DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28253; Directorate Identifier 2007–NM–031–AD; Amendment 39–15064; AD 2007–11–07]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737–100, –200, –200C, –300, –400, and –500 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting a typographical error in an existing airworthiness directive (AD) that was published in the **Federal Register** on May 22, 2007 (72 FR 28597). The error resulted in a confusing compliance time. This AD applies to all Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. This AD requires repetitive detailed inspections for damage of the electrical wire and sleeve that run to the fuel boost pump through a conduit in the fuel tank, and arcing damage of the conduit and signs of fuel leakage into the conduit; replacement of the sleeve with a new, smaller-diameter sleeve; and related investigative and corrective actions, as applicable.

DATES: Effective June 6, 2007.

ADDRESSES: The AD docket contains the proposed AD, comments, and any final disposition. You may examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Operations office (telephone (800) 647–5527) is located on the ground level of the West Building at the DOT street address stated in the **ADDRESSES** section. This docket number is FAA–2007–28253; the directorate identifier for this docket is 2007–NM–031–AD.

FOR FURTHER INFORMATION CONTACT: Suzanne Lucier, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 917–6438; fax (425) 917–6590.

SUPPLEMENTARY INFORMATION: On May 2, 2007, the FAA issued AD 2007–11–07, amendment 39–15064 (72 FR 28597, May 22, 2007), for all Boeing Model 737–100, –200, –200C, –300, –400, and –500 series airplanes. The AD requires repetitive detailed inspections for damage of the electrical wire and sleeve that run to the fuel boost pump through a conduit in the fuel tank, and arcing damage of the conduit and signs of fuel leakage into the conduit; replacement of the sleeve with a new, smaller-diameter sleeve; and related investigative and corrective actions, as applicable.

As published, paragraph (k) of AD 2007–11–07 reads ''* * * Thereafter, repeat the detailed inspection at intervals not to exceed 15,000 flight cycles. * * *'' The correct term, ''flight hours'' (not flight cycles), appears in all other compliance times cited in the AD, as intended.

No other part of the regulatory information has been changed; therefore, the final rule is not republished in the **Federal Register**.

The effective date of this AD remains June 6, 2007.

§ 39.13 [Corrected]

■ In the **Federal Register** of May 22, 2007, on page 28600, in the third column, paragraph (k) of AD 2007–11–07 is corrected to read as follows:

* * * * *

(k) At the applicable time specified by paragraph (k)(1) or (k)(2) of this AD: Do a detailed inspection for damage of the sleeve and electrical wire of the fuel boost pump; and, before further flight, install a new, smaller-diameter sleeve, and do related investigative and corrective actions, as applicable; in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–28A1263, Revision 1, dated March 19, 2007. Thereafter, repeat the detailed inspection at intervals not to exceed 15,000 flight hours. Accomplishment of the initial inspection, applicable corrective actions, and sleeve installation required by this paragraph terminates the requirements of paragraphs (f), (g), (h), and (i) of this AD.

* * * * *

Issued in Renton, Washington, on August 14, 2007.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–16304 Filed 8–20–07; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 232

[Release Nos. 33–8834; 34–56256; 39–2448; IC–27928]

RIN 3235–AG96

Adoption of Updated EDGAR Filer Manual

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (the Commission) is adopting revisions to the Electronic Data Gathering, Analysis, and Retrieval System (EDGAR) Filer Manual to reflect updates to the EDGAR system. Revisions are being made primarily to support the expansion of the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit supplemental tagged information contained in the risk/return summary section of their prospectuses on Form N–1A. The EDGAR system is being upgraded to support this functionality on August 20, 2007.

The filer manual is also being revised to incorporate changes in support of several final rules previously adopted by the Commission and implemented in EDGAR. Those rules include the termination of a foreign private issuer's registration of a class of securities under Section 12(g) and duty to file reports under Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (''Exchange Act''); the electronic filing of Transfer Agent (''TA'') forms TA–1, TA–2 and TA–W; and revisions to the accelerated filer definition under the Exchange Act. Other revisions were made to allow an issuer to indicate whether it is subject to reporting obligations after terminating registration of a class of equity securities under the Exchange Act and to remove references to submission types N–14AE and N–14AE/A for the filing of Form N–14 from ''Table 3–5: Investment Company Submission Types Accepted by EDGAR'' of the Filer Manual.

Revisions to the Filer Manual reflect changes within Volumes I and II, entitled EDGAR Filer Manual, Volume I: ''General Information,'' Version 4 (August 2007) and EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 5 (August 2007) respectively. The updated manual will be incorporated by reference into the Code of Federal Regulations.

DATES: *Effective Date:* August 20, 2007. The incorporation by reference of the EDGAR Filer Manual is approved by the Director of the Federal Register as of August 20, 2007.

FOR FURTHER INFORMATION CONTACT: In the Office of Information Technology, Rick Heroux, at (202) 551–8800; in the Division of Investment Management, for questions concerning the expansion of the current interactive data voluntary reporting program, Alberto H. Zapata, Senior Counsel, or Brent J. Fields, Assistant Director, Office of Disclosure Regulation, at (202) 551–6784, and for

questions concerning investment company filings, Ruth Armfield Sanders, Senior Special Counsel, Office of Legal and Disclosure, at (202) 551–6989; in the Division of Market Regulation, for questions concerning the electronic filing of Transfer Agent forms, Catherine Moore, Special Counsel, Office of Clearance and Settlement, at (202) 551–5710; and in the Division of Corporation Finance, for questions concerning the definition of accelerated filer for periodic reports, Katherine W. Hsu, Special Counsel, Office of Rulemaking, at (202) 551–3430 and for questions concerning termination of a foreign private issuer's registration, Elliot Staffin, Special Counsel, Office of International Corporate Finance, at (202) 551–3450.

SUPPLEMENTARY INFORMATION: Today we are adopting an updated EDGAR Filer Manual, Volumes I and II. The Filer Manual describes the technical formatting requirements for the preparation and submission of electronic filings through the EDGAR system.[1] It also describes the requirements for filing using EDGARLink[2] and the Online Forms/XML Web site.

The Filer Manual contains all the technical specifications for filers to submit filings using the EDGAR system. Filers must comply with the applicable provisions of the Filer Manual in order to assure the timely acceptance and processing of filings made in electronic format.[3] Filers should consult the Filer Manual in conjunction with our rules governing mandated electronic filing when preparing documents for electronic submission.[4]

Revisions are being made primarily to support the final rule[5] adopted by the Commission to extend the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit supplemental tagged information contained in the risk/return summary section of their prospectuses from Form N–1A using the mutual fund risk/return summary taxonomy developed by the Investment Company Institute (''ICI''). As with the voluntary interactive data program initiated by the Commission in 2005, in which companies voluntarily agree to furnish financial data as exhibit documents in eXtensible Business Reporting Language (''XBRL'') format, the risk/return summary data submitted by mutual funds must also be provided as exhibit documents in XBRL format. A mutual fund submitting tagged risk/return summary information as an exhibit to Form N–1A will be required to name each document ''EX–100'' as specified in the EDGAR Filer Manual. In addition, the XBRL exhibit documents submitted require the use of the appropriate version of standard taxonomies supported by EDGAR. Those standard taxonomies, including the ICI's Mutual Fund Risk/Return Summary Taxonomy, are provided on the SEC's ''Information for EDGAR Filers'' webpage and include a listing of applicable XBRL schemas and linkbases. Core XBRL, XBRL linkbase, eXtensible Markup Language (XML), and XLink schemas and specifications are listed in the EDGAR Filer Manual, Volume II: ''EDGAR Filing''. A mutual fund choosing to tag its risk/return summary information also would continue to file this information in HTML or ASCII format, as currently required.

The filer manual is also being revised to incorporate changes made to support final rules previously adopted by the Commission and implemented in EDGAR. Those rules and EDGAR changes are described below.

- The termination of a foreign private issuer's 12(g) reporting obligations[6] regarding a class of debt securities and to cease its duty to file reports under Section 13(a) or 15(d) of the Exchange Act;

This revision included the addition of new submission types 15F–12B, 15F–12B/A, 15F–12G, 15F–12G/A, 15F–15D, 15F–15D/A which can be submitted using the EDGARLink software and Submission Template #3.

- The electronic filing of forms[7] TA–1, TA–2 and TA–W;

This revision included the addition of electronic forms for the filing of the registration, annual report, and withdrawal from registration of transfer agents. The EDGARLite application was introduced as the tool for filers to use in the creation of their EDGAR submissions. Filers download the EDGARLite package from the EDGAR OnlineForms/XML Web site and install it on their desktop. EDGARLite consists of a Commercial off the Shelf (COTS) software package, Microsoft InfoPath[8] (MS InfoPath), and electronic form templates provided by the Commission. The forms are encoded in Extensible Markup Language (XML) and are submitted to EDGAR using the OnlineForms/XML Web site.

- Revisions to the accelerated filer definition[9] and accelerated periodic report filing deadlines under the Exchange Act;

The addition of a required ''Accelerated Filer Status'' indicator to EDGARLink submission headers for 10–K, 10–K/A, 10–KT, 10–KT/A, 20–F, and 20–F/A forms allows filers of these form types to select one of the following accelerated filer classification values: Large Accelerated Filer, Accelerated Filer, Non-accelerated Filer, and Not Applicable (should be used if a filer is filing an amendment to a Form 10–K or Form 20–F submission for a period that occurred before the accelerated filer

[1] We originally adopted the Filer Manual on April 1, 1993, with an effective date of April 26, 1993. Release No. 33–6986 (April 1, 1993) [58 FR 18638]. We implemented the most recent update to the Filer Manual on February 6, 2006. *See* Release No. 33–8656 (January 27, 2006) [71 FR 5596].

[2] This is the filer assistance software we provide filers filing on the EDGAR system.

[3] *See* Rule 301 of Regulation S–T (17 CFR 232.301).

[4] *See* Release Nos. 33–6977 (February 23, 1993) [58 FR 14628], IC–19284 (February 23, 1993) [58 FR 14848], 35–25746 (February 23, 1993) [58 FR 14999], and 33–6980 (February 23, 1993) [58 FR 15009] in which we comprehensively discuss the rules we adopted to govern mandated electronic filing. *See also* Release No. 33–7122 (December 19, 1994) [59 FR 67752], in which we made the EDGAR rules final and applicable to all domestic registrants; Release No. 33–7427 (July 1, 1997) [62 FR 36450], in which we adopted minor amendments to the EDGAR rules; Release No. 33–7472 (October 24, 1997) [62 FR 58647], in which we announced that, as of January 1, 1998, we would not accept in paper filings that we require filers to submit electronically; Release No. 34–40934 (January 12, 1999) [64 FR 2843], in which we made mandatory the electronic filing of Form 13F; Release No. 33–7684 (May 17, 1999) [64 FR 27888], in which we adopted amendments to implement the first stage of EDGAR modernization; Release No. 33–7855 (April 24, 2000) [65 FR 24788], in which we implemented EDGAR Release 7.0; Release No. 33–7999 (August 7, 2001) [66 FR 42941], in which we implemented EDGAR Release 7.5; Release No. 33–8007 (September 24, 2001) [66 FR 49829], in which we implemented EDGAR Release 8.0; Release No. 33–8224 (April 30, 2003) [68 FR 24345], in which we implemented EDGAR Release 8.5; Release Nos. 33–8255 (July 22, 2003) [68 FR 44876] and 33–8255A (September 4, 2003) [68 FR 53289] in which we implemented EDGAR Release 8.6; Release No. 33–8409 (April 19, 2004) [69 FR 21954] in which we implemented EDGAR Release 8.7; Release No. 33–8454 (August 6, 2004) [69 FR 49803] in which we implemented EDGAR Release 8.8; Release No. 33–8528 (February 3, 2005) [70 FR 6573] in which we implemented EDGAR Release 8.10; Release No. 33–8573 (May 19, 2005) [70 FR 30899] in which we implemented EDGAR Release 9.0; Release No. 33–8612 (September 21, 2005) [70 FR 57130] in which the Commission granted the authorization to publish the release adopting the reorganized EDGAR Filer Manual; Release No. 33–8633 (November 1, 2005) [70 FR 67350] in which we implemented EDGAR Release 9.2; and Release No 33–8656 (January 27, 2006) [71 FR 5596] in which we implemented EDGAR Release 9.3.

[5] See Release No. 33–8823 (July 11, 2007) [72 FR 39290].

[6] See Release No. 34–55540 (March 27, 2007) [72 FR 16934].

[7] See Release No. 34–54864 (December 4, 2006) [71 FR 74698].

[8] MS InfoPath 2003 or MS InfoPath 2007 can be used and comes with the Professional Enterprise Edition of Microsoft Office or can be purchased separately for approximately $200.

[9] See Release No. 33–8644 (December 21, 2005) [70 FR 76626].

definition went into effect). The accelerated filer classification is directly related to the filer's reporting deadline as illustrated in the following: [10]

Category of filer	Revised deadlines for filing periodic reports	
	Form 10–K deadline	Form 10–Q deadline
Large Accelerated Filer ($700MM or more)	75 days for fiscal years ending before December 15, 2006 and 60 days for fiscal years ending on or after December 15, 2006.	40 days.
Accelerated Filer ($75MM or more and less than $700MM).	75 days	40 days.
Non-accelerated Filer (less than $75MM)	90 days	45 days.

Additional revisions were made to permit a domestic issuer to indicate whether reporting obligations still exist after terminating registration of a class of equity securities under the Exchange Act. The addition of a required ''Duty to File Reports Remains'' indicator in EDGARLink submission headers for submission types 15–12B, 15–12B/A, 15–12G, 15–12G/A, 15–15D and 15–15D/A allows filers of these form types to indicate whether it is still subject to reporting obligations under the Exchange Act.

Finally, we removed from ''Table 3–5: Investment Company Submission Types Accepted by EDGAR'' of the Filer Manual the reference to submission types N–14AE and N–14AE/A for the filing of Form N–14. All open-end investment companies, including those filed with automatic effectiveness under Rule 488 (business combinations), are to use submission types N–14 and N–14/A for these filings.

For the extension of the current interactive data voluntary reporting program to enable mutual funds voluntarily to submit supplemental tagged information contained in the risk/return summary section of their prospectuses being implemented in EDGAR Release 9.7, the EDGARLink software and submission templates will not be updated. Notice of the new release has previously been provided on the EDGAR Filing Web site and on the Commission's public Web site. The discrete updates are reflected in the updated Filer Manual Volumes.

Along with adoption of the Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of today's revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

You may obtain paper copies of the updated Filer Manual at the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1580, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. We will post electronic format copies on the Commission's Web site; the address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml.* You may also obtain copies from Thomson Financial, the paper document contractor for the Commission, at (800) 638–8241.

Since the Filer Manual relates solely to agency procedures or practice, publication for notice and comment is not required under the Administrative Procedure Act (APA).[11] It follows that the requirements of the Regulatory Flexibility Act [12] do not apply.

The effective date for the updated Filer Manual and the rule amendments is August 20, 2007. In accordance with the APA,[13] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The EDGAR system upgrade to Release 9.7 is scheduled to become available on August 20, 2007. The Commission believes that it is necessary to coordinate the effectiveness of the updated Filer Manual with the scheduled system upgrade.

Statutory Basis

We are adopting the amendments to Regulation S–T under Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[14] Sections 3, 12, 13, 14, 15, 23, and 35A of the Exchange Act,[15] Section 319 of the Trust Indenture Act of 1939,[16] and Sections 8, 30, 31, and 38 of the Investment Company Act of 1940.[17]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendment

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for part 232 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77sss(a), 78c(b), 78*l*, 78m, 78n, 78o(d), 78w(a), 78*ll*(d), 79t(a), 80a–8, 80a–29, 80a–30, 80a–37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets out the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the updated EDGAR Filer Manual, Volume I: ''General Information,'' Version 4 (August 2007). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 5 (August 2007). Additional provisions applicable to Form N–SAR filers are set forth in the EDGAR Filer Manual, Volume III: ''N–SAR Supplement,'' Version 1 (September 2005). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the

[10] See Release No. 33–8644 (December 21, 2005) [70 FR 76626].

[11] 5 U.S.C. 553(b).

[12] 5 U.S.C. 601–612.

[13] 5 U.S.C. 553(d)(3).

[14] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[15] 15 U.S.C. 78c, 78*l*, 78m, 78n, 78o, 78w, and 78*ll*.

[16] 15 U.S.C. 77sss.

[17] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 100 F Street, NE., Room 1580, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m., or by calling Thomson Financial at (800) 638–8241. Electronic copies are available on the Commission's Web site. The address for the Filer Manual is *http://www.sec.gov/info/edgar.shtml.* You can also photocopy the document at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Dated: August 15, 2007.

By the Commission.

Florence E. Harmon,

Deputy Secretary .

[FR Doc. E7–16414 Filed 8–20–07; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2006F–0059]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Polydextrose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry, baby foods, and infant formula. This action is in response to a petition filed by Danisco USA, Inc.

DATES: This rule is effective August 21, 2007. Submit written or electronic objections and requests for a hearing by September 20, 2007. See section VII of the **SUPPLEMENTARY INFORMATION** section of this document for information on the filing of objections. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 172.841(b) (21 CFR 172.841(b)) as of August 21, 2007.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2006F–0059, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1267.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of February 15, 2006 (71 FR 7975), amended April 27, 2006 (71 FR 24856), FDA announced that a food additive petition (FAP 6A4763) had been filed by Danisco USA, Inc., 440 Saw Mill River Rd., Ardsley, NY 10502–2605. The petition proposed to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841). Currently, § 172.841 lists 13 specific categories of foods in which polydextrose may be used safely as a bulking agent, formulation aid, humectant, and texturizer. The petition proposed to amend § 172.841 to provide for the safe use of polydextrose as a bulking agent, formulation aid, humectant, and texturizer in all foods, except meat and poultry.

The petition also proposed to incorporate by reference the specifications for polydextrose in the 5th edition of the Food Chemicals Codex (FCC V), effective January 1, 2004. After the petition was filed, Danisco amended the petition to exclude the proposed uses of polydextrose in baby food and infant formula.

II. Determination of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, existing toxicological data, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.