Consumer Specialty Products Association

December 21, 2004

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Subject: Revised Draft Report to the California Legislature: Indoor Air Pollution in California

Dear Ms. Shimer:

The Consumer Specialty Products Association (CSPA) appreciates the opportunity to submit additional comments on the Air Resources Board's (ARB's) *Draft for Public Review of the Report to the California Legislature: Indoor Air Pollution in California* as required by Assembly Bill 1173 (Keeley, 2002; Cal. Health & Safety Code § 39930).

CSPA appreciates the numerous changes that ARB has made in the Draft Report in response to our comments and others. One of the most important and appropriate changes was segregating the categories of sources formerly in Table ES-3 into "High Priority" in new Table ES-3.1 and "Medium Priority" in new Table ES-3.2. The high-priority source categories in Table ES-3.1 are well-documented and certainly should be the focus of any ARB or State of California activities for the remainder of the decade. Further, we note that Section 2.3.4 (pages 75-82) on "Biological Contaminants" has been expanded significantly and appropriately.

However, CSPA continues to be concerned about the undue emphasis on indoor emissions that present little or no health risks while failing to highlight more significant risks. In addition, ARB still fails to appreciate fully the rigorous federal product safety regulations that govern formulated consumer products as well as the efforts of manufacturers of those products to assure product safety that go beyond mere regulatory compliance, as discussed in detail in our earlier comments. Consumer product manufacturers conduct safety assessments of their products to assure that the products can be used safely. These assessments consider both acute and chronic exposures and effects, and consider both proper use (according to label instructions) and reasonably foreseeable misuse. CSPA members apply these principles to assure that their products do not create indoor air quality problems, and in many cases to assure that the products are effective in improving indoor air quality and overall indoor environments. This approach should be recognized in this Report.

Another critical flaw that remains throughout the Draft Report is the failure to consider adequately the public health and indoor air quality benefits of many of the formulated consumer products, articulated in Attachment C to our previous comments; instead (and inappropriately), these products are considered only as potential sources of indoor air "pollutants." Many of our member companies' products play a key role in lowering indoor exposures to biological

contaminants such as dust mites, cockroaches, bacteria, viruses, and mold, which cause significant health problems in California and elsewhere. We ask that Attachment C, as well as our earlier Attachment A reviewing key statutes and regulations assuring product safety, be included on your website's compilation of comments and be incorporated in the next version of the Report.

STATEMENT OF INTEREST

CSPA is a voluntary, nonprofit national trade association representing approximately 240 companies engaged in the manufacture, formulation, distribution, and sale of consumer specialty products for household, institutional, commercial and industrial use. CSPA member companies' wide range of products includes nonagricultural pest management products, antimicrobial products, air care products, industrial and automotive specialty products, cleaning products, polishes and floor maintenance products, and various types of aerosol products. These products are formulated and packaged in many forms and are generally marketed nationally. Many of these products are designed to maintain hygienic and healthy homes, institutions and workplaces, and contribute to maintaining and improving the quality and safety of the indoor environment.

COMMENTS ON REVISED DRAFT REPORT

The following represent our specific comments on the revised Draft for Public Review of the Report to the California Legislature on Indoor Air Pollution in California.

Executive Summary

Table ES-1 (page 3), which summarizes the "Sources and Potential Health Effects of Major Indoor Air Pollutants," improperly aggregates large classes of "pollutants" with a wide range of properties, toxicity, sources, and health effects, to the point that the reader may mistakenly believe that each individual "pollutant" in any category is emitted by each source listed. Only the most toxic pollutants likely to be present indoors, their most likely sources, and their most likely health effects given the known levels indoors should be listed, with each pollutant individually paired with its sources and effects.

The category of "Organic Chemicals" is particularly misleading, implying that all the listed examples are present in all the listed sources, when that is clearly not the case. Neither air fresheners nor cleaning agents, for instance, are major sources of any of the "Organic Chemicals" listed, with the minor exception of para-dichlorobenzene – a chemical compound which will be eliminated by December 31, 2005, pursuant to the ARB's CONS-1 Rulemaking. Neither aerosol sprays nor candles contribute significantly to the emissions of respirable particulate matter that potentially presents the listed potential health effects. Regarding "endocrine disrupters," it is too early to assess this potential class of pollutants, with significant ongoing research needed to determine what potential health effects might occur and what substances might present risks of adverse health effects. Without proper specificity and context, the current Table will only serve to needlessly frighten, confuse and deceive California residents.

As noted in our previous comments, it is inaccurate to characterize the 2003 study by Rosenman et al. (page 4) as having "further demonstrated an association between asthma symptoms and VOCs, primarily from cleaning products." Epidemiological studies such as this are often subject to confounding factors that mask actual causes; in the case of cleaning personnel, it is very likely that they were also subject to increased exposures to the soils they were cleaning, which include many biological contaminants (such as insects and molds) that are known asthma triggers. This is recognized by Delfino in the paper also cited on page 4 of the Draft Report, which notes in its review of the evidence of potential connections between VOCs and asthma that:

> All of the above studies of indoor VOCs may be subject to unmeasured confounding by other causal agents that increase indoors under low ventilation conditions, including aeroallergens, or that are correlated with VOCs for other reasons. Most, but not all, of the studies controlled for ETS. The research to date is too sparse to evaluate causality from indoor home VOCs, but there is even less information to evaluate the public health impact on respiratory health from outdoor VOCs, which include some of the same compounds found indoors.

In the review of the potential "irritant effects" of indoor air pollutants (page 6), the Report is contradictory and speculative in discussing Sick Building Syndrome (SBS), correctly noting that "the specific causes of SBS have not yet been firmly identified" (indeed the very definition of SBS) but only after the innuendo that "irritant chemicals" are suspected.

The review of the potential sources of harmful particulate matter (page 6) includes "candle burning" in the list of sources of "PM with harmful components similar to those in outdoor air." It is not clear what size particles are being discussed: PM_{10}, $PM_{2.5}$, respirable (generally considered to be in the size range of one micron), or some other classification. Various particles vary greatly in their size and chemistry, as well as their potential for adverse effects. Studies have shown that most of the particulates emitted by candles are above the one-micron range and therefore not considered respirable. Furthermore, this section does not analyze the important differences in the physics and chemistry of particles outdoors and indoors, including the greater tendency indoors for particles to agglomerate and fall out, and to be captured in "sinks" such as fabrics and carpeting.

In the section on toxic air contaminants (page 8), the use of the broad term "Volatile Organic Compounds" (VOCs) to represent a very narrow class of chemicals that may present health concerns is misleading. Most of the many thousands of chemicals that are in the broad chemical class of VOCs are not "Toxic Air Contaminants" and do not present potential health impacts at the levels at which they exist in indoor air.

The term "Pesticides" (page 8) is also a broad term, covering a broad range of chemicals. From the perspective of insecticides used indoors to control allergen-producing cockroaches, dust mites, and the like, the class of chemicals that are commonly used indoors are photolabile chemicals that do not persist for long in the environment. Synthetic-pyrethroids insecticides have replaced the organophosphate chemicals that were more persistent indoors, only lasting six to seven weeks before degrading. In addition, pesticides are regulated by the US Environmental Protection Agency (EPA) in both formulation and labeling. The California Department of

Pesticide Regulation also reviews products fully before they may be sold and used in the state. Risk assessments are conducted by registrants and regulatory agencies to assure that products are not capable of producing "adverse developmental and neurological effects".

The review of "Biological Contaminants" (page 9) here remains a woefully inadequate two paragraphs, especially given the concluding sentence that Building-Related Illness (BRI) "impacts can be substantial, and are of increasing interest as the role of buildings in promoting diseases of biological contaminants becomes better understood." This section should be elaborated upon, as the relevant portion in the body of the Draft Report was so well.

The discussion of "Environmental Justice Considerations" (page 9) properly notes that "dust mites, cockroaches, and mold are important triggers for asthmatics that are more likely to be present in locations where lower income individuals most often live." Unfortunately, by repeatedly stigmatizing cleaning products, which eliminate mold, and pesticides, which eliminate dust mites and roaches, as sources of indoor air "pollutants" throughout this Draft Report, ARB is reducing the opportunity for, and thus likelihood of, mitigating these pests.

Table ES-2 (page 11), which provides "Summary of Estimated Costs of Some Indoor Air Pollution in California," shows that the vast majority of estimated costs are associated with environmental tobacco smoke (ETS) and radon. Unfortunately, estimates have not been developed on the impacts of major biological contaminants such as infectious diseases caused by airborne bacteria and viruses. The costs of those illnesses, in medical costs and lost productivity, could exceed the $35 billion annual costs estimated for all other indoor air pollution impacts. According to the U.S. Centers for Disease Control (CDC), each year Americans are sick more than 4 billion days from infectious diseases and as a result spend more than $950 billion on direct medical costs. In addition, over 160,000 people in the United States die yearly with an infectious disease as the underlying cause.

Further, Table ES-2 implies that all VOCs cause cancer, misleading the public into possibly believing that any product creating a VOC exposure will increase cancer risk. The few VOCs contributing the most to this alleged risk should be specified here.

The section on "Existing Regulations, Guidelines and Practices" (page 12) understates the regulations affecting products used indoors. Specifically, the section summarizing existing regulations setting "consumer product standards" (pages 13-14) notes only ARB's own VOC regulations and inappropriately dismisses U.S. Consumer Product Safety Commission (CPSC) regulations. As noted in our previous comments, there are numerous and comprehensive federal regulations, as well as California pesticide regulations, aimed at assuring the safety and efficacy of various consumer products.

The section on "Methods to Prevent and Reduce Indoor Air Pollution" (page 15) has been improved by removing inapt comments about terpenes. However, the assertion that "Low emission product designs or reformulations can usually be accomplished by the manufacturer, with minimal impact on the consumer, often with only minor increased costs" is patently false, as ARB's experience with its VOC regulations will validate. Industry, working with CARB, has achieved considerable reductions in VOC levels as technology permits. The general experience

there is that product efficacy has been difficult to maintain while reformulation costs in many categories have been substantial.

As noted above, CSPA is gratified with one of the most important and appropriate changes – segregating the categories of sources formerly in Table ES-3 into "High Priority" in new Table ES-3.1 and "Medium Priority" in new Table ES-3.2. The high-priority source categories in Table ES-3.1 are well-documented and certainly should be the focus of any ARB or State of California activities for the remainder of the decade.

In discussing mitigation strategies, the draft report offers on page 19 that, "non-toxic cleaning products are currently sold in the marketplace." Unfortunately, that viewpoint does not take efficacy into account, which may require more product (with consequently more emissions) to perform the cleaning task, if it can be accomplished at all. In addition, the legitimacy of "non-toxic" claims on some of these products is questionable and, in the case of antimicrobials, would be in violation of FIFRA regulations.

Under "Medium Ranked Source Categories" (page 21), we take issue with the allegation that "there is an apparent need to reduce emissions from consumer products to prevent high personal exposures and risks." As discussed earlier, these products are subject to meaningful federal regulation and do not present substantial risk when used according to label instructions.

In Table ES-3.2 (page 22), although the footnotes reveal that "All of the examples of pollutant sources may not emit all of the pollutants listed in the corresponding box in column two," the inevitable consequence of viewing the table is a totally unjustified broad-brush condemnation of large categories of consumer specialty products. Very few of the "Consumer Products" listed emit the "Pollutants" listed as examples. Further, the relevance of "Direct State Authority to Take IAQ Mitigation Actions" is minimal where there is already a comprehensive federal regulatory system in place. This table should be edited to convey accurate and relevant information.

Because of those federal regulations, we dispute the need to "create a management system for indoor air quality" or requiring formulators "to submit . . . consumer products . . . for emissions testing" as described on page 23. Neither the necessity, as consumer products are properly designated as a medium priority, nor the infrastructure, as noted in the Draft Report (page 24), exists at this time.

To conclude, all in all the Executive Summary is much improved but still requires some additional editing based on these comments.

Introduction and Background

The paragraph on page 29 discussing "consumer products . . . so-called 'air fresheners' . . . [and] burning candles" comes across as a sweeping condemnation of those categories with no context of risk or regulation. Following a sentence describing effects such as "cancer and even sudden death" immediately with a broad list of common products and activities can serve only to frighten, not inform. Only the specific substances and exposures likely to result in significant adverse health effects should be linked in that manner.

We are uncertain exactly which "room fresheners" are being described on page 32 when referring to a 1991 study. It would be better to encourage "those who live in substandard housing" to use appropriate consumer specialty products to alleviate their indoor environmental problems.

Health Impacts, Sources and Concentrations of Indoor Air Pollutants

Although the observation (page 33) that "aerosol sprays or solvents emit much smaller quantities of pollutants" is correct, the allegation that "a high concentration of the chemical is consequently inhaled during product use" is generally not true. Aerosol products are sealed when not in use, highly directional and provide the already properly diluted amount of ingredients to the intended target.

Table 2.1 (page 34) on "Sources and Potential Health Effects of Major Indoor Pollutants" includes the same incorrect or misleading information we noted above regarding Table ES-1 (page 3). Please see our earlier comments on Table ES-1.

The discussion of asthma (page 35) ignores more recent CDC data which indicate that the rate of Americans (per 1,000) experiencing an asthma attack in a 12-month period has decreased from 43.2 in 2001 to 42.6 in 2002 to 38.7 in 2003.

Tables 2.2 (page 36) and 2.3 (page 37) provide an accurate summary of the findings of the National Academy of Science Institute of Medicine study on the development and exacerbation of asthma. It is important to note that the only exposures with sufficient evidence of a causal relationship in the exacerbation of asthma (cat, cockroach, house dust mite, preschool ETS) or the development of asthma (house dust mite) are (except for ETS) biological contaminants. In addition, the only exposures with sufficient evidence of an association in the exacerbation of asthma (dog, fungi or molds, rhinovirus, and NO_x) or the development of asthma (preschool ETS) are also (except for ETS and NO_x) biological contaminants. No chemical found in any consumer product is known to be associated with the development or exacerbation of asthma. Yet, most of the discussion in this Report inexplicably relates to the few chemical contaminants for which there is "limited or suggestive evidence" or even just "possible but insufficient evidence" of a relationship of the exposure to asthma. More focus on biological contaminants is necessary in this discussion,

As we noted earlier, the results of the 2003 Rosenman study and the 2002 Delfino review regarding potential relationships between asthma and exposure to cleaning products or related VOCs have not been accurately characterized in this Draft Report (see page 37). There is no clear evidence that these VOCs are associated in any causative way with asthma.

The discussion based on the ten-year-old CCRP (page 38), much of which requires significant updating based on product reformulations, is of limited relevance. There is today no significant use of formaldehyde in consumer specialty products. Para-dichlorobenzene usage has decreased significantly over the past decade and will be almost completely eliminated in California next year. Trichloroethylene is used in virtually no consumer products, and none for use indoors. Many of the other chemicals on which this assessment was apparently based have not been used

in consumer products for decades, if ever. More recent data or estimates must be used in this assessment for it to have any relevance. It is disingenuous to claim that the decade-old CCRP estimates "remain the best available" when all parties recognize the serious drawbacks; an updated study should be a condition precedent for any new initiatives on indoor air pollution.

The referenced 2003 study by Fan et al is described in a very misleading manner (page 42). The authors of that study actually concluded that the best strategy to attenuate this potential problem would be to lower outdoor ozone levels and/or minimize ozone migration to indoors. It is currently not possible to determine whether potential health impacts might exist due to the indoor air chemistry research being done relating to mixtures of alkenes and oxidants. It is not yet clear what chemistry occurs at the levels of these compounds actually found in indoor environments or whether the reaction products present any potential health risks. The U.S. EPA has cautioned the news media and their audience that the ongoing studies have not shown evidence of health concerns.

The section on particulate matter contains a single small paragraph on biological contaminants (page 48), despite abundant evidence on the widespread health impacts of fungi, bacteria, viruses, dust mites, cockroaches, pollen, and other such biological indoor particulates. Although a thorough review of the health effects and risks of biocontaminants would require hundreds of pages, these important indoor pollutants should be given more substantial treatment as compared to the many pages used to review other particulates in order to provide a more accurate and balanced perspective.

The Report states that consumer products are a source of formaldehyde (page 59). With the possible exception of some coatings and adhesives, this is not accurate. There is little or no contribution to indoor formaldehyde levels from our industry's formulated household consumer specialty products.

Section 2.3.2 (pages 63-72) uses the broad term "volatile organic compounds" or "VOCs" when it appears that what is actually meant is the small class of VOCs currently classified as Toxic Air Contaminants. Most VOCs have no adverse health effects at the levels found in indoor air. Again, specific VOCs associated with specific exposures and specific health effects should be the focus of this discussion.

Section 2.3.2.2 on "Sources and Emissions of VOCs" (page 65) contains significant amounts of dated or inaccurate information. Consumer products are not formulated with benzene, nor has benzene been used in such products for many decades. Toluene is seldom if ever used in consumer products meant for indoor uses. Para-dichlorobenzene, as noted earlier, has seen a very significant decrease in use since 1991 when EPA's TEAM studies were conducted, and most uses of this compound will be restricted in California next year. Methylene chloride is used only in some paint strippers and such products are carefully labeled for use with adequate ventilation.

Further, this section on VOCs is grossly misleading due to its failure to acknowledge that the mere existence of a VOC in a product or in indoor air, even if it is currently classified as a Toxic Air Contaminant, does not mean that any risk exists of adverse health impacts. This fact should

be conveyed to put many of the studies cited in perspective. Consumer products are carefully evaluated to assure that exposure levels are well below known no-effect levels.

The study by Akland and Whitaker (2000) cited on page 68 that purports to have found benzene and acetaldehyde in consumer cleaning products is simply in error. Similar errors appear to have occurred in the study cited by Zhu et al. (2001), since neither 2-methoxyethanol nor 2-ethoxyethanol is used in household or institutional cleaning products. The claims in the paper by Cooper et al. (1995), cited on page 69, regarding the potential adverse effects of chemicals used in perfumes are appropriately attenuated, but we question the need to include a nine-year-old study that shows the risk is low.

We note and appreciate that Section 2.3.4 (pages 75-82) on "Biological Contaminants" has been expanded significantly and appropriately.

Costs of Indoor Air Pollution

As noted earlier in these comments, it is important to distinguish between the estimated costs associated with illnesses where etiology can be established on as case-by-case basis (*e.g.*, CO poisoning or specific microorganisms) and illnesses where etiology can be estimated only through worst-case risk assessment methodologies (*e.g.*, chronic diseases and multiple associated exposures). While relative accurate estimates can be made, for instance, of the mortality and morbidity attributable to CO poisoning or influenza viruses, the estimates from cancer risk assessments represents the upper limit of potential cases, with a lower limit that often is zero.

For this reason, the estimated mortality data shown in Table 3.2 (page 100) are at best highly misleading and in other cases provide an inaccurate portrayal of the data. In this Table, only the CO-poisoning data and some of the mold/asthma/allergy data are based on cases where etiology has been reasonably established. The ETS assessments on cancer and heart disease are based on estimates from epidemiological investigations, which should provide a wide range of statistical probabilities. (For this reason, we must question the lack of a range provided in the ETS cancer estimate. This is handled more appropriately in the ETS heart disease estimates.) The estimate for "VOCs" (now attributed to "Lung cancer") is undoubtedly based on the even more uncertain data and assessments contained in the 10-year-old CCRP, often by extrapolating animal data to obtain maximum human risk estimates and applying these risk estimates to maximum lifetime exposure estimates, to obtain an estimate for attributable mortality. The reference of a single number (115) for "low," "average" and "high" estimates for cases/year is not only misleading but grossly inaccurate considering the multiple uncertainties in the methodology. To provide an accurate characterization of data from such assessments, the "average" should be significantly lower than the "high" estimate and the "low" estimate of premature deaths should be zero.

Table 3.3 (page 104) noting the "Estimated Annual Medical Costs of Indoor Air Pollution in California" suffers from all the same problems as Table 3.2, as it mixes cost estimates of very different types. In addition, the terminology on this Table should be revised to be more accurate and less misleading. While "CO: poisoning" may be a "Health End Point," "VOCs: cancer" is not a diagnosable health end point. We suggest using the term "Health End Point with Potential Causative Exposure" for the column heading, and "Cancer potentially caused by certain toxic air contaminants" instead of the misleading "VOCs: cancer".

Noticeably lacking in Table 3.6 (page 110), as mentioned earlier in these comments, is any assessment of the costs for the many other diseases caused by biological contaminants other than allergies and asthma from mold and SBS. Even a cursory analysis will find that diseases attributable to bacteria, fungi, insects, po1len, and other biological contaminants in indoor air far exceeds that currently included from all other sources in terms of mortality, morbidity, and societal costs. CSPA believes that the statutory mandate to assess these risks and costs fully is clear, and that this information is essential to a complete and unbiased assessment of indoor air quality challenges in California.

Existing Regulations, Guidelines, and Practices

This section fails to recognize the practices of the consumer specialty products industry in assuring the safety of its products. Consumer product manufacturers conduct safety assessments to assure that their products can be used safely. State and federal regulatory bodies also conduct risk assessments on pesticide products to assure that product use does not create "unacceptable adverse effects on man or the environment." These assessments consider both acute and chronic exposures and effects, and consider both proper use (according to label instructions) and reasonably foreseeable misuse. CSPA members that have joined CSPA's Product Care[sm] program, in particular, have committed to a very rigorous set of product safety management principles. CSPA members apply these principles to assure that their products do not create indoor air quality problems and, in many cases, to assure that the products are effective in improving indoor air quality and overall indoor environments.

Methods to Prevent and Reduce Indoor Air Pollution

Section 5.2 (page 142) on "Ventilation" properly notes ASHRAE Standard 62, though it fails to distinguish between 62.1 for commercial and high-rise residential spaces and 62.2 for all other residential spaces. ARB is hereby cautioned of the recent addendum "n" to 62-2001, which CSPA appealed unsuccessfully to both ASHRAE and ANSI. Addendum "n" reduces the prescribed minimum ventilation rates for many commercial and institutional spaces, based on low-emitting European buildings. We strongly urge ARB to ensure that California does not adopt those lowered ventilation rates and potentially jeopardize the health of many Californians.

Prioritization of Sources and Pollutants Based on Exposure and Adverse Impacts

This section offers on page 147 that "non-toxic cleaning products are currently available." Unfortunately, that viewpoint does not take efficacy into account, which may require more product (with consequently more emissions) to perform the cleaning task, if it can be accomplished at all. In addition, the legitimacy of "non-toxic" claims on some of these products is questionable and, in the case of antimicrobials, would be in violation of FIFRA regulations.

In addition, as noted earlier regarding Table ES-3.2 on page 22, although the footnotes to Table 6.2 reveal that "All of the examples of pollutant sources may not emit all of the pollutants listed in the corresponding box in column two," the inevitable consequence of viewing the table is a totally unjustified broad-brush condemnation of large categories of consumer specialty products. Very few of the "Consumer Products" listed emit the "Pollutants" listed as examples. Further,

the relevance of "Direct State Authority to Take IAQ Mitigation Actions" is minimal where there is already a comprehensive federal regulatory system in place. This table must be edited to convey accurate and relevant information.

Options to Mitigate Indoor Air Pollution

CSPA generally concurs with the general mitigation options outlined in Section 7.1 (page 154). Our only concerns relate to the possible suggestion in option 12 that consumer products be included among the materials requiring "emissions testing" and "labeling," as well as the failure to address any specific mitigation options for the biological contaminants that present the greatest health risks and costs in California.

Summary

It is not an accurate characterization of the carcinogenic risk analysis performed in the CCRP to state that "about 230 excess cancers per year may occur in California due to indoor carcinogens from residential and consumer sources, such as formaldehyde." A more accurate characterization of the estimate would be "as many as 230 excess cancers."

SUMMARY AND CONCLUSIONS

CSPA and its member companies appreciate this opportunity to review this Draft Report and provide our input. We believe that significant improvements are needed for this Report to represent a comprehensive and balanced scientific review of the indoor air quality challenges currently facing California. In these comments, we have made the following key recommendations for improving the Report:

- The Draft Report underestimates the key health hazards presented by biological contaminants such as bacteria, fungi, insects and pollen.
- The Draft Report fails to consider the key roles played by various consumer products in improving indoor air quality and protecting public health.
- The Draft Report presents estimates based on potential risks that are misleading and require clarification.
- The Draft Report still includes some inaccurate, dated and misleading information on consumer products that should be corrected to accurately reflect their impact on indoor air quality and public health.

We look forward to continuing to work cooperatively with ARB staff in its efforts to finalize this Report to the Legislature. Please feel free to contact us at any time if you have any questions.

Respectfully submitted,

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Attachment A

BRIEF OVERVIEW OF KEY FEDERAL LAWS AND REGULATIONS TO ASSURE THE SAFETY OF CONSUMER PRODUCTS

Most consumer products, in order to be successful, must be purchased and used by many consumers. Therefore, the ingredients of these products are routinely evaluated for toxicity in safety evaluations that ensure that the levels of exposure from product use or foreseeable misuse are far below the level that would pose risks. In addition, chemical specialty products are comprehensively regulated by numerous federal agencies. Various federal statutes and regulations apply to manufacture, distribution, use and disposal of these products. The U.S. Consumer Product Safety Commission (CPSC) and the U.S. Environmental Protection Agency (EPA) are the primary regulators, but the Department of Transportation, the Food & Drug Administration, and the Occupational Safety & Health Administration play significant roles. Two of the primary provisions to which consumer specialty products are subject are summarized below. The Federal Hazardous Substances Act (FHSA) is described in some detail, while the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is briefly discussed.

The FHSA applies to most consumer products used in the home or school other than pesticides, foods, drugs, cosmetics, fuels, and tobacco products. Among the key provisions relating to children are consideration of any foreseeable use including ingestion by children and labeling guidelines for chronic hazards such as cancer, neurotoxicity, and developmental or reproductive toxicity. FIFRA covers all pesticides, which include not only insecticides and herbicides but also disinfectants and other antimicrobials. Among the provisions relating to children are child-resistant closures and application of a differential safety margin based on potential pre-natal and post-natal toxicity.

FHSA

The FHSA, enacted in 1960 and subsequently amended, is administered by the CPSC and requires labeling of "hazardous substances" if they are "intended, or packaged in a form suitable, for use in the household or by children." A hazardous substance that does not bear the labeling specified by section 2(p)(1) of the FHSA is misbranded and its introduction or receipt in interstate commerce is a prohibited act under the FHSA, subjecting the violator to penalties.

A hazardous substance under the FHSA includes "any substance or mixture of substances which (i) is toxic . . . if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." This definition encompasses two components: that the substance is "toxic" and that its reasonably foreseeable or customary use may cause substantial personal injury or illness.

Section 2(g) of the FHSA defines the term "toxic" very broadly as "any substance . . . which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." This broad statutory definition covers both acute and

chronic toxicity. The CPSC's regulatory definitions that interpret and supplement the statutory definitions provide specific tests that can be used to determine whether a product is acutely toxic by oral ingestion, inhalation, and skin contact.

The CPSC issued a supplemental definition in 1992 under the authority of section 10 of the FHSA that authorizes the Commission to issue regulations "for the efficient enforcement of this Act." The definition clarified that chronically toxic substances are "toxic" (and must be labeled appropriately) under the FHSA. Guidelines promulgated concurrently with the supplemental definition discuss the particular chronic hazards of cancer, neurotoxicity, and developmental or reproductive toxicity. However, the definition is not limited to only these hazards.

The guidelines present exhaustive discussions of the chronic hazards of cancer, neurotoxicity, and reproductive and developmental toxicity, as well as the principles of exposure and risk assessment. The guidelines clearly recommend a risk level of 10^{-6} for carcinogens and certain safety factors for neurotoxins and reproductive and developmental toxicants. The guidelines provide that these levels should generally be followed in making labeling decisions, but they recognize that sound scientific data may warrant deviation from these levels. Rather than requiring set risk levels, the final supplemental definition defines "toxic" as including such chronic toxicants as carcinogens, neurotoxins and reproductive and developmental toxicants.

The FHSA does not require manufacturers to use a particular, federally approved label; instead, the FHSA requires the use of specific signal words (e.g., "CAUTION" or "DANGER"). Section 2(p)(1) of the FHSA requires hazardous substances to bear certain types of label messages. Included within the types of labeling required are:

- The name of each component that contributes substantially to the hazard,
- A signal word (in the case of chronic hazards, "WARNING" or "CAUTION"),
- An affirmative statement of the hazard(s) (e.g., "Vapor harmful"),
- Precautionary statements describing the action(s) to be taken or avoided,
- Any necessary or appropriate instruction for first aid treatment,
- Any required instruction for special handling or storage of the package, and
- The statement "Keep out of the reach of children," or its equivalent.

Except for the signal word, the FHSA generally does not require particular label language and permits manufacturers to decide on the specific language. (In addition, the CPSC may, by rule, require different or additional labeling where required by a special hazard presented by the substance. Where labeling cannot adequately protect the public, the CPSC may ban a hazardous substance.)

In this regard, it should be noted that the term "label" is broadly defined by FHSA and expansively interpreted by the CPSC to include all written, printed or graphic matter upon the immediate container of any substance, and in any accompanying literature as designated by the Commission. "Accompanying literature" is defined as "any placard, pamphlet, booklet, book, sign, or other written, printed or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or

merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children."

Under the FHSA's labeling requirements for a hazardous substance that is intended or packaged for household use or for children, it is the manufacturers' responsibility to determine if their products are or contain a hazardous substance and must be labeled under the FHSA. Section 3(a)(1) of the FHSA provides for the CPSC to declare a particular substance to be a "hazardous substance" under the act in order to avoid or resolve uncertainty. However, the CPSC is not required to designate a substance as hazardous before enforcing the labeling requirements of section 2(p).

Other Regulatory Requirements

Child-resistant closures are required for products under two statutes. For products under the jurisdiction of the CPSC, the Poison Prevention Packaging Act (PPPA) requires such closures for twenty-nine types of materials or chemicals. For products governed by the EPA, FIFRA requires child-resistance closures based on the toxicity of the product. FIFRA references the PPPA protocol for the testing of child-resistant closures. This protocol was amended in 1995 to require that the closures used are both child-resistant and senior-friendly. The CPSC regularly reviews these requirements and is currently examining whether to require child-resistant closures across the board for household products containing certain levels of hydrocarbons.

EPA regulates the sale and use of all pesticides under FIFRA. Prior to any manufacture, formulation, or distribution, each pesticide must be registered with EPA. In order to obtain or maintain a registration, each product must be thoroughly tested, being subject to well over 100 tests, depending on use. The tests include data requirements for product chemistry, physical and chemical characteristics, toxicology, reentry protection, and environmental fate. EPA also conducts an extensive risk assessment, including any possible risks associated with exposure following an application of the end-use product. In 1996 FIFRA was amended by passage of the Food Quality Protection Act (FQPA). FQPA provided heightened health protections for infants and children from pesticide risks by requiring the application of a ten-fold margin of safety (or a different margin based on reliable data) to take into account potential pre-natal and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. FQPA created a need for new techniques and methods that can provide quantitative data leading to comprehensive assessments of aggregate and cumulative exposure to pesticides, and the calculation of potential health risks associated with their use.

Consumer Specialty Products Association

Attachment C

OVERVIEW OF THE HEALTH BENEFITS OF CONSUMER SPECIALTY PRODUCTS

Consumer specialty products pay key roles in lowering risks of infectious diseases, including those for which insects and/or rodents serve as disease vectors, and diseases such as asthma, which is caused primarily by various biological allergens. Household and institutional cleaning products, antimicrobial products, and pest management products play a critical role in protecting the public health.

According to the U.S. Centers for Disease Control, each year Americans are sick more than 4 billion days from infectious diseases, and as a result spend more than $950 billion on direct medical costs. In addition, over 160,000 people in the United States die yearly with an infectious disease as the underlying cause of death.

The many benefits of deep cleaning and dust control with typical household consumer specialty products have been documented in an EPA-sponsored study.[1] That study, conducted in a daycare center, reported that improved housekeeping reduced total fungi by 61%, airborne dust by 52%, volatile organic compounds by 49%, and total bacteria by 40%. Thus it was shown that frequent cleaning with products such as cleaners, disinfectants, polishes and carpet shampoos significantly reduces contaminants in children's indoor environments. A study of children's bedrooms in Boston-area homes showed that cleaning -- mopping or vacuuming -- the floor at least once a week resulted in lower levels of fungi per gram of dust on hard floors than did less frequent cleaning.[2]

Disinfectants used on kitchen sinks, floors and bathrooms eliminate *Salmonella, Staphylococcus*, and fecal coliform bacteria such as *E. coli* that can cause food poisoning and other diseases. A study of the use of disinfectants in day care (where 80% of U.S. families place their children while parents work), showed that proper and consistent use of disinfectants resulted in a 24% reduction in children's overall infections and a 37% decrease in respiratory illnesses.[3] Use of sanitizers and other cleaners on accessible parts of the air handling systems in homes, as part of regular maintenance to remove microbial growth, mitigates the biological contaminants that infiltrate the home.[4]

A recent study assessed the economic benefits that could be obtained from a comprehensive infection control program which included an effective cleaning and disinfecting regimen in a

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[1] "Indoor Environment Characterization of a Non-Problem Building: Assessment of Cleaning Effectiveness," Research Triangle Institute, prepared for Environmental Criteria and Assessment Office, U.S. E.P.A., March 1994.

[2] "Relationship between Levels of Fungi in House Dust and Occupant's Responses to Home Characteristic Questions," Journal of Allergy and Clinical Immunology, Part III, Vol. 97, No.1, p. 222, 1996.

[3] "Impact of an Infection Control Program in a Specialized Preschool," American Journal of Infection Control, June 1996.

[4] "Knowing HVAC System Basics Can Stop Microbials," Gary Luepke, Indoor Environment Review, January 1998.

pre-school for children with Down syndrome.[5] The study found an estimated savings in health care costs of $13,224 based on an investment of $2,371, thereby providing a net societal benefit of $10,853 for the pre-school program.

Viruses can survive on environmental surfaces for many hours, which can lead to spreading viral infections. Studies have confirmed the effectiveness of antimicrobials in inhibiting the spread of viruses such as rhinovirus type 14 from environmental surfaces to hands.[6] A more scientific review of the factors that impact the spread of infections in American and Canadian homes found that regular and thorough cleaning can lead to reductions in microbial loads in homes, and also reduce the levels of allergens, endotoxins and heavy metals, as well as microbial disease organisms such as hantavirus.[7]

A major report from the National Academy of Science's Institute of Medicine concluded that there was a sufficient evidence of a causal relationship for house dust mite exposure to lead to the development of asthma, and for allergens associated with dist mites, cockroaches and cats to be associated with causing asthma symptoms to worsen.[8] Asthma-related hospital stays now cost over $350 million annually in the state of California alone.

Controlling cockroaches in the home with residential insecticides is an important step in protecting vulnerable children suffering from asthma and indoor air-related illness. Asthma is one of the leading causes of children missing school, and is called the most prevalent chronic disease of children by the American Lung Association. Asthma is aggravated in youngsters who are allergic and are further exposed to cockroach allergen. A study published in *The New England Journal of Medicine* recommends the use of insecticides and roach traps as a method of reducing illness due to asthma. Research was conducted in six major cities among asthmatic inner-city 4- to 9-year-olds who were exposed to cockroaches in their bedrooms. Their hospitalizations were 3.4 times higher than for other asthmatic youngsters who were allergic to dust mites or cats. The roach-allergic children had 78% more unscheduled medical visits than the other children in the study.[9] In the US, about 7.5% of the population is allergic to cockroaches.

Asthmatics also are susceptible to the dust mites that feed on organic matter in house dust.[10] That matter is primarily human skin scales, but also fungi and food or waste particles. Up to 12,000 mites per gram of house dust have been found in mattresses. While 5% of the population is believed to be allergic to house dust, from 45% to 85% of asthmatics have been shown to be

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[5] "Economic Impact of an Infection Control Education Program in a Specialized Pre-School Setting," Ackerman SJ, Duff SB, et al., *Pediatrics* 108:6, 2001.

[6] "Chemical Disinfection to Interrupt Transfer of Rhinovirus Type 14 from Environmental Surfaces to Hands," Sattar, S.A., et al., Applied Environmental Microbiology, 59:5, 1993.

[7] "Impact of Changing Societal Trends on the Spread of Infections in American and Canadian Homes," Sattar, S.A. et al., American Journal of Infection Control, 27:6, 1999.

[8] "Clearing the Air: Asthma and Indoor Air Exposures," National Academy Press, January 2000.

[9] "The Role of Cockroach Allergy and Exposure to Cockroach Allergen in Causing Morbidity among Inner-City Children with Asthma," The New England Journal of Medicine, May 8, 1997.

[10] "Indoor Allergens -- Assessing and Controlling Adverse Health Effects," A.M. Pope, R. Patterson, and H. Burge, editors, Committee on the Health Effects of Indoor Allergens, Institute of Medicine, National Academy of Sciences, 1993.

sensitive to mites (compared to 5% to 30% of the general population).[11] Over time, exposure to dust mite allergen increases the risk of allergic sensitization, making cleaning all the more important.

Studies have shown the importance of eliminating household pollutants and allergens to control asthma. A recent study in *Pediatrics* found that eliminating household allergens could result in a nearly 40% decrease in asthma among children ages six and younger.[12] Among the common allergens that are asthma triggers is animal dander, such as from cats and dogs, cockroaches and dust mites. These allergens have also been shown to be associated with the development of asthma in infants.[13] Normal laundering using laundry detergents is effective in removing dust mites and cat dander, while the use of just soap and water are less effective, according to another recent study.[14]

Researchers at Johns Hopkins concluded that cockroach allergens in inner city homes could be reduced up to 90% with both insect pest extermination and rigorous household cleaning, although the remaining allergens may still remain high enough to cause disease even after these steps are taken.[15] Cockroach and dust mite allergen exposure in a baby's first three months was found to lead to acute episodes of wheezing early in the life of the child.[16]

Insects are also often vectors for infectious diseases, and insect pest management products play an important public health role in this area. Mosquitoes carry West Nile encephalitis, malaria, dengue fever, and other diseases. There are currently over 4,000 encephalitis cases each year in the United States. Ticks can carry serious diseases such as Lyme disease and Rocky Mountain spotted fever, which can last a lifetime and cause permanent disability. More than 18,000 cases of Lyme disease are reported each year, and many cases go unreported and undiagnosed.

The common house fly also spreads bacteria known to cause human disease, including Acinetobacter baumanni, Bacillus cereus, Enterobacter sakazakii, Escherichia coli, Shigella sonnei, Staphylococcus saprophyticus, and Bacillus thuringiensis. These bacteria cause diseases such as meningitis, pneumonia, food poisoning, intestinal infections, dysentery, bacteremia, and many others. They also carry a number of parasitic worms. Red fire ants also constitute a serious pest problem in California and many southern states, and have been known to get indoors to inflict their flesh-stinging bites on humans.

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[11] "Dust Mite Allergens and Asthma: a Worldwide Problem," *International Workshop Report, Bulletin, World Health Organization*, 66(6) 769-780, 1988.

[12] "Residential Exposures Associated with Asthma in U.S. Children," Lanpher BP, Aligne CA, Auinger P et al., *Pediatrics* 2001 (107) 3 505-511.

[13] "Avoiding Allergen Exposure in Infancy Reduces the Development of Asthma," Ashad H, presented at the 57th Annual Meeting of the American Academy of Allergy, Asthma and Immunology, New Orleans, 2001.

[14] "Effectiveness of Laundry Washing Agents and Conditions in the Removal of Cat and Dust Mite Allergen from Bedding Dust," Tovey ER, Taylor DJ, Mitakakis TZ et al*., J. Allergy Clin Immunol* 2001; 108: 369-374.

[15] "Cockroach Allergen Remains After Extermination and Thorough Cleaning," Eggleston P et al, presented at 56th Annual Meeting of the American Academy of Allergy, Asthma and Immunology, 2000; San Diego, California.

[16] "Cockroach and Dust Mite Allergen Exposure in Homes of Children with Acute Episodes of Wheezing," Camara, A.A. et al., AAAAI 56th Annual Meeting, Abstract No. 244.

Molds and other fungi represent very serious health threats in the US. An entire issue of a recent scientific journal was dedicated to the topic of "Indoor Mold and Children's Health," which noted that asthma incidence in children has increased 58% since 1980, and that molds are a contributor to this increase.[17] The most common indoor molds are Cladosporium, Penicillium, Aspergillus, and Alternaria. Some indoor molds have the potential to produce extremely potent toxins called mycotoxins. Such molds include Fusarium, Trichoderma and Stachybotrys. The American Academy of Pediatrics recommends the use of chlorine bleach to disinfect and inhibit mold growth after floods or other water damage.[18]

Residential mold growth has recently been found to be associated with respiratory symptoms such as those previously associated with dust mites and bacterial endotoxins.[19] Infant pulmonary hemorrhage has also been found to be caused by exposure to mold, and chlorine bleach was required to remove the source of the fungal exposure.[20] Fungal spores have been found to be able to enter the lungs and potentially cause toxic pneumonitis, hyperpneumonitis, tremors, chronic fatigue syndrome, kidney failure, and cancer[21]

Rodenticides also play a key role in fighting diseases where rodent pests are vectors in the spread of infectious microorganisms. There are more than 250 million rats in the US, and an even larger number of house mice. Both rats and mice carry and spread disease producing bacteria and parasites that cause 35 known diseases, including leptospirosis (Weil's disease), hantavirus, Listeriosis, rabies, salmonellosis, Trichinosis, various forms of typhus, various forms of tapeworm, and ringworm. In 2000, a rare virus called arenavirus, transmitted through inhalation of dust from rodent droppings, was linked to deaths in California. A study published in the British Journal of Cancer in 2000 found that a virus found in the house mouse might be responsible for two of every five human breast cancers.

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[17] Environmental Health Perspectives Supplements, 107:S3, June 1999.

[18] American Academy of Pediatrics Policy Statement, Pediatrics, 101:4, April 1998.

[19] "Residential Fungal Contamination and Health: Microbial Cohabitants as Covariates," Dales, R.E and Miller, D., Environmental Health Perspectives 107:3, 1999.

[20] "Infant Pulmonary Hemorrhage in a Suburban Home with Water Damage and Mold," Environmental Health Perspectives, 107:11, November 1999.

[21] "Fungal Spores: Hazardous to Health?" Sorenson, W.G., Environmental Health Perspectives 107:S3, June 1999.