(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 727, 727C, 727–100, 727–100C, 727–200, and 727–200F series airplanes, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 57, Wings.

(e) Unsafe Condition

This AD was prompted by reports of spanwise cracks and corrosion in the wing center box upper skin and rear spar upper chord between left buttock line (LBL) 70.50 and right buttock line (RBL) 70.50 at body station (STA) 870. We are issuing this AD to detect and correct cracking and corrosion of the upper skin and rear spar upper chord of the wing center box, which could result in loss of the airplane wing and consequent loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections

Except as specified in paragraph (h) of this AD, at the applicable time specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 727–57–0187, dated March 8, 2012: Inspect the wing center box between LBL 70.50 and RBL 70.50, at STA 870, as specified in paragraphs (g)(1), (g)(2), (g)(3), (g)(4), and (g)(5) of this AD, as applicable, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 727–57–0187, dated March 8, 2012. Repeat the inspections thereafter at the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Special Attention Service Bulletin 727–57–0187, dated March 8, 2012. If any crack, corrosion, or damage is found during any inspection required by this AD, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (i) of this AD.

(1) Do a high frequency eddy current (HFEC) or detailed inspection for cracking around the forward fastener row in the rear spar upper chord horizontal flange.

(2) Do a low frequency eddy current inspection for cracking around the aft fastener row in the rear spar upper chord horizontal flange.

(3) Do a detailed or HFEC inspection for cracking in the rear spar upper chord radius.

(4) Do a detailed or HFEC inspection for cracking in the upper skin around the forward fastener row common to the rear spar upper chord horizontal flange.

(5) Do a detailed inspection for damage, cracking, and corrosion in the pressure seal.

(h) Exception to the Service Information

Boeing Special Attention Service Bulletin 727–57–0187, dated March 8, 2012, specifies compliance times ''after the original issue date of this service bulletin.'' However, this AD requires compliance within the specified compliance times ''after the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD. Information may be emailed to: *9–ANM-Seattle-ACO–AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Berhane Alazar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: (425) 917–6577; fax: (425) 917–6590; email: *berhane.alazar@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Ave SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on February 28, 2013.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–05598 Filed 3–11–13; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. CPSC–2013–0010]

16 CFR Part 1500

Hazardous Substances and Articles; Supplemental Definition of ''Strong Sensitizer''

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Consumer Product Safety Commission (CPSC or Commission) proposes to update the supplemental definition of ''strong sensitizer'' under the Federal Hazardous Substances Act (FHSA). The proposed amendment clarifies or adds language to eliminate redundancy, remove certain subjective factors, incorporate new and anticipated technology, rank the criteria for classification of strong sensitizers in order of importance, define criteria for ''severity of reaction,'' and indicate that a weight-of-evidence approach will be used to determine the strength of the sensitizer.

DATES: Written comments must be received by May 28, 2013.

ADDRESSES: You may submit comments identified by Docket No. CPSC–2013–0010, by any of the following methods:

• Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (email) except through *www.regulations.gov.*

• Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically.

Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joanna Matheson, Ph.D., Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987–2564; *jmatheson@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The FHSA, 15 U.S.C. 1261–1278, requires appropriate cautionary labeling on certain hazardous household products to alert consumers to the potential hazards that a product may present. Among the hazards addressed by the FHSA are products that are toxic, corrosive, irritants, flammable, combustible, or strong sensitizers.

Included within the FHSA's definition of ''hazardous substance'' is ''any substance or mixture of substances'' that ''is a strong sensitizer,'' 15 U.S.C. 1261(f)(1)(iv). Section 2(k) of the FHSA, 15 U.S.C. 1261(k), defines ''strong sensitizer'' as:

> A substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Commission. Before designating any substance a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

On August 12, 1961, the Food and Drug Administration (FDA) (which at that time administered the FHSA), issued regulations under the FHSA that supplemented the statutory definition of ''strong sensitizer.'' The regulations also provided a list of substances that the FDA had determined met the statutory definition for ''strong sensitizer.'' The five substances identified were: (1) Paraphenylenediamine and products containing it; (2) powdered orris root and products containing it; (3) epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight less than 200; (4) formaldehyde and products containing 1 percent or more of formaldehyde; and (5) oil of bergamot and products containing 2 percent or more of oil of bergamot. No additional substances have been determined to be ''strong sensitizers'' by the FDA or the Commission since promulgation of this regulation.

In 1973, the responsibility for the administration of the FHSA was transferred to the Commission, and the supplemental definition of ''strong sensitizer'' was published in title 16 of the Code of Federal Regulations. On May 30, 1984, the Commission revoked the above supplemental definition of ''strong sensitizer.'' 49 FR 22464. The Commission concluded at that time that the statutory definition of ''strong sensitizer'' was adequate for any future regulatory determination that a substance is a strong sensitizer.

On August 14, 1986, the Commission issued a rule supplementing the definition of ''strong sensitizer'' in the FHSA, 51 FR 29094, which currently is in effect. 16 CFR 1500.3(c)(5). As recommended by a Technical Advisory Panel on Allergic Sensitization (TAPAS), the supplemental definition clarifies how the statutory definition should be interpreted and explains the factors the Commission will consider in determining whether a substance is a ''strong sensitizer.'' The supplemental definition states that an ''allergic'' response is one that is directed by the immune system, such that a sensitization reaction could not be caused by an irritant or other nonallergenic qualities of the substance. The supplemental definition also clarifies that active sensitizers—substances that produce a sensitivity reaction solely as the result of a person's first exposure to the substance as opposed to after reapplication of the same substance—are included within the class of substances that can be determined to be strong sensitizers. The supplemental definition did not address strong sensitizers that cause hypersensitivity by a photodynamic process, principally because Commission staff was unaware of any household product subject to the FHSA that would cause significant exposure of consumers to a photodynamic chemical.

The current supplemental definition makes clear that a sensitivity reaction could occur after the sensitizer is applied to the body's tissues by contact, ingestion, or inhalation; that relevant exposure is not limited to skin contact; and that targets for hypersensitivity reactions include the skin and other organ systems, such as the respiratory or gastrointestinal tracts, either alone or in combination. The supplemental definition states that the minimal severity of the reaction caused by the substance for purposes of determining whether the substance is a strong sensitizer is a clinically important allergic reaction and provides examples of such clinically important reactions. Whether a substance has a significant potential for causing hypersensitivity is a relative determination that must be made separately for each substance under consideration by the Commission. The supplemental definition sets forth the criteria to be considered in making this determination. Finally, the supplemental definition provides the quantitative and qualitative factors that the Commission should consider in determining that a substance is a ''strong'' sensitizer, such as the frequency of occurrence and range of severity in normal and susceptible populations and the results of experimental assays in humans and animals.

Recognizing that the science on sensitization has changed since promulgation of the supplemental definition in 1986, the CPSC convened a panel of scientific experts from academia, industry, and the federal government to examine the available scientific and medical information concerning sensitizers, and if appropriate, propose revisions to the supplemental definition of strong sensitizer.

B. Effect of Strong Sensitizer Determination

The Commission is proposing to revise its supplemental definition of strong sensitizer. Additional Commission action would be needed for any substance to be designated a strong sensitizer. In order for the Commission to issue a rule declaring any particular substance (or product containing that substance) to be a strong sensitizer, it must engage in notice and comment rulemaking, separate from this rulemaking, and make the findings specified in 15 U.S.C. 1261(k), *i.e.,* that based upon consideration of the frequency of occurrence and the severity of the reaction, the substance has a significant potential for causing hypersensitivity. However, a determination that a substance is a strong sensitizer does not automatically trigger a labeling requirement for products containing that substance. Under the FHSA a substance (or product containing that substance) that is a hazardous substance requires appropriate labeling. 15 U.S.C. 1261(p). If manufacturers of products containing a designated strong sensitizer determine that the strong sensitizer in their products may cause substantial injury or illness as a result of reasonably foreseeable handling or use, that product would be a ''hazardous substance'' as defined under the FHSA, and therefore would warrant

appropriate labeling. Alternatively, where there is uncertainty, the Commission has the option under section 3(a)(1) of the FHSA to determine through notice and comment rulemaking that a product containing a strong sensitizer is a ''hazardous substance.'' Hazardous substances intended or packaged in a form suitable for use in the household that do not bear the appropriate cautionary labeling would be considered ''misbranded'' in violation of the FHSA. 15 U.S.C. 1261(p).

Such cautionary labeling would be insufficient, however, if a toy or other article intended for the use of children is, bears, or contains a hazardous substance (as that term is defined in section 2(f) of the FHSA), and the hazardous substance is accessible to a child to whom the article is entrusted. Under that scenario, the toy or children's article would be considered a ''banned hazardous substance'' under section 2(q)(1)(A) of the FHSA unless a particular exemption applies. 15 U.S.C. 1261(q)(1)(A).

C. Proposed Amendment

The proposed amendment to 16 CFR part 1500 clarifies or adds language to the supplemental definition of ''strong sensitizer'' to eliminate redundancy, remove certain subjective factors, incorporate new and anticipated technology, rank the criteria for classification of strong sensitizers in order of importance, define criteria for ''severity of reaction,'' and indicate that a weight-of-evidence approach will be used to determine the strength of the sensitizer.

1. *Definition of sensitizer.* The current definition of *sensitizer* in § 1500.3(c)(5) is, ''a substance that will induce an immunologically-mediated (allergic) response, including allergic photosensitivity. The allergic reaction will become evident upon reexposure to the same substance. Occasionally, a sensitizer will induce and elicit an allergic response on first exposure by virtue of active sensitization.''

The proposed amendment reflects the traditional definition for sensitization; sensitization is a multi-stage immune mediated process which occurs over a period of time. Under the proposed amendment, those substances that sensitize through atypical mechanisms, rather than by inducing an obvious ''immunologically-mediated response'' will be captured by the assessment process. The proposed amendment also eliminates the last sentence of the current definition based on concerns that it may be misinterpreted such that substances that cause an irritant response only [1] (the response that is noted after the first exposure to a substance is more frequently an irritant response and not an allergic response) could be erroneously included in the category of ''strong sensitizers.'' Typically, allergic responses are the result of a two-step process: (1) Induction (sensitization) which requires sufficient or cumulative exposure to induce an immune response with few or no symptoms and (2) elicitation when an individual who has been sensitized demonstrates symptoms upon subsequent exposures. The phrase ''variable period of exposure'' is included in the proposed amendment to reflect the latency period which is a characteristic in the development of sensitization.

2. *Definition of significant potential for causing hypersentivity.* Currently, 16 CFR 1500.3(c)(5)(iv) provides that '' 'significant potential for causing hypersensitivity' is a relative determination that must be made separately for each substance. It may be based upon the chemical or functional properties of the substance, documented medical evidence of allergic reactions obtained from epidemiological studies surveys or individual case reports, controlled *in vitro* or *in vivo* experimental assays, or susceptibility profiles in normal or allergic subjects.''

The proposed revision to this section reiterates the statutory requirement that before designating any substance a ''strong'' sensitizer, the Commission must find that the substance has significant potential for causing hypersensitivity. The proposed revision adds qualifiers for susceptibility profiles—genetics, age, gender, and atopic status— to the list of information or data that may be considered in determining whether a substance has a significant potential for causing hypersensitivity; and the proposed revision also replaces the term ''normal'' with ''non-sensitized.'' These characteristics are well-known modifiers in the development and exacerbation of allergic responses to chemical sensitizers; and replacing the term ''normal'' with ''non-sensitized'' reflects more accurately what would be considered the general control population.

The proposed revision of this section also incorporates a discussion of the factors to be considered in determining whether a substance is a ''strong'' sensitizer. The current supplemental definition of ''strong sensitizer'' contains a separate subsection that sets forth factors that should be considered in determining the strength of a sensitizer. (16 CFR 1500.3(c)(5)(ii)). The current section includes several factors that are subjective rather than quantitative (*i.e.,* physical discomfort, distress, hardship) and allows for risk assessment considerations in connection with an analysis that should only be a hazard characterization step.

The current definition of *strong* reads:

> In determining that a substance is a ''strong'' sensitizer, the Commission shall consider the available data for a number of factors. These factors include any and or all of the following (if available): Quantitative or qualitative risk assessment, frequency of occurrence and range of severity of reactions in healthy or susceptible populations, the result of experimental assays in animals or humans (considering dose-response factors), with human data taking precedence over animal data, other data on potency or bioavailability of sensitizers, data on reactions to a cross-reacting substance or to a chemical that metabolizes or degrades to form the same or a cross-reacting substance, the threshold of human sensitivity, epidemiological studies, and other appropriate *in vivo* or *in vitro* test studies.

The proposed amendment eliminates the ''quantitative or qualitative risk assessment factor'' because the Commission believes this terminology is a source of confusion in that it places a risk assessment step within the hazard identification step of the overall process of determining whether a product containing a strong sensitizer requires labeling. The proposed amendment makes clear that a weight-of-the-evidence approach is to be used in determining the strength of a sensitizer because of the imprecise nature of some of the current factors and the potential lack of information or data available to permit useful consideration of certain factors. Rather than allowing an ''any or all'' approach to what factors would be considered by the Commission in determining whether a sensitizer is strong, the amendment ranks data sources in order of importance, following the FHSA preference for human data over animal data; and the amendment takes into consideration the value and relevance that certain data would provide in evaluating the potential of a substance to cause hypersensitivity. For example, the proposed amendment expresses a preference for general population epidemiological studies over occupational studies because the degree of sensitization in the workplace is likely to be greater than that of the general population, due to greater

[1] An ''irritant response'' is a nonimmune mediated response and one that results from direct injury to the tissue. An irritant is any agent that is capable of producing cell damage in any individual if applied for sufficient time and concentration.

exposure (both in time and concentration) to the sensitizing agent.

The proposed amendment provides that for a substance to be considered a ''strong'' sensitizer the substance must be found to produce a ''clinically important reaction,'' which is defined as a reaction with a significant impact on the quality of life. Examples of such reactions included in the proposed revision to this section are substantial physical discomfort or distress, substantial hardship, functional or structural impairment, or chronic morbidity. The proposed revision to this section also directs the Commission to consider the location of the hypersensitivity response, such as the face, hands, and feet, and the persistence of clinical manifestations in determining whether the substance produces a ''clinically important reaction.''

The proposed revision to this section adds several factors the Commission can consider in determining a substance's sensitizing potential, for which validated methods currently do not exist but are in development, such as: Quantitative Structure-Activity Relationships (QSARs), and *in silico* [2] data, along with the caveat that using these techniques would be in addition to consideration of human and animal data. We expect that *in vitro* and *in silico* validated methods will be available as part of an integrated testing strategy within the next 5 years, and including these components in the amendment ensures that the definition is compatible with current science. The proposed revision also includes a definition of ''bioavailability'' (*i.e.,* the dose of the substance available to interact with a tissue and that tissue's ability to absorb the substance and the actual penetrating ability of the substance).

3. *Definition of Normal Living Tissue.* Currently, 16 CFR 1500.3(c)(5)(v) defines *normal living tissue* as:

> the skin and other organ systems, such as the respiratory or gastrointestinal tract, either singularly or in combination, following sensitization by contact ingestion or inhalation.

The proposed revision adds a specific reference to mucous membranes, such as ocular and oral systems, as types of normal living tissue upon which a substance can cause a hypersensitivity that warrants a determination that a substance is a ''strong sensitizer.''

4. *Definition of Severity of Reaction.* The current definition for *severity of reaction* at 16 CFR 1500.3(c)(5)(iii)) states that the minimal severity of a reaction for the purpose of designating a material as a ''strong sensitizer'' is a clinically important reaction, and provides examples of the types of illnesses that could satisfy this criteria, such as physical discomfort, distress, hardship, or functional or structural impairment.

The proposed amendment eliminates this subsection and incorporates the factors to be considered in determining whether a substance is a ''strong'' sensitizer into the proposed revised section *Significant potential for causing hypersensitivity.*

D. Staff Guidance and Notice of Availability

Commission staff has developed a guidance document that is intended to clarify the ''strong sensitizer'' definition and assist manufacturers in understanding how CPSC staff would assess whether a substance and/or product containing that substance should be considered a ''strong sensitizer.'' A Notice of Availability is published elsewhere in this issue of the **Federal Register**, which provides a link to the location on the Commission's Web site where the staff guidance document can be found.

E. Impact on Small Businesses

Under the Regulatory Flexibility Act (RFA), when an agency issues a proposed rule, it generally must prepare an initial regulatory flexibility analysis describing the impact the proposed rule is expected to have on small entities. 5 U.S.C. 603. The RFA does not require a regulatory flexibility analysis if the head of the agency certifies that the rule will not have a significant effect on a substantial number of small entities. *Id.* 605(b).

The Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of revising the supplemental definition of ''strong sensitizer.'' That assessment found that there would be little or no effect on small businesses and other entities because the proposed amendment, which simply modifies the existing supplemental definition of ''strong sensitizer,'' will not result in product modifications to comply; nor will the revised supplemental definition impose any additional testing or recordkeeping burdens. The obligation to label a product as a ''strong sensitizer'' and any costs associated with that obligation will not arise until the Commission has designated a substance contained in the product as a ''strong sensitizer,'' which would occur only in connection with a separate notice and comment rulemaking proceeding. Thereafter, we would assess the potential small business impact of designating the particular substance as a strong sensitizer. Moreover, the proposed amendment is not expected to impose any indirect burden on small businesses or other entities because it is not expected to lead to any additional substances being designated as strong sensitizers that would not be so designated in the absence of the amendment. Based upon the foregoing assessment, the Commission finds preliminarily that the proposed rule would not have a significant impact on a substantial number of small entities.

F. Environmental Considerations

Generally, CPSC rules are considered to ''have little or no potential for affecting the human environment,'' and environmental assessments and environmental impact statements are not usually prepared for these rules (see 16 CFR 1021.5(c)(1)). The Commission does not expect the proposed rule to have any adverse impact on the environment under this categorical exclusion.

G. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations. Section 18 of the FHSA addresses the preemptive effect of certain rules issued under the FHSA. 15 U.S.C. 1261n. Because this rulemaking would revise a regulatory definition rather than issue a labeling or banning requirement, section 18 of the FHSA does not provide for the proposed rule to have preemptive effect.

H. Paperwork Reduction Act

This rule would not impose any information collection requirements. Accordingly, this rule is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

I. Effective Date

The Administrative Procedure Act generally requires that a substantive rule be published not less than 30 days before its effective date, unless the agency finds, for good cause shown, that a lesser time period is required. 5 U.S.C. 553(d)(3). We propose that the rule would take effect 30 days after

[2] QSARs are mathematical models that relate a quantitative measure of chemical structure to biological activity. *In silico* data is a computational approach using sophisticated computer models for the determination of a sensitizing potential. Both of these approaches are evolving methodologies that have not yet been validated, but are being pursued as testing options that would reduce the numbers of expensive laboratory and animal experiments being carried out.

publication of a final rule in the **Federal Register**.

List of Subjects in 16 CFR Part 1500

Consumer protection, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Reporting and recordkeeping requirements, and Toys.

Accordingly, 16 CFR part 1500 is proposed to be amended as follows:

PART 1500—[AMENDED]

■ 1. The authority citation for part 1500 continues to reads as follows:

Authority: 15 U.S.C. 1261–1278.

■ 2. In § 1500.3, revise paragraph (c)(5) to read as follows:

§ 1500.3 Definitions.

* * * * *

(c) * * *

(5) The definition of *strong sensitizer* in section 2(k) of the Federal Hazardous Substances Act (restated in 16 CFR 1500.3(b)(9)) is supplemented by the following definitions:

(i) *Sensitizer.* A sensitizer is a substance that is capable of inducing a state of immunologically mediated hypersensitivity (including allergic photosensitivity) following a variable period of exposure to that substance. Hypersensitivity to a substance will become evident by an allergic reaction elicited upon reexposure to the same substance.

(ii) *Significant potential for causing hypersensitivity.* Before designating any substance a ''strong sensitizer,'' the Commission shall find that the substance has significant potential for causing hypersensitivity. *Significant potential for causing hypersensitivity* is a relative determination that must be made separately for each substance. It may be based on chemical or functional properties of the substance; documented medical evidence of allergic reactions upon subsequent exposure to the same substance obtained from epidemiological surveys or individual case reports; controlled *in vitro* or *in vivo* experimental studies; and susceptibility profiles (*e.g.,* genetics, age, gender, atopic status) in non-sensitized or allergic subjects.

(A) In determining whether a substance is a ''strong'' sensitizer, the Commission shall consider the available data for a number of factors, following a weight-of-evidence approach. The following factors (if available), ranked in descending order of importance, should be considered: well-conducted clinical and diagnostic studies, epidemiological studies, with a preference for general population studies over occupational studies, well-conducted animal studies, well-conducted *in vitro* test studies, cross-reactivity data, and case histories. Criteria for a ''well-conducted'' study would include validated outcomes, relevant dosing and route of administration, and use of appropriate controls. Studies should be carried out according to national and/or international test guidelines and according to good laboratory practice (GLP), compliance with good clinical practice (GCP), and good epidemiological practice (GEP).

(B) Before the Commission designates any substance a ''strong'' sensitizer, frequency of occurrence and range of severity of reactions in exposed subpopulations having average or high susceptibility will be considered. The minimal severity of a reaction for the purpose of designating a material a ''strong sensitizer'' is a clinically important reaction. A clinically important reaction would be considered one with loss of function and significant impact on quality of life. Consideration should be given to the location of the hypersensitivity response, such as the face, hands, and feet and persistence of clinical manifestations. For example, strong sensitizers may produce substantial illness, including any or all of the following: substantial physical discomfort and distress, substantial hardship, functional or structural impairment, chronic morbidity.

(C) Additional consideration may be given to Quantitative Structure-Activity Relationships (QSARs), *in silico* data, specific human sensitization threshold values, and other data on potency and sensitizer bioavailability, if data are available and methods are validated. Bioavailability is the dose of the allergen available to interact with a tissue. It is a reflection of how well the skin or another organ can absorb the allergen and the actual penetrating ability of the allergen, including factors such as size and composition of the chemical.

(iii) *Normal living tissue.* The allergic hypersensitivity reaction occurs in normal living tissues, including the skin, mucous membranes (*e.g.,* ocular, oral), and other organ systems, such as the respiratory tract, gastrointestinal tract, or either singularly or in combination, following sensitization by contact, ingestion, or inhalation.

* * * * *

Dated: March 7, 2013.

Todd A. Stevenson,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2013–05577 Filed 3–11–13; 8:45 am]

BILLING CODE 6355–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2009–0710; FRL–9789–4]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Interstate Transport of Fine Particulate Matter

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a portion of a State Implementation Plan (SIP) submittal from the State of New Mexico to address Clean Air Act (CAA or Act) requirements in section 110(a)(2)(D)(i)(I) that prohibit air emissions which will contribute significantly to nonattainment or interfere with maintenance in any other state for the 2006 fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS). EPA proposes to determine that the existing SIP for New Mexico contains adequate provisions to prohibit air emissions from significantly contributing to nonattainment or interfering with maintenance of the 2006 24-hour $PM_{2.5}$ NAAQS (2006 $PM_{2.5}$ NAAQS) in any other state as required by section 110(a)(2)(D)(i)(I) of the Act.

DATES: Comments must be received on or before April 11, 2013.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2009–0710, by one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email:* Mr. Guy Donaldson at *donaldson.guy@epa.gov.* Please also send a copy by email to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- *Fax:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.
- *Mail or Delivery:* Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Deliveries are only accepted ruing the Regional Office's normal hours of operation.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2009–