

§ 217.6 Reporting instructions.

(a) A complete report shall be made on CAB Form 217 for all charter operations conducted by foreign air carriers to or from the United States and for all international charter operations conducted by U.S. certificated air carriers. Charter flights performed with small aircraft are exempt.

(b) Reporting of charter flights shall be on a charter type basis, by flight leg; that is, there will be a separate line of data for each flight leg of each charter type that is flown between a different set of points. If the charter type, flight leg, point of enplanement, point of deplanement and aircraft type utilized are identical, the reported data then shall be reported in the aggregate for the entire month, regardless of the number of flights flown between those points.

(c) Each CAB Form 217 submitted shall consist of three separate monthly reports within each of the respective calendar quarters. Data for each flight leg shall be reported for that month in which the flight leg began. The reported month, year, and name of carrier shall be inserted in the areas provided in the upper left hand corner of the report. The date code shall show the year first and then the month (e.g., 8301 for January 1983). The carrier area shall show the carrier's standard 2-position alpha code as shown in the Official Airline Guide (OAG). If the carrier has no such code, it should leave those two positions blank until assigned a code by the Information Management Division, Office of Comptroller.

(d) Column (1) is reserved.

(e) Column (2) shall reflect the code number for the type of aircraft operated as provided in the Official Airline Guide (OAG). If no aircraft code exists in the OAG, the manufacturers type and model shall be provided so that the Information Management Division, Office of Comptroller can assign a code to be used in subsequent filings.

(f) Column (3) shall reflect the number of charter flights performed.

(g) Column (4) shall reflect each type of charter by the following codes:
EC—Entity-Cargo (Own Use)
EF—Cargo (Forwarder/Consolidator)
EP—Part Charter (Passenger)
PZ—Other Passenger Charters

Charters flown for the transportation of charter traffic of another air carrier or foreign air carrier shall be reported solely by the carrier in operational control of the aircraft, naming the type of charter, e.g., EP, and traffic carried. Charters flown to accommodate the scheduled traffic of another direct air carrier shall be reported as entity charters.

(h) Column (5) shall identify each leg by the following numbers:

- 1—One-way flight.
- 2—Originating leg of round trip.
- 4—Return leg of round trip.

The outbound and return legs of any round trip group movement shall not be reported as one-way flight legs.

(i) Column (6) shall reflect any point at which a charter group, cargo load, or part of a group or load was enplaned. Departure points for ferry legs shall not be reported. Technical stops, e.g., for departure formalities or refueling, shall not be reported. Where a diversion occurs for weather or other reasons, the planned rather than the actual point of enplanement shall be reported. The point of enplanement shall be identified by the three-letter airport code used in the OAG. If no OAG code exists, the point of enplanement shall be written out, in a footnote if necessary.

(j) Column (7) shall reflect any point at which a charter group, cargo load, or part of a group or load was deplaned. Arrival points for ferry legs shall not be reported. Technical stops, e.g., for entry formalities or refueling, shall not be reported. Where a diversion occurs for weather or other reasons, the planned rather than the actual point of deplanement shall be reported. The point of deplanement shall be identified by the three-letter airport code used in the OAG. If no OAG code exists, the destination name shall be written out, in a footnote if necessary.

(k) Column (8) is reserved.

(l) Column (9) is reserved.

(m) Column (10) is reserved.

(n) Column (11) shall reflect the number of charter passengers transported. Part charter entries shall exclude scheduled passengers.

(o) Column (12) shall reflect the number of tons (to the nearest tenth of a short ton) of property enplaned in Entity-Cargo (Own Use) and Cargo (Forwarder/Consolidator) charters only.

§ 217.7 Waivers from reporting requirements.

A waiver from any reporting requirement contained in CAB Form 217 may be granted by the Civil Aeronautics Board upon its own initiative, or upon the submission of a written request to the Board's Office of Comptroller from any air carrier, when such a waiver is in the public interest. Each request for waiver must expressly demonstrate that: Existing peculiarities warrant a departure from the prescribed reporting; a specifically defined alternative procedure or technique will result in a substantially equivalent or more accurate portrayal of the prescribed reporting; and the application of such

alternative procedure will maintain or improve uniformity in reporting as between air carriers.

§ 217.8 Computer prepared submissions.

Carriers may submit the data required by CAB Form 217 on a comparable form prepared on automatic data processing equipment. Such substitute form shall be subject to prior approval by the Chief, Information Management Division, Office of Comptroller and shall contain the same column headings arranged in the same sequence as CAB Form 217.

By the Civil Aeronautics Board.

Note.—CAB Form 217 is filed as part of the original document.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 83-2412 Filed 1-27-83; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 241

[Economic Regs. Amdt. No. 48; Reg. ER-1319]

Uniform System of Accounts and Reports for Certificated Air Carriers; Amendment of Fuel Cost and Consumption Reporting

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB reduces the amount of fuel cost and consumption data reported monthly by certificated air carriers. This action also establishes a new procedure for withholding monthly fuel cost and consumption data of individual carriers from public disclosure for a limited period of time. This action will more closely align the data collected with the CAB's data needs.

DATES: Adopted: January 12, 1983. Effective: April 1, 1983; however, in accordance with the Paperwork Reduction Act (44 U.S.C. 3507), these reporting provisions have been or will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until a control number is issued by OMB.

FOR FURTHER INFORMATION CONTACT: Jack M. Calloway or M. Clay Moritz, Jr., Data Requirements Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428, (202) 673-6042.

SUPPLEMENTARY INFORMATION: In a notice of proposed rulemaking dated April 3, 1981, the Board proposed to reduce the level of detailed fuel data reported on CAB Form 41 Schedule P-

12(a) "Fuel Consumption by Type of Service and Specific Operational Markets" (EDR-422, 48 FR 21185, April 9, 1981). This reporting reduction was to be accomplished by:

1. Eliminating the requirement that fuel cost and consumption data be reported separately for bonded, nonbonded and foreign fuel;
2. Consolidating from seven into two the number of operational markets in domestic scheduled service for which fuel consumption would be reported;
3. Consolidating from seven into three the number of operational markets in international scheduled service for which fuel consumption would be reported; and
4. Consolidating the reporting of nonscheduled services in the same way as scheduled services.

EDR-422 also proposed to amend Part 241 so as to withhold the individual carrier fuel data reported on Schedule P-12(a) from public disclosure until thirty days after the end of the calendar quarter to which the monthly schedules relate. This limited confidential treatment was proposed in response to a Delta Air Lines, Inc. February 13, 1981, motion for confidential treatment of CAB Form 41 Schedules P-12 and P-12(a).¹ Pan American World Airways, Inc., Trans World Airlines, Inc. and United Air Lines, Inc. filed subsequent motions for confidential treatment of Schedules P-12 and P-12(a) on February 27, 1981, March 20, 1981, and March 23, 1981, respectively. The limited confidential treatment proposed in EDR-422 was intended as the Board's response to these subsequent motions as well.

Thirteen comments were received in response to the rulemaking notice. Of the thirteen, ten were from certificated air carriers², two from other Federal agencies³, and one from the Boeing Commercial Airplane Company (Boeing). American's Continental's and TWA's comments support the rule as proposed, while the remaining comments suggest certain modifications

to the rulemaking proposal. The modifications are discussed below under separate captions.

Schedule P-12(a) Data Format

Piedmont, United, Boeing, Bureau of Economic Analysis, and Defense Fuel Supply Center each submitted comments concerning the proposed reporting of fuel data on the revised Schedule P-12(a) "Fuel Consumption by Type of Service and Entity." In its comments, Piedmont suggests that the final rule include a sunset provision to coincide with the Board's loss of its ratemaking authority on December 31, 1982.

Attaching a sunset date to the Board's collection of fuel data is unwarranted at this time for two reasons. First, the Board's authority over international fares and rates transfers, under the provisions of the Airline Deregulation Act of 1978, to the Department of Transportation on January 1, 1985. Thus, the need for international fuel data will continue beyond sunset. Second, both domestic and international fuel data are still needed to determine the Standard Industry Fare Level (SIFL) and the Standard Foreign Fare Level (SFFL). While the SFFL calculations will continue beyond sunset, SIFL will be retained at least until the Board's January 1, 1984, Report to Congress on the impact of deregulation is due. Both SIFL and SFFL are used to provide benchmarks in evaluating the effects of deregulation. Furthermore, eliminating the domestic fuel data used in the SIFL calculations would also eliminate certain transborder operations that are reported in the domestic entity but are still needed in monitoring international fares.

Piedmont's comments also question the need for the Board to continue collecting fuel data since EDR-422 points out that average fuel prices are available in quarterly reports submitted to the Securities and Exchange Commission (SEC). The availability of fuel data from the SEC was mentioned in EDR-422 merely to point out that the Board's proposed public release of fuel data on a quarterly basis coincides with the availability of fuel data from other sources. The data available from the SEC, however, is not of sufficient detail to satisfy the Board's regulatory need for fuel data. Typically, publicly held air carriers have been reporting, as part of their SEC Form 10-Q, "Quarterly Report under Section 13 or 15(d) of the Securities Exchange Act of 1934," average fuel prices and the number of gallons consumed on a system basis; however, the Board requires fuel consumption and price data broken down by entity and reported on a

monthly basis. Therefore, the data that are available fall short of the level of detail and the filing frequency needed by the Board. It should also be noted that the submission of carrier fuel data to SEC is voluntary under a Form 10-Q general "management discussion of significant items" reporting requirement. As a result, carrier fuel data reporting is not uniform. Accordingly, we must continue to collect fuel data in order to meet our regulatory needs.

The comments of Bureau of Economic Analysis (BEA), Boeing and Defense Fuel Supply Center (DFSC) all suggest retaining some or all of the data that would be eliminated on the revised Schedule P-12(a). Both BEA and Boeing recommend continuing the separate reporting of domestic and foreign fuel data. BEA uses foreign fuel data in preparing estimates of trade in petroleum products between the United States and other countries. Moreover, BEA identifies the Board as the sole source of data on the volume of foreign fuel utilized by U.S. air carriers. Boeing, on the other hand, cites dissimilar price characteristics between the domestic and foreign fuel markets in recommending that the reporting of domestic and foreign fuel not be combined in the revised P-12(a).

DFSC recommends continuing the current Schedule P-12(a) reporting requirement. In its comments, DFSC states that, along with other relevant market research data, the Schedule P-12(a) data are used to evaluate offers it receives under its fuel procurement solicitations. In support of its position, DFSC states that every cent per gallon negotiated off the average jet fuel price procured from domestic sources represents a savings to the U.S. taxpayer of nearly \$46 million per year. The DFSC goes on further to state that it believes that the loss of the P-12(a) data would adversely affect its ability to negotiate favorable price terms on its jet fuel procurements. Adoption of DFSC's recommendation would result in retaining schedule P-12(a) in its present form and enable us to meet Boeing's and BEA's expressed data needs as well.

While we believe the above comments do have merit, the Paperwork Reduction Act of 1980 (Pub. L. 96-511) precludes the Board from collecting data that are not needed for its own regulatory programs. However, this Act does provide that the Director, Office of Management and Budget (OMB) has the authority to designate the Board as a central agency for collecting data needed by one or more agencies.

With this in mind, we sent a letter to OMB asking for their views as to

¹ Delta's motion for confidential treatment for Schedule P-12 was rendered moot by the Board's July 8, 1982, adoption of ER-1297 (47 FR 32915, July 28, 1982), which eliminated Schedule P-12, "Fuel Inventories and Consumption" as a reporting requirement.

² Air Florida, Inc. (Air Florida), American Airlines, Inc. (American), Continental Air Lines (Continental), Delta Air Lines, Inc. (Delta), Northwest Airlines (Northwest), Pan American World Airways, Inc. (Pan American), Piedmont Aviation, Inc. (Piedmont), United Air Lines, Inc. (United), Trans World Airlines, Inc. (TWA) and U.S. Air, Inc. (USAir).

³ United States Department of Commerce (Bureau of Economic Analysis) and Department of Defense—Defense Logistics Agency (Defense Fuel Supply Center).

whether the Board should be designated to collect the data needed by DFSC and BEA even though the Board no longer requires such detailed fuel data. After its review, OMB informed us that they decided not to designate the Board as a central collection agency for carrier fuel data. We have contacted both BEA and DFSC, informing them of OMB's decision and soliciting any additional comments they may have. Neither BEA nor DFSC have commented further. Accordingly, we have decided to finalize the Schedule P-12(a) data format as it was proposed in EDR-422.

In its comment, United has asked that Mexican transborder operations be reported in the domestic entity instead of the Latin American entity, as proposed. The carrier contends that most Mexican cities are relatively close to domestic points and their fares are monitored through the domestic Standard Industry Fare Level (SIFL). Furthermore, United claims these flights more closely parallel fifty-state enterprises than Atlantic, Pacific or Latin American flights.

We have included Mexican operations in the Latin American entity in the final rule. Only a limited number of carriers currently have their Mexican operations monitored through SFFL. The remaining majority of carriers conducting Mexican operations are monitored through the Standard Industry Fare Level (SIFL). With the termination of the Board's domestic ratemaking authority on December 31, 1982, the monitoring of Mexican operations will start to shift toward the SFFL.

Public Disclosure

The remainder of the comments submitted pertain to the Board's proposed limited confidential treatment period for Schedule P-12(a) whereby individual carrier fuel data would be withheld from public disclosure until thirty days after the end of the calendar quarter to which the monthly schedules relate. As mentioned previously, American, Continental and TWA support the proposed confidential treatment contained in EDR-422. The DFSC commented that Schedule P-12(a) data should be withheld from public release until such time that concern for commercial sensitivity does not exist.

Against this backdrop of support for limited confidential treatment, Air Florida, Delta, Northwest, Pan American, Piedmont, United and USAir all support the concept of confidential treatment but suggest certain modifications to the proposed rule.

Early Release of Fuel Data

Air Florida, Delta, Northwest and Pan American have suggested certain modifications to the proposed criteria for the early release of fuel data. The proposed rule provides that aggregate data may be released before the expiration of the confidential treatment period without identifying individual carriers; however, individual carrier fuel data withheld from public disclosure may be disclosed by the Board to (1) parties to any proceeding before the Board to the extent such material is relevant and material to the issues in the proceeding upon a determination to this effect by the administrative law judge assigned to the case or by the Board; (2) agencies and other components of the Federal Government for their internal use only; and (3) such persons and in such circumstances as the Board determines to be in the public interest or consistent with its regulatory functions and responsibilities.

Air Florida wants to expand the above criteria to permit the early release of individual carrier fuel data to those carriers participating in the submission of fuel cost and consumption data. Pan American also wants to expand the above list so as to include access by persons designated by each reporting carrier to verify the reported fuel data compiled by and used by the Board in the Standard Industry Fare Level calculations, the Standard Foreign Fare calculations and mail rate determinations.

Air Florida contends that principles of fairness dictate that carriers obligated to supply fuel data should be able to access such data. Air Florida compares the release of fuel data with the Board's policy of releasing restricted international Origin and Destination Survey (O & D) statistics to participating U.S. carriers. The carrier further comments that carriers should have access to other carriers' cost data to insure that fuel suppliers do not try to take advantage of a carrier in the pricing of their product. This, Air Florida feels, would help negate or minimize the tendency of fuel prices to move toward an average market price.

The analogy that Air Florida draws between the release of international O & D data and fuel data is tenuous at best. Historically, international O & D data have not been released to the public whereas fuel data have. While international O & D data are accorded permanent confidential treatment and made available to participating carriers under a reciprocal exchange agreement, the proposed rule grants only limited confidential treatment to Schedule P-

12(a); therefore, Air Florida will have prospective access to the fuel data it seeks for any purpose it wishes, including dealings with suppliers. We do not feel that the length of the confidential treatment period poses an undue burden on the carrier.

We are also not persuaded by Pan American's argument that early access is needed to verify the Board's fare and rate calculations. Since early 1981, when we started granting confidential treatment to individual carrier P-12(a) filings, we have received no requests for individual carrier fuel data and no comments that question the Board's compilation of fuel data in setting fares and rates.⁴ Should a situation arise where Pan American feels it has a legitimate need for individual carrier fuel data, we believe the carrier's concern can be properly addressed under the third exception to confidential treatment listed in EDR-422. This exception covers "such other persons and in such circumstances as the Board determines to be in the public interest or consistent with its regulatory functions and responsibilities."

In more general comments, Delta has asked that the provisions allowing early access provide more specific guidance as to under what exact circumstances fuel data would be released. For example, Delta feels that "relevant and material" do not adequately indicate when and under what circumstances data would be considered for release to parties to a Board proceeding. Northwest, on the other hand, has asked that Federal agencies be required to obtain prior Board approval before they can publicly release restricted fuel data that was obtained under the confidential treatment exception provisions of the proposed rule.

We have considered Delta's comments and feel that further specification of the exact circumstances surrounding the public release of fuel data is not feasible. Not every circumstance can be anticipated and reduced to regulation. Flexibility is needed so that each situation that arises can be judged on its own merits.

As to Northwest's concern that other Federal agencies obtain and release restricted fuel data, it should be noted that the guidelines proposed for early release are similar to the current guidelines in the Board's regulations that

⁴The Schedule P-12(a) filings of the following carriers are currently being withheld from public disclosure: Air Florida, American Airlines, Delta Air Lines, Northwest Airlines, Pacific Southwest Airlines, Pan American World Airways, Transamerica Airlines, Trans World Airlines, United Air Lines, USAir, and Western Air Lines."

govern the release of international passenger origin and destination (O & D) statistics. To date, we have experienced no problems in releasing international O & D statistics and expect no difficulty in administering the proposed public release provisions for fuel data. Based on the above discussion, we have included in the final rule the criteria for the early release of fuel data as they were proposed in EDR-422.

Length of Confidential Treatment Period

United, USAir and Piedmont have commented on the proposed length of the period of confidentiality. United and USAir have asked for permanent confidential treatment of schedule P-12(a). As an alternative, United suggests the Board consider a one-year confidential treatment period. In a similar vein, Piedmont asks for either the elimination of Schedule P-12(a) or a six-month period of confidentiality.

We are not inclined to extend confidential treatment to Schedule P-12(a) on a permanent basis. Over time, fuel data loses its sensitivity; moreover, as we have previously indicated, system average fuel prices can be computed using quarterly reports to the SEC and other Form 41 schedules. With the availability of pricing data from these other sources, we see no reason to significantly extend the proposed confidential treatment period.

On our own initiative, however, we have decided to delay the release of restricted fuel data to coincide with the filing date for the quarterly CAB Form 41 P schedules. This delay will effectively withhold carrier fuel data from public disclosure until the time when average entity fuel prices can be computed from other Form 41 schedules. Under this plan, fuel data would not be released until forty days after the end of the calendar quarter and, in the case of fourth quarter fuel data when certain preliminary financial schedules are filed under the provisions of paragraph (b) of Section 22 of this Part, fuel data would be withheld for ninety days or until March 30. This delay in releasing Schedule P-12(a) should eliminate some of the concerns of those carriers that argue for a release date later than the one proposed.

Requests for Individual Carrier Fuel Data

For administrative convenience, we are delegating to the Chief, Information Management Division, Office of Comptroller, the authority to grant or deny requests for the early release of the individual carrier fuel data reported on Schedule P-12(a). This action consolidates the responsibility for

collecting, maintaining the confidential treatment of, and authorizing the early release of individual carrier fuel data. The release of fuel data will be governed by the provisions of paragraph (k) of the reporting instructions for Schedule P-12(a), which are contained in Section 24 of this Part. An amendment to the Board's Organization Regulations, reflecting this change, is being issued simultaneously with this rule.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), as added by the Regulatory Flexibility Act (Pub. L. 96-354), the Board certifies that this rule will not have a significant economic impact on a substantial number of small entities. Although some of the carriers that are subject to Schedule P-12(a) are small businesses, they are not the ones that will be most significantly affected by this rule.

LIST OF SCHEDULES IN CAB FORM 41 REPORT

Schedule No.	Title	Filing frequency	Applicability by carrier group		
			I	II	III
P-12(a)	Fuel Consumption by Type of Service and Entity.	M	(1)	X	X

3. Section 24 is amended by revising the title and reporting instructions for Schedule P-12(a) to read:

Section 24—Profit and Loss Elements

Schedule P-12(a)—Fuel Consumption by Type of Service and Entity

(a) This schedule shall be filed by all Group II and Group III air carriers and Group I air carriers that receive section 406 subsidy or have annual operating revenues of \$10 million or more.

(b) A single copy (original only) of this schedule shall be filed to report monthly fuel consumption data by type of service and entity.

(c) For the purposes of this schedule, type of service shall be either scheduled service or nonscheduled service as those terms are defined in Section 03 of Part 241.

(d) For the purpose of this schedule, scheduled service shall be reported separately for: (1) Intra-Alaskan operations; (2) domestic operations, which shall include all operations within and between the 50 States of the United States (except Intra-Alaska), the District of Columbia, the Commonwealth of Puerto Rico and the United States Virgin Islands and Canadian transborder operations; (3) Atlantic operations (excluding Bermuda); (4) Pacific

List of Subjects in 14 CFR Part 241

Air carriers, Uniform system of accounts, Reports.

Final Rule

PART 241—[AMENDED]

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 241, Uniform System of Accounts and Reports for Certificated Air Carriers as follows:

1. The authority for Part 241 is:

Authority: Sections 204, 401, 407, 416, 417, 901, 902, 1002, Pub. L. 85-726, as amended, 72 Stat. 743, 754, 766, 771, 783, 784, 786, 78 Stat. 145; 49 U.S.C. 1324, 1371, 1377, 1386, 1387, 1471, 1472, and 1482.

2. Section 22, is amended by revising the title of Schedule P-12(a) in the List of Schedules in CAB Form 41 Report in paragraph (a) to read:

operations which shall include the North/Central Pacific, South Pacific (including Australia) and the Trust Territories; and (5) Latin American operations which shall include the Caribbean (including Bermuda and the Guianas), Mexico and South/Central America.

(e) For the purpose of this schedule, nonscheduled service shall be reported separately for domestic operations and international operations as defined in paragraph (d) above, except that domestic and international MAC operations shall be reported on separate lines.

(f) The cost data reported on each line shall represent the average cost of fuel, as determined at the station level, consumed in that entity.

(g) The cost of fuel shall include shrinkage but exclude (1) "through-put" and "in to plane" fees, i.e., service charges or gallonage levies assessed by or against the fuel vendor or concessionaire and passed on to the carrier in a separately identifiable form and (2) nonrefundable Federal and State excise taxes. However, "through-put" and "in to plane" charges that cannot be identified or segregated from the cost of fuel shall remain a part of the cost of fuel as reported on this schedule.

(h) Each air carrier shall maintain records for each station showing the computation of fuel inventories and consumption for each fuel type. The periodic average cost method shall be used in computing fuel inventories and consumption. Under this method, an average unit cost for each fuel type shall be computed by dividing the total cost of fuel available (Beginning Inventory plus Purchases) by the total gallons available. The resulting unit cost shall then be used to determine the ending inventory and the total consumption costs to be reported on this schedule.

(i) Where amounts reported for a specific entity include other than Jet A fuel, a footnote shall be added indicating the number of gallons and applicable costs of such other fuel included in amounts reported for that entity.

(j) Where any adjustment(s) recorded on the books of the carrier results in a material distortion of the current month's schedule, carriers shall file a revised schedule P-12(a) for the month(s) affected.

(k) Data reported on this schedule shall be withheld from public release until the quarterly Form 41 P schedules for the calendar quarter to which the monthly schedules relate are due at the Board. However, aggregate data may be released before that time without identifying individual carriers. Provisions governing the due dates for submitting the quarterly P schedules are contained in paragraphs (a) and (b) of Section 22 of this Part. Individual carrier fuel data withheld from public disclosure may be disclosed by the Board to (1) parties to any proceeding before the Board to the extent such material is relevant and material to the issues in the proceeding upon a determination to this effect by the administrative law judge assigned to the case or by the Board; (2) agencies and other components of the Federal Government for their internal use only; and (3) such persons and in such circumstances as the Board determines to be in the public interest or consistent with its regulatory functions and responsibilities.

2. CAB Form 41 Schedule P-12(a) is amended as shown in the attached exhibit. The exhibit is filed as part of the original document.

By the Civil Aeronautics Board.
Phyllis T. Kaylor,
Secretary.

[FR Doc. 83-2411 Filed 1-27-83; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 241

[ER-1321; Amdt. No. 49; Docket 40551]

Reporting of Charter Air Transportation and Elimination of Schedule T-6

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The CAB eliminates the reporting of domestic charter flights, reduces air carriers' reporting burden by filing less detailed international charter market data and consolidates the filing requirements so U.S. and foreign carriers use the same form (CAB Form 217). These actions eliminate unnecessary data as the Board moves toward sunset. Supplementary information about this rule appears in ER-1320, also adopted today.

DATES: Adopted: January 12, 1983. Effective: April 1, 1983; however, in accordance with the paperwork Reduction Act of 1980, (44 U.S.C. 3507), these reporting or recordkeeping provisions have been or will be submitted for approval to the Office of Management and Budget (OMB). They are not effective until OMB approval has been obtained.

FOR FURTHER INFORMATION CONTACT: Jack M. Calloway or Thad Machcinski, Data Requirements Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428, (202) 673-6042.

SUPPLEMENTARY INFORMATION:

List of Subjects in 14 CFR Part 241

Air carriers, Uniform system of accounts and reports.

Final Rule

PART 241—[AMENDED]

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 241 *Uniform System of Accounts and Reports for Certificated Air Carriers*, as follows:

1. The authority for Part 241 is amended to read:

Authority: Sections 101, 204, 401, 402, 403, 404, 407, 411, 416, 417, 901, 902, 1002, 1601, Pub. L. 85-726, as amended, 72 Stat. 737, 743, 754, 758, 766, 769, 774, 783, 788; 76 Stat. 145; 92 Stat. 1744; 49 U.S.C. 1301, 1324, 1371, 1372, 1373, 1374, 1377, 1381, 1472, 1482, 1551; sec. 43, Pub. L. 95-504, 92 Stat. 1750, 49 U.S.C. 1552.

Section 22 [Amended]

2. Section 22(a), General reporting instructions, is amended by removing all references to Schedule T-6, and by revising the following entries to read:

LIST OF SCHEDULES IN CAB FORM 41 REPORT

Schedule No.	Title	Filing frequency	Applicability by carrier group		
			I	II	III
T-3(c)	Airport Activity Statistics—Nonscheduled Revenue Service	Quarterly	X	X	X
T-8	Report of All-Cargo Operations	Semiannually	(6)	(6)	(6)

DUE DATES OF SCHEDULES IN CAB FORM 41 REPORT

Due date		Schedule No.		
January 30	P-1(a), T-1, T-2, T-3, T-9			
April 30	P-1(a), T-1, T-2, T-3, T-9			
July 30	P-1(a), T-1, T-2, T-3, T-9			
October 30	P-1(a), T-1, T-2, T-3, T-9			

Section 25 [Amended]

3. Section 25, *Traffic and Capacity Elements*, is amended by removing the "Schedule T-6 Report of Civil Aircraft Charters" subheading and reporting instructions for Schedule T-6.

By the Civil Aeronautics Board.
Phyllis T. Kaylor,
Secretary.

[FR Doc. 83-2411 Filed 1-27-83; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 82N-0378]

D&C Red No. 6 and D&C Red No. 7

Correction

In FR Doc. 82-35102 beginning on page 57681, in the issue of Tuesday, December 28, 1982, make the following corrections.

1. On page 57688, third column, first line of the first paragraph below the Note, "8 NHC1" should read "8 NHCl".

2. On page 57688, third column, second line of the fifth paragraph below the Note, "H2o" should read "H₂O".

3. On page 57688, third column, eighth line from the bottom of the page, "NaHO" should read "NaOH".

4. On page 57689, first column, last line of the second paragraph, "12 mL" should read "15 mL"; in the following two lines, "Spectrophotometer Analysis" should read "Spectrophotometric Analysis"; and "Spectrophotometric Parameters:" should read "Spectrophotometer Analysis".

BILLING CODE 1505-01-M

21 CFR Parts 155 and 156

[Docket No. 77P-0090]

Tomato Concentrates, Catsup, and Tomato Juice; Amendments to Standards of Identity and Establishment of Standards of Quality and Fill of Container

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending and establishing certain definitions and standards for canned vegetables and vegetable juices. This action will promote honesty and fair dealing in the consumers' interest and will facilitate international trade.

DATES: Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance: March 29, 1983. Objections by February 28, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 155.3 and 156.3 effective as of March 29, 1983.

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

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: FDA is amending the definition section for canned vegetables and establishing a separate definition section for vegetable juices. It also is amending the standards of identity and establishing standards of quality and fill of container for tomato concentrates, catsup, and tomato juice by, among other things: (1) Establishing separate standards for tomato concentrates to include tomato puree, tomato paste, and concentrated tomato juice, (2) providing for the use of tomato concentrates and safe and suitable nutritive carbohydrate sweetening ingredients in catsup, (3) providing for the use of concentrated tomato juice to prepare "tomato juice from concentrate" and establishing a minimum tomato soluble solids requirement of 5.0 percent, by weight, for "tomato juice from concentrate", and (4) providing for safe and suitable organic acids in tomato juice and tomato juice from concentrate. This document also revokes the standard of identity for yellow tomato juice (21 CFR 156.147).

A proposal to adopt, insofar as practicable, the Recommended International Standard for Processed Tomato Concentrates (CAC/RS 57-1972) (Codex concentrate standard), the Recommended International Standard for Tomato Juice Preserved Exclusively By Physical Means (CAC/RS 49-1971) (Codex juice standard), and a petition by the Campbell Soup Co., Camden, NJ, was published in the Federal Register of May 9, 1978 (43 FR 19864). ABCO Laboratories, Concord, CA, has also petitioned for honey as a sweetening ingredient of catsup.

Fourteen letters, each containing one or more comments, were received in response to the proposal from food processors, industry associations, a food-processing equipment specialist, and a Federal agency.

One of the comments was from a grape processor association in anticipation that some action would issue with regard to grape juice standards developed by the Codex Alimentarius Commission.

FDA has published advanced notices of proposed rulemaking in the Federal Register of February 23, 1979 (44 FR 10729, 10730, and 10732). The notices

offered interested persons an opportunity to review the Codex Recommended International Standard for Grape Juice Preserved Exclusively By Physical Means, the Recommended International Standard for Concentrated Grape Juice Preserved Exclusively by Physical Means, and the Recommended International Standard for Sweetened Concentrated Labrusca Type Grape Juice Preserved Exclusively by Physical Means, and to comment on the desirability and need for U.S. standards for these foods. FDA concluded in the Federal Register of October 26, 1979 (44 FR 61605 and 61606) that, based on the comments received, there was insufficient support to warrant proposing U.S. standards at that time for these foods. These actions were without prejudice to further consideration of the development of U.S. standards for these foods, upon appropriate justification, at a later date.

The comments received in response to the May 9, 1978 proposal and FDA's responses are discussed below.

Definitions

1. Two comments pointed out that the proposed § 155.3 (21 CFR 155.3), "Definitions and procedures," does not correspond to the § 155.3, "Definitions," proposed in the Federal Register of June 7, 1977 (42 FR 29014), in conjunction with the proposed amendment of the U.S. standards for canned peas.

Section 155.3, "Definitions," was proposed initially, in conjunction with the proposed amendment of the standards for canned peas and canned dry peas, to provide for all canned vegetables a single location for the procedures for determining drained weight (§ 155.3(a)), for compliance (§ 155.3(b)), and for sampling and acceptance (§ 155.3(c)). A final regulation ruling on that proposal and establishing a definition section in § 155.3 was published in the Federal Register of June 27, 1980 (45 FR 43394). FDA recognizes that the definition section designations proposed in conjunction with the tomato products document do not correspond to those proposed in conjunction with the June 27, 1980 canned pea document and concludes that the proposed definition redesignations are unnecessary. Accordingly, the final rule set forth below only amends § 155.3 by defining in new paragraphs (d), (e), and (f) "strength and redness of color," "tomato soluble solids," and "salt," respectively, as applicable to the standards for tomato concentrates and catsup.

Strength and Redness of Color

2. Four comments recommended the alternate use of electronic color meters for the determination of color of tomato products (tomato concentrates and tomato juice) because it is quicker, widely accepted, and not as susceptible to variation as the subjective comparison system.

FDA agrees and, therefore, is providing for the alternate use of electronic color meters to determine the color of tomato concentrates in § 155.3(d) and tomato juice in § 156.3(a) as set forth below.

Footcandle Intensity

3. One comment stated that use of the term "footcandle intensity" is technically incorrect. Footcandle, the comment noted, is a measure of the illumination or light being received by an area or object. Intensity relates to the level of light emanating from the source or, more precisely, "candela." The use of these terms which, by definition, measure light in different ways, is inconsistent, and clarification is requested. A second comment suggested that the use of the word "candela" be added parenthetically following the word "footcandle."

FDA agrees with the first comment, but not the second. A footcandle is defined as the illumination on a surface 1 foot distance from a source of 1 candela equal to 1 lumen per square foot. By definition, therefore, at a distance of 1 foot, the numerical value of the "footcandle" is equal to the value of the "candela." Therefore, FDA is replacing in § 155.3(d) the phrase "250 footcandle intensity" with "approximately 2691 lux (250 footcandles)" and is also inserting this phrase in § 156.3(a) as set forth below.

Previously FDA has noted certain differences in the composition and format of the Codex standard and the U.S. standards. (See 39 FR 14971; 39 FR 18660.) The agency recognizes that the International (Metric) System is commonly used throughout most of the world, and in the United States for technical purposes, and that it may eventually be adopted by the United States for common usage. Therefore, the agency is listing the International (Metric) System with the equivalent units of the customary U.S. system shown parenthetically, in all food standards of identity.

Sampling and Acceptance Procedure

4. One comment asked whether a "quality defective," a "fill of container defective," and a "solids defective" will be regarded as a cumulative defective (a

total of three) or under separate sampling plans.

Each category in question is separate and the "defectives" are not cumulative. Each category is subject to the sampling plans set forth in §§ 155.3(c)(2) and 156.3(e)(2) (21 CFR 155.3(c)(2) and 156.3(e)(2)).

*Tomato Concentrates**Scope of Standard*

5. One comment addressing proposed § 155.191 suggested clarifying the scope of the standard by adding the following sentence before paragraph (a), "Identity"—"This standard for Tomato Concentrates does not include the products commonly known as tomato sauce, chili sauce, and ketchup, or similar products which are highly seasoned products of varying concentrations containing characterizing ingredients, such as pepper, onions, vinegar, sugar, etc., in quantities that materially alter the flavor, aroma, and taste of the tomato component."

The suggested statement is unnecessary. The cited ingredients, e.g., pepper, onions, etc., are not provided for in paragraph (a)(2), and therefore cannot be used. Likewise, the product names referred to are not provided for in paragraph (a)(3) and therefore cannot be used. Therefore, no change is made in the final regulation as set forth below.

Tomato Residue

6. Three comments requested that references to the use of the liquid from tomato residue as an optional tomato ingredient be deleted from the proposed standards for tomato concentrates and catsup. One comment stated that under current industry practices, most comminuted tomatoes in the United States are produced from coreless tomatoes, and peeling procedures and techniques have practically eliminated the type of food historically designated as "residual material from canning."

Commensurate with modern-day production techniques, economics, and consumer acceptance, provision for the use of such "residual" materials simply prolongs the use of a concept which has long since served its intended purpose.

FDA agrees that technological advances in the growing of tomatoes and the production of tomato products largely have eliminated the use of residual liquids in the tomato industry. However, FDA has no basis to conclude that there are not any packers that still use either one or the other residual optional tomato liquids. In view of this, and the fact that the ingredients in question are not mandatory, the provisions for the use and label

declaration of the two optional residual liquids are retained in the final regulations for tomato concentrates and catsup as set forth below.

Acid-Break

7. Two comments recommended that the words "prior to straining" under §§ 155.191(a)(1) and 155.194(a)(1) (21 CFR 155.191(a)(1) and 155.194(a)(1)) be deleted so that the sentences read, "Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2 ± 0.2 ." The comments indicated that the change in wording is needed to reflect the fact that the restoration of the pH to 4.2 ± 0.2 may occur either before or after straining.

FDA agrees, and §§ 155.191(a)(1) and 155.194(a)(1) are changed as set forth below.

Crushed Tomato Concentrate

8. Four comments recommended permitting a concentrate obtained by crushing whole or pieces of tomatoes. One comment suggested that this would greatly increase the efficiencies to tomato product processing by permitting the manufacture of tomato products when fresh tomatoes for processing are not available. One comment proposed a standard for crushed tomato concentrates that included crushed tomato puree and crushed tomato paste. The comments indicated that such concentrates are now being sold in the marketplace for direct consumption by consumers and by industry for remanufacturing purposes. Three comments recommended that crushed tomato concentrate be provided for as an optional tomato ingredient in § 155.191(a)(1).

Historically, the tomato concentrates to which the standard applies are screened to remove peel and seeds. This final rule established a standard of quality for these tomato products and requires that substandard quality be declared on the label when the foods contain excessive pieces of peel and seeds. Consequently, in the interest of honesty and fair dealing § 155.191(a) has not been changed to provide for the crushed tomato products. The comments go beyond the scope of this standard and this proceeding and, in effect, seek to establish a new standard. Any interested person who believes that it will promote honesty and fair dealing in the interest of consumers to establish a standard for tomato products from which peel and seeds have not been removed is invited to submit a petition, as prescribed in 21 CFR 10.30, supported

by adequate data that demonstrates such a need.

Preservation Method

9. Three comments favored expanding the method of preservation for tomato concentrates, catsup, and tomato juice to include procedures other than heat sterilization. One comment indicated that, in some instances, it may be advantageous to freeze tomato concentrates for remanufacturing purposes. Several comments recommended that the provision in the Codex standards for preservation of the foods by physical means be adopted in the proposed standards.

FDA agrees and the appropriate changes are made in paragraph (a)(1) of §§ 155.191, 155.194, and 156.145, as set forth below, to provide for refrigeration and freezing as additional methods of preservation.

Lemon Juice

10. Two comments opposed the use of lemon juice and concentrated lemon juice as optional ingredients in tomato concentrates. One comment said the basic identity of tomato puree and tomato paste could be materially changed by the flavor impact of lemon juice. Another objected because the acidulants (lemon juice, concentrated lemon juice, and organic acids) used in concentrates may have an effect on the quality of catsup.

The proposed use of lemon juice, concentrated lemon juice, and organic acids was as pH regulators and not as flavoring ingredients. If, however, acidulants are used in such quantity that the identity of the concentrate is changed to the extent of adding a new flavor to the tomato concentrate, the acidulants must be declared on the principal display panel in the manner prescribed by § 101.22 (21 CFR 101.22). The standard of identity for catsup, as set forth below, does not provide for the use of lemon juice, concentrated lemon juice, or organic acids, and manufacturers who use concentrates should specify that these ingredients may not be used in the concentrate to be used in the manufacture of catsup. Therefore, the proposed provision for the optional use of lemon juice, concentrated lemon juice, and organic acids is retained in the final regulation as set forth below.

Sodium Hydrogen Carbonate

11. Three comments recommended that the provision for the optional ingredient "sodium hydrogen carbonate" be changed to "sodium bicarbonate" because consumers unfamiliar with the

term may become confused even though it is more scientifically correct.

FDA agrees, and the requested change is made in § 155.191(a)(2)(i)(c) below.

Puree From Paste and Water

12. One comment requested clarification whether tomato paste may be diluted with water to the tomato puree solids range and whether the resultant product may be marketed as puree.

The purpose of the proposed provision in § 155.191(a)(1) for the addition of water to adjust composition was to allow both tomato puree and concentrated tomato juice to be prepared from tomato paste and water. However, for clarification, FDA is listing water as an optional ingredient in § 155.191(a)(2)(i)(d) below.

Flavorings and Vegetable Ingredients in Tomato Puree

13. Two comments recommended that optional ingredients, such as flavorings and vegetable ingredients, be provided for in the tomato puree standard. One of the comments asserted that the consumer would be adequately informed because the use of optional ingredients which characterize the product must be declared as specified in § 101.22.

FDA is not providing for the requested optional ingredients in tomato puree. To do so would change the basic identity of the food. Tomato puree has historically been marketed and recognized by consumers as a food which does not contain such characterizing ingredients. The comments disregard the fact that tomato concentrates in which such characterizing ingredients are used have separate identities and have long been known under names like tomato sauce, chili sauce, etc., and are outside the scope of this standard. Therefore, FDA concludes that the use of flavorings and vegetable ingredients in tomato puree is inappropriate and the requested change is not made in the final regulation as set forth below.

Vegetable Ingredients in Tomato Paste

14. Two comments opposing the addition of vegetable ingredients to tomato paste suggested that use of such ingredients would radically change the basic identity of tomato paste. One comment stated that, with few exceptions, the myriad nonstandardized tomato condiments, barbeque sauces, taco sauces, etc., can be created, in concentrated form, through the addition of the proposed optional ingredients in tomato concentrates.

FDA agrees that the addition of vegetable ingredients may affect the

basic identity of tomato paste. The Codex concentrate standard, 3.1, provides for vegetable ingredients, such as basil leaves and onions, as seasonings and flavorings. However, the standard further states, in 1. "Scope," that the standard does not include " * * the products commonly known as tomato sauce, chili sauce, and ketchup, or similar products which are highly seasoned products of varying concentrations containing characterizing ingredients, such as pepper, onions, vinegar, sugar, etc., in quantities that materially alter the flavour, aroma, and taste of the tomato component." FDA concludes that the Codex concentrate standard should not be interpreted as permitting the uses of fresh or processed vegetable ingredients as was provided for in § 155.191(a)(2)(i)(c) of the proposed regulation. Accordingly, FDA is not providing for such use in the final regulation as set forth below. FDA advises, however, that § 155.191(a)(2)(ii), as set forth below, does provide for the use of spices and flavorings and that these terms are defined in § 101.22(a) (2) and (3).

Labeling

15. Two comments opposed requiring the statement "for remanufacturing purposes only" on the container whenever processors use the name "tomato concentrate" in lieu of the names tomato puree, tomato pulp, or tomato paste. They stated that as long as the phrase "for remanufacturing purposes only" is declared, either on the purchase order, bill of lading, invoice, etc., or on the container, there is no reason to require and restrict such declaration to "on the container."

FDA has reconsidered the conditions under which the phrase "for remanufacturing purposes only" should appear on containers labeled "tomato concentrate" and agrees that, in the case of large containers not normally offered for sale to consumers, such a label declaration is unnecessary since the product is clearly intended for remanufacturing purposes. FDA recognizes that "tomato concentrate" is not a name familiar to consumers and concludes that such a statement is necessary on the labels of smaller containers to preclude the possible diversion of products labeled "tomato concentrate" into retail sales. Therefore, FDA is revising § 155.191(a)(3)(i)(c) to require such a statement only on the labels of No. 10 or smaller containers.

Natural Tomato Soluble Solids

16. One comment suggested that the term "natural tomato soluble solids"

(N.T.S.S.) be used in place of the proposed term "tomato soluble solids."

FDA concludes that the addition of the word "natural" serves no useful purpose because there are no tomato soluble solids in tomatoes other than those which occur naturally. Therefore, no changes are made in the final regulation set forth below.

Concentrated Tomato Juice—Label Declaration for Dilution of Concentrate

17. One comment opposed the requirement that concentrated tomato juice be of such concentration that when diluted according to label directions the diluted product will contain not less than 5.5 percent tomato soluble solids. The consumer, it stated, is familiar with label directions for diluting concentrated foods of a similar nature which utilize uncomplicated volume measures (e.g., three cans of water). Simplified measurements provide for consistency in the diluted or finished food, unlike label directions which require odd volume measurements (e.g., "add 27.5 ounces of water").

FDA believes that the commentor has read too much into the proposed requirement. The proposed requirement would permit manufacturers to produce concentrated tomato juice of such concentration that dilution with multiple volumes of water would produce a diluted product containing not less than 5.5 percent tomato soluble solids. Therefore, it is unnecessary for dilution directions to be expressed in terms of odd volume measures. For purposes of clarity and to be consistent with the definition of concentrated tomato juice in § 155.191(a)(3)(i)(d), FDA is requiring, in § 155.191(a)(3)(iii) of the final regulation as set forth below, a label statement of directions for dilution.

Labeling Declaration of Tomato Residue

18. Two comments opposed the requirement in the standards for tomato concentrates and catsup that the statement "made from" or "made in part from" "residual tomato material from canning" or "residual tomato material from partial extraction of juice," shall be included as part of the name or in close proximity to the name of the food, if liquid from tomato residue is the optional tomato ingredient.

The residual liquid is derived from peelings and cores with or without mature tomatoes or pieces thereof. FDA concludes, that in the interest of honesty and fair dealing, consumers should be advised of this. Accordingly the requirement is retained in the standards. FDA inadvertently omitted the requirement that catsup shall also bear this statement when prepared from

tomato concentrate which in turn was prepared from the residual tomato liquid. This requirement is consistent with the foregoing and its inclusion at this point in this proceeding is logical and nonprejudicial. Accordingly, the labeling provisions in proposed § 155.194(a)(3) (ii) and (iii) have been revised.

Clarification of Requirements

19. Two comments requested clarification of the applicability of § 101.22 to tomato paste. Another comment argued that those who use full ingredient labeling would not need to label separately spice as part of the name of the product.

If flavorings or spices are added to tomato paste in amounts that do not change the basic flavor of the food, FDA interprets section 403(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(g)) as requiring only that they be declared as such in the ingredient statement. See 21 CFR 101.22(a) (2) and (3). However, if any flavoring, including spice oils, oleoresins, or other natural extractives, is added in amounts that characterize the product, that flavoring should be declared, as provided in § 101.22, as part of, or in close proximity to, the name of the food. As stated in the preamble to the proposal, FDA believes that consumers should be alerted to the addition of seasonings or flavorings in quantities which significantly affect the taste of the food. No commentor submitted information on this issue. Therefore, no change is made in the final regulation as set forth below.

Dilution of Sample for Determining Color

20. One comment suggested that for the determination of the strength and redness of color of the concentrate, the sample should be diluted with water to 8.5 percent (± 0.1 percent) tomato soluble solids rather than the proposed 8 to 9 percent tomato soluble solids. It indicated that this more precise figure would reduce the possibility of variability in the results.

The intent behind the proposed requirement was to provide a range for the dilution beginning above the 8.0 percent minimum. FDA agrees that a dilution to ± 0.1 percent is more accurate than a dilution that may vary within 1 percent. Therefore, for the determination of strength and redness of color, the sample should be diluted to 8.1 ± 0.1 percent tomato soluble solids. FDA is revising the provision for dilution of the concentrate in § 155.191(b)(1) (i), (ii), and (2) to 8.1 ± 0.1 percent tomato soluble solids.

Increase in Allowance for Seeds and Peel

21. Two comments recommended that defect allowances for whole seeds be increased from one to eight and that the allowance for peel be increased from 5 millimeters (0.20 inch) to 6.4 millimeters (0.25 inch). These recommendations were made simply because the proposed allowances would not permit the production and marketing of certain crushed tomato concentrates, unless labeled substandard in quality.

Crushed tomato concentrates are not in this final regulation. Therefore, there is no need to increase the tolerances for seeds and peel in the final regulation as set forth below.

Fill of Container

22. The standards of identity for tomato concentrates, catsup, and tomato juice contain provisions for preservation by refrigeration, freezing, and heat sterilization. (See paragraph 9.) FDA has no data, however, which demonstrate that the general method for fill of container, as set out in § 130.12, is applicable to frozen products, nor does it have data with which to establish what minimum fill of container requirement, if any, is needed for frozen tomato products. Therefore, exemptions for frozen tomato products have been established in §§ 155.191(c), 155.194(c), and 156.145(c) as set forth below.

Catsup

Tomato Concentrate as Ingredient

23. One processor, addressing proposed § 155.194, questioned whether tomato concentrate, as an optional tomato ingredient in the catsup standard, must meet all the requirements of both the standards of identity and quality for tomato concentrate, § 155.191 (a) and (b).

FDA advises that the tomato concentrate ingredient provided for in § 155.194(a)(1)(i) also must comply with the standard of quality for tomato concentrate. Therefore, § 155.194(a)(1)(i), as set forth below, requires that the tomato concentrate ingredient shall be as defined in § 155.191(a)(1) and shall comply with § 155.191(b).

Other Tomato Ingredients

24. One processor suggested that the list of optional tomato ingredients be expanded to provide that any form of fresh or physically preserved tomatoes can be used in catsup. The commentor reasoned that there is no basis to exclude from the list foods like canned or frozen tomatoes (not concentrated), drum "pizza pulp", bulk storage

concentrated chopped tomatoes, or other wholesome forms of tomatoes which can be preserved for use in off-season production. The processor also requested that the standard provide for mature tomatoes of red or reddish varieties (with or without skins and/or seeds) which have been preserved by physical means in accordance with good manufacturing practice and which may have been concentrated (with or without subsequent dilution). The comment proposed that the standard of identity for tomato concentrates provide for the use of any optional ingredients permitted in catsup.

The tomato concentrates standard permits food to be preserved by freezing and refrigeration as well as heat sterilization. Section 155.194(a)(1)(i) provides for the use of tomato concentrates in catsup. Therefore, the use of frozen or refrigerated tomato concentrate as well as the heat-sterilized tomato concentrate is permitted in catsup. FDA does not object to the suggested provision for other wholesome forms of tomatoes, but believes that such ingredients need to be defined more clearly so that all interested persons will know what is meant by, for example, drum "pizza pulp". Consequently, no additional optional tomato ingredients are included in § 155.194(a)(1). Interested persons may submit a petition proposing the use of additional forms of tomato ingredient in catsup. However, the petition should clearly identify the forms to be used and demonstrate how the proposed use will promote honesty and fair dealing in the interest of consumers. With regard to the comment that the standard for tomato concentrates should allow any optional ingredient permitted in catsup, FDA points out that tomato concentrate may be used in foods in which the ingredients used in catsup would be inappropriate. Therefore, FDA is not providing, in the standard of identity for tomato concentrates, for all optional ingredients that are provided for in the standard of identity for catsup.

Water

25. One comment suggested that the sentence "Water may be added to adjust the final composition" be added to § 155.194(a) to be consistent with § 155.191(a)(1) of the tomato concentrate standard. Another comment recommended that the sentence "The liquid is then concentrated" be deleted from the paragraph.

FDA agrees with both comments. Section § 155.194(a)(1), as set forth below, provides for the use of water to adjust the final composition. The

proposed sentence "The liquid is then concentrated" is deleted.

Minimum Soluble Solids Requirement

26. Five comments concerned the 25-percent minimum soluble solids requirement proposed for catsup. Three comments did not object to a minimum requirement, but suggested that the figure be decreased to 24 percent soluble solids to be equivalent to the USDA requirement of 25 percent total solids. Two comments opposed the proposed requirement and asserted that adoption of the 25-percent minimum requirement for soluble solids would eliminate the marketing of USDA "substandard" grade products that are made for special purposes, such as emergency uses and special orders.

FDA has reconsidered the proposed requirement. In proposing it the agency did not focus on the fact that the term soluble solids for catsup includes soluble tomato solids and added sweetener. FDA believes that a soluble solids requirement would therefore be of little benefit in promoting honesty and fair dealing in the interest of consumers. Furthermore FDA has no basis for concluding that catsup presently manufactured at less than 25 percent total soluble solids and sold as a USDA substandard grade product is not, in fact, catsup. Therefore, FDA is not providing for a minimum soluble solids requirement in the standard of identity for catsup.

Vinegar

27. Two comments favored retention of the provision for the use of vinegar in catsup, but opposed permitting the use of lemon juice, concentrated lemon juice, and organic acids. One comment favored expanding the use of acidulants. One comment stated that the use of vinegar as the sole acidulant in catsup has been effective in providing two important contributions to the food, namely flavor and safety. As a preservative, vinegar's presence, in concert with the normal acidity of tomatoes, salt, and added sweeteners, has provided microbiological stability for the product in the container both before and after opening. The comment argued that the stability and preserving qualities of other acidulants used in concert with ingredients in catsup formulations is not known, and, if spoilage were to occur through use of alternatives, the image of all catsup products would be adversely affected. Both comments asserted that the use of acidulants other than vinegar would change the basic characteristics of catsup because the fermentation of vinegar produces certain natural flavors

which appear to enhance the flavor of catsup. One of the comments believed that to effect a change employing the "safe and suitable" concept, at the same time the concept is being questioned by the agency which employs it, would seem precipitous at the very least.

Although FDA is not convinced that acidulants other than vinegar could not be used in catsup, it agrees that their stability and preserving qualities, when used in concert with ingredients in catsup formulations, have not been established. Therefore, lemon juice, concentrated lemon juice, and organic acids are not provided for in the standard of identity for catsup as set forth below. FDA's policy regarding the use of "safe and suitable" ingredients is discussed below.

Sweeteners

28. Two processors favored "broadening" the use of sweeteners in catsup, and one suggested that the reference to the sweetener in § 155.194(a)(2)(ii) be made plural. Another processor favored the proposed provision because it would allow for the manufacture of "honey catsup." One processor opposed the expansion of sweetener usage beyond the options available in the current standard. The company expressed the concern that, in the absence of a definition for nutritive carbohydrate sweeteners, the provision could open the door for the use of pseudo-sweetener ingredients that could affect the quality of catsup products. It requested clarification whether ingredients such as honey, low dextrose equivalent corn syrup, maltodextrins, or even extracts of vegetables or fruits with a sugar fraction, can be classified as nutritive carbohydrate sweeteners. It was asserted that the present list of permitted sweeteners should not be broadened without a complete evaluation of the quality impact of the use of additional sweeteners. ABCO Laboratories, Concord, CA, had also petitioned for honey as a sweetening ingredient of catsup, stating that honey as a sweetener has history in antiquity and is generally recognized as safe for its intended use.

The May 9, 1978, proposal provided for the use of safe and suitable nutritive carbohydrate sweeteners. Subsequent to the proposal, FDA, the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announced their tentative positions on a variety of food related issues in the Federal Register of December 21, 1979 (44 FR 75990). A tentative revision in FDA's current

policy with regard to safe and suitable ingredients in standardized foods was considered.

Upon review and evaluation of the comments received in response to the December 21, 1979, tentative position, however, FDA has determined that, at this time, it would be in the best interest of consumers and the regulated industry to retain its established policy for use of safe and suitable optional ingredients in standardized foods. In the *Federal Register* of January 21, 1983 (48 FR 2836), FDA announced this decision.

FDA does not agree with the comment that the proposed class of safe and suitable nutritive carbohydrate sweeteners, which includes honey, should be broadened. It is not aware of any sweetener, presently regarded as suitable for use in catsup, which would be excluded from such use by restricting the class of sweeteners to safe and suitable nutritive carbohydrate sweeteners. Furthermore, it was not FDA's intention, as one commentor inferred, to limit the sweetener to any one nutritive carbohydrate sweetener. Accordingly, § 155.194(a)(2) has been revised to identify that any one or combination of two or more of the safe and suitable ingredients, which includes nutritive carbohydrate sweeteners, may be used.

A nutritive carbohydrate sweetener that affects the basic characteristic of the food, whether by degrading its taste, smell, appearance, or nutritional characteristic, would not be an appropriate ingredient. Maltodextrins and low dextrose equivalent corn syrup are not generally considered sufficiently sweet to be considered suitable as nutritive carbohydrate sweeteners and therefore are not permitted in catsup. Extracts of vegetables or fruits with an enriched sugar fraction have not been demonstrated to be suitable for use in catsup.

Filtrate vs. Serum

29. One comment recommended that the words "of the filtrate" used in the definition of "Soluble solids" in the proposed § 155.194(a)(3) be replaced by the words "of the clear serum" to clarify that the portion of the product to be examined by refractometers may be obtained by methods other than filtering (e.g., centrifugation).

The proposed minimum total soluble solids requirement is not provided for in the final regulation as set forth below. Therefore, there is no need for the proposed definition.

Labeling—Honey

30. One comment wanted affirmation that catsup made with honey as the only

sweetening ingredient could be labeled "honey catsup" or "catsup."

No data were submitted to demonstrate that honey, when used as a sweetener in catsup, imparts a taste, flavor, or other characteristic to the finished food in addition to sweetness. Therefore, the name of the food which contains honey as a sweetener and complies with the requirements of § 155.194 is "catsup." In any event, "honey catsup" is not an appropriate name for a product in which the principal characterizing ingredient is tomatoes.

Optional Ingredients

31. One processor recommended that a phrase such as "sugar and/or high quality corn derived syrups" be used on the label in lieu of declaring sugars by their common or usual names in order of predominance. It stated that requiring the declaration of the name of each sugar creates problems in regard to label costs and inventory control of labels, without providing any benefit to consumers. Another processor indicated that the requirement that each optional ingredient used be declared on the label by its common or usual name should not apply to catsup. The company stated that two sets of labels will have to be maintained: one set that declares "tomatoes" for catsup produced during the season and another set that declares "tomato concentrate" for catsup produced during the off-season from tomato concentrate. It asserted that a label declaration of "red ripe tomatoes" should more than suffice in both cases.

FDA recognizes that the requirement to declare ingredients on the label of foods by their common or usual name sometimes creates problems for processors. Testimony from consumers on the labeling of ingredients used in foods was presented at the public hearings referred to in the discussion of sweeteners which appears earlier in this preamble. The desire most frequently expressed by consumers was for complete ingredient declaration on the labels of all foods. FDA's policy, as set forth in § 101.6 (21 CFR 101.6), is to amend the definitions and standards of identity for foods, in accordance with section 401 of the act (21 U.S.C. 341), to require label declaration of all optional ingredients (with the exception, in the case of catsup, of optional spices and flavorings which may continue to be designated as such without specific ingredient declaration). Therefore, no change is made in the final regulation as set forth below.

Determination of Consistency

32. One comment recommended that the sentence in proposed § 155.194(b)(1), "Always remix sample before transferring to instrument" be deleted from the proposed procedure for determining consistency. It stated that, unlike tomato concentrate, catsup is not diluted prior to testing and that it is imperative that the sample be transferred to the instrument with a minimum of agitation, because remixing disrupts the pectin gel and gives a false reading.

FDA agrees with the recommended change. Further, FDA concludes that, for the reason given above, the instructions to mix without incorporating air bubbles, which appear earlier in § 155.194(b)(1), also should be deleted from the proposed procedures for determining consistency. Therefore, the proposed mixing instructions do not appear in the procedure for determining consistency in § 155.194(b)(1) of the final regulation set forth below.

Ninety Percent Fill of Container Exemption

33. A trade association requested that single-service containers of catsup with a declared net weight or net volume of 2 ounces or less be exempted from the proposed 90-percent fill of container requirement. It stated that single-service portions of catsup are generally packaged in sealed pouches made of flexible films or laminates. The physical nature of these containers makes a determination of their volume or capacity difficult, if not impossible. The association also stated that, while standards of fill are generally thought to be for the protection of consumers, a 90-percent fill of container requirement for single-service portions of catsup would be a real disadvantage to consumers. A single-service container of catsup filled to 90 percent capacity (even in a rigid cup) would likely spill or squirt as the consumer attempted to open the container. To open a flexible film container without spilling or squirting its contents, the container must be filled in such a way that, when held upright, there is air in the space where the consumer will tear open the container. The association stated that the basis for the 2 ounces or less exemption to the 90-percent fill of container requirement is that catsup is currently packaged in single-service containers with a declared net volume of $\frac{1}{2}$ ounce, $\frac{3}{4}$ ounce, and 1 ounce, and that a 2-ounce container is under consideration.

The agency agrees, and § 155.194(c)(1) below exempts from the 90-percent fill

of container declaration, catsup packaged in individual serving size packages containing 56.7 grams (2 ounces) or less.

Tomato Juice

Blending of Tomato Juice and Tomato Juice From Concentrate

34. Two comments, addressing proposed § 156.145, requested that FDA provide for the blending of tomato juice with tomato juice from concentrate so that a more uniform and better quality product can be produced. One of the comments said FDA should establish by regulation a realistic proportion of tomato juice from concentrate that may be blended with tomato juice (directly expressed tomato juice). The comments maintained that the name of the blend should be "tomato juice."

FDA agrees that blending of tomato juice and tomato juice from concentrate should be provided for, and § 156.145(a)(1) below so provides. FDA does not agree that the name "tomato juice" is appropriate for mixtures of tomato juice and tomato juice from concentrate because the unqualified name "tomato juice" does not adequately inform consumers that the food is, in fact, concentrated tomato juice that has been reconstituted with water. Consequently, FDA concludes that there is no need to establish proportions for the blending of tomato juice and tomato juice from concentrate. Therefore, § 156.145(a)(2)(i)(b) requires the name "tomato juice from concentrate" for those finished juices prepared from tomato juice and tomato juice from concentrate.

Minimum Soluble Solids for Tomato Juice From Concentrate

35. Two comments recommended retaining the proposed 5.5 percent soluble solids requirement. Three comments recommended that the minimum soluble solids be established at 4.5 percent. One comment suggested a minimum soluble solids of 4.7 percent. One comment representing 30 fruit and vegetable canning companies in California stated that the State of California produces 68 percent of all the tomato juice canned in the United States. The comment submitted data for the soluble tomato solids for tomato juice produced in California for the years 1971 through 1977. The yearly average varied between 5.5 percent and 6.0 percent; however, in 1975, 57 percent of the tomatoes had a soluble tomato solids below 5.5 percent. Another comment from a producer of tomato juice stated that "Our considerable experience in the tomato juice business

confirms the Commissioner's opinion that very few domestically grown tomatoes would yield a juice with less than 5.5 percent soluble solids." The comment enclosed results of recent testing that they had done on the soluble solids of 12 samples representing 9 brands of tomato juice that they understood to be processed from locally grown tomatoes. The percent soluble solids of the samples purchased in New York State (5) ranged from 4.80 to 7.52 with an average of 6.00. The percent soluble solids of the samples picked up in California (7) ranged from 5.85 to 7.52 with an average of 6.49. Another comment pointed out that tomato juice produced in the Midwest has had a lower soluble solids, slightly higher acidity, and somewhat different flavor than tomato juice produced in California. This comment stated that 3,400 analyses of tomato juice produced over the last 3 years have shown that the larger portion of their product was below 5.5 percent soluble solids. It was their opinion that a 5.5 percent soluble solids requirement would cause severe cost penalties to producers of tomato juice from concentrate in the Midwest. In addition, the comment stated that there could also be serious quality problems because of the unacceptably high acidity. Another comment stated that since 1970 the average soluble solids of tomatoes processed in the Northeast has been 4.7 percent. This comment asserted that a requirement of a 5.5 percent soluble solids minimum would severely limit their ability to compete in the marketplace and this, in turn, would have an adverse effect on the consumer. One comment stated that a 1979 revision in the State of California grade standard that penalizes growers for soft fruit has accelerated the development of a firm-fruited varieties that have a lower soluble solids content. The comment stated that during 1982, analyses by the California Department of Food and Agriculture, which grades all California tomatoes for canning use, show a weighted average tomato soluble solids of 5.0 percent. The comment suggested that the minimum soluble solids for tomato juice from concentrate should be between 4.5 and 5.0 percent.

FDA recognizes that there is a variation in percentage tomato soluble solids in tomatoes from year to year and in different areas of the country. However, regardless of where FDA sets the minimum tomato soluble solids for tomato juice from concentrate, a given quantity of juice from tomatoes having high soluble solids will result in more units of "juice from concentrate" than an equal quantity of juice from tomatoes

having lower soluble solids. FDA recognizes that setting a minimum tomato soluble solids requirement at 5.0 percent will place some packers at an economic advantage. But, this advantage will exist regardless of where the figure is set. Obviously, producers of tomatoes with higher soluble solids will meet any soluble solids requirement by using fewer tomatoes than producers of tomatoes with lower soluble solids. FDA has issued numerous temporary permits to market test tomato juice from concentrate at 5.5 percent soluble solids. However, based on available information, FDA is persuaded that 5.0 percent is a reasonable minimum requirement for tomato juice from concentrate. Consequently, FDA is establishing 5.0 percent as the minimum soluble solids requirement for tomato juice from concentrate in the final regulation set forth below.

Minimum Soluble Solids for Concentrated Tomato Juice

36. Two comments focused on the proposed 20 percent minimum soluble solids requirement for concentrated tomato juice. One suggested that the requirement be lowered to 18 percent to allow processors flexibility. The other comment suggested that the proposed requirement be deleted entirely because it is not easily translated into uncomplicated label directions for dilution to the Codex 4.5 percent soluble solids for reconstituted tomato juice or to the proposed minimum 5.5 percent.

The 20-percent figure for minimum soluble solids was not proposed as a new requirement to coincide exactly with either the 4.5 or 5.5 percent figures, but rather as a helpful indicator that would reflect industry practice. To avoid confusion and misunderstanding, the agency has revised § 155.191(a)(3)(i)(d) to provide that "concentrated tomato juice" should be of such concentration that upon diluting the food according to label directions it will not contain less than 5.0 percent by weight tomato soluble solids. No minimum percent soluble solids for concentrated tomato juice is now specified.

Addition of Concentrate To Adjust Minimum Soluble Solids

37. One comment favored a minimum soluble solids level for "fruit juices" at the same level as that for "juice from concentrate". It suggested that, in view of today's high technology, there can be no justification for establishing different "Brix (soluble solids) levels for the two products or for establishing a minimum level for one product and not for the other. It recognized that when a

minimum "Brix level was established there would be some single strength juice which would fall below that minimum. It suggested that, in order not to discriminate against a processor who cannot divert low "Brix juice to some other use, FDA should permit adjustment of "Brix by the addition of a limited amount of concentrate, without requiring a change in the product name to "juice from concentrate" or some other label declaration. In the minds of many consumers, the comment continued, the name "from concentrate" connotes an inferior product. The comment noted, however, the addition of minimal amounts of concentrate simply insures that the consumer receives a high quality, uniform product. The comment also stated there is no reason to discriminate against a product that has been adjusted with minimal amounts of concentrate because the addition of concentrate will in no way adversely affect the flavor or quality of the juice.

As stated in the responses to the previous comments, FDA did not propose and is not establishing a minimum soluble solids requirement for tomato juice. FDA agrees that it may be in the interest of consumers to permit the addition of some quantity of concentrated juice in an amount reasonably necessary to adjust the soluble solids content of "tomato juice." However, since public comment has not been received on this issue, it is inappropriate at this stage of the rulemaking proceeding to provide for the addition of tomato concentrate to adjust the soluble solids of tomato juice without labeling the food "tomato juice from concentrate." Interested persons are invited to submit a petition, including support by adequate data, which demonstrates the need for such a provision in the standards. The petition should also demonstrate what limitation should be placed on the quantity of concentrated tomato juice which may be added to adjust the soluble solids of tomato juice and what type of labeling would be appropriate to inform the consumer of such addition.

Declaration of Water

38. Two comments requested that the declaration of water not be required when it is used to reconstitute concentrated tomato juice to single-strength juice. One comment maintained that the declaration of water and concentrated tomato juice is superfluous because it is of the opinion that consumers recognize that "juice from concentrate" is made by the addition of water and/or concentrated juice. The comment also stated that water and

concentrated tomato juice should not be required in the ingredient listing because they are mandatory ingredients. The second comment stated that the separate listing of "water" should be reserved for diluted juice beverages.

Juice from concentrate is prepared from water and concentrated juice. Concentrated tomato juice can be diluted either by the addition of water or tomato juice. As discussed previously in regard to the use of sweeteners and optional ingredients in catsup, many consumers want full ingredient labeling. Therefore, FDA is providing, in § 156.145(a)(1) below, for water and tomato juice as optional ingredients and requiring in § 156.145(a)(2)(ii) that each of the optional ingredients used shall be declared in the ingredient statement according to Part 101.

Quality Defects

39. Two comments stated that the language proposed in § 156.145(b)(1)(ii) does not reflect current industry practice. One of the comments suggested that the paragraph be replaced by the following: "There are not more than two of the following defects present for peel and blemishes, either singly or in combination, and no more than 3 defects for seeds or pieces of seeds 3.2 millimeters (0.125 inch) or more in length per 500 milliliters (16.9 fluid ounces) of juice."

FDA has reevaluated the quality requirements for tomato juice and agrees with this comment. FDA concludes that it is reasonable to require that there be not more than two defects for peel and blemishes, either singly or in combination, in addition to three defects for seeds or pieces of seeds 3.2 millimeters (0.125 inch) or more in length per 500 milliliters (16.9 fluid ounces) and has amended § 156.145(b)(1)(ii) accordingly.

Sample Size

40. One comment suggested that the 500-milliliter sample proposed for use in determining the number and size of defects in tomato juice be divided into two 250-milliliter aliquots. The suggestion was made in the interest of accuracy.

FDA agrees. An aliquot of 250 milliliters in each of two grading trays would provide for greater accuracy in the examination for quality defects rather than having all of the sample in a single grading tray. The proposed procedure is also being revised to delete the statement that the trays should be slightly inclined. The method in § 156.145(b)(2)(ii) below reflects these changes.

Defect Levels

41. One processor recommended that more allowance be made for mold in the defect action levels for homogenized tomato juice. The comment indicated that in the process of reducing the particulate matter to a uniform size in tomato juice the mold filaments are also pulverized, thereby seemingly increasing their number. In light of this occurrence, it recommended a 21 percent mold count before homogenization and 42 percent after homogenization.

Defect action levels (DAL's) are not a part of food standards, but are provided for in § 110.99 (21 CFR 110.99). DAL's for mold or other natural or unavoidable defects in food for human use which present no health hazard are listed in an FDA publication entitled "The Food Defect Action Levels", which is available from FDA, Industry Programs Branch, Bureau of Foods (HFF-326), 200 C St. SW., Washington, DC 20204. FDA has established a microscopic mold count average of 21 percent as the defect action level for tomato juice. It recognizes that tomato juice passed through particle size reducing equipment, including homogenizers, has a higher microscopic mold count. Although FDA is not listing homogenized tomato juice separately from other types of tomato juice, in deciding whether a product meets an applicable DAL, FDA makes allowances, based upon a particular plant's processes, for tomato products that are homogenized.

Tomato Juice as an Ingredient of Tomato Juice From Concentrate

42. FDA believes that it is in the public interest to provide for the optional use of water and/or tomato juice in the preparation of tomato juice from concentrate. A provision for the use of tomato juice, in addition to water, for reconstituting concentrated tomato juice was inadvertently omitted from the proposal. The agency believes that to invite comment on this revision is impractical and contrary to the public interest and sees no prejudice resulting to interested persons. Therefore, § 156.145(a)(1)(i) is amended accordingly.

Definitions

43. Definitions applicable to tomato juice were inadvertently cross-referenced to § 155.3, the definitions for the canned vegetable standards. This has been corrected in the final regulation below by establishing, and appropriately referencing in § 156.145, a new § 156.3 in Part 156—Vegetable Juices, containing the procedures for

determining strength and redness of color, tomato soluble solids, salt, compliance of a lot, and sampling and acceptance that were proposed for canned vegetables (43 FR 19864; May 9, 1978).

Effective Date

44. Two comments requested that the proposed effective date be July 1, 1981, to provide processors with adequate time for any changes which may be required by a final regulation.

FDA is changing the effective date of the final regulation to the new uniform effective date of July 1, 1985.

Certain editorial changes, including insertion of a provision that the name "tomato concentrate" may be used in lieu of the name "tomato puree", "tomato pulp", or "tomato paste" in the ingredient statement for catsup, are made in the final regulation set forth below for the purpose of clarification. The proposed standard of quality for tomato concentrate incorrectly considered "pieces of seed" (seed particles) a defect when 3.2 millimeters (0.125 inch) or greater in length and provided that not more than four blemishes in the combined total of 36 defects allowed for pieces of peel, pieces of seeds (seed particles), and blemishes may exceed 1.6 millimeters (0.063 inch) in length. Based on USDA administrative guidelines for grading canned tomato paste and tomato puree, § 155.191(b)(1)(iii) (b) and (c) as set forth below considers "pieces of seed (seed particles)" a defect when 1 millimeter (0.039 inch) or greater in length, and considers blemishes, dark brown or black particles (specks), a defect when not more than four exceed 1.6 millimeters (0.0625 inch) in length of which not more than one exceeds 3.2 millimeters (0.125 inch) and none exceed 6.4 millimeters (0.25 inch).

In consideration of the comments received and other relevant information, FDA concludes that it will promote honesty and fair dealing in the interest of consumers and that it will facilitate international trade to amend the definition section for canned vegetables, to establish a definition section for vegetable juices and to amend the standards of identity, and to establish standards of quality and fill of container for tomato concentrates, catsup, and tomato juice as set forth below.

List of Subjects

21 CFR Part 155

Canned vegetables; Food standards; Incorporation by reference; Vegetables.

21 CFR Part 156

Food standards; Incorporation by reference; Vegetable juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 155 and 156 are amended as follows:

PART 155—CANNED VEGETABLES

1. In Part 155:

a. By adding new paragraphs (d), (e), and (f) to § 155.3 to read as follows:

§ 155.3 Definitions.

(d) "Strength and redness of color" means at least as much red as is obtained by comparison of the prepared product, with the blended color produced by spinning a combination of the following concentric Munsell color discs of equal diameter, or the color equivalent of such discs:

Disc 1—Red (5R 2.6/13) (glossy finish)

Disc 2—Yellow (2.5 YR 5/12) (glossy finish)

Disc 3—Black (N1) (glossy finish)

Disc 4—Grey (N4) (mat finish)

Such comparison is to be made in full diffused daylight or under a diffused light source of approximately 2691 lux (250 footcandles) and having a spectral quality approximating that of daylight under a moderately overcast sky, with a correlated color temperature of 7,500 degrees Kelvin \pm 200 degrees. With the light source directly over the disc and product, observation is made at an angle of 45 degrees from a distance of about 24 inches from the product. Electronic color meters may be used as an alternate means of determining the color of tomato concentrates. Such meters shall be calibrated to indicate that the color of the product is as red or more red than that produced by spinning the Munsell color discs in the combination as set out above.

(e) "Tomato soluble solids" means the sucrose value as determined by the method prescribed in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, sections 32.014 to 32.016 and 52.012, under the headings "Soluble Solids in Tomato Products Official Final Action" and "Refractive Indices (n) of Sucrose Solutions at 20°," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or are available

for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. If no salt has been added, the sucrose value obtained from the referenced tables shall be considered the percent of tomato soluble solids. If salt has been added either intentionally or through the application of the acidified break, determine the percent of such added sodium chloride as specified in paragraph (f) of this section. Subtract the percentage so found from the percentage of total soluble solids found (sucrose value from the refractive index tables) and multiply the difference by 1.016. The resultant value is considered the percent of "tomato soluble solids."

(f) "Salt" means sodium chloride, determined as chloride and calculated as percent sodium chloride, by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, sections 32.025 to 32.030, under the heading "Method III (Potentiometric Method)," which is incorporated by reference.

b. By revising § 155.191 to read as follows:

§ 155.191 Tomato concentrates.

(a) *Identity*—(1) *Definition*. Tomato concentrates are the class of foods each of which is prepared by concentrating one or any combination of two or more of the following optional tomato ingredients:

(i) The liquid obtained from mature tomatoes of the red or reddish varieties (*Lycopersicon esculentum* P. Mill).

(ii) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(iii) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining the tomatoes, with or without heating, as to exclude skins (peel), seeds, and other coarse or hard substances in accordance with good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than 2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2 ± 0.2 . Water may be added to adjust the final composition. The food contains not less than 8.0 percent tomato soluble solids as defined in § 155.3(e). The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at

ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Optional ingredients.* One or any combination of two or more of the following safe and suitable ingredients may be used in the foods:

(i) In all tomato concentrates:

(a) Salt (sodium chloride formed during acid neutralization shall be considered added salt).

(b) Lemon juice, concentrated lemon juice, or organic acids.

(c) Sodium bicarbonate.

(d) Water, as provided for in paragraph (a)(1) of this section.

(ii) In tomato paste:

(a) Spices.

(b) Flavoring.

(3) *Labeling.* (i) The name of the food is:

(a) "Tomato puree" or "tomato pulp" if the food contains not less than 8.0 percent but less than 24.0 percent tomato soluble solids.

(b) "Tomato paste" if the food contains not less than 24.0 percent tomato soluble solids.

(c) The name "tomato concentrate" may be used in lieu of the names "tomato puree," "tomato pulp," or "tomato paste" whenever the concentrate complies with the requirements of such foods and the statement "for remanufacturing purposes only" is declared on No. 10 containers (3.1 kilograms or 109 avoirdupois ounces total water capacity) or containers that are smaller in size.

(d) "Concentrated tomato juice" if the food is prepared from the optional tomato ingredient described in paragraph (a)(1)(i) of this section and is of such concentration that upon diluting the food according to label directions as set forth in paragraph (a)(3)(iii) of this section, the diluted article will contain not less than 5.0 percent by weight tomato soluble solids.

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(a) The statement "Made from" or "Made in part from," as the case may be, "residual tomato material from canning" if the optional tomato ingredient specified in paragraph (a)(1)(ii) of this section is present.

(b) The statement "Made from" or "Made in part from," as the case may be, "residual tomato material from partial extraction of juice" if the optional tomato ingredient specified in paragraph (a)(1)(iii) of this section is present.

(c) A declaration of any flavoring, as provided in paragraph (a)(2)(ii) of this section that characterizes the product as

specified in § 101.22 of this chapter and a declaration of any spice that characterizes the product, e.g., "Seasoned with _____," the blank to be filled in with the words "added spice" or, in lieu of the word "spice," the common name of the spice.

(iii) The label of concentrated tomato juice shall bear adequate directions for dilution to result in a diluted article containing not less than 5.0 percent by weight tomato soluble solids.

(iv) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(v) Determine percent tomato soluble solids as specified in § 155.3(e). Determine compliance as specified in § 155.3(b). A lot shall be deemed to be in compliance for tomato soluble solids as follows:

(a) The sample average meets or exceeds the required minimum.

(b) The number of sample units that are more than 1 percent tomato soluble solids below the minimum required does not exceed the acceptance number in the sampling plans set forth in § 155.3(c)(2).

(b) *Quality.* (1) The standard of quality for tomato concentrate (except for concentrated tomato juice, which when diluted to 5.0 percent tomato soluble solids shall conform to the standard of quality for tomato juice set forth in § 156.145 of this chapter) is as follows:

(i) The strength and redness of color of the food, when diluted with water (if necessary) to 8.1 ± 0.1 percent tomato soluble solids is not less than the composite color produced by spinning the Munsell color discs in the following combination:

53 percent of the area of Disc 1;
28 percent of the area of Disc 2; and
19 percent of the area of either Disc 3 or Disc 4; or

9½ percent of the area of Disc 3 and 9½ percent of the area of Disc 4, whichever most nearly matches the appearance of the sample.

(ii) Not more than one whole seed per 600 grams (21 ounces).

(iii) Not more than 36 of the following defects, either singly or in combination, per 100 grams (3.5 ounces) of the product when diluted with water to 8.1 ± 0.1 percent tomato soluble solids:

(a) Pieces of peel 5 millimeters (0.20 inch) or greater in length (without unrolling).

(b) Pieces of seed (seed particles) 1 millimeter (0.039 inch) or greater in length.

(c) Blemishes, such as dark brown or black particles (specks)—not more than

four exceed 1.6 millimeters (0.0625 inch) in length of which not more than one exceeds 3.2 millimeters (0.125 inch) and none exceed 6.4 millimeters (0.25 inch).

(2) *Methodology.* Dilute with water, if necessary, to 8.1 ± 0.1 percent tomato soluble solids.

(i) Determine strength and redness of color as prescribed in § 155.3(d).

(ii) Whole seeds—Weigh out 600 grams (21 ounces) of the well-mixed, diluted concentrate; place a U.S. No. 12 screen (1.68 millimeters (0.066 inch) openings) over the sink drain; transfer the product sample onto the screen; rinse container thoroughly with water and pour through screen; flush sample through screen by using an adequate spray of water; check screen for whole seeds; apply the appropriate allowance.

(iii) Peel, pieces of seed, and blemishes—Spread the prepared concentrate evenly on a large white tray and remove the individual defects, identify, classify, and measure.

(3) *Sampling and acceptance.* Determine compliance as specified in § 155.3(b).

(4) If the quality of the tomato concentrate falls below the standard prescribed in paragraph (b) (1) and (3) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the tomato concentrate falls below the standard in one or more respects, the label may bear the alternative statement, "Below Standard in Quality _____," the blank to be filled in with the words specified after the corresponding paragraph(s) under paragraph (b)(1) of this section which such tomato concentrate fails to meet, as follows:

(i) "Poor color."

(ii) "Excessive seeds."

(iii)(a) "Excessive pieces of peel."

(b) "Excessive pieces of seed."

(c) "Excessive blemishes."

(c) *Fill of container.* (1) The standard of fill of container for tomato concentrate, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity, except when the food is frozen.

(2) Determine compliance as specified in § 155.3(b).

(3) If the tomato concentrate falls below the standard of fill prescribed in paragraph (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill specified

in § 130.14(b) of this chapter, in the manner and form therein prescribed.

§ 155.192 [Removed]

c. By removing § 155.192 *Tomato puree*.

d. By revising § 155.194 to read as follows:

§ 155.194 Catsup.

(a) *Identity*—(1) *Definition*. Catsup, ketchup, or catchup is the food prepared from one or any combination of two or more of the following optional tomato ingredients:

(i) Tomato concentrate as defined in § 155.191(a)(1) and in compliance with § 155.191(b).

(ii) The liquid derived from mature tomatoes of the red or reddish varieties *Lycopersicon esculentum* P. Mill.

(iii) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(iv) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is strained so as to exclude skins, seeds, and other coarse or hard substances in accordance with good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than 2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2 ± 0.2 . The final composition of the food may be adjusted by concentration and/or by the addition of water. The food ingredients may contain salt (sodium chloride formed during acid neutralization shall be considered added salt) and is seasoned with ingredients as specified in paragraph (a)(2) of this section. The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) *Ingredients*. One or any combination of two or more of the following safe and suitable ingredients in each of the following categories is added to the tomato ingredients specified in paragraph (a)(1) of this section:

(i) Vinegars.

(ii) Nutritive carbohydrate sweeteners. Such sweeteners if defined in Part 168 of this chapter shall be as defined therein.

(iii) Spices, flavoring, onions, or garlic.

(3) *Labeling*. (i) The name of the food is "Catsup," "Ketchup," or "Catchup."

(ii) The following shall be included as part of the name or in close proximity to the name of the food:

(a) The statement "Made from" or "Made in part from," as the case may be, "residual tomato material from canning" if the optional tomato ingredient specified in paragraph (a)(1)(iii) of this section or tomato concentrate containing the ingredient specified in § 155.191(a)(1)(ii) is present.

(b) The statement "Made from" or "Made in part from," as the case may be, "residual tomato material from partial extraction of juice" if the optional tomato ingredient specified in paragraph (a)(1)(iv) of this section or tomato concentrate containing the ingredient specified in § 155.191(a)(1)(iii) is present.

(iii) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter except that the name "tomato concentrate" may be used in lieu of the names "tomato puree," "tomato pulp," or "tomato paste" and when tomato concentrates are used, the labeling requirements of § 155.191(a)(3)(ii) (a) and (b) do not apply.

(b) *Quality*. (1) The standard of quality for catsup is as follows: The consistency of the finished food is such that its flow is not more than 14 centimeters in 30 seconds at 20°C when tested in a Bostwick Consistometer in the following manner: Check temperature of mixture and adjust to $20 \pm 1^\circ\text{C}$. The trough must also be at a temperature close to 20°C . Adjust end-to-end level of Bostwick Consistometer by means of the spirit level placed in trough of instrument. Side-to-side level may be adjusted by means of the built-in spirit level. Transfer sample to the dry sample chamber of the Bostwick Consistometer. Fill the chamber slightly more than level full, avoiding air bubbles as far as possible. Pass a straight edge across top of chamber starting from the gate end to remove excess product. Release gate of instrument by gradual pressure on lever, holding the instrument down at the same time to prevent its movement as the gate is released. Immediately start the stop watch or interval timer, and after 30 seconds read the maximum distance of flow to the nearest 0.1 centimeter. Clean and dry the instrument and repeat the reading on another portion of sample. Do not wash instrument with hot water if it is to be used immediately for the next determination, as this may result in an increase in temperature of the sample. For highest accuracy, the instrument should be maintained at a temperature

of $20 \pm 1^\circ\text{C}$. If readings vary more than 0.2 centimeter, repeat a third time or until satisfactory agreement is obtained. Report the average of two or more readings, excluding any that appear to be abnormal.

(2) Determine compliance as specified in § 155.3(b).

(3) If the quality of catsup falls below the standard prescribed in (b) (1) and (2) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the catsup falls below the standard, the label may bear the alternative statement, "Below Standard in Quality—Low Consistency."

(c) *Fill of container*. (1) The standard of fill of container for catsup, as determined by the general method for fill of container prescribed in § 130.12(b) of this chapter, is not less than 90 percent of the total capacity except:

(i) When the food is frozen, or

(ii) When the food is packaged in individual serving-size packages containing 56.7 grams (2 ounces) or less.

(2) Determine compliance as specified in § 155.3(b).

(3) If the catsup falls below the standard of fill prescribed in paragraph (c) (1) and (2) of this section, the label shall bear the general statement of substandard fill as specified in § 130.14(b) of this chapter, in the manner and form therein specified.

PART 156—VEGETABLE JUICES

2. In Part 156:

a. By adding Subpart A, consisting of new § 156.3, to read as follows:

Subpart A—General Provisions

§ 156.3 Definitions.

For the purpose of this part:

(a) "Strength and redness of color" means at least as much red as obtained by comparison of the prepared product, with the blended color produced by spinning a combination of the following concentric Munsell color discs of equal diameter, or the color equivalent of such discs:

Disc 1—Red (5R 2.6/13) (glossy finish)

Disc 2—Yellow (2.5 YR 5/12) (glossy finish)

Disc 3—Black (N1) (glossy finish)

Disc 4—Grey (N4) (mat finish)

Such comparison is to be made in full diffused daylight or under a diffused light source of approximately 2691 lux (250 footcandles) and having a spectral quality approximating that of daylight

under a moderately overcast sky, with a correlated color temperature of 7,500 degrees Kelvin ± 200 degrees. With the light source directly over the disc and product, observation is made at an angle of 45 degrees from a distance of about 24 inches from the product. Electronic color meters may be used as an alternate means of determining the color of tomato juice. Such meters shall be calibrated to indicate that the color of the product is as red or more red than that produced by spinning the Munsell color discs in the combination as set out above.

(b) "Tomato soluble solids" means the sucrose value as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, sections 32.014 to 32.016 and 52.012, under the headings "Soluble Solids in Tomato Products Official Final Action" and "Refractive Indices (n) of Sucrose Solutions at 20," which is incorporated by reference. Copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. If no salt has been added, the sucrose value obtained from the referenced tables shall be considered the percent of tomato soluble solids. If salt has been added, either intentionally or through the application of the acidified break, determine the percent of such added sodium chloride as specified in paragraph (c) of this section. Subtract the percentage so found from the percentage of tomato soluble solids found (sucrose value from the refractive index tables) and multiply the difference by 1.016. The resultant value is considered the percent of "tomato soluble solids."

(c) "Salt" means sodium chloride, determined as chloride and calculated as percent sodium chloride, by the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed., 1980, sections 32.025 to 32.030, under the heading "Method III (Potentiometric Method)," which is incorporated by reference.

(d) "Compliance" means the following: Unless otherwise provided in a standard, a lot of canned vegetable juice shall be deemed in compliance for the following factors, to be determined by the sampling and acceptance procedure as provided in paragraph (e) of this section, namely:

(1) **Quality.** The quality of a lot shall be considered acceptable when the number of defectives does not exceed

the acceptance number (c) in the sampling plans.

(2) **Fill of container.** A lot shall be deemed to be in compliance for fill of container when the number of defectives does not exceed the acceptance number (c) in the sampling plans.

(e) "Sampling and acceptance procedure" means the following:

(1) **Definitions—(i) Lot.** A collection of primary containers or units of the same size, type, and style manufactured or packed under similar conditions and handled as a single unit of trade.

(ii) **Lot size.** The number of primary containers or units in the lot.

(iii) **Sample size (n).** The total number of sample units drawn for examination from a lot.

(iv) **Sample unit.** A container, a portion of the contents of a container, or a composite mixture of product from small containers that is sufficient for the examination or testing as a single unit. For fill of container, the sample unit shall be the entire contents of the container.

(v) **Defective.** Any sample unit shall be regarded as defective when the sample unit does not meet the criteria set forth in the standards.

(vi) **Acceptance number (c).** The maximum number of defective sample units permitted in the sample in order to consider the lot as meeting the specified requirements.

(vii) **Acceptable quality level (AQL).** The maximum percent of defective sample units permitted in a lot that will be accepted approximately 95 percent of the time.

(2) **Sampling plans:**

ACCEPTABLE QUALITY LEVEL (AQL) 6.5

Lot size (primary containers)	Size of container	
	Net weight equal to or less than 1 kg (2.2 lb)	
	n	c
4,800 or less	13	2
4,801 to 24,000	21	3
24,001 to 48,000	29	4
48,001 to 84,000	48	6
84,001 to 144,000	84	9
144,001 to 240,000	126	13
Over 240,000	200	19
	Net weight greater than 1 kg (2.2 lb) but not more than 4.5 kg (10 lb)	
	n	c
2,400 or less	13	2
2,401 to 15,000	21	3
15,001 to 24,000	29	4
24,001 to 42,000	48	6
42,001 to 72,000	84	9
72,001 to 120,000	126	13
Over 120,000	200	19

ACCEPTABLE QUALITY LEVEL (AQL) 6.5—
Continued

Lot size (primary containers)	Size of container	
	Net weight greater than 4.5 kg (10 lb)	
	n	c
600 or less	13	2
601 to 2,000	21	3
2,001 to 7,200	29	4
7,201 to 15,000	48	6
15,001 to 24,000	84	9
24,001 to 42,000	126	13
Over 42,000	200	19

n=number of primary containers in sample.
c=acceptance number.

b. By revising § 156.145 to read as follows:

§ 156.145 **Tomato juice.**

(a) **Identity—(1) Definition.** Tomato juice is the food intended for direct consumption, obtained from the unfermented liquid extracted from mature tomatoes of the red or reddish varieties of *Lycopersicon esculentum* P. Mill, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such juice is strained free from peel, seeds, and other coarse or hard substances, but contains finely divided insoluble solids from the flesh of the tomato in accordance with current good manufacturing practice. Such juice may be homogenized, may be seasoned with salt, and may be acidified with any safe and suitable organic acid. The juice may have been concentrated and later reconstituted with water and/or tomato juice to a tomato soluble solids content of not less than 5.0 percent by weight as determined by the method prescribe in § 156.3(b). The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

(2) **Labeling.** (i) The name of the food is:

(a) "Tomato juice" if it is prepared from unconcentrate undiluted liquid extracted from mature tomatoes of reddish varieties.

(b) "Tomato juice from concentrate" if the finished juice has been prepared from concentrated tomato juice as specified in paragraph (a)(1) of this section or if the finished juice is a mixture of tomato juice and tomato juice from concentrate.

(ii) Each of the optional ingredients used shall be declared on the label as required by the applicable sections of Part 101 of this chapter.

(b) *Quality.* (1) The standard of quality for tomato juice is as follows:

(i) The strength and redness of color is not less than the composite color produced by spinning the Munsell color discs in the following combination:

53 percent of the area of Disc 1;
28 percent of the area of Disc 2; and
19 percent of the area of either Disc 3 or Disc 4; or 9½ percent of the area of Disc 3 and 9½ percent of the area of Disc 4, whichever most nearly matches the appearance of the tomato juice.

(ii) Not more than two defects for peel and blemishes, either singly or in combination, in addition to three defects for seeds or pieces of seeds, defined as follows, per 500 milliliters (16.9 fluid ounces):

(a) Pieces of peel 3.2 millimeters (0.125 inch) or greater in length.

(b) Blemishes such as dark brown or black particles (specks) greater than 1.6 millimeters (0.0625 inch) in length.

(c) Seeds or pieces of seeds 3.2 millimeters (0.125 inch) or greater in length.

(2) *Methodology.* (i) Determine strength and redness of color as specified in § 156.3(a).

(ii) Examine a total of 500 milliliters for peel, blemishes, and seeds. Divide the 500-milliliter sample into two 250-milliliter aliquots and pour each aliquot onto separate 30.5 x 45.7 centimeters (12 x 18 inches) white grading trays. Remove defects and evaluate for color and size as defined in paragraph (b)(1)(ii) of this section.

(3) Determine compliance as specified in § 156.3(d).

(4) If the quality of the tomato juice falls below the standard prescribed in paragraph (b)(1) and (3) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified, but in lieu of such general statement of substandard quality when the quality of the tomato juice falls below the standard in one or more respects, the label may bear the alternative statement, "Below Standard in Quality _____", the blank to be filled in with the words specified after the corresponding paragraph (s) under paragraph (b)(1) of this section which such tomato juice fails to meet, as follows:

- (i) "Poor color".
- (ii)(a) "Excessive pieces of peel".
- (b) "Excessive blemishes".
- (c) "Excessive seeds" or "excessive pieces of seed".

(c) *Fill of container.* (1) The standard of fill of container for tomato juice, as determined by the general method for fill of container prescribed in § 130.12(b)

of this chapter, is not less than 90 percent of the total capacity, except when the food is frozen.

(2) Determine compliance as specified in § 156.3(d).

(3) If the tomato juice falls below the standard of fill prescribed in paragraph (c)(1) and (2) of this section, the label shall bear the general statement of substandard fill specified in § 130.14(b) of this chapter, in the manner and form therein prescribed.

§ 156.147 [Removed]

c. By removing § 156.147 *Yellow tomato juice.*

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 28, 1983, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin March 29, 1983, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply. Notice of the filing of objections or lack thereof will be published in the *Federal Register*.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)).

Dated: January 17, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-3096 Filed 1-27-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 176

[Docket No. 82F-0300]

Indirect Food Additives: Paper and Paperboard Components

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 dialkyl(C₁₂-C₁₈)carbamoyl chloride as a sizing agent in the manufacture of paper and paperboard. This action is in response to a petition filed by AB Casco.

DATES: Effective January 28, 1983; objections by February 28, 1983.

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

FOR FURTHER INFORMATION CONTACT: Julius Smith, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of October 15, 1982 (47 FR 46139), FDA announced that a petition (FAP 0B3490) was filed by AB Casco, Box 11010, 100 61, Stockholm, Sweden, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) of the food additive regulations be amended to provide for the safe use of dialkyl(C₁₂-C₁₈)carbamoyl chloride as a sizing agent in the manufacture of paper and paperboard.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed food additive use is safe 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 Bureau of Foods (address above) by appointment with the contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are