April 18, 2008

Green Seal is in the process of revising the Environmental Standard for Industrial and Institutional Cleaners, GS-37. Comments from the public were solicited on a Proposed Revised Standard from November 16, 2007 until January 30, 2008.

Included in this document are the comments received on the Proposed Revised Standard for Industrial and Institutional Cleaners GS-37, November 16, 2007 with responses and explanation on how the Proposed Revised Standard was modified accordingly.

By participating in Green Seal's standard setting process, the following organizations that provided comments played an important role in Green Seal's effort to encourage the design, manufacture and end use of environmentally superior products. Their assistance and involvement is greatly appreciated.

3M
Aha-Yes! LLC
Alaska Community Action on Toxics Anchorage
Amano Pioneer Eclipse Corporation
American Chemistry Council
American Federation of Teachers, AFL-CIO
Association of Vermont Recyclers
Betco Corporation
Breast Cancer Fund
Brulin and Company
Building Dynamics
California Asthma Partners
California Department of Public Health, Environmental Health Investigations Branch
California Department of Public Health, Indoor Air Quality Section
California Department of Public Health, Occupational Health Branch
California Teachers Association
Carpet and Rug Institute
Fragrance Materials Association of the United States
Center for Environmental Health
Center for Health, Environment, and Justice
City of Santa Monica - Environmental Programs Division
Clean Water Action
Community Action to Fight Asthma Coalition
Consumer Specialty Products Association
Contra Costa Asthma Coalition
Controlled Release Technologies, Inc
Council of State and Territorial Epidemiologists
Deirdre Imus Environmental Center, Hackensack University Medical Center
DuPont
EcoISP
Ecolab, Inc.
East Bay Municipal Utility District
Florida Chemical Company
For A Better Bronx
Friends and Advocates for Children, Teachers and Schools

Gabriel First Corp.
Grassroots Environmental Education
Great Neck Breast Cancer Coalition
Green Blue
Green Purchasing Institute
Green Schools Initiative
Greenbank Associates
GreenFaith
Hagelin & Co
Health Care Without Harm
Healthy Children Organizing Project
Healthy Building Network
Healthy Schools Campaign
Healthy Schools Network- VT/New England
Industrial Cleaning Supply Co.
INFORM
Innovative Chemical Technologies, Inc.
Institute for Children's Environmental Health
ISSA
JohnsonDiversey
King County, WA
Maintex
Martinez Unified School District, Martinez, CA
Massachusetts Coalition for Occupational Safety and Health
Massachusetts Operational Services Division
Multnomah County, OR
Natural Resources Defense Council
New Jersey Department of Environmental Protection
New York Department of Environmental Conservation
City of Palo Alto, CA
Pesticide Research Institute
PortionPac Chemical Corp
City of Portland, OR
Preventing Harm MN
Product Policy Institute
Racine Industries, Inc.
R.E. Whittaker Company
Regional Asthma Management and Prevention Initiative
RegNet Environmental Services
Rhode Island Committee on Occupational Safety & Health
San Francisco Asthma Task Force
San Francisco Department of the Environment
San Francisco Department of Public Health
City of San Jose, CA
City of Santa Monica, CA
School Environments Consultant
Science and Environmental Health Network
Sciencecorps
Scot Laboratories
City of Seattle, WA
Seattle & King County, WA
Seattle Public Utilities
ServiceMaster Clean
SI Group, Inc.
The Soap and Detergent Association
Solano Asthma Coalition
Spray Nine Corporation
Stearns Packaging Corporation
TD Research Ltd.
Toxics Information Project
University of California, Berkley
University of Connecticut Health Center
University of Massachusetts Lowell
Washington State Department of Ecology
Women's Voices for the Earth
Woolsafe Organisation
Yale Occupational and Environmental Medicine Program

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The language from the Proposed Revised Standard is included in bold, followed by comments, and Green Seal's response to the comments. Any modifications to the language in the Proposed Revised Standard are included in italics in the response.

1.0 SCOPE

This standard establishes environmental requirements for industrial and institutional general-purpose, bathroom, glass, and carpet cleaners. For purposes of this standard, general-purpose, bathroom, glass, and carpet cleaners are defined as those cleaners intended for routine cleaning of offices, institutions, warehouses, and industrial fcilities. Further, the criteria in this standard include consideration of vulnerable population requirements in institutional settings such as schools, day care facilities, nursing homes, and other facilities. The standard does not focus on the use of cleaners in households, food preparation operations, or medical facilities. Due to the large number of possible cleaning products, processes, soil types, and cleaning requirements, the compatibility of cleaners with surface materials is not specifically addressed in this standard. Product users should follow the manufacturers' instructions on compatibility.

Each criterion states whether it applies to the undiluted product or to the product as used.

Comment:

The general public simply takes note of the Green Seal without reviewing the detail or appreciating the limitations of this process. In this respect, many users are likely to assume that use of a certified product will provide a healthier indoor environment and be more protective of the outdoor environment than use of a non-certified product.

1. Certification does not consider product effectiveness regarding the control of pathogens and mold growth. Since few, if any, green cleaners are registered sanitizers, they can be expected to be much less effective than traditional disinfectants for the control of contagious viruses on hard surfaces and treatment of surface mold growth. These are clearly important considerations in judging environmental health risks.

2. Few if any, certifiied products seem to claim that use will help with respect to global warming. Many users will simply assume an advantage over non-certified products where a lower carbon footprint is not demonstrated.

Recommendation: The Certification process is misleading with respect to environmental health and global warming. Findings should be evidence-based. Green Seal focusses on the mere presence of an ingredient posing only theoretical risks where dose response and real-world experience are not considered. At a minimum, Green Seal limitations should be clearly spelled out, particularly with respect to sanitizing hard surfaces against cold and flu viruses, effective treatment of surface mold growth and relation to global warming.

Comment:

I would suggest exclusion of products containing known or suspected endocrine disruptors. As an example, Triclosan and Triclocarban are known to be thyroidal and androgenic, respectively. The American Medical Association has stated that hand washing with soaps containing Triclosan does not convey any additional antimicrobial effect, and may cause antimicrobial resistance issues.

Comment:
Having noticed that the EPA is considering an about-face in regards to ecolabeling on registered antimicrobials and also noting that the revised GS-37 standard would include RTU toilet bowl cleaners (many of which happen to be registered antimicrobials) I thought I'd take the time to point out that federal regulations cover what you can and can't do in regards to packaging antimicrobial cleaners. Green Seal may want to consider updating the packaging requirements section with some information on packaging specific to antimicrobials if it intends to allow them in the category. 40CFR165.25 references the applicable regulations. Note that the California RPPC rules exempt EPA registered antimicrobials for exactly the same reasons as those listed in the CFR.

Response:
The raw material, product manufacturing, use, and disposal are considered during the development of criteria. There may be cases when use exposure has demonstrate a "safe" limit, however exposure at the other stages of the life cycle may not have such "safe" levels and thus should be prohibited, when there are better alternatives available.

The carbon footprint of products is currently addressed through various standard criteria such as concentration and packaging. There is not a requirement for developing a carbon footprint for manufacturers. Green Seal will be offering a means to verify carbon claims on products, through an optional claim verification program.

The US EPA regulates the use of pesticides such as disinfecting and sanitizing products. It is under the EPA regulation, through Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that reviews and registered pesticides. The EPA currently does not allow for third-party claims to be made on FIFRA registered products. As a result, Green Seal does not include these items covered through EPA regulatory authority in this standard, GS-37. A separate standard may be developed that includes such products if EPA allows third-party claims to be made on FIFRA registered products in the future. This will be clarified in the scope of the standard.

This standard does not apply to any enzymatic or microbially active products or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), such as those making claims as sterilizers, disinfectants, or sanitizers.

Comment:
Proposal: Broaden the Scope of the GS-37 Standard to include Drain Pan Cleaners and Sanitizers

I would propose that the scope of the GS-37 standard be expanded to include Drain pan cleaners and sanitizers for HVAC systems. The sanitizers are regulated by FIFRA but the cleaners are not. In addition, some ingredients listed in the GS-37 standard are not yet prohibited for use under FIFRA. Drain pans are located within the air handler unit of the air conditioning system. The conditioned air that leaves the air handler impacts IAQ and the water stream leaving the pan impacts the environment. Therefore, it is important for the public to become educated when choosing these products.

> **Response**:
> The goal of GS-37 is to address the primary product categories utilized to accomplish the majority of cleaning tasks performed on a daily basis within a facility. Specialty cleaners are not included in the scope of this standard. The scope of the standard includes general-purpose, bathroom, glass, and carpet cleaners. If a product primarily functions as one of these cleaners, and has another use (ex. drain pan cleaner), it may be considered for certification. The scope does exclude cleaners in households, food preparation operations, or medical facilities. Additionally, biological cleaners will be explicitly excluded since they have specialty cleaning functions. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registered products are excluded from the standard.
>
> *This standard does not apply to air fresheners, enzymatic or microbially active products or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, such as those making claims as sterilizers, disinfectants, or sanitizers.*

Comment:
One type of hard surface cleaner that GS 37 doesn't take into consideration is abrasive cleaners, whether they come as powders or viscous suspensions. Such products cannot be diluted to 1:32 let alone the original 1:8. By their very nature, they are used as is.

> **Response**:
> An abrasive cleaner may be suitable for certification under GS-37, if its primary focus and labeling is for use as a restroom cleaner.

Comment:
Overall the goals and desires of the revision to make products safer specifically for children and the vulnerable population is laudable but we disagree with the approach. It would be more reasonable to develop a new standard for products that would be used in environments in which these populations would reasonably be expected to spend time such as schools or health care facilities. The revisions have the potential to drive up cost or lower performance of products in settings which are unlikely to pose a risk to the vulnerable populations.

Comment:
The background document for the standard includes a discussion of the importance of addressing children's health concerns in the standard. However, this does not seem to be reflected in specific language in the standard to address the concerns noted. This would seem to be an important area to address specifically in the standard itself.

Response:
The Scope section of the standard is used to define "what" is included in the standard, rather than "how" things are included in the standard. The background document described how vulnerable populations were included in the criteria development process. To briefly summarize, exposure to chemicals in the environment, including chemicals from cleaning products, can affect children differently and more severely than adults, for a number of reasons. Children's physiology differs from adults in ways that could result in greater health risks from chemical exposures. They have a higher ratio of skin surface to body weight. Children also eat, drink, and inhale more in proportion to their body weight than adults. Their metabolic pathways may also differ from those of an adult, which may limit their ability to detoxifying chemicals. At the same time, while children grow, their neurological, immune, and other body systems are still developing and exposure to toxic chemicals could more easily damage those systems, sometimes irreversibly. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. As a result, there are many uncertainties inherent to health risk assessment are compounded when applied to children. One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels of carcinogens, reproductive toxins, toxic heavy metals, etc. Another approach is to use exposure thresholds based on child exposure assumptions rather that those developed for adults, or to apply additional safety/uncertainty factors to modify threshold levels targeted for adults. These precautionary steps would be most acceptable where alternative ingredients are available. As a result, each criterion evaluated these considerations and developed the most suitable approach. When taking this approach, feasibility was also considered. Throughout the development of the criteria, feasibility was checked by looking at the portfolio of currently certified GS-37 products and with discussions with product manufacturers.

Comment:
ADD 4.17 Promoting Biodegradation: The product may contain Biosafety Level 1 Non-Pathogenic organisms for the purpose of aiding or promoting biodegradation.

Response:

The standard does not include biological/microbially active components. This was not explicit in the scope, but the scope was modified to clarify this:

… This standard does not apply to air fresheners, enzymatic or microbially active products…

Comment:
The Background Document to the Proposed Revisions to GS-37 indicates that toilet bowl cleaners, carpet spot removers, graffiti removers, and dry erase board cleaners will be included in the revised standard, but it is not mentioned in the proposed standard document. We recommend that the scope of the standard be clarified. If these products are to be included, we recommend the Proposed Revision document be amended to allow stakeholders to re-review the proposal with that in mind.

Comment:
Graffiti Remover. In the Background Document that accompanied the release of the Proposed Revisions to GS-37, reference is made to the intent to expand the scope of the product categories covered by the standard by adding toilet bowl cleaners, carpet spot removers, dry erase board cleaners, and graffiti removers. We concur with the addition of these product categories.

In reviewing the text of the proposed revisions, however, we note that all of the aforementioned product categories are addressed in Section 2, Definitions except for graffiti removers. We therefore recommend that graffiti removers be added to the definition of general purpose cleaners or be added as a separate definition.

Response:
The goal of GS-37 is to address the primary product categories utilized to accomplish the majority of cleaning task performed on a daily basis within a facility. Specialty cleaners are not included in the scope of this standard. A graffiti remover may be suitable for certification under GS-37, if its primary focus and labeling is for use as a general purpose cleaner. The definition for general purpose cleaner will be clarified.

General-purpose Cleaners. This category includes products used for routine cleaning of hard surfaces including impervious flooring such as concrete, stone surfaces, or tile. It does not include cleaners intended primarily for the removal of rust, mineral deposits, or odors. It does not include products intended primarily to strip, polish, or wax floors, and it does not include cleaners intended primarily for cleaning dishes, laundry, toilets, restrooms, glass, carpets, upholstery, wood, or polished surfaces or biological cleaners. Other cleaners may be included if they meet the requirements and marketed for general purpose cleaners. Other terms used for these cleaners may include, multi-surface cleaner.

Toilet bowl cleaners and urinal cleaners are included in the restroom cleaner product category, but require an additional performance test, for hard water stain

removal, since relying solely on the ASTM 5343-06 for soap scum removal does not represent the uses of this product. There is not an international or nationally standardize method for hard water stain removal (there is however a common method called the marble slab test), so alternate test performance requirements would apply for this test.

Restroom Cleaners. Products in this category include those used to clean hard surfaces in a restroom such as counters, walls, floors, fixtures, basins, tubs, toilets, urinals, and tile. Other terms used for these cleaners may include restroom cleaners or toilet cleaners.

Restroom Cleaners. The product shall remove at least 75% of the soil in ASTM D5343-06 as measured by the method. If the product is used for toilet bowl or urinal cleaning, then it also must demonstrate efficacy for water hardness removal following the requirements outlined in 3.2 for Alternative Performance Requirements.

The definition for carpet cleaners was clarified to include spot removers:

Carpet Cleaners. Products developed to perform routine cleaning or spot cleaning of carpets and rugs. This category may include, but is not limited to, products used in cleaning by means of extraction, shampooing, dry foam, bonnet or absorbent compound. These products shall have a pH between 3-9.

The definition for glass cleaners was clarified to include dry erase board cleaners:

Glass Cleaners. This category includes products used to clean windows, glass, dry erase boards, and mirrored surfaces.

2.01 Asthma

Asthma is a chronic respiratory illness that intermittently impairs breathing. It is characterized by variable airflow obstruction, commonly presenting with symptoms of cough, wheeze, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life-threatening. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure or up to 24 hours later in a "late phase," even interrupting sleep.

A chemical is considered capable of causing asthma if it is specifically listed as an Asthmagen by the Association of Occupational and Environmental Clinics (AOEC).

Comment:

1. The definition of respiratory irritant in the proposed standard is derived from the OECD classification of R-37. It would make NO SENSE to review each individual

ingredient for this classification down to the 0.01% ingredient cutoff, because of a high probability of over classifying the product.
2. Data on individual chemicals as to their status of respiratory irritants is very limited, and more than likely would require animal testing to obtain.
3. Data to prove that a product is not a respiratory irritant is virtually non-existent and will require animal testing.
4. Most products as-used are greater than 95% water and have almost no chance of being a respiratory irritant.

We recommend completely removing this as a requirement. It does not add value to the standard.

> **Response**:
> There was not a definition for respiratory irritant included in the proposed revised standard. And there was not a criterion to prohibit ingredients that would be respiratory irritants. However, a definition was added to clarify the criterion for terpenes and limonene below.
>
> *Respiratory Irritant. A chemical that may cause serious irritation the nose, throat, airways and lungs of humans or result in positive results from appropriate animal tests.*
>
> *Respiratory Irritants. The product as used shall not contain the following ingredients that are respiratory irritants above the specified levels:*
> - *D-limonene shall be limited to a concentration of 20 millimoles (mmol) or less per liter.*
> - *Terpene hydrocarbons, other than d-limonene, (e.g. pinene, myrcene) shall be limited to 10 mmol or less per liter.*

Comment:
We support Green Seal's addition of criteria to exclude ingredients known to cause asthma since it is documented that janitorial workers can develop occupational asthma from cleaning products, and some workers with asthma can have their asthma triggered or made worse by exposure to asthmagens or other respiratory irritants such as those if fragrances. Using the AOEC list makes sense and we hope that Green Seal will update it's asthmagen restrictions when new chemical ingredients are added to that list.

Comment:
I am writing to comment on the proposed revisions to GS-37, entitled “Ingredients that Cause Asthma.” I commend Green Seal in their effort to include criteria designed to limit ingredients known to cause asthma in cleaning chemicals. I appreciate your efforts to minimize the likelihood that workers and occupants will come in contact with cleaning chemicals that contain asthmagens.

It is well documented in the literature that janitorial workers, custodians and professional cleaners are one of the high risk groups for work-related asthma. Our experience with

patients in our environmental and occupational medicine clinic show that exposure to cleaning chemicals effects both the health of workers using the chemicals and the occupants in the building of use.

I strongly support the proposed standard that will define an asthmagen according to the Association of Occupational and Environmental Clinic's list (AOEC). Under this proposed standard, chemicals with an "A" designation on the AOEC list will be prohibited, and reduce the number of new cases of asthma associated with these ingredients. The AOEC Exposure Codes currently lists 359 substances as asthmagens which are easily accessible at the URL www.aoec.org/aoeccode.htm. It is important to prohibit known asthmagens in cleaning chemicals, and to continue to strengthen the GS-37 Standard so that other ingredients that are related to asthma exacerbations are identified and prohibited. I urge your executive committee to continue to work on this issue. I recognize that further work is needed to define and identify respiratory irritants and I would be happy to work with you on this in the future.

Comment:
For many years, we have been concerned at the alarming rates of asthma in our schools. Not only are we experiencing an epidemic of asthma among students, but also among school staff. In fact the National Institute for Occupational Safety and Health (NIOSH) has documented a higher prevalence of asthma in school employees compared to the general working population. We understand from NIOSH's research that a significant amount of the work-related asthma exacerbations can be attributed to exposure to cleaning products. We are heartened that you have referenced the AOEC Clinic's list of asthmagens when designating prohibited chemicals.

Response:
Comments acknowledged.

Comment:
2.1 Asthma. The second paragraph of this section establishes the Association of Occupational and Environmental Clinics (AOEC) as the authority for defining "asthmagens" and bases the criteria for asthmagens on the AOEC list. Green Seal believes that this list is based on "clear criteria" that are utilized in a peer-reviewed process. However, it is not clear to us how the list was generated and what the specific columns mean. We therefore question the validity and relevance of the criteria and the list itself to determine limitations on ingredients used in fragrance formulations.

There are few points to review here. First, in the definition of asthma it is important to note that, while it is correct that it is a chronic respiratory condition, variable airflow obstruction is reversible. Second, although the criteria have been developed by a well-respected epidemiologist/physician, Dr. Bill Beckett, who specializes in occupational asthma research, the language he uses in his "asthmagen protocol" document clearly indicates that he is hesitant to conclude that any of the materials on the AOEC list are truly asthma-causing. He further states that asthma-exacerbation can even be induced "by inhalation to non-specific substances such as nuisance dust or cold, dry air." Dr.

Beckett specifically notes that while the AOEC list has been developed in an attempt to identify materials that may cause de novo asthma, the fact that pre-existing asthma can confound the finding of a new irritant airways response precludes the ability of the AOEC list to address work-aggravated asthma in all scenarios. Third, Dr. Beckett wisely states that asthma is diagnosed on the basis of clinical signs/symptoms and not by a "single test, biomarker, or gene specific for asthma." Therefore, we strongly object to the use of the AOEC list as a bright line criterion for identifying materials that should not be present in I&I cleaning products. We further question the need to include asthma as a criterion in the standard at all.

Comment:
Green Seal Should Not Use the AOEC List as Justification for Banning of Substances in Products

We object to the wholesale inclusion of the American Occupational Environmental Clinic (AOEC) list as the basis for prohibiting ingredients in products. Adoption of the AOEC list could prohibit the use of more than 350 ingredients without consideration of the actual risks that these substances might pose in cleaning products. In particular, any criteria for asthmagens should be based on appropriate risk-based concentrations and exposure threshold levels rather than a blanket prohibition.

Proposed Standard 37 implies that all chemicals on the AOEC list are capable of causing asthma. The AOEC list was developed to provide guidance for occupational settings, generally in the manufacturing sector. The AOEC list highlights exposures that might need to be managed to reduce the likelihood of occupationally induced asthma to limit occupational exposures. AOEC methodology for listing includes a process that can rely on a potentially small database (sometimes only one or two workers) from occupational settings, where exposures are generally many times greater those encountered during typical product use.

The relevance of the AOEC list to cleaning product ingredients has not been adequately discussed. While a particular chemical may be listed as an occupational asthmagen by the AOEC, the mere presence of that chemical in a cleaning product, particularly at a low concentration, does not demonstrate a risk of producing an asthmatic response or condition.

Therefore, it is inappropriate for Green Seal to adopt the AOEC list as the justification of the wholesale banning of substances when used as an ingredient in commercial product(s) and preparation(s).

Comment:
Any Criteria for Asthmagens Should Include Scientifically Appropriate Concentration Threshold Levels

The mere presence of an ingredient in a product is insufficient to determine whether that product, as used, poses a potential for respiratory exposure or health risk. A basic rule of

toxicology is that the actual chemical exposure, not the mere presence of the chemical, is an essential factor in determining the response.

For many chemicals, there are thresholds below which an adverse health effect is not likely. Such threshold concentration limits are routinely recognized in health-based approaches by governmental authorities for triggering the application of product regulations on labeling and content. For example, within the European Union Directive 1999/45/EC (Dangerous Preparations Directive), a product is allowed to have up to 20% concentration of any non-gaseous substance with the risk phrase R37 (irritating to the respiratory system) in the product/preparation and up to 5% concentration of any gaseous substance PRIOR to the application of the R37 classification on the product's label or the MSDS. Green Seal's Discussion Document does not reflect this important aspect of exposure and response.

We believe that the AOEC list is best used by Green Seal as a starting point for the further evaluation of product ingredients. If warranted, Green Seal could establish concentration triggers for individual constituents in cleaning products. Each compound covered in the criteria should have its own concentration limit set based on a risk analysis taking exposure calculations into consideration.

Response:

More than 30 articles over the last several years have documented the increased incidence and prevalence of asthma among janitors and other cleaning workers in many countries (Nazaroff, 2005, Rosenman, 2006). Henneberger (2005) commented that, "Over the past 15 years, professional cleaners have emerged as one of the high risk groups for work related asthma in industrialized nations." This adverse effect is not limited to individuals who professionally perform cleaning tasks; cleaning products also affect other building occupants and bystanders (Nazaroff, 2004, Rosenman, 2003). Case reports and epidemiologic studies have documented asthma among individuals who use spray cleaners at home (Zock, 2007, Rosenman, 2007). And a new study has documented wheezing and decrements in lung function in children whose mothers had high domestic cleaning chemical exposure during pregnancy (Henderson 2007).

Children have a higher rate of asthma than adults. There are a number of developmental and physiological factors that may contribute to this higher rate, including incomplete metabolic defenses and immunological mechanisms, a higher breathing rate, greater surface area to volume ratio as well as behavioral differences including hand to mouth activities and more time on the ground. Some of these characteristics may contribute to greater exposure and/or to greater susceptibility to hazardous effects from chemicals in the environment. An article by Mendell (2007) reviewed 21 published epidemiologic studies on associations between indoor residential chemicals and respiratory health and/or allergy in children. Specifically, Mendell found associations between formaldehyde and phthalates and asthma, as well as suggestive evidence for aromatics, aliphatics, limonene, tetrachloroethylene, trichloroethylene and either asthma-related effects

or allergy/atopy indicators or both. Note that Mendell's previous research had documented an association between indoor pollutants in schools and poorer student performance (Mendell and Heath, 2005).

Asthma is not a condition in which dose can be determined which is why risk assessments have been ineffective/irrelevant and one reason that testing methodology hasn't been available to screen chemicals. As a result, reliance on clinical data is essential. Asthma is a clinical diagnosis, and, as such, it includes consideration of underlying pathology as well as the symptoms that occur during episodes. Dr. Beckett specifically describes the efforts to identify agents "known to cause asthma *de novo*." He further explains that the underlying mechanism may be immunological, "another form of sensitization, or a chronic state due to non-sensitizing inflammatory stimuli." The evidence considered specifically exclude inhalation exposures that only exacerbate existing asthma. Dr. Becket also specifically addresses specificity. The purpose, he wrote is to allow avoidance of specific substances "without requiring unnecessary avoidance of non-asthmagens."

The Association of Occupational and Environmental Clinics, established in 1987, is a non-profit organization, "committed to improving the practice of occupational and environmental health through information sharing and collaborative research." The Association of Occupational and Environmental Clinics (AOEC) receives support through multi-year cooperative agreements with the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH). It represents a network of 60 occupational and environmental clinics and 250 individuals dedicated to sharing information and improving practice of diagnosis, workplace evaluation and research. Regular feedback is provided by clinics and departments of public health that utilize AOEC educational materials and the list of chemicals.

The criteria for identifying a chemical as an asthmagen (A) were formally adopted, as revised, by the AOEC board in 2005. Since the list was intended for clinical use, some of the "A" were assigned prior to this formal adoption. However, AOEC has been systematically reviewing A chemicals to ensure that they meet the criteria as originally developed (one of two major criteria or two of four minor criteria, see http://www.aoec.org/content/Asthmagen_Protocol_4-9-05_revision.doc) This review provides scientific (as it relates to this health concerns) evaluation to now enable any subsequent listings as usable for product reviews.

As a result, Green Seal will prohibit chemicals that meet the criteria for a sensitizer, after a full review of the evidence is completed on those chemicals. The criteria for the review have been included in the standard as the means to identify if a chemical is an asthmagen. The AOEC has acknowledged that chemicals that have been reviewed according the criteria included in the standard do cause asthma and Green Seal will recognize/prohibit those chemicals that have gone through the AOEC review (so listing as an asthmagen by AOEC does not

mean that is will be recognized by Green Seal since not all chemicals on the list have been reviewed by the panel and meet the established criteria for sensitizers). Since the current form of the list is not clear about which chemicals would meet Green Seal's requirements, Green Seal will provide this list on its web site. Currently, in using these criteria diethanolamine and triethanolamine would be prohibited. Monoethanolamine is under review by AOEC, with conclusions expected in September 2008.

The criteria, and this standard, do not cover chemicals or items that exacerbate asthma, also called asthma triggers. This is because, for at least one reason, once an individual is sensitized it is unclear all the possible triggers beyond the initiating chemical.

Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. The chronic inflammation is associated with variable airflow obstruction, commonly presenting with symptoms of cough, wheezing, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life-threatening. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure or up to 24 hours later in a "late phase," frequently interrupting sleep. Chemicals that cause asthma include those listed as asthmagens after a full review of that chemical's evidence by the Association of Occupational and Environmental Clinics that have evidence of being sensitizers which are those that lead to hypersensitivity of the airways through sensitizing biologic mechanisms or meet the criteria outlined in Appendix A.

Appendix A
A substance will meet criteria for causing asthma if it first meets the test of specificity (it can be identified as a discrete workplace substance) and clinical relevance (it is present in the air of workplaces) and in addition meets sufficient criteria as listed below. To be included as a sensitizing cause of asthma, it must meet one or more of the major criteria, or two or more of the minor criteria.

A. *Specificity. A substance must be defined in such a way that, if it is a cause of asthma, it can be avoided specifically by the patient without requiring unnecessary avoidance of non-asthmagens.*
B. *Clinical relevance. Substances must be currently used or have been used in workplaces where there is potential for inhalation exposure. A peer-reviewed case report, outbreak report, or case series report is also required to establish clinical relevance where circumstances described in the report indicate the possibility of this substance as an asthmagen.*

<u>Major Criteria (at least one)</u>

1. Specific inhalation challenge indicates occupational asthma (i.e. immediate or delayed fall in FEV_1 after exposure) in at least one patient with asthma who

appears to have developed the asthma as a result of exposure to the implicated substance. Peer reviewed study should indicate a response to sub-irritant levels of sensitizing substances. Ideally, a positive challenge will be controlled by negative challenges in asthmatic patients who are not believed to be sensitized to the particular substance, but this design is not characteristic of many specific exposure challenges.

2. Workplace challenge with physiologic response (serial spirometry or serial peak expiratory flow) showing reversible expiratory airflow obstruction or changing airway reactivity in relation to exposure, with a comparable control period without significant variable airflow obstruction or airway reactivity. Subjects tested should be reasonably considered to be without asthma prior to testing in the workplace, to exclude work-aggravated asthma. Peer reviewed publication.

OR

Minor Criteria (at least two):

1. Non-Specific airway hyperresponsiveness is demonstrated in patients with suspected occupational asthma while they are still employed at the workplace in question, based on methacholine, histamine, or cold-air challenge, published in a peer-reviewed journal.

2. Work-exposure related reversible wheezing heard with repeated exposures in at least one patient with a compatible clinical picture, published in a peer-reviewed journal.

3. Positive IgE antibody (skin test or serologic test) for the suspected antigen in at least two patients, indicating potential IgE sensitization, published in a peer-reviewed journal.

4. Clinical response of remission of symptoms with cessation of exposure and recurrence of symptoms with re-exposure in one or more patients in each of two or more subjects published in a peer-reviewed journal.

Ingredients that Cause Asthma. The undiluted product shall not contain any ingredients that cause asthma.

Nazaroff, W.W., Weschler, C.J. 2004. “Cleaning products and air fresheners: exposure to primary and secondary air pollutants.” *Atmospheric Environment.* 38:2841-2865.

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Comment:
Green Seal Should Replace its Definition for Asthma with the Clinically Based Definition Identified by GINA

Asthma is a multi-factorial condition for which there is no standard diagnostic test. The clinical diagnosis of asthma requires more information than the physical characteristics of coughing and wheezing. As AOEC states, "Asthma is a clinical diagnosis since there is no single test, biomarker, or gene specific for asthma."

Within the clinical community, the international definition of asthma put forward by the Global Initiative for Asthma (GINA) is "... a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role. The chronic inflammation causes an associated increase in airway hyper responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment"
Green Seal should change the definition of asthma in Standard 37 to the definition used and accepted by the Global Initiative for Asthma and international asthma experts.

Response:
The definition for asthma was modified, and includes some of the features included in the GINA definition, but also includes how ingredients that cause asthma are determined.

Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. The chronic inflammation is associated with variable airflow obstruction, commonly presenting with symptoms of cough, wheezing, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life-threatening. Symptoms may resolve completely between active episodes. Symptoms may occur during exposure, immediately after exposure or up to 24 hours later in a "late phase," frequently interrupting sleep. Chemicals that cause asthma include those listed as asthmagens after a full review of that chemical's evidence by the Association of Occupational and Environmental Clinics that have evidence of being sensitizers which are those that lead to hypersensitivity of the airways through sensitizing biologic mechanisms or meet the criteria outlined in Appendix A.

Comment:
2.1 Asthma. This definition of asthma recognizes that asthma attacks can involve "symptoms of cough, wheeze, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life threatening." Yet, the standard will effectively screen out only a couple of chemicals (notably monoethanolamine and triethanolamine) for which documented cases show they are capable of causing new cases of asthma (i.e., those on the "AOEC" asthma list). For this standard to protect workers as well as children and other vulnerable populations, it will need to screen chemicals that can trigger asthma attacks among the millions of people who already have asthma. This includes highly corrosive respiratory irritants that are not on the AOEC list such as sodium and potassium hydroxide, ammonia, hydroxyacetic acid and lactic acid, all of which are reported on MSDSs of GS-37-certified products. One manufacturer of lactic acid (JT Baker) reports that "Inhalation of dust or vapors may be corrosive to the mucous membranes. Symptoms may include sore throat, coughing, and shortness of breath. MSDS for Lactic Acid, JT Baker, 8/18/05, http://www.jtbaker.com/msds/englishhtml/l0522.htm." Conntinuing to allow these substances in Green Seal-certified products will result in exposure to substances that can trigger asthma attacks. Green Seal should consider adding these corrosive respiratory irritants to its prohibited ingredients list. Applying the new pH requirement will address this problem some but not completely. One product with a relatively neutral pH (7.5 to 9), for example, reported on its MSDS that it "may aggavate existing skin or respiratory conditions such as dermatitis or asthma. May cause respiratory irritation." Green Seal should ensure that its products do not trigger asthma attacks in workers, children or other people who may be exposed to them.

Response:
Efforts to extend protection against all respiratory irritants are hampered by the absence of a commonly agreed upon definition, or tests that assess the capacity of

chemicals to cause respiratory irritation. The absence of a commonly accepted definition of respiratory irritation may be due, in part, to the complex mix of factors that can contribute to respiratory irritation. These include volatility, method of application, concentration in the product, pH, presence of other materials that may bind ingredients so that they are not released, or oxygenate ingredients yielding peroxides and other more irritating compounds. Nor does it consider the wide range of individual sensitivity to irritants. However, it has been acknowledged by experts in the field that the other criteria in the standard address most of the respiratory irritation concerns (ex. chronic inhalation, VOC content, terpenes).

Comment:
Asthmagen: A late addition to the standard, the definition of an asthmagen is equivalent to a respiratory sensitizer. The definition proposed in the standard, however, refers to a clinical definition. All of the tests listed are patient related data – that is, human data is required. It will be very difficult, if not impossible to find this data for the vast majority of chemicals.

Response:
The definition for asthmagen considers respiratory sensitization since it is the leading mechanism for causing asthma, but does need to consider the clinical relevance, effect in a human, since there are no screening methods available for testing chemicals for their ability to cause asthma. Only those chemicals that have undergone a full review of the evidence by the AOEC panel and meet the criteria for sensitization will be prohibited.

2.02 Bathroom Cleaners
Products in this category include those used to clean hard surfaces in a bathroom such as counters, walls, floors, fixtures, basins, tubs, toilets, and tile.

Comment:
I would like to suggest a clearer distinction be made between cleaners and disinfectants/sterilizers in your standard.

An example of a marketed "green" cleaner:
Multi-Purpose Cleaner-Sanitizer-Virucide-HBV. It not only cleans, but destroys 99.99% of common bacteria, such as salmonella, staph, strep and E-coli. It also kills 99.9% of specified viruses, including Herpes 2, Influenza A2/Japan, HIV-1 and Hepatitis B.

Among the listed ingredients is hydrogen peroxide. But not specified is what the concentration of HP in this product. HP at 3% concentration is a mile irritant, at 8-10% is classified as corrosive and should labeled as severely irritating to eyes skin and lungs. At higher concentrations (27.5) pulmonary edema and chemical pneumonitis is a risk. At 50% or above it is oxidizer and has been pegged as an instrument of terrorism.

This product which is aggressively marketed as a green cleaner is actually a sterilizer.

To avoid confusion I suggest you might include definitions of disinfectant and sterilizer and note that the application of the Green Seal to is to cleaning compounds and makes no assessment regarding sterilizers or disinfectants.

Following the International Society for Infectious Disease, ISID:

A disinfectant is a physical or chemical product or procedure that destroys most pathogenic organisms, except bacterial spores.

A sterilizer: a procedure or chemical product that eliminates all living organisms, including bacterial spores.

Response:
The US EPA regulates the use of pesticides such as disinfecting and sanitizing products. It is under the EPA regulation, through Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that reviews and registered pesticides. The EPA currently does not allow for third-party claims to be made on FIFRA registered products. As a result, Green Seal does not include these items covered through EPA regulatory authority in this standard, GS-37. A separate standard may be developed that includes such products if EPA allows third-party claims to be made on FIFRA registered products in the future. This will be clarified in the scope of the standard.

This standard does not apply to air fresheners, enzymatic or microbially active products or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, such as those making claims as sterilizers, disinfectants, or sanitizers.

Comment:
Not to put too fine a point on this, but I suggest a clarification of terms in this area. "Bathroom" is a term more descriptive of a space with a single commode or urinal and possibly a sink. Bathroom tends to imply a space similar to one in the home, which would include a shower and/or tub.

In most public spaces, this is not the case. "Rest Room" is a more accepted and descriptive term when refering to public spaces with multiple fixtures, that is two or more commodes, urinals and/or sinks. Whether a stand-alone space or as part of a larger space, such as a school locker room, rest room conotes a space with much greater and more complicated cleaning issues than does bathroom.

Please consider changing or adding to this space description as it applies to the standard.

Response:

This modification has been made, along with including alternate names for the product category in the definition.

Restroom Cleaners. Products in this category include those used to clean hard surfaces in a restroom such as counters, walls, floors, fixtures, basins, tubs, toilets, urinals, and tile. Other terms used for these cleaners may include bathroom cleaners, toilet bowl cleaners, or urinal cleaners.

2.03 Carcinogens
Chemicals listed as a known, probable, reasonably anticipated, or a possible human carcinogen by the International Agency for Research on Cancer (IARC) (Groups 1, 2A, and 2B), the National Toxicology Program (NTP) (Groups 1 and 2), the U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) (weight-of-evidence classifications A, B1, B2, C, carcinogenic, likely to be carcinogenic, and suggestive evidence of carcinogenicity or carcinogen potential), or the Occupational Safety and Health Administration (OSHA).

Comment:
The use of the EPA Letter classification for carcinognes is outdated. It is based on a 1986 criteria and has been superceded by a qualitative system established in 2005.

Since some classifications are old, it is important to address how differences in classifications between IARC, NTP EPA, etc. will be handled.

Response:
The various EPA IRIS cancer guidelines weight of evidence classifications used throughout the years have been included in the definitions for carcinogens since they are all still active. From the IRIS web site, "… the 1986, 1996, 1999, and 2005 Guidelines for Carcinogen Risk Assessment. These guidelines reflect the evolution of the science in this area and the corresponding evolution of the Agency's approach to characterizing weight-of-evidence for human carcinogenicity." A chemical classified A in 1986 was not relisted in 1996, 1999 and 2005. So each classification must be included. As a result, all the classifications will remain in the definition for carcinogen.

Comment:
The Proposed Definition for "Carcinogens" is Overly-Broad and Misrepresents EPA Descriptor Categories

The proposed definition for carcinogens includes weight-of-evidence classifications (A, B1, B2, and C) from U.S. EPA's 1986 guidelines for carcinogen risk assessment, as well as narrative descriptors (Carcinogenic to Humans, Likely to Be Carcinogenic to Humans, Suggestive Evidence of Carcinogenic Potential) from EPA's 2005 guidelines. We believe it is inappropriate to define all substances falling under such a broad range of classifications and descriptions as "carcinogens."

In particular, substances characterized as having Suggestive Evidence of Carcinogenic Potential should not be included. According to EPA, this descriptor "covers a spectrum of evidence associated with varying levels of concern for carcinogenicity." This range would include "a single positive cancer result in an extensive database that includes negative studies in other species." Such a range of evidence is entirely appropriate for the Suggestive Evidence descriptor, but is overly-broad for inclusion for the proposed definition of "carcinogens."

Green Seal's use of EPA descriptors runs counter to science-based approach that EPA has taken in characterizing carcinogenicity. Under the EPA's 2005 guidelines, a narrative approach is used in place of classifications. Weight-of-evidence descriptors are used as part of the overall narrative, but are not intended to serve as stand-alone classifications.

A narrative characterization explains an agent's human carcinogenic potential and the conditions that characterize its expression. It would include, for example, if carcinogenicity is possible only by one exposure route or only above a certain human exposure level. Such information can help identify whether a substance may actually pose a cancer concern as a cleaning product ingredient. However, such information is completely disregarded in Green Seal's list–based criteria.

Comment:
Carcinogens: The designation of substances as carcinogens under the standard continues to be overly broad. It appears to include substances that, based upon mode of action data and well known mechanisms of toxicity, are not considered to pose carcinogenic risks to humans.

> **Response**:
> This standard is aimed to identify leadership products. Leadership products do not, and should not, include carcinogenic chemicals or those that are likely or have suggestive evidence of carcinogenicity. Green Seal uses the multiple sources of recognized international and national lists for carcinogens. A chemical would be prohibited if it is listed on any one of the lists cited. Since this definition is not a modification from the current GS-37 standard, it has proven that meeting the criterion has not been an issue for GS-37 products for many years.

Comment:
1. Expand the definition of Carcinogens used (Section 2.3)
Currently, the definition states "Chemicals listed as a known, probable, reasonably anticipated, or a possible human carcinogen" by the International Agency for Research on Cancer (IARC) plus the three U.S. programs.
A. Include chemicals listed as carcinogens by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq.) (compounds with NSRLs, http://oehha.ca.gov/prop65/pdf/October2007StatusRpt.pdf)
B. Explicitly define that the most current lists shall be applied and that product

certifications are subject to changes in these lists.
C. Although the proposed criteria appear to prohibit carcinogens, the way that an ingredient has been defined to mean any compound that is 0.01% by weight means that many carcinogens at levels of concern may be in GS-37 formulations. The list of safe harbor levels published by CA EPA OEHHA, http://www.oehha.ca.gov/prop65/pdf/October2007StatusRpt.pdf clearly lists the daily Level (?g/day) no significant risk levels (NSRLs) for carcinogens. This list shows many chemical limits that are well below the 100 ppm limit (0.01%)

Response:
Green Seal uses the multiple sources of recognized international and national lists for carcinogens. A chemical would be prohibited if it is listed on any one of the lists cited. Since Green Seal follows ISO 14020 for criteria development, there is preference for international and national lists. With IARC, EPA, NTP, and OSHA available the California Prop 65 list of carcinogens is not used.

The criterion that prohibit the inclusion of carcinogens according to the definition discussed, prohibits chemicals not only that are ingredients (0.01% or more in the products), but also any intentionally added component (also defined in the standard, and would include anything added below 0.01%). This was further expanded to include ingredients or components that produce or release carcinogens (this would include components like formaldehyde donors).

Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens or reproductive toxins. The product shall not contain any ingredients known to produce or release carcinogens, mutagens or reproductive toxins.

2.05 Concentrate
Product, as sold, that must be diluted by at least thirty-two parts by volume water (1:32 dilution ratio) prior to its intended use.

Comment:
This sounds very reasonable. We agree.

Response:
Comment acknowledged.

Comment:
The GS-37 section 2.5 definition of “Concentrate” is too limiting. Many products that are not only efficacious but also having additional product attributes are formulated so that they will be diluted 1:16. These are concentrated products, hence the required dilutions. However, in order to formulate such products that have additional benefits for the

purchaser, additional chemistries must be added. These chemistries increase the total number of actives in the formula, thereby requiring a 1:16 final dilution ratio to ensure the stability of the concentrate while delivering sufficient actives to meet all of the performance requirements. Revising this definition by replacing 1:32 with 1:16 will enable these multi-faceted products to continue to be manufactured. In doing so, such products replace two or more separate products effectively reducing by 50% (or better) their packaging, labeling, energy, and transportation requirements.

The revised definition being proposed is: "Concentrate. Product, as sold, that must be diluted at least sixteen parts by volume water (1:16 dilution ratio) prior to its intended

Comment:
Definitions
Concentrate – We disagree with the definition of concentrate as 1:32 dilution. It is capricious and arbitrary. Although the stated purpose of this change is to save energy, packaging, and transportation it does not take into account the potential that the end user will just use more product to make up for performance deficiencies this change may drive. Although performance requirements have been modified there is a law of diminishing returns that will result from driving concentrations too high. Unnecessary components may be added just to stabilize the product increasing the chemical burden on the environment. In addition, many dispensing systems exist in the field which may be obsoleted by this change resulting in unnecessary replacement of functioning systems at a cost to end users, increased landfill use and an economic burden on manufacturers to redesign and resupply the community.

Comment:
Carpet cleaning product concentrates are diluted prior to use between 1:4 and 1:264. We therefore suggest that the specified dilution rate is omitted. Suggested test:

"Products, as sold, that must be diluted with water prior to its intended use".

Comment:
I agree that to put a dilution ratio into the standard is self-defeating. The range of dilution for carpet cleaners is true, however, for hard floor care products, the range can be even greater, with a high rate of 2:1 or 3:1 for some floor strippers to as low as 500:1 for some degreasers.

One addition to the suggestion from the above comment would to add "potable" as a proper descriptor of the water used to dilute a concentrate.

Comment:
Green Seal should revoke the proposed increase in minimum concentration levels. Point-of-use dilutions such as 1:8 or 1:16, currently allowable under GS-37, already save substantial amounts of transportation energy over ready-to-use products. The most measurable benefits from shipping concentrates have already been impounded in the current GS-37; any further concentration from the current levels yields benefits that are

marginal and incrementally insignificant.

The phenomenon of diminishing returns makes the incremental energy-savings yield from further concentration of GS-37 products miniscule. Each doubling of the part 2.05 minimum dilution-ratio yields an exponentially smaller benefit. Additionally, the counter-productive effort to increase concentrations is counter to and obstructs compliance with the other, conflicting elements of the revised standard; namely, part 3.1 Product Performance and part 4.0 Product-Specific Health and Environmental Requirements.

Green Seal's imposition of a higher minimum product concentration, for a marginal benefit, triggers the need for animal testing. the determination of a product's acute oral toxicity has to come from the calculation of each chemical component's toxicity on a weighted-average basis per part 4.1 Oral Toxicity. This is the only way open to my firm as I will not willingly sponsor the testing of my finished products on live animals.

Green Seal should revoke the proposed increase in minimum concentration levels in part 2.05. Green Seal's imposition of a higher minimum concentration reflects yet another bias in favor of mechanical dilution systems and against portion-controlled packets. The other bias is found in part 4.4 Skin and Eye Irritation. Portion-controlled packets have a tremendous benefit to offer society and the environment in the reduction of solid waste through "source-reduction". The use of portion-controlled packets also reduces wasted time and energy in cleaning operations because of their portability.

The portability of portion-controlled packets also results in a possiblity of their being pilfered by cleaning staff. Control of the pilfery of customers' property, every other kind of cleaning supply and portion-controlled packets is a challenge for the cleaning industry. Making the portion-controlled packets ever smaller only makes pilfery more tempting and easier to accomplish.

Comment:
We agree that 1:32 is not representative of most carpet cleaners. A commenter at "definitions" has it right.

"The GS-37 section 2.5 definition of concentrate is too limiting. Many products that are not only efficacious but also having additional product attributes are formulated so that they will be diluted 1:16. These are concentrated products, hence the required dilutions. However, in order to formulate such products that have additional benefits for the purchaser, additional chemistries must be added. These chemistries increase the total number of actives in the formula, thereby requiring a 1:16 final dilution ratio to ensure the stability of the concentrate while delivering sufficient actives to meet all of the performance requirements. Revising this definition by replacing 1:32 with 1:16 will enable these multi-faceted products to continue to be manufactured. In doing so, such products replace two or more separate products effectively reducing by 50% (or better) their packaging, labeling, energy, and transportation requirements.

The revised definition being proposed is: “Concentrate. Product, as sold, that must be diluted at least sixteen parts by volume water (1:16 dilution ratio) prior to its intended use.”

This seems reasonable to us.

Comment:
The requirement for a minimum dilution of 1:32 is much too restrictive in that formulations for some cleaners, otherwise deserving of Green Seal certification, cannot be made to that concentration level and remain stable. Moreover, it is incongruous that, in the same standard, some cleaners are to be held to this very stringent criterion while some bathroom cleaners are allowed to be ready-to-use based on the dubious feature of "thick and clinging." The fact is that effective bathroom cleaners can be formulated at 1:8 dilution ratios thus negating the RTU exception.

Comment:
Product as sold, that must be diluted by at least thirty two parts by volume water (1:32 dilution Ratio prior to its intended use)

The intention here was excellent. The concept is to increase the concentration of the chemicals manufactured, packaged, transported and sold and thereby reducing the carbon footprint for the lifecycle. Unfortunately, as a single dilution ratio for all products it may result in unnecessary increased safety hazard and not reduce the carbon footprint as much as possible. Let us suggest two different dilution ratio requirements based upon the use of the formulation.

Bucket and tank products represent the largest consumption products and should have relatively large dilution rations. Chemical manufacturers know how to make products that are dilutable at least 1:128. These are products that are mixed in a bucket where you are making 2-4 gallons of product for use. There is no reason why this will be difficult to accomplish and the impact of measuring variations will not have a great impact. On the other had, in the process of properly diluting a quart bottle can be more difficult and the variation in measurement can have a greater impact. To illustrate, adding the right amount of chemical to end up with 32 ounces of material in a quart bottle would be impossible to do with bulk chemicals. Trying to accurately measure .96 ounces of chemical to add to 31.04 ounces of water would be tough.

A cursory knowledge of the quality and precision of metering machines would lead one to not rely upon their accuracy for measurement. A 1:16 minimum ratio would be more than sufficient to meet the goals of the proposed standard.

A second reason for using different concentrations for quart products than bucket or tank products has to do with the intended use of the product. You can make a mineral acid bowl cleaner and utilize dilutions of 1:32, however, the human health consequences of selecting a mineral acid as the base chemical may not be the most human health, or environmentally friendly chemical choice. A much healthier and environmentally sound

chemical choice might be to select an organic acid as the base chemical for you bowl cleaner. The problem would arise when you tried to utilize that bowl cleaner in a concentration of 1:32. It would probably no be strong enough to work adequately. The end result would be that the standard would discourage the use of more human health, and environmentally, benign chemicals in order to ensure that in dilution the product worked.

Again, as a friend to Green Seal, we could see where the dramatic increase to the dilution requirements would make the next step more difficult for manufacturers and especially smaller companies. As you have previously told us, rather than to aspire to be the ultimate and most restrictive standard, the goal of Green Seal is to take the leadership position and have the greatest impact. The sheer volume of GS-37 registered products is a testament to the validity of this strategy. We believe you can continue to successfully take the leadership position with a less dramatic increase in the dilution requirements.

Comment:
The change in the definition of a concentrate from 8:1 to 32:1 may not adversely affect product performance for most product categories covered by the GS-37 standard, but for bathroom cleaners that rely on being acidic for soap scum and stain removal, the extended dilution could be problematic. Keeping an acidic bathroom cleaner within the proper pH range to meet the concentrate requirements and maintain performance at 32:1 would be difficult. A wide variety of products are covered under the standard, should just one definition of what a concentrated product is be used to cover them all? Should a glass cleaner and a bathroom cleaner share the same definition of a concentrate?

Comment:
I have a concern with the increased allowance of the concentrate. There is a very real behavioral issue and user safety issue with the increased concentrated product. First off a 1 to 32 dilution ratio for a product is already a hard sell for many custodial workers. The higher the dilution, the lower the perceived performance by custodial staff. Perception in itself is not a health concern, but attempting to bypass the dilution systems or other attempts to lower the dilution to increase performance does put custodians at risk of being exposed to concentrated product. This may be addressed by tamper-proof, fail-safe dilution systems, but I don't know of any that exist in the real world and I expect the industry will not develop them purely from a financial limitation.

Comment:
Requiring all products to be highly concentrated (1:32) will undoubtedly save energy associated with transporting chemicals from manufacturing plants to end-users, but it is likely to have the unintended consequence of exposing workers at manufacturing plants as well as custodians to highly concentrated cleaning chemicals. When there is a requirement that the product needs to be effective when mixed with at least 32 parts water, it makes it difficult for companies to use relatively mild surfactants and still meet performance requirements. Green Seal should consider backing off of the requirement that all products have that high of a dilution requirement. In fact, some facilities (especially small offices and institutions) have expressed interest in Green Seal-certified

RTU products because they don't want to have their staff involved with mixing chemicals at all.

Comment:
Concentrates. A significant number of our members polled were concerned with Green Seal's proposed revision to the definition of concentrates. We therefore opposes the four-fold increase in concentration that would require a product to be diluted at 1:32.
The reasons articulated in opposition to this drastic increase are as follows:
Manufacturers of products distributed in portion control packs were particularly concerned with the proposed revision. One such commenter pointed out that in order to meet the performance requirements, they will need to add more chemical ingredients at the new use-dilution ratio. Such a scenario will pose difficulties in their ability to meet the new acute oral toxicity threshold and potentially other health end points. On the other hand, if they adjust the formulation to meet the health data requirements, the product will suffer in performance.

Other manufacturers pointed out that at the new use dilution ratio, it is likely that the end user will just use more of the product to make up for performance deficiencies. Further the new dilution ration may require manufacturers to add what heretofore were unnecessary components for the purpose of stabilizing the product, having the unintended consequence of increasing the chemical burden on the environment.
Moreover, many dispensing systems in the field may be made obsolete by the change in dilution ratio resulting in unnecessary replacement (and waste) of otherwise functioning systems at a significant financial cost to end users. In addition, this scenario would increase waste going to landfills and place an economic burden on end users.

Comment:
Section 2.5 changes to 1:32 from 1:8
Glass Cleaners commonly are commonly made for 1:32 dilution rate for normal use but recommends more concentration for extreme soils. Should allow 1:8 on the label for extreme soil conditions. This saves end-user from unnecessarily stocking up multiple items which is a waste of packaging.

Response:
Although GS-37 is not designed to be exclusionary, it must also strive to maintain its leadership position on environmental and health attributes. Product concentration plays a major role in reduction of a product's environmental footprint as associated with such attributes as transportation and packaging. In the continuing effort to advance the standard's environmental stewardship aspects, it is necessary to address the current definition of a product concentrate. Industry statistics show that the majority of products sold in the market (and about 90% of Green Seal certified products) as general purpose cleaners currently meet the requirement of a 1:32 minimum concentration. Adjusting the definition of concentrate for general purpose cleaners to this level is therefore an attainable criterion for industry. This level of concentration is not, however, a viable alternative for the other GS-37 categories of glass, carpet, and restroom cleaning. The concentrate requirement for these

categories will be at 1:16, which can currently be met by close to 90% of the Green Seal certified products. (A higher concentration like 1:32 would exclude close to 50% of the products). There will be an allowance for ready-to-use concentrations for toilet bowl/urinal cleaners, carpet spot removers, and absorbent carpet cleaners since their performance would suffer with concentration and subsequent dilution. The modified definition and requirement will be as follows:

Concentrate. Product, as sold, must be diluted by water prior to its intended use.

Concentrates. The product, except for toilet bowl/urinal cleaners, dry/absorbent compound carpet cleaners, or products solely labeled as carpet spot removers, must be concentrated as follows:

- *General purpose cleaners: 1:32*
- *Glass, restroom, and carpet cleaners: 1:16*

Testing requirements for products submitted for certification under GS-37 are not determined by formula concentration, but the chemical ingredients used to build the product. For nearly all criteria (exception for product performance), testing is only required when insufficient data is available on materials used. As mentioned above, the survey of currently certified products show that the increase in concentration is attainable.

Labeling requirements for dilutions state that "The manufacturer's label shall state clearly and prominently that dilution with water from the cold tap is recommended and shall state the recommended level of dilution." The recommended dilution level for normal use shall meet the requirement for concentrate.

2.06 Dispensing-system Concentrates
These are products that are designed to be used in dispensing systems that cannot be practically accessed by users.

Comment:
Since product transportation directly affects Carbon Footprint, nothing should impede maximizing concentration of a cleaning agent (e.g. LD50 being less than 5000 for a product). Degree of product concentration should be parallel to the Response to Green Seal December 2007 dispensing equipment manufacturers' ability to guarantee equipment accuracy and consistency. i.e. The more accurately mixing equipment can perform, the more concentrated may be products that get run through the equipment. As much as the equipment manufacturers evade discussing the problem, it does exist. And, too much detergent in the mix will cause sticky floors with a soil film—a prime breeding ground for germs and ultimately unhealthy environments.

Comment:

I applaud the use of dispensing equipment as part of the standard. One major reason is the reduction of solid waste put into the waste stream. In one recent example we encountered, 1 - 2 liter bottle of concentrate replaced 132 metal aerosal cans being sent to the waste stream from one of 5 community college campuses.

However, almost any concentrate in any container size can be used through a variety of dispensing systems. The term "practiclly accessed" is a bit vague. This part of the Standard should focus more on the "system" concept. Any school custodian can practically access a gallon jug of concentrate when filling a mop bucket as they free-pour the concentrate into the bucket.

The Standard should state that the concentrate should be used through a dispensing device, either stationary or portable, in order maximize the control over the proper use of that product.

Comment:
The definition presented in the standard is too vague. There should be minimum safety requirements on both the container as well as the dispensing system to make sure that neither can be practically accessed by the end user. During "green cleaning" pilot tests, we have consistently heard stories from custodial staff that the bottles break or lead during transport and that workers break into bottles of concentrated cleaning chemicals for a variety of reasons. They somtimes puncture or cut open bottles of concentrates when the dispensing system breaks down, when the wrong product is ordered, when the dilution equipment is malfunctioning, too far away or inaccessible, or when they are not trained on how to properly use the equipment or want a higher concentration than the manufacturer recommends. We have seen many DSC containers that make it easy to access the concentrated.

Allowing the standard to be watered down with respect to DSCs, takes away an important safety net because it sets up situations where workers are only protected if the product is used exactly as the manufacturer intended. If anything goes wrong, workers and surrounding building occupants will be at risk. Finally, because there are a myriad of exemptions in the standard for DSCs, they are likely to be much more toxic than other concentrates. This could have the unintended consequence of discouraging workers from using them.

> **Response**:
> The definition for products contained in packaging and used with a dispensing system to minimize exposure of the user to the concentrated product and facilitate use was refined to be more explicit that only those that are considered “closed” which includes spill resistant design. These products are not (and have not included) hand-dilutable products. The definitions for concentrate, the product, and the system used to dispense these products, as follows:
>
> *Concentrate. Product, as sold, must be diluted by water prior to its intended use.*

Closed Dilution-Control System. Systems that control the dilution of a concentrate product so the undiluted product cannot be practically accessed by users.

Closed Dilution-Control System Concentrate. Products that are designed to be used in closed dilution-control systems that cannot be practically accessed by users and spill resistant.

Safety requirements for systems that meet these definitions and require evaluation in an as-used dilution (vs. undiluted) for acute toxicity and skin/eye irritation have been outlined in the packaging requirements as follows:

Closed Dispensing-Control System and Concentrate Packaging: Products that are evaluated as outlined in 4.23, shall meet the following requirements for packaging and system design:

- *The primary package shall be a rigid plastic package.*
- *The primary package shall be durable as demonstrated by passing a drop test with the results that the packages must not leak, contents must be retained, and no damage to the outer package likely to adversely affect safety must be sustained.*
- *The closed dispensing-control system shall draw the product out of package, rather than using gravity.*
- *Backflow prevention that meets the American Society of Sanitary Engineering's (ASSE) 1055B standard shall be included in the closed dispensing-control system.*

The drop test was defined as:

Drop Test. The primary package dropped from a height of 48 inches with 4 drops: flat-on-bottom, flat-on-top, flat-on-side, and corner.

2.07 Fragrance
An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of changing the scent of the product.

Comment:
2.7 Fragrance: This should be revised to read, "An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of *imparting* a scent to the product

Comment:
An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of imparting a scent to the product.

Response:
These modifications were made:

Fragrance. An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of imparting a scent in the product.

2.08 General-purpose Cleaners
This category includes products used for routine cleaning of hard surfaces including impervious flooring such as concrete or tile. It does not include cleaners intended primarily for the removal of rust, mineral deposits, or odors. It does not include products intended primarily to strip, polish, or wax floors, and it does not include cleaners intended primarily for cleaning dishes, laundry, toilets, glass, carpets, upholstery, wood, or polished surfaces.

Comment:
2.7 General-purpose Cleaners. This definition should be expanded to mention other surfaces other than impervious floors. As written, it seems like the general purpose cleaner is used only on floors while the restroom cleaner is designed for walls, counter tops, etc. This could encourage the use of more harsh restroom cleaners rather than a more neutral all purpose cleaner for most applications.

Response:
The definition was modified as follows:

General-purpose Cleaners. This category includes products used for routine cleaning of hard surfaces including impervious flooring such as concrete, stone surfaces, or tile. It does not include cleaners intended primarily for the removal of rust, mineral deposits, or odors. It does not include products intended primarily to strip, polish, or wax floors, and it does not include cleaners intended primarily for cleaning dishes, laundry, toilets, restrooms, glass, carpets, upholstery, wood, or polished surfaces or biological cleaners. Other cleaners may be included if they meet the requirements and marketed for general purpose cleaners. Other terms used for these cleaners may include, multi-surface cleaner.

2.10 Ingredients
Any constituent of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.

Comment:
The definition of an ingredient cutoff at 0.01% is inconsistent with any international regulatory cutoff for hazardous ingredients, including GHS, the OSHA HAZCOMM Standard and REACH. These are internationally recognized methods for handling hazard communication and hazard determination. If GS would like to incorporate an additional

safety factor into the percentage cutoff, then we suggest using 0.01% for carcinogens, and 0.1% for all other hazard categories. This would still include an additional 10 fold safety factor for the percentage cutoffs.

Comment:
The definition of an ingredient cutoff at 0.01% is inconsistent with any international regulatory cutoff for hazardous ingredients, including Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the OSHA HAZCOMM Standard and the Registration, Evaluation and Authorization of Chemicals (REACH). These are internationally recognized methods for handling hazard communication and hazard determination

Requiring disclosure of all materials known to be a contaminant at a level of 0.01% and higher will result in inconsistent disclosure from company to company. Some manufacturers get detailed composition information on the raw materials they use and analyze the content of the raw materials, whereas some manufacturers rely solely on the MSDS from their supplier. Since many of the criteria in GS-37 rely on the hazard classification of formula constituents, inconsistent ingredient disclosure could also lead to errors in certification.

We recommend that a level playing field be set for ingredient disclosure. While some product formulators in the industry go to great lengths to obtain constituent information beyond what is typically provided by raw material manufacturers, some rely solely on what is provided in the form of standard industry practice such as data on MSDSs, technical data sheets, etc. Taking this disparity into account, the definition for ingredient should specify that a material is only "known" to be in the formula if it is disclosed on the raw material MSDS and present in the formula at a level of 0.01% or higher. If Green Seal would like to incorporate an additional safety factor into the percentage cutoff, then we suggest using 0.01% for carcinogens, and 0.1% for all other hazard categories. This would still include an additional 10 fold safety factor for the percentage cutoffs while promoting consistency.

Skin absorption: It will be very difficult to use this classification because it is apparently going to be based on a 0.01% cutoff. The definition will be overly inclusive and as a result, many products will be over classified as potential skin absorption hazards. Also, no quantitative or qualitative source of data to aid in classification is provided.

Comment:
We recommend removing the phrase, "…or known to be a contaminant…" from this definition. Contaminant should be separately defined.

Comment:
Ingredient: Requiring disclosure of all materials known to be a contaminant at a level of 0.01% and higher will result in inconsistent disclosure from company to company. Some manufacturers get detailed composition information on the raw materials they use and analyze the content of the raw materials, whereas some manufacturers rely solely on the

MSDS from their supplier. Since many of the criteria in GS-37 rely on the hazard classification of formula constituents, inconsistent ingredient disclosure could also lead to errors in certification. We recommend that a level playing field be set for ingredient disclosure. The definition for ingredient should specify that a material is only "known" to be in the formula if it is disclosed on the raw material MSDS and present in the formula at a level of 0.01% or higher. While some product formulators in the industry go to great lengths to get constituent information beyond what is typically provided by raw material manufacturers, some rely solely on what is provided in the form of standard industry practice such as data on MSDSs, technical data sheets, etc. A level playing field is important to ensure consistency.

Comment:
The health hazard definitions and portions of this proposed standard do not include necessary elements of exposure and risk assessment. The mere presence of a component at a trace level (0.01%) in a product does not equate to elevated health risk and overexposure potential to the individual using the product. The standard should incorporate currently recognized scientific methodology for appropriate risk and exposure characterization, rather than utilizing an unrealistic 0.01% cutoff for predicting health hazard potential.

One of the unintended consequences of this standard will be to increase the amount of animal testing required for classification, not to discourage animal testing, as is the stated goal in GS-4.16.

Response:

Green Seal uses the level of an ingredient at 0.01% because it promotes a higher level of performance than that required by OSHA (0.1%). Several states already have more stringent reporting requirements than OSHA under their right-to-know laws. For example, California's Proposition 65 requires reporting of hazardous substances that are present above any detectable amount. Massachusetts requires extraordinarily hazardous substances be reported if they are present at a level of 0.0001% or greater. The Pennsylvania right-to-know law requires special hazardous substances be reported at a 0.01% level or greater.

Green Seal requires all manufacturer's to disclose the added components (including fragrances) for evaluation. Green Seal staff works with a company's suppliers to ensure all the information is available, to help level the playing field. This has been done for the current version of GS-37 and has not been in issue for the hundreds of currently certified products.

Further, this standard represents an environmental leadership standard that must provide protection to vulnerable populations. Such populations are not adequately represented by risk assessment evaluation and thus a more precautionary/hazard-based approach is needed. Further, existing data continue to be used for evaluation to the criteria in the standard, and there are no new criteria that require new data sources or any additional means for testing. So data

availability is not an issue. As mentioned already, this approach has been used without issue for the hundreds of certified products.

2.11 Intentional Component
A deliberately added product component, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 Code of Federal Regulations (CFR) Part 141.

Comment:
In 1995, Bonnie Rice of Greenpeace wrote: "Ever since the International Joint Commission's 1992 unequivocal recommendation to the US and Canadian governments to phase out the use of chlorine and chlorinated compounds, the momentum for a chlorine-free future has been building worldwide. In just the last two years, the Paris Commission, the International Whaling Commission, the Nordic Council and parties to the Barcelona Convention—together representing over 35 countries—have called for a phase-out or zero discharge of chlorine and all chlorine-based compounds." Resolutions in the 1990s by the American Public Health Association and the San Francisco Board of Supervisors have also highlighted the problem.

Chlorine, and chlorinated products, should be an important concern addressed by the Green Seal standard. Although I haven't had time to read every word of the document, I haven't seen in it specific references to this major pollutant and threat to health. For further information about this hazard and why it should be addressed, see the following:
www.toxicsinfo.org/environment/ChlorineFreeFuture.htm
www.toxicsinfo.org/environment/SanFranciscoDioxin.htm
www.toxicsinfo.org/healthconnections/aphachlorine.htm
www.toxicsinfo.org/house/12FactsChlorine.htm
www.toxicsinfo.org/house/CHECChlorine.htm
www.toxicsinfo.org/environment/awwafactsheet.htm
www.toxicsinfo.org/environment/ChlorineEverywhereElement.htm

Comment:
Naturally Occurring Elements and Chlorinated Organics - It is not clear why the decision has been made to treat naturally occurring elements and chlorinated organics differently than other compounds. There does not appear to be a clear basis for treating compounds that are the result from the chlorination of drinking water any different than other compounds in conformance with their MCL. Also, the use of the MCL is a risk based value which should be extended to non-drinking water standards.

It seems a bit awkward to state that a compound present at a concentration that can be consumed in drinking water cannot be used in a cleaning product.

Response:
The provision for chlorinated water is consistent with the U.S. water supply. Green Seal cannot require a manufacture to source water from a special supply nor can Green Seal set regulations on how to treat the water supply, thus this provision shall remain.

Comment:
We recommend removing this definition. By defining "Ingredient" and "Contaminant", this term is unnecessary.

Response:
Both definitions are used since they represent different parts of the formula and used in various criteria in the standard, thus they shall remain.

2.13 Mutagen
A chemical that meets the criteria for category 1, chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans, under the Harmonized System for the Classification Of Chemicals Which Cause Mutations in Germ Cells (United Nations Economic Commission for Europe, Globally Harmonized System of Classification and Labeling of Chemicals (GHS). First Edition 2003).

Comment:
This adopts the GHS definition of a class 1 mutagen which will require either human data or in vivo animal data. This data will be very difficult to find and using a 0.01% cutoff is unreasonable. The end result will require more animal testing to prove the product is not a mutagen. THIS WOULD BE COST PROHIBITIVE. TO DO EVEN (1) IN VIVO ANIMAL TEST COSTS AROUND $20,000.

Comment:
Mutagen definition: This definition adopts the GHS definition of a class 1 mutagen which will require either human data or in vivo animal data. This data will be very difficult to find and using a 0.01% cutoff is unreasonable. Sufficient data is not readily available on most chemicals to classify them as mutagens under GHS criteria. For the purpose of classifying a chemical as a mutagen, the GHS Guidelines state that "Evaluation of the test results should be done using expert judgment and all of the available evidence should be weighed for classification". The end result will require more animal testing to prove the product is not a mutagen. In addition, inclusion of the requirement for products not to contain mutagens without reference to an internationally or nationally recognized list will result in inconsistent classification from company to company. This would be unreasonably costly-even one in vivo animal test costs approximately $20,000.

Comment:

Mutagen: The GHS Category 1 definition of mutagen should not be used because there is currently limited mutagenicity data on raw materials to make this classification for many products. Sufficient data is not readily available on most chemicals to classify them as mutagens under GHS criteria. For the purpose of classifying a chemical as a mutagen, the GHS Guidelines state that "Evaluation of the test results should be done using expert judgment and all of the available evidence should be weighed for classification". Inclusion of the requirement for products not to contain mutagens without reference to an internationally or nationally recognized list will result in inconsistent classification from company to company.

Response:
Existing data is used for this evaluation. No testing is done to meet the mutagen criterion. Chemicals that are mutagens are required to be labeled as follows: R46 May cause heritable genetic damage.

2.21 Refillable Package
A container which is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package. For the purpose of this program, the product manufacturer or the product manufacturer's agent may refill a package.

Comment:
A product should only qualify as having a refillable package if the manufacturer has developed and presented a plan for collecting and refilling its containers. Many packages could be considered refillable in theory but never get refilled in practice.

Response:
The definition was modified:

Refillable Package. A container which is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package, and demonstrated in practice. For the purpose of this program, the product manufacturer or the product manufacturer's agent may refill a package.

2.23 Reusable Package
A container which is routinely reused at least five times to store the original product contained by the package.

Comment:
How is this definition different than refillable? GS should consider consolidating these definitions.

Response:
This definition was removed, and refillable package used in the standard.

2.24 Serious Eye Damage
The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Comment:
The inclusion of this definition serves no purpose, provided the standard will keep the existing definition for corrosive to eyes. Also, a portion of this definition, "production of…. serious physical decay of vision" is not possible to validate. How can it be determined if an animal has suffered "serious physical decay of vision?" Furthermore, it will not be possible to have human data to satisfy this requirement. It is recommended this definition be removed AND JUST STICK WITH THE CURRENT REQUIREMENT OF GS-37.

Comment:
Serious eye damage: The inclusion of this definition serves no purpose, provided the standard will keep the existing definition for corrosive to eyes. Also, a portion of this definition, "production of…. serious physical decay of vision" is not possible to validate. How can it be determined if an animal has suffered "serious physical decay of vision?" It is recommended that this definition should follow the procedure typically used for hazard classification of industrial and institutional products, which can be found in 16 CFR 1500.

Comment:
Serious Eye Damage: The definition should follow the procedure typically used for hazard classification of industrial and institutional products, which can be found in 16 CFR 1500.

Response:
The requirement for eye corrosion was not changed, only the terminology and definition so it would be more consistent with GHS.

Comment:
2.23 Serious Eye Damage. This definition should be stronger since workers using these chemicals can be exposed daily. Allowing for damage that is reversible within 21 days means that workers can effectively experience continuous eye damage due to their continuous exposure. Green Seal should not allow its products to cause serious eye damage at all.

Response:

The definition for serious eye damage is consistent with GHS and is verifiable. Levels of injury below this do not have objective means of determination and thus difficult to define and verify. The requirement will remain.

2.25 Skin Corrosion
The production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars.

Comment:
Skin corrosion: This definition is deficient. It should be replaced by referencing an already established definition of skin corrosivity, i.e. the GHS or Organisation for Economic Co-operation and Development (OECD) test.

Response:
The definition used for skin corrosion is consistent with GHS and OECD.

2.26 Skin Sensitizer
A substance that causes an immunologically mediated cetaceous reaction, also known as allergic contact dermatitis

Comment:
Skin sensitizer is defined as "a substance that causes an immunologically mediated cetaceous reaction…" We are not aware that sensitization testing was ever conducted in whales. This should be changed to read cutaneous.

Comment:
A substance that causes an immunologically mediated cetaceous cutaneous reaction, also known as allergic contact dermatitis. The above recommended changes are more technically correct than the original proposed language.

Comment:
Clarify the definition of Skin Sensitizer used (Section 2.26)
The word "cause" in the definition should be clarified to include substances that "induce or elicit" immunologically mediated cetaceous reaction, also known as allergic contact dermatitis.

Response:
The definition was corrected and clarified:

Skin Sensitizer. A substance that will lead to an allergic response following skin contact.

3.1 Product Performance
Each product shall clean common soils and surfaces in its category effectively, at the most dilute/least concentrated manufacture-recommended dilution level, as measured by a standard test method. Products shall be diluted, as required, just prior to testing using water from the cold tap at no more than 50ºF. Carpet cleaners may be diluted with warm or hot water where required by the test method or performance considerations.

Comment:
A cleaner is designed to remove soil. Microorganisms live in soil and consume the nutrients in the soil. As they process their "food", they give off gases which we refer to as odors. Odor emission exists with both high and low pH soils and cannot be associated with only high pH soils that are cleaned with low pH detergents such as most bathroom cleaners. My thinking is that it is safe to say that clean surfaces and relatively clean air is the best condition for preventing allergy triggers because facility occupants have to ingest particulate that is left behind during a cleaning process. Cleaning chemicals are handled by the custodians and if they are properly trained to handle and use high-performance chemicals, maximum cleaning results will be achieved using 70% less chemicals. A clean facility fosters a healthy environment. Children exposed to clean surfaces are residing in a clean environment. If we would all focus on product efficacy, our school children would live and grow under optimal conditions. I know of no report of a child's health being cast into jeopardy when they were confined within a clean facility.

> **Response**:
> Green Seal includes performance requirements for all product types to ensure the product can function for its intended use as cleaners.

Comment:
Cleaning products need to have performance testing procedures involving realistic soils as found in a modern day facility… e.g. fossil fuel residues, animal fats, vegetable oils, etc. Testing procedures using crude formulations for concocting almost irremovable soils that were found in yesteryear industrial foundries may look good in a bound report, but good products can fail the test and harsh products can make the grade… Or, testing is modified and the results are erroneous to say the least. Not only do we need to develop pragmatic testing using laboratory soil conditions that mimic today's most common facility conditions. Most importantly, a product's efficacy results must be printed on its container label.

> **Response**:
> The soils are specified in the standardized methods cited. Alternative soils are allowed but would fall under the alternative performance requirements section. This includes more "common" soils (like food stains) since they are not standardized like the soils in the standardized methods cited. Since Green Seal certification includes performance test requirements, there is no need to include

performance test results on a product label, the Green Seal certification mark would indicate that the product met the performance requirements.

Comment:
The new, higher performance threshold in part 3.1 will require more chemical ingredients to be present in my product at use-dilution.

Response:
There were no increases in performance thresholds included in 3.1. Rather, industry standard tests continue to be used.

Comment:
3.1 Product performance

"…manufacture-recommended dilution…" should read:

"…manufacturer-recommended dilution…"

Response:
This modification was made:

Product Performance. Each product shall clean common soils and surfaces in its category effectively, at the most dilute/least concentrated manufacturer-recommended dilution level for routine cleaning, as measured by the following applicable standard test method. Products shall be diluted, as required, just prior to testing using water from the cold tap at no more than 50ºF. Carpet cleaners may be diluted with warm or hot water where required by the test method or performance considerations.

Comment:
3.1 We agree that performance requirements should be modified to eliminate 'comparable performance' testing. The background document references a credible third party testing organization. The Revised Standard does not reference a third party organization and would it seem that would open the door for manufacturers to perform this testing internally and submit results which we favor. We would like to point out that reputable organizations can be trusted to perform such testing. We would also like to point out that the more cost Greenseal imposes on manufacturers to test, certify and maintain products the more likely companies will be to turn to other Green certifying organizations.

Response:
Product testing according to the specified methods in the standard may be done at in-house laboratories that have ISO 9001 registration or equivalent quality control verification; however, Green Seal may request additional testing. In fact all testing laboratories used to meet the criteria in the standard must meet such

quality control verification. This is already included in the certification procedures.

3.1.1 General-Purpose Cleaners Performance
The product shall remove at least 80% of the particulate soil in the American Society for Testing and Materials (ASTM) D4488-95, A5.

Comment:
Green Seal should either:

provide downloadable copies of cited ASTM standards (and other standards) on its website so that these are readily available; or

provide URLs for the host location where these standards are available.

Response:
ASTM standards are available to any organization, through ASTM. Green Seal cannot provide copies of these standards because it is prohibited by ASTM's Intellectual Property Policy (http://www.astm.org/Itpolicy.pdf).

Comment:
Neutral floor cleaners have different expectations of cleaning efficacy in the industry than do all-purpose cleaners. The ASTM 4488 test method referenced in the standard is a fine test for demonstrating efficacy between all-purpose cleaners but isn't really very suitable for neutral floor cleaners. Neutral floor cleaners generally get diluted quite a bit and for the most part serve the purpose of increasing the wetting ability of the mop water and provide some light cleaning. Most of these products are used without a clean water rinse and so don't generally carry a very heavy surfactant load. The mop is doing most of the work here. If comparisons to traditional products are no longer allowed to demonstrate cleaning efficacy, then a new test method should be chosen that realistically reflects the performance of these products just as glass and bathroom cleaners make use of separate cleaning tests to demonstrate efficacy.

Response:
There is no accepted standardized method/s available to effectively evaluate performance of floor cleaners. The application of these cleaners can be tested using the ASTM 4488-95, A5 method cited for general purpose cleaners. However, the soil used in this method is not representative of that encountered for floor cleaners. The soil is characterized as being sticky and greasy and more typical for general purpose cleaning uses, like kitchen cleaning. As a result, many manufacturers have used the alternative performance requirements to determine product performance for floor cleaners. This will continue to be allowed.

Comment:

Green Seal should restore the option under part 4.0, Product-Specific Performance Requirements, that allows alternate dilutions of a product in addition to those that meet the 80% minimum soil-removal requirement using ASTM D4488. Damp-mopping of finished floors is an example that would require an alternate dilution.

Green Seal proposes to revoke the product manufacturer's discretion to suggest alternate, less-concentrated dilutions by deleting the current option that states: "Using standard test methods, a manufacturer can also demonstrate that its product performs as well as a nationally recognized product in its category or achieves the removal efficiency defined in this section." By requiring every general-purpose cleaner to meet or exceed 80% soil-removal under ASTM D4488 at its most extreme dilution, Green Seal is causing more chemical to be used than necessary for most cleaning operations while needlessly spoiling the gloss of finished floors. If the gloss of the floor finish is not considered, and over-strength solutions mandated for every cleaning application, then Green Seal will have needlessly caused untold waste of chemicals and energy by triggering floor-stripping and re-coating operations.

If Green Seal is sensitive about criticism that their certified products do not perform adequately, let them require the ASTM D4488 80% minimum soil removal at the product's most concentrated dilution only.

Response:

There is no accepted standardized method/s available to effectively evaluate performance of floor cleaners. The application of these cleaners can be tested using the ASTM 4488-95, A5 method cited for general purpose cleaners. However, the soil used in this method is not representative of that encountered for floor cleaners. The soil is characterized as being sticky and greasy and more typical for general purpose cleaning uses, like kitchen cleaning. As a result, many manufacturers have used the alternative performance requirements to determine product performance for floor cleaners. This will continue to be allowed.

The dilution tested for product performance is the least concentrated dilution recommended for routine cleaning. And the product label shall be clear if there are multiple dilutions recommended, identifying the routine, most commonly used dilution (which would be the dilution tested to meet product performance). This will be clarified in the section 3.1 as follows:

Product Performance. Each product shall clean common soils and surfaces in its category effectively, at the most dilute/least concentrated manufacturer-recommended dilution level for routine cleaning, as measured by a standard test method. Products shall be diluted, as required, just prior to testing using water from the cold tap at no more than 50ºF. Carpet cleaners may be diluted with warm or hot water where required by the test method or performance considerations.

3.1.3 Carpet Cleaners Performance

Using a standard test method, the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency and resoiling resistance. Acceptable test methods/procedures to demonstrate performance include, but are not limited to, the following sources: the American Association of Textile Chemists and Colorists (AATCC), ASTM, the Institute of Inspection, Cleaning and Restoration Certification (IICRC), the International Organization for Standardization (ISO), WoolSafe, the Carpet and Rug Institute Seal of Approval program (CRI), or laboratory testing conducted as part of a bid evaluation by a government purchasing entity.

Comment:

If this standards indeed requires that "the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency and re-soiling resistance" then this can only be achieved by a systematic evaluation, as performed under the WoolSafe and CRI SOA certification programs. In fact, these programs test for other properties as well, such as influence on color fastness (of the carpet), the presence of prohibited ingredients and safety aspects.

Sources such as AATCC, ASTM, IICRC and ISO only provide at best test methods, not performance standards and test protocols. One test method, as currently specified, will definitely not provide the correct information.

We therefore suggest this paragraph should read:

"Using a recognized certification program, the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency, re-soiling resistance and safety. Acceptable test methods/procedures to demonstrate performance include the WoolSafe and Carpet and Rug Institute's Seal Of Approval certification programs. Both use national (AATCC, ASTM) and international (ISO) standards and test procedures."

Comment:

The wording in the current language of this standard to require product performance that "the manufacturer must demonstrate that its product performs as well as a nationally recognized product in its category in both cleaning efficiency and re-soiling resistance" is meaningless, arbitrary and open to multiple interruptions. Just because a product is the market leader does NOT insure that the product performs properly. Professional Testing Laboratory, a NVLAB certified laboratory, tested a nationally recognized, leading spot remover and found it to re-soiled badly. Insuring product performance can only be achieved by a systematic evaluation, as performed under a nationally recognized certification program such as WoolSafe and the CRI SOA certification programs.

We therefore suggest this paragraph should read:

"Using a nationally recognized certification program, the manufacturer must demonstrate

that its product performs to at least the minimum performance level as outlined in a nationally recognized certification program for cleaning efficiency, re-soiling resistance, absence of optical brightener, appropriate PH level, and safety. Acceptable test methods/procedures to demonstrate performance include the WoolSafe and Carpet and Rug Institute's Seal of Approval certification programs. Both use national (AATCC, ASTM) and international (ISO) standards and test procedures."

Comment:
Why are product comparison tests unacceptable for demonstrating cleaning efficacy for some product classes but acceptable for carpet cleaners? The reasoning behind eliminating the option of comparison testing is just as applicable to carpet cleaners. A "marginally performing" nationally recognized product could still be chosen for comparison. It seems strange that this reasoning would apply to all GS-37 product categories except for carpet cleaners.

Comment:
We believe that a door should be left open for manufacturers who have efficacy testing evidence but are not otherwise certified. To require more certifications on top of testing costs to become GS certified adds unnecessary (yearly) expense to the GS program and would limit participation, especially by smaller manufacturers at a disadvantage. Such flexibility is more in harmony with other product categories' requirements.
Also,
-- We believe "efficacy" is a more appropriate word in this context than "efficiency".

-- The IICRC does not create standard test methods/procedures, so it is not applicable in this context and should be removed from the list.

-- We believe "safety" is an ambiguous and misleading term in this context and should not be used.

Therefore we suggest something along the lines of, "3.1.3 Carpet Cleaners. Manufacturers must either pass WoolSafe or Carpet and Rug Institute Seal of Approval standards for efficacy and re-soiling resistance, or demonstrate that it performs as well as a product that has. Acceptable standard test methods/procedures to demonstrate efficacy and re-soiling resistance include, but are not limited to, the following sources: the American Association of Textile Chemists and Colorists (AATCC), ASTM International, the International Organization for Standardization (ISO), or laboratory testing conducted as part of a bid evaluation by a government purchasing entity."

Comment:
We concur with the changing efficiency to efficacy in the context of performance.

Comment:
We concur with changing efficiency to efficacy if this adds clarity to the context of measuring performance.

As to allowing manufacturers to demonstrate their performance through efficacy testing evidence is ambiguous at best and could lead to misrepresentation or misinterpretation of data. What is the standard for this evidence? How is it to be verified? If we are to allow manufacturers to self certify than why do we need GS 37 at all? The point is we want products that not only are good for the environment but also perform well.

We don't understand why you would leave out the reference to "absence of optical brighteners". Optical brighteners are designed to hid efficacy of a cleaning product, can cause fiber fading, and should not be allowed.

As to appropriate PH level – high PH levels lead to discoloration of the carpet fiber and acid high PH levels can results in safety hazards therefore we recommend retaining the ref to appropriate PH levels

We have no problem with the deletion of "safety".

We therefore suggest this paragraph should read:

"3.1.3 Carpet Cleaners. Using a nationally recognized certification program, the manufacturer must demonstrate that its product performs to at least the minimum performance level as outlined in a nationally recognized certification program for cleaning efficacy, re-soiling resistance, absence of optical brightener, and appropriate PH level. Acceptable test methods/procedures to demonstrate performance include the WoolSafe and Carpet and Rug Institute's Seal of Approval certification programs. Both use national (AATCC, ASTM) and international (ISO) standards and test procedures."

Comment:
As to allowing manufacturers to demonstrate their performance through efficacy testing evidence is ambiguous at best and could lead to misrepresentation or misinterpretation of data. What is the standard for this evidence? How is it to be verified? If we are to allow manufacturers to self certify than why do we need GS 37 at all? The point is we want products that not only are good for the environment but also perform well.

Manufacturers would not be "self-certifying"; they would simply be passing along 3rd-party test results to Green Seal as they do with many other prerequisites.

We don't understand why you would leave out the reference to "absence of optical brighteners". Optical brighteners are designed to hid efficacy of a cleaning product, can cause fiber fading, and should not be allowed. As to appropriate PH level – high PH levels lead to discoloration of the carpet fiber and acid high PH levels can results in safety hazards therefore we recommend retaining the ref to appropriate PH levels

Optical Brighteners are covered elsewhere for all chemistries, not just carpet cleaners. (See Prohibited Ingredients.) pH is also being discussed elsewhere, but perhaps you (or others) could suggest a narrower range specifically for carpet cleaners?

Response:
Optical brighteners were already prohibited in the standard. The definition for carpet cleaners was clarified to include the pH appropriate for these products.

Carpet Cleaners. Products developed to perform routine cleaning or spot cleaning of carpets and rugs. This category may include, but is not limited to, products used in cleaning by means of extraction, shampooing, dry foam, bonnet or absorbent compound. These products have a pH between 3-9.

As noted by the commenter, IICRC does not have efficacy methods for carpet cleaning (rather focuses on training and provider evaluation), so the reference to IICRC will be removed.

The performance measures of interest for carpet cleaners have been cleaning efficacy and resoiling resistance. However, there are no standardized method/s accepted throughout the industry that include the aspects needed to effectively test performance of all types of carpet cleaners. As a result, the use of alternative performance requirements will continue to be used, in addition to other options previously included such as certification to WoolSafe or CRI Cleaning Solutions Seal of Approval, or equivalent.

Carpet Cleaners. The product shall be tested following the requirements outlined in 3.2 Alternative Performance Requirements for cleaning efficacy and resoiling resistance. Alternatively, WoolSafe certification or Carpet and Rug Institute Cleaning Solutions Seal of Approval, or equivalent, will be accepted.

When alternative performance test methods are used by manufacturers, the comparison to another product will be added as follows:

Alternative Performance Requirements. Alternatively, using another objective, scientifically-validated method conducted under controlled and reproducible laboratory conditions, the product performs as well as or better than a conventional, nationally-recognized product in its category and at equivalent concentration. Test methodology and results must be documented in sufficient detail for to make this determination.

Product testing according to the specified methods in the standard may be done at in-house laboratories that have ISO 9001 registration or equivalent quality control verification; however, Green Seal may request additional testing. In fact all testing laboratories used to meet the criteria in the standard must meet such quality control verification. This is already included in the certification procedures.

3.2 Alternative Performance Requirements
Alternatively, a product can demonstrate adequate performance through testing using another scientifically validated method conducted by a credible third party

under controlled and reproducible laboratory conditions. Test methodology must be documented in sufficient detail for Green Seal's review.

Comment:
There has been some discussion previously on whether or not to allow for comparison to a current industry product for product performance. The decision was made to remove that option from the final standard. It may be useful to require that during another scientifically validated method conducted by a credible third party include an industry product in its validation methodology. The Toxics Use Reduction Institute's laboratory typically validates products in this manner to ensure the results are more meaningful for the manufacturer of the proposed product.

Comment:
We would like to comment on Section 3.2 Alternative Performance Requirements. We believe that this section should include the same allowance for a comparison to a nationally recognized product in its category, which is allowed in the current standard.

The reasons are as follows:

1) Proposed standard allows the submitter to use alternatively a scientifically validated method to demonstrate performance. This sounds good on paper, but is not a preferred option to comparing to a national brand, as this easily could result in the following short comings:

a) create a scenario were products with substandard performance are being approved as the chosen test conditions, soil etc. may be tailored for their particular chemistry.
b) Performance may appear to be acceptable, but in reality the standard is not holding the products in a given category to the same performance requirements as a plethora of methods/conditions may be used. Consistency in the evaluation of performance is important in order to keep the approval process consistent from company to company.

2) More importantly, not being able to compare a product to a national brand equivalent could prevent cost effective and chemically efficient products from being certified. For example many general purpose cleaners are being used at 1:128 or 1:256 for light duty cleaning, (mopping floors, wiping down walls, etc.) and would not be able to achieve 80% cleaning as per ASTM
D4488 A5, but would be comparable in cleaning to a national brand that is used at similar dilutions. Therefore, if 80% cleaning is required the submitter would not be able to offer the market these products.
Alternatively, the submitter would have to offer products that are unnecessarily used at a stronger concentration that what should be considered acceptable, (i.e. label would say use at 64;1 instead of 128:1 in order to achieve the required performance of the standard). This would result in increased chemical usage and reduced cost efficiency, which would make the products less environmentally sustainable and less competitive. It is important that the submitter be able to offer green certified products that offer the same

performance, chemical consumption levels and cost effectiveness as the national brands. If this is not allowed, these products will have limited acceptance in the market place, as it will be better for the market to use products that are more concentrated, cost effective, with the least amount of chemical usage per task.

In summary, if this proposed performance standard does not allow for a comparison to national brands, the green cleaners are likely not to be as sustainable as the national brands from a cost, chemical and energy view point, which will undermine and erode the value of these certified products and therefore the penetration of these products into the market place.

Product testing according to the specified methods in the standard may be done at in-house laboratories that have ISO 9001 registration or equivalent quality control verification; however, Green Seal may request additional testing. In fact all testing laboratories used to meet the criteria in the standard must meet such quality control verification. This is already included in the certification procedures. There are performance tests that do not have a well-accepted method or soil so alternative performance testing must remain available (for floor cleaners or hard water removal for toilet bowl cleaners). When alternative performance test methods are used by manufacturers, the comparison to another product will be added and clarified that it be for a comparable concentration as follows:

Alternative Performance Requirements. Alternatively, using another objective, scientifically-validated method conducted under controlled and reproducible laboratory conditions, the product performs as well as or better than a conventional, nationally-recognized product in its category and at equivalent concentration. Test methodology and results must be documented in sufficient detail for to make this determination.

4.0 Product-Specific Health and Environmental Requirements
Any comments, questions or idea pertaining to Product-Specific Health and Environmental Requirements should be posted here.

Comment:
If the Green Seal Standard still applies to a 150 pound male, to change that to include how the standard would apply to children as well since children are in schools where Green Seal products are used daily.

Response:
This standard is a leadership standard and was taken up for revision specifically to ensure that vulnerable populations' considerations were included. As a result, when considering vulnerable populations such as children with smaller body masses than used in risk assessment reviews it's important to consider more preventative measures. One approach, where an ingredient or its class exhibits

potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels of carcinogens, reproductive toxins, toxic heavy metals, etc. These precautionary steps would be most acceptable where alternative ingredients are available. As a result, each criterion evaluated these considerations and developed the most suitable approach.

Comment:
With regard to the potential for chronic health effects (not acute health effects) --

The standard as a whole does a good job of identifying existing lists of chemicals that have the identified health-related hazard traits. For example, for carcinogens, it includes the lists of carcinogens that have been identified by the main authoritative bodies such as the International Agency for Research on Cancer, the US National Toxicology Program, and US EPA.

However, it would seem to be important for the authors and users of this standard to recognize that the kinds of lists that are cited reflect very limited testing of chemicals. As has been demonstrated in many analyses, a small fraction of chemicals that are used have been tested for the relevant hazard traits.

Any process like Greenseal that relies on such existing lists will miss all of the ingredients that simply have not been tested. It would seem to be important to address the need for adequate testing. Without that, the certification can not be relied upon to ensure that the products certified actually meet safety standards and will in many cases simply reflect a lack of information.

Greenseal cannot solve this alone, but this needs to be shown as an important limitation of this process until the overall problem of lack of adequate and reliable testing is solved in the US.

One additional concern is that the standard does not address all of the hazard traits that pose potential health hazards. This should be remedied.

Response:
Green Seal uses the multiple sources of recognized international and national lists for carcinogens. A chemical would be prohibited if it is listed on any one of the lists cited. Further, Green Seal also specifically prohibits concerning chemicals that may not be on such lists yet.

Comment:
Implication of acute health effects is misleading. While eye irritation may be a common symptom of cleaner misapplication, virtually all cleaning products are considered eye irritants. Wearing suggested eye protection should equalize risk in this category. Similarly, criteria favor products with low injestion and inhalation toxicity ratings. Proper storage should virtually eliminate risks from drinking a product. After-hours application

and adequate ventilation are generally available to most commercial cleaners with respect to inhalation concerns. For exceptional situations, alternative exposure control measures are generally available.

Recommendation: Credit mitigating factors. For example, where label precautions are followed, health risks may be considered minimal.

Ecological considerations simply consider the presence of theoretical risk factors, notwithstanding demonstrated problems or dose/response considerations. Lacking realistic risk factors, such criteria should be eliminated.

> **Response**:
> Training, labeling, and MSDS communication requirements include proper use instructions and proper use of protective equipment, in addition to other means to prevent misuse.

Comment:
Concerning neurotoxicity exposure in GS-37 products, the background document is somewhat unclear. Although several known neurotoxicants are prohibited from use in GS-37, the document appears to state that evaluating for neurotoxicity would be "prohibitively expensive and time-consuming to require for all products or their ingredients." We recommend Green Seal remain vigilant in preventing neurotoxic chemicals from entering GS-37 products, keeping in mind the Precautionary Principle. We believe that this extends to the life cycle of chemicals from production to final product.

Comment:
The standard is not strong enough on identifying and restricting ingredients that affect the central nervous system. I agree that GS should be vigilant in promoting the precautionary principle in preventing neurotoxic chemicals from entering GS 37 products.

Comment:
Some important health criteria continues to be omitted from the standard. For example, GS-37 does not specifically address central nervous system effects (which are common with cleaning products containing glycol ethers and other neurotoxins).

> **Response**:
> Grandjean and Landrigan list more than 200 specific industrial chemicals that produce neurological effects. Many of the chemicals are not ingredients in cleaning products (e.g. pesticides and many listed organic substances). In general, many of the other criteria in GS-37 have already restricted or prohibited many of the neurotoxicants. For example, the ATSDR MRLs and CA RELs used in the inhalation toxicity criterion include on neurotoxic effects. Benzene is prohibited because it is also a carcinogen. The glycol ethers, ethylene glycol monomethyl ether and ethylene glycol monoethyl ether and their acetates are listed as reproductive toxins and therefore prohibited ingredients. At this time, no other known neurotoxicants were identified that need to be restricted or prohibited. So only the remaining chemicals

were listed as neurotoxins, heavy metals such as hexavalent chromium and selenium). However, to me more clear about why those materials are listed as prohibited a criterion was added, with a definition on neurotoxins. This addition also provides a means to add new chemicals as their weight of evidence grows.

Neurotoxin. A chemical that is suspected to or determined to adversely affect the nerve cells and nervous system of humans or animals.

Neurotoxins. The undiluted product shall not contain ingredients that are neurotoxins, including:

- *Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds*

Grandjean, P. and P.J. Landrigan. 2006. Developmental neurotoxicity of industrial chemicals. Lancet 368:2167-2178. Available www.thelancet.com/journals/lancet/article/PIIS0140673606696657/abstract [accessed 14 Nov 2007].

Comment:
Respiratory Irritant – The definition of respiratory irritant in the proposed standard is derived from the OECD classification of R-37. Reviewing each individual ingredient for this classification down to the 0.01% ingredient cutoff will not generate dependable, useful, or accurate date, because of a high probability of over-classifying the product. Data on individual chemicals as to their status of respiratory irritants is very limited, and data to prove that a product is not a respiratory irritant is virtually non-existent. In both cases, obtaining the data more than likely would require animal testing, which is counter to the view expressed in 4.16. Most products as-used are greater than 95% water and have almost no chance of being a respiratory irritant.

For all of these reasons, we recommend completely removing respiratory irritant from the standard.

Response:
There was not a definition for respiratory irritant included in the proposed revised standard. And there was not a criterion to prohibit ingredients that would be respiratory irritants. However, a definition was added to clarify the criterion for terpenes and limonene below.

Respiratory Irritant. A chemical that may cause serious irritation the nose, throat, airways and lungs of humans or result in positive results from appropriate animal tests.

Respiratory Irritants. The product as used shall not contain ingredients that are respiratory irritants above the specified levels:

- *D-limonene shall be limited to a concentration of 20 millimoles (mmol) or less per liter.*
- *Terpene hydrocarbons, other than d-limonene, (e.g. pinene, myrcene) shall be limited to 10 mmol or less per liter.*

Comment:
In a recent review California EPA scientists [Kuwabara Y, et al, Environ Health Perspect 115; 1609-1616 (2007)] have analyzed the usefulness of the RD50 test in setting protective levels with respiratory irritation as an endpoint. They believe the RD50 would help identify health protective values that could prevent respiratory irritation. Perhaps the GS-37 Standard Development Team could revisit this issue and include a respiratory irritation criterion using the RD50.

Comment:
In addition to testing for skin irritation and sensitivity, inhalation toxicity should be measured by the manufacturer using the most up to date methods and tools. According to our state scientists, small chamber and RD50 testing are the most effective for measuring airway irritation. All products, including concentrates, should be tested in their original formulation. These tests should be repeated at least every two years or when there is a known change in manufacturing practices.

Response:
RD50s were reviewed throughout the process and determined to not achieve the desired goal. Efforts to extend protection against all respiratory irritants are hampered by the absence of a commonly agreed upon definition, or tests that assess the capacity of chemicals to cause respiratory irritation. The absence of a commonly accepted definition of respiratory irritation may be due, in part, to the complex mix of factors that can contribute to respiratory irritation. These include volatility, method of application, concentration in the product, pH, presence of other materials that may bind ingredients so that they are not released, or oxygenate ingredients yielding peroxides and other more irritating compounds. Nor does it consider the wide range of individual sensitivity to irritants. Other criteria in the standard, however, address respiratory irritation (chronic inhalation toxicity, VOCs, terpenes).

4.01 Oral Toxicity
The undiluted product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply:
Oral lethal dose 50 (LD50) < 5,000 mg/kg

Toxicity shall be measured on the product as a whole. The toxicity testing procedures should meet the requirements put forth by the Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals Acute Oral Toxicity Test (TG 401). Testing is not required for any

ingredient for which sufficient information exists.

Dispensing-system concentrates may be tested as used, but will require the qualification designation (see Labeling section 6.5).

To demonstrate compliance with this requirement, a mixture need not be tested if existing toxicological information demonstrates that each of the ingredients complies. It is assumed that the toxicity of the individual ingredients is additive and that there are no synergistic effects. The toxicity values are adjusted by the weight of the ingredient in the product and summed using the following formula:

(see 4.1 of the proposed revised standard for formula)

Where,
TP = toxicity of the product
wti = the weight fraction of the ingredient
TV = the toxicity value for each ingredient (LD50)
n = number of ingredients

Comment:
We especially applaud Green Seal for proposing the amendment in section 4.1 that would increase the oral lethal dose

Comment:
I am pleased to see the criteria defined by the UNDILUTED product. The new GS37 standard follows this trend in assessing UNDILUTED products for carcinogenicity, irritation, sensitization, absorption, asthma triggering, combustibility. This further products workers using the product in undiluted form and ensures the diluted product is even less hazardous to those around it.

Comment:
We strongly support the proposal to strengthen the standard's oral toxicity provision (Section 4.1). As a precautionary approach to protecting the health of children and other sensitive populations, we support the standard's increase in the oral lethal dose from 2,000 mg/kg to 5,000 mg/kg in order to "account for the decreased body mass of small children which will lead to increased dosages and the increased sensitivities of vulnerable populations that may become exposed,"

Comment:
We strongly support the proposal to strengthen the standard's oral toxicity provision (Section 4.1). As a precautionary approach to protecting the health of children and other sensitive populations, we support the standard's increase in the oral lethal dose from 2,000 mg/kg to 5,000 mg/kg in order to "account for the decreased body mass of small children which will lead to increased dosages and the increased sensitivities of vulnerable populations that may become exposed," (Section 4.1).

Response:
Comments acknowledged.

Comment:
The higher threshold of acute oral toxicity and the higher minimum concentration level require me to know the exact acute oral toxicity of each chemical component or else I will not be able to put enough in the finished concentrate to satisfy the performance requirement; presently the exact acute oral toxicity levels of my chemical components are not known. The knowledge will have to come from the chemical component manufacturers and these are predominantly giant corporations. Giant corporations are reluctant to undertake acute oral toxicity testing as they: 1. have a multitude of products, 2. do not wish to be associated with the practice of live animal testing and 3. do not want to spend the money.

The manufacturers of the chemical components only publish vague, generic data for the component's acute oral toxicity. The published values of acute oral toxicity are usually excessively toxic because the manufacturers do not know what the value is themselves and need to play it "safe". The use of the vague and generic toxicity values in the calculation of my finished product's acute oral toxicity results in an excessively toxic result; one that does not represent the true, lower toxicity of my product.

Comment:
Green Seal has needlessly complicated compliance with this new, 2-1/2 times higher, threshold of acute oral toxicity with a conflicting counter-productive requirement; Part 2.5, Concentrates. Part 2.5 now requires my product to be twice as concentrated than its current GS-37 compliant level at the same time it must be 2-1/2 times less toxic and yet perform better than ever.

The data to accomplish compliance with these three conflicting requirements does not currently exist. The most unsavory part of resolving the conflicting requirements is that animal testing may be required to generate the acute oral toxicity data for each chemical component.

The manufacturers of chemical components are invariably large corporations who only publish vague, generic values of acute oral toxicity. The values that the chemical component manufacturers publish are generally toxic for two reasons: 1. they do not know the actual value themselves and 2. they err on the side of caution. When these values are used in the computation of my finished products' acute oral toxicity, the resultant value is overly toxic and I cannot, therefore, put enough chemical component in the formula to meet the new, higher performance requirements. Green Seal may retort that the performance requirement has not been raised, but a beneficial, alternate method of proving product performance has been revoked in the new standard.

If it were not for the mandatory minimum concentration level of 1:32 in Part 2.5, Concentrates, I believe that Part 4.1, Oral Toxicity, would be more readily complied with using existing data.

Comment:
Oral Toxicity: Increasing the acute oral toxicity threshold from < 2,000 mg/kg to < 5,000 mg/kg actually sets a trend toward divergence from the standards of the international community with respect to acute oral toxicity testing. Although several US regulatory agencies, including the Consumer Product Safety Commission, continue to use 5,000 mg/kg as the upper limit dose for acute oral toxicity tests, the international community has endorsed the 2,000 mg/kg upper limit dose for more than 15 years. . It is also well accepted under the ICCA High Production Volume Chemical initiatives. As of December 18, 2007, OECD changed its guideline for toxicity to be 1000 mg/kg. Green Seal should adopt this new standard.

Since protocol refinement for animal welfare reasons was a key motivation for reducing the acute oral toxicity limit dose from 5,000 mg/kg to 2,000 mg/kg, Green Seal may inadvertently be encouraging new animal testing by changing this standard. Although the Green Seal intent is admirable, the 2.5-fold increase in stringency on the acute toxicity endpoint will have adverse consequences from the animal welfare viewpoint without providing significant protection to children or other susceptible subpopulations which might be exposed to the products covered by this standard.

> **Response**:
> Existing data will continue to be used to evaluate toxicity and if the manufacturer cannot provide this information, Green Seal staff gets this information from suppliers and the literature (as they do today). As a result, no additional testing will be needed.
>
> Further, as stated by the commenter, this new limit is aligned with the CPSC. And after reviewing currently certified products, this new level is feasible.

Comment:
We strongly opposes allowing the proposed standard's oral toxicity requirement to apply to the diluted formulation -- especially at such at such a high dilution rate. Allowing the oral toxicity requirement, which is based on a mathematical weighted-average formula, to include at least 32 parts water when doing the calculation for dispensing system concentrates (DSCs), will render it meaningless as virtually any chemical can be in the bottle and pass this criterion. The most precautionary approach is to ensure that each individual ingredient is low-toxicity. There are some arguments for requiring that as a way to stimulate products to be reformulated with safer ingredients. This is approach taken by the EPA's Design for the Environment (DfE) program and support's Green Seal's overall claim that "GS-37 continues to be a leadership standard for health and the environment." Green Seal should consider adopting a minimum LD50 for each individual ingredient in addition to the overall LD50 for the product as there is evidence that some ingredients -- particularly sensitizing agents -- can be dangerous at low levels over time and there is limited evidence proving that highly toxic chemicals are rendered safe simply by mixing them with less-toxic ingredients, including water.

Green Seal should explain why its oral toxicity minimum (5,000 mg/kg) is lower than some that are in the Canadian Ecologo (e.g., the 10,000 mg/kg average applied to concentrated glass cleaners).

It does not make sense to apply the same oral toxicity requirement to concentrates as sold and DSCs as used and giving them both the same "green" label.

> **Response**:
> The 5,000 mg/kg level is consistent with the OECD. While the Canadian EcoLogo, CCD-146, glass cleaner is higher than this, the other products in the standard are much lower. Further, all of these criteria in CCD-146 do not apply to concentrated products (they do not require concentration), thus may be a significantly lower hurdle since it is met by a much more dilute product. Further, to determine if a product meets the criterion, Green Seal evaluates each ingredient's data. As a result, the evaluation is similar to the DfE approach (the DfE criterion, while not readily available, may not be as stringent as 5,000 mg/kg).

Comment:
We recommend this section be made clearer. The test used to determine oral toxicity is an ACUTE toxicity test for RATS. The underlying reasoning for the increase is for the protection of children's and other vulnerable populations' health. This should be stated in the revised standard. Also, the Consumer Product Safety Commission (CPSC) Code allows for exemptions to labeling a product as toxic (16 Code CFR Chapter II, Part 1500, Section 82). Green Seal should also take this into account.

> **Response**:
> Acute toxicity testing was included in the standard, however, data to determine if a product meets the criterion is readily available and used instead of testing. The exemptions for CPSC labeling do not apply to the ability to pass the requirements.

4.02 Inhalation Toxicity
The product as used shall not produce room air levels of an ingredient or ingredients that are considered toxic by inhalation. A product is exempt from the inhalation toxicity criterion if it contains no ingredients with a vapor pressure greater than 0.1 mm Hg.

A product is considered to be toxic through inhalation if it has an acute inhalation toxicity (LC50) of <= 20 mg/L at 1 hr, or if the weighted ingredient average LC50 is <= 20 mg/L at 1 hr, determined from all ingredients with a vapor pressure greater than 0.1 mm Hg at ambient temperature.

Alternatively, a product may undergo chamber testing. When tested using the Small Chamber Emissions Test Method (Attachment B), a product is considered toxic if any of the following criteria are exceeded:

Short-Term (Acute) Long-Term (Chronic)
TVOC (mg/m3) <=5.0 <=0.22
Formaldehyde (ppm) 2 <=0.040 <=0.013
Toxins with inhalation threshold values Less Than the ATSDR MRL and the CA AREL3 Less Than the ATSDR MRL, the CA CREL, and the EPA RfC4
NA = Not Applicable

1Defined to be the total response of measured VOCs falling within the C4 – C16 range, with responses calibrated to a toluene surrogate.
2Short-term level based on the ATSDR Acute Duration Minimal Risk Level (MRL). Long-term level based on ½ CAL-EPA 1-hour Reference Exposure Level (REL).
3 Compared to ATSDR Acute Duration MRL and CA Acute Reference Exposure Level (AREL), or other relevant threshold value.
4 Compared to the EPA Reference Concentration (RfC), CA CREL, and the ATSDR Intermediate or Chronic Duration MRL. Intermediate MRLs shall be used if a Chronic MRL is not available for that compound, or other relevant threshold value.

Comment:
We support the addition of inhalation criteria is important as well.

Response:
Comment acknowledged.

Comment:
We strongly support the standard's addition of inhalation toxicity criterion (Section 4.2) without the proposed exemption for products with a high vapor pressure. This criterion is necessary because inhalation is an important way in which custodial workers and building occupants become exposed to toxic chemicals in cleaning products. We are concerned, however, about the exemption for ingredients with a vapor pressure >0.1 mm Hg; while these products may not quickly evaporate, they may volatilize over time or become airborne if they are dispersed in a spray bottle.

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necessary because inhalation is an important way in which custodial workers and building occupants become exposed to toxic chemicals in cleaning products. We are concerned, however, about the exemption for ingredients with a vapor pressure >0.1 mm Hg; while these products may not quickly evaporate, they may volatilize over time or become airborne if they are dispersed in a spray bottle.

Response:
The reference to VOCs will follow the EU Directive 1999/133/EC (Solvent Emissions Directive) where volatile organic compound (VOC) mean any organic compound with a vapor pressure of greater than 0.1mm Hg. The intent is that this addresses indoor air concerns, in addition to outdoor air concerns. Chemicals that fall below this vapor pressure cut-off are typically prohibited by other criteria (ex. glycol ethers are reproductive toxins) and through their more likely route of exposure like the skin. Further, given that these materials do not volatize or require unusual conditions for volatilization (which don't apply to this standard, since Green Seal prohibits aerosol packaging and do not include specialty cleaners like oven cleaners), testing is difficult and there is minimal data available. So the exemption for inhalation criteria will remain for chemical with a vapor pressure less than 0.1mmHg.

Comment:
4.2 Inhalation toxicity. The criteria is being changed for acute inhalation toxicity (LC50) of <=20mg/L at 1 hr. We are concerned that this data is not readily available at the 1 hour period for many ingredients and to generate this data for a significant number of components would be expensive, as is small chamber testing. We have read the background document and understands the rationale but would be interested to know how many Greenseal approved raw materials would be disallowed by this change? Is this a study that Greenseal would be willing to perform to help us better understand the ramifications of this change?

Response:
This data are readily available and after a review of the currently certified products is feasible.

Comment:
It is important to include inhalation toxicity in the scope of this standard, and the sponsors should be commended for doing so.

With regard to chronic inhalation (repeated inhalation over a long time period), the standard does not require testing for chronic inhalation toxicity as it does for acute inhalation toxicity. Instead, it requires comparisons to reference values developed by ATSDR, the State of California, and the US Environmental Protection Agency.

It is important to note that these lists of reference values are developed primarily for substances commonly found at hazardous waste sites (in the case of the ATSDR values) and for substances addressed in environmental programs (for the California and EPA

values). There is no reason to believe that these source of values would provide coverage for ingredients used in cleaning products. Perhaps there are additional sources that could be included here, perhaps including those that originate in occupational health.

But this again raises the issue that relying on lists of chemicals that have been identified as being of concern from the very limited testing data available in the US cannot identify all of the products of potential health concern.

In some other contexts, toxicity values generated through testing performed through other routes of exposure (such as ingestion) are used to assess potential for toxicity from exposure through inhalation when no information is available for the inhalation route of exposure. Such comparison values are more commonly available because more toxicity tests are performed through ingestion than inhalation.

> **Response**:
> Green Seal will look directly to the source of such risk assessment values (NOAEL) since there is more data available, they are based on repeated exposure and inhalation, and it provides a better assessment of the hazard associated with a chemical.
>
> *Chronic Inhalation Toxicity. The product as used shall not contain any ingredients with a repeated dose inhalation NOAEL for mammals at or below 1.0 mg/L (1,000 mg/m^3). The NOAEL shall be from a test duration of at least 90 days. An ingredient with a vapor pressure less than 0.1 mm mercury is exempt from the chronic inhalation toxicity criterion. Alternatively, GREENGUARD Children and Schools certified cleaning products and systems, or equivalent, meets this criterion.*

Comment:
Further, the test mentioned on Page 10, Chamber Testing, does not relate to inhalation toxicity. It is only a measure of volatiles. This test has no correlation to acute toxicity.

> **Response**:
> Acute toxicity is included as a separate criterion. The chamber testing is an alternative means to demonstrate a product doesn't present chronic inhalation toxicity.

Comment:
Inhalation Toxicity: we suggest adding language which is equivalent to what is found in Section 4.9. This weighted average approach would make sense. In addition, this standard would increase animal testing, contrary to the stated goal of 4.16. Opting out of testing based on vapor pressure of components is unacceptable unless the vP is raised to 2.0 mmHg. Below this level the inclusion of fragrance would automatically make the finished good subject to inhalation testing.

Comment:

Refine criteria for Inhalation Toxicity (Section 4.2)
Currently, the criteria for Inhalation Toxicity include an allowable limit for acute inhalation toxicity (LC50). Chamber testing to acceptable room air concentrations (per Appendix A) is given as an alternative criterion.

A. It is stated that the product is considered to be "toxic" through inhalation if it has an acute inhalation toxicity (LC50) of below or equal to 20 mg/L at 1 hr. The LC50 option addresses only lethality from 1 hour exposures and does not address any other endpoints aside from mortality. Fatality should not be used as a "toxic" endpoint from a chemical or product exposure. Damage to the body (liver, kidneys, respiratory system, etc) may not cause death. Carcinogens or reproductive toxicants may take time before the effect is known. Many chemicals cause eyes, nose, and lung irritation, and exacerbate asthma, and not considered "toxic" using this criterion. All products should be tested for inhalation effects if inhalation is a route of exposure. The Inhalation criteria should be expanded to include specific criteria aside from LC 50 testing to address chronic toxicity. Endpoints that address disease risks and damage to body systems should be included not as an alternative but as legitimate criteria aside from LC 50 criteria.

B. Product should be required to meet acceptable room air concentration based on chamber testing. The proposed 48 hour chamber test and protocols to define decay curves should be further discussed by the GS-37 inhalation toxicity sub-committee. The chamber testing provisions are needed but further development of the specific guidance for applying to cleaners should be further discussed and worked on in committee to finalize. The committee work was intended to continue.

C. Products should be required to meet acceptable room air concentrations for product dilutions that occupants are expected to encounter during use. Products should be required to meet the limits established by the following toxicity lists: including (i) Agency for Toxic Substance Disease Registry (ATSDR) Minimum Risk Levels (MRLs); (ii) California EPA's Office of Environmental Health Hazard Assessment (OEHHA) Acute Reference Exposure Levels (ARELs); (iii) California EPA's OEHHA non-cancer chronic Reference Exposure Levels (RELs); and (iv) U.S. EPA RfC4; and (v) ASTM E981 RD 50 levels (to ensure protection from lung irritant toxics that are associated with asthma exacerbation and other lung dysfunction).

D. The definition of VOC should be put into the definition section. Need to have a definition that includes organic compounds such as glycols that have boiling points above 250 F.

E. A product should NOT be exempted from inhalation testing if it contains no ingredients with a vapor pressure greater than 0.1 mm Hg (at 20 degrees C?). Current regulations presume the availability of low-pressure VOCs in air (see US EPA Method 24). There are many semi-volatile compounds (including heavy hydrocarbons, C10-C20) that may exist as gases if they are emitted at high temperature. Even though these compounds have slow evaporation rates, they may react with other ingredients to form more volatile compounds. Moreover, products containing semi-volatile compounds may be found in products that are applied as an aerosol. Many glycol ethers will be exempted based on this definition.

F. Additional comments:

- We advocate with the IAQ Section of CDPH an approach to evaluating potential inhalation toxicity that relates to the endpoint of sensory irritation, rather than lethality.

This endpoint could be guarded against by developing a standardized protocol for vapor dilution relative to the headspace above the undiluted cleaning product, then evaluating this vapor dilution for mucous membrane / upper airway irritancy using the ASTM E981-84 (RD50) assay in rodents. By starting with the actual product formulation, such an approach avoids any theoretical assumptions regarding the degree of additivity among the product's constituents, and would most closely approximate real-life exposures. The RD50 has been successfully employed to predict human sensory irritation in the past, and with appropriate safety factors could be employed for certification of commercial / industrial cleaning products. A GS-37 sub-committee should be formed to finalize the final parameters needed for chamber testing that includes the testing labs and toxicologists working in irritancy.

- Chamber Testing Rationale (Background document, page 9) On page 9, it was stated that only products not meeting the initial screening (LC50 equal or less than 20 mg/L for acute toxicity at 1 hour) will need to be chamber tested. The LC50 is not a good method to screen whether or not a product should be chamber tested. LC50 is a statistically derived single dosage of a substance (product) that can be expected to cause death in 50% of animals. The number does not provide information on which body system(s) is damaged.

Comment:
I support the efforts of Green Seal to revise the criteria for green seal approval to ensure that any emissions from approved consumer products are safe for the public.

One general concern I have is that many products have emissions that are respiratory irritants to sensitive individuals, including asthmatics.

The proposed criteria for Inhalation Toxicity (Section 4.2) is inadequate

Currently, the criteria for Inhalation Toxicity include an allowable limit for acute inhalation toxicity (LC50). The LC50 option addresses only lethality (death) in animal toxicology studies from 1 hour exposures.

Acute respiratory irritant properties should be considered. At a minimum, all products where inhalation is a route of exposure should be evaluated for acute mucous membrane (eye, nose, lung irritation, and asthma exacerbation). Also, there may be damage to the organ systems (liver, kidneys, respiratory system, etc) at levels that are not fatal. Carcinogens or reproductive toxicants may take time before the effect is known.

Response:
The acute inhalation toxicity requirement was moved back to the acute toxicity considerations. Such data is readily available and thus will not increase testing needs. The average approach will be used, as it is in the current version of GS-37.

As a result, acute inhalation toxicity is not going to be used for screening for repeated inhalation toxicity, rather a chemical's repeated dose NOAEL or LOAEL will be used. The ingredients will be evaluated individually for this

criterion to provide a more protective approach for this repeated dose concern. This data is more available than risk assessment data (like CRELs) and provides a more hazard-based approach to inhalation toxicity, which is important for cleaning products given their repeated uses. The reference to VOCs will follow the EU Directive 1999/133/EC (Solvent Emissions Directive) where volatile organic compound (VOC) mean any organic compound with a vapor pressure of greater than 0.1mm Hg. This is a more conservative approach than used previously. The intent is that this addresses indoor air concerns, in addition to outdoor air concerns. Chemicals that fall below this vapor pressure cut-off are typically prohibited by other criteria (ex. glycol ethers are reproductive toxins) and through their more likely route of exposure like the skin. Further, given that these materials do not volatize or require unusual conditions for volatilization (which don't apply to this standard, for example Green Seal prohibits aerosol packaging and does not include specialty cleaners like oven cleaners), testing is difficult and there is minimal data available. The GHS classification of potentially toxic by chronic inhalation will be used to identify those chemicals with a chronic inhalation toxicity hazard (for example those with respiratory issues but aren't asthmagens). The chamber testing will remain an alternative means for a product to be evaluated for inhalation toxicity.

RD50s were reviewed throughout the process and determined to not achieve the desired goal. Efforts to extend protection against all respiratory irritants are hampered by the absence of a commonly agreed upon definition, or tests that assess the capacity of chemicals to cause respiratory irritation. The absence of a commonly accepted definition of respiratory irritation may be due, in part, to the complex mix of factors that can contribute to respiratory irritation. These include volatility, method of application, concentration in the product, pH, presence of other materials that may bind ingredients so that they are not released, or oxygenate ingredients yielding peroxides and other more irritating compounds. Nor does it consider the wide range of individual sensitivity to irritants. Other criteria in the standard, however, address respiratory irritation (chronic inhalation toxicity, VOCs, terpenes).

Acute Toxicity. The undiluted product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply:

Oral lethal dose 50 (LD_{50})	*$\leq$ 5,000 mg/kg*
Inhalation lethal concentration (LC_{50})	*<= 20 mg/L at 1 hr*

Toxicity shall be measured on the product as a whole. Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the ingredients complies. The toxicity testing procedures should meet the requirements put forth by the OECD Guidelines for Testing of Chemicals. These protocols include Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402). Testing is not required for any ingredient for which sufficient information exists.

To demonstrate compliance with this requirement. It is assumed that the toxicity of the individual ingredients is additive. The toxicity values are adjusted by the weight of the ingredient in the product and summed using the following formula:

$$TP = \left(\sum_{i=1}^{n} \frac{wt_i}{TV_i} \right)^{-1}$$

Where,
TP = toxicity of the product
wt_i = the weight fraction of the ingredient
TV = the toxicity value for each ingredient (LD_{50})
n = number of ingredients

For inhalation toxicity, it is determined from all ingredients with a vapor pressure greater than 0.1 mm Hg at ambient temperature

Chronic Inhalation Toxicity. The product as used shall not contain any ingredients with a repeated dose inhalation NOAEL for mammals at or below 1.0 mg/L (1,000 mg/m^3). The NOAEL shall be from a test duration of at least 90 days. An ingredient with a vapor pressure less than 0.1 mm mercury is exempt from the chronic inhalation toxicity criterion. Alternatively, GREENGUARD Children and Schools certified cleaning products and systems, or equivalent, meets this criterion.

4.03 Carcinogens, Mutagens, and Reproductive Toxins
The undiluted product shall not contain any ingredients or intentional components that are carcinogens, mutagens or reproductive toxins.

Comment:
Criteria for Reproductive Toxins Should Not Be Based on Proposition 65 Listings

The California Safe Drinking Water and Toxic Enforcement Act of 1996 (Proposition 65) is not a risk-based statute. Accordingly, many compounds listed under Proposition 65 are entirely appropriate for use in products. The listing of a compound on Proposition 65 does not mean that it cannot be used as a constituent in a product; it simply means that a label is required on the finished product if it contains the listed compound. Most important - Proposition 65 itself contemplates that exposure to certain levels of listed compounds may be low enough that a label is not required at all – these are so called safe harbor levels.

A science-based, risk-based standard recognizes that exposures to particular levels of a compound may present no significant risk to human health, minimum. While we do not consider Proposition 65 to be a science-based, risk-based standard, even this labeling statute recognizes the relevance of exposure in its safe harbor provisions, and does not

require labeling where exposure are sufficiently low. The safe harbor calculation is not an arbitrary one (e.g., “1%” of total product) but one based on scientific calculation of the likelihood of risk of adverse health effects following particular levels of exposure. It is therefore inappropriate for Green Seal to prohibit an ingredient based solely on it being listed under Proposition 65.

Comment:
The California list of reproductive and development toxicants is a good starting point and probably the most complete list. However, it cannot be viewed as complete. As noted in comments on the scope, using this list as the only way to identify reproductive toxicants will not capture all of them. For the Greenseal to ensure that its certified products do not contain reproductive toxicants, the program would need to ensure that each ingredient receiving the seal had in fact been tested or cleared. Absence from the California list is in no way definitive, as the California process does not require any testing and simply reflects the subset of chemicals that have been tested and found to have effects.

Comment:
No rationale is provided for relying on California's Propositon 65 list as the basis for list of Reproductive Toxicants. Similarly, no basis is provided for restricting the use of all of the substances on the Proposition 65 list. These chemicals are not restricted in California and this list was developed for a very different purpose. Additionally, the substances on the list should not be considered as presenting a reproductive risk of concern unless there is exposure to the substance above its No Significant Risk Level. Many substances in high concentrations can present a reproductive risk including vitamins and other substances that are essential elements or nutrients.

The manner in which this issue has been adderssed is inconsistent with science based principles.

Comment:
Criteria for Reproductive Toxins Should Not Be Based on Proposition 65 Listings

The California Safe Drinking Water and Toxic Enforcement Act of 1996 (Proposition 65) is not a risk-based statute. Accordingly, many compounds listed under Proposition 65 are entirely appropriate for use in products. The listing of a compound on Proposition 65 does not mean that it cannot be used as a constituent in a product; it simply means that a label is required on the finished product if it contains the listed compound. Most important - Proposition 65 itself contemplates that exposure to certain levels of listed compounds may be low enough that a label is not required at all – these are so called safe harbor levels.

A science-based, risk-based standard recognizes that exposures to particular levels of a compound may present no significant risk to human health, minimum. While we do not consider Proposition 65 to be a science-based, risk-based standard, even this labeling statute recognizes the relevance of exposure in its safe harbor provisions, and does not require labeling where exposure are sufficiently low. The safe harbor calculation is not an

arbitrary one (e.g., "1%" of total product) but one based on scientific calculation of the likelihood of risk of adverse health effects following particular levels of exposure. It is therefore inappropriate for Green Seal to prohibit an ingredient based solely on it being listed under Proposition 65.

Comment:
We all applaud the use of less toxic substances as long as the substitute can be shown to be less toxic in its use. An important concept that needs to be taken into account is "the dose makes the poison". GS Standard Development Team needs to consider using the CA Prop 65 approach to looking at the risk of a substance in a product and not ban specific substances just because they are on a list. What this means is the manufacturer need to produce a risk assessment, similar to the ones required by CA, for his product. If a product has a toxic substance and can demonstrate acceptable risk than the use of that substance should be acceptable, on the other hand if following a risk assessment of a product has an exposure level that is equal to or exceeds the Prop 65 NSRL (No Significant Risk Level) than exclude this product for products certified by GS 37. This is a concept that would take into account risk of a particular substance and would clearly go beyond CA Prop 65 which only requires a warning label and would be in keeping with the desire to demonstrate/practice environmental leadership. Further it should be noted that any product with a substitute substance (one considered safer) needs to undergo a similar risk assessment to insure that we haven't replaced a toxic substance with something equally as bad or worse because of necessary concentration or exposure need to make the product effective for its intended use. The guiding principle should be to insure safe, effective products. We don't want to ban substances thus requiring some substitution without understanding the consequences which can lead to unintended outcomes.

> **Response**:
> California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA) "has established safe harbor levels (levels of exposure that trigger the warning requirement) for some, but not all, listed chemicals." "A business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure." "Proposition 65's warning requirement has provided an incentive for manufacturers to remove listed chemicals from their products."
>
> As a result, it is relevant to protective initiatives, such as an environmental leadership standard like Green Seal's, to prohibit chemicals listed as reproductive toxins. Further, since this definition is not a modification from the current GS-37 standard, it has proven that meeting the criterion has not been an issue for GS-37 products for hundreds of products.

Comment:
The basis for the 0.01% cut-off for ingredients is not clear. It is inconsistent with GHS. For example, the GHS criteria for Mutagens relies on a 0.1% cut-off.

Response:
The revision of GS-37 included consideration of vulnerable populations. With this consideration a precautionary approach is taken, and using a cut-off of 0.01% for mutagens was a means to provide this protection. Further, Green Seal uses the level of an ingredient at 0.01% because to promote a higher level of performance than that required by OSHA (0.1%). This is consistent with state programs with more stringent reporting requirements under their right-to-know laws. For example, Massachusetts requires extraordinarily hazardous substances be reported if they are present at a level of 0.0001% or greater. The Pennsylvania right-to-know law requires special hazardous substances be reported at a 0.01% level or greater

Comment:
The requirement that the product not contain any ingredients that are known to cause these toxicities without consideration of the risk posed by those ingredients in inappropriate.

Response:
This standard is aimed to identify leadership products. Leadership products do not, and should not, include carcinogenic chemicals or those that are likely or have suggestive evidence of carcinogenicity. Green Seal uses the multiple sources of recognized international and national lists for carcinogens. A chemical would be prohibited if it is listed on any one of the lists cited. Since this definition is not a modification from the current GS-37 standard, it has proven that meeting the criterion has not been an issue for GS-37 products for hundreds or products.

Further, one of the purposes of revising GS-37 was to address the health concerns of vulnerable populations, such as children, since these products are being used increasingly in settings such as schools. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products.

One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels.

Comment:
Ingredients may take some time to become added as a reproductive hazard on the Prop. 65 list. Once a commonly-used ingredient has been adequately identified as having carcinogenic or reprotoxic hazards it should be added to the GS-37 list of prohibited ingredients. Examples include diethanolamine and n-methyl pyrollidone. When the Prop. 65 list 'catches up', an ingredient could be then dropped by the GS-37 list.

Response:
Green Seal uses a prohibited ingredient list, specifying chemicals with concerning effects that are not otherwise prohibited by other criteria. For example, alkylphenol ethoxylates have been included on this list.

4.04 Skin and Eye Irritation
The undiluted product shall not be corrosive to the skin or cause serious eye damage as defined by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Further, a product is considered corrosive to skin or to cause serious eye damage if it has a pH of 2 or less or a pH of 11.5 or greater, unless tested and proven otherwise. Dispensing-system concentrates may be tested as used, but will require the qualification designation (see Labeling section 6.5).

A product shall be evaluated for skin corrosion and eye damage following the testing and evaluation strategy described in the GHS. Green Seal prefers that an in vitro test validated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) or the European Centre for the Validation of Alternative Methods (ECVAM) be used. Green Seal will also accept the results of other peer-reviewed or standard in vitro or in vivo test methods demonstrating that the product mixture is not corrosive. Testing is not required for any ingredient for which sufficient information exists.

Comment:
In the background document, Green Seal has indicated "Additional In Vivo testing for skin and eye irritation where a negative result is obtained through In Vitro testing". This could not only be considered cost prohibitive (over $1500 per test) but would also cause concern over Green Seal goal to avoid or reduce animal testing wherever possible. 4 In Vitro tests have been presented that should suffice for eye irritancy.

Comment:
Point of clarification:
...A product shall be evaluated for skin corrosion and eye damage following the testing and evaluation strategy described in the GHS....Green Seal will also accept the results of

other peer-reviewed or standard in vitro or in vivo test methods demonstrating that the product mixture is not corrosive. *Testing is not required for any ingredient for which sufficient information exists.*

The background document appears to indicate (via citation from European Commission's Manual of Decisions EC 2006) that *in vivo* tests will be needed if the *in vitro* result is not conclusive:

"Where a Negative result is obtained, an *in vivo* test should subsequently be required, as the *in vitro* tests have not been shown to adequately discriminate between eye irritants and non-irritants..."

This clause could indicate that Green Seal would require *in vitro* tests followed by *in vivo* tests. The language in section 4.4 is ambiguous for what constitutes "sufficient information". In the prior standard, *in vitro* tests were considered "sufficient". Given criterion 4.16 discouraging animal testing, I do not think that it is the standard's intent to introduce an *in vivo* requirement, and the language of what will be considered "sufficient information" may require elaboration. We support that testing only be performed when literature review is inadequate to determine potential for eye and skin injury, but also support the use of *in vitro* tests to make that determination over *in vivo* tests.

Response:

Existing data is used for the evaluation of skin and eye irritation. However, in the event that data is not available, testing will need to be done. Although the need for testing is very rare, the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the European Centre for the Validation of Alternative Methods (ECVAM) are internationally recognized groups that have objectively evaluated the scientific validity of new, revised, and alternative toxicological test methods applicable to US and European safety testing requirements, including tests for assessing damage, corrosion and irritation to skin and eyes. Both groups have found that several in vitro methods are effective as screening tests for corrosive and strongly irritating substances and products and must be used prior to in vivo testing to address animal welfare concerns. However, both groups have found that the validated in vitro tests still incorrectly identify whether substances are corrosive or strongly irritating, i.e. the tests are negative when in vivo tests are positive. Therefore, in vivo testing may be needed to confirm or validate a claim that an ingredient or product will not cause severe eye irritation or be corrosive to the skin.

Comment:

We strongly support the standard's new requirement that concentrated products fall within a pH range that is not considered corrosive (Section 4.4). By prohibiting products that have a pH that is 2 or less or 11.5 or more, Green Seal will effectively prevent exposure to products that contain ingredients which can trigger asthma attacks (involving coughing, wheezing and bronchial restriction) among people who already have asthma.

Response:

Comment acknowledged.

Comment:
We strongly support the standard's new requirement that concentrated products fall within a pH range that is not considered corrosive (Section 4.4). By prohibiting products that have a pH that is 2 or less or 11.5 or more, Green Seal will effectively prevent exposure to products that contain ingredients which can trigger asthma attacks (involving coughing, wheezing and bronchial restriction) among people who already have asthma. An analysis of Green Seal-certified products shows that over 70 percent can meet the proposed pH requirement on concentrates.

Of the currently certified products that would need to be reformulated, many contain extreme pHs -- in some cases as low as .5 or as high as 13 -- and contain ingredients that are known to be corrosive or severely irritating to the respiratory system such as sodium hydroxide (lye), ammonia, and phosphoric acid and other strong acids and bases. One Green Seal-certified bathroom cleaner with a highly acidic pH of 1-2, for example, states on its MSDS: "Will cause serious eye irritation, possible burns. Corrosive to eyes, leading to possible corneal damage or blindness. Will cause skin irritation and inflammation." See www.woodwyant.com/en/home.asp. Certifying concentrates that can cause chemical burns undermines the integrity of the Green Seal standard and puts custodial workers at risk. In the absence of criteria to screen out individual chemicals known to cause serious respiratory effects, it is critical for the standard to have an absolute pH requirement. Therefore, we urge Green Seal to delete the proposed exemption to the pH requirement that states that a product outside this pH range is considered corrosive "unless tested and proven otherwise."

Comment:
We strongly support the standard's new requirement that concentrated products fall within a pH range that is not considered corrosive (Section 4.4). By prohibiting products that have a pH that is 2 or less or 11.5 or more, Green Seal will effectively prevent exposure to products that contain ingredients which can trigger asthma attacks (involving coughing, wheezing and bronchial restriction) among people who already have asthma. An analysis of Green Seal-certified products shows that over 70 percent can meet the proposed pH requirement on concentrates. Of the currently certified products that would need to be reformulated, many contain extreme pHs -- in some cases as low as .5 or as high as 13 -- and contain ingredients that are known to be corrosive or severely irritating to the respiratory system such as sodium hydroxide (lye), ammonia, and phosphoric acid and other strong acids and bases. One Green Seal-certified bathroom cleaner with a highly acidic pH of 1-2, for example, states on its MSDS: "Will cause serious eye irritation, possible burns. Corrosive to eyes, leading to possible corneal damage or blindness. Will cause skin irritation and inflammation." See www.woodwyant.com/en/home.asp. Certifying concentrates that can cause chemical burns undermines the integrity of the Green Seal standard and puts custodial workers at risk. In the absence of criteria to screen out individual chemicals known to cause serious respiratory effects, it is critical for the standard to have an absolute pH requirement. Therefore, we urge Green Seal to delete the proposed exemption to the pH requirement

that states that a product outside this pH range is considered corrosive "unless tested and proven otherwise."

Comment:
Support new requirement for concentrated products (Section 4.4)
We strongly support the standard's new requirement that concentrated products fall within a pH range that is not considered corrosive (Section 4.4). Delete the proposed exemption to the pH requirement that states that a product outside this pH range is considered corrosive "unless tested and proven otherwise."

> **Response**:
> The GHS notes that measurement of pH alone may not be adequate to predict skin corrosion or serious eye damage. GHS suggests that an assessment of acid or alkali reserve (buffering capacity) is more predictive. However, methods need to be developed to assess buffering capacity and its ability to ameliorate the expected effects of pH on the skin and eyes. Testing for the effect, rather than buffering capacity, is thus a more reliable means of assessing skin corrosion and serious eye damage. Thus, the provision for testing will remain.

Comment:
Eye and Skin Irritation: Until the final sentence of this section, it appears that the product must be tested. The final sentence suggests that the product can be classified on the basis of the classification of the ingredients. If this is the case, it should be clearer that classification according to the ingredients is allowable.

Comment:
Until the final sentence of this section, it appears that the product must be tested. The final sentence suggests that the product can be classified on the basis of the classification of the ingredients. If this is the case, it should be clearer that classification according to the ingredients is allowable.

> **Response**:
> Existing data is available for most chemicals used in GS-37 products. Thus this data will be used to evaluate if the product meets the criterion.

4.05 Skin Sensitization
The undiluted product shall not be a skin sensitizer, as tested by the local lymph node assay (LLNA) or following EPA test guidelines for skin sensitization (OECD Guideline 429, OPPTS 870.2600). Green Seal will accept the results of other standard test methods, such as the guinea pig maximization test (OECD Guideline 406) or the Buehler test (OECD 406), as proof that the product in its most concentrated form is not a skin sensitizer when data from LLNA tests are not available. Any new product or ingredient testing should use the LLNA. Dispensing-system concentrates may be tested as used, but will require the qualification

designation (see Labeling section 6.5). Testing is not required for any ingredient for which sufficient information exists.

Comment:
We support the proposed testing and denial of skin irritating and sensitizing products/ingredients which will ultimately reduce airway irritants as well.

Response:
Comment acknowledged.

Comment:
The section now references a LLNA sensitization test, which is still an in vivo animal model of sensitization. This requirement will cause more animal testing to be performed and will be very expensive. The proposed standard says: "Testing is not required for any ingredient for which sufficient information exists." What does "sufficient information" mean? Can we use chemical structure activity relationships?

Comment:
Skin sensitizer: The section now references a LLNA sensitization test, which is still an in vivo animal model of sensitization. This requirement will cause more animal testing to be performed, which is contrary to the position advanced in 4.16, and will be very expensive. The proposed standard says: "Testing is not required for any ingredient for which sufficient information exists." This is ambiguous in regards to what does "sufficient information" mean and whether chemical structure activity relationships can be used. The proposed standard must be clarified.

Comment:
4.5 Skin Sensitization. This section states that the product shall not be a skin sensitizer as tested by the Local Lymph Node Assay (LLNA). The fragrance industry through the Research Institute for Fragrance Materials, Inc. (RIFM) evaluates fragrance ingredients for dermal sensitization. A dermal sensitization quantitative risk assessment approach is employed so that fragrance raw materials which have the potential for dermal sensitization are used at levels that will NOT induce sensitization. As such, it is not necessary to test the final fragrance compound. Further, the use of a single LLNA to test a mixture is not appropriate.

Comment:
As proposed, Section 4.5 states that the product shall not be a skin sensitizer as tested by the Local Lymph Node Assay (LLNA), in addition to other referenced test methodologies. In conferring with representatives of the fragrance industry, we have learned that the Research Institute for Fragrance Materials, Inc. (RIFM) evaluates fragrance ingredients for dermal sensitization. A dermal sensitization quantitative risk assessment approach is employed so that fragrance raw materials which have the potential for dermal sensitization are used at levels that will not induce sensitization. As such, it is not necessary to test the final fragrance compound.
Furthermore, we contend that LLNA is inappropriate for evaluating complex mixtures

such as fragrance compounds because of the immunologic mechanism by which contact allergy occurs and the manner in which LLNA measures allergic potential.
we therefore urges Green Seal to exempt fragrance compounds from the need to be so evaluated.

Comment:
Skin Sensitization: Until the final sentence of this section, it appears that the product must be tested. The final sentence suggests that the product can be classified on the basis of the classification of the ingredients. If this is the case, it should be clearer that classification according to the ingredients is allowable.

Comment:
Specify full mixture and undiluted testing for skin sensitization criteria (Section 4.5)
A. Make clear than only undiluted (and not single ingredient mixtures) shall be permitted, as there may be synergistic or cumulative effects on skin sensitization that may not be properly revealed otherwise.
B. Ingredient-by-ingredient testing should be disallowed for skin sensitization because of synergistic effects. .
C. The local lymph node assay (LLNA) according to the test guidelines for skin sensitization in the OECD Guideline 429 and the US EPA OPPTS 870.2600 are sufficient and should be used as the criteria for the GS-37 skin sensitization criteria.. The OECD Guideline 429, and US EPA's OPPTS 870.2600 are the most up-to-date test protocols. It is essential that these criteria be used to ensure fairness and uniformity in third party certification for skin sensitization to allow a level playing field
D. Remove the allowance to "Testing is not required for any ingredient for which sufficient information exists."-- "sufficient information" is not defined. .

Comment:
Until the final sentence of this section, it appears that the product must be tested. The final sentence suggests that the product can be classified on the basis of the classification of the ingredients. If this is the case, it should be clearer that classification according to the ingredients is allowable.

Response:

Existing data is available for most chemicals used in GS-37 products. Thus, this data will be used to evaluate if the product meets the criterion. For example, fragrance ingredients that have been evaluated by RIFM would have such data available. Further, if quantitative SAR assessment can be documented to be effective at predicting whether a product will be a sensitizer, that information will be adequate and additional testing will not be required. In October 2006, the World Health Organization convened an international workshop that reviewed the usefulness of various approaches to assessing skin sensitization ability of substances (WHO 2007). The panel of experts concluded that "(Quantitative) SARs and expert systems for identification of sensitizing capacity have not been validated to date, but may be used as part of a weight of evidence approach for identifying the sensitizing capacity of chemicals. There are certain local (Q)SARs

that can be used for a small range of chemicals. However, these are currently insufficient to cover the full range of chemicals."

If such data is not available, the GHS notes that for classifying a substance as a sensitizer: "evidence should include any or all of the following:

(a) Positive data from patch testing, normally obtained in more than one dermatology clinic;

(b) Epidemiological studies showing allergic contact dermatitis caused by the substance; Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) Positive data from appropriate animal studies;

(d) Positive data from experimental studies in man (see Chapter 1.3, para. 1.3.2.4.7);

(e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic.

Positive effects seen in either humans or animals will normally justify classification. Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on contact sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must therefore be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies.

If none of the above mentioned conditions are met the substance need not be classified as a contact sensitizer. However, a combination of two or more indicators of contact sensitization as listed below may alter the decision. This shall be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) Epidemiological studies of limited power, e.g. where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result, but which are sufficiently close to the limit to be considered

significant;

(d) Positive data from non-standard methods;

(e) Positive results from close structural analogues."

WHO. 2007. General Conclusions and Recommendations of an IPCS International Workshop on Skin Sensitization in Chemical Risk Assessment. www.who.int/ipcs/methods/harmonization/areas/sensitization_summary.pdf [accessed 4/2/2008]

4.06 Skin Absorption

The undiluted product shall not contain ingredients, present at greater than or equal to 1% in the product, that are listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) carrying a skin notation, or substances that are listed on the German Deutche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list with a skin absorption H notation. Dispensing-system concentrates may be evaluated as used, but will require the qualification designation (see Labeling section 6.5).

Comment:

Limit the cumulative/additive concentrations of multiple chemicals The proposed standard for skin absorbing chemicals listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) or on the German DFG Maximum Allowable Concentrations (MAK) list requires that they be limited to 1% (though the DSC exemption applies as well). However, there is no limit on the total cumulative amount of multiple skin absorbing chemicals allowed; individual amounts may be under 1% but the total of multiple ingredients would add to more than 1%. We recommend that Green Seal include a “cap” on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

Comment:

The proposed standard for skin absorbing chemicals listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) or on the German DFG Maximum Allowable Concentrations (MAK) list requires that they be limited to 1% (though the DSC exemption applies as well). However, there is no limit on the total cumulative amount of multiple skin absorbing chemicals allowed; individual amounts may be under 1% but the total of multiple ingredients would add to more than 1%. We recommend that Green Seal include a “cap” on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

Comment:

We recommend that Green Seal include a “cap” on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

Comment:
Skin absorption criteria will not work as intended (Section 4.6)
Skin absorption criterion are needed since several products certified under the current GS-37 standard contain chemicals that can penetrate the skin and damage the central nervous system (CNS), blood and internal organs, or cause other serious health effects. We recommend that Green Seal consider the use of OECD Test 427 and 428 to screen out skin absorbing chemicals*. Green Seal include a "cap" on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

*Environment Directorate, Organisation for Economic Co-operation and Development (OECD), Guidance Document for the Conduct of Skin Absorption Studies, March 5, 2005, http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT00000DFA/$FILE/JT00159305.PDF

Response:
Both the ACGIH and DFG lists are used. So if a chemical is listed on one of these lists, it is restricted (diethanolamine and ethylene glycols are on the DFG list). The OECD tests suggested were considered but found to not be adequate for products with mixed compositions and the costs would be exceptional with the results misleading.

The "cap" modification was included since there is a chance that multiple ingredients in a product could have the same target organ, thus having the potential to cause systemic toxicity even if the single ingredients were below 1%. So the suggested "cap" will be specific to a target organ**.**

Skin Absorption. The undiluted product shall not contain ingredients, present at greater than or equal to 1% in the product, that are listed on the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value list (TLV) carrying a skin notation, or substances that are listed on the German Deutche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list with a skin absorption H notation. Further, the product shall not contain ingredients that sum to 1% in the formula that are listed on ACGIH or DFG with the same target organ.

Comment:
This n will be very difficult to classify because it is apparently going to be based on a 0.01% cutoff? Many products will be over classified as potential skin absorption hazards. Also, no quantitative or qualitative source of data to aid in classification is provided.

Response:

Skin absorption is evaluated on an ingredient by ingredient basis. The criterion applies when an ingredient is used at 1% or more (not 0.01%) in a formula and on either ACGIGH or DFG. These lists apply to its skin absorption potential and its systemic effects (not only its skin absorption).

Comment:
I suggest that the 2-3 dozen common chemicals with a known, significant potential for skin absorbtion be listed in the section of GS-37 that designates prohibited ingredients (e.g., butoxyethanol is already listed there).

Response:
The skin notation lists were evaluated and it was found that 2-butoxyethanol was prohibited due to its multiple effects on the body, including systemic effects from exposures like skin. Other chemicals listed with skin notations are prohibited for other reasons (carcinogens). If a chemical does not have a skin notation and it has system effects it would then be captured by chronic inhalation toxicity (ex. monoethanolamine).

Comment:
This skin absorption criterion is needed since several products certified under the current GS-37 standard contain chemicals that can penetrate the skin and damage the central nervous system (CNS), blood and internal organs, or cause other serious health effects. For example, some products with chemicals that can be absorbed through the skin such as Diethylene glycol monobutyl ether (also called 2-(2-butoxyethoxy)-ethanol) (CAS #112-34-5), and have serious effects on the nervous system and target organs. Chemicals with this level of potential harm should not be allowed in GS-37 certified products.

However, the skin absorption criterion, as proposed using the ACGIH list of chemicals with a skin absorption notation, will not succeed in screening out either of these chemicals because they do not appear on this list, despite their serious warnings. The ACGIH list is not acceptable (and also is not available publicly and only available through a paid subscription). Instead, we recommend that Green Seal consider the use of OECD Test 427 and 428 to screen out skin absorbing chemicals.

Comment:
Skin absorption criterion will not work as intended (Section 4.6)
This skin absorption criterion is needed since several products certified under the current GS-37 standard contain chemicals that can penetrate the skin and damage the central nervous system (CNS), blood and internal organs, or cause other serious health effects. For example, a review of current GS-37-certified products found some products with chemicals that can be absorbed through the skin, such as diethylene glycol monobutyl ether (also called 2-(2-butoxyethoxy)-ethanol) (CAS #112-34-5) and ethanolamine (CAS #141-43-5), and have serious effects on the nervous system and target organs*. Chemicals with this level of potential harm should not be allowed in GS-37 certified products.

However, the skin absorption criterion, as proposed using the American Conference of Governmental Industrial Hygienists (ACGIH) list of chemicals with a skin absorption notation, will not succeed in screening out either diethylene glycol monobutyl ether or ethanolamine because they do not appear on this list, despite their serious warnings. Furthermore, 2-butoxyethanol - a prohibited chemical that is widely known to be absorbed through the skin - does not appear on the ACGIH list either. The ACGIH list, therefore, is not acceptable (and also is not available publicly and only available through a paid subscription). Instead, we recommend that Green Seal consider the use of OECD Test 427 and 428 to screen out skin absorbing chemicals**.

Limit the cumulative/additive concentrations of multiple chemicals
The proposed standard for skin absorbing chemicals listed on the ACGIH Threshold Limit Value list (TLV) or on the German DFG Maximum Allowable Concentrations (MAK) list requires that they be limited to 1% (though the DSC exemption applies as well). However, there is no limit on the total cumulative amount of multiple skin absorbing chemicals allowed; individual amounts may be under 1% but the total of multiple ingredients could add to more than 1%. We recommend that Green Seal include a "cap" on the total amount of skin absorbing chemicals that can be in a product to prevent the cumulative amount from surpassing the standard when several skin absorbing chemicals are added to a product, each of which falls under the 1% limit.

* Diethylene glycol monobutyl ether according to one manufacturer's MSDS "may be absorbed into the blood stream with symptoms similar to ingestion… Ingestion may cause signs of intoxication, such as nausea, headache, incoordination, dizziness, drowsiness, and slurred speech depending on the amount ingested." (See http://www.jtbaker.com/msds/englishhtml/b6124.htm). At least one GS-37-certified glass cleaner contains ethanolamine and has a warning on its MSDS that the product "may be harmful if absorbed through the skin…and May be absorbed following inhalation and cause target organ effects."

** Environment Directorate, Organisation for Economic Co-operation and Development (OECD), Guidance Document for the Conduct of Skin Absorption Studies, March 5, 2005,
http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT00000DFA/$FILE/JT00159305.PDF

Comment:
Skin absorption criteria will not work as intended (Section 4.6) This skin absorption criterion is needed since several products certified under the current GS-37 standard contain chemicals that can penetrate the skin and damage the central nervous system (CNS), blood and internal organs, or cause other serious health effects. For example, the A review of current GS-37-certified products found some products with chemicals that can be absorbed through the skin such as Diethylene glycol monobutyl ether (also called 2-(2-butoxyethoxy)-ethanol) (CAS #112-34-5), and have serious effects on the nervous

system and target organs*. Chemicals with this level of potential harm should not be allowed in GS-37 certified products. However, the skin absorption criterion, as proposed using the ACGIH list of chemicals with a skin absorption notation, will not succeed in screening out either of these chemicals because they do not appear on this list, despite their serious warnings. Furthermore, 2-butoxyethanol - a prohibited chemical that is widely known to be absorbed through the skin and - does not appear on the ACGIH list. The ACGIH list, therefore, is not acceptable (and also is not available publicly and only available through a paid subscription). Instead, we recommend that Green Seal consider the use of OECD Test 427 and 428 to screen out skin absorbing chemicals**.

* Diethylene glycol monobutyl ether according to one manufacturer's MSDS "may be absorbed into the blood stream with symptoms similar to ingestion… Ingestion may cause signs of intoxication, such as nausea, headache, incoordination, dizziness, drowsiness, and slurred speech depending on the amount ingested." (See http://www.jtbaker.com/msds/englishhtml/b6124.htm). At least one GS 37-certified glass cleaner contains ethanolamine and has a warning on its MSDS that the product "may be harmful if absorbed through the skin…and May be absorbed following inhalation and cause target organ effects."
** Environment Directorate, Organisation for Economic Co-operation and Development (OECD), Guidance Document for the Conduct of Skin Absorption Studies, March 5, 2005,
http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT00000DFA/$FILE/JT00159305.PDF

Comment:
4.6 Skin Absorption - We object to evaluating the undiluted product. Components that have the potential to cause acute effects from a single exposure are already excluded through other test criteria. The chances for developing a chronic health condition through multiple exposures to undiluted product when proper training and personal protection equipment are utilized should not be significant.

Concern over certain solvents presenting systemic hazards when placed into cleaning solutions do not appear to need a secondary heading under skin absorption as these would be prohibited due to Flammability and/or toxicity concerns elsewhere in the existing standard.

Response:
This criterion captures systemic toxins that would not otherwise be captured by other criteria and thus should remain**.**

4.07 Ingredients and Cause Asthma
The undiluted product shall not contain any ingredients that cause asthma. Dispensing-system concentrates may be evaluated as used, but will require the qualification designation (see Labeling section 6.5).

Comment:
We appreciate that the revised standard aims to include asthma and respiratory effects in its criteria and there are many requirements that we support. However, aspects of the standard need to be strengthened to truly restrict products that cause the onset of asthma or its exacerbation.

We support the use of the Association of Occupational and Environmental Clinics (AOEC) list of chemicals that are known to cause asthma and exacerbate it. While this list may not be comprehensive at this point, using it as criteria would at least eliminate known asthmagens. We fully support denying Green Seal approval to any concentrate or ready to use products with ingredients on the current or future iterations of the AOEC asthmagen list.

Comment:
We strongly support Green Seal's addition of criteria designed to limit ingredients known to cause asthma (Section 4.7). Based on the definition provided in Section 2.1 of the proposed standard, chemicals included on the Association of Occupational and Environmental Clinic's list (AOEC) with an "A" designation will be prohibited. This is important because it is well known that a high percentage of custodial workers suffer from asthma. Some of these cases are caused by the chemical they are using during the course of their job; in other cases, their asthma is triggered or worsened by their exposure to asthmagens and severe or corrosive respiratory irritants found in cleaning products (including GS-37-certified products).

Response:
Comment acknowledged.

Comment:
Regarding the restrictions of chemicals that are known to cause asthma, Green Seal identifies these as listed as an asthmagen by the Association of Occupational and Environmental Clinics (AOEC). There are 13 listed chemicals by the AOEC.[1] The NYS DOH Occupational Lung Disease Registry website[2] provides a work-related listing of occupational asthmagens of 405 chemicals and substances.[3] The Department recommends that Green Seal review the more inclusive list used by NYSDOH for consideration into its proposed standard.
[1] http://www.aoec.org/aoeccode.htm

[2] http://www.health.state.ny.us/environmental/workplace/lung_disease_registry/

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1 http://www.aoec.org/aoeccode.htm

2 http://www.health.state.ny.us/environmental/workplace/lung_disease_registry/

3 http://www.asmanet.com/asmapro/agents.htm

[3] http://www.asmanet.com/asmapro/agents.htm

Response:
The evaluation by AOEC is based on criteria and a peer review process. The robustness of such an approach provides greater scientific validity to any prohibition that may result. While both listings are long (AOEC actually has over 350 "A" agents listed) and include mostly agents that are not found in cleaning products, the listing found through the NYS DOH Occupational Lung Disease Registry website is not based on criteria and only cites sources of information on asthma relation. As a result the AOEC will continue to serve a source for asthmagen information.

Comment:
Specifically, we urge adoption of the proposed language that expressly references use of the list published by the Association of Occupational and Environmental Clinics (AOEC) as the best available criteria for designating agents that cause asthma, and that prohibits their inclusion as ingredients in industrial and institutional cleaners. Adoption of this language will strengthen the GS-37 standard and will allow us to use it to recommend cleaning products with a Green Seal designation in our work-related asthma prevention efforts.

We suggest one major revision to further strengthen the proposed standard. Section 4.7., Ingredients that Cause Asthma, states that dispensing-system concentrates may be evaluated as used. It is our understanding that this provision will allow manufacturers to include ingredients on the AOEC asthmagen list at levels greater than 0.01% as long as the intended dilution will bring that concentration below 0.01%. There is no assurance that dispensing-system concentrates will be used as such or that spills will not occur. That these products could carry a Green Seal label, even a qualified one, sends a misleading message that the product is inherently safe. Because extremely low levels of air contaminants can trigger asthma, and because of the lack of data about actual thresholds, we recommend that the dispensing-system qualification for ingredients that cause asthma be removed. Dispensing-system concentrates should not be allowed to have ingredients that are listed as asthmagens on the AOEC list.

Comment:
However, we have one major proposed revision to strengthen the current version of the proposed standard: Section 4.7. Ingredients that Cause asthma, states that dispensing-system concentrates may be evaluated as used. It is our understanding that this provision will allow manufacturers to include ingredients on the AOEC Asthmagen list at levels greater than 0.01% as long as the intended dilution will bring that concentration below 0.01%. There is no assurance that dispensing-system concentrates will be used as such or that spills will not occur.

That these products could carry a Green Seal label, even a qualified one, sends a false message that the product is inherently safe. In addition, because extremely low levels of air contaminants can trigger asthma and because of the lack of data about actual

thresholds, we recommend that the dispensing-system qualification for ingredients that cause asthma be removed. Dispensing-system concentrates should not be allowed to have ingredients that are listed as asthmagens on the AOEC list.

Comment:
We are generally in support of the new proposed standards. The current GS-37 standard does not include a prohibition of ingredients known to cause asthma. Therefore, we strongly support the proposed GS-37 standard, dated November 16, 2007 and urge the adoption of the proposed language the expressly references use of the list published by the Association of Occupational and Environmental Clinics (AOEC) as the best available criteria for designating argent that cause asthma, and that prohibits their conclusion as ingredients and institutional cleaners. Adoption of this language will strengthen the GS-37 standard and facilitate the use of cleaning products with a Green Seal designation in school-related asthma prevention efforts.

We do have some concerns and proposed change in the standards to eliminate the exemptions for diluted dispensing system concentrates. All of the standard's criteria should apply to the most concentrated form of the product available so that workers and building occupants will not become exposed to toxic chemicals anywhere in the product's life-cycle. Currently, the proposed standard relies heavily on dilution to be the solution.

In Section 4.7 Ingredients that Cause Asthma, the standard states that dispensing-system concentrates may be evaluated as used. This provision may allow manufacturers to include ingredients on the AOEC asthmagen list as levels greater than 0.01% as long as the intended dilution will bring the concentration below 0.01%. There is no assurance that dispensing-system concentrates will be used as such or that spills will not occur. That these products could carry a Green Seal label, even a qualified one, sends a misleading message that the product is inherently safe. We recommend that the dispensing-system qualification for ingredients that cause asthma be removed. Dispensing-system concentrates should not be allowed to have ingredients that are listed as asthmagens on the AOEC list.

We are concerned that the products that are certified using the "dispensing system exemption" will have an additional online-only "qualification designation," creating a two-tier labeling system of which consumers may be unaware. It will be difficult--if not impossible--for consumers to tell which products are devoid of highly toxic chemicals and which ones contain them but are masked with large amounts of water. Few purchasing agents are likely to go to the Green Seal website to determine which concentrates passed based on multiple exemptions.

Comment:
Exclude ingredients that cause asthma (Section 4.7)
Add the provision that “the undiluted product shall not contain any ingredients that cause asthma.” The allowance for dispensing-system concentrates to be evaluated as used should be deleted, since this allowance may result in products containing amounts of these chemical compounds that may cause asthma. Chemicals on the Association of

Occupational and Environmental Clinics (AOEC) would easily be able to slip-through. As used MSDS requires only compounds more than 1% by weight- this is 10,000 ppm! All detectable hazardous chemicals found on the AOEC list in the undiluted formulations should be prohibited. Inhalation toxicity occurs at levels less than 1 ppm several orders of magnitude below the 10,000ppm level now proposed

Response:
This modification was made and dispensing systems will be evaluated for this criterion undiluted.

Comment:
I suggest that a list of commonly used chemicals with a significant potential for causing or agrivating asthma be included in the section of GS-37 that lists prohibited ingredients.

If the AOEC list, or another list is cited, then provide a URL where the current edition may be downloaded.

Response:
Green Seal does not provide URLs in its standards since such information changes frequently and as a result may not be accurate. The listing of specific chemicals in the standard is limited those issues for which criteria for evaluation cannot be done. There are accepted criteria for the evaluation of ingredients that cause asthma, and thus they are included in the standard. If there are questions about what may or may not be included, Green Seal staff is available to answer those questions. Further, Green Seal will provide a list of asthmagens on its web site to further clarify which chemicals meet the criteria.

Comment:
The GS-37 background document states that AOEC list is periodically updated through a peer review process. However, AOEC does not provide to the public the chemical files that explain and document the factual basis and studies that support listing an individual chemical as an asthmagen. As a result, there is insufficient transparency in the process by which individual chemicals will become prohibited as alleged asthma inducing agents. By comparison, the ACGIH publishes the "Documentation of the Threshold Limit Values and Biological Exposure Indices" which provides a clear and transparent discussion of the criteria that support occupational exposure criteria for an individual chemical. Prohibiting a chemical on the basis of inducing asthma must be data driven, and should require documentation equivalent to that provided by ACGIH for occupational exposure criteria such as TLVs.

Response:
The data AOEC evaluates is available.

Comment:
We strongly support Green Seal's addition of criteria designed to limit ingredients known to cause asthma (Section 4.7). Based on the definition provided in Section 2.1 of the

proposed standard, chemicals included on the Association of Occupational and Environmental Clinic's list (AOEC) with an "A" designation will be prohibited. This is important because it is well known that a high percentage of custodial workers suffer from asthma. Some of these cases are caused by the chemical they are using during the course of their job; in other cases, their asthma is triggered or worsened by their exposure to asthmagens and severe or corrosive respiratory irritants found in cleaning products (including GS-37-certified products).

A review of existing Green Seal-certified cleaning products shows that a small percentage (approximately 6%) contains chemicals that can cause new cases of asthma. Therefore, this limit would not prevent the market from continuing to offer a wide supply of green cleaning products. The primary asthmagens found in GS-37-certified products are monoethanolamine and triethanolamine.

Comment:
We strongly support Green Seal's addition of criteria designed to limit ingredients known to cause asthma (Section 4.7). Based on the definition provided in Section 2.1 of the proposed standard, chemicals included on the Association of Occupational and Environmental Clinic's list (AOEC) with an "A" designation will be prohibited. This is important because it is well known that a high percentage of custodial workers suffer from asthma. Some of these cases are caused by the chemical they are using during the course of their job; in other cases, their asthma is triggered or worsened by their exposure to asthmagens and severe or corrosive respiratory irritants found in cleaning products (including GS-37-certified products). A review of existing Green Seal-certified cleaning products shows that a small percentage (approximately 6%) contains chemicals that can cause new cases of asthma. Therefore, this limit would not prevent the market from continuing to offer a wide supply of green cleaning products. The primary asthmagens found in GS-37-certified products are monoethanolamine and triethanolamine.

Response:
While the list of asthmagens published by AOEC includes monoethanolamine, the list does not designate which chemicals have gone through the full panel review against the peer reviewed criteria. Green Seal feels that the full review and evaluation against the criteria is essential to recognition as an asthmagen and use of the list for product reviews. As a result, monoethanolamine is not included as an asthmagen at this point. The AOEC is reviewing the data on this chemical and will have a conclusion by September 2008 (it however would be prohibited for its inhalation toxicity). The only ingredients currently found in GS-37 products that meet the criteria are diethanolamine and triethanolamine. The versatility of a list like the AOEC is that chemicals are continually reviewed and that chemicals of concern can be added or removed as the weight of evidence grows. So, the chemicals considered asthmagens and prohibited may change. While the AOEC is looking to clarify which chemicals meet the criteria after a full panel review, the list currently does not make such a designation. As a result, Green Seal will provide a list of chemicals on its web site so that information is available to those interested and for formulators.

Comment:
We object to Green Seal recognizing the Association of Occupational and Environmental Clinics (AOEC) as the authority in defining "asthmagens" based on the list generated by the AOEC. The AOEC list of asthmagens is intended as a diagnostic tool for clinicians and is limited to that utility. Further it is a poor indicator of asthmagens in the context of cleaning product formulations. In addition, the list lacks adequate functionality that would allow formulators to identify with confidence potential asthamgens. Lastly, we note that the New York State Office of General Services rejected the use of this list when it recently visited this issue in of implementing its green cleaning for schools program. Dr. Bill Beckett, who developed the criteria for the AOEC list, clearly indicates in the language that he uses in the "asthmagen protocol" document that he is hesitant to conclude that any of the materials on the AOEC list are truly asthma causing. Further he indicates that the exposure code system used in the AOEC list is intended as a tool to help clinicians. In fact, Dr. Beckitt acknowledges that the list is not intended to be considered as the "final authority", but rather is intended as a tool to help clinicians be more consistent in reporting.

Moreover, the AOEC list is a poor indicator of asthmagens in the context of cleaning product formulations. According to Dr. Beckitt, asthma exacerbation can be induced by "inhalation of non-specific substances such as nuisance dust or cold, dry air." Dr. Beckitt specifically notes that while the AOEC list has been developed in an attempt to identify materials that may cause de novo asthma, the fact that pre-existing asthma can confound the finding of a new irritant airways response precludes the ability of the list to address work-aggravated asthma in all scenarios.

In addition, Dr. Beckett wisely states that asthma is diagnosed on the basis of clinical signs/symptoms and not by a "single test, biomarker, or gene specific for asthma." We note with interest that some of the ingredients on the AOEC list, such as monoethanolamine, are classified as an asthmagen based on a single case study. Thus it would appear that the approach taken by AOEC in listing asthmagens is very casual, lacks rigorous peer review as well as is without an assessment based on the weight of the evidence. Based on Dr. Beckitt's own words, the use of the list in the context of GS-37 should be flat out rejected.

Moreover, the AOEC list lacks adequate functionality to allow formulators of cleaning products to identify specific chemical substances with any degree of confidence, and should be rejected for this reason alone. Along these lines, we note the following observations we have made in searching the AOEC list:

- A number of materials that the list classifies as asthmagens do not have a CAS number and / or have an unclear description of the chemical identity (see Tall Oil, Oil Mist, and Ethanol Ethylene Diamine).
- The list includes a number of materials with multiple and contradictory entries (see Acetic Acid and Glacial Acetic Acid).
- A number of dyes and pigments are listed without an identifying CAS number.

• Some agents commonly regarded as asthmagens, such as tobacco smoke, are not so classified in the AOEC list.

These issues strongly indicate that the AOEC list is an inferior tool for formulators to use in identifying cleaning product ingredients as asthmagens with any level of scientific confidence. Stated simply formulators of cleaning products will not be able to use this list to identify potential asthmagens. The utility of the list therefore in the context of GS-37 and the proposed revisions is non-existent.

Lastly, we note that the New York State Office of General Services clearly rejected the AOEC list of asthmagens for use in identifying "green" cleaning products in the context of implementing that State's green cleaning for schools act. In so rejecting the AOEC list, OGS specifically noted that the list was not intended for use in formulated products. For all of the aforementioned reasons we strongly urge Green Seal to strike reference to the AOEC list of asthmagens from its proposed revisions to GS-37 as a means of identifying acceptable / unacceptable ingredients for institutional and industrial cleaning product formulations.

Comment:
Ingredients that Cause Asthma: The database provided by the Association of Occupational and Environmental Clinics (AOEC) should not be used to classify ingredients as potential causes of asthma. The AOEC database does not adequately identify the chemical nature of the materials classified as 'asthmagens', it does not allow for adequate searching functionality, and a review of the classifications raises several important questions for how manufacturers will consistently search the database and apply the results. The following are some relevant search findings from the AOEC database accessed at http://www.aoec.org/tools.htm

1. Materials classified as 'asthmagens' with no CAS # and an unclear description of the chemical identity:
Alkyl Aryl Polyether Alcohol/Polypropylene Glycol Mixture
Trimethylhexanediamine/Isophorondiamine Mixture
Ethanol Ethylene Diamine
Isononanyl Oxybenzene Sulfonate
Tall Oil
Oil Mist

2. Material with multiple, contradictory entries:
Acetic acid (CAS # 64-19-7). One is listed as an asthmagen (Glacial Acetic Acid), one is not (Acetic Acid). Nothing in the online database clarifies to the formulator or Green Seal reviewer to clarify and/or interpret the difference.

3. Dyes and pigments in the database are listed without a C.I. or CAS number.
Rifazol Brilliant Orange 3R
Drimaren Brilliant Blue K-BL
Levafix Brilliant Yellow E36

Drimaren Brilliant Yellow-K-3GL
Rifafix Yellow 3 RN
Lanasol Yellow 4G

4. Some materials commonly regarded as agents that can be an underlying cause of asthma, but are not classified as 'asthmagens' by the AOEC database.
Tobacco smoke
Enzymes
Aziridine

These four issues suggest that the AOEC database should not be used to classify ingredients. Manufacturers will not be able to easily search for the classification status of their ingredients because CAS and C.I. numbers are not readily available for all materials classified as 'asthmagens'. Therefore, even multiple searches for several synonyms of an ingredient could still result in a false negative. The contradictory entry for acetic acid and the lack of classification for substances such aziridine further illustrate that the AOEC database is intended to be a tool for clinicians but should not be used by groups such as Green Seal to authoritatively classify substances.

Comment:
The database provided by the AOEC should not be used to classify ingredients as potential causes of asthma. The AOEC database does not adequately identify the chemical nature of the materials classified as 'asthmagens', it does not allow for adequate searching functionality, and a review of the classifications raises several important questions for how manufacturers will consistently search the database and apply the results. The following are some relevant search findings from the AOEC database accessed at http://www.aoec.org/tools.htm

1. Materials classified as 'asthmagens' with no CAS # and an unclear description of the chemical identity:
Alkyl Aryl Polyether Alcohol/Polypropylene Glycol Mixture
Trimethylhexanediamine/Isophorondiamine Mixture
Ethanol Ethylene Diamine
Isononanyl Oxybenzene Sulfonate
Tall Oil
Oil Mist

2. Material with multiple, contradictory entries:
Acetic acid (CAS # 64-19-7). One is listed as an asthmagen (Glacial Acetic Acid), one is not (Acetic Acid). Nothing in the online database clarifies to the formulator or Green Seal reviewer to clarify and/or interpret the difference.

3. Dyes and pigments in the database are listed without a C.I. or CAS number.
Rifazol Brilliant Orange 3R
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Rifafix Yellow 3 RN
Lanasol Yellow 4G

4. Some materials commonly regarded as agents that can be an underlying cause of asthma, but are not classified as 'asthmagens' by the AOEC database (e.g.,Tobacco smoke, Enzymes, Aziridine).

These four issues suggest that the AOEC database should not be used to classify ingredients. Manufacturers will not be able to easily search for the classification status of their ingredients because CAS and C.I. numbers are not readily available for all materials classified as 'asthmagens'. Therefore, even multiple searches for several synonyms of an ingredient could still result in a false negative. The contradictory entry for acetic acid and the lack of classification for substances such aziridine further illustrate that the AOEC database is intended to be a tool for clinicians but should not be used by groups such as Green Seal to authoritatively classify substances.

Lastly, we reiterate our stated concerns about the decisionmaking to classify a chemical as an asthmagen in the AOEC database. While the AOEC criteria for a substance to be included as an asthmagen appears to be a good approach, we question the rigor with which these criteria have been applied. At the very least, there are examples, as in the case of monoethanolamine, where there is no readily available documentation to describe how this substance met the AOEC criteria. Without such transparency, the scientific validity of the results has to be drawn into question as does the use of this list.

Response:
More than 30 articles over the last several years have documented the increased incidence and prevalence of asthma among janitors and other cleaning workers in many countries (Nazaroff, 2005, Rosenman, 2006). Henneberger (2005) commented that, "Over the past 15 years, professional cleaners have emerged as one of the high risk groups for work related asthma in industrialized nations." This adverse effect is not limited to individuals who professionally perform cleaning tasks; cleaning products also affect other building occupants and bystanders (Nazaroff, 2004, Rosenman, 2003). Case reports and epidemiologic studies have documented asthma among individuals who use spray cleaners at home (Zock, 2007, Rosenman, 2007). And a new study has documented wheezing and decrements in lung function in children whose mothers had high domestic cleaning chemical exposure during pregnancy (Henderson 2007).

Children have a higher rate of asthma than adults. There are a number of developmental and physiological factors that may contribute to this higher rate, including incomplete metabolic defenses and immunological mechanisms, a higher breathing rate, greater surface area to volume ratio as well as behavioral differences including hand to mouth activities and more time on the ground. Some of these characteristics may contribute to greater exposure and/or to greater susceptibility to hazardous effects from chemicals in the environment. An article

by Mendell (2007) reviewed 21 published epidemiologic studies on associations between indoor residential chemicals and respiratory health and/or allergy in children. Specifically, Mendell found associations between formaldehyde and phthalates and asthma, as well as suggestive evidence for aromatics, aliphatics, limonene, tetrachloroethylene, trichloroethylene and either asthma-related effects or allergy/atopy indicators or both. Note that Mendell's previous research had documented an association between indoor pollutants in schools and poorer student performance (Mendell and Heath, 2005).

Asthma is not a condition in which dose can be determined which is why risk assessments have been ineffective/irrelevant and one reason that testing methodology hasn't been available to screen chemicals. Further, there are no methods to screen chemicals for their ability to cause asthma. As a result, reliance on clinical data is essential. Asthma is a clinical diagnosis, and, as such, it includes consideration of underlying pathology as well as the symptoms that occur during episodes. Dr. Beckett specifically describes the efforts to identify agents "known to cause asthma *de novo*." He further explains that the underlying mechanism may be immunological, "another form of sensitization, or a chronic state due to non-sensitizing inflammatory stimuli." The evidence considered specifically exclude inhalation exposures that only exacerbate existing asthma. Dr. Becket also specifically addresses specificity. The purpose, he wrote is to allow avoidance of specific substances "without requiring unnecessary avoidance of non-asthmagens." Further, the Global Initiative for Asthma states that "The early identification of occupational sensitizers and the removal of sensitized patients from any further exposure are important aspects of the management of occupational asthma."

The Association of Occupational and Environmental Clinics, established in 1987, is a non-profit organization, "committed to improving the practice of occupational and environmental health through information sharing and collaborative research." The Association of Occupational and Environmental Clinics (AOEC) receives support through multi-year cooperative agreements with the Agency for Toxic Substances and Disease Registry (ATSDR) and the National Institute for Occupational Safety and Health (NIOSH). It represents a network of 60 occupational and environmental clinics and 250 individuals dedicated to sharing information and improving practice of diagnosis, workplace evaluation and research. Regular feedback is provided by clinics and departments of public health that utilize AOEC educational materials and the list of chemicals.

The AOEC has developed criteria that were formally adopted by the AOEC board in 2005 for identifying chemicals that cause asthma, an asthmagen (A). Some of the asthmagens were identified prior to this formal adoption. AOEC has been systematically reviewing the identified asthmagen chemicals to ensure that they meet the criteria as originally developed (one of two major criteria or two of four minor criteria, see http://www.aoec.org/content/Asthmagen_Protocol_4-9-05_revision.doc) AOEC can provide the information used for the review.

The evaluation of chemicals by AOEC is based on criteria and a peer review process. The robustness of such an approach provides greater scientific validity to any prohibition that may result. As a result the AOEC will continue to serve a source for asthmagen information. However, Green Seal feels that the full review and evaluation against the criteria is essential to recognition as an asthmagen and use of the list for product reviews. As a result, the criteria have been included in the standard as the means to identify if a chemical is an asthmagen. Currently, in using these criteria diethanolamine and triethanolamine would be prohibited. Monoethanolamine is under review by AOEC, with conclusions expected in September 2008. The versatility of a list like the AOEC is that chemicals are continually reviewed and that chemicals of concern can be added or removed as the weight of evidence grows. So, the chemicals considered asthmagens and prohibited may change.

While the AOEC is looking to clarify which chemicals meet the criteria after a full panel review (since as noted there are some chemicals on the list that were included prior to the formalization of the review process), the list currently does not make such a designation. As a result, Green Seal will provide a list of chemicals on its web site so that information is available to those interested and facilitating formulation.

The NYS OGS acknowledged the desirability of reducing the presence of asthmagens and asthma triggers in schools "to the greatest extent practical." They intended to further review AOEC, partly through the GS-37 revision process, "to see if asthmagens and asthma triggers can be further restricted." Through this GS-37 revision process it was found that the AOEC list was initially designed without peer-reviewed/accepted criteria or a formal panel review process and thus the asthmagen listings could be considered preliminary. Green Seal and NYS OGS recognize that such an approach is not appropriate for formulation or product review. However, as was stated above, with the formalized criteria and review process, use of the asthamgen listing (of chemical that met the criteria after the review) for product review has been enabled. Further, it was stated that "OGS will support a review and revision of these criteria to see if asthmagens and asthma triggers can be further restricted while still allowing for reasonable variety and innovation in the market."

The criteria, and this standard, do not cover chemicals or items that exacerbate asthma, also called asthma triggers. This is because, for at least one reason, once an individual is sensitized it is unclear all the possible triggers beyond the cause of the asthma.

Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. The chronic inflammation is associated with variable airflow obstruction, commonly presenting with symptoms of cough, wheezing, shortness of breath, or chest tightness, which may be mild, moderate, severe and even life-threatening. Symptoms may resolve completely between active episodes.

Symptoms may occur during exposure, immediately after exposure or up to 24 hours later in a "late phase," frequently interrupting sleep. Chemicals that cause asthma include those listed as asthmagens after a full review of that chemical's evidence by the Association of Occupational and Environmental Clinics that have evidence of being sensitizers which are those that lead to hypersensitivity of the airways through sensitizing biologic mechanisms or meet the criteria outlined in Appendix A.

Appendix A
A substance will meet criteria for causing asthma if it first meets the test of specificity (it can be identified as a discrete workplace substance) and clinical relevance (it is present in the air of workplaces) and in addition meets sufficient criteria as listed below. To be included as a sensitizing cause of asthma, it must meet one or more of the major criteria, or two or more of the minor criteria.

C. *Specificity. A substance must be defined in such a way that, if it is a cause of asthma, it can be avoided specifically by the patient without requiring unnecessary avoidance of non-asthmagens.*
D. *Clinical relevance. Substances must be currently used or have been used in workplaces where there is potential for inhalation exposure. A peer-reviewed case report, outbreak report, or case series report is also required to establish clinical relevance where circumstances described in the report indicate the possibility of this substance as an asthmagen.*

<u>Major Criteria (at least one)</u>

1. Specific inhalation challenge indicates occupational asthma (i.e. immediate or delayed fall in FEV_1 after exposure) in at least one patient with asthma who appears to have developed the asthma as a result of exposure to the implicated substance. Peer reviewed study should indicate a response to sub-irritant levels of sensitizing substances. Ideally, a positive challenge will be controlled by negative challenges in asthmatic patients who are not believed to be sensitized to the particular substance, but this design is not characteristic of many specific exposure challenges.

2. Workplace challenge with physiologic response (serial spirometry or serial peak expiratory flow) showing reversible expiratory airflow obstruction or changing airway reactivity in relation to exposure, with a comparable control period without significant variable airflow obstruction or airway reactivity. Subjects tested should be reasonably considered to be without asthma prior to testing in the workplace, to exclude work-aggravated asthma. Peer reviewed publication.

OR

<u>Minor Criteria (at least two):</u>

1. Non-Specific airway hyperresponsiveness is demonstrated in patients with suspected occupational asthma while they are still employed at the workplace in question, based on methacholine, histamine, or cold-air challenge, published in a peer-reviewed journal.

2. Work-exposure related reversible wheezing heard with repeated exposures in at least one patient with a compatible clinical picture, published in a peer-reviewed journal.

3. Positive IgE antibody (skin test or serologic test) for the suspected antigen in at least two patients, indicating potential IgE sensitization, published in a peer-reviewed journal.

4. Clinical response of remission of symptoms with cessation of exposure and recurrence of symptoms with re-exposure in one or more patients in each of two or more subjects published in a peer-reviewed journal.

Ingredients that Cause Asthma. The undiluted product shall not contain any ingredients that cause asthma.

Nazaroff, W.W., Weschler, C.J. 2004. "Cleaning products and air fresheners: exposure to primary and secondary air pollutants." *Atmospheric Environment.* 38:2841-2865.

Rosenman, K. 2006. "Cleaning products-related asthma." *Clinical Pulmonary Medicine.* 13(4):221-228.

Henneberger, P.K. 2005. "How "clean" is the cleaning profession?" *Occ Environ Med*. 62:586-587.

Rosenman, K.D., Reilly, M.J., Schill, D.P., Valiente, D., Flattery, J., Harrison, R., Reinisch, F., Pechter, E., Davis, L., Tumpowsky, C.M., Filios, M. 2003. "Cleaning products and work- related asthma." *Journal of Occupational and Environmental Medicine.* Volume 45(5):556-563.

Zock, J-P, Plana, E., Jarvis, D., Antó, J.M., *et al.* 2007. "The use of household cleaning sprays and adult asthma: An international longitudinal study." *Amer J Respir Crit Care Med* 176:735-741.

Rosenman, K.D. 2007. "Clean as a whistle, but what about that wheeze?" *Amer J Respir Crit Care Med*. 176:731-732.

Henderson J, Sherriff A, Farrow A, Ayres JG. 2007. Household chemicals, persistent wheezing and lung function: Effect modification by atopy? *European Respiratory Journal Express (online prior to publication)* 10.1183/09031936.00086807 [Accessed 31 October 2007]

Mendell, M.J. 2007. “Indoor residential chemical emissions as risk factors for respiratory and allergic effects in children: a review.” *Indoor air*.17:259-277.

Mendell, M.J., Heath, GA. 2005. “Do indoor pollutants and thermal conditions in schools influence student performance? A critical review of the literature.” *Indoor air*. 15(1):27-52

Global Initiative for Asthma:
http://www.ginasthma.com/Guidelineitem.asp?l1=2&l2=1&intId=1389

Comment:
We recommend this criterion be deleted. This term is not standardized. The designation of substances as “asthmagens” is under constant review by the Association of Occupational and Environmental Clinics (AOEC) as stated on their website. Therefore, this criterion is a moving target with ingredients being added and deleted from AOEC’s list and should not be included in the standard.

Response:
The AOEC has developed criteria to which they evaluate chemicals for their ability to cause asthma. This has been peer reviewed and accepted. The versatility of a list like the AOEC is that chemicals are continually reviewed and that chemicals of concern can be added or removed as the weight of evidence grows. So, the chemicals considered asthmagens and prohibited may change. This is similar to the well-recognized lists of carcinogens, and thus is not seen as limitation for its use.

4.08 Volatile Organic Compounds
The product as used shall not contain substances that contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The volatile organic content of the product as used shall not exceed the following:

- **0.1% by weight for dilutable carpet cleaners**
- **1% by weight for general-purpose and bathroom cleaners**
- **1% by weight for glass cleaners**
- **1% by weight for ready-to-use carpet cleaners**

The volatile organic content shall be determined by California Air Resources Board Method 310, modified to not allow the exemptions for fragrances and low vapor pressure organic compounds specified under Method 310.

Comment:
The standard should just require that products comply with CARB VOC regs. CARB VOC regs are very stringent and constantly evolving as well as technology evolves. This way, the standard is not stagnant.

Comment:
We recommend harmonizing the GS-37 VOC guidelines with the the state of California Air Resources Board (CARB) rules, including LVP-VOC designation. Significant effort is already in place to address VOC emissions, and diverging from CARB standards will place a high burden on manufacturers to manage multiple thresholds VOC compliance. CARB has intensively studied VOC emissions and determines their product limits based on a survey of current and emerging technology. This process provides adequate opportunity for trade associations and industry to determine the technical feasibility and safety of proposed limits while pushing new technology and innovation.

Comment:
The standard should just require that products comply with CARB VOC regs. CARB VOC regs are very stringent and constantly evolving as well as technology evolves. This way, the standard is not stagnant.

We agree. (Although it should be stated that since California has made laws requiring themselves to make more and more VOC restrictions, their cuts are getting less and less based on available technology and more based on the legal need to make cuts.)

Comment:
In regard to the proposed revisions of GS-37 that address Volatile Organic Compounds, we urge Green Seal to adopt an approach that is consistent with the VOC regulations adopted by the California Air Resources Board. VOC Limitations. We object to the VOC limitations to the extent that they deviate from those established by CARB and the Ozone Transport Committee, both of which have established very aggressive limits. Specifically Green Seal has proposed 1% VOC limitations for General Purpose Cleaners, Glass Cleaners and Ready to Use Carpet Cleaners whereas CARB and OTC have established limits of 4% for general purpose and glass cleaners, and 3% for ready to use carpet cleaners.
It is important to note that both CARB and the OTC both have recently had the opportunity to revisit these limitations. In so doing, both organizations have reviewed extensively the environmental, product performance, commercial feasibility and other related issues in assessing what would be an appropriate, yet aggressive VOC limitation for these product categories. These organizations have given this issue due deliberation and their decision should be given due deference by Green Seal in its proposed revisions to GS-37.
We therefore urge Green Seal to revise this aspect of its proposed revisions by providing a 4% VOC limitation for General Purpose and Ready to Use Carpet Cleaners, and a 3% VOC limitation for Ready to Use Carpet Cleaners.

Comment:
Volatile Organic Compounds: We recommend Green Seal simply state that the product must meet CARB VOC regulations. The regulations set by CARB are the most stringent in the world, they consistently are reviewed and updated, and involve the latest product

development information available. This approach would prevent the standard from becoming stagnant.

Comment:
Concerns exist with the proposed VOC limits for products. Green Seal should consult the rules as applied by CARB, EPA and other regulatory bodies in determining VOC levels and align the proposed standard with those rules.

Comment:
The relevance of the total VOC determination to assessing acute and chronic effects should be explained. Also, not clear why the standard proposes to adopt the California VOC standards rather than the federal standards. It appears that the definition of VOC is inconsistent with the federal standard. At a minimum an explanation should be provided regarding how the provisions relate to federal requirements.

> **Response**:
> Setting appropriate levels of VOC content is essential to minimizing the potential health effects of cleaning products on workers, children, and otherwise vulnerable or sensitive populations. Poor indoor air quality as a result of VOCs is also one of the biggest contributors to asthma and other respiratory ailments in school aged children. Adverse health responses potentially caused by VOCs in non-industrial indoor environments fall into three categories, namely 1) irritant effect including the perception of unpleasant odors and mucous membrane irritation, 2) systematic effects such as fatigue and difficulty concentrating, and 3) toxic effects such as carcinogenicity. CARB's development of VOC's limits was based on pollution and outdoor concerns (photochemical reactions), thus does not adequately address the need for VOC limits in this standard.

Comment:
We express support of Green Seal's new VOC standard of 1% by weight VOC content with no exemption for fragrance or low vapor pressure (LVP) solvents for GS-37 Industrial and Institutional Cleaners.

The new standard demonstrates leadership in environmental protection, particularly in terms of air quality. Additionally, having a standard superior to the minimum federal or state law distinguishes certified products as environmentally preferable. Products that just meet federal or state regulations are merely compliant.

In April 2007, the South Coast Air Quality Management District (AQMD) approved the Clean Air Choices Cleaner certification program. The program certifies janitorial products that have a VOC content less than 10 g/L (1% by weight) and do not contain prohibited ingredients including heavy metal, carcinogens, mutagens, nitrogen and endocrine disruptors such as dibutyl phthalates and aklylphenol ethoxylates. Participation in this program is strictly voluntary. Companies can opt to have the AQMD test their products or alternatively, the AQMD will only test the VOC content, if the company can demonstrate environmental preference by being certified by Green Seal or

another recognized third party certification organization. A copy of the Board letter and certification criteria are available.

In establishing a 10 g/L VOC content standard for AQMD's Clean Air Choices Cleaner certification program, the AQMD tested 21 "environmentally preferable" Industrial and Institutional cleaning products from six different manufacturers. Of the 21 products tested, 19 met the 10 g/L VOC content standard with multiple certifiable products in all categories including bathroom, carpet, general purpose and glass cleaners. Twelve of the 21 products were Green Seal certified and eleven of them had VOC content below 10 g/L. When calculating the VOC content, no exemptions were made for fragrance or LVP solvents. If all companies used ultra-low VOC I&I cleaning products, the AQMD would see a decline of 1.7 tons per day of VOC emissions. California would realize nearly a 4 ton per day reduction and nationwide there would be over 35 tons per day reduced. This does not include unquantified reductions realized from the removal of the fragrance and LVP solvent exemptions, base on our analysis. This reduction will be greatly accelerated by your acceptance of the revised VOC calculation method.

While the testing conducted was limited, the high ratio of certifiable cleaners suggests that many of the Green Seal I&I cleaners currently would meet the more stringent standard. It also demonstrates that there is unlikely to be any impact on product performance or efficacy because the products already meet the product-specific performance requirement in order to be certified by Green Seal.

The 1% by weight VOC content standard will further distinguish a Green Seal I&I product as environmentally preferable. There is an opportunity to recognize the superiority of these products and demonstrate environmental leadership as opposed to merely compliance with the law.

Response:
Comment acknowledged.

Comment:
What is the purpose of having a material classification of Low Vapor Pressure Organic Compound if it is being treated the same as all others? Why does the CARB even address this if the impact is the same? I believe that not allowing the exemption per the CARB rules for fragrances and LVPs, will clearly limit the ability of industry to supply efficacious products that meet the needs of the public. The rule is too restrictive to be practical for many applications. I believe it will lead to poor maintenance practices that will ultimately reduce the lifecycle of the assets being maintained and possibly to decreased indoor air quality. Reinvesting the energy to replace poorly maintained assets will far outweigh the impact of LVPs on the built enivronment and the environment at large. I am not sure being more restrictive than another carefully considered standard is necessarily better for society. It is simply more restrictive. This area requires more thought.

Response:

The comment above this one noted that there are products that can meet this requirement with the exemptions removed. Further, Green Seal has included this type of evaluation, through a calculation determination including fragrance ingredients, and have found that products can meet the requirement.

Comment:
4.8 Volatile Organic Compounds. This section states that the volatile organic content shall be determined by the California Air Resources Board Method 310, modified to not allow the exemptions for fragrances and low vapor pressure organic compounds. We strenuously object to this proposed revision and question the basis for it. The 2 percent fragrance exemption has been in place in California for many years; it is based on technical feasibility and must be retained.

Comment:
4.8 Volatile Organic Compounds – We object to eliminating the exemptions for fragrances and low vapor pressure organic compounds. We would not object to evaluating fragrance components present at or above the 0.1% by weight in the product.

Testing for VOC

We disagree with Green Seal estimated cost of less than $400 per product for Chamber testing. Quotes received for testing of VOC's in pesticides started in the thousands per test creating an economic hardship, especially for smaller companies.

Comments:
CARB Method 310. In regard to California Air Resources Board Method 310, Green Seal proposes to revise GS-37 so as to not allow the exemptions for fragrances and low vapor pressure organic compounds specified under Method 310. We strenuously object to this proposed revision and questions the basis for it. The 2 percent fragrance exemption has been in place in California for many years; it is based on technical feasibility and must be retained.

Comment:
Regarding modifying the CARB 310 test method, fragrance VOCs will not be an issue for those opting for fragrance-free product manufacturing, so restricting it here would be redundant.

We also agree with previous statements that Green Seal's estimated chamber testing costs are very low.

Comment:
Section 4.8 …to not allow the exemption for fragrance and low vapor pressure organic compounds…
This exclusion forces formulators to spend the money to perform the test. It can become a very expensive. Suggest to allow the same exemption, but require test confirmation

when it (either TVOC or VOC after exemption) is close to (say within 10% range) the limit. In other words, it does not make sense to spend the money indiscriminately.

Response:
As mentioned above, poor indoor air quality has demonstrated health effects on the population. The health effects are not limited to non-fragrance ingredients. Further, the CARB method was developed for air pollution and outdoor concerns, rather than indoor air concerns. Finally, Bridges (2002) noted many health concerns including skin sensitization, skin irritation, respiratory sensitization, respiratory irritation, neurological, and systemic effects from fragrance ingredients. Many of the cited health concerns were linked to air quality issues with fragrances including total VOC's. As a result, they will be included in the VOC limits.

VOC testing is not done with chamber testing, rather a laboratory chromotagraphy method, thus if one were to need the test (which is not required) it would cost $400. The test is not required since Green Seal can calculate the VOC content based on vapor pressure of each ingredient. This calculation has been done for all currently certified products (including fragrance ingredients). This was added to the criterion:

Volatile Organic Compound Content. The product as used shall not contain substances that contribute significantly to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality. The volatile organic compound content of the product as used shall not exceed the following:

- *0.1% by weight for dilutable carpet cleaners*
- *1% by weight for general-purpose and restroom cleaners*
- *1% by weight for glass cleaners*
- *1% by weight for ready-to-use carpet cleaners*

The volatile organic compound content shall be determined either by summing the percent by weight contribution from all components of the product that have a vapor pressure of greater than 0.1 mm mercury at standard conditions or by the California Air Resources Board Method 310, modified to not allow the exemptions for fragrances and low vapor pressure organic compounds specified under Method 310.

Bridges, B. 2002. “Fragrance: emerging health and environmental concerns.” *Flavour and Fragrance Journal*. 17: 361-371.

4.09 Toxicity to Aquatic Life
The product as used shall not be toxic to aquatic life. A compound is considered not toxic to aquatic life if it meets one or more of the following criteria:
Acute LC50 for algae, daphnia, or fish >100 mg/L

For purposes of demonstrating compliance with this requirement, aquatic toxicity testing is not required if sufficient aquatic toxicity data exist for each of the product's ingredients to demonstrate that the product mixture complies, using a weighted average approach. Aquatic toxicity tests shall follow the appropriate protocols in ISO 7346-2 for fish, OECD test guidance 203 for fish, OECD test guidance 201 for algae, and OECD test guidance 202 for daphnia.

Comment:
Consideration of aquatic toxicity should only be done in the context of environmental risk assessment. Only applying criteria for aquatic toxicity for products fails to consider the environmental fate of aqueous cleaning products which are typically disposed into wastewater treatment systems and, thus, do not directly enter the environment. The ability of a product to exert aquatic toxicity in the environment is a function of many factors beyond just its toxicity, including the mitigation due to fate mechanisms and dilution levels upon discharge into the environment.

Comment:
Green Seal proposes that all ingredients shall be readily biodegradable. As currently written, this must be determined by actual testing. If every fragrance ingredient must be physically tested for biodegradability, with no de minimis level for ingredients in products, fragrances will effectively be banned because the fragrance industry routinely uses computerized QSAR models such as the U.S. EPA's "PBT Profiler" and "EpiWin" to predict the biodegradability and ecotoxicity of fragrance materials.

Regarding the section on the testing of mixtures, under some conditions some mixtures have been tested with modifications to the procedures. For example, petroleum products use an approach referred to as "water accommodated fractions" – essentially an equilibrium solution of the test material. Furthermore, whole effluent test methods used to monitor waste water might be worth investigating for the testing of mixtures. However, for complex fragrance mixtures, testing will be difficult if not often impossible. An additional assessment option for multi-component materials might be an analysis by parts, i.e. summation of the aquatic toxicity by weighted average.

Comment:
Not clear of the basis for assessing aquatic toxicity on ""as used" formulations given that the concentration of any toxic ingredients will be very different by the time the product reaches the environment. This should be explained.

> **Response**:
> The product is most typically exposed to the environment in is diluted form, however, the concentrated form could be disposed of down the drain. Thus, the environmental evaluation at an as used concentration represents an appropriately conservative approach. Only components that meet the ingredient definition at the as used level would be evaluated. So for fragrances, this is limited to only those used at high levels. The data on these components, along with all other

chemicals in the product, has been available and not limited certification of the existing certified products.

4.10 Aquatic Biodegradability

Each of the individual organic ingredients in the product as used shall exhibit ready biodegradability in accordance with the OECD definition except for the polymer portion of a carpet cleaner. However, all other ingredients in a carpet cleaner must comply. Biodegradability shall be measured according to any of the following methods: ISO 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310. Specifically, within a 28-day test, the ingredient shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10%:

- **Removal of dissolved organic carbon (DOC) > 70%**
- **Biological oxygen demand (BOD) > 60%**
- **% of BOD of theoretical oxygen demand (ThOD) > 60%**
- **% CO2 evolution of theoretical > 60%**

Per OECD guidance (2003) the 10-day window requirement does not apply to structurally-related surfactant homologues.

For organic ingredients that do not exhibit ready biodegradability in these tests the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating dissolved organic carbon (DOC) removal > 90%.

An exception shall be made for an organic ingredient that does not exhibit ready biodegradability if it has low aquatic toxicity, is not bioaccumulating, and exhibits biodegradation rates above 70% (measured as BOC, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C.

For purposes of this section, low aquatic toxicity is defined as having an acute and chronic aquatic toxicity >100 mg/L where chronic aquatic (fish) toxicity is measured per OECD Method 204. Bioaccumulating is defined as having a bioconcentration factor (BCF) greater than 100 (or log BCF >2).

Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases.

Comment:

We recommend that EPIWIN or EPISWEETS be allowed to be used. This modeling program is made by the EPA and will be utilized with REACH. This is a valid modeling program that will save time and money.

Comment:

Green Seal proposes that all ingredients shall be readily biodegradable. As currently written, this must be determined by actual testing. Presumably this requirement applies to the individual ingredients found in fragrance compounds. If every fragrance ingredient must be physically tested for biodegradability, with no de minimis level for ingredients in products, fragrances will effectively be banned because the fragrance industry routinely uses computerized QSAR models such as the U.S. EPA's "PBT Profiler" and "EpiWin" to predict the biodegradability and ecotoxicity of fragrance materials. We urge Green Seal to modify its proposal to accept such data as indicative of a substance's biodegradability as a substitute for actual testing.

Comment:
Aquatic Biodegradability: We recommend that EPIWIN or EPISWEETS be allowed to be used. This is an EPA modeling program and will be utilized with REACH. Using this valid modeling program will save time and money.

> **Response**:
> Only components that meet the ingredient definition at the as used level would be evaluated. So for fragrances, this is limited to only those used at high levels. The data on these components, along with all other chemicals in the product, has been available and not limited certification of the existing certified products. While biodegradability data has been available for the products reviewed by Green Seal, may accept QSAR data from EPA's BioWin model when data is not available.
>
> *…Testing is not required for any ingredient for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases. In the absence of experimental data, QSAR data from EPA's BioWin (EpiSuite) models may be considered*.

Comment:
The proposed revision to the standard requires that all organic ingredients are readily biodegradable, effectively excluding the use of certain performance chemicals, such as polymers and chelants that are safe at the low levels that they are used. At the same time, they provide significant performance improvements which allow for the use of less product for the same standard cleaning job. From a holistic Life Cycle Analysis (LCA) viewpoint, products without these performance chemicals may not have a superior environmental profile than products containing them.

> **Response**:
> Further an exemption is already allowed for active components of carpet cleaners since as the commenter points out there are life cycle benefits of these ingredients. …"Each of the individual organic ingredients in the product *as used*, except for the polymer portion of a carpet cleaner, shall exhibit ready biodegradability in accordance."

4.11 Eutrophication
The product as used shall not contain more than 0.5% by weight of total phosphorus.

Comment:
It is well known that phosphorus can contribute to nutrient-loading in water bodies, leading to adverse effects on water quality. The relative loadings of phosphorus to surface waters from detergents should be put into context. The relative phosphorus contribution from cleaning products, particularly household cleaners, has been demonstrated to be negligible or non-existent (Legislative Report: Detailed Assessment of Phosphorus Sources to Minnesota Watersheds, Minnesota Pollution Control Agency, 2004; http://www.pca.state.mn.us/hot/legislature/reports/phosphorus-report.html).

> **Response**:
> Phosphorus is known to tax the efficiency of waste water treatment facilities and contribute to eutrophication of bodies of water after disposal. This has prompted many states to limit phosphorus concentrations to 0.5% in cleaning products. Further, it is the aim of Green Seal to encourage the design of products that do not to contribute to environmental degradation. As a result, the standard will not be changed.

4.13.1 Prohibited Ingredients
The undiluted product shall not contain the following ingredients:
- **Alkylphenol ethoxylates**
- **Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds.**
- **Ozone-depleting compounds**
- **Optical brighteners**
- **Phthalates**
- **Nitro-musks**
- **Polycyclic musks**
- **2-butoxyethanol**
- **Formaldehyde-donors**

Comment:
We support the addition of several important chemicals to the standard's list of prohibited and chemicals and ingredients.

Comment:
We strongly support the proposed addition of several important chemicals to the standard's lists of prohibited and restricted ingredients (Section 4.13). Among the prohibited ingredients are phthalates, nitro-musks, polycyclic musks, 2-butoxyethanol, and formaldehyde-donors. With the exception of 2-butoxyethanol, these chemicals rarely show up on MSDSs because they are often hidden components found in fragrances. Since some end-users prefer to use scented cleaning products, it is important to ensure that the fragrances are devoid of these hazardous ingredients.

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We strongly support the proposed addition of several important chemicals to the standard's list of prohibited and restricted ingredients -some of which are components of product fragrance

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We strongly support the proposed addition of several important chemicals to the standard's lists of prohibited and restricted ingredients (Section 4.13). Among the prohibited ingredients are phthalates, nitro-musks, polycyclic musks, 2-butoxyethanol, and formaldehyde-donors. With the exception of 2-butoxyethanol, these chemicals rarely show up on MSDSs because they are often hidden components found in fragrances. Since some end-users prefer to use scented cleaning products, it is important to ensure that the fragrances are devoid of these hazardous ingredients. We also support the proposed restrictions on d-Limonene and other terpene hydrocarbons because they are skin and potential respiratory sensitizers that can contribute to the formation of formaldehyde (a human carcinogen) when they mix with ground-level ozone.

Response:
Comments acknowledged.

Comment:
All product ingredients should be assessed against the same criteria. Also, prohibiting all members of a class of ingredients (e.g., optical brightener) without regard to differences within the class inappropriately captures chemicals of varied environmental impacts and creates disincentives to innovation within the class. For example, optical brighteners should be removed from the list of prohibited ingredients. Innovation may in the future offer a fully biodegradable and non-toxic brightener, which under this standard would be banned. Finally, this criterion inappropriately focuses on the hazard potential of ingredients and not the risk they pose as a result of use in cleaning products.

Response:
Some of Green Seal's principles of standard development are that the criteria are scientifically-justified and measurable/verifiable. There are health and environmental concerns for chemical products like the cleaners. However, if development of test methods is not yet in a state where it is widely recognized as the standard for a particular end point of concern and there is not widespread data available then use of such a method may not be scientifically-justified or verifiable. As a result, Green Seal, and other ecolabel programs, use a prohibited ingredient list when specific chemicals have a recognized hazard (ex. Endocrine disruptors and neurotoxins).

Optical brighteners (with their current environmental and health concerns) are not needed to meet product performance requirements, and thus even if less harmful options become available, that are not needed in GS-37 products.

Comment:
Lists of prohibited and restricted ingredients (Section 4.13)
Add several important chemicals to the standard's lists of prohibited and restricted ingredients (Section 4.13). Although the prohibited ingredients include phthalates, nitro-musks, polycyclic musks, 2-butoxyethanol, and formaldehyde-donors this list is not specific enough for phthalates, nitro-musks, polycyclic musks, and formaldehyde-donors. GS-37 should use these general catagories and list the specific cas numbers of the compounds in these categories that are currently known to be found in cleaners. The following compounds should be prohibited: monoethanolamine, diethanolamine, and triethanolamine, since these chemicals have multiple serious health consequences such as causing new cases of asthma, triggering asthma among people who currently have it (by being corrosive to the respiratory system), and absorbing through the skin to cause central nervous system effects. We also urge Green Seal to add to the prohibited ingredients list any chemical that is currently prohibited in similar products under Canada's EcoLogo for "green" hard surface cleaners (CCD-146); These include specific ingredients of concern such as ammonia and any ammonium compounds, aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid or the salts of these compounds. Allow only the use of food grade dyes, which are known to be safe; do not allow chlorinated (PVC) plastic in packaging.

Comment:
Asthmagens - additional chemicals should be prohibited that trigger asthma; and be comparable to the EcoLogo list of prohibited ingredients

Comment:
We believe that several additional chemicals should be prohibited to better ensure the safety of the concentrates, including monoethanolamine, diethanolamine, and triethanolamine, since these chemicals have multiple serious health consequences such as causing new cases of asthma, triggering asthma among people who currently have it (by being corrosive to the respiratory system), and absorbing through the skin to cause central nervous system effects. In a review, a relatively small number of products (6%) were found to contain asthmagens; therefore, prohibiting these chemicals would not overly restrict available products.

We also urge Green Seal to add to the prohibited ingredients list any chemical that is currently prohibited in similar products under Canada's EcoLogo for "green" hard surface cleaners (CCD-146). Given that several of these health effects occur even at low-level exposures over time, we believe that they should be eliminated from GS-37 certified products altogether. Adding these chemicals would only affect a small number of currently certified products, but will go a long way toward protecting custodial and manufacturing workers.

Comment:
The list of prohibited ingredients should be expanded to be consistent with the Environmental Choice program: aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid

or the salts of these compounds.

Only allows the use of food grade dyes, which are known to be safe. In contrast, Green Seal has no specific restrictions on the types of dyes that can be used.

Comment:
We strongly support the proposed addition of several important chemicals to the standard's lists of prohibited and restricted ingredients (Section 4.13). Among the prohibited ingredients are phthalates, nitro-musks, polycyclic musks, 2-butoxyethanol, and formaldehyde-donors. With the exception of 2-butoxyethanol, these chemicals rarely show up on MSDSs because they are often hidden components found in fragrances. Since some end-users prefer to use scented cleaning products, it is important to ensure that the fragrances are devoid of these hazardous ingredients. We also support the proposed restrictions on d-limonene and other terpene hydrocarbons because they are skin and potential respiratory sensitizers that can contribute to the formation of formaldehyde (a human carcinogen) when they mix with ground-level ozone. An analysis shows that a few Green Seal-certified products contain d-limonene and other terpenes; so screening them out would not significantly reduce the number of products available on the market.

Add several chemicals to the list of prohibited ingredients
We believe that several additional chemicals should be prohibited to better ensure the safety of the concentrates, including monoethanolamine, diethanolamine, and triethanolamine, since these chemicals have multiple serious health consequences such as causing new cases of asthma, triggering asthma among people who currently have it (by being corrosive to the respiratory system), and absorbing through the skin to cause central nervous system effects. In a review, a relatively small number of products (6%) were found to contain asthmagens; therefore, prohibiting these chemicals would not overly restrict available products.
We also urge Green Seal to add to the prohibited ingredients list any chemical that is currently prohibited in similar products under Canada's EcoLogo standard for "green" hard surface cleaners (CCD-146) (see B below). Given that several of these health effects occur even at low-level exposures over time, we believe that they should be eliminated from GS-37 certified products altogether. Prohibiting these chemicals would only affect a small number of currently certified products, but would go a long way toward protecting custodial and manufacturing workers.

Comment:
We also urge Green Seal to add to the prohibited ingredients list any chemical that is currently prohibited in similar products under Canada's EcoLogo for "green" hard surface cleaners (CCD-146) (see B below). Given that several of these health effects occur even at low-level exposures over time, we believe that they should be eliminated from GS-37 certified products altogether. Adding these chemicals would only affect a small number of currently certified products, but will go a long way toward protecting custodial and manufacturing workers.

Response:

Green Seal aims to list specific chemicals that have evidence of concerning effects, but may not have otherwise been prohibited by the other criteria in the standard. Further, Green Seal aims to provide guidance with any listed chemicals by only citing those that would potentially be used in the products covered in the scope of the standard. As a result, many of the chemical suggested are not listed – NTA is a carcinogen, EDTA is not biodegradable, aromatic and halogentated solvents are not used in products covered in the scope of GS-37, ammonia and ammonium compounds are limited with aquatic criteria. Asthma causing chemicals (prohibiting DEA, TEA) and chronic inhalation toxins (ex MEA) were addressed in a separate criterion. Bioaccumulating chemicals were addressed in a separate criterion (prohibiting musks). Formaldehyde donors, and other ingredients that release or produce carcinogens (ex. DEA) are prohibited in the carcinogen criterion. CAS numbers are available for reviewing products.

Colors are used in some Green Seal certified products to help with the identification of product use (ex. so it isn't confused with water). However, dyes may contain hazardous components. Green Seal already prohibits heavy metals, which are a significant concern for dyes. However, an additional level of evaluation to these product components is possible by requiring the use of only FDA certified colors or natural ingredients. The FDA certified colors shall be FD&C approved – for food, drug and cosmetic use, so if a dye is used less than 0.01% then it would have been evaluated for acute oral toxicity, dermal toxicity, irritation, sensitization, and carcinogenicity. The new definition and criterion will be as follows:

Color Component. A deliberately added product component, where it is added for its ability to change the product's color, typically dyes or pigments.

Color Components. Any color component must meet all relevant criteria of this standard and shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use or be a natural ingredient.

While the criteria have restricted the use of PVC packaging (not being recyclable according to the standard and contain phthalates), with developments there may be a means for PVC packaging to be allowed. Given the hazards associated with PVC from production to disposal, it will be specifically prohibited in packaging.

Other Restrictions. Phthalates and chlorinated packaging material are prohibited from being intentionally introduced; an exception is allowed for packages that would not have added phthalates or chlorinated packaging material but for the addition of recovered material.

Comment:
The Discussion Document states that it is the "intention of the SDT to, where possible, develop criteria that prohibit undesirable chemicals due to their particular attributes, rather than to simply list them on a prohibited materials list. As such, this list will be used

as a last resort to prohibit chemicals known to be undesirable, but for some reason are difficult to draft criteria to affect them (e.g. a highly absorptive chemical known to be toxic to humans that is too costly to test for)."

There does not appear to be any scientific basis to put a chemical on a restricted list unless clearly defined criteria can be developed that explains the basis for the restriction. The cost of testing should not be an impediment.

Comment:
Restrictions on Product Ingredients Must Be Based on Clear Criteria

We strongly object to the list of prohibited and restricted ingredients included in the proposed standard. As stated in our previous comments, we believe that Green Seal should adopt science-based criteria in all cases. Criteria should define a required level of performance on a relevant health or environmental indicator. The performance criteria should apply to all products.

The Background Document states that the list of prohibited ingredients is used because "not all the criteria in the standard can include all the chemicals of concern." This indicates that some proposed restrictions are not based on sound scientific principles and some ingredients are selectively restricted, even when products using them can meet all relevant performance criteria. This approach is blatantly incompatible with a credible, transparent and science-based environmental certification standard that includes consideration of exposure and risk.

Comment:
Our primary concern with the Draft GS-37 Standard is the inclusion of a section on "prohibited ingredients." We believe that there should be a sound scientific basis to prohibit a particular ingredient or class of ingredients from the standard and believe that this can best be addressed by defining risk based, objective criteria.

The standard contains several criteria addressing toxicology, ecotoxicology and biodegradation properties. The standard allows for the cleaning product as a whole or its individual ingredients to be evaluated and assessed relative to these defined criteria. There does not appear to be any technically sound reason to include in the Standard a list of prohibited ingredients and as such recommend that this section be removed. To the extent that there are perceived needs to restrict certain ingredients that would not be covered by the existing criteria, it would be more appropriate to define new criteria, rather than to adopt a potentially biased list of prohibited ingredients.

> **Response**:
> One of the purposes of revising GS-37 was to address the health concerns of vulnerable populations, such as children, since these products are being used increasingly in settings such as schools. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response

relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development were considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products.

One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels.

To be more transparent about the rationale for listing a chemical on a prohibited ingredient list, the list has been separated according to the primary reasons for prohibiting the chemical (though in many cases there is more than one reason for prohibiting a chemical). The result is new criteria for endocrine disruptors, respiratory irritants, neurotoxins, and systemic toxins. These criteria have definitions for each end point, to help illustrate the rationale, though some of the challenge with developing a criterion lies in finding an accepted definition (there may not an accepted definition). However, listing of chemicals within each criterion is still dependent on its weight of evidence; along with the evaluation of the best way to protect vulnerable populations since there is are not accepted methods and widespread data available.

Endocrine Disruptors. A chemical that is suspected to or determined to adversely affect the endocrine system of humans or animals by disrupting or mimicking the physiologic function of endogenous hormones. Consideration will also be given to the metabolites of the parent compound. This may be determined through one or more internationally validated endocrine activity screens, such as the uterotrophic assay, Hershberger assay, or OECD fish screening assay, or other screening assays as they become validated.

Neurotoxin. A chemical that is suspected to or determined to adversely affect the nerve cells and nervous system humans or animals.

Respiratory Irritant. A chemical that may cause serious irritation the nose, throat, airways and lungs of humans or result in positive results from appropriate animal tests.

Systemic Toxin. A chemical that when it enters the body, through any route of exposure, causes organ or tissue damage, such as to the red blood cells or the liver.

Comment:
APES – No scientific rational or data are presented to support restrictions on the use of APEs; they are simply asserted as being a concern.

Comment:
Data show that APEs biodegrade under anaerobic conditions and that removal is greater than 99% in sewage treatment plants (Nimrod and Benson 1996; Keith 1997). Therefore, APEs are in the environment at concentrations well below effects concentrations. Because there is low likelihood of injury to the environment, this ingredient should be deleted from the criterion.

Response:
Due to considerable evidence that APEs and their breakdown products (ex. nonylphenol) act as endocrine disrupters and given the availability of alternatives to APEs, Green Seal believes that there is sufficient evidence to exclude the use of APEs in an environmentally preferable cleaner. They will be listed under the new endocrine disruptor criterion.

Endocrine Disruptors. The undiluted product shall not contain ingredients that are endocrine disruptors, including:

- *Alkylphenol ethoxylates*
- *Phthalates*

Comment:
Ingredients that have a known, significant potential for these hazards should be listed in this section of GS-37 as soon as that potential is adequately defined (rather than waiting for the State of California to update it Prop. 65 list, etc.).

Response:
Green Seal uses the prohibited ingredient list for such a purpose, specifying chemicals with concerning effects that are not otherwise prohibited by other criteria.

Comment:
The Proposed Prohibition 2-butoxyethanol (BE) Does Not Reflect the Best Available Science

The inclusion of 2-butoxyethanol (BE) on the list of prohibited substances lacks adequate scientific support and is at odds with an impressive series of findings by regulatory and widely respected scientific bodies. Specifically:

- As confirmed by the recent findings of EPA, Health Canada, IARC, ACGIH, the World Health Organization and others, the potential health and environmental effects of exposure to BE have been thoroughly evaluated in appropriate human and toxicological studies, and the resulting scientific data indicates that BE-containing cleaning products are not expected to cause adverse effects under conditions of normal use

- The justifications offered in the Background Document for the proposed prohibition of BE do not withstand scientific scrutiny and reflect an unsound basis for achieving Green Seal's objective to identify "leadership products" that are "protective of human health and the environment" [Green Seal 2007]. The designation of BE as a carcinogen is based on an EPA classification that has been superseded by a more recent EPA carcinogenicity assessment concluding, based on new scientific data, that BE is not expected to be carcinogenic at or below environmental, consumer or occupational exposure levels. In addition, to prohibit BE on the basis of dermal absorption inappropriately confuses exposure with hazard and, in the specific case of BE, disregards persuasive scientific evidence that even worst-case dermal exposure scenarios are not expected to cause adverse health effects in humans including potentially susceptible populations such as children.

We urge Green Seal to remove the proposed prohibition on BE. These issues are discussed more thoroughly in separate comments.

Comment:
Adding 2-butoxethyanol to the list of prohibited ingredients is unwarranted. The mechanism of potential animal tumor formation is not considered relevant to humans, which is exactly why the EPA is considering a reclassification.

Comment:
Butoxyethanol should be listed here as a prohibited ingredient, primarily because of its potential for absorbing through skin and then affecting the blood, liver, and kidneys.

Comment:
No credible data have been presented to maintain 2-butoxyethanol (2-BE, CASRN 111-76-2) as a prohibited ingredient. The prohibition of 2-BE is apparently based on its listing in 1999 as a Group C carcinogen in the US EPA IRIS database. However, the EPA subsequently determined in 2003 that 2-BE is not reasonably anticipated to cause tumors in humans, and de-listed 2-BE as a Clean Air Act hazardous air pollutant (Fed Reg 68:65648-65663). In addition, IARC evaluated 2-BE in 2004 (IARC Volume 88) and classified 2-BE as Group 3 (not classifiable as to carcinogenicity to humans). Therefore, there is no credible information that supports listing 2-BE as a possible human carcingoen, as two authorative bodies (the EPA and IARC) have concluded that 2-BE is not carcinogenic.

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- As confirmed by the recent findings of EPA, Health Canada, IARC, ACGIH, the World Health Organization and others, the potential health and environmental effects of exposure to BE have been thoroughly evaluated in appropriate human and toxicological studies, and the resulting scientific data indicates that BE-containing cleaning products are not expected to cause adverse effects under conditions of normal use.

- The justifications offered in the Background Document for the proposed prohibition of BE do not withstand scientific scrutiny and reflect an unsound basis for achieving Green Seal's objective to identify "leadership products" that are "protective of human health and the environment" [Green Seal 2007]. The designation of BE as a carcinogen is based on an EPA classification that has been superseded by a more recent EPA carcinogenicity assessment concluding, based on new scientific data, that BE is not expected to be carcinogenic at or below environmental, consumer or occupational exposure levels. In addition, to prohibit BE on the basis of dermal absorption inappropriately confuses exposure with hazard and, in the specific case of BE, disregards persuasive scientific evidence that even worst-case dermal exposure scenarios are not expected to cause adverse health effects in humans including potentially susceptible populations such as children.

We urge Green Seal to remove the proposed prohibition on BE. These issues are discussed more thoroughly in separate comments submitted by our Glycol Ethers Panel.

Comment:
2-butoxethyanol : Adding 2-butoxethyanol to the list of prohibited ingredients is unwarranted. The mechanism of potential animal tumor formation is not considered relevant to humans, which is exactly why the EPA is considering reclassification.

Comment:
IARC recently reviewed an extensive data set for 2-butoxyethanol and classified it in Group 3 based upon findings of inadequate evidence of carcinogenicity in humans and limited evidence of carcinogenicity in experimental animals (IARC Monographs Volume 88, 2006). Carcinogens and reproductive toxins should be further designated as known and listed by a validated source such as NTP, IARC, or similar sources. The Green Seal proposal to prohibit 2-butoxyethanol in spite of its recent designation as an IARC Group 3 and in-progress reevaluation by EPA is extremely conservative.

Comment:
This submission addresses one provision of the proposal – the inclusion of 2-butoxyethanol (BE) on the list of prohibited substances in Section 4.13 of the proposed standard. As explained below, this prohibition lacks adequate scientific support and is at odds with an impressive series of findings by regulatory and widely respected scientific bodies. Specifically:

- As confirmed by the recent findings of EPA, Health Canada, IARC, ACGIH, the World Health Organization and others, the potential health and environmental effects of exposure to BE have been thoroughly evaluated in appropriate human and toxicological studies, and the resulting scientific data indicates that BE-containing cleaning products are not expected to cause adverse effects under conditions of normal use.
- The justifications offered in the Background Document for the proposed prohibition of BE do not withstand scientific scrutiny and reflect an unsound basis for achieving Green Seal's objective to identify "leadership products" that are "protective of human health and the environment" [Green Seal 2007]. The designation of BE as a carcinogen is based on an EPA classification that has been superseded by a more recent EPA carcinogenicity assessment concluding, based on new scientific data, that BE is not expected to be carcinogenic at or below anticipated environmental, consumer or occupational exposure levels. In addition, to prohibit BE on the basis of dermal absorption inappropriately confuses exposure with hazard and, in the specific case of BE, disregards persuasive scientific evidence that even "worst-case" dermal exposure scenarios are not expected to cause adverse health effects in humans including potentially susceptible populations such as children.

Scientific Data and Evaluations Relating to the Safety of BE in Cleaning Products
2-Butoxyethanol, CAS 111-76-2, has an over-50-year history of beneficial and effective use in cleaners. It is effective at relatively low concentrations (generally 6% or less). Extensive testing in both animals and humans indicates that BE is not immunotoxic, genotoxic, or teratogenic, and does not cause adverse reproductive effects [EPA 1999]. The evidence shows that the most sensitive adverse effect high doses in animals is the rupture of red blood cells (hemolysis), an effect to which humans are resistant. Recent reviews by EPA [1999, 2004], Health Canada [2002], WHO [2005] and others have concluded that the toxic effects of BE are secondary to its irritant and hemolytic effects, and that prevention of hemolytic effects in humans will also protect against other toxic effects.
The rich database for BE reveals, moreover, that even minor prehemolytic effects are not expected at concentrations well above anticipated environmental, consumer or occupational exposure levels. As summarized by ACGIH [2001], physiologically based pharmacokinetic (PBPK) modeling validated against data from human volunteer and rodent pharmacokinetic studies [Corley 1994] has provided "strong evidence" that exposure to a saturated atmospheric concentration (~1,160 ppm), or to a "worst case dermal contact scenario," would likely generate human blood concentrations of BE's toxic metabolite "well below those capable of causing human red blood cell hemolysis." Accordingly, even highly conservative public health protection criteria explicitly or implicitly permit the use of BE in cleaning products. For example, based on stringent health criteria developed by Health Canada, recently adopted regulations under the Canadian Environmental Protection Act permit the use of BE at concentrations of up to

6% in non-aerosol cleaners, 5% in aerosol cleaners, and 10% in carpet and rug cleaners [Canada Gazette 2006]. Similarly, the Cosmetic Ingredient Review Expert Panel [Anderson 1996] has concluded that BE may be used safely in hair and nail cosmetic products at concentrations up to 10%.

Health benchmarks set on the basis of exposure also indicate that BE-containing cleaning products can be used without appreciable risk of adverse toxic effects. These include the IRIS Reference Concentration (RfC) value for continuous lifetime exposure to BE of 13 mg/m3 (~2.7 ppm) [EPA 1999]; the ACGIH TLV for occupational exposures of 20 ppm (~97 mg/m3) [ACGIH 2001]; and the California acute REL for 1-hour exposures of 14 mg/m3 (~2.9 ppm) [Cal EPA 1999]. Like the Health Canada health benchmarks, these criteria include wide margins of safety intended to provide additional protection for children and other potentially sensitive populations, even though BE's extensive database does not reveal increased susceptibility among such groups [EPA 1999, Udden 1994b, Udden 2002].

Measured against these highly conservative health protection criteria, BE exposure data indicate that adverse health effects are extremely unlikely. Singer, et al. [2006] found maximum 1-hour air concentrations of only 2.3 mg/m3 (~ 0.5 ppm) when conducting a counter cleaning task in a room sized chamber using an undiluted cleaner containing 6.2 % BE at high product use rates. In doing similar counter cleaning and floor mopping tasks in the chamber with other cleaners containing BE in concentrations from 0.6 to 3.1 percent, 1-hour air concentration ranged from 0.2 to 1.6 mg/m3 (~0.04-0.1 ppm). Likewise, Koontz, et al. [2006] modeled an occupational institutional floor stripping/mopping scenario and found 8-hour TWA air concentrations of EGBE of 1.2 mg/m3 (~0.2 ppm), and reported independent personal air sampling on a similar cleaning operation yielded 8-hour TWAs of 4.5 mg/m3 (~0.95 ppm).

The Flawed Rationale for the Proposal to List BE as a Prohibited Substance

The Background Document for Proposed Standard GS-37 [Green Seal 2007] offers two reasons for the proposal to include BE on the list of prohibited substances. First, it references the classification of BE as a Group C "possible human carcinogen" in the existing IRIS assessment [EPA 1999]. Second, it relies on findings that BE can be absorbed through the skin. As explained below, neither of these rationales can survive scientific scrutiny, and both of them rest on flawed public health policies that do not advance – and could well undermine – the fundamental objectives of the Green Seal program.

a. Potential Carcinogenicity

There are two critical problems with the carcinogenicity rationale for listing BE as a prohibited substance.

First, the 1986 EPA Carcinogen Risk Assessment Guidelines [EPA 1986] on which the Group C classification is based have been replaced by a new set of guidelines that reflect the most recent scientific tools available for the evaluation of potential cancer risks. Of particular importance to the Green Seal GS-37 proposal, the new EPA guidelines [EPA 2005a, b] now formally recognize the widely accepted scientific posistion [e.g., IARC 1999, 2006a] that well conducted mechanistic studies can provide persuasive data on a substance's mode of action in the development of cancer, and permit the determination, if detailed scientific criteria are satisfied, that species differences may exist, or that mechanisms of carcinogenicity do not operate below threshold levels of exposure.

Certainly, if Green Seal's program is to provide "credible" "science-based environmental certification standards," its carcinogenicity evaluation criteria should reflect the latest available guidance for characterizing hazards and risks.

Second, and much more important, the EPA Group C classification in the existing IRIS assessment has been superseded by subsequent scientific data and evaluations by the Agency. The IRIS carcinogenicity assessment [EPA 1999] was based on a draft National Toxicology Program study in rodents [NTP 1998] that EPA judged to support a finding that BE was a "possible human carcinogen" (Group C) under its former cancer risk assessment guidelines. Immediately after the release of the NTP results, the Panel, working with EPA and independent scientists, designed and sponsored a series of mechanistic studies to explore the implications of the NTP rodent findings for humans exposed to BE in real world settings. After several rounds of peer review by government and independent scientists, EPA determined that that nonlinear, nongenotoxic modes of action are likely responsible for the increased incidence of tumors observed in the NTP and other rodent studies of BE. Consequently, even if the limited rodent tumor findings are relevant to humans, the relatively low sensitivity of humans (including subpopulations such as children) to the hemolytic effects of BE means that, as EPA has put it, "we would not expect to find these tumors in humans" exposed below the IRIS reference values [EPA 2004].

These findings have been formally incorporated into an EPA carcinogenicity evaluation for BE [EPA 2005c], and EPA's assessment is now consistent with that of IARC [2006], which classifies BE in Group 3, "not classifiable" as to carcinogenicity in humans. The current IRIS assessment for BE [EPA 1999] is currently being reevaluated to incorporate the current EPA findings on potential carcinogenicity [EPA 2008]. According to the current IRIS tracking report , the updated assessment is expected to be posted in September 2008.

b. Skin Absorption

The second basis for the proposed listing of BE as a prohibited substance relates to skin absorption. Expressing concern about "exposure to sensitive populations such as pre-school and primary school children as well as residents of nursing homes," the Background Document for the GS-37 proposal [Green Seal 2007] concludes that BE is "rapidly absorbed through skin," and that its "absorption is enhanced in the presence of water making the diluted product more hazardous" (p. 14). These assertions are not scientifically accurate and, more importantly, inappropriately equate exposure with hazard.

The claim that dilution increases skin absorption of BE is not supportable at concentrations found in hard surface cleaning formulations and under realistic conditions of use. Consider, for example, an extreme scenario in which a hand is submerged for 10 minutes in a 5% aqueous solution (a concentration that is comparable with many cleaning formulations), compared to a hand submerged for 10 minutes in undiluted BE. In the cleaning formulation, approximately 14 mg would be absorbed compared to 25 mg for the undiluted BE.

Of greater concern is the proposal's failure to recognize a fundamental principal of toxicology. Hazard, an intrinsic property of a substance, is entirely distinct from exposure in the assessment of risk. For example, the Background Document for the proposal [Green Seal 2007] identifies ACGIH as a "credible scientific source" that lists

"substances with a high potential for skin absorption (skin notation) and systemic health effects." However, ACGIH assigns the skin notation when data demonstrate "the potential for a significant contribution to the overall exposure by the cutaneous route" [ACGIH 2000]. The ACGIH definition makes no reference to hazard or "systemic health effects." The reason is obvious – the skin notation is just one part of the assessment of the potential of a substance to cause adverse affects in humans, the other part being, of course, the intrinsic hazard of the material.

The scientific data on dermal exposures to BE provide an apt illustration of the principle. As noted above, although BE is readily absorbed through the skin, PBPK modeling accepted as valid by EPA for the purpose of risk assessment [EPA 1999] show that even a worst case dermal exposure scenario would likely generate human blood concentrations of BE's toxic metabolite "well below those capable of causing human red blood cell hemolysis" [Corley 1994]. In addition, while it is certainly appropriate to address potential risks to sensitive or susceptible exposed populations, investigations of population groups that might be expected to show increased sensitivity to hemolytic effects of BE, (e.g., the young, the elderly, and individuals with blood disorders), have repeatedly failed to reveal increased susceptibility [Udden 1994b, 2002, EPA 1999]. The IRIS RfD for BE nevertheless incorporates a 10-fold safety factor to address such potential effects. The upshot can be appreciated by returning to the extreme scenario posited above: For a 50 kg female using an undiluted cleaning formulation containing 5% BE, the percutaneous dose under these conditions would be 0.3 mg/kg/day, below the IRIS reference dose (RfD) of 0.5 mg/kg/day, despite the application of a safety factor for susceptible groups which, according to the scientific data for BE, is not necessary to provide health protection.

Conclusion

The Green Seal program seeks to recognize and reward innovative products that improve public health and the environment "based on state-of-the-art science and information." To achieve its objectives, however, the program should recognize existing products that have been extensively investigated for adverse health effects and stood the tests of time and rigorous scientific scrutiny. To exclude such products does a disservice to the consumers the program seeks to serve by excluding crediable alternatives; penalizes manufacturers for thoroughly testing existing products; and undermines the integrity of the program and its long-term prospects for success by turning a blind eye to state-of-the-art scientific methods and data.

In the current setting, once safety questions were raised about BE by the 1999 NTP rodent study, manufacturers responded immediately, working with EPA to thoroughly assess the implications of the findings for workers, users of BE-containing products, and neighbors of BE-using facilities. This product stewardship program has now led EPA to revise its 1999 evaluation of BE. The Panel submits that it would be scientifically unsound and contrary to the objectives of the Green Seal program, for BE to be included on the prohibited substances list on the basis of a now-superseded EPA carcinogenicity classification, or because BE can be percutaneously absorbed when the available data show that dermal exposure even under worst-case conditions – much less under conditions of expected use – is not likely to pose health risks, including children and other potentially susceptible populations.

For these reasons, the Panel respectfully requests that 2-butoxyethanol be removed from

the list of prohibited substances in the GS-37 standard. We would also ask that, in announcing this decision, Green Seal make clear that the inclusion of BE on the prohibited substances list in Section 4.9 of the GS-8 standard (General-Purpose, Bathroom, Glass, and Carpet Cleaners Used for Household Purposes) will be reevaluated at the next opportunity and that, in the interim, applications for certification under that standard will be processed accordingly.

References

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Response:
Both the ACGIH and DFG lists of chemicals with skin notations are currently defined as being able to be absorbed through the skin and be able to elicit a systemic effect apart from skin irritation (a hazard). 2-butoxyethanol has systemic effects and is absorbed through the skin, thus it has a skin notation through the German Deutche Forschungsgemeinschaft (DFG). Further, the ACGIH Biological Exposure Indices (BEI) have documented that contact of liquid 2-butoxyethanol as well as vapor in contact with wet skin, can be absorbed through the skin, urinary metabolites of 2-butoxyethaonl found, and can elicit systemic effects. Animal studies show hematotoxicity from inhalation, dermal exposure and dermal exposure in water mixtures sufficient to cause systemic toxicity . The BEI committee, based on more recent data showing much more absorption of 2-butoxyethanol through the skin than previously reported developed a BEI for the active hematotoxin, the urinary metabolite, 2-butoxyacetic acid. Given this heightened concern, especially in dilute mixtures, 2-butoxyethanol will remain listed as a prohibited ingredient. It's worth noting that since 2-butoxyethanol had been listed on EPA IRIS, it has not been used in GS-37 products (no certified products contain it), thus there are alternatives with less concern. Other glycol ethers are prohibited due to their reproductive/development toxicity.

As stated already, one of the purposes of revising GS-37 was to address the health concerns of vulnerable populations, such as children, since these products are being used increasingly in settings such as schools. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to

health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products.

One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels. Thus, 2-butoxyethanol will remain a prohibited ingredient.

Systemic Toxins. The undiluted product shall not contain ingredients that are systemic toxins, including:

- *2-butoxyethanol*

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Comment:
There is No Justification for Prohibiting "Phthalates" as a Class of Chemicals

The Proposed GS-37 standard would prohibit "phthalates" (as a broad class of chemicals versus only dibutyl phthalate) because of alleged "endocrine disruption" properties. There is no justification, from either a product application or a toxicological perspective, for an indiscriminate prohibition against the use of all "phthalates" in industrial and institutional cleaning products.

"Phthalates," or phthalate esters, comprise a diverse group of chemicals that have different physical and chemical properties, which leads to their having different product applications and toxicological profiles. Because of these differences, it is not appropriate to simply group all phthalates together for regulatory or product decisions. Rather, phthalates should be addressed individually, based on their actual product use – which determines their exposure potential – and their particular toxicological profiles. When taking product application and individual toxicology into account, it becomes clear that the presence of phthalates in cleaning products poses very little risk to the users and that prohibiting their use in such products is not justified.

As recognized in the Discussion Document, a phthalate added to a cleaning product covered by GS-37 would be present as a component of a fragrance added to the product and not as an active cleaning ingredient. Because phthalates have different physical properties and as a result differ in their suitability for various technical applications, only one phthalate – diethyl phthalate ("DEP") – would be expected to be used in conjunction with a fragrance in such a cleaning product. Thus, from a product application standpoint, prohibiting the use of all phthalates from such cleaning products is unnecessarily broad and would have little practical effect – just as the current prohibition against dibutyl phthalate has no practical effect on the use of phthalates in such products. Furthermore, because DEP would be present only as a fragrance component, its concentration in any cleaning product as used would be very low – likely well below 1%. Accordingly, potential exposures to DEP from the appropriate use of cleaning products are exceedingly low.

The prohibition of all phthalates also is not justified from a toxicological prospective. As stated in the Discussion Document, the recommendation to prohibit phthalates is based on their supposed "endocrine disruption." While a comprehensive treatment of phthalate toxicity is beyond the scope of these comments, two points are emphasized here: 1) phthalates, and in particular DEP, have not been shown to exhibit endocrine disruption properties in humans or in rodents at doses humans would likely be exposed to from the use of consumer products containing phthalates; and 2) as discussed below, numerous independent risk assessments have concluded that exposures to phthalates as used in commercial products generally pose little or no risk to consumers.

Although phthalates are frequently referred to as endocrine disruptors, science does not bear this out. The major phthalates in commerce today do not interfere with or mimic either the estrogen or androgen receptors when tested in laboratory animals; that is, they neither activate the male or female hormone receptors nor prevent activation by natural hormones. This has been demonstrated for DEP in particular. As reported in the National Toxicology Program's recent Chemical Information Profile for DEP, DEP was not estrogenic in in vitro ecombinant/receptor gene bioassay with HeLa cells and human breast cancer cell line ZR-75 and exhibited only weak activity in human breast cancer cell line MCF-7 and in yeast cells with human estrogen receptor (hER) (Api, 2001) and DEP did not induce cell proliferation in human MCF-7 cells (Hong et al., 2005). In addition, DEP was not estrogenic in immature female Wistar rats, recombinant yeast strain (Saccharomyces cerevisiae) containing hER and lac-Z, or in in vitro estrogen receptor-binding assay using rat uterine cytosol (Api, 2001). Moreover, DEP is not included on the European Union's list of substances of concern for evaluation of their role in endocrine disruption. Thus, the scientific evidence shows that the phthalate most likely to an ingredient in products subject to GS-37 is of particularly low concern based on potential for endocrine disruption.

In addition to specific toxicity information for DEP, numerous comprehensive risk assessments performed by independent government agencies have demonstrated that

phthalates pose very little risk to humans from their use in consumer products . These include:

- the U.S. Consumer Product Safety Commission, which found that phthalates (in particular diisononyl phthalate) in toys pose "no demonstrated health risk" to children;

- the National Toxicology Program Center For Evaluation of Risks to Human Reproduction (NTP-CERHR), which generally found "minimal" or "negligible" concern for developmental effects in humans from typical consumer exposures to phthalates; and

- the European Union, which has generally found no likely risks to consumers from exposure to phthalates in consumer products.

Notably, none of these risk assessments are of DEP, as the various agencies have recognized that DEP's toxicity profile does not warrant an assessment. This is supported by EPA's decision in 1996 to remove DEP from the Toxics Release Inventory list based on its finding that due to its low acute and chronic toxicity "DEP cannot reasonably be anticipated to cause a significant adverse effect on human health or the environment." [61 Fed. Reg. 39356 (July 29, 1996)]. The safety of DEP in cleaning products also is supported by the determination of the Cosmetic Ingredient Review that DEP is "safe as used" in its various cosmetics applications at concentrations up to 2% by volume.

The overwhelming conclusion of the risk assessments and other determinations mentioned above is that exposure to phthalates as used in consumer products poses little or no risk to human health. The same is true of the cleaning products subject to GS-37. As such, these reviews do not support the indiscriminate prohibition of phthalates contemplated by the recommended revisions to GS-37.

For the same reasons, the prohibitions against the use of phthalates in household cleaners (GS-8) and industrial and institutional floor-care products (GS-40) also are not justified and should be removed.

Comment:
4.13.1 Prohibited Ingredients
This section recommends that the undiluted product not contain phthalates and polycyclic musks, among others. Phthalates is a broad term that refers to a wide variety of compounds of differing chemical structure. Not all phthalates are the same; the chemical profiles of phthalates differ significantly.

While some reports continue to raise questions about "phthalates" in general, it is important to define the specific chemicals of concern, as well as the scientific legitimacy of the associated data. The scientific validity of some frequently cited research has been seriously questioned through the process of scientific peer review. For example, recent studies reporting the potential association of "phthalates" with male reproductive

biomarkers are inconsistent and have been rejected by government experts who have reviewed these data and found the conclusions to be based on insufficient evidence. In addition, a recent study found no effects on reproductive or thyroid hormone levels in males who topically applied diethyl phthalate (DEP) repeatedly for 28 days.

Moreover, since DEP has not been demonstrated to have a potential for adverse reproductive effects, it is inaccurate to imply that there are concerns similar to those for other phthalates. DEP presents no safety concern from use in fragrances; it has a very strong safety profile. DEP is commonly used in cosmetics, toothbrushes and food packaging. It is used in fragrances as a solvent to blend fragrance ingredients and as a fixative to make fragrances last longer when applied to the skin. DEP has been extensively tested and subjected to a wide array of technical reviews in both the United States and Europe.

In a recent review completed in March of 2007 by the European Commission's Scientific Committee on Consumer Products (SCCP), the SCCP reconfirmed that DEP is safe for use in cosmetics and represents no quantifiable risk for the consumer. The SCCP also found that none of the latest information on DEP would change its longstanding conclusion. The SCCP is the regulatory arm of the European Union comparable to the U.S. Food and Drug Administration. We would be happy to provide a copy of the SCCP opinion upon request.

For the above reasons, we believe it has been demonstrated that diethyl phthalate is safe for use in fragrances and is among the most thoroughly tested substances in the class of phthalates. Therefore, we strongly object to the Green Seal proposal to ban the use of ALL phthalates, including DEP, in GS-37 products.

Comment:
There is No Justification for Prohibiting "Phthalates" as a Class of Chemicals

The Proposed GS-37 standard would prohibit "phthalates" (as a broad class of chemicals versus only dibutyl phthalate) because of alleged "endocrine disruption" properties. There is no justification, from either a product application or a toxicological perspective, for an indiscriminate prohibition against the use of all "phthalates" in industrial and institutional cleaning products.

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As recognized in the Discussion Document, a phthalate added to a cleaning product covered by GS-37 would be present as a component of a fragrance added to the product and not as an active cleaning ingredient. Because phthalates have different physical properties and as a result differ in their suitability for various technical applications, only one phthalate – diethyl phthalate ("DEP") – would be expected to be used in conjunction with a fragrance in such a cleaning product. Thus, from a product application standpoint, prohibiting the use of all phthalates from such cleaning products is unnecessarily broad and would have little practical effect – just as the current prohibition against dibutyl phthalate has no practical effect on the use of phthalates in such products. Furthermore, because DEP would be present only as a fragrance component, its concentration in any cleaning product as used would be very low – likely well below 1%. Accordingly, potential exposures to DEP from the appropriate use of cleaning products are exceedingly low.

The prohibition of all phthalates also is not justified from a toxicological prospective. As stated in the Discussion Document, the recommendation to prohibit phthalates is based on their supposed "endocrine disruption." While a comprehensive treatment of phthalate toxicity is beyond the scope of these comments, two points are emphasized here: 1) phthalates, and in particular DEP, have not been shown to exhibit endocrine disruption properties in humans or in rodents at doses humans would likely be exposed to from the use of consumer products containing phthalates; and 2) as discussed below, numerous independent risk assessments have concluded that exposures to phthalates as used in commercial products generally pose little or no risk to consumers.

Although phthalates are frequently referred to as endocrine disruptors, science does not bear this out. The major phthalates in commerce today do not interfere with or mimic either the estrogen or androgen receptors when tested in laboratory animals; that is, they neither activate the male or female hormone receptors nor prevent activation by natural hormones. This has been demonstrated for DEP in particular. As reported in the National Toxicology Program's recent Chemical Information Profile for DEP, DEP was not estrogenic in in vitro ecombinant/receptor gene bioassay with HeLa cells and human breast cancer cell line ZR-75 and exhibited only weak activity in human breast cancer cell line MCF-7 and in yeast cells with human estrogen receptor (hER) (Api, 2001) and DEP did not induce cell proliferation in human MCF-7 cells (Hong et al., 2005). In addition, DEP was not estrogenic in immature female Wistar rats, recombinant yeast strain (Saccharomyces cerevisiae) containing hER and lac-Z, or in in vitro estrogen receptor-binding assay using rat uterine cytosol (Api, 2001). Moreover, DEP is not included on the European Union's list of substances of concern for evaluation of their role in endocrine disruption.

Thus, the scientific evidence shows that the phthalate most likely to an ingredient in products subject to GS-37 is of particularly low concern based on potential for endocrine disruption.

In addition to specific toxicity information for DEP, numerous comprehensive risk assessments performed by independent government agencies have demonstrated that

phthalates pose very little risk to humans from their use in consumer products. These include:

- the U.S. Consumer Product Safety Commission, which found that phthalates (in particular diisononyl phthalate) in toys pose "no demonstrated health risk" to children;

- the National Toxicology Program Center For Evaluation of Risks to Human Reproduction (NTP-CERHR), which generally found "minimal" or "negligible" concern for developmental effects in humans from typical consumer exposures to phthalates; and

- the European Union, which has generally found no likely risks to consumers from exposure to phthalates in consumer products.

Notably, none of these risk assessments are of DEP, as the various agencies have recognized that DEP's toxicity profile does not warrant an assessment. This is supported by EPA's decision in 1996 to remove DEP from the Toxics Release Inventory list based on its finding that due to its low acute and chronic toxicity "DEP cannot reasonably be anticipated to cause a significant adverse effect on human health or the environment." [61 Fed. Reg. 39356 (July 29, 1996)]. The safety of DEP in cleaning products also is supported by the determination of the Cosmetic Ingredient Review that DEP is "safe as used" in its various cosmetics applications at concentrations up to 2% by volume.

The overwhelming conclusion of the risk assessments and other determinations mentioned above is that exposure to phthalates as used in consumer products poses little or no risk to human health. The same is true of the cleaning products subject to GS-37. As such, these reviews do not support the indiscriminate prohibition of phthalates contemplated by the recommended revisions to GS-37.

For the same reasons, the prohibitions against the use of phthalates in household cleaners (GS-8) and industrial and institutional floor-care products (GS-40) also are not justified and should be removed.

Comment:
Prohibited Ingredients. This section recommends that the undiluted product not contain phthalates and polycyclic musks, among others. Phthalates is a broad term that refers to a wide variety of compounds of differing chemical structure. Not all phthalates are the same; the chemical profiles of phthalates differ significantly. While some reports continue to raise questions about "phthalates" in general, it is important to define the

specific chemicals of concern, as well as the scientific legitimacy of the associated data. The scientific validity of some frequently cited research has been seriously questioned through the process of scientific peer review. For example, recent studies reporting the potential association of "phthalates" with male reproductive biomarkers are inconsistent and have been rejected by government experts who have reviewed these data and found the conclusions to be based on insufficient evidence. In addition, a recent study found no effects on reproductive or thyroid hormone levels in males who topically applied diethyl phthalate (DEP) repeatedly for 28 days. Moreover, since DEP has not been demonstrated to have a potential for adverse reproductive effects, it is inaccurate to imply that there are concerns similar to those for other phthalates. DEP presents no safety concern from use in fragrances; it has a very strong safety profile. DEP is commonly used in cosmetics, toothbrushes and food packaging. It is used in fragrances as a solvent to blend fragrance ingredients and as a fixative to make fragrances last longer when applied to the skin. DEP has been extensively tested and subjected to a wide array of technical reviews in both the United States and Europe. In a recent review completed in March of 2007 by the European Commission's Scientific Committee on Consumer Products (SCCP), the SCCP reconfirmed that DEP is safe for use in cosmetics and represents no quantifiable risk for the consumer. The SCCP also found that none of the latest information on DEP would change its longstanding conclusion. The SCCP is the regulatory arm of the European Union comparable to the U.S. Food and Drug Administration. For the above reasons, we believe it has been demonstrated that diethyl phthalate is safe for use in fragrances and is among the most thoroughly tested substances in the class of phthalates. Therefore, we strongly object to the Green Seal proposal to ban the use of ALL phthalates, including DEP, in GS-37 products.

Comment:
Phthalates: Adding phthalates to the list of prohibited ingredients is not substantiated by sound science. With 50 years of use, there is no reliable evidence that phthalates have caused harm to humans. Detecting the mere presence of a phthalate in a product is not sufficient justification for prohibiting its use. As is true of other chemicals, while very high doses of phthalates have been linked to certain cancers in animals, scientific research institutions such as the International Agency for Research on Cancer (IARC) have found that the mechanism that causes cancer in rodents is not significant in humans. In addition, animals administered high doses of phthalates over extended periods of time were not observed to have these types of cancers.

Regarding reputed endocrine disruption claims, some studies claim to show phthalates did not block the action of male or female hormones or mimic their behavior in laboratory tests involving rodents. In 2007, an independent government-sponsored panel reviewed the most often cited studies that claimed to show a link between phthalate exposure and reproductive effects in humans. The panel found those studies to be "insufficient" for drawing any conclusions. Other research looked at the mechanism and suggested that, as is the case with cancer, reproductive effects observed in rodents are not relevant in humans. Ongoing research continues to examine these claims. The key point gleaned from reviewing the research that should govern Green Seal's decision is that no human health effect has ever been reliably linked to exposure from any phthalate, or any

combination of phthalates. Phthalates should be removed from the list of prohibited ingredients.

Response:
EPA is currently developing and validating screening and testing assays for the Endocrine Disrupter Screening program. A variety of assays are being validated (www.epa.gov/oscpmont/oscpendo/pubs/assayvalidation/status.htm [accessed une 20, 2007]), but none have achieved regulatory acceptance by EPA. The Organization for Economic and Cooperation and Development (OECD) has also been working for about 10 years to develop new or revise existing Test Guidelines to detect endocrine disrupters (www.oecd.org/document/62/0,2340,en_2649_34377_2348606_1_1_1_1,00.html [accessed June 20, 2007]). Although several test methods are in the final stages of acceptance by the OECD, none have been published as a validated, approved method. In October 2004, the European Commission accepted a staff working document on implementation of the Community Strategy for Endocrine Disrupters (European Commission, 2004). Part of the strategy entailed a literature review of chemicals that identified those chemicals with evidence of endocrine disruption or potential endocrine disruption in humans or wildlife. Annex 3 of the document includes a listing of "substances with evidence (Category 1) or evidence of potential endocrine disruption (Category 2)." Dicyclohexyl phthalate and diethyl phthalate were identified as substances with evidence of endocrine disruption (Category 1). NAS (1999) identified several chemicals that might be used in cleaning products to have the potential endocrine: alkylphenol ethoxylates, butyl benzyl phthalate (BBP), dibutyl phthalate (DBP). In 2000, the Canadian Depository Services Program reviewed literature to summarize information about endocrine disrupters and included a list of eight phthalates as "known and suspected hormone disruptors." In 2004, the Australian CSIRO and Australian Water Association reviewed endocrine disrupting chemicals associated with recycled water, and the report included a list of "suspected/known endocrine disrupting chemicals" that also included the same list of eight phthalates. While it is recognized that the class of phthalates includes a range of physical and chemical characteristics, hormone disruptor potential is evident across the class. A number of phthalates are prohibited due to their reproductive toxicity (dibutyl phthalate, diethylhexyl phthalate, etc). Others have demonstrated hormone disrupting potential, such as with in vitro estrogen receptor binding activity (diethyl phthalate). There are no phthalates that are necessary for cleaning functioning in GS-37 products. As a result, only diethyl phthalate is found in GS-37 products currently and to a very limited extent. Since there are alternatives with less concern over health effect potential, phthalates shall continue to be prohibited.

As stated already, one of the purposes of revising GS-37 was to address the health concerns of vulnerable populations, such as children, since these products are being used increasingly in settings such as schools. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults.

For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products.

One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels. Because a variety of phthalates have evidence of being endocrine disrupters and because phthalates are not important functional ingredients in cleaning, they should be prohibited ingredients. Thus, phthalates will remain prohibited.

Endocrine Disruptors. A chemical that is suspected to or determined to adversely affect the endocrine system of humans or animals by disrupting or mimicking the physiologic function of endogenous hormones. Consideration will also be given to the metabolites of the parent compound. This may be determined through one or more internationally validated endocrine activity screens, such as the uterotrophic assay, Hershberger assay, or OECD fish screening assay, or other screening assays as they become validated.

Endocrine Disruptors. The undiluted product shall not contain ingredients that are endocrine disruptors, including:

- *Alkylphenol ethoxylates*
- *Phthalates*

European Commission. 2004. Commission Staff Working Document on Implementation of the Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife. SEC(2004) 1372. Available http://ec.europa.eu/environment/endocrine/documents/sec_2004_1372_en.pdf [accessed 21 June 2007].

NAS. 1999. Hormonally Active Agents in the Environment. National Academy Press, Washington, DC. Available http://www.nap.edu/books/0309064198/html [accessed 21 June 2007].

Comment:
We appreciate the inclusion of additional chemicals on the prohibited and restricted lists. Specifically the categories of phthalates and 2-butoxyethanol are key ingredients which must be prohibited. The Household Hazards report discusses these chemicals specifically in relation to their potential impacts on reproductive harm. So many cleaning workers are women, and many are women of childbearing age. Little research has been done to assess the reproductive outcomes of this demographic, but we remain concerned given the laboratory research on these chemicals. Prohibiting these chemicals from the Green Seal standard is key to providing reassurance to the consumer interested in green cleaning products.

Response:
Phthalates and 2-butoxyethanol are prohibited.

Comment:
Adding known or suspected endocrine disruptors to your list of prohibited ingredients to further protect human health and the environment. There is a large, growing body of evidence that chemicals that demonstrate hormonal activity can cause hormonal cancers such as breast, ovarian, thyroid, prostate and testicular.

Comment:
Persistent endocrine disruptors are problematic for wastewater treatment, because some (like nonylphenol, Triclosan and phthalates) are not completely removed or degraded in wastewater treatment processes. Their introduction to surface waters can present a "pseudo" persistence in the environment in that wastewater is continuously discharged to the waterbody.

Comment:
I urge you to make strong provisions in the new standard to remove toxic chemicals including asthmagens and hormone mimics.

Comment:
We also objects to the proposed ban on the use of polycyclic musks (PCMs). There are over 40 publications in the scientific literature that demonstrate the environmental safety of the PCMs and they should not be restricted or prohibited. The European Chemicals Bureau has twice assessed these materials and found them not to be persistent, bioaccumulative and toxic materials (PBTs). In addition, the European Scientific Committee for Cosmetics and Non-Food Products has affirmed their continued safe use in consumer products, and a recent summary of the environmental risk assessments of these materials is available at the HERA website (http://www.heraproject.com/RiskAssessment.cfm). In addition to the determination that these materials are not persistent, bioaccumulative and toxic, data are available to indicate that they are also not subject to long range transport.
Therefore, we respectfully requests that Green Seal amend its proposed revisions to GS-37 consistent with the comments above.

Comment:
With respect to the proposed ban on the use of polycyclic musks, again we must object to this as there are over 40 publications in the scientific literature that demonstrate the environmental safety of the PCMs and they should not be restricted or prohibited. The European Chemicals Bureau has twice assessed these materials and found them not to be persistent, bioaccumulative and toxic materials (PBTs). In addition, the European Scientific Committee for Cosmetics and Non-Food Products has affirmed their continued safe use in consumer products (SCCNFP, 2002a and SCCNFP, 2002b), and a recent summary of the environmental risk assessments of these materials is available at the HERA website (http://www.heraproject.com/RiskAssessment.cfm). In addition to the determination that these materials are not persistent, bioaccumulative and toxic, data are available to indicate that they are also not subject to long range transport; a key parameter in identifying a material as a "POP". (Aschmann et al., 2001)

Response:
To be more transparent about the rationale for listing a chemical on a prohibited ingredient list, the list has been separated according to the primary reasons for prohibiting the chemical (though in many cases there is more than one reason). The result is a new criterion for endocrine disruptors. This criterion has a definition to help illustrate the rationale, though some of the challenge with developing a criterion lies in finding an accepted definition (there may not an accepted definition since there is not a common method for determination). However, listing of chemicals within each criterion is still dependent on its weight of evidence; along with the evaluation of the best way to protect vulnerable populations since there is are not accepted methods and widespread data available.

Endocrine Disruptors. A chemical that is suspected to or determined to adversely affect the endocrine system of humans or animals by disrupting or mimicking the physiologic function of endogenous hormones. Consideration will also be given to the metabolites of the parent compound. This may be determined through one or more internationally validated endocrine activity screens, such as the uterotrophic assay, Hershberger assay, or OECD fish screening assay, or other screening assays as they become validated.

Further, bioaccumulation was added to further protect from potential endocrine disruptors. Nitromusks and polycyclic musks would be prohibited with this new requirement, and they are not readily biodegradable (according to the reference provided by the commenter HERA) and some are already prohibited by IFRA.

Bioaccumulating Compounds. The product as used shall not contain any ingredients that bioaccumulate or that form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a bioconcentration factor (BCF) greater than 100 (or log BCF >2) as determined by ASTM E-1022-94(2007) Standard Guide for Conducting Bioconcentration test with Fishes and Saltwater Bivalve Mollusks or OECD 305 Bioconcentration:

Flow-through Fish Test. If the chemical meets the requirement for biodegradability, 4.16, it is considered to not bioaccumulate. Testing is not required for any ingredient for which sufficient information exists.

Comment:
In a 2007 report entitled "Household Hazards: Potential Hazard of Home Cleaning Products" (available at www.womenandenvironment.org), the scientific research on five classes of chemicals linked to either asthma or reproductive harm was outlined. Three of the classes of chemicals which were identified in common household cleaners were linked to asthma: monoethanolamine, quaternary ammonium compounds and phthalates. We hope the revised criteria will limit the inclusions of these and other chemicals in industrial products. In fact, we recommend that these chemicals particularly monoethanolamine and its related chemicals diethanolamine and triethanolamine are added to the "prohibited chemicals list". The report also discussed the ongoing research documenting the high rates of asthma in cleaning workers, including recent research which links the asthma to specific types of cleaners. We are very concerned about these impacts and believe that the Green Seal certification should be one which can be trusted to help consumers avoid asthmagens.

Comment:
Add several chemicals to the list of prohibited ingredients We believe that several additional chemicals should be prohibited to better ensure the safety of the concentrates, including monoethanolamine, diethanolamine, and triethanolamine, since these chemicals have multiple serious health consequences such as causing new cases of asthma, triggering asthma among people who currently have it (by being corrosive to the respiratory system), and absorbing through the skin to cause central nervous system effects. In a review, a relatively small number of products (6%) were found to contain asthmagens; therefore, prohibiting these chemicals would not overly restrict available products.

Response:
A separate criterion addressed asthmagens. Diethanolamine and triethanolamine would be prohibited as they are asthmagens. Monoethanolamine is currently being reviewed by the clinical expert panel of the AOEC and they will have a determination on its ability to cause asthma by September 2008. Monoethanolamine would however, be prohibited based on its chronic inhalation toxicity. Only diethanolamine has a skin notation by the authorative bodies on this issue and a criterion addresses skin absorption hazards. Additional criteria on inhalation toxicity (and VOC content) address hazards from inhalation (acute and repeated exposure/chronic). Phthalates were explicitly prohibited for their endocrine disruptor activity.

Comment:
While the standard prohibits known asthmagens, it does not resist respiratory irritants that can trigger asthma attacks.

Response:
The criteria, and this standard, do not cover chemicals or items that exacerbate asthma, also called asthma triggers. This is because, for at least one reason, once an individual is sensitized it is unclear all the possible triggers beyond the cause of the asthma. Efforts to extend protection against all respiratory irritants are hampered by the absence of a commonly agreed upon definition, or tests that assess the capacity of chemicals to cause respiratory irritation. The absence of a commonly accepted definition of respiratory irritation may be due, in part, to the complex mix of factors that can contribute to respiratory irritation. These include volatility, method of application, concentration in the product, pH, presence of other materials that may bind ingredients so that they are not released, or oxygenate ingredients yielding peroxides and other more irritating compounds. Nor does it consider the wide range of individual sensitivity to irritants. However, it has been acknowledged by experts in the field that the other criteria in the standard address most of the respiratory irritation concerns (ex. chronic inhalation, VOC content, terpenes).

Comment:
Formaldehyde donor compounds: Formaldehyde is a natural component that is found in the body at approximately 3ppm, according to Heck, H. d'A, et al. "Formaldehyde (CH2) Concentrations in the Blood of Humans and Fischer-344 Rats Exposed to CH2O Under Controlled Conditions." American Industrial Hygiene Association Journal 46:1-3 (1985). Chronic inhalation of formaldehyde at high concentrations, not dermal contact or oral ingestion leads to exposures that make it a probable/possible human carcinogen, and people normally would not chronically inhale the GS-37 cleaners at levels that would put them this risk. The addition of formaldehyde donor compounds to the list of prohibited ingredients is unnecessary since any donor compound that releases levels of free formaldehyde in excess of 0.01% cannot meet the requirements specified for ingredients in the proposed revised standard and will already be excluded. In addition, under the Product Specific Health and Environmental Requirements [4.2 of the Proposed Revised GS-37 Standard] any formaldehyde donor that resulted in air concentrations exceeding 0.04 ppm for short-term or 0.013 ppm for long-term exposures would already be ineligible for Green Seal designation. These two provisions of Green Seal will provide sufficient protection and make a ban on formaldehyde donor compounds unnecessary.

Response:
Formaldehyde donors release the known carcinogen formaldehyde. Formaldehyde is prohibited at the ingredient level and if it is knowingly added to the product. Green Seal believes that adding chemicals that are known to release the carcinogen is the same as adding it directly to the product. Formaldehyde donors are prohibited (though no longer explicitly) through the modified carcinogen criterion. This modification would include reaction products or synergistic reactions, for example the formation of nitrosamines from ethanolamines.

Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens or reproductive toxins. The product shall not contain any ingredients known to produce or release carcinogens, mutagens or reproductive toxins.

Comment:
Prohibit mercury concentrations appearing via unintentional ingredients (Sections 2.11 and 4.13.1). Exclude fly ash and other pollution control residues as examples of ingredients with "intentional content" if they have toxic content. Even though Section 4.13.1 prohibits heavy metals such as mercury, they may be allowed in cleaning products through the allowance in Section 2.11, if fly ash or lime based injection sorbents are used as an additive. Fly ash and other injected pollution control sorbents are being added to many commercial, institutional, and residential products including wall boards, toothpaste and flooring and concrete. There is currently no regulatory mercury testing requirements on fly ash because fly ash is exempt from hazardous waste regulations. Scientific evidence has been published showing that this unregulated substance may contain mercury concentrations to varying degrees depending on the coal type and the power plant pollution control devices. GS-37 criteria should be explicitly added to prohibit mercury concentrations via fly ash within the context of the Section 2.11 naturally occurring allowance.

Comment:
The standard prohibits the intentional addition of mercury. It has been found that some cleaning products contain low levels of mercury that has been attributed to the use of feedstocks that were made in chloralkali plants using mercury catalysts. Green Seal should ensure that mercury is not intentionally added to cleaning products by requiring that all chemical ingredients in Green Seal-certified products be made in chloralkali plants that do not use a mercury cell process. These plants, which are mostly operating outside the United States, can contribute significant pollution to the environment and result in mercury contamination of cleaning products that can be detected in facility waste water.

Response:
Green Seal believes that adding chemicals that are known to contain a carcinogen is the same as adding it directly to the product. The carcinogen criterion was modified to clarify the described intent:

Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens or reproductive toxins. The product shall not contain any ingredients known to produce or release carcinogens, mutagens or reproductive toxins.

4.13.2 Restricted Ingredients
The product as used shall not contain the following ingredients above the specified restricted levels:
• D-limonene shall be limited to a concentration of 20 millimoles (mmol) or less per liter.
• Terpene hydrocarbons, other than d-limonene, (e.g. pinene, myrcene) shall be limited to 10 mmol or less per liter.

Comment:
A late addition to the standard, this section on restricted ingredients did not appear in the August 23, 2007 Discussion Document. Perhaps there has not been enough time to evaluate the merits of choosing certain ingredients and placing limits on their use. What are the guidelines for evaluating candidates for a "Restricted Ingredient" list?

One may start with a premise that all ingredients can be used freely and then take away ingredients that should be prohibited such as known carcinogens. But, what are the criteria for restricted ingredients? How do we go about reviewing all ingredients and determining which ones should be restricted? And then what parameters do we use to set the maximum use levels? What good does it do to restrict the level of an ingredient in a product when you cannot control the amount of the product that is used in a confined area, and you cannot control the way in may become concentrated after use?

I am more than a little troubled by this precedent that Green Seal is setting. I am certainly not aware of all the standards used worldwide that are considered acceptable. Do other standards have restricted lists?

We should review these other standards and adopt their selection and limit criteria into the GS-37 Standard or we should abandon the restricted list.

Comment:
While we support the continued use of terpene compounds as they provide a preferable alternative to other cleaning ingredients, we support a limit on Terpene Hydrocarbons of 10 mm per liter based on potential for allergic response at higher levels.

Comment:
Be more specific in defining acceptable levels for D-limonene and Terpenes. As I understand it, it is the peroxide value that is measured, not the chemical itself. I believe it should read as follows:

4.13.2 Restricted Ingredients. The product as used shall not contain the following ingredients above the specified restricted levels:
• D-limonene shall be limited to a PEROXIDE VALUE OF 20 millimoles (mmol) or less per liter.
• Terpene hydrocarbons, other than d-limonene, (e.g. pinene, myrcene) shall be limited to a PEROXIDE VALUE OF 10 mmol or less per liter.

Also, I believe these levels match those of the European Union (although this should be confirmed). What I do not know is how/why these levels were set. Flammability? Chemical and allergy sensitization? Manufacture convenience? This is important to determine. The levels set in this section MUST take health effects into account. And, if the levels, as set above, DO take health effects into account, on what basis were the levels set?

Comment:
In 4.13.2, you restrict D-limonene and terpene hydrocarbons which makes sense given their propensity to oxidize to sensitizers. Would it make sense to consider whether or not an anti-oxidant is used to inhibit oxidation? Perhaps limiting the level in combination with an anti-oxidant would be more ideal.

Comment:
We also support the proposed restrictions on d-Limonene and other terpene hydrocarbons because they are skin and potential respiratory sensitizers that can contribute to the formation of formaldehyde (a human carcinogen) with they mix with ground-level ozone. An analysis shows that a few Green Seal-certified products contain d'limonene and other terpenes; so screening them out would not significantly reduce the number of products available on the market.

Comment:
D-Limonene should be considered a safe and acceptable ingredient in Green Seal Certified GS-37 Cleaners and Degreasers.

Numerous regulatory agencies consider D-Limonene to be safe and acceptable for use. For example, D-Limonene is on FDA lists as GRAS ("generally regarded as safe'). D-Limonene is not on the California Proposition 65 List, The NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), nor does OSHA list it as a carcinogen to humans. D-Limonene does not contain any known reproductive or developmental toxins. This product, is a citrus derived essential oil, which is produced by steam distillation and does not contain any heavy metals. Additionally, d-Limonene is non-toxic as defined by TSCA (Toxic Substance Control Act). It is not a material that would be subject to reporting under the requirements of SARA Title III (Section 313).

Another positive aspect in using D-Limonene is that it is a natural product. It is extracted from naturally resources (citrus fruit peels) it's use in a cleaning product would not result in the release into the environment any more materials that would occur naturally. It is also a renewable resource which is positive for the environment.
The banning of the use of D-Limonene in GS-37 approved products would severely impact many industries, including the household and industrial cleaning industry as well as the fragrance industry.

Not too long ago companies were advised to replace petroleum based solvents with citrus solvents due to their affinity for grease and oil combined with low or no toxicity. This made D-limonene an effective alternative.

D-Limonene is extremely versatile. In many instances it allows simplification in formulation development due to it's effectiveness. There is no suitable replacement available that performs as effectively and provides the natural fragrance that D-limonene can produce.

Replacement of d-Limonene in already approved products by Green Seal creates an unfair burden on manufacturing companies who have spent significant amount of money to test the products for performance and literature development. End user customers have a significant investment in personnel training with these previously approved products and have installation costs for proportioning devices to dispense these previously approved items.

Comment:
A late addition to the standard, this section on restricted ingredients did not appear in the August 23, 2007 Discussion Document. Perhaps there has not been enough time to evaluate the merits of choosing certain ingredients and placing limits on their use.

It is faulty logic to restrict the amount of a specific ingredient in an indoor cleaning product for health reasons, because the total amount of that ingredient admitted to the cleaning space is determined by how much product is used. Limiting the amount of an ingredient in a product does not control the concentration of that ingredient in an indoor work environment.

Green Seal should not begin a precedent of restricting specific chemicals, such as terpenes, to specific levels unless scientific criteria have been established and the threshold limits have a scientific basis. There is no sound scientific basis for limiting terpenes in a cleaning formulation. Green Seal should not seek to restrict specific chemicals. Expanding a list such as this in the future could become very cumbersome.

Terpenes, including d-limonene, are already being limited in this standard to a level of 1.0% or less due to their combustibility and their volatile organic compound (VOC) content without being singled out by chemical name.

The Background Document released on the same date as the Proposed Revisions to the GS-37 Standard tries to justify the restricting of terpenes, but does not have a sound scientific foundation:

1. The document mentions increasingly raised concerns, study suggestions, numerous studies, anecdotal reports, observations, etc., but does not cite the references for all to review.

2. Green Seal is proposing that terpenes when formulated with other chemicals could convert to their oxidation products and cause skin sensitization and "may be respiratory allergens as well." Green Seal is not specific about whether this will happen in the container, on a person's skin if misapplied, or in the air when the volatile components

evaporate. Green Seal does not offer any proof this conversion will take place under any of these scenarios. Green Seal is ignoring the fact that as a good manufacturing practice, all terpenes after purification are protected from oxidation with an antioxidant. Green Seal could better serve users with reinforced, stronger labeling to wash skin with soap and water following any exposure to skin and to provide additional ventilation when using all “green” products because while "safer," they still contain chemicals.

3. Green Seal is misinterpreting the IFRA recommendation for fragrance ingredients. IFRA does not limit the total amount of terpenes in a fragrance; IFRA places a limit on the peroxide level in a fragrance. The purpose of the IFRA recommendation is to describe a quality terpene product for the purpose of compounding a fragrance. See: http://www.ifraorg.org/GuideLines.asp, and select the pinacea derivatives and/or limonene tabs.

4. The U.S. EPA DfE Formulator Program, while a very worthwhile undertaking, is not transparent to all and their internal documents should not be used to develop a green standard; that was not its intended purpose. Green Seal should be using peer reviewed studies and official government publications to develop their standard.

We therefore urge Green Seal to eliminate Section "4.13.2 Restricted Ingredients" from their Revised GS-37 Standard.

Comment:
Restricted Ingredients. We are concerned with the approach Green Seal has taken in regards to d-limonene and terpene hydrocarbons. In effect Green Seal proposes to establish for the first time a chemical specific threshold limit, and in so doing would establish a precarious precedent. Why set a limit only for d-limonene and terpene hydrocarbons? Why not other substances? Such a proposed approach will only add confusion to the marketplace and lead to inconsistent treatment of chemical ingredients. This proposed action is particularly questionable because it comes at a time when the U.S. EPA Design for the Environment Formulator Program is itself contemplating raising its acceptable limit for d-limonene. Will Green Seal re-open comment to GS-37 when DfE makes its changes? We suggest that Green Seal will not move as nimbly, and therefore we will be left with two different threshold limits in the marketplace. Moreover, terpenes generally, including d-limonene are effectively limited in other ways under GS-37 through VOC limitations and combustibility requirements.
We therefore request that Green Seal reject its proposed approach of specifically restricting ingredients / chemicals in this manner, in particular d-limonene and other terpene hydrocarbons.

Comment:
Restricted Ingredients: It is an unwelcome precedent to begin restricting specific chemicals (to certain arbitrary levels) without first having developed scientific criteria for which chemical ingredients will be on this list. In effect, this approach is setting chemical-specific threshold limits for only one group of chemicals, terpenes. There should be a sound scientific basis and objective criteria for limiting any chemical ingredient in a cleaning formulation. Green Seal should focus on eliminating products

that are aquatic toxins, asthmagens, carcinogens, irritants, mutagens, reproductive toxins, and sensitizers, and not seek to restrict specific chemicals.

The justification being offered by Green Seal is not sound science. The Background Document of November 16, 2007 states on page 19 that in the case of d-limonene and other terpene hydrocarbons, "…these ingredients have increasingly raised concerns because the oxidation products (e.g. hydroperoxides, oxides) [not the terpenes themselves] are well-recognized as potent skin sensitizers and studies suggest that the oxidation products may be respiratory allergens as well."

It is unreasonable to propose that d-limonene and other terpenes (when released indoors) will in a short period of time convert entirely to their oxidation products and cause skin sensitization. Any oxidation products formed will be in the vapor phase and are unlikely to have contact with human skin at a high enough concentration that would result in skin sensitization. At the most, any oxidation products would cause only a minor skin irritation.

The transformation of d-limonene and other terpenes to oxidation products depends largely on the presence of other highly-reactive oxidizer chemicals, namely ozone. Ozone is well-known to be a strong respiratory irritant. There is limited evidence that the components of this oxidation reaction can become intimate enough for the reaction to take place to completion. Any oxidation of terpenes would consume oxidizer and lower the oxidizer (i.e. ozone) level, thus removing a strong respiratory irritant from the room where the cleaning is taking place. There is a lack of information to show that these oxidation products are respiratory allergens with respect to human lung cells. Green Seal does not identify the "studies." Green Seal does not offer a definition for "respiratory allergen." Green Seal is merely suggesting the oxidation products "… may be respiratory allergens…"

It is possible that any oxidation products thus formed could condense from the gas phase, forming airborne particulate matter, but there are no studies showing these particles are respiratory irritants or respiratory allergens, only concern about the potential for associated health risks. Contrary to these "suggestions" and "concerns" is a recent study by Keinan supporting that electron-rich olefins such as d-limonene, are known ozone scavengers, and could be used for prophylactic treatment of asthma. Please see Attachment A by E. Keinan et al titled "Natural ozone scavenger prevents asthma in sensitized rats."

Green Seal further states in the Background Document that "The International Fragrance Association (IFRA) recognizes these concerns, and the IFRA standard for limonene notes that products should have a peroxide value of less than 20 millimoles peroxide per liter. For pinacea derivatives, products should have a peroxide value of less than 10 millimoles peroxide per liter." We fully agree with these statements and a quality terpene product for the personal care industry used for skin application will meet that standard. In fact, all quality terpene products will meet this standard as a good manufacturing practice (GMP). But, it is faulty logic on the part of Green Seal to infer that the total amount of d-

limonene in the cleaning product should be limited to 20 millimoles per liter of product, or in the case of other terpenes limited to 10 millimoles per liter of cleaning product. That was not the intention of the IFRA standard; IFRA sets standards for fragrance ingredients that are used to formulate personal care and household products.

Green Seal further states that "…numerous studies are finding that limonene and other terpenes in indoor air are oxidized by ozone to form secondary organic aerosols and other chemicals known or suspected to be respiratory irritants or allergens." Green Seal states "numerous studies" with respect to indoor air without referencing these studies; Green Seal should cite these studies. Green Seal goes on to say, "Although the health significance of these secondary air pollutants in indoor air is not well established yet, they may be associated with the many anecdotal and case reports of workers and other(s) who experience respiratory symptoms such as shortness of breath and irritation when using cleaners including these fragrances and solvents." The phrases "…the health significance of these secondary air pollutants in indoor air is not well established…," "…may be associated…," and "… anecdotal and case reports…" are not sound scientific facts, but show Green Seal is biased and this information is at best, equivocal.

The Background Document further states that "Limonene is also recognized as an effective functional component in cleansers and degreasers, often an alternative to petroleum-based or hazardous ingredients. The EPA Design for the Environment (DfE) Formulator Program recognizes this use and the above described concerns, and considers products 'acceptable' when limonene is present at 20 millimoles (mmol) per liter (or approx. 0.36%) or less in an overall formulation. This is based on the observation that a high percentage of the limonene (up to 90%) converts to hydroperoxides by reaction with oxygen and other oxidizers." The DfE does not have transparent standards for individual chemicals. The current DfE profile is in draft form, is incomplete, contains mathematical errors (levels should be defined as percent concentration in the final product, not as mmol/L), is not an official governmental publication, and should not be used as a basis for the GS-37 standard.

Green Seal is misquoting the DfE when they say "This is based on the observation that a high percentage of the limonene (up to 90%) converts to hydroperoxides by reaction with oxygen and other oxidizers." This comment is taken out of context and being incorrectly attributed to DfE. The DfE profile reads "…oxygen or UV light…", not "…oxygen and other oxidizers" as Green Seal suggests.

Finally, there is no overall explanation of why limiting a specific chemical to a certain percentage makes the product an approved "green" product. Setting the VOC level for an approved "green product" at 1% VOC, for example, is admirable and a standard that all approved products must meet; the purpose of such standards is to improve outdoor air quality. Restricting the level of a specific ingredient to a fixed level for supposed indoor health or environmental reasons does not limit the amount of that ingredient in the indoor cleaning space. The total amount of that ingredient admitted to the cleaning space is a function of how much product is used. One use for a product could involve a spritz of the product for cleaning a mirror, and another use for the product could involve cleaning the

walls, ceiling, and floor of a room and all the objects in that room. Limiting the amount of an ingredient in a product does not control the concentration of that ingredient in the work space; the concentration remains a function of how much product is used in the work space. It is good logic to prohibit the use of a chemical that is, for instance, a proven carcinogen; it is faulty logic to restrict a specific chemical to a certain percentage in an attempt to limit the total amount being released in an indoor cleaning area because one construes the chemical could be a health hazard.

Green Seal should focus their attention on the health and environmental effects resulting from exposure to chemical ingredients and not potential oxidation by-products of chemical ingredients. Limiting the level of d-limonene and related citrus terpenes in a green product standard could spuriously lead people to associate citrus products with adverse health effects, when in reality citrus consumption is associated with a number of important health benefits.

We therefore urge Green Seal to remove section 14.3.2 from the Revised GS-37 Standard.

Response:
Limonene, pinacea derivatives (e.g. pinene) and other terpene hydrocarbons (e.g. myrcene) are commonly used in cleaning products. They are recognized as an effective alternative to petroleum-based or hazardous ingredients. Green Seal does not want known undesirable reaction products to be in green products. These ingredients have increasingly raised concerns because their oxidation products (e.g. hydroperoxides, oxides) are well-recognized as potent skin sensitizers and studies suggest that the oxidation products may be respiratory allergens as well.

Furthermore, numerous studies are finding that limonene and other terpenes in indoor air are oxidized by ozone to form secondary organic aerosols and other chemicals known or suspected to be respiratory irritants or allergens. (references included below)

The International Fragrance Association (IFRA) recognizes these concerns, and the IFRA standard for limonene notes that products should have a peroxide value of less than 20 millimoles peroxides per liter. For pinacea derivatives, products should have a peroxide value of less than 10 millimoles peroxide per liter. The peroxide value is determined using the Fragrance Materials Association analytical method (www.ifraorg.org/Enclosures/News/Peroxide%20Method%202001-25-01.pdf). The EU regulations follow this guidance as well (ex. Cosmetic Directive). While this doesn't place a limit on the terpene ingredients, rather on the reaction product of peroxide, it is well known that measuring terpene peroxides is difficult, so another approach is preferred. It can be estimated that oxidation of the terpenes is complete, and thus a limit on the terpene ingredients is appropriate. This gets more directly at the cause of the concern, the reactants. Since the level of oxidants (ex. ozone) can't be controlled, and the amount of products used is limited, a limit within the product on the reactants (terpenes) is appropriate.

Another approach could be to ensure limited oxidation of the terpenes, with an effective, standardized, antioxidant dose and system. However, antioxidant dosing (to prevent the development of the potentially harmful oxidation products of terpenes) hasn't been recognized broadly and may not prevent such oxidation during use, especially given the availability of oxidants.

Terpenes are limited in the product due to the volatile organic content but to further protect against the above concerns, the standard will continue to limit these materials based on the IFRA peroxide value limits. The levels cited in the standard were found to be feasible by manufacturers who include these ingredients in their products.

References not cited by implied:

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Nazaroff, W. and C.J. Weschler. 2004. Cleaning products and air fresheners: exposure to primary and secondary air pollutants. Atmospheric Environment. 2004. 38: 2841-2865.

Mendell, M.J. 2006. Indoor Residential Exposures as Risk Factors for Asthma and Allergy in Infants and Children: A Review. Environmental Energy Technologies Division Indoor
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Li, T-H et al. 2002. Indoor hydrogen peroxide derived from ozone/*d*-limonene reactions. Environ. Sci. Technol. 2002. 36:3295-3302.

Mendell, M.J. 2007. Indoor residential chemical emissions as risk factors for respiratory
and allergic effects in children: a review. Indoor Air. 2006. 17: 259–277.

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4.14 Fragrances
Fragrances added to the product must follow the Code of Practice of the International Fragrance Association. All fragrance components must be disclosed to Green Seal and meet all other criteria of this standard. The material safety data sheet (MSDS) must identify that fragrance has been added.

Comment:
Based on the comments provided herein, we respectfully requests that Green Seal make revisions to the GS-37 standard to allow the continued use of fragrances in those products.

People have enjoyed fragrances for thousands of years. Fragrances contribute to our individuality, self-esteem and personal hygiene. When used in hard surface cleaning products they also serve as a signal that surfaces have been cleaned. Fragrances date as far back as the Egyptians who used aromatic plants to create massage oils, medicines, embalming preparations, skin care products, fragrant perfumes and cosmetics.

Under conditions of intended use and even under reasonably foreseeable misuse, fragrance ingredients are safe. In addition to a long history of safe use, a well-established program exists within the fragrance industry for objective evaluation of the safety of its materials and this is backed up by government requirements that establish expectations for safety substantiation of chemicals. Green Seal need not reinvent this wheel.

We would be pleased to provide you with any additional information you might require.

> **Response:**
> Green Seal will continue to allow fragrances as long as they meet the criteria in the standard.

Comment:
Several studies have documented that some people are highly sensitive to fragrances that these substances can trigger asthma attacks and other adverse health effects. The proposal to prohibit phthalates and other fragrance components of concern (e.g., musks) is a good first step; but it is not clear that this will completely address the concerns that have been raised about fragrances. The product label should make it clear when products are fragrance-free; and perhaps being fragrance-free could be a prerequisite for qualifying for a higher (gold) standard designed to protect children and other sensitive populations. A similar special designation is included under the Canadian Ecologo for institutional cleaners.

Comment:
Fragrance can be health and life threatening to people with asthma and other respiratory conditions, since it may stimulate serious reactions in these populations, as well as the growing number of chemically sensitive individuals. It is recognized as a trigger for (potentially fatal) asthma attacks by both the American Lung Association and the FDA among many other sources.

For that reason, it should not be allowed in cleaning products used in institutional setting such as schools, health care facilities and nursing homes. It has, in fact, been banned in many such places already. The Green Seal label should be an assurance of safety for these vulnerable individuals and for significant numbers of others adversely affected, especially by the synthetic fragrance chemicals derived from petroleum. (Some folks react allergically to even natural fragrances). Fragrance-free should be the norm in all places where susceptible people are not in a position to escape the fumes. For more information on this concern, see the following:

www.toxicsinfo.org/canary/fragrancechemsinlaundry.htm
www.toxicsinfo.org/asthma/FragranceAllergies.htm
www.toxicsinfo.org/personal/fragrance_safety.htm
www.toxicsinfo.org/canary/perfumeanalysis.htm
www.toxicsinfo.org/canary/fragrancechems.htm
www.toxicsinfo.org/canary/perfumefragrancewarnings.htm
www.toxicsinfo.org/canary/scentskidsgowildfor.htm
www.toxicsinfo.org/personal/sweetpoison.htm
www.toxicsinfo.org/personal/SenseOfScents.htm
www.toxicsinfo.org/personal/HealthierAir.htm
www.toxicsinfo.org/personal/News%20for%20Nurses%20Info%20Sheet.htm
www.toxicsinfo.org/canary/fragranceregulation.htm

Comment:
Disclosure of all fragrance components is essential. Thank you.
Also, it is key that the user know fragrance is in the product, and not all users have the MSDS readily available. Add the following:

"All fragrance components must be disclosed to Green Seal and meet all other criteria of this standard. The material safety data sheet (MSDS) must identify that fragrance has been added." THE UNDILUTED PRODUCT LABEL MUST ALSO IDENTIFY THAT FRAGRANCE HAS BEEN ADDED.

Comment:
Fragrances should be evaluated in the undiluted formulation and packaging should be clearly labeled to indicate that added fragrances are present.

> **Response:**
> Fragrances are allowed in the standard, since a science-based approach was taken for the development of the criteria. At this point, the research points to specific end points of concern for certain chemicals, rather than stating that any scent imparting chemical/fragrance component is an issue. As a result, this standard includes the end points of concern (ex. skin sensitization, causing asthma, volatile organic compounds, and inhalation toxicity) and fragrances will be evaluated against these criteria. Further, suggestion has been to prohibit scented products (ex. CCD-146 approach for a few of the products that standard) however there are

many products that don't have a scent, but have added fragrance components to "neutralize" any inherent odor of the product (which are allowed by CCD-146). Further, there are many cleaning components, like solvents, that impart scent (also allowed by CCD-146). Complex fragrances such as natural ingredients or essential oils may contain known carcinogens and thus are not safer than other fragrance options (Jansson and Loden, 2001). Thus the best approach is to use strict end point criteria, and just prohibiting ingredients added to impart scent, to acheive the desired effect of minimize health effects.

Over 60% of currently certified GS-37 products do not have added fragrances, so there are many options available for those interested in products without added fragrances. It is important that any use of fragrance components be disclosed to the public. As a result, use of fragrance ingredients, when added or not, shall be disclosed on the MSDS and label. The labeling requirements have been updated accordingly.

Fragrances. Fragrances added to the product must follow the Code of Practice of the International Fragrance Association. All fragrance components must be disclosed to the certifying body and must meet all relevant criteria of this standard. The product label and material safety data sheets shall reflect the use of fragrances (present or not) in accordance with section 6.3.

Label and Material Safety Data Sheet Fragrance Declaration. The product shall declare on the product and on the MSDS if a fragrance has been added or if no fragrance has been added.

Jansson, T. and M. Loden. 2001. "Strategy to decrease the risk of adverse effects of fragrance ingredients in cosmetic products." *Am J Contact Dermat*. Sep;12(3):166-9.

Comment:
In 4.14 Fragrances, it is not clear what you mean by fragrance components. There is no definition for the word component. Do you mean ingredient? And are you considering ingredients at the level of the undiluted product? That would be my recommendation.

Response:
This is clarified with a definition for component since all fragrance components are disclosed to Green Seal for evaluation.

Component. A deliberately added product compound, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141.

Comment:
Fragrances: Since this requirement specifies that fragrances are to meet "all other criteria" for the finished product, the following sentence should be added to the requirement: The final presence level in the diluted product, therefore, will be used to determine the level of concern for the individual ingredients instead of using the concentrated fragrance."

Response:
All fragrance components are evaluated (ex. carcinogens are not allowed at any level in the product).

Comment:
The requirement for fragrances to be disclosed on MSDSs could entail disclosure of confidential business information. Provisions should be included in the criterion to allow protection of fragrance information that is confidential.

Response:
Fragrance disclosure to Green Seal for review is done under confidentiality. The requirement for disclosure on the label and MSDS is for a statement about "added fragrance" rather than the specific components of a fragrance.

4.15 Concentrates
The product must be a concentrate, except for toilet bowl cleaners, carpet spot removers, and absorbent compound carpet cleaners.

Comment:
Be careful of this one. Numerous toilet bowl cleaners and carpet spotters are available in concentrate and work just fine in most applications. This smacks of allowing ready-to-use products in the standard and adding to the waste stream.

Response:
The concentrate criterion does not require toilet bowl cleaners to be ready-to-use, rather is allows for toilet bowl cleaners that perform better at such a concentration to be certified. The current market of toilet bowl products have both types (concentrated and ready-to-use), so a requirement would limit a significant portion of the market.

4.16 Animal Testing
Green Seal wants to discourage animal testing and will accept the results of past peer reviewed or standard tests demonstrating compliance with a criterion. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results

may be accepted, providing that the test methods are referenced in peer-reviewed literature and the manufacturer provides the reasons for selecting the particular test method.

Comment:
It is probably true that everyone would prefer to avoid animal testing where possible.

However, this exclusion is far too broad. This provision would seem to allow the substitution of any assay that has been published in the peer reviewed literature for an animal model, as long as a manufacturer provides a reason. This is not sufficient. It would also be important for the proponent of the substitution to make a showing as to why the proposed substitute assay will provide information of equivalent value. This is not a trivial question to answer, as assays often test for some subset of the outcomes that would be seen in a whole animal study. There are cases when a substitute method may be justified, and there are cases where it will not be. This would need to be assessed for each proposal.

> **Response**:
> Available data is primarily used for evaluation. If testing is needed preference is given to in vitro methods. As mentioned, such in vitro methods need to be sufficient to demonstrate meeting the criteria.

5.0 Packaging Requirements
Any general comments, questions or ideas pertaining to packaging requirements should be posted here.

Comment:
- 5.1 Recyclable Package. The primary package must be recyclable or be a source-reduced container that has been light-weighted by at least 20% compared to traditional packaging.
- 5.2 Recovered Material Content. The primary package must contain at least 25 percent post-consumer material or be a refillable or reusable package.

The intention of theses two sections is admirable. Unfortunately, they illustrate the other side and the cause of our concerns. These two sections are written as if the only method of mixing is a metering machine. It specifically ignores pre measured portion control. We are not aware of technology that exists for pre-measured portion control to use recycled material and be recyclable. Our packaging material is not made from recycled material but it is made of standard type 2 recyclable material and can be recycled. It is not bonded to other materials that would make it unsuitable for recycling. We have explored the use of recycled materials in our packaging and have been forced to realize that the material is unsuited to our packaging format. Using recycled materials actually results in consumption of larger amounts of material consumed and significantly higher amounts of waste. The recycled content requirement may be appropriate for rigid container manufacturing, however, as previously recognized by Green Seal, unit dose

packaging has already achieved a significant reduction in packaging material and should resultantly be exempt from this requirement.

Comment:
In regard to Sections 5.1 and 5.2, Green Seal purports to model the requirements established by the California Rigid Plastic Container Act. In fact the approach taken by Green Seal significantly deviates from the specific requirements set forth in the Act and its implementing regulations in such a manner that makes it extremely difficult if not impossible for formulators of cleaning products to comply with these provisions.
For example, the California Act and its implementing regulations apply only to "rigid plastic containers", a term that is specifically defined and which excludes packaging such as plastic pouches. Green Seal makes no such distinction. Presumably Sections 5.1 and 5.2 would apply to any type of packaging: plastic, cartons, pouches, bag in the box, flexible or rigid containers, as well as portion control packets.
In regard to this latter packaging type, as drafted, the proposed packaging requirements would effectively eliminate portion control packets as an option because they would not be able to comply with the provisions as drafted.
Further, the California Act requires that formulators comply with only one of several options. Green Seal, on the other hand has adopted an approach that requires formulators to adhere to two discrete but bundled options: 1) packaging is recyclable or source reduced by 20%; AND 2) packaging contains at least 25% post consumer material or be refillable / reusable.
In so twisting the provisions of the California Act, Green Seal has removed the necessary element of flexibility, which will make it virtually impossible for formulators to meet the requirements of Sections 5.1 and 5.2. Stated simply, Green Seal fails to recognize that there are many factors totally outside the control of cleaning product formulators that would make it impossible to comply with Sections 5.1 and 5.2 as currently drafted
For example, the availability of recycling centers varies substantially from region to region as well as from city to city across the United States. While California has developed a respectable recycling infrastructure, the fact remains that the same is not true in many areas of the U.S., making it difficult if not impossible for many formulators to be able to legitimately claim that their containers are recyclable as contemplated by the proposed revisions to GS-37.
In addition, there is a shortage of post consumer plastic available for use in packaging in the U.S. to the extent that it is extremely difficult for cleaning product formulators to acquire containers or other packaging with a 25% or more post-consumer content. For example, because of market conditions, substantial quantities of post-consumer plastic waste are diverted to China to be recycled or burned for energy. Chinese markets are simply willing to pay more for such material, therefore drying up the market here for post-consumer plastic waste. Moreover, the lack of adequate plastic recycling centers across the U.S. by definition means there is a low supply of post-consumer plastic that can be recycled into packaging.
Other practical issues enter into play as well. For instance, in many cases, the use of post-consumer content in plastic packaging degrades the structural integrity of the packaging itself. Formulators have observed stress cracks in such containers that have resulted in the release of the product during transportation as well as when in storage. To

compensate for the reduced structural integrity of the plastic container, formulators ship such products in cardboard boxes that are more strongly constructed by using more corrugated paperboard in the process, which in itself raises additional environmental issues (use of more trees, paper, processing, etc.).
Lastly, in section 5.1 Green Seal states that the container shall be source reduced by being "light-weighted" by 20%. The California Act calls for 10% light-weighting by contrast. Green Seal fails to justify why it believes 20% is a workable approach. Furthermore, while California law clearly defines what source reduction and light-weighting mean, Green Seal fails to provide any such definition. In so doing, Green Seal fails to recognize that this approach is a subjective one that requires specific criteria to make it workable.
For example, the approach taken by Green Seal presumably would penalize those formulators that have already engaged in such source reduction. Must they now compare any further source reduction with their already source reduced packaging? This lack of clarity is especially egregious because Green Seal has tied this requirement inextricably with the use of post-consumer content rather than presenting it as an additional option as done under California law.
B. Recommended Revisions to Sections 5.1 and 5.2. The argument and rationale set forth above underscores the critical need for Green Seal to adopt an approach to packaging that provides the much needed flexibility to make it workable. We call upon Green Seal to adopt an approach more similar to that of California's, tempered with the reality of the limited options formulators have in the way of selecting packaging options as well as limited access to containers with recycled content.
Specifically we recommend the following:
1. Revise Section 5.1 as follows:
"5.1 Rigid Plastic Containers. A rigid plastic container that constitutes the primary package must meet one of the following options:
a) Must be recyclable;
b) Must consist of at least 15% post-consumer resin;
c) Must be routinely reused or refilled at least 5 times; or
d) Must be source reduced by at least 10%. Manufacturers who seek to use the source reduction option must establish that their containers are reduced by at least 10% compared with:
• Containers used for the product by that manufacturer on [insert effective date of revised GS-37]; or
• Containers used in commerce the same year for similar products housed in similar containers whose containers have not been considered source reduced. Comparison may be made to products made by the same manufacturer or by another.
2. Revise Section 2.0, Definitions by adding the following definition:
Rigid Plastic Container. Any plastic package having a relatively inflexible finite shape or form. with a minimum capacity of eight fluid ounces or its equivalent volume and a maximum capacity of five fluid gallons or its equivalent volume, that is capable of maintaining its shape while holding other products, including, but not limited to, bottles, cartons, and other receptacles.

Comment:

The proposed packaging provisions are extremely vague. Manufacturers would be unable under the proposed definitions and provisions to ascertain which products would be covered. While favorable references are made to the California Rigid Plastic Packaging Container Act, with the goal of "allowing industry to select from those environmental-preferred packaging options," it is unclear what "options" would be permitted: what specific provisions and exemptions, if any, would apply? Moreover, how would the GS-37 standard interact with recognized U.S. Department of Transportation (DOT) and United Nations packaging rules and provisions? Without further clarification, we are unable at this time to provide more substantive comment on specific aspects of the standard.

Comment:
5.1 Recyclable Package: The initial part of the first requirement, that the "primary package must be recyclable", is indistinct. It makes no reference to which materials are considered recyclable under this standard. Nor does it specify which method(s) of recycling are acceptable.

Response:
Requiring that a package include recovered content is desired as a means to reduce material and resource use. However, some package types are designed for such resource reduction through lightweighting or reuse. Further, recovered content seems to present significant limitations in functionality for plastic packaging in this product category. As a result, the packaging requirements will follow the California Rigid Plastic Packaging Container requirements for plastic packages. The post-consumer content requirement will remain for other packaging materials.

Refillable Package. A container which is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package, and demonstrated in practice. For the purpose of this program, the product manufacturer or the product manufacturer's agent may refill a package.

Source-Reduced Package. A package that has at least 20% less material (by weight) compared to containers commonly used for that product type. For bag in the box type packages, the box is included in the weight when the box is used during product use.

Plastic Package. A plastic primary package shall be recyclable, a refillable package, a source-reduced package, or contain at least 25% post-consumer material. The package must be clearly marked with the appropriate Society of the Plastics Industry (SPI) symbol to identify the type of plastic for recycling.

Post-Consumer Material. The primary package, for materials other than plastic, shall contain at least 25% post-consumer material or demonstrate that efforts were made to use the maximum available post-consumer material in the package.

Comment:
The standard's packaging requirements should apply to all product packaging -- primary and secondard -- (except lids), not just to primary packaging. Therefore, if the product is packaged in a corrugated carboard case, for example, it could pass this part of the standard if it is recyclable and is made with the minimum amount of recycled content specified in the proposed standard.

Response:
Secondary packaging is used for merchandizing of products for retail markets (a package around the primary package). This standard does not cover products sold at retail. If the primary package is not plastic, there is a requirement for using post-consumer material.

Comment:
Section 5.3, Concentrated Product Packaging. As proposed, this section would prohibit concentrated products from being packaged in ready-to-use forms, including but not limited to spray dispenser bottles. As presently drafted, this section lacks clarity and is otherwise vague. Without clear direction manufacturers will be hard pressed to comply with this section. For example, it is common for manufacturers to distribute ready to use products in one gallon jugs. On the other hand, it is just as common for manufacturers to distribute concentrated products in one gallon jugs as well. Does the fact that manufacturers use such containers to house ready to use products transform them into "ready-to-use forms" for purposes of the proposed revision to GS-37, rendering them prohibited? For the sake of clarity and pragmatism, we urge Green Seal to limit the prohibition to spray dispenser bottles. At the same time, Green Seal should make clear that spray bottles are an appropriate container for application of the use dilution. In adopting such an approach, Green Seal will adequately address its stated concern of encouraging correct dilution of cleaning products, while addressing potential exposure issues. We are unaware of any other packaging type that may give rise to such concerns and thus warrant such a harsh prohibition.

Response:
Products are required to be concentrated. As a result, products should not be packaged in a form that would lead a user to think they can use it without dilution. This will be clarified as follows:

Concentrated Product Packaging. Concentrated products are prohibited from being packaged in spray-dispenser bottles or other ready-to-use package types.

5.1 Recyclable Package
The primary package must be recyclable or be a source-reduced container that has been light-weighted by at least 20% compared to traditional packaging.

Comment:

In Section 5.1, your definition of a recyclable package is very loose. Can you identify up front which packaging materials would currently qualify. I think there will be confusion and controversy if you do not. This is something that could be amended as materials used and recycling opportunities change.

Is pvc considered recyclable?. I would argue that it is not and that it confounds the recycling of other more recyclable materials. Does the phthalate restriction as written allow for pvc packaging as long as it contains recovered material? Or if it is fillable or recyclable? The implications of this criterion are unclear.

Comment:
In Section 5.1, your definition of a recyclable package is very loose. Can you identify up front which packaging materials would currently qualify. I think there will be confusion and controversy if you do not. This is something that could be amended as materials used and recycling opportunities change.

Is pvc considered recyclable?. I would argue that it is not and that it confounds the recycling of other more recyclable materials. Does the phthalate restriction as written allow for pvc packaging as long as it contains recovered material? Or if it is fillable or recyclable? The implications of this criterion are unclear.

We agree that more clarification would be important here.

> **Response**:
> The recyclable definition used follows the guidance provided by the Federal Trade Commission (FTC). Using this definition, currently plastic resin codes 1 and 2 would qualify.
>
> While the criteria have restricted the use of PVC packaging (not being recyclable according to the standard and contain phthalates), with developments there may be a means for PVC packaging to be allowed. Given the hazards associated with PVC from production to disposal, it will be specifically prohibited.
>
> ***Other Restrictions.*** *Phthalates and chlorinated packaging material are prohibited from being intentionally introduced; an exception is allowed for packages that would not have added phthalates or chlorinated packaging material but for the addition of recovered material.*

Comment:
I recommend removing the exemption to requiring recyclable packaging for "source-reduced" containers. Purchasers most likely to specify GS-37 certified products are also likely to have waste reduction and other pollution prevention mandates and/or programs. To allow non-recyclable packaging creates more waste for end-users of the product. From an end-user perspective, a container that will end up in the trash is not representative of a “green” product. If a manufacturer wants to reduce the amount of material used in packaging without compromising product quality, great! But do not give

them an exception in the standard that results in more waste at the end of the product's life.

Response:
Requiring that a package include recovered content is desired as a means to reduce material and resource use. However, some package types are designed for such resource reduction through lightweighting or reuse. The goal is source reduction. Further, recovered content seems to present significant limitations in functionality for plastic packaging in this product category. So post-consumer content will remain one option for source reduction for plastic packaging, however, the post-consumer content requirement will remain for other packaging materials.

Comment:
The second part of this requirement says if the package is not recyclable, then it must "be a source-reduced container that has been light-weighted by at least 20% compared to traditional packaging." This standard is totally subjective and without clearly identifiable, discrete criteria. Why was the value of 20% chosen when the current California Legislation only calls for 10%? Also, the reference to traditional packaging is unclear, ambiguous and open to inconsistent interpretation. There is no guide as to what is considered traditional packaging, and it does not indicate what the weight of the traditional items would be so that source-reduction value could be calculated.

Response:
While the California legislation is calls for 10% source reduction, Green Seal has found that 20% is feasible and thus has included that in the definition of source-reduced packaging.

Source-Reduced Package. A package that has at least 20% less material (by weight) compared to containers commonly used for that product type. For bag in the box type packages, the box is included in the weight when the box is used during product use.

5.2 Recovered Material Content
The primary package must contain at least 25 percent post-consumer material or be a refillable or reusable package.

Comment:
Green Seal needs to exempt flexible, source-reduced containers from the part 5.2, Recovered Material Content requirement. If the packaging is source-reduced, how will you ever find enough material in the recycled materials market? I was told by Green Seal, when they dropped the recyclable requirement for source-reduced packaging, that a market for #4 LDPE (low-density polyethylene) film does not exist in practice. They are

correct. I was informed by my film vendors that #4 LDPE film with any post-consumer content does not exist in the marketplace.

If this material did exist, it would undoubtedly be fraught with pinholes due to the debris, melt-point inconsistency and impurities inherent with recycled material. The successful filling of liquid into pouches requires the film to be pinhole-free or tremendous waste through leakage and rework is the result. The thin-film extrusion process is intolerant of post-consumer content, I am told.

Comment:
The requirement of using 25% Post-Consumer recycled content raises several concerns. Post-consumer plastic and virgin resin are not chemically identical, and incorporation of PCR begins to affect package integrity at levels above 10%. The practical consequence is that any shock to the package is more likely to result in failure of the package, which would cause more spills/exposure/etc, damage to surrounding packages, transportation equipment, slip/fall hazards, and so forth. The requirement should be take into account the effect PCR has on a package, such that inclusion of PCR should not exceed the level demonstrated to substantially increase the likelihood of package failures.

Also, inclusion of PCR may only be achieved for certain forms of plastic, generally not those used to create "source reduced" containers.

Additionally, PCR supply is lean compared to PCR demand - there are many users and markets to which PCR content is supplied, only one of which is packaging materials. The inevitable consequence of an increase in requiring more PCR in packaging is higher costs for PCR content, which in turn would lead to more expensive packaging. The requirement of 25% PCR appears arbitrary and does not seem to consider the consequences of increased PCR use.

Modern packaging is designed to maximize safety, storage and transportation density, and functionality. Many of the innovative solutions for preventing practical access to chemistry would be jeopardized by the mentality portrayed in the standard that packaging is simply waste.

Manufacturers should be encouraged to use PCR as one strategy among source reduction, reuse, and recycling for providing more sustainable packaging.

Recommend adding source reduction clause to 5.2 and otherwise modifying as follows:
5.2: The primary package must contain at least *10* percent post-consumer material, be a refillable or reusable package, or demonstrate source reduction of at least 20% compared to traditional packaging. The level of post-consumer material in a package must not substantially reduce the integrity of the primary package.

Comment:
We agree with the suggested changes:
"5.2: The primary package must contain at least 10 percent post-consumer material, be a

refillable or reusable package, or demonstrate source reduction of at least 20% compared to traditional packaging. The level of post-consumer material in a package must not substantially reduce the integrity of the primary package."

To add to the previous comments...
While demand is increasing for recycled-content packaging, suppliers are only starting to be able to meet the quality level required at a reasonable price. Much of this country's used plastic is still being shipped overseas. What PCR packaging is available is typically purchased by large manufacturers who buy in bulk and take advantage of a price break, but smaller manufacturers who buy in smaller quantities (and thus don't get a bulk discount) not only find the cost prohibitive, but have a more difficult time sourcing smaller quantities at all (especially in their regions).

With a goal of keeping the price of "green cleaning" on par with traditional things, flexibility in responsible packaging options is extremely important to help keep prices down. Perhaps in a number of years the market and technology will have caught up with demand and the standard may be "upped" at that time.

Comment:
We have found that containers containing 25% recycled material do not have the structural integrity associated with containers utilizing virgin material. It is our contention that such packages are much more likely to fail in transport and storage increasing the risk of exposure and a burden to the environment

Comment:
By requiring that the packaging item must contain recycled content and be source reduced, the standard adopts an unnecessarily stringent position that complicates compliance. A better approach that will encourage compliance would be to make the two requirements mandatory alternatives, e.i., choose one or the other.

Comment:
Section 5.2 The primary package must contain at least 25 percent post-consumer material or be a refillable or reusable package.
What form of data is needed for proof?

Comment:
Section 5.2 is fairly straight forward. However, the requirement is quite stringent to stipulate that the packaging item must contain recycled content AND be source reduced. The standard should allow products to comply with one of these requirements.

> **Response**:
> Requiring that a package include recovered content is desired as a means to reduce material and resource use. However, some package types are designed for such resource reduction through lightweighting or reuse. Further, recovered content seems to present significant limitations in functionality for plastic packaging in this product category. As a result, the packaging requirements will

follow the California Rigid Plastic Packaging Container requirements for plastic packages. The post-consumer content requirement will remain for other packaging materials.

Refillable Package. A container which is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package, and demonstrated in practice. For the purpose of this program, the product manufacturer or the product manufacturer's agent may refill a package.

Source-Reduced Package. A package that has at least 20% less material (by weight) compared to containers commonly used for that product type. For bag in the box type packages, the box is included in the weight when the box is used during product use.

Plastic Package. A plastic primary package shall be recyclable, a refillable package, a source-reduced package, or contain at least 25% post-consumer material. The package must be clearly marked with the appropriate Society of the Plastics Industry (SPI) symbol to identify the type of plastic for recycling.

Post-Consumer Material. The primary package, for materials other than plastic, shall contain at least 25% post-consumer material or demonstrate that efforts were made to use the maximum available post-consumer material in the package.

5.3 Concentrated Product Packaging
Concentrated products are prohibited from being packaged in ready-to-use forms, including but not limited to, spray-dispenser bottles.

Comment:
Again, the statement "concentrated products are prohibited from being packaged in ready-to use forms" is unclear. There is a need to further define which packaging forms are considered ready-to use. For example, a one (1) gallon bottle will often contain a ready-to-use formula, but it can also contain a concentrated product.

Comment:
Again, the statement concentrated products are prohibited from being packaged in ready-to use forms is unclear. There is a need to further define which packaging forms are considered ready-to use. For example, our 1 gallon bottle will often contain a ready-to-use formula, but it can also contain a concentrated product.

Response:
Products are required to be concentrated. As a result, products should not be packaged in a form that would lead a user to think they can use it without dilution. This will be clarified as follows:

Concentrated Product Packaging. Concentrated products are prohibited from being packaged in spray-dispenser bottles or other ready-to-use package types.

5.4 Dispensing-System Concentrate Packaging

5.4.1 Dispensing-system concentrate packaging shall deliver the recommended dilution accurately and shall not function when the water flow is inadequate to provide an accurate dilution of the concentrate..

5.4.2 The dispensing-system concentrate packaging shall be closed and tamper-proof such that the undiluted product is inaccessible to the user.

5.4.3 The dispensing system shall have a backflow prevention assembly that has been certified by the Foundation for Cross Connection Control and Hydraulic Research (FCCC&HR) to have successfully completed the Laboratory and Field Evaluation phases of the approval program.

Comment:
The proposed exemptions for the diluted dispensing system concentrates are particularly worrisome as they would allow a potentially toxic product to have GS approval prior to its dilution. Although labeling to this effect would occur, it could be confusing to the purchaser, user and consumer. Custodial workers using this system may not speak/understand English or have very limited understanding, especially of the written word. They may not dilute the concentrate properly or at all. English-speaking workers may be illiterate as well. The preceding workers may not understand the importance of proper dilution and dilute less for "heavier" stains, etc. During manufacture, delivery, storage and set up of the undiluted product, factory workers, delivery people and custodians could be exposed to the undiluted product in the event of a leak, spill or malfunction. In fact, any by-stander could be impacted by any one of these incidents. We are concerned that some toxic chemicals may not be included in the MSDS sheets of these cleaners since by following the recommended dilution of the cleaner the toxic chemical may be less than the regulatory reporting threshold of 1%. This concern appears valid. The American Nurses Association's 2006 House of Delegates passed a Resolution on "Nursing Practice, Chemical Exposure and Right-to-Know". Part of this resolution advocates for a course of action that reduces the use of toxic chemicals by requiring that less harmful chemicals be substituted whenever possible and for labeling and full disclosure mechanisms.

Comment:
This 5.4.1 and 5.4.2 are conspicuously vague and general when compared to the rest of the GS-37 standard or even section 5.4.3 which references an accepted standard for the effective functioning of back flow devices. The word accurate is used but not defined; the known issue of inconsistent measurement when water pressure varies is addressed but what about other areas of concern. For instance:

- How does the standard address that many machines are designed to be adjusted in the

field?
- Many machines are manufactured with limited quality so even if the machine is adequate when new, how does the standard address the inevitable problems as the machine functions less efficiently.
- Many machines have parts that need to be regularly cleaned or replaced in order to be accurate, how will the standard address this issue?

Obviously, as a company we are not supportive of metering machines but given the real life problems of using meter machines we would be encouraged if the new standard addressed these problems. Personally, we don't see the logic of encouraging the use of resources and energy to produce an unnecessary machine with so many known issues and then to realize that the machine has a very limited lifespan and most likely is not designed to be recyclable.

Comment:
5.4.1 We are not aware of existing technology to prevent the functioning of a dilution control system if the water flow is inadequate to provide an accurate dilution. If such technology does exist it is our contention that it will impose an undo financial burden on companies supplying this equipment.

Comment:
Allows for higher concentrations of toxins through the exemption for Dispensing System Concentrates (applies to numerous sections throughout).
The proposed standard allows for much higher concentrations of toxic chemicals in Dispensing System Concentrates (DSCs), which use an automated system to dilute the concentrate to the correct “ready to use” (RTU) form. Since all GS-37-certified products must be diluted with at least 32 parts water, these concentrates will be able to contain significant amounts of toxic chemicals and still pass. The exemptions are allowed - with the “qualification designation” that will be listed on Green Seal’s website but is unlikely to be viewed easily by consumers or end-users - for virtually all 14 relevant criteria with three exceptions for carcinogens, mutagens and reproductive toxins (Section 4.3); combustibility (4.12); and prohibited ingredients (4.13.1). All other criteria allow the exemption for dispensing-system concentrates to be tested in the “as used” dilution. These exemptions undermine the true intent of strengthening standards for oral toxicity, inhalation toxicity, skin and eye irritation, skin sensitization, skin absorption, and ingredients that cause asthma, among others.

As written, a dispensing system concentrate may contain up to 32% of each chemical that is known to be able to penetrate the skin, for example, and cause toxic effects; only after it is diluted, the concentration of these ingredients would be under 1%. As another example, these DSCs will be allowed to contain asthmagens at levels of 0.32% and higher, whereas regular concentrates will only be allowed to contain 0.01%. This DSC exemption poses an unacceptable health risk and creates a two-tiered standard.

The exemptions allowed for DSCs rely on the misguided assumption that workers or building occupants will never be exposed to unsafe levels of toxic chemicals as long as

the products are used according to the automated dilution dispensing system. Yet exposures may occur whenever these products are not used as the manufacturer recommends or if there are accidental spills or releases. Unfortunately, we know from numerous accounts that accidents happen and workers sometimes cut open or puncture “tamper-resistant” bottles when the dilution equipment malfunctions, the wrong product is ordered, or they want a stronger solution. Moreover, after the water evaporates from the cleaning solution that has been applied to the floor, the chemicals of concern may remain as residues that can cause unsafe exposures. GS-37 contains few standards for these dispensing systems or the concentrates that go into them. Since we cannot predict how concentrated cleaning products will be used in the field, the prudent approach is to ensure that the concentrates themselves are as safe as possible while still performing well. Finally, while we generally support the use of concentrates and dispensing systems because they help reduce costs, exposures, and shipping impacts, we think that the DSC exemption may have the unintended negative consequence of discouraging the use of automated dispensing systems once end-users discover that these concentrates are more toxic than other Green Seal-certified products. If Green Seal is offering this exemption as a means of truly encouraging the use of dispensing systems, then perhaps it should simply require that all products be offered as dispensing system concentrates.

We recommend that the revised GS-37 standard eliminate the exemption for dispensing system concentrates throughout. The criteria should apply to the undiluted product.

Comment:
Dispensing-System Concentrate Packaging
We recommend that the dispensing system backflow prevention standard match ASSE 1055b standards and/or cUPC (Universal Plumbing code approval including Canadian Standards) for chemical dispensers. The proposed Foundation for Cross Connection Control certification is not recognized by plumbing inspectors. Rather, this is more of a "Water Purveyor" group that is not as interested in the backflow prevention at every faucet as in protecting the water supply at their facility and at the "mains".

Comment:
Section 5.4.1 Dispensing-system … and shall not function when the water flow is inadequate...
If this implies to have a pressure-sensitive shut-off mechanism, we are not aware of any dispensing system on the market can do that. This means a major reengineering and huge economical impact on both manufacturers and end-users.

Comment:
We recommend that the dispensing system backflow prevention standard match ASSE 1055b standards and/or cUPC (Universal Plumbing code approval including Canadian Standards) for chemical dispensers. The Foundation for Cross Connection Control proposed is not recognized by plumbing inspectors. Rather, this is more of a "Water Purveyor" group that is not as interested in the backflow prevention at every faucet, but protecting the water supply at their facility and at the "mains".

Response:
Green Seal acknowledges the environmental benefits of concentrating products and the user benefits of dispensing system concentrates. This is why Green Seal includes a concentrate definition and requirement in this standard and has tried to permit highly concentrated products in dispensing systems with the appropriate protection for users. It is recognized that users can misuse the products, and often this is through forcefully accessing the package by puncturing. The packaging requirements for the dispensing systems were modified to provide the necessary protections, adding spill resistance and durability measures to the primary package and system requirements for back flow protection as suggested. Green Seal cannot regulate how the products are used and systems maintained in the field, however training and labeling requirements were strengthened as a means ensure that communication is being done to minimize such use issues.

Closed Dilution-Control System. Systems that control the dilution of a concentrate product so the undiluted product cannot be practically accessed by users.

Closed Dilution-Control System Concentrate. Products that are designed to be used in closed dilution-control systems that cannot be practically accessed by users and spill resistant.

Drop Test. The primary package dropped from a height of 48 inches with 4 drops: flat-on-bottom, flat-on-top, flat-on-side, and corner.

Closed Dilution-Control Systems and Concentrates. Products that meet the definition for closed dilution-control systems (2.4) and concentrates (2.5) and the closed dilution-control system and concentrate packaging requirements (5.4) may be evaluated as-used for skin and eye irritation (4.2) and acute toxicity (4.1), but must meet the closed dilution-control concentrate labeling requirements in 6.5 and 6.7

Closed Dispensing-Control System and Concentrate Packaging: Products that are evaluated as outlined in 4.23, shall meet the following requirements for packaging and system design:

- *The primary package shall be a rigid plastic package.*
- *The primary package shall be durable as demonstrated by passing a drop test with the results that the packages must not leak, contents must be retained, and no damage to the outer package likely to adversely affect safety must be sustained.*
- *The closed dispensing-control system shall draw the product out of package, rather than using gravity.*

- *Backflow prevention that meets the American Society of Sanitary Engineering's (ASSE) 1055B standard shall be included in the closed dispensing-control system.*

Training. The product manufacturer, its distributor, or a third party shall offer training or training materials on the proper use of the product. This shall include step-by-step instructions for the proper dilution, use, consequences of improper use or improper dilution, disposal of the product, and the use and maintenance of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use. Product manufacturers shall make the appropriate product and/or equipment training information, including MSDSs and technical data sheets, available electronically as well as in hard copy.

Closed Dilution-Control Concentrate Labeling. Products that are evaluated as outlined in 4.23, shall meet the following labeling and communication requirements:

- *The MSDS shall include the applicable text "meets Green Seal's requirements for skin and eye irritation and oral toxicity at the as-used dilution"*

- *The web site of the certifying body listing certified products shall identify which products were evaluated as-used, and which health criteria were evaluated as-used.*

5.6 Heavy Metal Restrictions
Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be intentionally introduced. Further, the sum of the concentration levels of these metals present shall not exceed 100 parts per million by weight (0.01%); an exception is allowed for refillable packages or packages that would not exceed this maximum level but for the addition of recovered materials. Further, intentional introduction does not include the use of one of the metals as a processing aid or intermediate to impart certain chemical or physical changes during manufacturing, where the incidental retention of a residual of that metal in the final packaging or packaging component is not desired or deliberate, if the final packaging or packaging component complies with the incidental concentration restrictions of 100 ppm.

Comment:
Section 5.6 Will limit heavy metals to <100ppm in packaging materials
What form of data is needed for proof?

Response:
The packaging supplier must provide a written statement of content.

5.7 Other Restrictions
Phthalates are prohibited from being intentionally introduced; an exception is allowed for packages that would not have added phthalates but for the addition of recovered material.

Comment:
Section 5.7 Will prohibit Phthalates in package materials
What form of data is needed for proof?

> **Response**:
> The packaging supplier must provide a written statement of content.

6.0 Training and Labeling Requirements
Any general comments, questions or ideas pertaining to training and labeling requirements should be posted here.

Comment:
Manufacturers should be required to provide training on the use of their products. Some manufacturers have very good training programs and routinely offer them to facilities personnel. Other manufacturers do not. Training on the use of these products is essential for a successful program.

> **Response**:
> Training has been required for certification. This will continue, with the addition of a few best practices recommended by commenters.
>
> *Training. The product manufacturer, its distributor, or a third party shall offer training or training materials on the proper use of the product. This shall include step-by-step instructions for the proper dilution, use, consequences of improper use or improper dilution, disposal of the product, and the use and maintenance of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use. Product manufacturers shall make the appropriate product and/or equipment training information, including MSDSs and technical data sheets, available electronically as well as in hard copy.*

Comment:
All ingredients, including those in fragrances should be fully disclosed.

Comment:
We strongly believe that in addition to the many guarantees of safety the Green Seal certification offers, consumers have the right to know the complete list of ingredients in a cleaning product they purchase. Individuals have many different sensitivities to chemicals, which makes specific ingredient information crucial to avoiding potential health impacts. There may be some chemicals which cause allergies or other reactions in certain small segments of the population. While this may not be sufficient to justify

prohibiting the use of the chemical in all products, it is vital for those persons to be able to identify cleaners which contain the chemicals they wish to avoid. Currently there is very limited information on ingredients available to consumers on MSDS sheets. The Green Seal standards should require that all ingredients (at any concentration) be listed on the MSDS sheet for the product, and on the label of the product. Ingredients should be listed by their chemical name with an associated unique identifier such as a CAS #. WVE is working with the cleaning products industry to help move the household cleaning products industry in this direction. We believe it is essential that Green Seal take up this charge within the realm of industrial and institutional cleaners.

Comment:
Add labeling requirements for the toxic chemical content (Section 6.0)
Labeling should be added to require the list of toxic chemical ingredients contained in the product on their label for users to read. Additionally, all of the toxic chemical ingredients and their associated concentrations by weight percent should be posted with the product information on the Green Seal and product manufacturer website given on the label. We recommend that Green Seal require full-disclosure of ingredients listed on the MSDSs of certified products to be put on product labels

> **Response**:
> Some of the value of a certification program is that a third-party verifies that all the ingredients in a product meet the requirements in the standard (including many health end points such as sensitization). Many manufacturers find their ingredient lists proprietary and would provide too much information to competitors – there are some products with very few ingredients and thus would be easy to reproduce. Fragrance addition has been required on MSDSs and now will be required for labels to help with communication about that class of additives. Additionally, the MSDS regulation requires hazardous and carcinogen disclosure.

Comment:
Best practices for training should be added to the standard. Required training is made part of the vendor contracts for the Massachusetts EPP program. Language and literacy need to be addressed in the best practices and standard MSDSs should be required under the the new standard. A model for a standard format is the New Jersey (www.nj.gov/healthy/oeh/rtk).

> **Response**:
> Best practices were added to the training requirement. Labeling of multiple languages will continue to be required. Each manufacturer customizes how they meet this multiple language requirement based on their market and who uses the product (additional languages could be graphical, Spanish, Polish, Russian, French, etc.). There is not a universal best-practice for the additional language requirement, given the range of users, so this will remain a requirement, without standardizing the formatting for the additional language.

Training. The product manufacturer, its distributor, or a third party shall offer training or training materials on the proper use of the product. This shall include step-by-step instructions for the proper dilution, use, consequences of improper use or improper dilution, disposal of the product, and the use and maintenance of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use. Product manufacturers shall make the appropriate product and/or equipment training information, including MSDSs and technical data sheets, available electronically as well as in hard copy.

Comment:
GS website should provide direct links to the MSDSs for all certified products.

Comment:
All MSDS information should also be available on the GS website.

Response:
As a third-party certification organization, Green Seal has refrained from distributing any sales or marketing literature for the products and services certified. Green Seal does not get involved in pricing and does not post catalogs or product literature on our website. This also extends to Material Safety Data Sheets, which are considered technical literature and necessarily should be obtained directly from the product manufacturer. While Green Seal does maintain a file copy to ensure that the MSDS complies with any specific requirements in the applicable Green Seal environmental standard, such as the disclosure of an added fragrance, the file copy is not distributed to customers or purchasers since Green Seal would then be directly involved in the marketing/sale of a certified product.

The MSDS is a regulated document that is covered by the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR, Hazard Communication - 1910.1200, http://www.osha.gov/SLTC/hazardcommunications/standards.html). The legal obligations of preparing, keeping current and providing (as outlined under the Hazard Communication Standard) Material Safety Data Sheets are borne by the product manufacturer. Specific manufacturer requirements for making Material Safety Data Sheets available to employers, employees, customers and retail/wholesale distributors are provided in the Hazard Communication Standard. In the event of an emergency, it is imperative that users or medical professionals contact the manufacturer (the "responsible party") directly and not Green Seal, which is an error that also could occur if Green Seal were to distribute an MSDS.

Compliance with governmental rules is a requirement for certification by Green Seal (as noted in the Forward to each Green Seal environmental standard), and therefore manufacturers are expected to have Material Safety Data Sheets that comply with OSHA regulatory requirements. In addition to the OSHA MSDS enforcement program

(http://www.osha.gov/dsg/hazcom/MSDSenforcementInitiative.html), Green Seal can and does investigate any allegations of non-compliance regarding the Material Safety Data Sheets for certified products, but is unable to provide them directly.

6.1 Training
The product manufacturer, its distributor, or a third party shall offer training or training materials on the proper use of the product. This shall include step-by-step instructions for the proper dilution, use, disposal of the product, and the use of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use.

Product manufacturers shall make the appropriate product and/or equipment training information, including MSDSs and technical data sheets, available electronically as well as in hard copy.

Comment:
I strongly support this requirement.

Response:
Comment acknowledged.

Comment:
I strongly support this requirement with the addition of making the training accessible by providing training in the languages spoken at the worksite and with the appropriate literacy level. Training should be provided for all new employees and on an annual basis.

Response:
Training will remain a requirement, and included in the annual monitoring program for certification. However, facility responsibilities for training new employees and ensuring employees are using products correctly on an ongoing basis is not within the scope of this product standard, rather a part of a cleaning service standard.

6.2 Label Language
The manufacturer's label shall include English and another language or English and a graphical representation or icons in order to assist illiterate or non-English speaking personnel.

Comment:
Label Language: Experience has shown that the requirement for additional language is not edifying or useful. The current amount of information, typeface and font requirements for labels on registered products makes adding language to the label

impractical. Using a hanging tag to convey the information adds cost, creates waste, and does not assure that the information will be read by the user.

Comment:
Having the requirement for additional language should be eliminated, Where we have included it on registered products, we have been forced to use a hang tag, which adds cost and creates waste as the labels by and large are not used.

> **Response**:
> The additional language labeling requirement has proven to be useful by most users and will be retained.

6.3 Label Dilution Directions
The manufacturer's label shall state clearly and prominently that dilution with water from the cold tap is recommended and shall state the recommended level of dilution. Carpet cleaner labels shall specify the use of cold water for products that do not suffer significant performance degradation in cold water.

Comment:
At 6.3 of the Proposed Revised Standard ("Carpet cleaner labels shall specify the use of cold water for products that do not suffer significant performance degradation in cold water."), it is not the product degradation that matters, it is the fact that since the carpet is attached to the building which is attached to the ground, performance degradation is assured when the cleaning solution turns cold within seconds. Even if a detergent works well in hot water, it will chill in seconds and suffer dramatic performance degradation. Today, there are onechemical carpet cleaning processes that just need clean cold water for the final injection/extraction step. i.e. Pretreat, wait 20 minutes, and inject/extract using fresh cold water.

> **Response**:
> The water temperature used to pass the performance requirement is the temperature that should be labeled. Cold water is preferred, but if the product needed warm water, then warm water should be labeled.

Comment:
Directions: Green Seal should provide sample language that is acceptable. Past experience has resulted in misunderstanding and confusion resulting in review delays. This can be simplified with guidance in the standard.

Comment:
Green Seal should provide sample language that is acceptable. Past experience has resulted in misunderstanding and confusion resulting in review delays. This can be simplified with guidance in the standard.

Response:
Sample language is available by contacting Green Seal, but it will not be included in the standard's criterion to provide some flexibility for labeling (style, space).

6.4 Label Use and Disposal Directions
The manufacturer's label shall have clear disposal, recycling, reuse, or refill instructions, proper and clear directions for use, appropriate precautions and recommendations for the use of personal protective equipment.

Comment:
Nature works in a very simple way. Germs must live in soil for a continuous supply of food. Remove the soil removes the germs. Yet, my readings of the Green Seal Background Document and the Proposed Environmental Standards say it is OK to have up to 20% "left behind" soil. Germs are definitely living in the up to 20% of the soil that may be "left behind". Also, the "left behind" soil contains the original cleaning solution that, if not removed, will grab onto even more soil. Even though cold water detergents that get picked up well do not require a rinse step, it is not hard to understand that custodian performance will vary as to how well a washing solution is removed from a surface.
Therefore, when an optimally clean environment is the rule, a product label should recommend fresh cold water rinsing if a vacuum pickup is not used. Rinsing, as was the practice of our custodial forefathers, would use the detergent mixed in with the left behind soil to hopefully complete the soil removal process. Fresh cold water rinsing will go miles toward helping solve a facility's unhealthy environmental problems.
For those who may suggest the use of disinfectant-detergent cleaning solutions, they need to understand that if the surface to be disinfected is not first made free of soil (pre-cleaned), there will be surviving germs and many of the surviving germs will be resistant to the disinfectant and will propagate freely in the "left behind" soil. Not only is a germ-free surface virtually impossible to achieve, maintaining the sought-after condition would be impossible. Once a surface is touched (contaminated) physically or by airborne soil, the disinfecting treatment is rendered useless. So, why not just mop with a quality cold water detergent and rinse with fresh cold water. A rinse cycle will go a long way toward rendering the surface healthy.

Response:
Green Seal includes performance testing to ensure the product functions as designed. The need for water rinsing is not universal for all products. Many products are formulated to have no residue. As a result, cold water rinsing will not be added. Further, the label requirements include use directions as recommended by the manufacturer to ensure performance is achieved.

Comment:

Directions: Green Seal should provide sample language that is acceptable. Past experience has resulted in misunderstanding and confusion resulting in review delays. This can be simplified with guidance in the standard.

Comment:
Green Seal should provide sample language that is acceptable. Past experience has resulted in misunderstanding and confusion resulting in review delays. This can be simplified with guidance in the standard.

> **Response**:
> Sample language is available by contacting Green Seal, but it will not be included in the standard's criterion to provide some flexibility for labeling (style, space).

6.5 DSC Qualification Designation
When a dispensing-system concentrate product requires the allowed exemptions to pass the health criteria in the standard, a qualification designation will be made available on Green Seal's listing of certified products.

Comment:
The proposed standard allows for much higher concentrations of toxic chemicals in Dispensing System Concentrates (DSCs), which use an automated system to dilute the concentrate to the correct "ready to use" (RTU) form. Since all GS 37-certified products must be diluted with at least 32 parts water, these concentrates will be able to contain significant amounts of toxic chemicals and still pass. The exemptions are allowed - with the "qualification designation" that will be listed on Green Seal's website but unlikely to be viewed easily by consumers or end-users - for virtually all 14 relevant criteria with three exceptions for carcinogens, mutagens and reproductive toxins (Section 4.3), combustibility (4.12), and prohibited ingredients (4.13.1). All other criteria allow the exemption for dispensing-system concentrates to be tested in the "as used" dilution. These exemptions undermine the true intent of strengthening standards for oral toxicity, inhalation toxicity, skin and eye irritation, skin sensitization, skin absorption, and ingredients that cause asthma, among others.

As written, a dispensing system concentrate may contain up to 32% of each chemical that is known to be able to penetrate the skin, for example, and cause toxic effects; only after it is diluted, the concentration of these ingredients would be under 1%. As another example, these DSC's will be allowed to contain asthmagens at levels of .32% and higher, whereas regular concentrates will only be allowed to contain .01%. This DSC exemption poses an unacceptable health risk and creates a two-tiered standard.

The exemptions allowed for DSC's rely on the misguided assumption that workers or building occupants will never be exposed to unsafe levels of toxic chemicals as long as the products are used according to the automated dilution dispensing system. Yet exposures may occur whenever these products are not used as the manufacturer recommends, or if there are accidental spills or releases. Unfortunately, we know from

numerous accounts that accidents happen and workers sometimes cut open or puncture "tamper-resistant" bottles when the dilution equipment malfunctions, the wrong product is ordered, or they want a stronger solution. Moreover, after the water evaporates from the cleaning solution that has been applied to the floor, the chemicals of concern may remain as residues that can cause unsafe exposures. GS-37 contains few standards for these dispensing systems or the concentrates that go into them. Since we cannot predict how concentrated cleaning products will be used in the field, the prudent approach is to ensure that the concentrates themselves are as safe as possible while still performing well. Finally, while we generally support the use of concentrates and dispensing systems because they help reduce costs, exposures, and shipping impacts, we think that the DSC exemption may have the unintended negative consequence of discouraging the use of automated dispensing systems once end-users discover that these concentrates are more toxic than other Green Seal-certified products. If Green Seal is offering this exemption as a means of truly encouraging the use of dispensing systems, then perhaps it should simply require that all products be offered as dispensing system concentrates.

We recommend that the revised GS-37 standard eliminate the exemption for dispensing system concentrates throughout. The criteria should apply to the undiluted product.

Comment:
Consider embellishing the definition of "Dispensing System Concentrates" further; "These are products that are designed to be used in closed-loop dispensing systems specifically designed to eliminate exposure of the concentrate to the user when used according to directions." Allowing manufacturers to simply 'add water' to achieve certification without a qualification designation will result in certified products that contain more water and utilize more packaging materials. Manufacturers that choose to design and sell highly concentrated products utilizing dispensers that eliminate exposure during use in spill-proof, closed loop packaging will be penalized by the qualification designation.

It is important to understand the significant environmental lifecycle benefits of concentrated cleaners that utilize closed loop dispensing technology. Closed looped dispensing technology eliminates the toxicological and physical hazards generally associated with concentrates from the end user when used as directed. Additionally, these dispensing systems are environmentally beneficial from a lifecycle standpoint, reducing the amount of produced plastics (greenhouse gas savings, energy production savings, waste savings, recyclability, etc.), reducing the amount of water that needs to be shipped, and providing many other sustainability benefits.

Green Seal proposes to further designate certified products that are concentrates packaged in closed loop dispensing technology where the concentrate by itself may not meet Green Seal criteria. We believe that any 'further designation' needs to be abandoned or balanced in its description. Merely noting that the concentrate formula may not meet Green Seal criteria on its own is not sufficient. As previously stated, closed loop dispensing systems provide significant health and environmental lifecycle benefits that should also be communicated in any "further designation". Without such a

balanced approach, Green Seal will be communicating a message that is an inconsistent and incomplete sustainability message.

Alternatively, a "further designation" is not necessary. Simply allowing the classifications on the "as used" formulas will not increase the potential for adverse impacts.

Comment:
We are especially concerned that the standard would permit much higher concentrations of toxic chemicals in Dispensing System Concentrates (DSC's). Our program has found that custodial maintenance staff are often poorly trained or worse not trained at all in the use of cleaning chemicals. Also, many of our members have challenges with literacy in either English or Spanish and don't always have access to instructions in the appropriate language or at the appropriate reading level. We have seen several examples of dispensing systems being corrupted and concentrated products being used undiluted. In several cases, we have been told by our members who are custodial workers that they have even been encouraged to use products in the concentrated form because they will be able to clean "faster" or "better" with the concentrated product. And, the right to OSHA protection is only available to public employees in 27 states. Our custodians in public schools in non-OSHA state plan states such as Texas, Louisiana and Alabama have no right to training under the OSHA Hazard Communication Standard. Those custodians are not entitled to Material Safety Data Sheets (MSDS's) or the appropriate training on the proper use of chemicals. An exemption to dispensing systems may mean that countless numbers of custodians, other school staff and children will be potentially exposed to toxic chemicals when dispensing systems are improperly used.

Comment:
Assumes that Dispensing Systems eliminate exposure to product concentrates and adequately control mixing rates (applies to numerous sections throughout). The proposed standard allows for much higher concentrations of toxic chemicals in Dispensing System Concentrates (DSCs), which use an automated system to dilute the concentrate to the correct "ready to use" (RTU) form. Since all GS 37-certified products must be diluted with at least 32 parts water, these concentrates will be able to contain significant amounts of toxic chemicals and still pass. The exemptions are allowed - with the "qualification designation" that will be listed on Green Seal's website but is unlikely to be viewed easily by consumers or end-users - for virtually all 14 relevant criteria with three exceptions for carcinogens, mutagens and reproductive toxins (Section 4.3), combustibility (4.12), and prohibited ingredients (4.13.1). All other criteria allow the exemption for dispensing-system concentrates to be tested in the "as used" dilution. These exemptions undermine the true intent of strengthening worker health standards, particularly for acute toxicity issues such as skin and eye irritation, oral toxicity, and inhalation toxicity.

As written, a dispensing system concentrate may contain up to 32% of each chemical that is known to be able to penetrate the skin, for example, and cause toxic effects; only after it is diluted, the concentration of these ingredients would be under 1%. As another

example, these DSC's will be allowed to contain asthmagens at levels of .32% and higher, whereas regular concentrates will only be allowed to contain .01%.

The exemptions allowed for DSCs rely on the misguided assumption that workers have no opportunity for exposure to concentrated product when a DSC is used, either before or after the seal is broken on the container. Unfortunately, we know from numerous accounts that accidents happen and workers sometimes open, cut open or puncture bottles when the dilution equipment malfunctions, the wrong product is ordered, or they want a stronger solution. A precautionary approach to worker health would dictate that the most serious acute health hazards should still be limited in DSC products, no matter how effective the dispensing system. In the proposed GS-37, however, even concentrates that are corrosive to the eyes and skin can receive the Green Seal label via the "qualification designation."

The DSC exemptions also assume that workers will always mix the concentrates according to directions when using a dispensing system, without "double-pumping." While dispensing systems as a rule undoubtably increase the chance that products will be properly mixed, and while worker behavior can never be fully controlled, GS-37 provides an opportunity to promote systems that provide more effective mixing control. Keeping dilution rates down to prescribed levels protects not only workers but building occupants, who are exposed when the final product is used. There is a wide variety of dispensing systems available with vastly different levels of tamper resistance and dosage control (for example, one-touch buttons vs. pumps). The proposed new GS-37 requirement that "products that are designed to be used in dispensing systems that cannot be practically accessed by users" says nothing about the method of opening the concentrate container, its tamper resistance, or the method of dosage control used by the system. For example, it is not even clear under the proposed language whether standard thickness, screw-top jugs (similar to milk jugs) are acceptable containers for DS concentrates.

We support the use of concentrates and dispensing systems because they help reduce costs, worker exposures, and the climate change impacts of shipping. However, providing DSC exemptions as proposed is only acceptable if dispensing systems themselves are adequately protective, and with basic safeguards in place to protect workers against the serious acute effects of accidental exposure to the concentrate, and with clear differentiation in labeling (see next section). In other words, the GS-37 certification should be considered as a certifying not only the product itself, but also the packaging and dispensing systems. This is the only approach that can

If Green Seal is offering the DSC exemption as a means of encouraging the use of dispensing systems, then perhaps it should simply require that all products be offered as dispensing system concentrates.

We recommend that the revised GS-37 standard:
1) Include an operational and protective definition of "dispensing system" as a prerequisite for "qualification designation" (Section 6.5). The definition should require:
a) tamper resistance of the product container (this may include the relevant ASTM

standard for puncture-resistance);
b) the container be designed so that it can be opened only after installation in the dispensing system;
c) one-touch dosage control, either using a dial or button system;
d) containers capable of displaying precautionary statements in a prominent location
2) Remove the qualification designation option for skin and eye irritation for DSC products.

If these improvements are not made, we recommend eliminating the exemptions for dispensing system concentrates throughout, and eliminating the entire Qualification Designation Section (6.5).

Comment:
We agree that it is useful for the standards to be applied to the most concentrated form wherever there is meaningful risk of exposure to that concentration. It is a valid point that dispensing systems can be compromised by aggressive misuse, so even though the likelihood of abuse is low, it is important to remind users that concentrated forms can represent a hazard even where diluted solutions do not. There may be labeling guidelines or other methods of delivering this information that might not require that the many possible dangers of exposure to the concentrate be comprehensively analyzed and reported. It seems more than an unfortunate oversight to altogether ignore the potential danger of failing to disclose the possibility of toxic exposures through misapplication.

We also agree that it may be useful for Green Seal to provide guidance or standards for automatic dispensing systems.

Comment:
We applaud Green Seal for recognizing that children and other sensitive sub-populations should also be protected from exposure to toxic chemicals used in cleaning products, and therefore some of the product-specific health and environmental requirements such as oral and inhalation toxicity have become more protective for children. We believe that Green Seal should be more protective by requiring that the undiluted product instead of the product as used should meet all the product specific health and environmental requirements. In other words, dilution is not the solution to pollution with respect to hazardous substances in cleaning products. This would ensure that training material and labeling requirements are not the first line of defense against preventing exposure to concentrations that may not pass some of the toxicity testing. This approach would be consistent with other certification programs such as Design for the Environment (DfE) Formulator Program, which reviews every chemical/component in every ingredient of the formulated product and optimizes it with respect to green chemistry.

Comment:
I generally support the use of concentrates and dispensing systems because they help reduce costs, exposures, and shipping impacts. A significant savings comes from re-using quart-sized trigger bottles that are filled by the dispensing system.

Since we cannot predict how concentrated cleaning products will be used in the field, the prudent approach is to ensure that the concentrates themselves are as safe as possible while still performing well.

Therefore, I recommend that the revised GS-37 standard eliminate the exemption for dispensing system concentrates throughout. The criteria should apply to the undiluted product.

Comment:
I recommend that the revised GS-37 standard remove the exemption for dispensing system concentrates throughout the revised standard. The criteria should apply to the undiluted product. The two-tier system proposed in the revised standard will be misleading and confusing to end-users looking to buy the least-toxic, safest, yet effective products on the market. The two-tier system may force purchasers to choose between using more-toxic products for use in dispensing systems versus less-toxic products that are not.

Comment:
Dispensing System Concentrates - If the DSC is allowed, they should be clearly marked that they pass ONLY when diluted. Or test and certify dispensing systems

Comment:
We are concerned about the concentrate exemption for the dilution systems. The concentrates will contain significant amounts of toxic chemicals that will "pass" the GS 37 test under this requirement. Dispensing systems are better designed then they used to be, but are still subject to being damaged or mis-used which will then cause potential worker exposure to the concentrate. The concentrates should be tested for the relevant criteria as they are for the diluted products. This undermines the true intent of strengthening the standard to protect children's and workers' health by minimizing exposure to toxic chemicals.

Comment:
Our overarching concern is with regard to the approach that appears to be taken in the development of the proposed standard. Our approach to formulations has always been to consider the unintended impact of our formulations on human health and the environment. We have a system that is designed for control, minimum human exposure, accountability and effectiveness. We actively work with customers to direct and encourage proper use but realize that we cannot ensure proper use. The proposed standard has the approach that a dilution control system and instructions can actually prevent improper usage and therefore protect human health and safety.

1) In the sections listed, the following phrase is included, "Dispensing-system concentrates may be tested as used, but will require the qualification designation"

4.1 Oral Toxicity
4.4 Inhalation Toxicity

4.5 Skin Sensitization
4.6 Skin Absorption
4.7 Ingredients that Cause Asthma

It would seem to us that a great deal of weight is placed on "Dispensing-systems" as if they are the magic panacea that will eliminate all users from ever touching a concentrate. Though a manufacturer could make the packaging tamper resistant or possibly tamper evident, we are not aware of any manufacturers producing, or internationally accepted standard to define "tamper-proof" packaging in our industry. In the absence of absolute protection, the GS-37 standard must assume that all formulations have the potential to come into contact with humans and therefore the standard must apply one consistent criteria to all formulations.

As a friend to Green Seal, it is easy to imagine outside parties viewing this special treatment for the manufacturers as a reason to question the standard as a whole.

Comment:
I do not agree with the recommendation to have different labels for different green seal certified products, such as a label stating that only the diluted product meets the green seal standard for environmental and human health performance. People, including custodians, rarely read labels, and will not read this. Best practice is to put a safe product out and not to rely on messaging to ensure protection of health and safety.

Comment:
The products that are certified by Green Seal using the “dispensing system exemption” will receive the same Green Seal label, and will have an additional online-only “qualification designation.” This “qualification designation” will create a two-tier labeling system of which consumers will generally be unaware. There is no requirement that the packaging or MSDS notify users that only the diluted formulation passed the standard. In our view, this will be confusing and misleading to consumers and end-users. It will be difficult – if not impossible – for consumers to tell which products are devoid of highly toxic chemicals and which ones contain them but are masked with large amounts of water. Few purchasing agents are likely to go to the Green Seal website to determine which dispensing system concentrates passed based on multiple exemptions. Even if they do, we are concerned that this “double standard” will force them to have to choose between these more-toxic products that are designed to be used in closed-loop dispensing systems (that we otherwise want to encourage), and less-toxic products that are not. Finally, this two-tiered system rewards those more-toxic concentrates with the same Green Seal label, rather than rewarding those less-toxic concentrates that did not use the exemption - a perverse incentive, indeed.

We recommend that the proposed standard should apply to all undiluted concentrates equally and that the “qualification designation” in Section 6.5 be eliminated. If a “qualification designation” is to be used at all, it should only apply to a defined “Green Seal GOLD” set of products that are more protective of health and the environment. As it

stands, the “qualification designation” allows the Green Seal label to be downgraded to apply to more toxic products.

Comment:
The standard should not allow for higher concentrations of toxins through the exemption for Dispensing System Concentrates (the proposed standard applies to numerous sections throughout). The proposed standard should apply to all undiluted concentrates equally and that the “qualification designation” for Dispensing System Concentrates should be eliminated in section 6.5 be eliminated.

Comment:
We strongly oppose the two-tiered labeling system that only consists of a posting on Green Seal's website. Most end-users would never think to look there to find out whether a product only is considered green because it qualified for one or more of the DSC exemptions. And once they find out the product passed with multiple exemptions, they are likely to become disillusioned with the standard.

One option to consider if the standard does continue with a two-tiered system, is to require DCS to state "APPROVED--ONLY WHEN USED IN CLOSED LOOP DILUTION SYSTEMS".

Comment:
I would like to go on record that concentrates should not have the same seal of approval as non-concentrates. This is dangerously misleading, particularly in the case of spills and leaks, or illiterate employees.

Concentrates should have a separate seal of approval, with the designation "APPROVED--ONLY WHEN USED IN CLOSED LOOP DILUTION SYSTEMS"

Comment:
We have some reservations that the proposed standard allows an exemption for Dispensing System Concentrates. Notwithstanding any multi-tier labeling system, this exemption has the potential to mislead the purchaser into believing that dangerously high concentrations of a corrosive or an irritant in its undiluted form is certified as an environmentally preferred cleaning product according to Green Seal standards. For example, a Green Seal certified product’s that is sold as a Dispensing System Concentrate MSDS states that the product in its undiluted form fails Green Seal’s skin and eye irritation, and combustibility criteria. However, under the proposed standard this product would receive an exemption because it would be *tested as used*. The potential for exposure to this product in its concentrated form from a spill or an accident still exists.

We appreciate that an argument can be made for the environmental benefits of concentrates in reduced packaging, transportation and waste generation. Ultimately, however, we are looking for the industry to reformulate, not just dilute, their products for green performance. We recommends that the revised GS-37

standard eliminate, or at least phase out, any exemption provided for dispensing system concentrates. The criteria should apply to all undiluted concentrates equally and that the "qualification designation" in Section 6.5 should be eliminated.

Comment:
We are opposed to the exemption given to allow higher concentrations of toxic chemicals in undiluted Dispensing System concentrates. This element of the standard seems antithetical to the goals of the GreenSeal program. Ideally, Green Seal certified products should be inherently safe in all their formats, not simply their diluted versions. The exclusion just for automated dispensing systems assumes that these dispensing systems would always operate correctly thus leaving no opportunity for exposure to workers. Experience shows that no dispensing system is perfect all the time. In addition these systems require reloading, where spills or other accidents leading to exposure could easily occur. Cleaning workers and their supervisors would be given the false impression that the chemicals they are using are safe, when they would in fact pose a health hazard in their undiluted form. This is unacceptable for Green Seal certification and should be changed in the final revision of these standards.

Comment:
The products that are certified by Green Seal using the "dispensing system exemption" will receive the same Green Seal label, and will have an additional online-only "qualification designation." This "qualification designation" will create a two-tier labeling system of which consumers will generally be unaware. There is no requirement that the packaging or MSDS notify users that only the diluted formulation passed the standard. In our view, this will be confusing and misleading to consumers and end-users. Few purchasing agents are likely to go to the Green Seal website to determine which dispensing system concentrates passed based on multiple exemptions.

We recommend that the two tiers of the proposed standard should be clearly identified on product packaging and MSDSs, with the note: "This product passes GS-37 standards in its dilute form" or "This product passes GS-37 standards in its concentrated form."

Comment:
We oppose the proposed revisions in Sections 4.1, 4.2, 4.5, 4.6, and 4.7 that would require the undiluted product to be evaluated whether the product is designed to be used in a dispensing system or not. Further we oppose the proposed approach in the aforementioned sections that would provide an exception provision that allows the dispensing system concentrate (DSC) to be evaluated as used, but which would require the DSC to bear a qualified designation.
Green Seal's stated objective for these proposed revisions is the health and safety of custodians and children who may come into contact with the concentrated product. While we agree that this objective is a laudable one, we believe that it can be achieved through a more pragmatic approach that recognizes the substantial benefits of DSCs dispensed through systems that render the concentrated product inaccessible to the user.
A. DSCs and Dispensing Systems. First, Green Seal's proposed revision that would

require DSCs to be evaluated in the undiluted state ignores the significant environmental and safety and health benefits that derive from the use of highly concentrated products that use dispensing systems that effectively eliminate exposure to users and others, including children.

The benefits alluded to derive from both the concentrated product itself and the dispensing systems as well.

Using sophisticated dispensing systems allows manufacturers to design and formulate highly concentrated products that provide a number of environmental benefits, especially when one considers the issue from a lifecycle perspective. Highly concentrated products drastically reduce the amount of plastics used in packaging. This single benefit alone results in reductions in greenhouse gas production, savings related to energy production, and reduced waste. Further such products also substantially reduce the weight of the product shipped, which in turn results in further energy savings and lower transportation costs.

Secondly, Green Seal's proposed approach discounts the significant benefits that derive from the use of dispensing systems. In fact, the use of dispensing systems provides us with a number of environmental and safety and health benefits.

Over the years, these systems have evolved into more sophisticated units that are specifically designed to eliminate exposure of the concentrate to the user and others. Moreover, dispensing systems ensure that the product is used in its proper dilution. This attribute ensures that custodial workers are not using the product in greater concentrations than intended by the manufacturer. In the absence of dispensing systems, all too often custodians and other workers believe that "more is better" and tend to use more of the product in water than that which is called for by the manufacturer. This situation creates waste, raises safety and health concerns, and may negatively affect product efficacy.

By rendering proper dilutions, dispensing systems generate a number of environmental and safety and health benefits. First they reduce waste through overuse of the product that may occur in the absence of dispensing systems. Furthermore, dispensing systems reduce exposure of custodians and others to greater concentrations of the product "as used" in water, than that which is recommended by the manufacturer's label. This ensures the safety and health of workers and others that may be so exposed.

Additionally, proper dilutions ensure the efficacy and performance of the product. Cleaning products are specifically formulated to be used at recommended dilutions and are most efficacious when used as directed. Conversely, use of greater concentrations of the product than recommended by the manufacturer is likely to negatively affect the product's performance. Moreover, use of greater concentrations often results in product residue remaining, which may itself raise certain safety and health concerns.

B. DSCs and Qualified Designations. Furthermore, we oppose Green Seal's proposed approach that would provide an exception that allows the dispensing system concentrate (DSC) to be evaluated as used, but which would require the DSC to bear a qualified designation.

This proposed approach essentially penalizes manufacturers who have invested in research and development, formulations, manufacturing processes and closed loop dispensing systems that render substantial environmental and safety and health benefits as described above. It would in effect brand their products in the marketplace with the proverbial "Scarlet Letter A" should they select an option that they have rightfully relied

on under the existing GS-37.
Additionally, the qualified designation approach to DSC's evaluated as used in effect creates a de facto two tier standard. This approach clearly would establish two distinct tiers of GS-37 certified products: one with the DSC qualified designation; and one without such designation.
A two tiered approach to GS-37 was soundly opposed by the GS-37 Stakeholder Committee at its September meeting as an approach that would cause confusion in the marketplace and therefore be rejected by institutional and industrial purchasers. For this reason, manufacturers likewise agreed they would reject such an approach. In addition, Green Seal representatives present at the September meeting of the Stakeholders Committee likewise concurred that this approach was not to be pursued.
For these reasons, we urge Green Seal to not pursue an approach that would provide an exception that allows the dispensing system concentrate (DSC) to be evaluated as used, but which would require the DSC to bear a qualified designation.
C. Recommendations. In lieu of the proposed approach Green Seal has taken in reference to DSCs, we recommend that Green Seal continue to allow DSCs to be evaluated as used. However to ensure added protection for custodial workers, children and others, we recommend that Green Seal revise the definition of DSCs to ensure that dispensing systems are used that render the undiluted product inaccessible. Specifically we recommend the following amendments to the proposed revisions of GS-37:
1. Revise 4.1, 4.4, 4.5, 4.6, and 4.7 by deleting the sentence in each of the aforementioned sections that currently states: "Dispensing system concentrates may be tested as used, but will require the qualification designation (see Labeling section 6.5)."
2. Add the following as the second sentence to each of the aforementioned sections: "Dispensing system concentrates shall be tested as used."
3. Revise the definition of Dispensing System Concentrate to be consistent with 5.4.2: "These are products that are designed to be used in dispensing systems that render the undiluted product inaccessible to the user."
4. Delete section 6.5 in its entirety.

Comment:
DSC Qualification Designation: The dispensing system requirement should specify a closed loop dispensing package that eliminates exposure to concentrates during use.

Comment:
Exemption for dispensing system concentrates (Sections throughout)
Criteria for health risks should apply to the undiluted product. Eliminate exemptions for dispensing system concentrates throughout.

Comment:
Consider embellishing the definition further; "These are products that are designed to be used in closed-loop dispensing systems specifically designed to eliminate exposure of the concentrate to the user when used according to directions." Allowing manufacturers to simply 'add water' to achieve certification without a qualification designation will result in certified products that have contain more water and utilize more packaging materials. Manufacturers that choose to design and sell highly concentrated products utilizing

dispensers that eliminate exposure during use in spill-proof, closed loop packaging will be penalized by the qualification designation.

It is important to understand the significant environmental lifecycle benefits of concentrated cleaners that utilize closed loop dispensing technology. Closed looped dispensing technology eliminates the toxicological and physical hazards generally associated with concentrates from the end user when used as directed. Additionally, these dispensing systems are environmentally beneficial from a lifecycle standpoint, reducing the amount of produced plastics (greenhouse gas savings, energy production savings, waste savings, recyclability,etc.), reducing the amount of water that needs to be shipped, and many other sustainability benefits.

Green Seal proposes to further designate certified products that are concentrates packaged in closed loop dispensing technology where the concentrate by itself may not meet Green Seal criteria. We believe that any 'further designation' needs to be abandoned or balanced in its description. Merely noting that the concentrate formula may not meet Green Seal criteria on it's own is not sufficient. As previously stated, closed loop dispensing systems provide significant health and environmental lifecycle benefits that should also be communicated in any 'further designation'. Without such a balanced approach, Green Seal will be communicating a message that is an inconsistent and incomplete sustainability message.

Alternatively, a 'further designation' is not necessary. Simply allowing the classifications on the 'as used' formulas will not increase the potential for adverse impacts.

Comment:
The dispensing system requirement should specify a closed loop dispensing package that eliminates exposure to concentrates during use.

Response:
Green Seal acknowledges the environmental benefits of concentrating products and the user benefits of dispensing system concentrates. This is why Green Seal includes a concentrate definition and requirement in this standard and has tried to permit highly concentrated products in dispensing systems with the appropriate protection for users.

Concentration of cleaning products, however, may increase hazards. The point at which the concentration impacts the product's hazards differs from product to product due to the range of chemistries used. There isn't a way to "buffer" the formula to minimize the hazards. Diluting such products to a level at which they would be able to meet all criteria in their new concentrate levels, rather than as-used, may not mitigate against all health hazards (ex. asthma causing) and at the same time create new concerns such as adding cost to the user (due higher product and transport cost), the environment (more greenhouse gas emissions, water use,

packaging waste, and petroleum use for packaging and distribution), and effect the industry with fewer formula options and innovation options. While other certification programs (ex. EcoLogo) allow ready-to-use products to encourage dilution as a solution to overcoming health hurdles they also do not evaluate sensitivity issues like skin and asthma to result in products with greater, rather than less, health concerns. Further, this approach also overlooks the significant life cycle and environmental benefits and user benefits of concentrating products. There is not a means to provide guidance on concentration requirements different from what is already in the standard because chemistries differ from product to product. However, it is known that most products that are packaged in this format are in the range of 1:1256, 1:582, 1:256, 1:128, 1:88 (vs. 1:32, 1:64 for hand dilutable products).

So, as-used evaluation allowances will be permitted for some of the health criteria that otherwise would be evaluated at the fully concentrated level (provided the product meets the other criteria related to dispensing systems, described below). These are for skin corrosion/severe eye irritation and acute toxicity. There was concern that non-green products could be packaged for dispenser use and pass – this is not the case since the product must pass all the other criteria in the standard, including sensitization concerns (skin, asthmagen) undiluted, along with all the other criteria in the standard.

Manufacturers were consulted and other health concerns were not raised. As a result, the as-used evaluation option shall only be available for those criteria. This results in the skin sensitization as used evaluation option being removed from the current version of GS-37. The evaluation for certification will assume the as used evaluation is not needed, until it is determined so. All ingredients in the product will be evaluated for all the criteria in the standard. As a result, the manufacturer, and communication about the product, will know which hazards needed the as used evaluation. It is recognized that there are highly concentrated products packaged in dispensing systems that can meet all the criteria without the as used evaluation.

While Green Seal has not allowed hand dilutable or any products that are accessible by the user (example given by commenter was a milk jug type design) to be evaluated as dispensing system concentrates, this will be clarified in the definition of these products, including a name change to closed dilution-control systems and concentrates. Since this is not a change in requirements, there should not be an impact to industry or systems out in the field.

Some packaging has had tampering and durability issues, which has resulted in the user being exposed to concentrated product. It is recognized that users can misuse the products, and often this is through forcefully accessing the package by puncturing. As a result, the packaging requirements for the dispensing systems were modified to provide the following necessary protections:

- Spill resistance: added to the definition of these products, which usually means a package has a cartridge at the opening to match with a mating/coupling device in the system; ensuring the system doesn't rely on gravity for dispensing, with higher probability for leaking, rather uses a draw-out mechanism which is the most widespread means of dispensing in industry.
- Durability measures on the primary package: by requiring a rigid plastic package since flexible films have been easier to tamper with; tested with a drop test similar to transportation testing.
- System requirements for back flow protection as suggested.

While, Green Seal cannot regulate how the products are used and systems maintained the field, training and labeling requirements were strengthened as a means ensure that communication is being done to minimize such use issues.

Communication about which products were evaluated in this way will be transparent since purchasers need this information as they look to bids and purchase contracts. This will be done, as was suggested by manufacturers, through the basis of certification statement on the package and MSDS. In addition, Green Seal's list of certified products on the web site will identify which products were evaluated as used and for which criteria. This does not create a two-tier standard, rather clarify how all products met the standard.

It is recognized that not all products packaged as dispensing systems will meet the packaging requirements outlined above, so it will be reiterated that only products that have been concentrated to the point that the hazards for skin/eye corrosion and acute toxicity require an as used evaluation must meet the described modifications (for packaging, labeling, etc.). There are already products in the marketplace that meet the health requirements without the as used evaluation and are packaged as dispensing systems.

As described above, the following modifications were made to the standard:

Definitions:
Closed Dilution-Control System. Systems that control the dilution of a concentrate product so the undiluted product cannot be practically accessed by users.

Closed Dilution-Control System Concentrate. Products that are designed to be used in closed dilution-control systems that cannot be practically accessed by users and spill resistant.

Drop Test. The primary package dropped from a height of 48 inches with 4 drops: flat-on-bottom, flat-on-top, flat-on-side, and corner.

Health Requirements:

Closed Dilution-Control Systems and Concentrates. Products that meet the definition for closed dilution-control systems (2.4) and concentrates (2.5) and the closed dilution-control system and concentrate packaging requirements (5.4) may be evaluated as-used for skin and eye irritation (4.2) and acute toxicity (4.1), but must meet the closed dilution-control concentrate labeling requirements in 6.5 and 6.7

Packaging Requirements:
Closed Dispensing-Control System and Concentrate Packaging: Products that are evaluated as outlined in 4.23, shall meet the following requirements for packaging and system design:

- *The primary package shall be a rigid plastic package.*
- *The primary package shall be durable as demonstrated by passing a drop test with the results that the packages must not leak, contents must be retained, and no damage to the outer package likely to adversely affect safety must be sustained.*
- *The closed dispensing-control system shall draw the product out of package, rather than using gravity.*
- *Backflow prevention that meets the American Society of Sanitary Engineering's (ASSE) 1055B standard shall be included in the closed dispensing-control system.*

Training and Labeling Requirements:
Training. The product manufacturer, its distributor, or a third party shall offer training or training materials on the proper use of the product. This shall include step-by-step instructions for the proper dilution, use, consequences of improper use or improper dilution, disposal of the product, and the use and maintenance of equipment, as well as recommended personal protection equipment for each stage of the product or equipment's use. Product manufacturers shall make the appropriate product and/or equipment training information, including MSDSs and technical data sheets, available electronically as well as in hard copy.

Closed Dilution-Control Concentrate Labeling. Products that are evaluated as outlined in 4.23, shall meet the following labeling and communication requirements:

- *The MSDS shall include the applicable text "meets Green Seal's requirements for skin and eye irritation and oral toxicity at the as-used dilution"*
- *The web site of the certifying body listing certified products shall identify which products were evaluated as-used, and which health criteria were evaluated as-used.*

Statement of Basis for Certification. Whenever the Green Seal certification mark

appears on a package, the package shall contain a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

> *"This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content."*

If the product was evaluated as outlined in 4.23, the description shall read as follow:

> *"This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content, with skin and eye irritation and oral toxicity met at the as-used dilution". [whichever health criteria apply to the product]*

6.6 Certification mark
The Green Seal Certification Mark may appear on the packaging and may appear on the product itself. The Green Seal Certification mark shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the certification.

Comment:
Make the following addition, which I've noted in capitals. I have often been frustrated by having in hand either the packaging or the product and finding different levels of labeling information on them. It would benefit the users to see the mark on both packaging and product.

6.6 Certification Mark. The Green Seal Certification Mark may appear on the packaging and may appear on the product itself. HOWEVER, IF THE GREEN SEAL CERTIFICATION MARK IS USED, IT MUST APPEAR ON BOTH THE PACKAGING AND THE PRODUCT ITSELF. The Green Seal Certification mark shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the certification

> **Response**:
> Green Seal is a voluntary program. The use of the certification mark, thus, is voluntary.

6.7 Statement of Basis for Certification
Whenever the Green Seal certification mark appears on a package, the package shall contain a description of the basis for certification. The description shall be in a

location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

"This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content."

Comment:
1. The draft statement mentions using the Statement in conjunction with logo use *on a package* but not elsewhere. Does this mean that the Statement is not going to be required in conjunction with logo use in marketing, etc.? If not, this should be clarified.

2. If any other logo use rules (such as print color, etc.) apply to the statement as well as the logo, consider mentioning that in this section.

3. I much prefer the new draft basic certification statement to the previous statement.

Response:
Reference to the rules of using the mark and statement of basis for certification are already included in the standard (in the Forward). The rules are also accessible on Green Seal's web site.

Comment:
This claim: "This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content." may be misleading for DSCs that have used multiple exemptions to qualify. For example, if the VOCs are based on the diluted formulation, the concentrate may be similar to conventional products.

Response:
This has been clarified as follows:

Statement of Basis for Certification. Whenever the Green Seal certification mark appears on a package, the package shall contain a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable. Unless otherwise approved in writing by Green Seal, the description shall read as follows:

> *"This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content."*

If the product was evaluated as outlined in 4.23, the description shall read as follow:

> *"This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content,*

with skin and eye irritation and oral toxicity met at the as-used dilution". [whichever health criteria apply to the product]

Addendum
GREEN SEAL CRITERIA FOR VERIFICATION OF OPTIONAL CLAIMS FOR GS-37 CERTIFIED CLEANERS

A. SCOPE

This criteria document establishes environmental requirements for optional verified claims on GS-37 certified products.

There is emphasis on demonstrated leadership in the following environmental impact areas: energy reduction, waste reduction, resource minimization (including water), emissions reduction, and biodiversity conservation.

B. DEFINITIONS

B.1 Biobased: The content of a product that is from biological products or renewable materials, forestry or agricultural materials (including plant, animal, and marine materials).

B.2 Carbon offsets: Mitigation of greenhouse gas emissions generated using reduction measures that may be purchased from a third-party carbon offset provider.

B.3 Fragrance: An additive, often (but not limited to) a multi-component additive, used in a product with the purpose of changing the scent of the product.

B.4 Greenhouse gas (GHG): Components of the atmosphere that contribute to the greenhouse effect including water vapor, carbon dioxide, methane, nitrous oxide, sulfur hexafluoride, hydrofluorocarbons, perfluorocarbons, chlorofluorocarbons, and ozone.
B.5 Ingredient: Any constituent of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.
B.6 Renewable energy: Energy from non-depleting sources and derived from natural processes that are replenished constantly including wind, solar, water, geothermal, and biofuels.
B.7 Waste: By-products from the manufacturing of the product and package not included in the finished product that are not salable and are disposed, including wastewater.

C. CLAIM CRITERIA

C.1 No Added Fragrance: A product will be verified to contain no added fragrance when no fragrance ingredients are in the product. However, this does not imply that the product has no scent or odor.

C.2 Manufactured with Green Energy: A product shall be verified to be manufactured with green energy if the energy requirements for product and package production were directly fueled with a minimum of 75% renewable energy, not including any renewable energy certificate purchases.

C.3 Made with Zero Waste: A product shall be verified to be manufactured with zero waste when there was no disposal of waste (solid or water) during the production of the product and package. Responsible material management can be done within the company or with proven partnerships to result in zero net waste.

C.4 Made with Zero GHG Emissions: A product shall be verified to be manufactured with zero greenhouse gas emissions when there is no net GHG emissions during production of the product and package. This can be achieved within the company, with proven partnerships, or through carbon offset programs. If a carbon offset program is used for 100% of the emissions, a successful emissions reduction program must be demonstrated, with 10% or greater annual reductions in emissions.

C.5 Biobased Product: A product is verified to be a biobased product when its biobased carbon content is determined to be at least 50% of the total carbon, as determined with the ASTM International Radioisotope Standard Method D6866. Alternatively, the biobased components shall comprise at least 50% of the total weight of product, minus product water content, as determined with ingredient information.

D. LABELING REQUIREMENTS:

D.1 The verified claim may only appear on packaging, literature, or marketing materials for GS-37 certified products.

D.2 The verified claim shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the verification.

D.3 Whenever the verified claim appears on a package, the package shall contain a description of the basis for the claim verified along with the description of the basis of certification. The description shall be in a location, style, and typeface that are easily readable; shall be on the same side of the product label as the Green Seal certification mark; and not detract from the Green Seal certification mark. Unless otherwise approved in writing by Green Seal, the description shall, as applicable, read as follows:

No Added Fragrances: This product meets the Green SealTM environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also verified by Green Seal to contain no added fragrance ingredients.

Made with Green Energy: This product meets the Green SealTM environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also was verified by Green Seal to have been manufactured with at least 75% renewable energy.

Made with Zero Waste: This product meets the Green SealTM environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also verified by Green Seal to have been manufactured in a process that produced no net water or solid waste.

Made with Zero GHG Emissions: This product meets the Green SealTM environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content . This product was also verified by Green Seal to have been manufactured with no net greenhouse gas emissions.

Biobased Product: This product meets the Green SealTM environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also verified to contain at least 50% biobased components.

Comment:
With the additional optional criteria in the addendum available to manufacturers, it should be clarified here how their Statement(s) would read. It should not be assumed how manufacturers are do deal with now up to 5 Statements. For instance, if one was to take the Standard at face value and hold to the rules, one could have an additional paragraph on their packaging that reads, "This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also verified by Green Seal to contain no added fragrance ingredients. This product was also was verified by Green Seal to have been manufactured with at least 75% renewable energy. This product was also verified by Green Seal to have been manufactured in a process that produced no net water or solid waste. This product was also verified by Green Seal to have been manufactured with no net greenhouse gas emissions. This product was also verified to contain at least 50% biobased components." OR it could read "This product meets the Green Seal™ environmental standard for industrial and institutional cleaners based on its reduced human and environmental toxicity and reduced volatile organic compound content. This product was also verified

by Green Seal to contain no added fragrance ingredients, to have been manufactured with at least 75% renewable energy, to have been manufactured in a process that produced no net water or solid waste, to have been manufactured with no net greenhouse gas emissions, and to contain at least 50% biobased components."

Comment:
If there is to be an optional "No Added Fragrance" claim, a category for it should be included in the scope. As it stands right now, fragrances are not covered (at least not clearly).

Reference SCOPE: "There is emphasis on demonstrated leadership in the following environmental impact areas: energy reduction, waste reduction, resource minimization (including water), emissions reduction, and biodiversity conservation."

Comment:
Based on work conducted for biobased cleaners at the Toxics Use Reduction Institute, the definition of a biobased material that is currently being used (U.S. government definition) may pose some problems. In some situation, biobased products with over 50% biobased content may pose work place hazards (i.e. slips) due to the high content of certain biobased products.

In addition, it is important to reward companies for utilizing biobased materials in their products. Perhaps the establishment of various levels of biobased content, such as <25%, <50%, >50% would allow for more products to be rewarded for using bio-based materials. This is a field where any little bit helps to make the case for using biobased products.

Comment:
I recommend:
1- Define "renewable materials" in the Addendum. The term "renewable materials" is used within the definition for "biobased." It is recommended that Green Seal also include a definition for "renewable materials" to ensure there is no misuse of the intent of the term "renewable materials." (e.g. some people argue petroleum is a renewable material)

2- Require biobased products seeking verification from Green Seal as part of GS-37 to verify that the biobased materials were harvested in a sustainable manner.
While many advocates consider biobased better no matter the harvest/extraction method, to not require biobased materials to be harvested in a sustainable manner would be short-sighted – especially as part of a green product standard. If Green Seal does not feel there are adequate standards to reference for determining whether a biobased product is harvested/extracted in a sustainable manner, then it is recommended that Green Seal remove biobased from the list of optional claims for verification as part of GS-37.

3- Expand definition of "carbon offsets" to reference a third-party certification of the offset. While the current definition of carbon offsets references purchasing the offset

from a third-party carbon offset provider, it does not specify whether the offsets themselves have been third-party certified (by organizations such as Green-e). If Green Seal determines that specifying third-party certified offsets is unreasonable, then it is recommended that Green Seal either a) further specify what constitutes a valid carbon offset or b) remove carbon offsets from the list of methods within the "made with zero GHG emissions" claim criteria.

Comment:
Although it is admirable that Green Seal wants to reward manufacturers for pursuing additional measures of sustainability, the addendum does not provide sufficient information on standards for meetings these claims, how these claims will be audited by Green Seal, and precisely what level of detail will be necessary to make these claims. Issues such as Green Energy can become exceedingly complicated when addressing confounding factors such as double counting and additionality. For instance, the Green-e document that specifies customer disclosure requirements under the Green Seal Green Energy certification program is 38 pages in length. For Green Seal to offer credible certification of Green Energy, Zero Waste, and Zero GHG Emissions, a substantial amount of additional information is necessary. There are many other entities that provide certification for many of these attributes and they provide very detailed and complex criteria.

Establishing criteria that, when compared with criteria developed by other entities, are vague and susceptible to potentially subjective interpretation is a troublesome aspect of the approach taken. The fact that the criteria in the Addendum apply to optional verified claims on GS-37 certified products does not mitigate the responsibility of Green Seal to articulate unambiguous criteria so that these standards are of the same caliber as the other highly qualified and recognized standards generated by other entities.

Comment:
Many of the optional claims being proposed are either currently under review (USDA is designating the biobased content of many product categories such as glass cleaners, bath and tile cleaners), or are considering guidelines for making such claims (the Federal Trade Commission is looking at carbon offsets). At this time, we recommend that Green Seal avoid using these claims until guidance is established by government.

Comment:
While it is admirable that Green Seal wants to reward manufacturers for pursuing additional measures of sustainability, the addendum does not provide sufficient information on standards for meetings these claims, how these claims will be audited by Green Seal and precisely what level of detail will be necessary to make these claims. Issues such as Green Energy can become exceedingly complicated when addressing confounding factors such as double counting and additionality. For instance, the Green-e document that specifies customer disclosure requirements under their Green Energy certification program is 38 pages in length. For Green Seal to offer credible certification of Green Energy, Zero Waste, and Zero GHG Emissions, a lot of additional information is necessary. There are many other bodies that provide certification for many of these

attributes where the criteria are very detailed and complex. Green Seal's strength lies in its ability to assess the chemicals used to make products. We believe it is in the best interest of all stakeholders to focus on these strengths.

The casual approach taken to include these criteria is troublesome and riddled with potential subjective treatment versus other highly qualified and recognized standards that already exist.

> **Response**:
> Green Seal appreciates the input on the optional claims. These will not be included in the Draft Final Revised Standard since will be available to all certified products/standards as a separate program. However, no-added fragrance verification was incorporated into the standard, rather than being a separate claim.

General Comments
Any general comments about the proposed standard shall be included here.

Comment:
We would like to commend Green Seal for strengthening the standard for Industrial and Institutional Cleaners (GS-37), in particular the oral and inhalation toxicity provisions of the standard and adding criteria designed to limit ingredients known to cause asthma.

> **Response**:
> Comment acknowledged.

Comment:
We recognize that Green Seal plays a very critical role providing information to consumers in the absence of federal law regarding green cleaners. While current Proposed Revised Standard for GS-37 does include new provisions that will help address some issues of concern, it does not meet all criteria for properly protecting children's and workers' health by minimizing exposures to toxic chemicals.

Please act to protect the health and safety of at risk populations in institutional settings like schools, day care facilities, nursing homes, hospitals and other facilities by adopting the precautious recommendations outlined for those most vulnerable.

Comment:
Independent certification such as Green Seal serves a critical role in ensuring products that meet strong, credible, and meaningful criteria to protect and reduce risks to occupants from harm. GS-37 is an important certification that will be used for environmentally preferable products by government agencies, businesses, schools, hospitals and other institutions. GS-37 is also of importance since it is to be integrated into many "green" building credits from organizations including the US Green Building Council, the Collaborative for High Performance Schools, and others.

In our view, while the current Proposed Revised Standard for GS-37 does include many important new provisions that help address some issues of concern, it does not contain all the criteria necessary to adequately minimize exposures to toxic chemicals. We have multiple serious concerns about the proposed revised standard. The following outline our key concerns. We would like to emphasize that we look forward to continuing to work with Green Seal Staff and other stakeholders in this process to finalize the criteria. We believe that there is more work to be done and we have tried to be as specific as possible to provide you with what areas need to be addressed per the listed items

Response:
Careful review of all health considerations were made throughout the development of the standard. Further, careful consideration was given to how vulnerable populations are affected. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products. One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products rather than attempting to determine risk-based acceptable levels. Further this approach was taken when some areas did not have adequate progress, methods or data, to allow for criteria – as a result known chemicals of concern were explicitly prohibited.

Comment:
The health hazard definitions and portions of this proposed standard do not include necessary elements of exposure and risk assessment. The mere presence of a component at at trace level (0.01%) in a product does not equate with elevated health risk and overexposure potential to the individual using the product. The standard should incorporate currently recognized scientific methodology for appropriate risk and exposure characterization, rather than utilizing an unrealistic 0.01% cutoff for predicting health hazard potential.

This standard will end up increasing the amount of animal testing required for classification, not minimize it.

Response:

Green Seal uses the level of an ingredient at 0.01% to promote a higher level of performance than required by OSHA (0.1%). Several states already have more stringent reporting requirements under their right-to-know laws. For example, California's Proposition 65 requires reporting of hazardous substances that are present above any detectable amount. Massachusetts requires extraordinarily hazardous substances be reported if they are present at a level of 0.0001% or greater. The Pennsylvania right-to-know law requires special hazardous substances be reported at a 0.01% level or greater.

Green Seal requires all manufacturer's to disclose the added components (including fragrances) for evaluation. Green Seal staff works with a company's suppliers to ensure all the information is available, to help level the playing field. This has been done for the current version of GS-37 and has not been in issue for the hundreds of currently certified products.

Further, this standard represents an environmental leadership standard that must provide protection to vulnerable populations. Such populations are not adequately represented by risk assessment evaluation and thus a more precautionary/hazard-based approach is needed. Further, existing data continue to be used for evaluation to the criteria in the standard, and there are no new criteria that require new data sources or any additional means for testing. So data availability is not an issue. Finally, this approach has been used without issue for the hundreds of certified products.

Comment:
You might refer to the definitions in certain criteria to help the reader know where to go for information on compliance. For example, Criterion 4.3 says that "the undiluted product shall not contain any ingredients or intentional components that are carcinogens, mutagens or reproductive toxins." It would be helpful to refer to the definitions of carcinogens, mutagens and repro toxins where the criteria are laid out. In general, the document needs to be reviewed to ensure that all key terms have definitions.

Response:
Comment acknowledged.

Comment:
What happens to products that were certified as meeting the earlier edition of GS-37, but do not meet the new requirements once these are adopted?

Will there be a transition period where already-manufactured products with a 'no-longer-valid' certificate are allowed to move through the supply chain?

Comment:
Transition to Revised GS-37 Standard and Certifications
We are very concerned that, to date, Green Seal has failed to address a critical element in relation to the proposed revisions to GS-37 that is not only of the utmost importance to industry, but which also has significant implications for Green Seal as well.
Specifically we are alluding to the fact that nowhere in this process has the issue of how

we transition to the revised GS-37 standard and certifications been raised.
There are a number of issues that are implicit in the transitioning to the revised standard that must be addressed through the consensus process. These issues can have huge financial and market implications for industry, and also raise substantial issues for Green Seal. For example, how will one distinguish products that are certified under the old GS-37 from those that are certified under the revised standard? In addition a number of logistical issues will come into play that will impact industry and Green Seal.
We suggest that Green Seal strongly consider a transitional timeline and / or "grand fathering" approach similar to that which is employed by the U.S. EPA Office of Pesticide Programs as it applies to pesticide products for which EPA has mandated label changes.
To illustrate the breadth and depth of the issues that are raised as a result of transitioning to the revised GS-37 and resultant certifications, we offer the following for Green Seal's consideration:
1. Product inventory management:

How will inventory turnover be managed and certifications be distinguished? Product inventory management is not limited to those inventories held and managed by the producers, but also inventories in various market channels (Distributors, Retailers, Customers, etc.).

2. Management of product support materials:

Product labels, collateral marketing (brochures, price lists, sales presentation materials, product information sheets, etc.), regulatory documentation (MSDS, etc.), training materials (videos, literature, wall charts, etc). are maintained in various forms in support of Green Seal Certified product offerings. As drafted, there appears to be no clear mechanism by which the end user will be able to distinguish materials supporting the current standard from those that support the revised standard. Failure to allow for a proper transition plan will result in manufacturers having to dispose of pre-printed literature, labels, etc., all at great expense to industry
3. Contractual notifications and timelines:

In many cases, contractual obligations mandate that suppliers provide written notification of product changes to customers well in advance of implementation. Any proposed time lines for migration to the revised standard must take such obligations into account.

Response:

Existing certified products will need to submit data to demonstrate that their products meet the revised standard. The manufacturer will have about 9 months from the issue date to provide this data so that one year from the issuance of the revised standard only products that meet the new criteria will be certified. Any manufacturers that choose not to provide the data or whose products do not meet the new criteria will have their certification terminated. During the recertification period Green Seal's web site will identify which products have met the revised

standard to assist purchasers, e.g., GS-37 [2006] or GS-37 [2008]. All new applications for product evaluation after the revised standard is issued will need to meet the criteria in the revised standard.

Comment:
I recommend that Green Seal require full-disclosure MSDSs be published for each product that it certifies under the revised GS-37.

Response:
As a third-party certification organization, Green Seal has refrained from distributing any sales or marketing literature for the products and services certified. Green Seal does not get involved in pricing and does not post catalogs or product literature on our website. This also extends to Material Safety Data Sheets, which are considered technical literature and necessarily should be obtained directly from the product manufacturer. While Green Seal does maintain a file copy to ensure that the MSDS complies with any specific requirements in the applicable Green Seal environmental standard, such as the disclosure of an added fragrance, the file copy is not distributed to customers or purchasers since Green Seal would then be directly involved in the marketing/sale of a certified product.

The MSDS is a regulated document that is covered by the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR, Hazard Communication - 1910.1200, http://www.osha.gov/SLTC/hazardcommunications/standards.html). The legal obligations of preparing, keeping current and providing (as outlined under the Hazard Communication Standard) Material Safety Data Sheets are borne by the product manufacturer. Specific manufacturer requirements for making Material Safety Data Sheets available to employers, employees, customers and retail/wholesale distributors are provided in the Hazard Communication Standard. In the event of an emergency, it is imperative that users or medical professionals contact the manufacturer (the "responsible party") directly and not Green Seal, which is an error that also could occur if Green Seal were to distribute an MSDS.

Compliance with governmental rules is a requirement for certification by Green Seal (as noted in the Foreward to each Green Seal environmental standard), and therefore manufacturers are expected to have Material Safety Data Sheets that comply with OSHA regulatory requirements. In addition to the OSHA MSDS enforcement program (http://www.osha.gov/dsg/hazcom/MSDSenforcementInitiative.html), Green Seal can and does investigate any allegations of non-compliance regarding the Material Safety Data Sheets for certified products, but is unable to provide them directly.

Comment:
The proposed revised standard, in whole or in part, do not adequately address the health concerns of our children. For example the proposed revisions still:

- Do not stipulate the use of natural or naturally derived ingredients (NOTE: They have added an Addendum for verification of optional claims, however, not part of primary standard),
- Allows for petroleum derived ingredients,
- Do not adequately address ingredients that may be potential carcinogens, teratogens, mutagens, endocrine/hormone disruptors (NOTE: They have improved on this area, however, still falls short and does not address endocrine disruptors at all),
- Allows for synthetic fragrances,
- Allows for chlorinated organics,
- Do not address the potential bioaccumulation of certain chemicals,
- Do not call for disclosure of all ingredients,
- Allows for phosphates

Additionally, they now have a statement in proposed standard that says "The standard does not focus on the use of cleaners in households, food preparation operations, or medical facilities".

Comment:
Green Seal should adopt standards for bio-based products that encourage sustainable growing and sourcing practices such as preventing the use of bio-based resources that were grown in rain forests or with genetically modified organisms. The EU is starting to adopt standards for bio-based fuels that can be used as a good model.

Response:
The standard focuses on products used for routine cleaning purposes – bathrooms, floors, carpets, and other hard surfaces. This standard has never covered specialty cleaners or those that require regulated cleaners (for food preparation areas or medical facilities). Naturally derived ingredients do not necessarily provide protection over other sources of ingredients and also do not guarantee an improved life cycle. As was noted for fragrances, many natural fragrances like essential oils have proven to contain carcinogens. As a result, the evaluation of each ingredient's health and environmental effects taken with this standard is more protective. A key benefit of a certification program is that a third-party evaluates the ingredients in the products so if a manufacturer feels that the ingredients are proprietary, the user or purchaser has the assurance that is passes the criteria of the standard. Chlorinated organics are not used in the products in the scope of this standard and further, would not pass the requirements in the standard (ex. aquatic toxicity). Bioaccumulation was added to the standard as follows:

Bioaccumulating Compounds. The product as used shall not contain any ingredients that bioaccumulate or that form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a bioconcentration factor (BCF) greater than 100 (or log BCF >2) as determined by ASTM E-1022-94(2007) Standard Guide for Conducting Bioconcentration test

with Fishes and Saltwater Bivalve Mollusks or OECD 305 Bioconcentration: Flow-through Fish Test. If the chemical meets the requirement for biodegradability, 4.16, it is considered to not bioaccumulate. Testing is not required for any ingredient for which sufficient information exists.

Comment:
The additional testing requirements and likely reformulation work (with the associated re-testing) could easily pose a financial barrier to small businesses in maintaining their certifications. The changes to the standard, each individually well reasoned, when taken together represent a "lowering of the limbo bar" that some small companies may not be able to manage. Large companies with their greater budgets for formulating and testing will likely have a much easier time adjusting to the new standard. I know that excluding small businesses from participation in the GS-37 standard is not Green Seal's intention, but I predict that many companies will have little choice but to pursue other methods of demonstrating environmental preferability. Can the market be transformed in a way that is more inclusive to small business?

Comment:
The costs associated with the generation of data due to the proposed revisions to GS-37 are significant. Moreover, these data driven costs are merely the tip of the iceberg. These costs are in addition to the significant certification fees and the other potential costs that are articulated in the section below. When taken together it is apparent that these costs are likely to act as a barrier to small businesses that would otherwise seek Green Seal certification. Fortunately, other options are now available in the marketplace. In light of Green Seal's failure to estimate costs associated with the data that formulators may need to generate to comport with the proposed revisions, we have compiled an estimate as follows:

- Efficacy testing: $ 400
- Skin/eye irritation: $1,500
- Skin sensitization: $1,400
- VOC: $ 400
- Aquatic toxicity: $ 500
- Aquatic biodegrade: $ 150

Based on the above estimate which we believe to be a conservative one, it is possible that formulators may incur an additional $4,350 per product in costs associated with testing to meet some of the new requirements established by the proposed revisions. This figure jumps to $6,350 if companies are required to conduct small chamber testing. Clearly these and other costs associated with certification are substantial and act as a financial barrier to small to medium size formulators that operate on primarily regional level.
It is incumbent upon Green Seal to work with stakeholders to devise a path forward that drives out costs as much as feasible during this revision process. Otherwise, manufacturers, particularly regional based operations, will have no choice but to consider other options in pursuing the green cleaning marketplace.

Comment:
If GS-37 is revised in this form, it will result in more, not less confusion in defining

green. It will result in unnecessary higher costs to product manufacturers and product to product compliance variability.

Response:
As is pointed out, Green Seal does not intend to limited small company's participation in the certification program. This is why efforts were made to ensure that no new testing will be needed. Existing data is used for all health and environmental criteria. The only criteria that require testing are product performance. This is no different than the current version of GS-37, so the impact should be no different than before. The estimates provided by the commenter are incorrect. The cost of performance testing is about $200-$400.

Comment:
I support the revisions to the GS-37 standard.

Response:
Comment acknowledged.

Comment:
We believe that Green Seal should do more to harmonize its standard with other certification standards for cleaners, including Canada's equivalent standard Environmental Choice (CCD-146). We do not want consumers in the United States to be exposed to higher levels of toxins and other potential health threats. There are several instances where Environmental Choice's standard is more protective:

- It prohibits some chemicals that Green Seal does not. These include specific ingredients of concern such as ammonia and any ammonium compounds, aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid or the salts of these compounds. An analysis found several Green Seal-certified products contain these chemicals.

- It puts a cap on the total amount of VOCs that can be in concentrated products while Green Seal only puts a limit on the VOCs in the ready-to-use formulations. Without a cap on the VOCs, these highly concentrated products can contain very high levels of VOCs that will eventually be released into the environment. The Canadian standard puts a cap of 12% by weight on general purpose hard surface cleaners. In contrast, the Green Seal standard only applies a VOC standard on the product as used. As a result, some highly concentrated products may end up being more than half VOC, making the standard meaningless.

- It only allows the use of food grade dyes, which are known to be safe. In contrast, Green Seal has no specific restrictions on the types of dyes that can be used.

- It does not allow chlorinated (PVC) plastic in packaging for products certified under its EcoLogo. PVC is a chlorinated plastic that can create dioxins during manufacture and disposal and is difficult to recycle.

We recommend that the revised GS-37 standard be harmonized with the Environmental Choice standard by prohibiting additional chemicals, creating a cap on total VOCs in concentrates, allowing only food grade dyes, and eliminating PVC plastic in packaging.

We need Green Seal-37 to be a rigorous, reliable, meaningful, trusted standard in order to keep our children and elderly, in particular, safe. I am disappointed to have to explain to clients why GS-37 has not been sufficient nor reliable despite many trusted organizations recommending GS-37 as a purchasing litmus test. At this point, it is relatively easy to explain why they cannot rely on GS-37 and that in fact following it may lead to poor choices that negatively affect the health of their constituents. I would much prefer that GS-37 were rigorous enough that I could assure clients they could trust and rely upon a meaningful GS-37 standard that is applied and enforced without exceptions. Cleaning product buyers are demanding a reliable and trustworthy standard.

It would be a great disservice to people of this country if GS-37 were to revise the standard and fail to make it sufficient to protect the health of the country's children and elderly including via the environment. People and organizations in the U.S. repeatedly demonstrate the creativity and innovation necessary to meet rigorous safety standards with effective products when so constrained. Purchasers of "green" products are becoming increasingly sophisticated and discriminating in their purchase decisions. Their sophistication will only continue, perhaps at a dramatic rate. If GS uses a model of adopting a lower threshold for the standard so that 15-20% of existing cleaning products can meet the standard, I fear that will be inadequate and Green Seal will lose the confidence of purchasers and thus the seal will not be valuable to manufacturers. Whereas if GS upholds a meaningful standard based on our current scientific knowledge of chemical health and safety, especially for children and elderly, purchasers will respect the standard and it will be valuable to manufacturers. This second scenario is the one that ensures the ongoing financial sustainability of Green Seal as a non-profit organization.

If Green Seal does not establish a meaningful standard, it will leave a gap that other organizations will fill (perhaps organizations from other countries given the advantage the EU regulatory constraints have given EU manufacturers by forcing them to innovate). Green Seal has lost considerable credibility with an insufficient GS-37. Another insufficient GS-37 would not bode well for Green Seal's long-term success. I hope that Green Seal follows these recommendations and thus helps to re-establish itself as an organization worthy of long-term trust.

Comment:
Harmonize the GS-37 standard with Canada's Environmental Choice standard for industrial and institutional cleaners
We believe that Green Seal should do more to harmonize its standard with other certification standards for cleaners, including Canada's equivalent standard Environmental Choice (CCD-146). We do not want consumers in the United States to be exposed to higher levels of toxins and other potential health threats. There are several instances where Environmental Choice's standard is more protective:

• It prohibits some chemicals that Green Seal does not. These include specific ingredients of concern such as ammonia and any ammonium compounds, aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid or the salts of these compounds. An analysis found several Green Seal-certified products contain these chemicals.

• It puts a cap on the total amount of VOCs that can be in concentrated products while Green Seal only puts a limit on the VOCs in the ready-to-use formulations. Without a cap on the VOCs, these highly concentrated products can contain very high levels of VOCs that will eventually be released into the environment. The Canadian standard puts a cap of 12% by weight on general purpose hard surface cleaners. In contrast, the Green Seal standard only applies a VOC standard on the product as used. As a result, some highly concentrated products may end up being more than half VOC, making the standard meaningless.

• It only allows the use of food grade dyes, which are known to be safe. In contrast, Green Seal has no specific restrictions on the types of dyes that can be used.

• It does not allow chlorinated (PVC) plastic in packaging for products certified under its EcoLogo. PVC is a chlorinated plastic that can create dioxins during manufacture and disposal and is difficult to recycle.

We recommend that the revised GS-37 standard be harmonized with the Environmental Choice standard by prohibiting additional chemicals, creating a cap on total VOCs in concentrates, allowing only food grade dyes, and eliminating PVC plastic in packaging.

Comment:
We believe that there are international models that GS-37 should incorporate into its requirements such as the Canadian Environmental Choice standard and Canada's EcoLogo. For instance, the Canadian Environmental choice standard prohibits ammonia and any ammonium compounds, aromatic solvents, halogenated solvents, ethylene diamine tetra acetic acid (EDTA), ethylene dinitrilotetra acetic acid, nitrilotriacetic acid or the salts of these compounds. Perhaps the committee should consider restricting the use of these chemicals in the GS-37 standard. The Canadian standard also puts a cap on the total amount of VOCs that can be in concentrated products while Green Seal only puts a limit on the VOCs in the ready-to-use formulations. Again, our experience tells us that too many custodians are routinely using concentrated cleaners when they should be diluted. Therefore we can assume that all occupants in too many school buildings have the potential to be exposed to unacceptable levels of VOC's.

Comment:
Harmonize the GS-37 standard with Canada's Environmental Choice standard for industrial and institutional cleaners We believe that Green Seal should do more to harmonize its standard with other certification standards for cleaners, including Canada's equivalent standard Environmental Choice (CCD-146). We do not want consumers in the

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• It puts a cap on the total amount of VOCs that can be in concentrated products while Green Seal only puts a limit on the VOCs in the ready-to-use formulations. Without a cap on the VOCs, these highly concentrated products can contain very high levels of VOCs that will eventually be released into the environment. The Canadian standard puts a cap of 12% by weight on general purpose hard surface cleaners. In contrast, the Green Seal standard only applies a VOC standard on the product as used. As a result, some highly concentrated products may end up being more than half VOC, making the standard meaningless.
• It only allows the use of food grade dyes, which are known to be safe. In contrast, Green Seal has no specific restrictions on the types of dyes that can be used.
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We recommend that the revised GS-37 standard be harmonized with the Environmental Choice standard by prohibiting additional chemicals, creating a cap on total VOCs in concentrates, allowing only food grade dyes, and eliminating PVC plastic in packaging.

Response:
Green Seal believes that its standard for institutional and industrial cleaners is as protective or more protective than any comparable environmental standard used in the marketplace today.

With specific reference to the EcoLogo standard (CCD-146) of the Canadian government ecolabeling program, there are several points that must be considered in a comparison. First, unlike GS-37, the EcoLogo standard allows ready-to-use products rather than requiring concentrates for most uses; this could encourage dilution as a solution to overcoming health problems. Further, this approach overlooks the significant life-cycle and environmental benefits and user benefits of concentrating products. Also, CCD-146 does not evaluate sensitivity issues like skin sensitization and asthma, which may result in products with greater, rather than less, health concerns. GS-37 also is proactive in the areas of training and labeling requirements, which are not included in the EcoLogo criteria.

Green Seal takes an effects-based approach with respect to chemical prohibition by using criteria to judge an effect rather than simply having a long list of prohibited ingredients. All the chemicals pointed out by commenters are already prohibited or appropriately restricted in GS-37-compliant products because they do not meet the criteria in the standard or are not included in the scope of the

standard. For example, NTA is a carcinogen, EDTA is not biodegradable, aromatic and halogentated solvents are not used in products covered in the scope of GS-37, ammonia and ammonium compounds are limited with aquatic criteria. Green Seal has also prohibited synergistic or reaction products that have health effects of concern – for example, formaldehyde donors have not been allowed.

Colors are used in some Green Seal-certified products to help with the identification of products for use (for example, so it isn't confused with water). However, dyes may contain hazardous components. Green Seal already prohibits heavy metals, which are a significant concern for dyes. However, an additional level of evaluation of these product components is possible by requiring the use of only FDA-certified colors or natural ingredients. The FDA-certified colors shall be FD&C approved for food, drug and cosmetic use, so if a dye is used at less than 0.01% then it would still have been evaluated for acute oral toxicity, dermal toxicity, irritation, sensitization, and carcinogenicity. The new definition and criterion will be as follows:

Color Component. A deliberately added product component, where it is added for its ability to change the product's color, typically dyes or pigments.

Color Components. Any color component must meet all relevant criteria of this standard and shall be FDA certified and permitted for food, drug, and cosmetic (FD&C) use or be a natural ingredient.

While the criteria have restricted the use of PVC packaging (not being recyclable according to the standard and contain phthalates), with developments there may be a means for PVC packaging to be allowed. Given the hazards associated with PVC from production to disposal, it will be specifically prohibited.

Other Restrictions. Phthalates and chlorinated packaging material are prohibited from being intentionally introduced; an exception is allowed for packages that would not have added phthalates or chlorinated packaging material but for the addition of post-consumer material.

Green Seal limits VOCs in the as used form of the product and also includes inhalation toxicity in its standard to address related air quality concerns. The most likely form of the product where VOCs will be released is when the product is being used. Adding VOC limits in the concentrated form only limits the ability to concentrate, and this is already addressed with the other criteria in the standard.

Regardless of the differences, Green Seal has informed TerraChoice (the for-profit contractor to the Canadian Government to run the EcoLogo program) of the technical findings learned throughout the process. Green Seal led this sharing to enable harmonization of the two programs in the future.

Comment:

There are several instances where both the existing and proposed standards make it difficult to access information about the chemical ingredients, limiting consumers' and end-users' abilities to make informed decisions about their purchases and practices. Green Seal should require that manufacturers report the pH of their product on the MSDS. More than a dozen products certified under the current GS-37 standard lack a pH on their MSDS. In addition, Green Seal should require that products they certify have MSDSs that use standard names and CAS numbers for chemicals, rather than generic terms such as "surfactant." To facilitate public access to information, the Green Seal website should provide a link to the MSDSs for all certified products. Finally, while we support Green Seal's definition that all ingredients shall be defined as those that comprise at least 0.01% by weight of the product, Green Seal should explain how this will be monitored since most MSDSs only report chemicals that are 1% or higher. How will the public know if chemicals are in the product if they are over 0.01% but under 1%? Requiring all ingredients on MSDSs would allow the public to fully understand and evaluate these products.

We recommend that Green Seal require full-disclosure of ingredients on the MSDSs of certified products, that MSDSs use standard names and CAS numbers, and provide links to the MSDSs for all certified products.

Response:
The MSDS will now include a pH declaration:

Material Safety Data Sheet pH Declaration. The MSDS shall declare the pH of the product, both undiluted and as used.

As a third-party certification organization, Green Seal has refrained from distributing any sales or marketing literature for the products and services certified. Green Seal does not get involved in pricing and does not post catalogs or product literature on our website. This also extends to Material Safety Data Sheets, which are considered technical literature and necessarily should be obtained directly from the product manufacturer. While Green Seal does maintain a file copy to ensure that the MSDS complies with any specific requirements in the applicable Green Seal environmental standard, such as the disclosure of an added fragrance, the file copy is not distributed to customers or purchasers since Green Seal would then be directly involved in the marketing/sale of a certified product.

The MSDS is a regulated document that is covered by the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR, Hazard Communication - 1910.1200, http://www.osha.gov/SLTC/hazardcommunications/standards.html). The legal obligations of preparing, keeping current and providing (as outlined under the Hazard Communication Standard) Material Safety Data Sheets are borne by the product manufacturer. Specific manufacturer requirements for making Material Safety Data Sheets available to employers, employees, customers and retail/wholesale distributors are provided in the Hazard Communication Standard.

In the event of an emergency, it is imperative that users or medical professionals contact the manufacturer (the "responsible party") directly and not Green Seal, which is an error that also could occur if Green Seal were to distribute an MSDS.

Compliance with governmental rules is a requirement for certification by Green Seal (as noted in the Foreward to each Green Seal environmental standard), and therefore manufacturers are expected to have Material Safety Data Sheets that comply with OSHA regulatory requirements. In addition to the OSHA MSDS enforcement program (http://www.osha.gov/dsg/hazcom/MSDSenforcementInitiative.html), Green Seal can and does investigate any allegations of non-compliance regarding the Material Safety Data Sheets for certified products, but is unable to provide them directly.

Comment:
We applaud Green Seal for using a public process to revise and improve Green Seal 37. We feel overall that the proposed changes will make improvements to the existing standard on the environment, custodial worker health, and improved indoor air quality for building occupants, including children.

We recognize key to success of any certification program is basing the criteria on good science and making additional testing affordable to keep the certification products affordable to the average consumer. Overall we feel that Green Seal has a good job of balancing these trade-offs.

Quality Control - Green Seal should develop Quality Control measures to ensure product meet the new standard and conduct periodic audits to ensure the standards are being met.

Right to Know: We recommend that Green Seal require full-disclosure of ingredients on the MSDSs of certified products, that MSDSs use standard names and CAS numbers, and provide links to the MSDSs for all certified products.

Comment:
Finally, to ensure full disclosure to product buyers and users, all ingredients, including proprietary blends, fragrances and hazardous chemicals should be included on package labels. If this is not possible, Green Seal, as a condition of certification, should require manufacturers to make Material Safety Data Sheets easily available, perhaps through a link from the Green Seal website.

Comment:
Right to Know: There are several instances where both the existing and proposed standards make it difficult to access information about the chemical ingredients, limiting consumers' and end-users' abilities to make informed decisions about their purchases and practices. Green Seal should require that manufacturers report the pH of their product on the MSDS. More than a dozen products certified under the current GS-37 standard lack a pH on their MSDS. In addition, Green Seal should require that products they certify have

MSDSs that use standard names and CAS numbers for chemicals, rather than generic terms such as “surfactant.” To facilitate public access to information, the Green Seal website should provide a link to the MSDSs for all certified products. Finally, while we support Green Seal’s definition that all ingredients shall be defined as those that comprise at least 0.01% by weight of the product, Green Seal should explain how this will be monitored since most MSDSs only report chemicals that are 1% or higher. How will the public know if chemicals are in the product if they are over 0.01% but under 1%? Requiring all ingredients on MSDSs would allow the public to fully understand and evaluate these products.

We recommend that Green Seal require full-disclosure of ingredients on the MSDSs of certified products, require that MSDSs use standard names and CAS numbers, and provide links to the MSDSs for all certified products.

We want to promote green cleaning products and practices widely and believe that there are enormous health and environmental benefits to reducing our manufacture and use of toxic chemicals. We believe that Green Seal can play a very important role in helping consumers identify the best products available and help manufacturers innovate and meet independently established and meaningful standards. As it is now proposed, we could not confidently encourage institutions to use products certified under the revised GS-37 standard without additional screens and specifications. We appreciate your consideration of our comments and input, and we look forward to the next phase of finalizing the standard for industrial and institutional cleaners.

Comment:
To the end user, the usefulness of Green Seal is that they don't have to do a whole lot of research themselves and they can trust such an organization to do the work for them. The Logo speaks volumes.

To the product manufacturer, the usefulness of Green Seal lies in that Green Seal is a responsible 3rd party who has reviewed the products' ingredients and the whatnot so that the manufacturer need not divulge such things publicly.

If Green Seal agrees to require full-disclosure MSDSs be posted, it seems to me that they have undermined one of their key functions as the "translator". Why would public full-disclosure still be necessary if a product has passed the standard?

> **Response**:
> Green Seal has an annual monitoring program to ensure that products that are certified continue to meet the requirements in the standard.
>
> As a third-party certification organization, Green Seal has refrained from distributing any sales or marketing literature for the products and services certified. Green Seal does not get involved in pricing and does not post catalogs or product literature on our website. This also extends to Material Safety Data Sheets, which are considered technical literature and necessarily should be

obtained directly from the product manufacturer. While Green Seal does maintain a file copy to ensure that the MSDS complies with any specific requirements in the applicable Green Seal environmental standard, such as the disclosure of an added fragrance, the file copy is not distributed to customers or purchasers since Green Seal would then be directly involved in the marketing/sale of a certified product.

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Comment:
The provisions of the GS-37 Standard should be based on objective scientific criteria with clear scientific rationale. There are various provisions throughout that do not rely on scientific information. For example, the proposed GS-37 standard calls for restrictions on the use of all phthalates – This broad restriction is made despite the clear statement in the GS Discussion Document that not all phthalates possess properties of concern. Rather than consider the data on specific phthalates, the standard adopts what we consider to be an unscientific expedient approach of "guilt by association" and restricts all chemicals in this product family.

The standard should recognize the important role of exposure and risk.

The proposed standard ignores and, in fact, rejects the concept of risk (i.e., intrinsic hazard * exposure). The standard advocates bans on chemicals that are shown to have some potential toxic properties "rather than attempting to determine risk-based acceptable levels." [GS-37 Discussion Document, page 11] The Standard is driven by a philosophy

that a substance should be restricted from use, if a less toxic alternative might be available, even if a scientific assessment of the more toxic substance does not suggest an unacceptable risk.

Rejecting the risk concept is inconsistent with the basic tenants of toxicology and the principles that have long been adopted by responsible federal and state agencies as well as other third party standard-setting organizations.

An example of where the outright rejection of risk can be readily seen is the call for total restriction of any chemical identified on the California Proposition 65 list of Reproductive Toxicants. Proposition 65 calls for warning the public in the event that someone may be exposed above a particular risk-based concentration, referred to as the No Significant Risk Assessment Level (NSRL). The Proposition 65 list of Reproductive Toxicants, does not represent a list of restricted ingredients in California. Moreover, warning is not required in the event that exposures are below the defined NSRL. GS's decision to ban the use of any chemical on the Proposition 65 list and to disregard the NSRL is without any scientific credibility and makes the Standard inconsistent with decisions by EPA, FDA and other federal agencies and standard setting organizations.

Comment:
GS-37 had claimed its process would be open, transparent and scientific in its approach. Instead we found a the process actually had a general disregard for scientifically based criteria, e.g.,the incorporation of restrictions that are not based on sound scientific principles. In addition the failure to consider issues relating to potential exposure to cleaning agents and some estimate of allowable risks involved in favor of an "overdose" of precautionary principal exposes the GS-37 review process as one biased heavily towards the interest of advocates who see all chemicals as toxic in whatever form used.

Comment:
The protection of human health, including appropriate provisions for protection of susceptible subpopulations, is an important objective. However, the approach proposed by Green Seal in this proposed revision of GS-37 is overly conservative and suggests that it is not possible to determine acceptable levels of exposure to chemicals using risk assessment approaches, even when extensive and robust data sets exist. The Green Seal approach in the revised standard rejects the science of risk assessment and declares it incapable of protecting children. Although the precautionary approach proposed by Green Seal may be protective, it is draconian in its conservatism and will lead to bans on substances that may produce adverse effects at high doses in animal studies but do not pose risks to human health or the environment in the context of the products and uses covered by the proposed revised GS-37 standard.

In addition, the current proposal utilizes different criteria; some criteria are strictly hazard based, while others employ elements of risk (hazard and exposure, chamber testing) and still others attempt to incorporate elements of lifecycle considerations. Furthermore, some criteria do not consider the significant environmentally sustainable and lifecycle benefits (closed loop dispensing). Some criteria rely on scientifically marginal, less recognized sources (asthmagens) to define criteria in this standard.

Finally, the revised standard as it currently reads will result in inconsistencies in product compliance with the attributes. The end result is a set of proposed criteria that are inconsistent, less scientifically sound and seemingly primarily focused on human health.

Comment:
We believe that ignoring exposure- and hazard-based risk assessment does not provide environmental or human safety benefit. In fact, this could harm innovation, hampering the design of products which would provide a safety benefit. The criteria in the standard are hazard-based only, and the limits or cut-off values are not justified by any meaningful scientific rationale. As such, we do not believe that products that comply with this standard would have any environmental benefits when compared to products that do not meet the standard

To the best of our knowledge, no data exists to show that the Green Seal standards have led to real and measurable environmental improvements. Further, this standard provides a much lower level of safety and environmental protection than exposure and risk-based safety assessment methodologies widely used by the soap and detergent industry to assess the safety of products on a routine basis. Exposure and risk-based assessment often considers many more endpoints, including sorption, wastewater treatment removal, overall exposure (total volumes emitted to the environment and concentration at target sites), long-term toxicity, bioaccumulation, etc. Background materials and examples of these assessments can be viewed at:
http://cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf http://www.sdahq.org/AMINEOXIDES/
http://www.heraproject.com/Index.cfm http://www.heraproject.com/RiskAssessment.cfm

Comment:
The provisions of the GS-37 Standard should be based on objective scientific criteria with clear scientific rationale. There are various provisions throughout that do not rely on scientific information. For example, the proposed GS-37 standard calls for restrictions on the use of all phthalates. This broad restriction is made despite the clear statement in the GS Discussion Document that not all phthalates possess properties of concern. Rather than consider the data on specific phthalates, the standard adopts what we consider to be an unscientific expedient approach of “guilt by association” and restricts all chemicals in this product family.

The standard should recognize the important role of exposure and risk.

The proposed standard ignores and, in fact, rejects the concept of risk (i.e., intrinsic hazard * exposure). The standard advocates bans on chemicals that are shown to have some potential toxic properties “rather than attempting to determine risk-based acceptable levels.” [GS-37 Discussion Document, page 11] The Standard is driven by a philosophy that a substance should be restricted from use, if a less toxic alternative might be available, even if a scientific assessment of the more toxic substance does not suggest an unacceptable risk.

Rejecting the risk concept is inconsistent with the basic tenants of toxicology and the principles that have long been adopted by responsible federal and state agencies as well as other third party standard-setting organizations.

An example of where the outright rejection of risk can be readily seen is the call for total restriction of any chemical identified on the California Proposition 65 list of Reproductive Toxicants. Proposition 65 calls for warning the public in the event that someone may be exposed above a particular risk-based concentration, referred to as the No Significant Risk Assessment Level (NSRL). The Proposition 65 list of Reproductive Toxicants, does not represent a list of restricted ingredients in California. Moreover, warning is not required in the event that exposures are below the defined NSRL. GS's decision to ban the use of any chemical on the Proposition 65 list and to disregard the NSRL is without any scientific credibility and makes the Standard inconsistent with decisions by EPA, FDA and other federal agencies and standard setting organizations.

Comment:

It will seriously undermine the standard because of the inconsistent application of hazard versus risk versus lifecycle attributes, resulting in a standard that appears arbitrary.

Response:

One of the purposes of revising GS-37 was to address the health concerns of vulnerable populations, such as children, since these products are being used increasingly in settings such as schools. The science and approaches to assessing health risks from exposure to chemicals has primarily focused on adults. For example, adult laboratory animals are typically used to determine dose-response relationships for chemicals, and exposure assessment assumptions have typically been based on adult behavior patterns and physiology. In revising Green Seal's health and environmental standard for industrial and institutional cleaners, the uncertainty (inability) of risk assessment approaches to protect children in all stages of development must be considered. The many uncertainties inherent to health risk assessment are compounded when applied to children. Predictable and quantifiable dose-response data are required in order to determine safe or acceptable exposure limits, or thresholds, for toxic chemicals. The differences between children and adults, critical developmental windows, and uncertainty in the risk assessment process, all of these factors support taking a precautionary approach to protecting children from environmental chemical exposure, including those from cleaning products.

One precautionary approach, where an ingredient or its class exhibits potentially harmful characteristics, is to specifically prohibit or substantially reduce that ingredient or class of ingredients in products, where feasible alternative exist, rather than attempting to determine risk-based acceptable levels.

California Environmental Protection Agency Office of Environmental Health Hazard Assessment (OEHHA) "has established safe harbor levels (levels of exposure that trigger the warning requirement) for some, but not all, listed chemicals." "A business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure." "Proposition 65's warning requirement has provided an incentive for manufacturers to remove listed chemicals from their products." As a result, it is relevant to protective initiatives, such as an environmental leadership standard like Green Seal's to prohibit chemicals listed as reproductive toxins. Further, since this definition is not a modification from the current GS-37 standard, it has proven that meeting the criterion has not been an issue for GS-37 products for many years.

Another health consideration, asthma, does not allow for the risk assessment approach suggested since exposure is not predictive - further warranting a precautionary approach.

However, to be more transparent about the rationale for listing a chemical on a prohibited ingredient list, the list has been separated according to the primary reasons for prohibiting the chemical (though in many cases there is more than one reason for prohibiting a chemical). The result is new criteria for endocrine disruptors, respiratory irritants, neurotoxins, and systemic toxins. These criteria have definitions for each end point, to help illustrate the rationale, though some of the challenge with developing a criterion lies in finding an accepted definition (there may not an accepted definition). However, listing of chemicals within each criterion is still dependent on its weight of evidence; along with the evaluation of the best way to protect vulnerable populations since there is are not accepted methods and widespread data available.

Comment:
As one possible solution in reducing costs associated with the generation of data, we recommend that Green Seal recognize ingredients housed in the CleanGredients database as exempt from any of the data requirements. As Green Seal is probably aware, CleanGredients houses ingredients with known and preferred environmental, and safety and health profiles. While we realize this database is still under construction, it is rapidly undergoing development and will soon be a robust database that houses all the essential ingredients that are necessary to formulate a cleaning product. Ultimately, we call upon Green Seal to provide a "fast track" to certification for cleaning product formulations composed entirely of ingredients found on the CleanGredients database.

Response:
Green Seal supports the efforts to develop the CleanGredients database. In fact, Green Seal's technical staff has contributed to its development at times. When the development is complete, it could provide a useful tool for formulators.

It is an incorrect assumption that products require testing/generation of data. Green Seal staff uses existing data for evaluation of ingredients in a product applying for certification and have significant data available due to the hundreds of GS-37 products evaluated, which minimizes any potential for testing.

Comment:
Waste management:
In the event that an appropriate transitional plan is not devised, there is the very real potential to create significant obsolete inventory of product and support materials. All of this obsolete product and other materials would be treated as waste if not properly taken into consideration into a transitional plan. We sincerely hope that it is not the intent of Green Seal to create waste materials resulting from the implementation of the revised GS-37 Standard.

5. Green Seal resources and that of collateral services:
At last count, Green Seal had hundreds of products certified pursuant to GS-37. If the producers of all of these products were to come to Green Seal at one time to be certified under the new, revised GS-37, we sincerely doubt if Green Seal would have the resources to accommodate such a huge influx of applications. On the same note, the proposed revisions clearly call for additional testing requirements. Could organizations that provide such testing services meet the anticipated demand of such services if demanded all at or close to the same time. Clearly these issues must also be considered in defining a transitional plan going forward.
We believe that models exist for how we might best address such a situation. The U.S. EPA Office of Pesticide Programs provides such an example. When EPA requires a label change for registered pesticide products, it generally grandfathers products that are in the pipeline. In other words, the Agency generally allows formulators anywhere from 18 to 24 months to continue to sell existing inventory even though it is not in compliance with the new labeling requirements. This allows companies to sell existing inventory, use up advertising material, etc.
If Green Seal were to allow products that have been previously certified under the existing GS-37 to be “grandfathered” in a similar fashion it would alleviate many of the concerns outlined above. We strongly urge Green Seal to consider such a course of action.
In addition to the concerns outlined above, re-certification places significant burden on producers in terms of time and resource constraints. Time as well as human and financial resources must be allocated by producers to perform the following tasks:

- Re-evaluate existing products against new standard
- Reformulate products (where necessary)
  - Locate acceptable substitute ingredients
  - Revise manufacturing processes to accommodate new chemicals
- Execute testing in accordance with Section 3.1 of the GS-37 standard
- Where appropriate, perform customer placement or field evaluations
- Produce data package for GS Certification
- Commercialize reformulated product including but not limited to:
  - Label development and production

- Produce support materials, price lists, MSDS, etc.
- Produce Marketing collateral
- Produce revised training materials

All of these tasks place an additional burden on formulators' limited human and financial resources and must be given due consideration as part of the process going forward.

Comment:
A key area that is not adequately addressed in the revision of GS-37 is the handling, management and qualification criteria for those products that currently carry the Green Seal Certification Mark. For example, how will one distinguish compliance of products with the current standard from those compliant with the revised standard? This would suggest the need for a transition timeline to be included within the scope of the revision, which is currently not articulated. Subsequently, a transition plan for those products carrying the Green Seal Certification Mark must be defined. A significant number of logistics issues arise in managing migrations in standards. Examples of issues that require resolution in the revised standard include, but are not limited to, the following:

1. Product inventory management

How will inventory turnover be managed and certifications be distinguished? Product inventory management is not limited to those inventories held and managed by the producers, but also inventories in various market channels (Distributors, Retailers, Customers, etc.).

2. Management of product support materials

Product labels, marketing collateral (brochures, price lists, sales presentation materials, product information sheets, etc.), regulatory documentation (MSDS, etc.), training materials (videos, literature, wall charts, etc). are held in various forms in support of Green Seal Certified product offerings. As drafted, there appears to be no clear mechanism by which the end user will be able to distinguish materials supporting the current standard from those that support the revised standard. Failure to allow for a proper transition plan will result in manufacturers having to dispose of pre-printed literature.

3. Contractual notifications and timelines

In many cases, contractual obligations mandate that suppliers provide written notification of product changes to customers well in advance of implementation. Any proposed time lines for migration must take such obligations into account.

4. Waste management

It is clearly not the intent of Green Seal to create waste materials resulting from the implementation of the revised GS-37 Standard. However, the potential to create significant obsolete inventory of product and support materials exists and should be clearly addressed.

Allowing existing products that have been previously certified under the existing GS-37 to be 'grandfathered' would alleviate many of these concerns, and is strongly suggested.

In the event that 'grandfathering' is not viewed as a possible resolution, sufficient time must be afforded to make the appropriate migrations. In addition to the concerns outlined

above, re-certification places significant burden on producers in terms of time and resource constraints. Time must be afforded for producers to perform the following tasks:

1. Re-evaluate existing products against new standard
2. Reformulate products (where necessary)
3. Execute testing in accordance with Section 3.1 of the GS-37 standard
4. Where appropriate, perform customer placement or field evaluations
5. Produce data package for GS Certification
6. Commercialize reformulated product

a. Label development and production
b. Produce support materials, price lists, MSDS, etc.
c. Produce Marketing collateral
d. Produce revised training materials

All of these tasks come at significant expense to the producer. It is worthy of note that the points articulated above do not address the potential financial burden of data generation as it pertains to many product attributes (Sections 4 and 5).

Comment:

A key area that is not adequately addressed in the revision of GS-37 is the handling, management, and qualification criteria for those products that currently carry the Green Seal Certification Mark. For example, how will one distinguish compliance of products with the current standard from those compliant with the revised standard? This would suggest the need for a transition timeline to be included within the scope of the revision, which is currently not articulated. Subsequently, a transition plan for those products carrying the Green Seal Certification Mark must be defined. A significant number of logistics issues arise in managing migrations in standards. Examples of issues that require resolution in the revised standard include, but are not limited to, the following:

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3. Contractual notifications and timelines

In many cases, contractual obligations mandate that suppliers provide written notification of product changes to customers well in advance of implementation. Any proposed time lines for migration must take such obligations into account.

4. Waste management

It is clearly not the intent of Green Seal to create waste materials as a result of implementing the revised GS-37 Standard. However, the potential to create significant obsolete inventory of product and support materials exists and should be clearly addressed.

Allowing existing products that have been previously certified under the existing GS-37 to be 'grandfathered' would alleviate many of these concerns, and is strongly suggested.

In the event that 'grandfathering' is not viewed as a possible resolution, sufficient time must be afforded to make the appropriate migrations. In addition to the concerns outlined above, re-certification places significant burden on producers in terms of time and resource constraints. Time must be afforded for producers to perform the following tasks:

1. Re-evaluate existing products against new standard
2. Reformulate products (where necessary)
3. Execute testing in accordance with Section 3.1 of the GS-37 standard
4. Where appropriate, perform customer placement or field evaluations
5. Produce data package for Green Seal Certification
6. Commercialize reformulated product

a. Label development and production
b. Produce support materials, price lists, MSDS, etc.
c. Produce marketing collateral
d. Produce revised training materials

All of these tasks come at significant expense to the producer. It is worthy of note that the points articulated above do not address the potential financial burden of data generation as it pertains to many product attributes (Sections 4 and 5).

Response:

The revision process has been going on since the beginning of 2007. All certified product manufacturers were made aware of the upcoming revision before the process began. Thus when the revision gets issued there would have been adequate notice, and manufacturers could have prepared for any potential product or label development needed. To further facilitate this transition, existing certified products will need to submit data to demonstrate that their products meet the revised standard. The manufacturer will have about 9 months from the issue date to provide this data so that one year from the issuance of the revised standard only products that meet the new criteria will be certified. Any manufacturers that choose not to provide the data or whose products do not meet the new criteria will have their certification terminated. During the recertification period Green Seal's web site will identify which products have met the revised standard to assist purchasers, e.g., GS-37 [2006] or GS-37 [2008]. All new applications for product evaluation after the revised standard is issued will need to meet the criteria in the revised standard. This allows for sufficient time for a manufacturer to reformulate and develop new labels and support material.

Comment:
As with other similar GS standards, this one also provides a set of stagnant criteria that do not change in time, and ignores progress in technology and innovation. This proposed revision of the standard can also be a hurdle to innovation, which may potentially lead to more effective cleaning products with real environmental improvements.

Response:
Green Seal supports technological improvements and advancements. In fact, innovation is most commonly achieved when there is a challenge presented – and one needs to find a solution to that challenge. A product that doesn't meet the standard can use the criteria in the standard as goals for development/challenges to innovate towards. Green Seal has learned that companies use the criteria in this manner. This is one means for marketplace transformation.

Green Seal supports sustainability initiatives beyond what is included in the standard, such as use of renewable energy or reduced greenhouse gas emissions, and has developed a claim verification program for such initiatives. This program will be provided to all certified products for any Green Seal standard.

APPENDIX

GS-37 Draft Final Revised Standard Testing Requirements

Costs provided for required testing, since available data is used for all other criteria.

Criterion	Available Data Used	*Testing Secondary Approach	Testing Required	Estimated Cost of Required Testing
Performance			X	$200-$400
Acute Toxicity	X	X		
Skin and Eye Irritation	X	X		
Chronic Inhalation Toxicity	X	X		
Carcinogens, Mutagens, Reproductive Toxins	X			
Causes of Asthma	X			
Skin Sensitization	X	X		
Skin Absorption	X			
Neurotoxins	X			
System Toxins	X			
Endocrine Disruptors	X			
Respiratory Irritants	X			
Ozone Depleting Compounds	X			
Volatile Organic Compound Content	X	X		
Chronic Inhalation Toxicity	X	X		
Aquatic Toxicity	X	X		
Bioaccumulation	X	X		
Aquatic Biodegradability	X	X		
Eutrophication	X			
Combustibility	X			
Packaging	X			

**Testing is needed only if there is not available data or if data suggests the need for additional testing.*

The shaded rows indicate the criteria that require product testing.