

*EIS No. 20080249, Final Supplement, BLM, WY, Pinedale Anticline Oil and Gas Exploration and Development Project, Additional Information on Two New Alternatives, Consolidated Development with Year-Round Development (Construction, Drilling, Completion, and Production), Sublette County, WY, Wait Period Ends: 07/28/2008, Contact: Caleb Hiner 307-367-5352.*

*EIS No. 20080250, Draft EIS, FHW, CA, Orange County Gateway Project, To Provide Grade Separation Alternative along the Burlington Northern Santa Fe Railroad Tracks from west of Bradford Avenue to west of Imperial Highway (State Route 90), Cities of Placentia and Anaheim, Orange County, CA, Comment Period Ends: 08/11/2008, Contact: Scott McHenry 916-498-5854.*

*EIS No. 20080251, Draft EIS, AFS, CA, Moonlight and Wheeler Fires Recovery and Restoration Project, Proposes to Harvest Fire-Killed Merchantable Trees on 15,568 Acres, Mt. Hough Ranger District, Plumas National Forest, Plumas County, CA, Comment Period Ends: 08/11/2008, Contact: Rich Bednarski 530-283-7641.*

*EIS No. 20080252, Draft EIS, DHS, 00, National Bio and Agro-Defense Facility, Proposal to Site, Construct, and Operate at one of the Proposed Locations: (1) South Milledge Avenue Site, Clarke County, GA; (2) Manhattan Campus Site, Riley County, KS; (3) Flora Industrial Park Site, Madison County, MS; (4) Plum Island Site, Suffolk County, NY; (5) Umstead Research Park Site, Granville County, NC; and (6) Texas Research Park Site, Bexar and Medina Counties, TX, Comment Period Ends: 08/25/2008, Contact: James V. Johnson 202-254-6098.*

*EIS No. 20080253, Draft EIS, NOA, 00, Amendment 4 to the Spiny Lobster Fishery Management Plan of Puerto Rico and the U.S. Virgin Islands and Amendment 8 to the Spiny Lobster Fishery Management Plan of the Gulf of Mexico and South Atlantic, To Address the Harvest and Exportation of Undersized Lobster Tails to the United States, Comment Period Ends: 08/11/2008, Contact: Roy E. Crabtree, PhD 727-824-5301.*

*EIS No. 20080254, Final EIS, NOA, MA, ADOPTION—Neptune Liquefied Natural Gas (LNG), Construction and Operation, Deepwater Port License Application, (Docket Number USCG-2004-22611) Massachusetts Bay, Gloucester and Boston, MA, Contact: James H. Lecky 301-713-2332. US DOC/NOA adopted the US CGD &*

*MARAD Final Supplemental EIS 20060451 filed 10/27/2006. NOA was a cooperating agency on the project. Recirculation of the document is not necessary under 1506.3(b) of the CEQ Regulations.*

#### Amended Notices

*EIS No. 20080200, Draft EIS, AFS, UT, Dixie National Forest Motorized Travel Plan, Implementation, Dixie National and the Teasdale portion of the Fremont River Ranger District on the Fishlake National Forest, Garfield, Iron, Kane, Piute, Washington and Wayne Counties, UT, Comment Period Ends: 07/22/2008, Contact: Andi Falsetto 435-896-9233. Revision of FR Notice Published 05/23/2008: Extending Comment Period 07/07/2008 to 07/22/2008.*

Dated: June 24, 2008.

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#### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2008-0267; FRL-8371-5]

#### Formaldehyde Emissions from Composite Wood Products; Disposition of TSCA Section 21 Petition

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** On March 24, 2008, 25 organizations and approximately 5,000 individuals petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to use section 6 of TSCA to adopt a recently promulgated California State regulation concerning emissions of formaldehyde from three types of composite wood products: Hardwood plywood, particleboard, and medium density fiberboard. They petitioned EPA to assess and reduce the risks posed by formaldehyde emitted from these products by exercising its authority under TSCA section 6 to: Adopt and apply nationally the California formaldehyde emissions regulation for these composite wood products; and to extend the regulation to include composite wood products used in manufactured homes. For the reasons set forth in this notice, EPA has granted in part and denied in part the petitioners' requests.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact:* Colby

Linter, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

*For technical information contact:* Mary Belefski, Chemical Control Division (7405M), Office Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8461; e-mail address: [belefski.mary@epa.gov](mailto:belefski.mary@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who manufacture, process, import, or distribute in commerce composite wood products, including hardwood plywood, particleboard, or medium density fiberboard and others who are interested in Agency activities involving formaldehyde. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. How Can I Get Information About This Petition?

EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2008-0267. All documents in the docket are listed in the docket's index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is

(202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

## II. Background

### A. What is a TSCA Section 21 Petition?

Section 21 of TSCA allows any person to petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish the necessity for the action requested. EPA is required to grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period.

### B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?

1. *Legal standards regarding TSCA section 21 petitions.* Section 21(b)(1) of TSCA requires that the petition "set forth the facts which it is claimed establish that it is necessary" to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provisions under which actions have been requested to evaluate this petition.

2. *Legal standard regarding TSCA section 6 rules.* In order to promulgate a rule under TSCA section 6(a), the Administrator must find that "there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable

risk." 15 U.S.C. 2605(a). This finding cannot be made considering risk alone. In promulgating any rule under TSCA section 6(a), the statute requires that the Administrator consider:

- The effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture.
  - The effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture.
  - The benefits of such substance or mixture for various uses and the availability of substitutes for such uses.
  - The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.
- 15 U.S.C. 2605(c)(1).

Furthermore, the control measure or measures adopted are to be the "least burdensome requirements" that adequately protect against the unreasonable risk. 15 U.S.C. 2605(a).

Section 21(b)(4)(B) of TSCA provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): "If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that . . . there is a reasonable basis to conclude that the issuance of such a rule . . . is necessary to protect health or the environment against an unreasonable risk of injury," the court shall order the Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B).

### C. What Action is Requested Under this TSCA Section 21 Petition?

On March 24, 2008, the Sierra Club, National Center for Healthy Housing, National Coalition to End Childhood Lead Poisoning, Alliance for Healthy Homes, National Housing Institute, Healthy Building Network, Gulf Coast Environmental Restoration Task Force of Sierra Club, Next Generation Choices Foundation, Improving Kids' Environment, EarthRose Institute, Grassroots Environmental Education, Healthy Homes of Louisiana, Lower Mississippi Riverkeeper, Women's Community Cancer Project, Gulf Coast D'Iberville Volunteers Foundation, Advocates for Environmental Human Rights, Environmental Health Watch, North Gulfport Community Land Trust, Louisiana Environmental Action Network, Allergy and Environmental Health Assoc., Aspen River Construction, DeVany Industrial

Consultant, Protect Sacred Sites "Indigenous People, One Nation," United People of the Cherokee Nation, Clean Air Athens, and approximately 5,000 individuals petitioned EPA under TSCA section 21. The petitioners are concerned about risks to human health from exposure to formaldehyde emitted from composite wood products, including hardwood plywood, particleboard, and medium density fiberboard. They petitioned EPA to assess and reduce these risks by exercising its authority under TSCA section 6 to:

1. Adopt and apply nationally the formaldehyde emissions regulation (Airborne Toxics Control Measure (ATCM)) for three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard), recently adopted by the California Air Resources Board (CARB).

2. Extend the regulation to include composite wood products used in manufactured housing.

Among other requirements, the CARB ATCM specifies cap emission limits that are not to be exceeded.

In this notice, unless otherwise specified, "composite wood products" refers to the three types of wood products (hardwood plywood, particleboard, and medium density fiberboard) referred to in the California regulation. Composite wood products are a subset of "pressed wood products."

### D. What Support Do the Petitioners Offer for These Requests?

To support their request, the petitioners referenced CARB's webpage containing the documentation supporting the composite wood products rulemaking. In addition, petitioners cited information available from Federal agencies including the following:

1. U.S. Department of Housing and Urban Development (HUD), Office of Manufactured Housing Programs, and HUD's formaldehyde emission control regulations at 24 CFR 3280.308.

2. The U.S. EPA National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products at 40 CFR part 63, subpart DDDD regulation.

3. The U.S. Occupational Safety and Health Administration, Formaldehyde Standards for Toxic and Hazardous Substances, 29 CFR 1910.1048.

4. The U. S. Centers for Disease Control and Prevention (CDC) analyses and findings on formaldehyde in the Federal Emergency Management Agency's (FEMA) Hurricane Katrina trailers. The petitioners also

summarized in their submission the findings on exposure levels from the CDC trailer study.

### III. Comments Received

In response to EPA's request for comment on this TSCA section 21 petition (73 FR 22369, April 25, 2008) (FRL-8362-6), EPA received 25 comments. Three were short comments in support of the petition from concerned citizens and furniture manufacturers; one additional furniture manufacturer commented on his concern about effective enforcement against furniture importers. Another comment cautioned that developing a compliance testing method may be very difficult.

Eight manufactured housing trade groups and suppliers submitted similar comments opposed to EPA regulation of manufactured homes. The commenters stated that the HUD's standards have not been shown to be inadequate, HUD has the appropriate statutory authority (and EPA should use TSCA section 9 to refer the matter to HUD), and HUD has already received recommendations to amend its standards. Five furniture, window, door, and general manufacturing trade groups indicated their support for national application of formaldehyde emission standards, but noted that several challenges to the implementation and enforcement of California's rule still need to be worked out. Some indicated support for EPA development of a "performance-based standard" designed to reduce human exposure to formaldehyde, regardless of source (mentioning carpet and paints as other sources of formaldehyde exposure) and all were concerned about the administrative burdens of the CARB rule and California's or EPA's ability to manage the certification and testing requirements.

Three plywood and composite panel trade groups indicated support for expanding CARB's emission limits to the rest of the United States, but commented that a TSCA section 6 rule is neither appropriate nor justifiable. They suggest that a national standard would be "developed in a cooperative effort with industry" rather than through a TSCA section 6 rule. The Hardwood Plywood & Veneer Association (HPVA) stated that it would be willing to join the Manufactured Housing Institute to petition HUD to adopt the CARB standards, and is considering incorporating the CARB emission standards into their next revision of the American National Standards Institute-HPVA standards for hardwood plywood and engineered hardwood flooring. The American

Forest & Paper Association commented that it "supports adoption by EPA of the ATCM emission standards and testing and labeling provisions as a single, national paradigm for formaldehyde in composite wood panels, but developed in a cooperative effort with industry rather than through an (unjustified) Section 6 rule." The Composite Panel Association (CPA) estimated that 80% of their members' medium density fiberboard and particleboard production will be CARB-compliant, and CPA expects the CARB rule to become a de facto national standard. However, since compliance with the Phase 2 standards will be significantly more expensive, CPA commented that there will be a greater incentive to differentiate panel emission level by region or customer. CPA also noted that the industry estimates that the costs of the CARB rule, nationwide, will be close to \$650 million, significantly higher than the cost to affected parties predicted by California (commenters stated that CARB's cost estimate was \$147 million, but it is actually \$127 million). HPVA and CPA also noted concerns about the ability of California or the EPA to enforce the regulation against importers of panels and finished products, and suggested that imports may be a main source of higher emitting panels and finished products.

Comments were also received from a formaldehyde trade group and from a resin manufacturer. Hexion, a "major global supplier of thermosetting adhesives," opposed EPA using section 6 to adopt the California rule, but "could support a national, preemptive regulation limiting formaldehyde emissions from composite wood products . . ." The Formaldehyde Council, Inc. (FCI) disagreed with the idea that there is no safe level of exposure to formaldehyde. FCI also commented that the average level detected in the FEMA trailers does not typically cause sensory irritation, and cited a study of conventional homes, finding an average formaldehyde concentration of 0.37 parts per million (ppm) (370 parts per billion (ppb)), in which the occupants had not complained of irritation. They also cited studies that show sensory irritation thresholds of 0.5 ppm (500 ppb), and up to 0.9 ppm (900 ppb) for unsensitized people, and asserted that the empirical support for the studies that the International Agency for Research on Cancer (IARC) relied on to recategorize formaldehyde has been "steadily eroded."

The Sierra Club commented on the TSCA section 6(c) factors and suggested that EPA consider cost factors

associated with remediating the problems in the FEMA trailers. They suggested that EPA estimate the effect on the national economy by a simple mathematic extrapolation from the costs estimated by California and argue that adopting the ATCM would spur technological innovation and have a positive impact on human health and the environment.

HUD commented that it received (prior to EPA's receipt of this petition) a proposal to lower formaldehyde emissions limits from certain products used in the construction of manufactured homes from the Congressionally established Federal Advisory Committee, the Manufactured Housing Consensus Committee (MHCC). In addition, the MHCC recently received a new proposal from the public to adopt the CARB standard. HUD commented that it will work with the MHCC to review the new proposal regarding CARB levels. A supplemental comment was received from HUD on June 19, 2008, and is in the docket.

On June 13, 2008, EPA received an additional comment from CPA, summarizing new developments since they submitted their first comment. As also noted in their first comment, CPA is accredited by the American National Standards Institute (ANSI) as a standards developer. On June 3, 2008, the CPA Board of Directors "approved the insertion of the CARB Phase 1 and Phase 2 formaldehyde emission limits" into the new versions of the ANSI standards for Particleboard (ANSI A208.1) and for Medium Density Fiberboard (ANSI A208.2). When the standards are finalized, "companies would be able to reference either of those levels from these voluntary standards in their commercial dealings." A consensus committee must still approve the revised standard. A supplemental comment was also received from HPVA on June 17, 2008, and is in the docket.

### IV. Disposition of Petition

For the purpose of making its decision, EPA evaluated the information presented or referenced in the petition and its authority and requirements under TSCA sections 6 and 21. EPA also evaluated comments submitted and relevant information that was otherwise available to EPA during the 90-day petition review period. On the basis of the significant differences in the legal standards applicable to the California Health and Safety Code (H&SC) and TSCA section 6, and the insufficiency of the information available to EPA for purposes of conducting the TSCA section 6 analysis, EPA is not granting

the specific request in the petition to commence a proceeding under TSCA section 6 to impose the CARB formaldehyde ATCM nationwide. Even if the information available to EPA were sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk, petitioners have not provided sufficient information, and EPA does not otherwise have sufficient information, to evaluate whether the CARB ATCM would likely be the least burdensome alternative necessary to protect adequately against such risk. However, EPA has decided to initiate a proceeding to investigate whether and what type of regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from pressed wood products.

The discussion that follows provides the reasons for EPA's decisions to grant this petition in part and to deny it in part.

#### *A. EPA is Not Granting the Petitioners' Specific Requests*

1. *Differences between California's authority under State law, and EPA's authority under TSCA.* The petition requests that EPA use authorities under section 6 of TSCA to "adopt the California rules and apply them nationally," and apply them to composite wood products used in manufactured housing (Ref. 1). The authority under which the State of California issued its ATCM is quite distinct from the regulatory authority granted to EPA under TSCA, however, and EPA has determined that its authority under section 6 of TSCA does not permit it to simply adopt the California formaldehyde ATCM and impose these regulatory controls as a Federal standard without independently determining that formaldehyde in the relevant materials presents or will present an "unreasonable risk" under TSCA section 6(a). Neither the CARB rulemaking record nor other information available to EPA is adequate to support an evaluation of whether the use of formaldehyde in composite wood products presents or will present an unreasonable risk.

CARB's authority to regulate formaldehyde is discussed on pages 2–3 of CARB's "Initial Statement of Reasons" (ISOR), which was used to support its rulemaking (Ref. 2). According to the statement of authority in the ISOR, CARB asserted jurisdiction to regulate formaldehyde in composite wood products under the California H&SC. The H&SC authorizes CARB to control emissions of criteria pollutants and precursors from source categories.

In addition, CARB is authorized to regulate toxic air contaminants (TACs) under that portion of the H&SC known as the Tanner Act. In 1992, CARB identified formaldehyde as a TAC "based primarily on the determination that it was a human carcinogen with no known safe level of exposure" (Ref. 2). According to the ISOR, CARB's formaldehyde ATCM was issued principally under the Tanner Act on the basis of formaldehyde being a TAC. Because CARB had identified formaldehyde as a TAC "with no identified 'safe' threshold exposure level," it was required by the Tanner Act "to reduce emissions of the TAC to the lowest level achievable through application of BACT (best available control technology) or a more effective control method."

The TSCA section 6 authority specifically requested by the petition to be used to adopt and apply nationally the CARB ATCM is significantly different from CARB's authority under the H&SC. As discussed in Unit II.B.2., under TSCA section 6(a), EPA must make a finding that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical presents or will present an unreasonable risk of injury to health or the environment in order to promulgate a TSCA section 6(a) rule. The CARB rulemaking record does not analyze the issues in these terms because CARB does not have to make an unreasonable risk finding under the California H&SC.

TSCA section 6(a) identifies the actions that may be taken to protect against unreasonable risk, but does not prescribe a particular minimum control measure as California's law prescribes BACT. If EPA finds that there is a reasonable basis to conclude that one or more activities presents an unreasonable risk, EPA may:

- Prohibit or limit manufacture, processing, or distribution in commerce;
- Prohibit or limit the manufacture, processing, or distribution in commerce of the chemical above a specified concentration;
- Require adequate warnings and instructions with respect to use, distribution, or disposal;
- Require recordkeeping;
- Prohibit or regulate any manner of commercial use;
- Prohibit or regulate any manner of disposal; or
- Require manufacturers or processors to give notice of the unreasonable risk of injury.

TSCA section 6(a) also states that EPA must determine which one or more of the risk management options set forth in

the statute are the least burdensome means of adequately protecting against the risk. The CARB rulemaking record was constructed to support the single option (BACT or more effective control method) available under the California H&SC, and not for choosing from the multiple options available under TSCA. The California H&SC also does not require that CARB choose the least burdensome means of protecting adequately against the risk.

2. *Information in the petition and otherwise available to EPA is inadequate to support an unreasonable risk evaluation under TSCA.* Notwithstanding the substantial amount of information submitted by reference with the petition or otherwise available to the Agency, EPA has determined that this information is not sufficient to support an evaluation of whether formaldehyde emitted from composite wood products presents or will present an unreasonable risk to human health (including cancer and non-cancer endpoints) under TSCA section 6. Applying the TSCA section 6(a) and 6(c) requirements to the information provided by the petitioners reveals significant information gaps that would need to be filled to support an evaluation of whether use of formaldehyde in composite wood products presents or will present an unreasonable risk. EPA briefly summarizes its reasoning in this unit.

a. *Health risks and exposure.* With respect to health risks, the petition refers to the CARB record and to the CDC study on FEMA trailers, thus looking at both cancer risk and irritation risk. CARB based their health effects evaluation on cancer risk. In 1992, CARB identified formaldehyde as a TAC "based primarily on the determination that it was a human carcinogen with no known safe level of exposure" (Ref. 2). CARB also cites for support the higher (hazard) classification of formaldehyde as "Group 1, Carcinogenic to humans" by the International Agency for Research on Cancer (IARC) (Ref. 2, p. 155, see also Ref. 3). CARB's analysis was dependent on its determination of formaldehyde as a human carcinogen and its assumptions and analyses that rely on animal data and use two different kinds of models, the linearized multi-stage model and a model which takes into account the proliferation of premalignant cells, for quantification of the cancer risk. In this analysis CARB relied upon the animal data considered by EPA in its 1991 analysis and applied an additional model which places the result somewhere between that of EPA's 1991 assessment and that of the Chemical Industry Institute of

Toxicology's (CIIT) biologically based dose response (BBDR) approach used in EPA in 2004 (discussed in this unit). Given the recent availability of human cancer data which may provide the basis of a more appropriate quantification of human cancer risk, EPA questions the adequacy of the CARB approach and for this reason as well as other reasons discussed in this unit, EPA has determined that it is not able to rely on CARB's cancer risk assessment.

EPA has previously assessed formaldehyde's cancer risk. In 1991, EPA classified formaldehyde as a B1, probable human carcinogen, "based on limited evidence in humans, and sufficient evidence in animals" (Ref. 4). Increased incidences of nasal squamous cell carcinomas were observed in long-term inhalation studies in rats and mice. Based on the nasal cavity cancer data in rats and using a linearized multi-stage procedure (for genotoxic effects), EPA calculated an inhalation cancer unit risk/potency factor of  $1.3 \times 10^{-5}$  per microgram/meter cubed ( $\mu\text{g}/\text{m}^3$ ) (Ref. 4). As explained in this unit, the assessment and modeling procedure used to develop EPA's cancer risk assessment is not based on the most current information, and EPA may determine that the appropriate unit risk/potency factor is higher or lower than the 1991 value, after considering the currently available scientific information, including human data.

CIIT developed a health risk assessment for formaldehyde based upon animal toxicology data that utilized mechanistic and biological response information to develop a dose response model for the risk of squamous cell carcinoma in the respiratory tract (Ref. 5). The resulting BBDR model was published in the peer reviewed literature (Refs. 6–8). The cancer estimates obtained with the BBDR model are generally 2–3 orders of magnitude lower than corresponding estimates obtained with the linearized multistage procedure. In 2004, EPA's Office of Air and Radiation (OAR) determined that the CIIT's BBDR model was the most appropriate tool to assess the potential cancer risk associated with formaldehyde emissions to the atmosphere (Refs. 9–11). In the Plywood and Composite Wood Products National Emission Standard for Hazardous Air Pollutants (NESHAP), which was issued in 2006, OAR stated "In the case of formaldehyde, we have determined that the cancer potency derived using the approach developed by CIIT, which has been peer reviewed by an external review panel sponsored by EPA and the Canadian government, represents an

appropriate alternative to EPA's current IRIS URE for formaldehyde. Therefore, this potency represents the best available peer-reviewed science at this time." (Ref. 10, p. 8348).

In April 2008, the EPA Office of Pesticide Programs (OPP) issued a preliminary risk assessment of formaldehyde for the reregistration eligibility decision (RED) as part of Phase 3 of a modified, 4-Phase public participation process that the Agency uses to involve the public in developing pesticide reregistration decisions (Ref. 12). Through the reregistration program, EPA is ensuring that all pesticides meet current health and safety standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In this preliminary risk assessment, OPP decided to present the formaldehyde cancer risks as a range using both the 1991 EPA assessment and the CIIT BBDR model (Ref. 15). This approach, which recently underwent public comment, brackets a range of cancer risk estimates that span about three orders of magnitude (or a factor of a thousand), and depending on which value is being considered suggests potentially significant risk at one end and potentially insignificant risk at the other. In addition to these assessments, IARC, in their reevaluation of epidemiologic studies, concluded that there was "sufficient epidemiological evidence that formaldehyde causes nasopharyngeal cancer in humans," and upgraded formaldehyde to "Group 1, carcinogenic to humans" from "Group 2A, probably carcinogenic to humans" (Ref. 3). In addition, IARC concluded that "there is strong but not sufficient evidence for a causal association between leukemia and occupational exposure to formaldehyde" (Ref. 3). With these new human data, and considering the other available data, EPA's Office of Research and Development (ORD) is currently engaged in a re-assessment/update of the potential cancer and non-cancer risks of formaldehyde through the ORD Integrated Risk Information System (IRIS) program. An external peer review draft of this assessment is expected to be released in 2009. EPA offices which may be considering or are actively regulating formaldehyde, including the Office of Pollution Prevention and Toxic Substances (OPPTS), will coordinate and proceed accordingly once the assessment is finalized.

As discussed previously, because of the uncertainties in estimating formaldehyde's cancer risks, and the ongoing development of the science

with respect to cancer characterization and risk estimation based on the new human data, EPA has determined that it cannot rely on the CARB cancer assessment and believes it would be premature to render judgment on this complex issue for TSCA section 6 purposes. Thus, EPA does not believe that it has information sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk.

In addition, in the chronic exposure analysis for composite wood, the CARB rulemaking record makes assumptions that are not believed to be reasonable for use in an EPA risk assessment. For example, CARB assumed that individuals will live in new houses (and have associated elevated formaldehyde exposures) for 70 years. Their analysis did not account for formaldehyde concentration decay over time in new home environments, and they assumed all time spent indoors is spent at the same average formaldehyde concentration as at home, and that all time at home is spent indoors (Ref. 13).

With respect to irritation risk, the CDC study on FEMA trailers cited by petitioners provides data on exposure to formaldehyde in trailers, but does not provide a risk analysis. CARB did not rely on irritation risks for their decision to regulate formaldehyde emissions from composite wood products.

For these reasons, EPA believes that the information available on health risks (including cancer and non-cancer effects) and exposure is not adequate to support an unreasonable risk evaluation.

b. *Economics.* The economic analysis supporting CARB's ATCM is inadequate to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk. In its ISOR, CARB quantified some of the costs and benefits for the ATCM, but not all of the costs or any non-cancer benefits.

The ISOR estimated, for example, the cost for industry to comply with the ATCM using various substitute resin systems and discussed the characteristics, advantages, and disadvantages of these substitutes, as well as their effectiveness in reducing formaldehyde emissions from composite wood products. The ISOR cost estimate was based on the cost to purchase substitute resins and on the longer processing times required to manufacture composite wood products when using certain substitute resins. CARB received public comments on its rulemaking that companies will incur additional costs to manufacture

compliant panels due to increased costs for resin additives, new equipment, additional energy usage, or decreased throughput. In responding to these comments, CARB indicated that these costs would not necessarily be incurred, and that it expected future innovations in resin technology would decrease production costs over time. EPA suspects that the CARB analysis underestimated costs, particularly in the short term. But EPA was not able to assess the full extent of the likely costs based on the information available. For example, the ISOR cost estimate also does not fully reflect other requirements of the ATCM, such as third party certification and labeling. In addition, because data were not available on the quantity of composite wood contained in imported fabricated goods such as cabinets and furniture, the ISOR cost estimates did not reflect the increase in the cost of these goods. Thus, the information submitted provides an inadequate basis for assessing total incremental cost for the ATCM, or for a national version of the ATCM, including certification, labeling, and related activities required by the ATCM.

The trade associations representing composite wood product manufacturers have indicated that the CARB limits may have a significant impact on the national markets. For example, CPA estimated that 80% or more of its members' production nationwide will be compliant with CARB's requirements. The associations indicated, however, that they could not estimate how foreign manufacturers and importers will respond to the ATCM and that off-shore producers are an issue because they do not participate in the same voluntary compliance programs that are applicable to domestic producers. Furthermore, especially in view of the expected growth in imports of composite wood products and the fabricated goods made from them, the national baseline following the implementation of the CARB rule, which EPA would use as a starting basis in assessing whether there is an unreasonable risk, is uncertain (Ref. 13).

In addition to cancer benefits, the ATCM may result in benefits from avoided cases of non-cancer effects. The CARB ISOR does not, however, present sufficient information to assess benefits from non-cancer effects. For example, the CARB ISOR mentions a hazard quotient for non-cancer inhalation impacts, but the hazard quotient was not evaluated to estimate the number of people exposed to a hazard quotient above 1, the aggregate length of time that such exposures occur, and the intensity of the exposure over time. In

addition, the ISOR did not provide information on the size of the population exposed or the intensity of exposure from composite wood products in remodeled homes, newly purchased furniture, or non-residential settings. The benefits of avoiding irritation effects include reductions in medical costs, individuals' willingness to pay to avoid the pain and suffering resulting from these effects, and increases in productivity due to a decline in lost work days and school days. The ISOR and the other information available to EPA does not provide sufficient information to estimate the non-cancer benefits.

Thus, EPA does not have sufficient information to support an evaluation of the costs and benefits of implementing the ATCM requirements nationwide.

3. *Information in the petition and otherwise available to EPA is insufficient to support an evaluation of whether the CARB rule would be the least burdensome requirement under TSCA.* Even if the information available to EPA were sufficient to support an evaluation of whether formaldehyde in composite wood products presents or will present an unreasonable risk, petitioners have not provided sufficient information, and EPA does not otherwise have sufficient information, to evaluate whether the CARB ATCM would likely be the least burdensome alternative necessary to protect adequately against such risk. The information submitted with the petition does not provide an adequate basis for EPA to evaluate the likely costs and benefits of less burdensome alternatives. This is not surprising, since the CARB rulemaking does not require such an analysis. For example, EPA has no basis to evaluate whether the specific emission levels adopted by CARB would be appropriate levels under TSCA section 6, whether CARB's cap approach or an average emissions approach would be more appropriate, or whether the additional detailed requirements pertaining to third-party certification and other issues would be appropriate. Several aspects of the CARB ATCM are not in place yet, and EPA is not able to evaluate those aspects. Beyond that, it is entirely possible that some control measure(s) other than the emission cap approach that CARB selected for their ATCM would be appropriate. Especially in view of estimates in the record of nationwide compliance with the ATCM, EPA would want to assess the risk that was likely to remain following compliance with the rule and assess whether one or more of the options under TSCA section 6(a) was more

appropriate to address the remaining risk.

In summary, information in the petition and otherwise available to EPA, including health effects, exposure, and economic information, is inadequate to support an evaluation of whether there is an unreasonable risk under TSCA. Therefore, EPA is not granting the specific request in the petition to commence a proceeding under TSCA section 6 to impose the CARB formaldehyde ATCM nationwide.

#### *B. Additional Considerations*

Pressed wood products, of which the three composite wood products regulated by CARB are a subset, are a major source of formaldehyde concentrations. Other sources of formaldehyde include smoking, household products, and the use of un-vented, fuel-burning appliances like gas stoves or kerosene space heaters (Refs. 16 and 17). Formaldehyde emissions from pressed-wood products are the highest when these products are new and decline over time. Emissions of formaldehyde will increase as the temperature, humidity, and pressed wood surface area increase (Ref. 13).

Several Federal agencies and other entities have regulated or produced guidelines on appropriate air concentrations of formaldehyde. HUD presently limits formaldehyde emissions from plywood and particleboard used in manufactured home construction to 200–300 ppb, and is reviewing proposals to revise those emission limits. Among others, the Agency for Toxic Substances and Disease Registry (ATSDR) has established a Minimal Risk Level (MRL) chronic value of 0.008 ppm/8ppb; the National Institute for Occupational Safety and Health (NIOSH) has established a Recommended Exposure Limit (REL) of 0.016 ppm/16ppb (8-hour Time Weighted Average), and of 0.1 ppm/100ppb (15 minute ceiling); and American Conference of Governmental Industrial Hygienists (ACGIH) has established threshold limit value (TLV)-Ceiling of 0.3 ppm/300 ppb (Ref. 13).

In March 2008, several Federal agencies, including the Department of Health and Human Services (HHS), CDC, U.S. Department of Homeland Security (DHS), FEMA, and EPA finalized a document entitled: "Formaldehyde Exposure in Homes: A Reference for State Officials to Use in Decision-making," which summarizes the environmental health related aspects of formaldehyde exposure in homes and references the government standards in occupational settings (Ref. 14).

Foreign governments, including Japan and the European Union, have also regulated permissible levels of formaldehyde emissions from composite wood products and other building materials (Ref. 2).

EPA previously assessed formaldehyde's cancer risk based on the nasal cavity cancer data in rats and using a linearized multi-staged procedure (for genotoxic carcinogens) (Ref. 4). EPA is conducting a re-assessment/update of the potential cancer risks of formaldehyde through the Integrated Risk Information System (IRIS) process that will consider current human data and other data.

Depending on concentration, it is well recognized that formaldehyde can be an eye, nose, and throat irritant, even when exposure is of relatively short duration. In the indoor environment, sensory reactions and various symptoms as a result of mucous membrane irritation are potential effects, and, while there are large individual differences in the general population, the differences are even greater when hyper-reactive and sensitized people are included in an analysis. EPA acknowledges that there are uncertainties relating to irritation response levels in humans.

In light of information about the hazards of formaldehyde, in combination with the potential for prolonged exposure to potentially problematic levels of formaldehyde by residents in newly constructed housing (Ref. 13), EPA believes it is appropriate, in the Agency's discretion, to initiate a proceeding to better understand the risks from formaldehyde in pressed wood products (including the three types of composite wood regulated by CARB) and to assess various alternatives that EPA might pursue to address such risks. Most of the exposure information presently available to EPA pertains to formaldehyde emissions from pressed wood products in newly built homes (Ref. 13). While emissions from pressed wood products used in new home construction are themselves significant sources of formaldehyde in indoor air, EPA is interested in what other pressed wood sources contribute significantly to formaldehyde concentrations in indoor air. For example, large renovations projects in existing homes, which include a large amount of new pressed wood products, and microenvironments, such as baby cribs built with pressed wood products, could be important sources of exposure to a large number of children and adults.

The available information, guidelines, and regulations span a wide range of permissible formaldehyde levels. EPA believes that it is appropriate to

examine these various standards, analyze the risk level for formaldehyde in pressed wood products, and determine the appropriate course of action to reduce risks to human health.

#### *C. EPA's Decision to Initiate a Proceeding to Investigate Formaldehyde in Pressed Wood Products*

In sum, the petition does not, as required under TSCA section 21, set forth facts sufficient to establish that it is necessary to initiate a proceeding under TSCA section 6(a) to protect human health against an unreasonable risk of injury by applying the CARB regulation on a national basis. Further, the additional relevant information that EPA has identified does not support initiation of the requested proceeding. However, after considering the facts presented by the petitioners (including the California administrative record), information presented by commenters, and other information available to EPA, EPA has decided to initiate a proceeding to investigate whether and what type of regulatory or other action might be appropriate to protect against risks posed by formaldehyde emitted from pressed wood products.

In parallel with this effort, EPA's ORD will be developing and obtaining external peer review for the IRIS assessment of formaldehyde's cancer and non-cancer risks. OPPTS will coordinate with ORD and other EPA offices as it evaluates risks and options under TSCA, and the results of the IRIS effort will be incorporated into this proceeding if timely available. In addition, the preliminary risk assessment used in the Pesticide Reregistration Program will be considered in the effort to evaluate risks and options under TSCA if timely available, and OPP will also consider the efforts under TSCA, as well as other efforts.

In Fall 2008, EPA plans to issue an advance notice of proposed rulemaking (ANPR) to initiate a proceeding. As part of the ANPR process, EPA will engage stakeholders to contribute to obtaining a better understanding of the available control technologies and approaches, industry practices, and the implementation of CARB's ATCM. Concurrently, EPA plans to develop and conduct an industry survey and initiate development of an exposure assessment and an irritation concern level that could be used for evaluating emissions standards or other approaches. Subsequently, EPA plans to develop an irritation risk assessment, which will receive the appropriate external review, and quantify costs and benefits. At the conclusion of this work, OPPTS

anticipates determining whether it should take action, which may include action under TSCA section 6(a) or TSCA section 6(b), or via the development of a voluntary consensus standard or other approaches. As OPPTS evaluates risks and options under TSCA, OPPTS intends to coordinate its efforts with other interested EPA offices and agencies, as well as engage the public and stakeholders.

With respect to the petitioners' request that EPA use TSCA section 6 to apply the CARB rule to manufactured homes, EPA notes that HUD has regulations governing formaldehyde emission levels from plywood and particleboard materials installed in manufactured homes. (See 24 CFR 3280.308.) HUD is in the process of reviewing proposed changes to these regulations to include medium density fiberboard, among other things. HUD is also currently reviewing a proposal to amend its manufactured housing regulations governing formaldehyde to include the standards set forth in the CARB regulation. Section 9(d) of TSCA provides that the Administrator of EPA shall consult and cooperate with other Federal agencies "for the purpose of achieving the maximum enforcement of [TSCA] while imposing the least burdens of duplicative requirements." 15 U.S.C. 2608(d). Consistent with this provision, EPA will consult and cooperate with HUD as the two agencies work to address formaldehyde emissions from composite wood products.

#### **V. References**

The following is a list of the documents that are specifically referenced in this notice and placed in the docket that was established under Docket ID number EPA-HQ-OPPT-2008-0267. For information on accessing these documents in the docket, refer to Unit I.B. Some documents may also be accessed directly using the url provided.

1. Sierra Club, 25 other organizations, and approximately 5,000 individuals. Letter from Tom Neltner, Sierra Club, to Stephen Johnson, Administrator, Environmental Protection Agency. Re: Citizen Petition to EPA Regarding Formaldehyde in Wood Products. March 20, 2008.

2. California Environmental Protection Agency Air Resources Board. Proposed Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products, Staff Report: Initial Statement of Reasons for Proposed Rulemaking. March 9, 2007. <http://www.arb.ca.gov/>

[regact/2007/compwood07/compwood07.htm](http://regact/2007/compwood07/compwood07.htm).

3. International Agency for Research on Cancer (IARC). Formaldehyde. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans.

International Agency for Research on Cancer. Lyon, France. Meeting on June 2–9, 2004, as published by IARC in 2006. Vol. 88. <http://monographs.iarc.fr/ENG/Monographs/vol88/index.php>.

4. EPA, Office of Research and Development. Formaldehyde. Integrated Risk Information System. 1991. <http://www.epa.gov/iris/links.htm>.

5. Chemical Industry Institute of Toxicology (CIIT). Formaldehyde hazard characterization and dose-response assessment for carcinogenicity by the route of inhalation, revised ed. Chemical Industry Institute of Toxicology, Research Triangle Park, NC. 1999.

6. Conolly, R.B., Kimbell, J.S., Janszen, D., and Miller, F., J. Dose-response for formaldehyde-induced cytotoxicity in the human respiratory tract. *Regulatory Toxicology and Pharmacology*. 35: 32–43. 2002.

7. Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., and Miller, F., J. Biologically-motivated computational modeling of formaldehyde carcinogenicity in the F344 rat. *Toxicological Sciences*. 75:432–447. 2003.

8. Conolly, R.B., Kimbell, J.S., Janszen, D., Schlosser, P.M., Kalisak, D., Preston, J., and Miller, F., J. Human respiratory tract cancer risks of inhaled formaldehyde: Dose-response predictions derived from biologically-motivated computational modeling of a combined rodent and human dataset. *Toxicological Sciences*. 82: 279–296. 2004.

9. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; Effluent Limitations Guidelines and Standards for the Timber Products Point Source Category; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List; Final Rule. **Federal Register** (69 FR 45943, July 30, 2004) (FRL–7634–1). <http://www.epa.gov/ttn/atw/plypart/fr30jy04.pdf>.

10. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List; Final Rule. **Federal Register** (71 FR 8341, February 16, 2006) (FRL–8028–9). <http://www.epa.gov/ttn/atw/plypart/fr16fe06.pdf>.

11. EPA. National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; Final Rule. **Federal Register** (72 FR 61060, October 29, 2007) (FRL–8482–2). <http://www.epa.gov/ttn/atw/plypart/fr29oc07.pdf>.

12. EPA. Formaldehyde/Paraformaldehyde Risk Assessments; Notice of Availability and Risk Reduction Options; Notice. **Federal Register** (73 FR 21944, April 23, 2008) (FRL–8360–3). <http://www.epa.gov/fedrgstr/EPA-PEST/2008/April/Day-23/p8684.htm>.

13. EPA. Background Document of Technical Information Relevant to the Disposition of the TSCA Section 21 Petition on Formaldehyde. June 2008. Docket ID number EPA–HQ–OPPT–2008–0267.

14. Department of Health and Human Services, Centers for Disease Control and Prevention, Department of Homeland Security, Federal Emergency Management Agency, and EPA. Formaldehyde Exposure in Homes: A Reference for State Officials to Use in Decision-Making. March 2008. <http://www.cdc.gov/nceh/ehhe/trailerstudy/compendium.htm>.

15. EPA. Formaldehyde: Preliminary Risk Assessment for the Registration Eligibility Decision (RED). DP Barcode: 348474, April 7, 2008. Docket ID number EPA–HQ–OPP–2008–0121. <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2008-0121>.

16. CPSC. 1997. An Update On Formaldehyde: 1997 Revision. Consumer Product Safety Commission, Washington, DC, CPSC Doc. #725 <http://www.cpsc.gov/cpsc/pub/pubs/725.html>.

17. EPA. 2007. Indoor Air Quality (IAQ), Pollutants and Sources of Indoor Air Pollution, Formaldehyde/Pressed Wood Products, Office of Radiation and Indoor Air (ORIA), Indoor Environments Division, Washington, DC, Updated November 14, 2007. <http://www.epa.gov/iaq/formalde.html#Levels%20in%20Homes>.

#### List of Subjects

Environmental protection, Composite wood products, Formaldehyde, Housing, Toxic Substance Control Act (TSCA).

Dated: June 21, 2008.

**James B. Gulliford**,  
Assistant Administrator, Office of Prevention,  
Pesticides and Toxic Substances.

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## ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2008–0102; FRL–8369–6]

### Exposure Modeling Public Meeting

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** An Exposure Modeling Public Meeting (EMPM) will be held for one day on July 22, 2008. This notice announces the location and time for the meeting and sets forth the tentative agenda topics.

**DATES:** The meeting will be held on July 22, 2008 from 9:00 am to 4:00 pm.

To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

**ADDRESSES:** The meeting will be held at Environmental Protection Agency, Office of Pesticide Programs (OPP), One Potomac Yard (South Building), 1st Floor South Conference Room, 2777 S. Crystal Drive, Arlington, VA 22202.

**FOR FURTHER INFORMATION CONTACT:** Michael Barrett, Environmental Fate and Effects Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6391; fax number: (703) 305–6309; e-mail address: [barrett.michael@epa.gov](mailto:barrett.michael@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA), the Federal Food, Drug and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket ID number EPA–HQ–OPP–2008–0102.