Cantor, Analyst, Special Supervision Division (202) 447-1719.

**SUPPLEMENTARY INFORMATION:****Background**

CEBA permits an agricultural bank to amortize: (1) Losses on qualified agricultural loans shown on its annual financial statement for any year between December 31, 1983, and January 1, 1992; and (2) losses suffered as the result of an appraisal or sale of agriculturally related other property (related to a qualified agricultural loan) owned on January 1, 1983, or acquired prior to January 1, 1992.

CEBA also required that the federal banking agencies issue implementing regulations no later than November 9, 1987. The OCC initially published this regulation as a temporary rule on November 2, 1987 (52 FR 41959), effective November 9, 1987, in order to comply with this statutory requirement. Interested parties had the opportunity to comment by January 4, 1988. The Board of Governors of the Federal Reserve System, on November 3, 1987 (52 FR 42087), and the Federal Deposit Insurance Corporation ("FDIC"), on November 2, 1987 (52 FR 41966), proposed substantially identical regulations containing only those variations necessary to accommodate their own regulatory and organizational systems.

The intent of CEBA was to provide agricultural banks with added time to work out problems brought about by the extended downturn in the agricultural industry.

**Discussion of Comments Received**

Eight comments were received on the temporary rule. Comments were received from three banks, three banks trade associations (two national and one state-level), one law firm, and one Congressman. Comments were supportive of agricultural loan loss amortization, while suggesting that the OCC liberalize certain of the provisions in the temporary rule.

**Specific Comments**

The OCC received comments regarding the following specific items:

**Definition of "Agricultural Bank"**

Section 35.2(a) of the rule defines an agricultural bank as any bank: (1) With FDIC insured deposits; (2) located in an area of the country with an economy dependent on agriculture; (3) with total assets of \$100 million or less; and (4) with at least 25 per cent of its total loans in qualified agricultural loans and agriculturally related other property or with less than 25 per cent of its total loans in qualified agricultural loans and agriculturally related other property but which the OCC still recommends to the FDIC as eligible.

**Identification of Agricultural Areas**

Some commenters urged that the OCC list specific criteria to identify agricultural areas. The OCC believes that the normal means of identifying agricultural areas—income levels, revenue flows, acreage in production—are abnormally depressed due to the current state of the agricultural economy. Adopting a list of acceptable counties or geographic regions could leave the erroneous impression that a bank located outside such an area could not qualify even though it met the other requirements of an "agricultural bank". Additionally, the relatively low level of farm income compared to other income could artificially mask local areas that traditionally are dependent upon agriculture but currently have a depressed level of income from agriculture.

Consequently, each application should include a description of the bank's location, dominant lines of commerce in its service area, and any other information to support the bank's belief that it is located in an agricultural area. This information will be used to insure that no bank qualified for participation will be excluded due to arbitrary geographic demarcation.

**Bank Size**

The definition of an agricultural bank includes the statutory requirement that the bank have total assets of \$100 million or less. Comments were received by the other federal regulators asking for clarification as to what happens if a bank is approved for loss deferral and subsequently exceeds the size limitation. Congress did not intend for banks larger than \$100 million to defer loan losses. If size was unimportant, the law could have easily excluded it as a factor.

At the same time, it is of little value for a bank to defer a loss one year if it must reverse that deferral the next year because it grew to over \$100 million in assets. Therefore, the OCC expects a

bank to meet the definition of an agricultural bank, including the size limitation, upon initial application and as of every quarter that new agricultural losses are to be deferred. Any loss that was properly deferred initially, will be allowed to be fully amortized according to the regulation, regardless of a subsequent increase in the bank's size. However, if a bank exceeds the size limitation, new losses experienced in each quarter that the bank exceeds the size limitation may not be amortized.

#### Mergers

The OCC does not intend to allow banks to bypass the application/review process via a merger with another bank which has already been approved. Such mergers are not expected to be frequent. Therefore, the permissibility of loss deferral subsequent to a merger will be determined on a case-by-case basis. This issue should be discussed with representatives of the appropriate supervisory office and a determination made before a merger transaction is consummated.

#### Percentage of Agricultural Loans

Two commenters urged that the OCC be liberal when determining whether a bank meets the 25 per cent test. Prudent banks may have charged off substantial amounts of such loans but, due to the depressed agricultural economy, may not have been able to replace such loans with new agricultural loans. A commenter suggested that a bank should satisfy the test if, at any time since December 31, 1983, it met the requirements.

The OCC does not believe such a change is necessary since the 25 per cent test is not an absolute requirement, as it may be waived in some instances. Factors such as depressed collateral value or lack of prudent agricultural lending opportunities will be considered when applications for loan loss amortization are reviewed.

#### Definition of "Qualified Agricultural Loan"

Under section 801 of Title VIII of the CEBA,

the term "qualified agricultural loan" means a loan made to finance the production of agricultural products or livestock in the United States, a loan secured by farmland or farm machinery, or such other category of loans as the appropriate Federal banking agency may deem eligible.

Section 35.2(b) of the temporary rule defines a qualified agricultural loan to include any loan qualifying as "loans to finance agricultural production and other loans to farmers" or as "loans secured by farm land" for purposes of

Schedule RC-C of the FFIEC Consolidated Reports of Condition and Income ("Call Report"). The term also includes other loans and leases that the applying bank proves to be sufficiently related to agriculture to qualify in the opinion of the OCC. These Call Report definitions are virtually identical to those contained in Title VIII of the CEBA but are more comprehensive and permit the agencies to use the Call Reports as the predominant monitoring device for the amortization program. Several commenters suggested that the OCC specifically mention particular types of loans in this definition.

The OCC initially saw no reason to repeat the definition in the statute when the regulatory definition was of a more descriptive nature and referred to Call Report terms with which banks are familiar. Additionally, as suggested by Title VIII of the CEBA, the OCC retained discretion to deem other types of loans and leases to be "qualified" and to recommend them to the FDIC as eligible if the requesting bank demonstrates those assets to be sufficiently related to agriculture.

To clarify that the regulatory definition of "qualified agricultural loan" is as broad as the statutory definition and is not intended to limit the types of loans which a national bank may include in an application, the final rule includes farm machinery loans in the regulatory definition.

Bankers should refer to the "Line Item Instructions" for Schedule RC-C of the Call Report for an indication of the other types of loans that qualify for amortization. For example, qualified agricultural loans include loans reported under line item 1(b)—loans secured by farmland (land known to be used or usable for agricultural purposes, such as crop and stock production, grazing or pasture land whether tillable or not and whether wooded or not).

Similarly, loans reported under line item 3 qualify. These loans include loans to finance agricultural production (such as for growing or sorting crops, or breeding, raising, fattening, or marketing livestock), or for purchases of farm machinery, equipment, or implements.

The Call Report definitions are not exclusive descriptions of eligible loans. If a bank believes that a loan was made for an agricultural purpose, it may apply to amortize a loss on it even though the loan was not reported on the Call Report as an agricultural loan. The OCC will determine on a case-by-case basis whether a particular loan qualifies.

#### Inclusion of Charge-offs in Loan Volume Tests

A commenter suggested that banks be permitted to include charged-off agricultural loans and agriculturally related other property acquired through foreclosure for purposes of the loan volume tests. The temporary rule allowed the use of charged-off loans by virtue of including them in the definition of "qualified agricultural loans". These loans are still assets of the banks, even though off the books, and represent part of the banks' total credit commitment to agriculture. A similar argument applies to assets acquired through foreclosure on agricultural loans. Therefore, the OCC has included such assets in determining compliance with the loan volume tests in the rule.

#### Amortization

Section 35.3(b) of the rule provides that amortization of each qualified agricultural loan be computed over a period not to exceed seven years on a quarterly, straight-line basis commencing with the first quarter after the charge-off, so that each loan is fully amortized by December 31, 1998. Thus, loans written off in accounting periods ending prior to the adoption of the rule can be amortized *pro rata* beginning with the Call Report for December 31, 1987.

Several commenters suggested that the bank, rather than the OCC, decide whether to use the full seven-year amortization period. One commenter also believes that adopting the *pro rata* treatment of loans written down prior to adoption of the rule unfairly penalizes banks that were diligent in adjusting their assets.

Under the temporary and final rule, a bank that wishes to use an amortization schedule shorter than the maximum seven years can apply to do so. The OCC anticipates that a seven-year schedule will be the normal schedule, but has not required its use. The OCC's decision to permit the use of a shorter amortization period depends upon the applicant bank's financial position and is not likely to require consideration of any extraordinary issues.

With regard to adopting a *pro rata* treatment of loans written down prior to adoption of the rule, the OCC does not believe banks that were diligent in adjusting their assets are penalized. The technique prescribed reflects amortizations as though the program had been in effect from the first year deferral was allowed. Amortization in this manner does reduce the initial amount of deferred losses which can be

established, but it also reduces the future amortizations which must be absorbed. The OCC does not view this as a penalty.

Furthermore, accepted banking practice and Call Report instructions require banks to record a loss in the period it becomes apparent. Banks which had losses, but declined to recognize them, would have been in contravention of proper procedures. Therefore, differences in the actual occurrence of an economic loss should be a much greater cause of different timing patterns in loan charge-offs than differences in how quickly management elects to take a loss.

#### Losses Due to Agriculturally Related Real Estate Sales or Reappraisals

Section 35.3(a)(2) of the temporary rule allows a bank to amortize any loss reflected in its financial statements resulting from a reappraisal or sale of real or personal property it acquired in connection with a qualified agricultural loan owned on January 1, 1983, and still held on November 9, 1987, and of any additional property acquired on or before December 31, 1991.

Several commenters objected to the requirement that such property had to be held on November 9, 1987, in order for any losses to be eligible for amortizing. Commenters pointed out that neither the statute nor its legislative history explicitly calls for ownership of such property on the effective date of the regulation. The commenters suggested that better reference dates might be the date the loss was actually recognized or the date the legislation was introduced, passed both houses of Congress, or signed. One commenter suggested that any loss on such property be treated in the same manner as a loss on the loan it secured, that is, amortization should be allowed at least beginning with the date the loss was recognized so long as the loss is otherwise an eligible loss.

The OCC agrees that losses attributable to property, acquired as the result of agricultural lending, are as much a part of the bank's agricultural problem as the original loan loss. The intent of the legislation is to mitigate the immediate effect of those losses. Therefore, the final rule provides that losses on holding or selling property will be treated in the same manner as losses on agricultural loans. This change is the only substantive change in the final rule.

Furthermore, CEBA allows amortization for agricultural loan losses that would be reflected on annual financial statements for 1984-1991. It also allows amortization for losses resulting from reappraisals on

agriculturally related other property. To ensure that losses due to reappraisals are treated comparably to loan losses, the regulation requires that losses from reappraisals that the bank would be required to reflect on financial statements for 1983-1991 be amortized within seven years in the same manner as agricultural loan losses generally, *i.e.*, they must be fully amortized by 1998. For the same reason, the regulation provides that losses resulting from reappraisals after 1991 are not eligible for amortization.

#### "In need of Capital Restoration"

The language in the statute and legislative history of the provision indicate that Congress intended that only banks with capital in need of restoration be permitted to amortize losses. Further, it intended that only banks with reasonable prospects for survival be permitted to amortize losses. Section 35.5(b) provides that, (1) the current capital of a bank wishing to amortize qualifying losses must be in need of restoration, and (2) the bank must also be an economically viable, fundamentally sound institution. These are certainly not mutually exclusive conditions. A bank can have inadequate capital due to a variety of temporary problems or conditions yet also have enough underlying demand for banking services and earning capacity to restore capital if given sufficient time.

Several commenters suggested that this section is too restrictive and that any bank qualifying as an agricultural bank which has qualifying agricultural losses should be able to amortize those losses to restore capital to some higher level even if it is not "in need of" capital restoration for regulatory purposes.

The OCC believes most agricultural banks have strong capital positions and no need for loss deferral. The OCC further believes that Congress did not intend for these techniques to be used to artificially maintain unnecessarily high levels of capital. Congressional intent seems clear in that the statute required, as an essential condition of eligibility, the submission of "a plan to restore its capital \* \* \* to a level" acceptable to the OCC. If capital is to be restored to an acceptable level it must, by definition, not already be at an acceptable level.

Nevertheless, whether a particular bank is "in need of" capital restoration depends on its particular circumstances. Thus, a bank might be deemed "in need of" capital restoration even though its capital ratio equals or exceeds the minimum capital levels prescribed by 12 CFR Part 3. Because the OCC will make the determination of need in each case,

a bank applying to amortize agricultural loans should include a statement as to why it is "in need of" capital restoration.

#### *Economically Viable and Fundamentally Sound*

A commenter suggested that the requirement that a bank must be economically viable and fundamentally sound to be eligible is unnecessary. The OCC believes that no purpose would be served by allowing a non-viable and hopelessly unsound institution to temporarily avoid insolvency through the use of this accounting adjustment. The legislative history of the statute supports this interpretation.

A commenter also expressed concern over the conditions surrounding removal of a bank from the program once it has recovered financially. The OCC does not intend, as a matter of administrative practice, to remove a bank from the program so long as the bank continues to meet the Conditions on Acceptance prescribed in the regulation. Therefore, once a loss has been deferred a bank may continue to amortize it. However, once the bank has recovered sufficiently to no longer meet the eligibility requirements, because it is no longer "in need of" capital restoration, no new losses will be permitted to be deferred.

#### Other Issues

##### *Evidence of Fraud*

Several commenters suggested that the regulation clarify what constitutes evidence of fraud that would disqualify a loss from amortization.

The OCC decided not to list elements constituting fraud in the regulation. Some indicia might include criminal referral reports, for example, but the lack of such a report will not preclude excluding a loan if evidence of fraud exists. Normal sources of information used to determine whether fraud is present should include information collected in the examination process, as well. The OCC will use a case-by-case approach and will allow an applying bank an opportunity to explain ambiguous circumstances.

##### *CEO Certification*

The temporary rule required a certification by the bank's chief executive officer that there is no evidence that the losses resulted from fraud or criminal abuse. One commenter expressed concern over this requirement, in that it is not generally possible to be absolutely certain of every circumstance surrounding every loan.

The OCC understands this reluctance and therefore a specific form of certification was not dictated in the temporary or final regulation. A certification to the best of one's knowledge and belief was and is permissible.

#### Reference to Enforcement Proceedings

Several commenters suggested removing references to enforcement proceedings from the regulation. The presence of such references affirms that preexisting conditions or problems typically requiring correction by an enforcement action will be monitored and managed. Such references will not normally create information requirements or performance obligations not already existing. Accordingly, the references are retained in the final rule.

#### Compensation Levels

Several commenters also suggested removing references to compensation levels from the regulation. Compensation levels are typically an integral part of a capital plan. As with enforcement actions, the presence of such references in the rule only affirms that the program will be managed and monitored.

#### Legal Lending Limit

A commenter expressed concern over the interrelationship between 12 CFR 32.8 and the agricultural loan loss amortization program. Banks will be permitted to use the restated capital under this regulation for purposes of computing their regular legal lending limit under § 32.3. However, the OCC believes it would be inappropriate to permit a bank to include losses recapitalized under the amortization program in computing its substitute lending limit under § 32.8, because that would effectively give such losses double weight. In many cases, this would result in a legal lending limit far greater than the bank would have had if it had not suffered the agricultural losses. Accordingly, while a bank participating in the loan loss deferral program may calculate its lending limit under either section, the calculation of capital and surplus for purposes of the alternative lending limit under § 32.8 must be made without reference to the recapitalized unamortized losses permitted under this program.

#### Regulatory Impact Analysis

Pursuant to section 3(g)(1) of Executive Order 12291 of February 17, 1981, it has been determined that this final rule does not constitute a "major rule" within the meaning of the

executive order. Consequently, no regulatory impact analysis is necessary.

#### Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), the OCC certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

#### Paperwork Reduction Act

The collection of information requirements contained in this final rule have been submitted to and approved by the Office of Management and Budget under section 3504(h) of the Paperwork Reduction Act. (OMB Control No. 1557-0186). The estimated average burden associated with the collection of information contained in this final rule is 15 hours per respondent. The burden per respondent may vary depending on individual circumstances.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to: Legislative and Regulatory Analysis Division, Office of the Comptroller of the Currency, 490 L'Enfant Plaza E., SW., Washington, DC 20219 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention Treasury Desk Officer.

#### List of Subjects in 12 CFR Part 35

Banks, Banking, National banks, Agriculture, Amortization, Loans, Loss, Capital.

#### Section-by-Section Analysis

A number of clarifying technical changes and the following material amendments are made to Part 35:

**Section 35.1** "Office" is changed to "OCC" here and everywhere else it appears in the Part.

**Section 35.2** In paragraph (a), the word "national" is added.

In paragraphs (a)(4) (i) and (ii), the phrase "agriculturally related other property" is added.

In paragraph (b), a new paragraph (2) has been added. Old paragraphs (b) (2) and (3) become (b) (3) and (4). Also, a reference to paragraph (b)(3) is added to new paragraph (b)(4).

In paragraph (b)(4), the word "regulation" is removed and the word "part" is substituted.

A new paragraph (c) is added. Former paragraph (c) becomes paragraph (d).

**Section 35.3** Paragraphs (a) (1) and (2) are revised by removing the word "year" and substituting the word "period". Paragraph (a)(2) is also revised by removing "currently owned \* \* \*

prior to January 1, 1992" and substituting "agriculturally related other property."

**Section 35.4** The original text is revised and becomes paragraph (a). A new paragraph (b) is added.

**Section 35.5** The phrase "of this part" is removed. In paragraph (c) the term "related assets" is removed and the term "agriculturally related other property" is substituted.

**Section 35.6** In paragraph (d), the phrase "agriculturally related other property" is substituted.

**Section 35.7** In paragraph (a), the phrase "other related assets" is removed and the phrase "agriculturally related other property" is substituted. The phrase "reappraised property" is removed from paragraph (b)(6) and the term "agriculturally related other property" is substituted.

#### Authority and Issuance

For the reasons set out in the preamble, Part 35 of Chapter I of Title 12 of the Code of Federal Regulations is revised to read as follows:

#### PART 35—AGRICULTURAL LOAN LOSS AMORTIZATION

- Sec.
- 35.1 Authority and OMB control number.
  - 35.2 Definitions.
  - 35.3 Loss amortization and reappraisal.
  - 35.4 Accounting for amortization.
  - 35.5 Eligibility.
  - 35.6 Conditions on acceptance.
  - 35.7 Submission of proposals.
  - 35.8 Revocation of eligibility.

Authority: 12 U.S.C. 1823(j) and 93a.

#### § 35.1 Authority and OMB control number.

(a) *Authority.* This part is issued by the Office of the Comptroller of the Currency ("OCC") pursuant to 12 U.S.C. 1823(j) and 12 U.S.C. 93a.

(b) *OMB control number.* The collection of information requirements contained in this regulation were approved by the Office of Management and Budget under control number 1557-0186.

#### § 35.2 Definitions.

For purposes of this part:

(a) "Agricultural Bank" means a national bank—

(1) The deposits of which are insured by the Federal Deposit Insurance Corporation;

(2) Which is located in an area of the country the economy of which is dependent on agriculture;

(3) Which has total assets of \$100,000,000 or less as of the most recent Report of Condition; and

(4) Which has—

- (i) At least 25 percent of its total loans in qualified agricultural loans and

agriculturally related other property, as defined below; or

(ii) Less than 25 percent of its total loans in qualified agricultural loans and agriculturally related other property, but which bank the OCC has recommended to the Federal Deposit Insurance Corporation for eligibility under this part.

(b) "Qualified Agricultural Loans" means:

(1) Loans qualifying as "loans to finance agricultural production and other loans to farmers" or as "loans secured by farm land" for purposes of Schedule RC-C of the FFIEC Consolidated Reports of Condition and Income or such other comparable schedule that may be in effect;

(2) Loans secured by farm machinery;

(3) Other loans or leases that a bank proves to be sufficiently related to agriculture for classification as an agricultural loan by the OCC; and

(4) The remaining unpaid balance of any loans, as described in paragraphs (b) (1), (2) and (3) of this section, that have been charged off since January 1, 1984, and that qualify for deferral under this part.

(c) "Agriculturally related other property" means any property, real or personal, that a bank owned on January 1, 1983, and any such additional property that it acquires prior to January 1, 1992, in connection with a qualified agricultural loan. For purposes of §§ 35.2(a)(4)(i) and 35.6(d) the value of such property includes amounts previously charged-off.

(d) "Accepting Official" means the head of the appropriate supervisory office designated by the OCC for the applicant bank.

#### § 35.3 Loss amortization and reappraisal.

(a) Provided that there is no evidence that the loss resulted from fraud or criminal abuse on the part of the bank, its officers, directors, or principal shareholders, a bank that has been accepted under this part may, in the manner described below, amortize on its Reports of Condition and Income:

(1) Any loss on any qualified agricultural loan reflected in a bank's annual financial statements for any period between and including 1984 and 1991; and

(2) Any loss reflected in a bank's financial statements for any period between and including 1983 and 1991 resulting from a reappraisal or sale of agriculturally related other property.

(b) Amortization under this section shall be computed over a period not to exceed seven years on a quarterly straight-line basis commencing in the first quarter after the loss was or is

charged-off so as to be fully amortized not later than December 31, 1998.

#### § 35.4 Accounting for amortization.

(a) *General rule.* Any bank which is permitted to amortize losses in accordance with § 35.3, above, may restate its capital and other relevant accounts and account for future authorized deferrals and amortizations in accordance with the instructions to the FFIEC Consolidated Reports of Condition and Income. Any resulting increase in the capital account shall be included in primary capital under § 3.100 of this chapter.

(b) *Relationship with the substitute lending limit.* Unamortized losses on loans and other assets, which are capitalized under this rule for agricultural loan loss amortization, are not to be included in capital for the purpose of calculating the substitute lending limit under § 32.8 of this chapter.

#### § 35.5 Eligibility.

A proposal submitted in accord with § 35.7 shall be accepted, subject to the conditions described in § 35.6, if the Accepting Official finds that:

(a) The proposing bank is an agricultural bank;

(b) The proposing bank's current capital is in need of restoration, but the bank remains an economically viable, fundamentally sound institution;

(c) There is no evidence that fraud or criminal abuse by the bank or its officers, directors or principal shareholders led to significant losses on qualified agricultural loans and agriculturally related other property; and

(d) The proposing bank has submitted a capital plan approved by the OCC or the Accepting Official that will restore its capital to an acceptable level.

#### § 35.6 Conditions on acceptance.

All acceptances of proposals shall be subject to the following conditions:

(a) The bank shall fully adhere to the approved capital plan and shall obtain the prior approval of the Accepting Official for any modifications to the plan;

(b) With respect to each asset subject to loss deferral under the program, the bank shall maintain accounting records adequate to document the amount and timing of the deferrals, repayments and amortizations;

(c) The financial condition of the bank shall not deteriorate to the point where it is no longer a viable, fundamentally sound institution;

(d) The bank agrees to make a reasonable effort, consistent with safe and sound banking practices, to

maintain in its loan portfolio a percentage of agricultural loans, including agriculturally related other property, not lower than the percentage of such loans in its loan portfolio on January 1, 1986; and

(e) The bank agrees to provide the Accepting Official, upon request, with such information as the Accepting Official deems necessary to monitor the bank's amortization, its compliance with conditions, and its continued eligibility.

#### § 35.7 Submission of proposals.

(a) A bank wishing to amortize losses on qualified agricultural loans or agriculturally related other property shall submit a proposal to the appropriate Accepting Official.

(b) The proposal shall contain the following information:

(1) Name and address of the bank;

(2) Information establishing that the bank is located in an area the economy of which is dependent on agriculture; such as a description of the bank's location, dominant lines of commerce in its service area, and any other information the bank believes will support the contention that it is located in such area;

(3) A copy of the bank's most recent Reports of Condition and Income;

(4) If the Reports of Condition and Income fail to show that at least 25 percent of the bank's total loans are qualified agricultural loans, the basis upon which the bank believes that it should be declared eligible to amortize losses;

(5) A capital plan demonstrating that the bank will achieve an acceptable capital level not later than the end of the bank's amortization period. The plan should provide for a realistic improvement in the bank's capital over the course of the bank's amortization period from earnings retention, capital injections, or other sources. It should also include specific information regarding dividend levels, compensation to directors, executive officers and individuals who have a controlling interest and their related interests, and payments for services or products furnished by affiliated companies;

(6) A list of the loans and agriculturally related other property upon which the bank proposes to defer loss, including for each such loan or property the following information:

(i) The name of the borrower, the amount of the loan that resulted in the loss, and the amount of the loss;

(ii) The date on which the loss was declared; and

(iii) The basis upon which the loss resulted from a qualified agricultural loan.

(7) A certification by the bank's chief executive officer that there is no evidence that the losses resulted from fraud or criminal abuse by the bank, its officers, directors, or principal shareholders;

(8) A copy of a resolution by the bank's Board of Directors authorizing submission of the proposal; and

(9) Such other information as the Accepting Official may require.

#### § 35.8 Revocation of eligibility.

The failure to comply with any condition in an acceptance or the capital restoration plan is grounds for revocation of acceptance for loss amortization and for an administrative action against the bank under 12 U.S.C. 1818(b). Additionally, acceptance of a bank for loss amortization will not foreclose any administrative action against the bank that the OCC may deem appropriate.

Date: July 19, 1988.

Robert L. Clarke,

Comptroller of the Currency.

[FR Doc. 88-16684 Filed 7-27-88; 8:45 pm]

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### Customs Service

#### 19 CFR Part 10

[T.D. 88-45]

#### Customs Regulations Amendment Concerning Reciprocal Privileges Extended To Aircraft of Japan

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

**SUMMARY:** This document amends the Customs Regulations by changing the list of countries whose aircraft are exempt from the payment of Customs duties and internal revenue taxes on supplies and equipment withdrawn from Customs or internal revenue custody for use by aircraft. The amendment indicates that aircraft of Japanese registry are no longer entitled to free withdrawal of ground support equipment.

Prior to 1986, Japan had been extending aircraft of U.S. registry exemption privileges in connection with international commercial operations which were substantially reciprocal to those exemption privileges the U.S. provided to aircraft of foreign registry by sections 309 and 317 of the Tariff Act of 1930, as amended. Accordingly, the Customs Regulations provided that aircraft of Japanese registry were

entitled to free withdrawal privileges. However, the Department of Commerce has informed Customs that Japan is no longer extending the exemption privileges to ground support equipment of U.S. aircraft. Accordingly, the U.S. will no longer exempt aircraft of Japanese registry from the payment of duties and taxes when their ground support equipment is withdrawn from Customs or internal revenue custody.

**EFFECTIVE DATE:** July 28, 1988.

**FOR FURTHER INFORMATION CONTACT:** William G. Rosoff, Entry Rulings Branch, (202) 566-6040.

#### SUPPLEMENTARY INFORMATION:

##### Background

Sections 309 and 317, Tariff Act of 1930, as amended (19 U.S.C. 1309 and 1317), provide that foreign-registered aircraft engaged in foreign trade may withdraw articles of foreign or domestic origin for use as supplies (including equipment), ground equipment, maintenance or repair of the aircraft from Customs or internal revenue custody without the payment of Customs duties and/or internal revenue taxes. This privilege is granted if the Secretary of Commerce finds and advises the Secretary of the Treasury, that the country in which the foreign aircraft is registered allows substantially reciprocal privileges to U.S. registered aircraft. Section 10.59(f), Customs Regulations (19 CFR 10.59(f)), lists those countries whose aircraft have been found to be entitled to these privileges.

By virtue of the authority vested in the President by section 5 of the Act of May 28, 1908, 35 Stat. 425, as amended (46 U.S.C. 104), the President has delegated the authority to issue this list of nations to the Secretary of the Treasury by E.O. 10289, September 17, 1951. By Treasury Department Order 165-25, the Secretary of the Treasury delegated authority to the Commissioner of Customs to prescribe regulations relating to § 10.59(f) and other sections of the Customs Regulations relating to lists of countries entitled to preferential treatment in Customs matters because of reciprocal privileges accorded to vessels and aircraft of the U.S. Subsequently, by Customs Delegation Order No. 66 (T.D. 82-201), dated October 13, 1982, the Commissioner delegated authority to amend these sections to the Assistant Commissioner (Commercial Operations), who redelegated this authority to the Director, Office of Regulations and Rulings, who then redelegated it to the Chief, Regulations and Disclosure Law Branch.

In accordance with 19 U.S.C. 1309(d), the Secretary of Commerce previously found, and advised the Secretary of the Treasury that Japan allowed privileges substantially reciprocal to those provided for in 19 U.S.C. 1309 and 1317 to aircraft registered in the U.S. and engaged in foreign trade. Therefore, by T.D. 53550, Japan was listed in § 10.59(f), Customs Regulations and corresponding privileges were extended to aircraft registered in Japan engaged in foreign trade.

The Commerce Department has not determined, and conveyed to the Customs Service, that Japan no longer exempts ground support equipment of aircraft of U.S. registry from taxes and duties. The finding became effective on August 1, 1986. This document amends § 10.59(f), Customs Regulations (19 CFR 10.59(f)), by changing the list of countries whose aircraft are exempt from the payment of Customs duties and internal revenue taxes on supplies and equipment withdrawn from Customs or internal revenue custody for use by aircraft to indicate that Japan has discontinued its exemption regarding ground support equipment.

#### Executive Order 12291

This document does not meet the criteria for a "major rule" as defined in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

#### Regulatory Flexibility Act

Pursuant to the provisions of section 605(b) of the Regulation Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601, *et seq.*), it is certified that the change set forth in this document will not have a significant economic impact on any substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

#### Inapplicability of Public Notice and Delayed Effective Date Requirements

Because the subject matter of this document does not constitute a departure from established policy or procedures but merely announces the rescission of a previously granted exemption for which there is a statutory basis, it has been determined, pursuant to 5 U.S.C. 553(b)(B), that notice and public procedure thereon are unnecessary. As Japan has been found by the Department of Commerce to have discontinued its exemption privileges regarding ground support equipment in 1986, a delayed effective date is not appropriate.

**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
- II. Evaluation of the Petition
  - A. Estimated Daily Intake
  - B. Safety Studies
- III. Comments
- IV. Conclusions
- V. Objections
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**I. Summary of the Petition**

In a notice published in the *Federal Register* of October 15, 1982 (47 FR 46139), FDA announced that a petition (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(3H)-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 substance 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 estimate 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 (reticulum 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 females 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 hyperplasia, 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 preceding 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 § 25.31(a).

#### V. Objections

Any person who will be adversely 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(3H)-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, in 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 "Profenofos" 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. Camp,

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.