

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

4. Part 184 is amended in § 184.1366 by revising paragraphs (c), (d), and (e) to read as follows:

§ 184.1366 Hydrogen peroxide.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under Part 133 of this chapter.	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04	do
Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this chapter	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	Bleaching agent.
Herring	Amount sufficient for the purpose.	do
Wine	do	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter.
Starch	0.15	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter, to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose.	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey.	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.

Food	Maximum treatment level in food (percent)	Functional use
Emulsifiers containing fatty acid esters.	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,
Acting Associate Commissioner for
Regulatory Affairs.
[FR Doc. 17036 Filed 7-29-86; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 184

[Docket No. 81N-0348]

Benzoyl Peroxide; Affirmation of GRAS Status

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that benzoyl peroxide is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective August 29, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1157 effective on August 29, 1986.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 1, 1982 (47 FR 43402), FDA published a proposal to affirm that benzoyl peroxide is GRAS for use as a direct human food ingredient. FDA published this proposal in accordance with its announced review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review and the reports of the Select Committee on GRAS Substances (the Select Committee) on benzoyl peroxide

have been made available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents are also available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of benzoyl peroxide, FDA gave public notice that it was unaware of any prior-sanctioned food uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those prior sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of this ingredient recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181), or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for benzoyl peroxide were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of this ingredient under conditions different from those set forth in this final rule has been waived.

FDA received three comments in response to the proposal.

One comment, from a soya products company, supported the regulation as proposed. Thus, no response to that comment is necessary.

The other two comments did not question the agency's tentative determination that the use of benzoyl peroxide is GRAS. However, the comments did request that proposed § 184.1157(c)(2) be amended to include the use of benzoyl peroxide as a substitute for hydrogen peroxide for bleaching annatto-colored whey. Both comments presented published studies on the effectiveness of benzoyl peroxide for this use, as well as a study on the decomposition of benzoyl peroxide in whey.

One of these two comments, in response to a request from FDA, provided supplemental information clarifying the conditions of use of benzoyl peroxide in the manufacture of

whey, including the proposed level of use, the residue level, and the method of analysis for residues of benzoyl peroxide in bleached whey.

FDA has thoroughly reviewed these two comments as well as the supplemental information that was submitted. The agency finds that the use of benzoyl peroxide to bleach annatto-colored whey is a new use. FDA has estimated the increase in use of benzoyl peroxide in food that would result from this use. It finds that this use of benzoyl peroxide will result in an increase in dietary exposure to this substance that is so small that it falls within the level that the Select Committee considered to be safe.

This latter finding is based on (1) the Select Committee's conclusion that no evidence in the available information on benzoyl peroxide demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when benzoyl peroxide is used at levels that are now current or that might reasonably be expected in the future; (2) the Select Committee's estimate in its reports that the then current per capita level of addition of benzoyl peroxide to food was about 8.5 milligrams per day; (3) the agency's estimate that the per capita level of addition of benzoyl peroxide to food resulting from its use as a bleach for annatto-colored whey would be no more than 0.023 milligram per day; and (4) the Select Committee's finding, supported by the data in the comments to the proposal, that most of the benzoyl peroxide employed as a bleach would be converted to benzoic acid during food processing, and that only traces of residual peroxide would be ingested.

Based on the findings of the Select Committee and on its own review of the data, the agency concludes that it can affirm the use of benzoyl peroxide in food, including its use in whey, as GRAS. The agency is issuing § 184.1157(c)(2) to affirm these uses as GRAS.

The agency has made a minor editorial change in 21 CFR 184.1157(c)(2). The agency reconsidered the proposed language in this section that referred to the use of benzoyl peroxide in milk used in the production of certain cheeses, as specified in the appropriate food standards. Because the proposed language could be considered vague and could be misinterpreted, the agency has revised § 184.1157(c)(2) to list the specific food standards for cheese under which benzoyl peroxide may be used.

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the *Federal Register* of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a)(1).

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by the Order. The agency has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046-1047 as amended, 1055-1056 as amended, 72 Stat. 1784-1788 as amended (21

U.S.C., 321(s), 342, 348, 371); 21 CFR 5.10 and 5.61.

2. Part 184 is amended by adding new § 184.1157, to read as follows:

§ 184.1157 Benzoyl peroxide.

(a) Benzoyl peroxide $[(C_6H_5CO)_2O_2]$, CAS Reg. No. 94-36-0) is a colorless, rhombic crystalline solid. It is prepared by reaction of benzoyl chloride, sodium hydroxide, and hydrogen peroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 35, 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) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a bleaching agent in food.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§ 133.102), Asiago medium cheese (§ 133.103), Asiago old cheese (§ 133.104), Blue cheese (§ 133.106), Caciocavallo siciliano cheese (§ 133.111), Gorgonzola cheese (§ 133.141), Parmesan and reggiano cheese (§ 133.165), Provolone cheese (§ 133.181), Romano cheese (§ 133.183), and Swiss and emmentaler cheese (§ 133.195) in Part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in § 184.197(a) (1), (2), or (3), respectively.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Dated: July 17, 1986.

James W. Swanson,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 86-17035 Filed 7-29-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

(T.D. 8090)

Income Taxes; Possessions Tax Credit; Definition of Product, Significant Business Presence Test, and Cost Sharing and Profit Split Elections

Correction

In the issue of Friday, June 13, 1986, in the document beginning on page 21518 in the second column, make the following corrections:

§ 1.936-5 [Corrected]

1. On page 21525, in § 1.936-5(a), second column, Example (2), last line, insert "later" after "that".
2. On page 21530, in § 1.936-5(b)(4), third column, in the eleventh line, "to" should read "with", and in the thirteenth line, "located" should read "allocated".
3. On page 21531, in § 1.936-5(b)(7), third column, eleventh line, "the" should read "that".

§ 1.936-6 [Corrected]

4. On page 21539, in § 1.936-6(b)(1), third column, two lines above Example 3, "titles" should read "tiles".
5. On page 21546, third column, in the FR docket line, "86-13156" should have read "86-13158".

BILLING CODE 1505-01-M

PANAMA CANAL COMMISSION

35 CFR Part 103

General Provisions Governing Vessels

AGENCY: Panama Canal Commission.

ACTION: Interim rule with request for comments.

SUMMARY: The Panama Canal Commission is amending its regulations in Title 35, Code of Federal Regulations, § 103.8 concerning preference in transit schedulings and order of transiting vessels. The changes take into account the agency's experience with the Panama Canal Transit Booking System over the preceding three years and the corresponding needs of the shipping community.

EFFECTIVE DATE: The amendments made herein are effective July 30, 1986. Written comments should be submitted on or before August 29, 1986.

ADDRESSES: Comments should be sent to Secretary, Panama Canal Commission, 2000 L Street, NW., Suite

550, Washington, DC. 20036-4996 or Panama Canal Commission, Office of General Counsel, APO Miami, Florida 34011-5000.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael Rhode, Jr., Secretary, Panama Canal Commission, telephone: (202) 634-6441 TDD, or Mr. John L. Haines, Jr., General Counsel, telephone in Balboa Heights, Republic of Panama, 011-507-52-7511.

SUPPLEMENTARY INFORMATION: By a document published on March 4, 1983, (48 FR 27406), the Panama Canal Commission adopted a voluntary system by which a limited number of vessels may be assured a timely transit of the Canal, upon payment of a special charge. The purpose of this document is to make several changes to the booking system regulations based on numerous requests from Canal users that the Canal Commission revise the arrival time requirements in the present rules. The changes take into account the need to better serve our customers, without adversely affecting Canal operations.

The present regulations, in § 103.8(f)(1), require that booked vessels which are subject to transit restrictions arrive at a terminus of the Canal by midnight (2400 hours) of the day prior to the intended transit. At present, booked vessels not subject to transit restrictions must arrive prior to noon of the day of the intended transit. This section is being revised to allow both classes of vessels to arrive at a Canal terminus one hour later. Under this revision, restricted vessels must arrive not later than 0100 hours of the day of the transit, and non-restricted vessels must arrive not later than 1300 of the day of the transit.

In addition to the arrival time changes, the agency is revising the rules concerning forfeiture of the booking fee. The present rules provide that vessel which does not arrive by the specified arrival time forfeits the booking fee unless its arrival has been delayed by *force majeure*. The term *force majeure* has caused some confusion in the past, and accordingly, the grounds for waiving a forfeiture are being rephrased. Under the revised rule no forfeiture will occur, if the vessel's arrival is delayed by a natural event or major proportions, not caused by the intervention of man, which could not reasonably be predicted in advance. Heavy seas are not considered such a major natural event.

The amendment concerning the arrival times is a *de minimis* change that liberalizes current rules for booked vessels. The revision of the *force majeure* rule is not substantive, but is intended to clarify the rule. Accordingly,

these amendments are effective upon publication of this notice, but comments concerning these revisions are invited and will be carefully considered.

The Commission has determined that this rule does not constitute a major rule within the meaning of Executive Order 12291 dated February 17, 1982 (47 FR 13193). The bases for that determination are, first, that the rule, when implemented would not have an annual effect on the economy of \$100 million or more per year, and secondly, that the rule would not result in a major increase in costs or prices for consumers, individual industries, local governmental agencies or geographic regions. Further, the agency has determined that implementation of the rule will have no adverse effect on competition, employment, investment, productivity, innovation or the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets.

Finally, the Commission has determined that this rule is not subject to the requirements of sections 603 and 604 of Title 5, United States Code, in that its promulgation will not have a significant impact on a substantial number of small entities, and the Administrator of the Commission so certifies pursuant to 5 U.S.C. 605(b).

List of Subjects in 35 CFR Part 103

Panama Canal, Vessels, Booking system, Navigation (water).

PART 103—GENERAL PROVISIONS GOVERNING VESSELS

Accordingly, 35 CFR Part 103 is amended as follows:

1. The authority citation for Part 103 continues to read as follows:

Authority: 22 U.S.C. 3811, E.O. 12215, 45 FR 36043 and 44 U.S.C. 3501.

2. Section 103.8(f)(1) is revised to read as follows:

§ 103.8 Preference in the transit schedule; order of transiting vessels.

(f) *Penalties.* (1) When a vessel that is subject to transit restrictions (e.g., clear-cut; clear-cut daylight), has been booked for transit and does not arrive at a terminus of the Canal by 0100 of the day of the intended transit, the booking fee will be forfeited. Similarly, the fee will be forfeited if a booked vessel that is not subject to such transit restrictions does not arrive by 1300 hours of the day of the intended transit. In either case, upon arrival, the vessel will be placed in the regular transit schedule. This forfeiture will not occur if late arrival is

due to humanitarian reasons or a natural event of major proportions, which is not caused by the intervention of man, and which could not be reasonably predicted in advance. The booking fee will also be forfeited if the vessel arrives on time but cannot or, at the operator's election, does not, transit as scheduled when the agency is ready to proceed. In these latter cases, the Canal authorities shall have discretion to waive the forfeiture where it is established that the delay was due to external causes that the vessel operator could not reasonably have anticipated.

* * * * *

Dated: July 16, 1986.

D.P. McAuliffe,

Administrator, Panama Canal Commission.

[FR Doc. 86-17020 Filed 7-29-86; 8:45 am]

BILLING CODE 3640-04-M