

establish regulatory requirements to ensure that ozone-depleting substances (ODS) are replaced by alternatives that reduce overall risks to human health and the environment, and to promote an expedited transition to safe substitutes. To promote this transition, CAA specified that EPA establish an information clearinghouse of available alternatives, and coordinate with other Federal agencies and the public on research, procurement practices, and information and technology transfers.

Since the program's inception in 1994, SNAP has reviewed over 400 new chemicals and alternative manufacturing processes for a wide range of consumer, industrial, space exploration, and national security applications. Roughly 90% of alternatives submitted to EPA for review have been listed as acceptable for a specific use, typically with some condition or limit to minimize risks to human health and the environment.

Regulations promulgated under SNAP require that Motor Vehicle Air Conditioners (MVACs) retrofitted to use a SNAP substitute refrigerant include basic information on a label to be affixed to the air conditioner. The label includes the name of the substitute refrigerant, when and by whom the retrofit was performed, environmental and safety information about the substitute refrigerant, and other information. This information is needed so that subsequent technicians working on the MVAC system will be able to service the equipment properly, decreasing the likelihood of significant refrigerant cross-contamination and potential failure of air conditioning systems and recovery/recycling equipment.

**Burden Statement:** The annual public reporting and recordkeeping burden for this collection of information is estimated to average 5 minutes per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information;

and transmit or otherwise disclose the information.

The ICR provides a detailed explanation of the Agency's estimate, which is only briefly summarized here:

**Estimated total number of potential respondents:** 6,500.

**Frequency of response:** Once per a retrofit done on a motor vehicle air conditioner.

**Estimated total annual burden hours:** 1,500 hours.

**Estimated total annual costs:** \$205,000 which includes an estimated burden cost of \$100,000 for recordkeeping and an estimated cost of \$105,000 for capital investment or maintenance and operational costs.

The U.S. Department of Labor statistics indicated from the most current available data that there are approximately 650,000 automotive service technicians and mechanics (SOC Code Number 49-3023) in the US. Data from the Motor Air Conditioning Society (MACS) Worldwide, estimated that the mobile air conditioning service industry has over 170,000 service providers and over 600,000 technicians (MACS, 2008). EPA estimated that approximately 1% of the total automotive service technicians, or 6,500, would be responsible for retrofitting the estimated 100,000 MVACs over the three-year term of this ICR.

EPA estimated the time to complete and apply the label at 5 minutes per MVAC, making the total burden 4500 hours over three years (1,500 hours per year). At an estimated average labor rate of \$70 per hour, the overall cost associated with the burden hours is \$315,000 over three years (\$105,000 per year). The cost for designing, typesetting, printing and distributing 55,000 labels is estimated at \$0.10 per label to be \$5,500 (\$1,833.33 per year). Adding the labor and capital costs together yields a total cost burden of \$320,500 (\$106,833.33 per year).

The Agency welcomes public comment on the number of CFC-12 MVACs that will undergo a retrofit, the number of MVAC service technicians performing such service, the average labor rate of MVAC service technicians from 2007 to 2010 and any other relevant information.

#### **Are There Changes in the Estimates From the Last Approval?**

Based on the decline of CFC-12 MVACs in service today EPA estimates a continued reduction in the number of CFC-12 MVACs retrofits that will occur during the next three years. EPA estimated that the total percent of CFC-12 MVACs retrofitted in 2003 was 1.5%,

which equals an estimated 500,000 CFC-12 MVACs retrofitted to R-134a. EPA observed from MACS survey data that for each year, starting from 2003, an approximate decrease of 1% of retrofits occurred. Therefore, every three years, the amount of retrofits decreases approximately 3%. Based on this trend analysis, EPA estimated that the total percent CFC-12 MVACs retrofits for 2006, 2009, and 2012 are 0.5%, 0.2%, and a 0.1%, for an estimate of 62,000, 7,000 and 700, respectively. These reductions are due to the decrease of CFC-12 MVACs available on the road for retrofitting.

#### **What Is the Next Step in the Process for This ICR?**

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Dated: February 16, 2010.

**Brian J. McLean,**

*Director, Office of Atmospheric Programs.*

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**BILLING CODE 6560-50-P**

#### **ENVIRONMENTAL PROTECTION AGENCY**

[EPA-HQ-OPPT-2010-0015; FRL-8810-4]

#### **Baled Natural Rubber in Tires; TSCA Section 21 Petition; Agency Response**

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's response to a petition it received under section 21 of the Toxic Substances Control Act (TSCA). The petition was received from an individual on November 19, 2009. The petitioner requested EPA to "establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said rubber fails to satisfy *The American Society for Testing Materials method ASTM D1076-06* (Category 5)." The petition states: "Implementation of an EPA regulation that guides tire

manufacturers to use *Hevea brasiliensis* baled natural-rubber that satisfies ASTM D1076-06 (Category 5) may affect the incidence of *Hevea brasiliensis* natural-rubber allergies and allergy induced autism." After careful consideration, EPA has denied the TSCA section 21 petition for the reasons discussed in this notice.

**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: Robert Jones, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8161; e-mail address: [jones.robert@epa.gov](mailto:jones.robert@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 you if you manufacture, process, import, or distribute in commerce *Hevea brasiliensis* natural rubber. Potentially interested entities may include, but are not limited to:

- Tire Manufacturing (NAICS code 32621).
- Tire Manufacturing, except retreading (NAICS code 326211).
- Tire Retreading (NAICS code 326212).
- Tire and Tube Merchant Wholesalers (NAICS code 423130).
- Tire Dealers (NAICS code 441320).
- Recyclable Material Merchant Wholesalers (NAICS code 423930).
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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 Access Information About this Petition?

EPA has established a docket for this TSCA section 21 petition under docket identification (ID) number EPA-HQ-OPPT-2010-0015. All documents in the docket are listed in the docket 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 legal 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 Action was Requested Under this TSCA Section 21 Petition?

On November 19, 2009, an individual filed a petition with EPA to "establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said rubber fails to satisfy *The American Society for Testing Materials method ASTM D1076-06* (Category 5)," because "Implementation of an EPA regulation that guides tire manufacturers to use *Hevea brasiliensis* baled natural-rubber that satisfies ASTM D1076-06 (Category 5) may affect the incidence of *Hevea brasiliensis* natural-rubber allergies and allergy induced autism" (Refs. 1 and 2).

This petition is similar to a previous petition that the same individual filed with EPA in March 2008 requesting that EPA "establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* [italics added] natural rubber latex adhesives having a total protein content greater than 200

micrograms per [gram] dry weight of latex based on the American Society for Testing and Materials method ASTM D1076-06 (Category 4)." EPA denied the petition in June 2008 (Ref. 3).

###### B. What Support Does the Petitioner Offer for this Request?

1. Exhibit A is a Portable Document Format (PDF) of a webpage from the website of the *Journal of Allergy and Clinical Immunology* ([http://www.jacionline.org/article/S0091-6749\(95\)70156-7/abstract](http://www.jacionline.org/article/S0091-6749(95)70156-7/abstract)), dated November 13, 2009, providing an abstract of an article entitled "Latex Allergen in Respirable Particulate Air Pollution" (Ref. 1). Exhibit A is offered to support the petitioner's statements that "tires contain ... *Hevea brasiliensis* baled natural-rubber," "Hev-b proteins<sup>1</sup> are extractable from tire natural-rubber dust," "urban air samples have been shown to contain irregular inhalable-black particulates from airborne tire natural-rubber dust," and "the impact of the particles should be considered in the issue of morbidity and mortality rates associated with respiratory diseases and air pollution." For purposes of reviewing the petition, EPA obtained a full copy of the article (Ref. 8).

2. Exhibit B is a PDF of a webpage from the website of NOVA Science Publishers, Inc., ([http://www.novapublishers.com/catalog/advanced\\_search\\_result.php?keywords=allergies+and+autism&x=13+y=9](http://www.novapublishers.com/catalog/advanced_search_result.php?keywords=allergies+and+autism&x=13+y=9)) dated November 13, 2009, which advertises, and includes an abstract of, a publication written by the petitioner entitled "Allergies and Autism" (Ref. 1, Exhibit B) is offered to support the petitioner's statements that "Hev-b proteins affect the incidence of hyper-adaptive immunity and atypical neurological development in allergy sensitive children," and "repeated exposure to the Hev-b proteins from *Hevea brasiliensis* baled natural-rubber has been shown to cause an increased incidence of allergies." According to NOVA Science Publishers, Inc., "Allergies and Autism" is scheduled to be published in the first quarter of 2010. At EPA's request, the petitioner provided EPA with a copy of his publication, which "explores how certain proteins induce hyper adaptive-immunity affecting Autism Spectrum Disorders" (Ref. 4).

3. Exhibit C is a PDF of a photograph labeled "VYTEX-BALE." Exhibit C is offered to support the petitioner's statement that "ultra low-protein *Hevea*

<sup>1</sup> The petition refers to antigenic proteins from *Hevea brasiliensis* as "Hev-b proteins."

*brasiliensis* baled natural-rubber is available commercially” (Ref. 1).

*C. What are the Legal Standards Regarding TSCA Section 21 Petitions and TSCA Section 6 Rules?*

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 are required to issue the requested rule or order. In addition, TSCA section 21 establishes standards that a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B).

The petition asks EPA to “establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said rubber fails to satisfy *The American Society for Testing Materials method ASTM D1076-06* (Category 5),” but does not state under which provision of TSCA the regulation should be issued. Only TSCA section 6, however, appears to be applicable, because it authorizes the promulgation of regulations on chemical substances and mixtures to the extent necessary to protect adequately against unreasonable risk, including prohibiting the manufacture or distribution in commerce of a chemical substance for a particular use. Accordingly, EPA has relied on the standards in TSCA section 21 and section 6 to evaluate this petition.

In order to promulgate a rule under TSCA section 6, the EPA 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 of injury to health or the environment.” 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 EPA 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 adopted is to be the “least burdensome requirement” that adequately protects 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 or order is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment,” the court shall order the EPA Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B).

**III. Disposition of the TSCA Section 21 Petition**

*A. What is EPA’s Response?*

After careful consideration, EPA has denied the petition. A copy of the Agency’s response, which consists of a letter to the petitioner, is available in the docket for this TSCA section 21 petition.

*B. What is EPA’s Reason for this Response?*

The petition asks EPA to “establish regulations prohibiting the use and distribution in commerce of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said rubber fails to satisfy *The American Society for Testing Materials method ASTM D1076-06* (Category 5),” because “Implementation of an EPA regulation that guides tire manufacturers to use *Hevea brasiliensis* baled natural-rubber that satisfies ASTM D1076-06 (Category 5) may affect the incidence of *Hevea brasiliensis* natural-rubber allergies and allergy induced autism.” According to the petition, ASTM D1076-06 (Category 5) “defines *Hevea brasiliensis* natural-rubber latex having total protein content less than 200 µg/dm<sup>2</sup> and an antigenic Hev-b protein content less than 10 µg/dm<sup>2</sup>” (Ref. 1).

However, there is at present no ASTM D1076-06 (Category 5). ASTM refers to ASTM International (formerly the American Society for Testing Materials), which is a voluntary organization that develops consensus technical standards

for materials, products, systems, and services. See <http://www.astm.org>, ASTM D 1076-06, “Standard Specification for Rubber—Concentrated, Ammonia Preserved, Creamed, and Centrifuged Natural Latex,” is a specification that “covers requirements for first grade concentrated natural rubber latex” in only four categories. An ASTM D1076-06 (Category 5) does not yet exist. See <http://engineers.ihs.com/document/abstract/SKGGJBAAAAAAAAAA>, last visited December 9, 2009.

For the following reasons, the petition does not set forth facts sufficient to establish that it is necessary to issue a rule that prohibits the use and distribution in commerce of *Hevea brasiliensis* baled natural rubber for the manufacture of tires that has a “total protein content less than 200 µg/dm<sup>2</sup> and an antigenic Hev-b protein content less than 10 µg/dm<sup>2</sup>” (Ref. 1) in order to protect human health or the environment against unreasonable risk of injury.

First, the petitioner has not presented or identified any direct evidence that *Hevea brasiliensis* natural rubber antigens, or any other antigens, cause, induce, or affect autism. Based on the evidence provided by the petitioner (Exhibit B and the petitioner’s publication entitled “Allergies and Autism”) and evidence otherwise available to EPA, this idea is an unproven hypothesis (Refs. 1, 5, and 6). In “Allergies and Autism,” the petitioner states that “[a]llergy induced Autism is an area of research wherein immune responses to certain environmental proteins, and foodstuff proteins, may affect the development and intensity of atypical behaviors within the Autism Spectrum.” Thus, the petitioner recognizes that the allergy-induced-autism proposition remains indefinite and unproven. Moreover, reviewing different paths of research, the petitioner repeatedly characterizes “allergy induced autism” as a “hypothesis.” The petitioner also asserts that “research has shown that allergy may play a role in the pathogenesis of Autism,” and cited a study that purported to find “a significant positive association between autistic severity and the frequency of allergic manifestations.” However, the cited study does not directly test the allergy-induced-Autism hypothesis, notes that the causes of autism are “an area of significant controversy,” and only concludes that the “significant positive association between these manifestations and important disease characteristics . . . may shed light on the possible causal role of allergy in some

autistic children” (Ref. 5). A recent consensus report published in *Pediatrics*, the official peer-reviewed journal of the American Academy of Pediatrics, concludes that a direct cause-and-effect relationship between immune dysfunction and Autism Spectrum Disorders has yet to be proven (Ref. 6). Based on its controversial nature, the allergy-induced-Autism hypothesis and the supporting evidence are insufficient to sustain a finding of unreasonable risk required to support a regulation under TSCA section 6.

In addition, as noted in the **Federal Register** notice (Ref. 3) denying the petitioner’s previous petition, *Hevea brasiliensis* natural rubber latex allergies have already been the subject of considerable Federal Government evaluation. For example, the Consumer Protect Safety Commission concluded that the incidence of natural rubber latex allergy in the general population was very low (below 1%), that many consumer products contain natural rubber latex, and that “in spite of the prevalence of [natural rubber latex] in consumer products, there are few documented cases of reactions to [natural rubber latex]-containing consumer products,” most of which involved medical devices. See EPA’s response to the petitioner’s previous petition for a more detailed discussion (Ref. 3).

Second, the petition fails to demonstrate that there is a sufficient level of exposure to *Hevea brasiliensis* antigenic proteins<sup>2</sup> from the use of *Hevea brasiliensis* baled natural rubber in tires to cause adverse effects from this exposure. Available data are ambiguous and do not support the position that the general population is subject to widespread exposure to natural rubber latex proteins from tires. EPA obtained the full article referenced in Exhibit A and considered it in light of this petition (Ref. 7). In the study, particulates were collected and analyzed from ambient air samples from the Denver metropolitan area. The size of the particles was determined using optical microscopy, and it was reported that a significant portion (58.5%) was in the respirable range. The particles were also characterized using chemical solubility tests and mass spectrometry. The authors of the study hypothesized that the particles represent abraded tire

fragments and concluded that their hypothesis was supported by the mass spectroscopic, physical, and chemical data. In the study, the authors also demonstrated that *Hevea brasiliensis* antigenic proteins can be extracted from rubber tire fragments. The authors speculated that airborne tire fragments “could contribute, through direct and indirect mechanisms, to the increase in both latex sensitization and asthma,” but did not investigate the hypothesis or demonstrate that airborne tire fragments directly or indirectly contribute to an increase in, or have any impact on, latex sensitization and asthma. Moreover, the study only showed that *Hevea brasiliensis* antigenic proteins could be extracted from rubber tire fragments, not from particles that were collected from air samples.

“Allergies and Autism” describes a study that reports the presence of extractable *Hevea brasiliensis* antigenic proteins in ambient samples of sedimented freeway dust and airborne particulate matter from two locations within the Los Angeles basin (Ref. 8). However, in a subsequent study examining paved road dust and atmospheric particulate matter for allergen exposure in three sites within the greater Los Angeles area, the same authors reported no *Hevea brasiliensis* antigenic proteins were detected in paved road dust samples (Ref. 9). The authors concluded that the different results could be explained by “differences in driving conditions and sampling locations for the roadways examined in each of the two studies.” The authors also reported that material collected from guardrails contained about 75% rubber particles, but paved road dust collected from the center two-thirds of straight sections of city surface streets did not contain rubber particles.

EPA identified another study that investigated whether exposure to road traffic in a large city in Germany (Dresden) is associated with allergic sensitization to latex in children (Ref. 10). In this study, immunoglobulin E (IgE) levels against *Hevea brasiliensis* antigenic proteins and a panel of common aeroallergens were measured in 2,505 children, ages 5–11, and an analysis was conducted to determine whether there was any correlation between latex sensitization and exposure to road traffic as measured by parental self-reporting, traffic counts, and measurements of benzene. The authors concluded that their data suggest exposure to road traffic is not associated with allergic sensitization to latex in children.

Finally, a letter published in *Epidemiology*, the official, peer-

reviewed journal of the International Society of Environmental Epidemiology, reported that “[o]btaining solid natural rubber (NR) out of latex,” unlike “production and use of dipped latex products” used in personal products and medical devices, “involves intensive heating, which destroys many, [though] not all, proteins,” and that, “[i]n the rubber manufacturing industry, exposure to inhalable NR particles can be orders of magnitude higher ..., without producing any evidence of latex allergies,” and concluded that, “[b]ased on these results[,] an association between heavy traffic and sensitization to NRL in the general population seems to be unlikely” (Ref. 11). This letter is consistent with comments submitted by the Rubber Manufacturers Association in response to the petitioner’s previous petition to ban antigenic natural rubber latex adhesives. According to the Rubber Manufacturers Association, natural rubber latex “proteins in dry rubber products [including tires] are largely denatured, diluted, and immobilized to a far greater extent than in products formed from liquid latex” and “most dry rubber products that have been tested have had no detectable levels of latex allergens” (Ref. 12).

Third, the petition provides little information on the specific factors listed in TSCA section 6(c) that must be considered for a TSCA section 6 rulemaking. See Unit II.C.

For example, the petition provides little specific information on the magnitude of exposure of human beings or the environment. Exhibit A concludes that *Hevea brasiliensis* latex antigens are extractable from rubber tire fragments, which are abundant in urban air samples, but provides little factual information on the magnitude of exposure of human beings to the *Hevea brasiliensis* antigenic proteins from the tire fragments. See discussion in Unit II.B.1. concerning natural rubber latex proteins in tire particles, as referenced in Exhibit B (Ref. 4).

The petition provides little factual information on the reasonably ascertainable economic consequences of prohibiting the use and distribution in commerce of *Hevea brasiliensis* baled natural-rubber in tires that does not have a “total protein content less than 200 µg/dm<sup>2</sup> and an antigenic Hev-b protein content less than 10 µg/dm<sup>2</sup>.” In “Allergies and Autism,” for example, the petitioner recounts who are the major natural rubber latex consuming and producing countries, the percentage of natural rubber latex consumed today, and rates of natural latex consumption in the past 43 years. However, this information fails to offer specific factual

<sup>2</sup> ASTM D1076-06 uses the term “*Hevea* antigenic protein” to refer to antigenic proteins in natural rubber and its products as measured by test method ASTM D6499. EPA uses *Hevea brasiliensis* antigenic proteins throughout this notice to refer to any antigenic proteins from *Hevea brasiliensis* and not just those measured by test method ASTM D6499.

information on the “reasonably ascertainable economic consequences” that would occur as a result of enacting the proposed regulation (Ref. 4).

The petition states that “proteins inherent in *Hevea brasiliensis* baled natural-rubber can be substantially eliminated” and that “ultra low-protein natural-rubber latex (e.g., Vytex-NRL) that can be used to make *Hevea brasiliensis* baled natural-rubber that satisfies ASTM D 1076-06 (Category 5)” is available, but provides little other information on the availability and suitability of substitutes. In “Allergies and Autism,” the petitioner reports that non-*Hevea brasiliensis* latex does not provide a suitable substitute. According to the petitioner: “Efforts have been made to commercialize alternative latex having inherently lower antigenic protein content (i.e., guayule rubber latex and the Russian dandelion), but such materials are reported to be higher in cost and presently are available only in limited quantities” and “both of these materials have their own unique set of proteins with potential allergenic behavior not yet clearly understood.” With respect to Vytex, the petitioner reports that it “can be used for making surgical and examination gloves, condoms, foam, tubing, breather bags, balloons, adhesives as well as many other natural-latex based products across a wide range of industries” (Ref. 4). Vytex does not appear to be a viable substitute for use in tires, however, at this time. Vytex was developed and is produced by the Vystar Corp. According to the Vystar Corp. website, Vytex is Vystar Corp.’s first commercial product and is presently used only in Envy condoms, which were introduced commercially only in October of 2009. In addition, Vystar Corp.’s webpage focuses on Vytex’s suitability for the specialty use of medical devices. See <http://www.vytex.com>, last visited January 11, 2010.

Nor does the petition provide evidence showing that prohibiting the use of “*Hevea brasiliensis* baled natural-rubber” that does not have a “total protein content less than 200 µg/dm<sup>2</sup> and an antigenic Hev-b protein content less than 10 µg/dm<sup>2</sup>” in the manufacture of tires would be the least burdensome requirement to address the potential risks the petition identifies.

Finally, the petition has not demonstrated that a regulation prohibiting the use of “*Hevea brasiliensis* baled natural-rubber” that does not have a “total protein content less than 200 µg/dm<sup>2</sup> and an antigenic Hev-b protein content less than 10 µg/dm<sup>2</sup>” in the manufacture of tires is

likely to be successful in reducing the incidence of latex allergy or autism.

#### IV. 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-2010-0015. For information on accessing the docket, refer to Unit I.B.

1. Dochniak, M. “Citizen Petition under TSCA to prohibit the use of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said baled natural-rubber fails to satisfy *The American Society for Testing and Materials method ASTM D1076-06* (Category 5).” November 19, 2009.

2. EPA. Letter from OPPT, to Michael Dochniak, acknowledging receipt of his petition under TSCA section 21: “Citizen Petition under TSCA to prohibit the use of *Hevea brasiliensis* baled natural-rubber for the manufacture of tires, wherein said baled natural-rubber fails to satisfy *The American Society for Testing and Materials method ASTM D1076-06* (Category 5).” December 8, 2009.

3. EPA. Natural Rubber Latex Adhesives; Disposition of TSCA Section 21 Petition; Notice. **Federal Register** (73 FR 32573, June 9, 2008) (FRL-8368-4). Docket ID number EPA-HQ-OPPT-2008-0273. Available on-line at <http://www.regulations.gov>.

4. Dochniak, M. and Dunn, D. Allergies and Autism. Nova Science Publishers, Inc. 2008.

5. Mostafa, G. A.; Hamza, R. T.; and El-Shahawi, H. H. Allergic manifestations in autistic children: Relation to disease severity. *Journal of Pediatric Neurology*. 2008. 6(2):115-123.

6. Buie, T., et al., Evaluation, Diagnosis, and Treatment of Gastrointestinal Disorders in Individuals With ASDs: A Consensus Report. *Pediatrics*. 2010. 125:S1-S18.

7. Williams, P. B.; Buhr, M. P.; Weber, R. W.; Volz, M. A.; Koepke, J. W.; and Selner, J. C. Latex Allergen in Respirable Particulate Air Pollution. *Journal of Allergy and Clinical Immunology*. 1995. 95:88-95.

8. Miguel, A. G.; Cass, G. R.; Weiss, J.; and Glovsky, M. M. Latex Allergens in Tire Dust and Airborne Particles. *Environmental Health Perspectives*. November 1996. 104(11):1180-1186.

9. Miguel, A. G., Cass, G. R., Weiss, J., and Glovsky, M. M. Allergens in Paved Road Dust and Airborne Particles. *Environmental Science Technology*. 1999. 33:4159-4168.

10. Hirsch, T.; Neumeister, V.; Weiland, S. K.; von Mutius, E.; Hirsch,

D.; Grafe, H.; Duhme, H.; and Leupold, W. Traffic exposure and allergic sensitization against latex in children. *Journal of Allergy and Clinical Immunology*. 2000. 106:573-8.

11. Vermeulen, R.; Doekes, G.; and Kromhout, H. Latex Allergy Risk among the General Population due to Traffic-Related Airborne Dust? *Epidemiology*. Cambridge, MA. 2000. 11(1):92.

12. Rubber Manufacturers Association Letter to EPA (Docket ID number EPA-HQ-OPPT-2008-0273), Comments on Mr. Michael Dochniak TSCA Section 21 Petition. May 12, 2008.

#### List of Subjects

Environmental protection, Antigenic proteins, Autism, Health, *Hevea brasiliensis* baled natural rubber, Latex, Tires.

Dated: February 16, 2010.

**Stephen A. Owens,**

Assistant Administrator, Office of Prevention, Pesticides and Toxic Substances.

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#### ENVIRONMENTAL PROTECTION AGENCY

[FRL-9114-9]

#### North Carolina Waters Along the Entire Length of New Hanover County; Final No Discharge Zone Determination

On August 24, 2009, the Environmental Protection Agency (EPA) published a notice that the North Carolina Department of Environment and Natural Resources (DENR) Division of Water Quality (DWQ) had petitioned the Region 4 Regional Administrator to determine that adequate and reasonably available pumpout facilities exist for the designation of New Hanover County, North Carolina, Coastal Waters as a No Discharge Zone (NDZ). One comment in favor of this designation was received.

Specifically, these waters extend three nautical miles (nm) into the Atlantic Ocean along the entire length of New Hanover County, including Futch Creek, Pages Creek, Bradley Creek, Hewlett’s Creek, Howe Creek, Whiskey Creek, Snow’s Cut, as well as unnamed tributaries and all unnamed tidal creeks to those waters.

The geographic description including latitudes and longitudes are as follows: northern border of New Hanover County with southern border of Pender County (34°17’53.5” N 77°42’32.2” W), to a point 3 nm off the coast at the intersection of New Hanover and Pender Counties (34°16’01.9” N 77°40’20.5” W).