ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2007–1016; FRL–8345–9]

Air Fresheners; TSCA Section 21 Petition

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On September 20, 2007, the Sierra Club, the National Center for Healthy Housing, the Alliance for Healthy Homes, and the Natural Resources Defense Council (NRDC) petitioned EPA under section 21 of the Toxic Substances Control Act (TSCA) to: Call-in allegations of adverse reactions related to air freshener products recorded by manufacturers and processors pursuant to TSCA section 8(c) and 40 CFR part 717; adopt a rule pursuant to TSCA section 8(d) to require submittal of heath and safety studies related to air fresheners, including lab results of ingredients and health effects from respiratory exposures; adopt a rule pursuant to TSCA section 4 to require manufacturers to conduct acute and chronic studies to evaluate the impact of air fresheners on human health; and adopt a rule pursuant to TSCA section 6 to require that air fresheners be labeled to identify all of their ingredients. TSCA section 21 does not apply to the petitioners' request for a call-in under TSCA section 8(c), and, for the reasons set forth in this notice, EPA has denied the petitioners' remaining three requests.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Colby Lintner, 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*.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, process, import, or distribute in commerce air fresheners or their ingredients. Potentially affected entities may include, but are not limited to:

- Chemical manufacturers (including importers) and processors (NAICS code 325), e.g., air and room freshener manufacturers.
- Other manufacturers (including importers) and processors (NAICS code 3399), e.g., manufacturers of potpourri.

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. To determine whether you or your business may be affected by this action, you should carefully examine the TSCA section 21 petition on air fresheners. 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPPT–2007–1016. 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.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*.

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 standard 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 8(d) rules*. Section 8(d) of TSCA authorizes EPA to require the submission of unpublished health and safety studies initiated or conducted by, or known to or reasonably ascertainable by, manufacturers, processors, and distributors of chemical substances or mixtures. Studies may be excluded ''if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of [TSCA].'' 15 U.S.C. 2607(d)(1).

Section 21(b)(4)(B) of TSCA provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 8(d): ''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).

3. *Legal standard regarding TSCA section 4 rules.* EPA must make several findings in order to issue a rule to require testing under TSCA section 4. In all cases, EPA must find that data and experience are insufficient to reasonably determine or predict the effects of a chemical or mixture on health or the environment and that testing of the chemical is necessary to develop the missing data. 15 U.S.C. 2603(a)(1). In addition, EPA must find either that the chemical or mixture may present an unreasonable risk of injury or that the chemical is produced in substantial quantities and may either result in significant or substantial human exposure or result in substantial environmental release. Id.

In the case of a mixture, EPA must also find that ''the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture.'' 15 U.S.C. 2603(a)(2).

If EPA denies a petition for TSCA section 4 rulemaking and the petitioners challenge that decision, TSCA section 21 allows a court to order EPA to initiate rulemaking if the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence in a *de novo* proceeding that findings very similar to those described in this unit with respect to a chemical substance have been met. However, TSCA section 21 omits the finding that ''testing is necessary to develop the data'' from the findings that a petitioner must demonstrate in order for a court to require EPA to initiate TSCA section 4 rulemaking. 15 U.S.C. 2620(b)(4)(B)(i). Nonetheless, EPA believes TSCA section 21(b)(4) is best interpreted as incorporating this finding. The alternative would be to read the statute as empowering a court to require EPA to initiate a rulemaking even where the Agency could not make proposed findings consistent with TSCA section 4 or take final action on the rule. EPA's interpretation is supported by legislative history. House Conference Report 94–1679 at pp. 97–99 (1976).

In addition, EPA believes TSCA section 21(b)(4) does not provide for judicial review of a petition to promulgate a test rule for mixtures. Section 21(b)(4)(B)(i) of TSCA specifies that the court's review pertains to application of the TSCA section 4 factors to chemical substances. Moreover, TSCA section 21(b)(4)(B)(i) does not contain the additional finding that TSCA section 4 requires for issuing a test rule for mixtures (that the effect may not be reasonably and more efficiently determined or predicted by testing the chemical components). Congress left the complex issues associated with the testing of mixtures to the Administrator's discretion.

4. *Legal standard regarding TSCA section 6 rules.* In order to promulgate a rule under TSCA section 6, 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 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 ... 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 September 19, 2007, the Sierra Club, the National Center for Healthy Housing, the Alliance for Healthy Homes, and NRDC petitioned EPA to:

1. Call-in allegations of adverse reactions related to air freshener products recorded by manufacturers and processors pursuant to TSCA section 8(c) and 40 CFR part 717.

2. Adopt a rule pursuant to TSCA section 8(d) to require submittal of health and safety studies related to air fresheners, including lab results of ingredients and health effects from respiratory exposures.

3. Adopt a rule pursuant to TSCA section 4 to require manufacturers to conduct acute and chronic studies to evaluate the impact of air fresheners on human health.

4. Adopt a rule pursuant to TSCA section 6 to require that air fresheners be labeled to identify all of their ingredients (Ref. 1).

The petition defined air fresheners as:

> ...a broad range of product types, from traditional sprays to outlet- and battery-operated plug-ins, solid gel dispensers, hanging car air fresheners and potpourri. Air fresheners can serve two purposes: odor control (which includes unscented air fresheners) and aesthetic scent. Some products may serve both purposes, and others may serve only one. Cleaning products that kill germs, clean surfaces and leave a pleasant fragrance are not included in these petitions.
> (Ref. 1)

The petitioners also simultaneously petitioned the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261 *et seq.*) ''to undertake specific actions to assess fully the risk to the public from exposure to air fresheners and to take reasonable steps to reduce that risk'' (Ref. 1). In November 2007, the CPSC declined to docket the petition for rulemaking, because it did not meet the CPSC's statutory or regulatory requirements (Ref. 2). CPSC stated that it was rejecting the petition because the petition did not ''identify the specific toxic constituent(s) and their concentration(s) in the air fresheners, the mechanism of exposure and/or uptake of each such constituent or the 'substantial illness' that might result from customary or reasonably foreseeable handling or use of such air fresheners that contain each

of these substances.'' CPSC also found that the petition did not ''provide[] sufficient information to establish that a rule is necessary.''

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

Petitioners are concerned about potential risks from air fresheners and believe EPA should take the requested actions to assess and reduce any such risks. The petition discusses at length three reports in support of these requests:

• The American Association of Poison Control Centers' (AAPCC) 2005 Annual Report (Ref. 3).

• An ''opinion'' issued in January 2006 by the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) (Ref. 4) on a report issued in January 2005 by the Bureau Européen des Unions de Consommateurs (BEUC), which measured and assessed chemical emissions from 74 air fresheners sold in Europe (Ref. 5).

• A report issued in September 2007 by NRDC on the presence of phthalate esters in air fresheners (Ref. 6).

1. *Association of Poison Control Centers (AAPCC) Report.* In support of the assertion that air fresheners present ''a significant source of human exposure to a veritable cocktail of dangerous and potentially dangerous'' chemicals, the petition presents information drawn from the AAPCC 2005 Annual Report. EPA considered the AAPCC report and does not agree with the petitioners that the information in the report raises significant concerns about possible health effects of air fresheners.

According to the petition (Ref. 1), the AAPCC reported the following ''exposures'' to air fresheners based on calls to local poison control centers in 2005: 14,094 people overall (including 11,800 children younger than 6). Of the reported exposures, the petition indicates that 98% were unintentional, and 2,623 resulted in injuries (2,492 minor injuries; 125 moderate injuries; 5 major injuries; and 1 death).

These numbers, however, represent only a very small percentage (0.58%) of the total number of 2,424,180 exposures to all substances reported in the AAPCC's 2005 Annual Report (Ref. 3). This incidental percentage is the more striking considering the industry's assertion that 70% of U.S. homes use air fresheners (Ref. 7) and the petitioners' assertion that ''[a]lmost every American is exposed to air fresheners in some manner'' (Ref. 1). Moreover, according to the 2005 AAPCC report, only 32 (0.23%) of the 14,094 reported air freshener exposures involved an adverse reaction, which is defined by AAPCC as ''an adverse event occurring with normal, prescribed, labeled, or recommended use of the product, as opposed to overdose, misuse, or abuse'' (Ref. 3).

Considering the widespread use of air fresheners, the number of reported exposure incidents for air fresheners is relatively small when compared to the reported exposure incidents for other product categories. In the AAPCC report, air fresheners are one of five subcategories of deodorizers, and deodorizers have among the lowest number of reported exposures and injuries among the 55 categories in the AAPCC report (Refs. 3 and 8). In the AAPCC report, deodorizers are not included in the list of 23 categories ''most frequently involved in human exposures'' (Refs. 3 and 8). Deodorizers are 20th among 23 categories for ''most frequently involved in pediatric exposures (children younger than 6 years),'' but deodorizers were involved in only 1.3% of the total number of such exposures (Ref. 3). (The percentages for the 21st (asthma therapies), 22nd (dietary supplements/herbals/homeopathic), and 23rd (antidepressants) categories were 1.2%, 1.1%, and 1.1%, respectively, nearly the same as for deodorizers). Nearly 95% of the injuries resulting from air freshener exposures were minor, 4.8% were moderate, and only 0.2% (5) were major. Of the two deaths reported, one resulted from intentional misuse and the reason for the other was reported as ''unknown'' (Refs. 3 and 8).

The petitioners assert that these figures under-represent exposures because people may not recognize the relationship asserted by the petitioners between air freshener exposures and adverse effects (Ref. 1). On the other hand, EPA recognizes that asthma attacks and other health effects may be incorrectly attributed by callers to air freshener exposures. EPA has no basis to draw conclusions based on the possibility of unreported exposures to air fresheners or any other products. It is also important to note that these exposure reports, which provide the basis for the AAPCC report, rarely, if ever, include information about the concentrations or durations of the reported exposures and, therefore, cannot be used to make any conclusions about actual exposures during use or long-term health risks (Ref. 9).

2. *NRDC Report.* According to the petition, NRDC tested 14 air fresheners and found phthalate esters in 12 (Ref. 6). NRDC stated that none of these 12 air fresheners listed phthalate esters as ingredients on their labels. According to the petition, phthalate esters are associated with ''a number of reproductive health risks'' and with allergic symptoms and asthma. The petitioners also state that ''California's Office of Environmental Health Hazard Assessment lists some phthalates (including some found in these air fresheners) as chemicals known to the state to cause reproductive toxicity under California's Proposition 65'' (Ref. 1).

Phthalate esters are a broad category of chemicals with varying toxicological profiles. California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986) requires the State to publish a list of chemicals known to be carcinogens or developmental toxicants and requires businesses to provide public notice about any ''significant'' amount of a listed chemical in their products by, among other methods, labeling a consumer product (*http://www.oehha.ca.gov/prop65.html*) (Ref. 11). Of the five phthalate esters on the Proposition 65 list, only one (di-*n*-butyl phthalate (DBP)) was reported in the NRDC study as being detected in air fresheners. According to the U.S. Centers for Disease Control Third National Report on Human Exposure to Environmental Chemicals, many consumer products contain phthalate esters, including vinyl flooring, adhesives, detergents, lubricating oils, solvents, automotive plastics, plastic clothing (e.g., raincoats), personal-care products (e.g., soap, shampoo, deodorants, fragrances, hair spray, nail polish), medical pharmaceuticals, plastic bags, garden hoses, inflatable recreational toys, blood-storage bags, intravenous medical tubing, and children's toys (Ref. 10).

The NRDC study tested for 15 phthalate esters (including 4 of the 5 phthalate esters on the Proposition 65 list) and found one or more of 5 phthalate esters (including 1 (DBP) on the Proposition 65 list) in 12 of 14 air freshener products tested. The 5 phthalate esters were: Di-*n*-butyl phthalate (DBP), CAS No. 84–74–2; diethyl phthalate (DEP), CAS No. 84–66–2; diisobutyl phthalate (DIBP), CAS No. 84–69–5; diisohexyl phthalate (DIHP), CAS No.146–50–9; and dimethyl phthalate (DMP), CAS No. 131–11–3 (Ref. 6).

With the exception of DEP, the phthalate esters were detected at very low concentrations (less than 7 parts per million (ppm)), which might indicate their presence as an impurity or lab contaminant rather than as an intentional ingredient. DBP was the only phthalate ester on the California Proposition 65 list (where it is listed for

developmental toxicity) detected in the air fresheners examined in the NRDC report. DBP was detected at very low concentrations in 5 samples: At concentrations less than 1 ppm in four samples and at a concentration of 4.5 ppm in one sample.

DEP was detected in three samples at concentrations of 360 ppm, 1,100 ppm, and 7,300 ppm; DEP was detected in six other samples at concentrations of 6.3 ppm or less (Ref. 6). DEP is known to be used as a solvent and vehicle in a wide variety of fragrance and cosmetic products at concentrations ranging from <0.1% to 11% (i.e., 1,000 to 110,000 ppm) (Ref. 29), which could explain its detection at concentrations in the thousands of ppm in several air fresheners reported by NRDC. While higher than the very low levels of other detected phthalate esters, the levels of DEP in air fresheners identified in the NRDC Report are still quite low. In 2003, the European Union's (EU) Scientific Committee on Cosmetic Products and Non–Food Products Intended for Consumers (SCCNFP), a scientific advisory body to the European Commission (as is the EU's SCHER that is cited by the petitioners), concluded that the safety profile of DEP supports its use in European cosmetic products at ''current levels'' (Refs. 12 and 13).

The petitioners also referenced several studies in footnotes within the petition and in a public comment that reported possible associations between general exposure to phthalate esters (i.e., not specifically from exposure to air fresheners) and potential adverse health effects in humans. The NRDC report did not measure nor estimate the potential exposures or risks that may result from the use of air fresheners in which phthalate esters have been detected and so does not provide a basis to assess such exposure or potential risk. There are numerous other potential sources of phthalate esters to which consumers may be exposed that could lead to potentially higher exposures than those that may result from use of air fresheners.

In 2007, following release of a report by Greenpeace that reported concentrations of phthalate esters in perfumes (Ref. 14), the EU's Scientific Committee on Consumer Products (SCCP) issued an opinion on certain phthalate esters in cosmetic products (Ref. 15). The SCCP opinion addressed nine phthalate esters including four of the five phthalate esters detected in air freshener samples by NRDC. The magnitude of the phthalate ester concentrations reported in the Greenpeace report for perfumes are similar to those reported by NRDC. DIHP, detected by NRDC at a concentration of 2.1 ppm in one air freshener, was not included in the SCCP opinion. The SCCP concluded that: There was no need to update the SCCNFP opinion on the safe use of DEP in cosmetics; in view of the low concentrations of DIBP and DMP found in samples analyzed (38 and 2,982 ppm, respectively), there would be no quantifiable risk for the consumer; and that traces of DBP up to 100 ppm do not indicate a risk to the health of the consumer. Similarly, the Cosmetic Ingredient Review Expert Panel concluded in 2002/2003 that DBP, DMP, and DEP are safe for use in cosmetic products (including perfumes and hair sprays) ''in the present practices of use and concentrations'' (Ref. 29).

EPA recently contracted with the National Academy of Sciences (NAS) to evaluate human health risks and the potential for conducting a cumulative risk assessment for phthalate esters (Ref. 16). (Project information is available at *http://www8.nationalacademies.org/cp/projectview.aspx?key=48860*). Specifically, EPA is eliciting external expert consultation to evaluate the issues related to cumulative hazard and dose–response assessment. The study panel will examine the strengths and limitations of a cumulative approach opposed to or in addition to an individual chemical approach for risk assessment of phthalates. EPA anticipates that the final product of this study panel will be a report discussing the issues identified by the panel, the ways in which any assessment may be approached, the strengths and limitations of any of the proposed approaches, and whether any additional research is needed. The project began in September 2007 and NAS is scheduled to submit a report in December 2008.

In addition, EPA has developed five individual phthalate human health risk assessments (DEP, DMP, di(2-ethylhexyl)phthalate, dibutyl phthalate, and butyl benzyl phthalate) that are currently available on the Integrated Risk Information System (IRIS) database. The IRIS Summaries for these phthalates can be found at *http://cfpub.epa.gov/ncea/iris/index.cfm?fuseaction=iris.showSubstanceList*. The IRIS Program has also undertaken reassessments for di(2-ethylhexyl)phthalate, dibutyl phthalate, and butyl benzyl phthalate. The schedules for the reassessments of these phthalates are available on IRIS Track *http://cfpub.epa.gov/ncea/iristrac/index.cfm*).

In sum, the NRDC report indicates that some phthalate esters are present in some air fresheners at generally low concentrations. This information is not surprising and does not provide a basis to suspect that the presence of the phthalate esters at the concentrations detected presents a significant public health risk. In addition, the NAS evaluation, which is expected to address phthalate esters more comprehensively, rather than in a very specific use such as air fresheners, will help inform any risk assessment or testing needs.

3. *BEUC and SCHER reports.* The petition also relies on an opinion issued by SCHER in January 2006 about a report issued by the Bureau Européen des Unions de Consommateurs (BEUC) in January 2005 that measured and assessed chemical emissions from 74 air fresheners sold in Europe (Refs. 4 and 5).

In order to understand these reports, some background information is necessary. BEUC is a European association of national consumer organizations. In November 2004, BEUC announced that a study it had commissioned had found that air fresheners emitted toxic air pollutants (Ref. 17). According to the report, the study tested 74 ''products belonging to different categories (incense, natural products, scented candles, aerosols, liquid diffusers, electric diffusers and gels),'' ''simulate[ed] common use of such products by consumers,'' and measured, ''for each product, the concentration of Volatile Organic Compounds (VOCs) and aldehydes in the air after the use'' (Ref. 5). The BEUC report focused on emissions of ''total VOCs'' and several individual VOCs: Allergens, benzene, formaldehyde, terpenes, styrene, DEP, and toluene. The BEUC report found that the 74 products studied emitted over 350 different chemicals.

A company that produces air fresheners filed a lawsuit in Belgium to compel BEUC to withdraw public statements indicating ''that normal usage of the fragrances generates serious health risks, and that these fragrances are not subjected to regulations in terms of product safety standards'' (Ref. 28). In March 2005, the court found that the BEUC study did not support statements that air fresheners were ''dangerous to people's health.'' The court ordered BEUC to withdraw statements that ''might or could create the impression that fragrances are unsafe with normal usage'' and issue a statement that its ''repeated public communications on the subject of air freshener safety'' were ''not appropriate as the currently known results from [the BEUC study] on which [BEUC] based [its] statements in effect do not justify the conclusion that air

fresheners are diffusing substances ... in concentrations that present a hazard to public health'' and ''may unjustly have generated the unwarranted impression that the air fresheners on sale in the Netherlands can result in health risk under normal usage.''

SCHER was subsequently asked to consider whether the specific chemical emissions from air fresheners reported in the BEUC study represented a health risk to consumers and what further studies might be necessary to adequately assess the potential health risks from air fresheners. SCHER issued its assessment in January 2006 (Ref. 4). SCHER noted that ''Neither the composition of the tested products, nor the rationale for the selection of the individual substances studied are given in the BEUC report;'' that ''[t]he individual compounds in the reported results are, in most cases, well studied;'' and that ''[t]he results in the BEUC study may ... be regarded as realistic worst case values.'' SCHER noted that, with the exception of benzene emissions resulting from the burning of certain incense products, the air concentrations of the substances assessed in the BEUC report were below known limit values for adverse health effects and/or were within the range of typical indoor air concentrations.

SCHER reached the general conclusion that current scientific knowledge on ''the use of air fresheners, emissions and resulting concentrations in indoor air'' was ''limited'' and that ''the [exposure] data on air fresheners available to the SCHER are insufficient for an overall risk evaluation for consumers.'' SCHER concluded that ''[m]ore data, on e.g. the use pattern of these products, are required to allow assessment of the actual exposure of the residents'' and that, in particular, ''the frequency of the used air freshener, the duration of exposure and the frequency of peak levels needs to be considered.''

EPA conducted a literature review of sources of information relevant to human exposure to air freshener products (i.e., formulation, emission measurement, air monitoring, and modeling information) (Ref. 21). This review identified additional studies not reviewed in the BEUC and SCHER reports. Some of the same analytes reported in the BEUC report (e.g., terpenes and formaldehyde) were detected in these studies, usually at lower maximum concentrations than those reflected in the BEUC report.

EPA then reviewed the BEUC and SCHER reports in light of the information gathered during the literature review (Ref. 18). EPA concluded, as did the SCHER report, that there were deficiencies related to the quality of the data in the BEUC report. EPA concluded that the information and findings in the BEUC report did not appear to satisfy EPA's Information Quality Guidelines (Ref. 19). EPA also concluded that uncertainty about how representative the BEUC results are for the U.S. air freshener market is a key limitation in their usefulness for estimating potential U.S. consumer exposures.

The petitioners point out that BEUC found that ''for most products tested the emitted total VOC values exceeded 200 microgram/milligram cubed ($\mu g/m^3$), the proposed maximum limit value in indoor air in several countries...'' While total VOC does measure the presence of VOCs indoors, there is no validated evidence to indicate that this measure is a predictor of indoor air quality concerns or potential health effects. Total VOC does not indicate the impact of other pollutants present or building factors that may also impact indoor air quality and health. In addition, there is no standardized procedure for measuring total VOCs and, therefore, no ability to compare between reported measurements. Although under certain conditions total VOC measurements may be useful as a screening tool, EPA does not believe total VOC measurements should be used as an indicator of indoor air quality or health concerns.

4. *Epidemiological studies and other information.* In addition to the three sources listed in Unit II.D., the petitioners submitted to EPA epidemiological studies as additional support (Refs. 22 and 23). Reference 23 was submitted as part of the petition. Reference 22 was submitted after the petition and, consequently, is not considered by EPA to be part of the petition. However, EPA reviewed both studies. The studies attempted to determine whether there was an association between asthma and either the use of common household cleaners or chemical hypersensitivity. EPA's review concluded that both studies, neither of which was specifically designed to evaluate possible health effects related to exposure to air fresheners, contained numerous design limitations and could not be used to support an association between asthma and the use of air fresheners (Ref. 20).

Petitioners also present certain arguments about the risks and benefits of air fresheners. Petitioners assert that ''air fresheners provide no public health value'' (Ref. 1). Petitioners further assert that air fresheners may mask the presence of mold and other health threats (Ref 1). Petitioners have provided no basis for EPA to evaluate these assertions, although EPA agrees that, in general, air fresheners are not a solution for indoor air quality issues. In addition, public health value is not the only type of benefit cognizable under TSCA. As petitioners recognize, air fresheners are purchased in large quantities, and, as noted in comments submitted by industry, 70% of homes in the United States use air fresheners (Ref. 7); which together suggest that consumers place significant value on them. With regard to petitioners' second assertion, EPA sees no connection between the actions requested and any risk that might be presented by the masking of mold or similar conditions.

5. *Conclusion.* The information provided by petitioners does not support the conclusion that air fresheners present a significant health risk, or a health risk that is a priority in relation to risks potentially posed by other chemicals or products. In addition to the limitations discussed in Unit II.D., it is clear that the information supplied by petitioners is only a sample of the information available on health risks potentially associated with air fresheners. Based on comments received during the comment period and independent inquiry by EPA (see Unit III.C.1.), there are a number of additional publicly available studies and analyses of the potential health effects from air fresheners and air freshener ingredients. Industry commenters assert that some of these studies demonstrate that air fresheners in general do not present a significant risk (Refs. 24 and 25). EPA expresses no view on this industry characterization, but EPA cannot judge whether air fresheners generally, or any particular air fresheners, present an unreasonable risk, or a significant risk at all, without further review of available information.

E. Other Considerations

EPA has a number of high priority chemical assessment and risk management projects and actions already underway that are requiring a substantial amount of OPPT resources. EPA views many of these projects as being more broadly applicable, and as having greater potential to result in the understanding and reduction of possible chemical risks, than the actions suggested by the petitioners. These projects include, for example, the following:

In August 2007, the President committed the United States to join Canada and Mexico in a collaborative effort under the Security and Prosperity Partnership (SPP) to rapidly and efficiently improve chemical security

and safety throughout North America. The U.S. contribution to this partnership is, by 2012, to assess and initiate needed actions on the approximately 9,000 chemicals manufactured in, or imported into, the United States in volumes greater than 25,000 pounds. These include 3,000 ''high-production-volume'' (HPV) chemicals (produced or imported at 1 million lbs/year annually) and 6,000 ''medium-production-volume'' MPV chemicals (produced or imported between 25,000 and 1 million lbs/year). EPA expects that many of the ingredients of air fresheners will be encompassed within these groups of chemicals. The North American collaboration also provides for the sharing of scientific information and technical understanding, best practices, and research on new approaches to chemical testing and assessment. The scope and pace of this commitment represents a significant commitment of Agency resources over the period of the next 5 years. Additional information on this commitment can be found at: *http://www.epa.gov/chemrtk/index.htm*.

Another, chemical-specific, project involves conducting and integrating new studies into the ongoing risk assessment on perfluorooctanoic acid (PFOA) and managing the related 2010/15 PFOA Stewardship Program, in which companies have committed to reduce emissions and product content of PFOA and other perfluorinated compounds, many of which have been found in the blood of the general U.S. population. Additional information on this project can be found at: *http://www.epa.gov/oppt/pfoa/index.htm*.

In addition, EPA has several efforts underway under the Design for the Environment (DfE) Program. DfE works in partnership with a broad range of stakeholders to reduce risk to people and the environment by preventing pollution. One example of special relevance to fragrances and air fresheners is DfE's work with formulators of chemical products to identify safer chemical alternatives for ingredients of concern and to recognize those formulators who develop safer chemical products through green chemistry. Cleaning products can contain a wide variety of ingredients including surfactants, solvents, builders, and fragrances. Fragrances are key ingredients in some cleaning products. To enable and further environmental stewardship in the fragrance industry, and to help fragrance houses identify safer ingredients for the formulation of fragrances in cleaning products, DfE is working with stakeholders from the fragrance industry, formulators of cleaning products, environmental groups, and other Agency representatives. The goal of this stakeholder effort is to define safer fragrance materials for cleaning products, and provide fragrance houses and cleaning product formulators with a marketplace for those ingredients. Additional information on the DfE program in general and the formulators project in particular is available at: *http://www.cleangredients.org*.

III. Disposition of Petition

EPA has concluded that the petition does not set forth sufficient facts to support the petitioners' assertion that it is necessary to initiate the requested rulemakings under TSCA sections 4, 6, or 8(d). Furthermore, EPA has concluded that a TSCA section 8(c) data call-in is not a petitionable matter under TSCA section 21. A detailed explanation of EPA's determination follows.

A. TSCA Section 8(c) Request

The petitioners requested that EPA ''call-in allegations of adverse reactions recorded by manufacturers and processors [of air fresheners] pursuant to TSCA section 8(c) and 40 CFR part 717 [EPA's TSCA section 8(c) regulations].''

Section 8(c) of TSCA provides that ''[a]ny person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator [of EPA] by rule, alleged to have been caused by the substance or mixture,'' and that, ''[u]pon request of any duly designated representative of the Administrator, each person who is required to maintain records under [TSCA section 8(c)] shall permit the inspection of such records and shall submit copies of such records.'' 15 U.S.C. 2607(c). EPA issued regulations implementing TSCA section 8(c), 40 CFR part 717, which were published in the **Federal Register** issue of August 22, 1983 (48 FR 38187). These regulations provide that EPA may require that records of allegations of significant adverse reactions be reported either by letter or by notice in the **Federal Register**: ''EPA will notify those responsible for reporting by letter or will announce any such requirements for submitting copies of records by a notice in the **Federal Register**.'' 40 CFR 717.17(b).

The requested call-in is not a petitionable matter under TSCA section 21. Among the actions potentially available under TSCA section 8, only rules are proper objects of a TSCA section 21 petition. Pursuant to TSCA section 8(c), and EPA's implementing regulations at 40 CFR 717.17, allegations of adverse reactions are not called in by rule. In contrast, other provisions of TSCA—including part of TSCA section 8(c)—require or authorize the Administrator to act by rule. Section 21 of TSCA allows any person to petition ''to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607.'' 15 U.S.C. 2620(a). EPA interprets TSCA section 21 to apply only to the enumerated actions. EPA believes the Congress reasonably chose to extend TSCA section 21 only to the specific rules and orders identified under TSCA section 21. In general, rules are more broadly applicable and more significant regulatory actions than individual implementation actions, such as TSCA section 8(c) call-ins. While TSCA section 21 provides for petitions for 2 types of orders, these rest on findings related to potential health or environmental risks, or production and release of, or exposure to, a chemical or mixture, and each requires potentially significant action by the recipient of the order. Congress chose not to extend TSCA section 21 to other kinds of agency implementation actions.

B. Denial of TSCA Section 8(d) Request

Petitioners requested that EPA promulgate a rule pursuant to TSCA section 8(d) to require submittal of heath and safety studies related to air fresheners, including lab results of ingredients and health effects from respiratory exposures. This request is denied. Petitioners have not set forth sufficient facts to establish that it is necessary to initiate the requested TSCA section 8(d) rulemaking.

First, in order to grant petitioners' request, air fresheners would have to be treated as a category of mixtures, rather than an individual chemical or particular mixture, and based on the limited analyses undertaken in responding to the petition, EPA does not believe that it would be appropriate at this time to treat the vast array of air freshener products as a category. The issues associated with addressing air fresheners as a category are further discussed in Unit III.C.1. Second, petitioners have not provided sufficient facts or information to support their assertion that air fresheners present an unreasonable, or even a significant, risk. Finally, even if petitioners had demonstrated that air fresheners present an unreasonable risk, they have not demonstrated that the requested TSCA section 8(d) rule would be necessary or

an appropriate tool to protect human health against that risk.

As described in Unit II.D., the information that the petitioners relied upon to support their request is not persuasive and is not adequate to support the assertion that air fresheners present a significant public health risk, much less an unreasonable risk.

The cost of this TSCA section 8(d) rule would be substantial for both the industry and the Agency. Although such a rule would not require industry to perform new testing, the scope of studies covered by the requested rule would be very broad. It is not clear whether the ''manufacturers and processors'' that would to be subject to the rule petitioners request are intended to include manufacturers and processors of air freshener ingredients as well as products. Such a rule would potentially cover a very large group of entities, products, and ingredients.

In addition, this rulemaking would require substantial Agency resources to develop, and significant Agency resources would also be required to analyze submitted studies on air fresheners.

Petitioners request EPA to use a TSCA section 8(d) rule to obtain ingredient information. While information on air freshener ingredients could be a useful starting point for assessing whether air fresheners present any significant health risk, TSCA section 8(d) does not provide an efficient or effective way to obtain ingredient information because a TSCA section 8(d) rule would only obtain the ingredient information that was part of a health or safety study. Section 8(d) of TSCA is not designed for, and is not an efficient or effective means of obtaining general or comprehensive ingredient information on air fresheners.

As a second general type of information, petitioners request EPA to use a TSCA section 8(d) rule to obtain information on ''exposure of consumers to air fresheners,'' ''health effects of exposure to air fresheners,'' and ''toxicity, persistence, and other characteristics of air fresheners that affect health and/or the environment.'' EPA generally considers this type of information to be health and safety information, which could be obtained through a TSCA section 8(d) rule. However, air fresheners are mixtures of chemicals, not individual chemicals, and as such contain a large number and wide variety of different chemicals. As a result, the interpretation of individual air freshener study results could be very difficult. When assessing studies of mixtures it is frequently difficult to determine which chemical or combination of chemicals produced a given result or caused a given effect. Further, the likely compositional diversity of the tested air freshener formulations presents EPA with difficulties in assessing the significance of any such health and safety studies in relationship to the ingredients and concentrations that are commonly present in commercially available air fresheners. Moreover, since air freshener ingredients are likely to change over time, the value or significance of health and safety study information on particular air freshener formulations could be limited.

EPA would want a better general understanding of air freshener ingredients before concluding that the broad rule requested by the petitioners is a necessary or efficient tool to address possible health effects associated with air fresheners. In addition, EPA currently does not view collection of TSCA section 8(d) information on air fresheners, or analysis of such information should EPA obtain it, as a high priority among the many chemical issues and activities that the Agency could potentially expend resources investigating, and the petitioners have not persuaded EPA otherwise.

Accordingly, EPA concludes that the petitioners have not set forth sufficient facts to support their assertion (and information available to EPA does not otherwise indicate) that it is necessary or appropriate to issue the requested TSCA section 8(d) rule.

C. Denial of TSCA Section 4 Request

Petitioners requested that EPA promulgate a rule under TSCA section 4 to require ''acute and chronic studies that use appropriate exposure routes and that capture a diversity of life stages and health conditions, such as asthma, for large populations of mammals evaluating the impact of air fresheners on human health. These tests must consider the byproducts of a reaction of the air fresheners with ozone and analyze both exposure and sensitization'' (Ref. 1). This request is denied. Petitioners have not set forth sufficient facts to support their assertion that it is necessary to issue a TSCA section 4 rule, as required by TSCA section 21(b)(1).

In addition to the request for a TSCA section 4 testing rule with respect to ''air fresheners'' as described in the petition, petitioners also presented additional requests, orally and in written comments. EPA does not consider these additional requests part of the TSCA section 21 petition, but nonetheless does address the petitioners' suggested alternative approaches in this unit.

1. *TSCA section 4 request set forth in petition.* Petitioners have not set forth sufficient facts to support their assertion that it is necessary to issue a TSCA section 4 rule for air fresheners.

As a threshold matter, petitioners' request as articulated in the petition would entail treatment of ''air fresheners'' as a category of chemical substances or mixtures (almost certainly mixtures, since it is unlikely that any air freshener is composed of a single chemical substance). Petitioners present both their request and their support for the request in terms of ''air fresheners.'' For example, the petition states, ''air fresheners may pose a risk to public health'' and defines air fresheners broadly to include a ''broad range of product types,'' from sprays to ''plug-ins'' to potpourri. Thus, treatment of air fresheners as a category would be necessary to grant petitioners' request as articulated in the petition.

EPA has broad discretion to determine whether to regulate by category under TSCA section 26(c). Beyond the language of TSCA section 26(c), this discretion is evidenced by the fact that TSCA section 21(b)(4)(B)(i) provides an opportunity for a *de novo* hearing with respect to petitions for testing of chemical substances, but not for categories of chemicals or mixtures. As with mixtures, Congress left the complex issues associated with regulation by category to the Administrator's discretion. Congress intended this authority to ''facilitate the efficient and effective administration'' of TSCA. Senate Report No. 94–698 at p. 31.

While a broad category might be appropriate under certain circumstances, based on the limited analyses undertaken by EPA in responding to the petition, EPA does not believe that treating air fresheners as a category for the purposes of a TSCA section 4 testing rule would be appropriate, efficient, or effective at this time given the large number and wide variety of air fresheners. There is a vast array of mixtures and physical forms within the meaning of air fresheners that the petitioners provide. The category is so broad and varied that similar treatment for each member of the category (i.e., testing of each member) would not be practical, efficient or effective. In addition, EPA is not able at this time, nor would it be able in the reasonably foreseeable future, to identify a standard or standards for development of certain test data, as required by TSCA section 4(b)(1), that would be appropriate to the category as a whole. Specifically, EPA is currently not aware of any standard test

method for testing respiratory sensitization in animals. Given limited information and the lack of applicable standards, a testing rule for the category air fresheners would take years and a very large expenditure of resources for EPA to develop, promulgate and implement. In addition, a requirement to conduct the wide array of testing requested by petitioners would be costly for industry. The implementation of such a requirement would entail multiple methods to test a wide variety of products for each of the identified endpoints. Moreover, even if EPA could identify or devise appropriate test standards for respiratory sensitization, it is not at all certain that testing of air fresheners for this effect or other acute and chronic effects would provide useful data relevant to determining whether air fresheners as a class, or any particular chemical substances or mixtures, present an unreasonable risk. As described in Unit III.B., the interpretation of air freshener study results would be problematic.

Even if category treatment were appropriate, petitioners have not set forth sufficient facts and information to support the TSCA section 4 findings for air fresheners.

First, petitioners have not set forth facts sufficient to support the required finding for mixtures under TSCA section 4(a)(2): That the effects of air fresheners would not be ''reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture.'' 15 U.S.C. 2603(a)(2). EPA has broad discretion to make this finding, and EPA does not, at this time, believe this finding is warranted. (TSCA section 21(b)(4)(B)(i) provides an opportunity for a *de novo* hearing with respect to petitions for testing of individual chemical substances, but not for mixtures.) On the contrary, based on the limited analyses undertaken by EPA in responding to the petition, identifying individual substances used in air fresheners and proceeding with additional requirements only where appropriate with respect to particular substances would be the more reasonable and efficient approach and would allow the Agency to target both public and private resources towards developing useful data. Given more complete information on the chemical substances, EPA might conclude that testing of some air freshener mixtures or ingredients would be appropriate, but petitioners provide no basis to support this finding for the category of air fresheners as a whole.

Petitioners assert that the testing of individual chemical substances alone could lead to gaps in data about synergistic effects or byproducts of air fresheners with ozone. While this is possible, petitioners have not provided any information to support the assertion nor at present does EPA have any basis to evaluate the assertion.

In addition, petitioners have not set forth sufficient facts to support the other required TSCA section 4 findings as described in Unit II.B.2. For example, petitioners have not set forth sufficient facts for EPA to find that information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of air fresheners, or that testing of the air fresheners is necessary to develop missing data. 15 U.S.C. 2603. Petitioners have cited some information in an attempt to make these showings. For example, they point out that the EPA HPV Information System contains no repeat dose toxicity studies for respiratory exposure for the common fragrances reported in the BEUC study, and that more than 25 material safety data sheets (MSDSs) on air fresheners reviewed by the petitioners indicated no data are available for respiratory tract sensitization. This information could be suggestive of an insufficiency of data, but EPA cannot judge whether existing data or experience are insufficient to determine or predict the health effects of air fresheners and, even so, whether new testing would be necessary to develop such data without review of the additional available information. EPA's literature search indicates the existence of many published health and safety studies pertaining to the potential health effects of air fresheners or their ingredients (Ref. 24). Further, comments received on the petition indicate a large body of information created and maintained by the fragrance industry of which many are reported to be published in peer-reviewed scientific literature (Ref. 25).

In light of the large body of additional available information which was not considered by petitioners, the petition does not support petitioners' claims regarding the insufficiency of existing data or that testing is necessary.

For these reasons, the petitioners have not demonstrated that it is necessary or appropriate to issue the requested TSCA section 4 rule.

2. *Additional TSCA section 4 request articulated at meeting.* EPA met with petitioners at their request on October 24, 2007, to discuss this petition. At that time, petitioners indicated that they intended their TSCA section 4 request to be for the testing of individual chemical substances used in air fresheners, not the air fresheners themselves (Ref. 26). A request to promulgate a TSCA section 4 rule with respect to either a category of chemical substances or individual chemical substances is significantly different from the request as articulated in the petition. Given the petitioners' obligation to articulate requests and set forth facts in their petition, EPA does not view this request as part of the petition. Nonetheless, EPA will address the alternative approaches identified by petitioners.

First, EPA does not believe the designation of ''chemical substances used in air fresheners'' as a category of chemical substances for the purpose of the requested TSCA section 4 testing rule is appropriate, for reasons similar to those discussed in Unit III.C.1. This category is extremely large, undefined and indiscriminate. It appears that petitioners are requesting that EPA require testing for all of the chemical substances in all air fresheners (Ref. 27, p. 1). This would be a massive testing rule—significantly larger than any EPA has ever promulgated before. In addition to the sheer scope of the requested rule, similar treatment for each member of the category would not be practical, efficient or effective. The chemical substances in air fresheners have not been completely identified, and EPA has no reason to believe that by virtue of their use in air fresheners, these substances would be appropriate for treatment as a category for the purposes of a TSCA section 4 rule. In addition, petitioners have failed to set forth facts sufficient to support the TSCA section 4 findings as described in Unit II.B.3. with respect to the category of ''chemical substances used in air fresheners.'' The petitioners have not shown that the TSCA section 4 findings can be made for any chemical substance used in air fresheners. In addition, the category is likely to include chemicals that are benign, and/or are not produced in substantial quantities, and/or that have been extensively studied. Therefore, EPA does not believe that the requested testing of all chemical substances used in air fresheners should be applied.

To the extent petitioners seek testing on only some of the chemical substances used in air fresheners, petitioners have not specified for which ingredients testing should be required nor have they provided information that would enable EPA to make the TSCA section 4 findings with respect to any individual chemical substances. Petitioners have identified a few chemical substances used in air fresheners, but they have not set forth facts with respect to any individual

substances to support the TSCA section 4 findings. For example, petitioners identify phthalate esters as a category of chemicals they are concerned about, but they have not shown that phthalate esters as a category, or any particular phthalate ester, meet the findings under TSCA section 4(a)(1). In addition, with respect to phthalate esters, the NAS evaluation regarding phthalate esters will help inform consideration of the sufficiency of the existing data and the need for any testing.

3. *Additional TSCA section 4 request made in comments.* Through written comments on the petition dated November 5, 2007, petitioners presented an additional request for a rule requiring that ''[each of the] manufacturers [of air fresheners] specifically test at least one formulation for each category of air freshener that it sells'' (Ref. 27). EPA again considers this additional request to be different from the request in the petition, and not part of the petition, but will address the alternative approach identified by petitioners.

In order to require testing under TSCA section 4 on a particular mixture, the TSCA section 4 findings must be met with respect to the mixture to be tested. Petitioners' request is essentially for a rule requiring testing on individual mixtures, which they have identified as ''formulations.'' While petitioners' comments imply that any ''formulation'' might be a candidate for testing, they do not identify any particular mixture, nor have they provided a rationale for selecting which air fresheners should be tested.

The petitioners have not set forth facts sufficient to support their assertion that a TSCA section 4 testing rule is necessary with respect to any particular mixture. It is possible that some air freshener ''formulations'' may meet the standards for testing as described in Unit II.B.2., but the petitioners have not identified such a mixture or provided any information toward these findings. For example, the petitioners have not set forth sufficient facts to make the necessary finding under TSCA section 4(a)(2) with respect to any mixture. As described in Unit II.B.3., EPA would have to find that the effects of the mixture ''may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture.'' 15 U.S.C. 2603(a)(2). Here, as described in Unit III.C.1., EPA currently believes that identifying individual substances used in air fresheners and proceeding with additional requirements only where appropriate with respect to particular substances, would be the more reasonable and efficient approach. By way of further example, petitioners have also not set forth sufficient facts to show an insufficiency of data or necessity of testing for any particular formulations. Rather, ''air fresheners'' by the petitioners' own definition encompass a ''broad range of product types'' and varying formulations.

To the extent the petitioners assert that testing of some subset of air fresheners could be required as a category of mixtures, this approach presents the same problems identified in Unit III.C.1. While the category described in the petitioners' comment is not quite as sweeping as the request in their petition, it is still a very expansive and ill-defined category of mixtures, and more information and analysis would be needed to determine if such an approach even merits further consideration.

D. Denial of Request to Issue TSCA Section 6 Labeling Rule

The petitioners requested that EPA issue a rule under TSCA section 6(a)(3) requiring air fresheners to be labeled to identify all ingredients. This request is denied. Petitioners have not set forth sufficient facts to establish that it is necessary to initiate the requested TSCA section 6(a) rulemaking.

In support of their request, the petitioners assert that manufacturers and importers are already aware of the ingredients in their products, that their products are unnecessary, and that requiring the requested labeling would therefore impose an insignificant cost. The petitioners also assert that many of the chemicals present in air fresheners are toxic. However the petition does not provide a reasonable basis to conclude that air fresheners, or the chemicals used in air fresheners, present or will present an unreasonable risk of injury to health or the environment. In addition to the limitations of the three reports petitioners principally rely on, the petition does not provide a basis upon which to estimate the cost of the requested rulemaking. Furthermore, the petition does not provide a basis for finding that the action requested by petitioners would be necessary to protect adequately against any unreasonable risk, or that it is the least burdensome requirement that would adequately protect against such risk.

As a threshold issue, as with their other requests, the petitioners do not demonstrate that any particular air freshener or air freshener ingredient presents or will present an unreasonable risk. The petitioners do briefly discuss some specific risk issues, but their statements are not sufficient to support any risk conclusions about any particular products or ingredients. For example, they cite the conclusions of the SCHER report that burning of some incense products available in Europe generated high benzene concentrations and that such ''benzene emissions need attention to diminish the exposure'' (Ref. 4). EPA does not believe this information is relevant, because the definition of air freshener provided by the petitioners does not appear to include incense. The definition in the petition does not include any products involving combustion—a process that raises issues significantly different from those raised by non-combustion products. In addition, combustion—whether of incense, candles, or anything else—creates chemicals that are not present in the original article, and it does not appear to EPA that the listing of ingredients in the article would be an effective means of protecting against any risk that might result from combustion of the ingredients.

Because the petitioners have not set forth sufficient facts with respect to any particular air freshener mixture or ingredient, EPA would have to treat air fresheners as a category of mixtures in order to grant the petitioners' request under TSCA section 6(a). This would result in a rule requiring labeling for a very broad product type, despite the fact that the petitioners have not shown that any specific air freshener, or air fresheners generally, present or will present an unreasonable risk. As described in Unit II.D., the information that the petitioners relied upon to support their request do not provide sufficient facts to support the assertion that air fresheners present or will present a significant risk, much less an unreasonable risk to human health or the environment. In addition, while not part of the petition, EPA also considered information provided by the petitioners and others during the public comment period. This information also did not provide a reasonable basis to conclude that air fresheners, or the chemicals in air fresheners, present or will present an unreasonable risk of injury to health or the environment.

In addition to the limitations of the risk information provided by petitioners, petitioners did not provide adequate information to address the other components of the unreasonable risk standard. These relate not merely to the effects of the mixture (i.e., air freshener), or the chemicals comprising the mixture, but also to the benefits of the substance(s) for various uses and the availability of substitutes for such uses and to the reasonably ascertainable economic consequences of the control

mechanisms proposed to control the risk.

These considerations are integral to the determination that there is a reasonable basis to conclude that a substance presents or will present an unreasonable risk, and the petitioners have not presented sufficient facts to address them. The petitioners asserted that the costs of their requested controls would be small and that the benefits of their controls would reduce risk, but provided no data or other information to substantiate either their estimates of cost or of the efficacy of their proposed control action. With respect to cost, contrary to petitioners' assertion, it seems likely to EPA that the cost of a rule requiring the listing of every ingredient of every air freshener would be substantial. The cost to the Agency of promulgating such a rule would also be very large. EPA would need to develop sufficient information to provide a reasonable basis to conclude that air fresheners as a category present or will present an unreasonable risk (it would need a record significantly more extensive than the information supplied by petitioner), and that product labeling is the least burdensome requirement that would adequately address that risk. The petitioners made no attempt to address this last requirement.

With regard to the benefits of air fresheners, even assuming air fresheners provide no public health value, this is not the only kind of benefit cognizable under TSCA. As petitioners recognize, air fresheners are purchased in large quantities, which suggests that consumers place significant value on them.

In sum, the petitioners have not set forth sufficient facts to establish that the requested rulemaking under TSCA section 6 is necessary, and EPA has denied the request.

IV. Comments Received

EPA published a notice in the **Federal Register** issue October 23, 2007 (72 FR 60016) (FRL–8154–5) announcing receipt of the petition and inviting public comment on or before November 7, 2007. EPA received 28 timely comments, 4 of which were from the petitioners. One of the comments was received the day after the comment deadline due to a delivery problem on the part of the courier. EPA decided to consider this comment with the others.

Eleven comments were from individuals who supported the petition. Several were allergy or asthma sufferers who felt that air fresheners aggravate their health problems. Several indicated a belief that manufacturers are not adequately testing their products and were especially concerned about children and air freshener misuse.

Five comments were from health, environmental, or animal welfare non-profit organizations (Toxics Information Project, Environmental Health Coalition of Western Massachusetts, People for the Ethical Treatment of Animals (PETA), Ecological Health Organization (ECHO), and the American Lung Association of New England). Four of the five supported the petition, while the fifth, PETA, supported portions of the petition in principle, while opposing the portion calling for testing on large numbers of animals. PETA criticized some of the information that the petitioners cited in support of their petition, and argued that additional animal testing is not necessary and would not provide useful information on the effects of air fresheners on human health.

Eight comments were received from air freshener manufacturing companies named in the petition and from trade organizations representing manufacturers of fragrance and fragrance-related products. (Reckitt Benckiser, Soap and Detergent Association, Grocery Manufacturers/Food Products Association, Fragrance Materials Association of the United States, Consumer Specialty Products Association, Dial Corporation, American Chemistry Council Phthalate Esters Panel, and Blythe, Inc.). All of these companies and organizations opposed EPA granting any part of the petition. The American Chemistry Council Phthalate Esters Panel and the Fragrance Materials Association of the United States (FMA) comments focused on the safety of several phthalate esters and the remainder of the commenters focused on air fresheners and fragrances generally.

The Consumer Specialty Products Association (CSPA) comments are representative of the industry comments, and almost all of the other industry commenters specifically endorsed CSPA's comment submission. The CSPA comment argued that the petition should be denied because:

1. There is inadequate evidence that air fresheners cause significant adverse reactions.

2. Sufficient air freshener safety data are already available to EPA.

3. The fragrance industry is already engaged in safety testing.

4. Labeling requirements are unjustified and duplicative of FHSA.

CSPA's comments asserted that the fragrance industry is adequately self-regulating through an industry research and testing organization, Research Institute for Fragrance Materials, and an industry standards-setting organization, International Fragrance Association. The comment included documents explaining the role of these organizations in the evaluation of ingredient safety by the fragrance industry. CSPA comments (and those from the two companies) explained the product stewardship programs used by Reckitt Benckiser and SC Johnson. CSPA's comments included their disagreements with and criticisms of the studies and data that petitioners used to support their position, and supplied additional studies that CSPA argued demonstrate the safety of fragrances and/or air fresheners.

The petitioners submitted four more comments, including two epidemiological studies: One on household cleaning sprays and adult asthma and one on prenatal phthalate ester exposure. Petitioners also submitted a press release about a National Institutes of Health (NIH) study concluding that exposure to 1,4-dichlorobenzene, a VOC, used in household cleaning products, may cause reductions in lung function. Finally, petitioners submitted a comment clarifying two terms used in their petition, and further defining the type and scale of testing they are petitioning for under TSCA section 4. Given the petitioners' obligation to clearly articulate requests and set forth facts in their original petition and the short span of time within which EPA must respond to the petition as written, EPA does not view the clarifications and scope modifications subsequently submitted in petitioner's comments as components of the petition. Nevertheless, EPA has considered and addressed petitioners' comments, as detailed in Unit III.

V. References

1. Sierra Club, Alliance for Healthy Homes, National Center for Healthy Housing and Natural Resources Defense Council. Letter from Ed Hopkins, Sierra Club; Robert Zdnek, Alliance for Healthy Homes; Rebecca Morley, National Center for Healthy Housing; and Mae C Wu, Natural Resources Defense Council to Stephen Johnson, Administrator, Environmental Protection Agency and Commissioner Thomas Moore, U.S. Consumer Product Safety Commission. Re: Citizen Petition to EPA and CPSC Regarding Air Fresheners. September 19, 2007.

2. CPSC. Letter from Lowell F. Martin, Acting General Counsel, Office of the General Counsel, U.S. Consumer Product Safety Commission, to Mr. Ed Hopkins, Director, Environmental Quality Program, Sierra Club; Ms. Rebecca Morley, National Center for

Health Housing; Mr. Robert Zdenek, Alliance for Healthy Homes, and Mae C. Wu, Natural Resources Defense Council. November 23, 2007.

3. Lai, M.W.; Klein-Schwartz, W.; Rodgers, G. C.; Abrams, J. Y.; Haber, D. A.; Bronstein, A. C.; and Wruk, K. M. 2006. 2005 Annual Report of the American Association of Poison Control Centers' National Poisoning and Exposure Database. *Clinical Toxicology*. 44:803–932.

4. European Commission, Scientific Committee on Health and Environmental Risks (SCHER). Opinion on the Report: ''Emission of chemicals by air fresheners: Tests on 74 consumer products sold in Europe'' (BEUC report January 2005). January 27, 2006.

5. Bureau Européen des Unions de Consommateurs (BEUC). The European Consumers' Organization. Emission of chemicals by air fresheners: Tests on 74 consumer products sold in Europe. 54 pp. January 2005.

6. Cohen, A. Janssen, S. and Solomon, G. ''Clearing the Air: Hidden Hazards of Air Fresheners.'' Natural Resources Defense Council. September 2007.

7. Reckitt Benckiser, Inc. Letter from Eileen J. Moyer, Director of Regulatory Relations, to Document Control Office, Office of Pollution Prevention and Toxics (OPPT), EPA. Docket ID number EPA–HQ–OPPT–2007–1016–0018.1. November 6, 2007.

8. EPA. Memorandum from Dirk F. Young, Environmental Engineer, Exposure Assessment Branch, Economics, Exposure, and Technology Division, to Robert Jones, Biologist, Chemical Information and Testing Branch, Chemical Control Division. Subject: Review of 2005 AAPCC on Air Fresheners. November 18, 2007.

9. EPA. E-mail communication from Tala Henry, Toxicologist, Risk Assessment Division, to Andrea Pfahles-Hutchens, Epidemiologist, Risk Assessment Division with E-mail communication response from Andrea Pfahles-Hutchens to Tala Henry. Re: Poison control reports. November 5 and 6, 2007.

10. CDC, HHS. Third National Report on Human Exposure to Environmental Chemicals. National Center for Environmental Health, NCEH Pub. No. 05–0570. July 2005. Available on-line at: *http:// www.jhsph.edu/ephtcenter/ Third%20Report.pdf*.

11. State of California. Proposition 65 List of Chemicals. September 27, 2007. Available on-line at: *http:// www.oehha.ca.gov/prop65.html*.

12. SCCNFP. The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers. Opinion Concerning Diethyl Phthalate. December 9, 2003.

13. SCCNFP. The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers. Opinion Concerning Diethyl Phthalate. June 4, 2002.

14. Greenpeace. Perfume: An Investigation of Chemicals in 36 Eaux de Toilette and Eaux de Parfum. Greenpeace International. 16 pp. February 2005.

15. SCCP. Scientific Committee on Consumer Products. Opinion on Phthalates in Cosmetic Products. March 21, 2007.

16. NAS. The National Academies. Project Information: Health Risks of Phthalates. 2007 Available online at: *http://www8.nationalacademies.org/cp/ projectview.aspx?key=48860*.

17. Europe Information Service. Product Safety: BEUC Report Claims Air Fresheners are ''Risk to Health.'' Europe Environment. February 18, 2005.

18. EPA. Memorandum from Conrad Flessner, Jr., Biologist, Exposure Assessment Branch, Economics, Exposure, and Technology Division, to Robert Jones, Biologist, Chemical Information and Testing Branch, Chemical Control Division. Re: Exposure Information Review of the Scientific Committee on Health and Environmental Risks (SCHER) Report on Air Fresheners (December 13, 2007).

19. A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information, U.S. EPA, EPA 100/B–03/ 001 (June 2003).

20. EPA. Memorandum from Andrea Pfahles-Hutchens, Epidemiologist, Existing Chemicals Assessment Branch, Risk Assessment Division, to Robert Jones, Project Manager, Chemical Information and Testing Branch, Chemical Control Division. Subject: Review of Epidemiology Studies for TSCA Section 21 Petition. November 27, 2007.

21. EPA. Screening Review of Literature for Air Freshener Exposure Information. Submitted by Versar Inc., to U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics. EPA Contract No. EP–W–04–035. November 20, 2007.

22. Zock, J-P; Plana, E; Jarvis, D.;, Anto, J. M.; Kromhout, H.; Kennedy, S.M.; Kunzli, N.; Villani, S.; Olivieri, M.; Toren, K.; Radon, K.; Sunyer, J.;, Dahlman-Hoglund, A.; Norback, D., and Dogevinas, M. 2007. The Use of Household Cleaning Sprays and Adult Asthma: An International Longitudinal Study. *American Journal of Respiratory and Critical Care Medicine*. 176: 735–741.

23. Caress, S. M. and Steinemann, A. C. 2005. National Prevalence of Asthma and Chemical Hypersensitivity: An Examination of Potential Overlap. *Journal of Occupational and Environmental Medicine*. 47:518–522.

24. EPA. E-mail communication with sample search results from Randall Brinkhuis to Greg Schweer. Subject: Search strategy and results for TSCA section 21 petition on air fresheners. December 3, 2007.

25. CSPA. Consumer Specialty Products Association. Letter with enclosure from Robert A. Matthews, McKenna Long and Aldridge, LLP, to Document Control Office, Office of Pollution Prevention and Toxics (OPPT), EPA. Docket ID number EPA–HQ–OPPT–2007–1016–0029.1. November 7, 2007.

26. EPA. Minutes of meeting held October 19, 2007, between EPA and petitioners. Re: TSCA section 21 petitioners on air fresheners. October 19, 2007.

27. NRDC. Letter with attachment from Mae C. Wu, Natural Resources Defense Council and Ed Hopkins, Sierra Club on behalf of petitioners. Re: Docket ID number EPA–HQ–OPPT–1016, to Document Control Office, Office of Pollution Prevention and Toxics (OPPT), EPA. Docket ID number EPA–HQ–OPPT–2007–1016–0013.1. November 5, 2007.

28. Sara Lee B.V. v. BEUC, KG 05/64 (March 8, 2005).

29. Cosmetic Ingredients Review (CIR) Expert Panel, 2005. Annual Review of Cosmetic Ingredient Safety Assessments—2002/2003. *International Journal of Toxicology*. 24 (Supp. 1); 1–102.

30. CEPA. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, Reproductive and Cancer Hazard Assessment Branch. 2007. Proposition 65 Safe Harbor Levels: No Significant Risk Levels for Carcinogens and Maximum Allowable Dose Levels for Chemicals Causing Reproductive Toxicity. October 2007.

List of Subjects

Environmental protection, Air fresheners, Phthalates, Volatile Organic Compounds (VOCs).

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