Celebrating 75 Years of Energy Efficiency

NAIMA
NORTH AMERICAN INSULATION MANUFACTURERS ASSOCIATION

VIA E-MAIL

February 15, 2011

Ms. Fran Kammerer
Office of Environmental Health Hazard Assessment
P.O. Box 4010
Sacramento, CA 95812-4010

RE: Green Chemistry – Notice of Proposed Rulemaking Title 22, California Code of Regulations, Sections 69401 Through 69406 Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse

Dear Ms. Kammerer:

INTRODUCTION

The North American Insulation Manufacturers Association ("NAIMA") appreciates the opportunity to submit written comments on the California Office of Environmental Health Hazard Assessment's ("OEHHA") proposed identification of hazard traits, endpoints, and other relevant data under the California Safer Consumer Product Alternatives proposed regulation (Cal. Code Regs. Tit. 22, § 54 (2010) ("SCPA")).

NAIMA is the association for North American manufacturers of fiber glass, rock wool, and slag wool insulation products. NAIMA promotes energy efficiency and environmental preservation through the use of fiber glass, rock wool, and slag wool insulation, and encourages the safe production and use of these materials. NAIMA members operate four insulation manufacturing plants in California. Fiber glass insulation products are used widely throughout the State of California. NAIMA members' insulation products are sold at home improvement stores throughout the State and installed by homeowners as weekend do-it-yourself projects. Their products are also installed by professional insulation contractors in both new and existing homes and commercial buildings. The draft definition of hazard traits and endpoints is highly relevant to NAIMA and its manufacturing members.

NAIMA's comments will demonstrate the following:

- The proposed rule so broadly defines hazard traits that it substantially lowers the level and strength of evidence that can be used by the Department of Toxic Substances Control ("DTSC") to classify a substance.

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- The actual effect (albeit unintended) of the proposed rule is that it is likely to result in removing incentives to undertake product safety testing and placing a higher priority for substitution of substances (including substances in products) with weak scientific data.
- The examples under "Respiratory Toxicity" should be expanded to include concepts of biosolubility and biopersistence.
- Glass wool insulation is the most thoroughly tested insulation product on the market. Untested products present a far greater risk than those subjected to extensive testing.
- The proposal reduces the incentives to do safety testing and rewards products that have inadequate data.
- The proposed DTSC regulation threatens California's economic foundation and puts at risk the economic benefits provided by four fiber glass manufacturing facilities in the State of California.
- Glass wool insulation promotes energy efficiency and environmental preservation, which are two important goals of the State of California.

THE PROPOSED REGULATION SIGNIFICANTLY LESSENS THE DATA THAT CAN BE USED FOR A DETERMINATION OF A HAZARD TRAIT

The heart of the OEHHA proposal is the broad definition of "hazard traits" that will be used by the DTSC to evaluate and prioritize substances and to populate the Toxics Information Clearinghouse."[1] In particular, the SCPA proposed rule broadly specifies the type of evidence that can be used to determine whether a substance (and ultimately a product) is prioritized pursuant to the SCPA proposed rule and, therefore, ultimately whether the sale of a product containing a priority substance is restricted or banned.

The Broad Hazard Trait Framework May Undermine Generally Accepted Scientific Principles

Several key steps in the proposed hazard trait process significantly lessen the quantity and quality of scientific evidence needed by the DTSC to determine whether a substance possesses a hazard trait. Key decision steps are contrary to generally accepted scientific principles. The major provisions are discussed below.

First, the proposed SCPA rule explicitly states that a hazard trait "can be demonstrated by . . . 'suggestive evidence.'"[2] Suggestive evidence is described as "positive evidence" that is not definitive of a causal association.[3] The proposal clearly intends that suggestive evidence can be used without other evidence, *e.g.*:

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[1] Initial Statement of Reasons Supporting Green Chemistry Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse at 3 of 121 (December 17, 2010) ("Initial Statement").

[2] § 69402. Initial Statement at 20 of 121. *See Id.* at 92-93 of 121.

[3] Initial Statement at 22 of 121. Suggestive evidence is, by definition, evidence that is insufficient to prove causation. For example, a positive "association" between an exposure (*e.g.*, exposure to particulates) and a disease "is not necessarily proof that the exposure *caused* the disease." National Institute of Environmental Health Sciences, Questions and Answers, EMF in the Workplace, Electric and Magnetic Fields Associated with the Use of

> For example, if this regulation were to only describe "strong evidence" for hazard traits, an alternatives assessment might erroneously conclude that a chemical does not have a particular hazard trait even when there is evidence to suggest that it does. Overlooking suggestive evidence for a hazard trait would increase the likelihood of a business or regulatory decision that results in a regrettable substitution of one hazardous chemical for another in a product, thereby defeating one of the key purposes of the DTSC regulatory program. The description of "suggestive evidence" in this regulation will help ensure that such evidence is available in the Clearinghouse and is considered when DTSC, businesses and others weigh the advantages and drawbacks of using various chemicals as alternatives.
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> **Absence of data does not constitute absence of hazard, however, and the absence of strong or suggestive evidence does not translate to absence of the hazard trait** (bold face added).[4]

"Suggestive evidence" is defined in the rule as including evidence: (a) from a "single experiment;" (b) where the design, conduct or interpretation of the studies may be questionable; (c) that "the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential;" or (d) that is "restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs."[5] The proposal will encourage reliance on such limited data, even in the absence of more probative studies.

Second, the proposal does not include any indicia of scientific reliability, such as conducted in accordance with Good Laboratory Practice, or following a validated protocol. This raises the specter of a substance being classified as hazardous based on poor or even invalid laboratory practices.[6]

Third, the proposed rule by the DTSC permits hazard trait determination based solely on screening tools. For example, the Initial Statement cites an Environmental Protection Agency ("EPA") research Memorandum of Understanding used to develop screening tools as support for using *in vitro* data to identify toxicological hazards[7] and several other frameworks. Such screening tools provide only a basis for further investigation.

Electric Power at 10 of 40, (September 1996), *at* http://www.niehs.nih.gov/emfrapid/html/Q&A-Workplace.html ("NIEHS Q&As"). It is rare that any particular study, even a finding of a statistically significant increased risk in an exposed population in an epidemiological study, *proves* a causal relationship. According to the U.S. EPA, studies can only identify patterns or trends in disease occurrence over time or in different geographical locations but cannot ascertain the causal agent or degree of exposure. EPA, Guidelines for Assessment of Carcinogen Risk at 2-5 (2005), available at http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.pdf ("EPA Cancer Guidelines").

[4] Initial Statement at 21 of 121.

[5] *Id.* at 92 of 121.

[6] *Id.* at 18 of 121.

[7] *Id.* at 17 of 121.

Fourth, the proposed rule may encourage the DTSC to designate a substance due to a chemical or physical property. For example, the Initial Statement states that a substance may be classified a hazard because "a basic physico-chemical property is . . . associated with many hazard traits," such as the fact that many chemicals are strongly electrophilic (and thus, are "capable of binding to a number of large molecules in cells") and some strongly electrophilic chemicals have been demonstrated to cause a wide variety of adverse impacts. Similarly, the Initial Statement cites EPA's Oncologic™ as an example model that "should be considered as suggestive evidence that a chemical substance may cause cancer."[8]

The proposed rule describes how these bases for hazard trait determination can apply for all eighteen hazard traits, thereby undermining generally accepted scientific principles.

THE PROPOSED RULE DOES NOT ADDRESS DATA QUALITY OR PEER REVIEW, AND MAY PROMOTE DTSC RELIANCE ON INVALID OR POOR QUALITY DATA

The proposed rule's criteria to determine whether a substance possesses a hazard trait makes no provision for capturing data quality that deviates from generally accepted scientific principles regarding data quality. The minimal criteria for including a hazard trait, as a practical matter, render the determination of a hazard trait "virtually criteria-less."[9]

For example, the absence of meaningful criteria could lead to reliance by the DTSC on a single experiment with methodological flaws showing an increase in benign tumors. But benign tumors, in and of themselves, do not demonstrate hazard.[10] Similarly, one experiment demonstrating a statistically significant higher rate of disease in, for example, a rat study could be due to random variation, confounding factors, or methodological flaws.

While some physical traits (*e.g.*, acidity) may cause an adverse effect and thus a hazard trait in most uses (*e.g.*, irritation when sprayed in the eyes), the proposed rule could be interpreted as allowing the designation of any hazard trait based on physical and chemical properties. Thus, for some substances, the proposed rule may be interpreted to allow chemical/physical data to demonstrate all substances containing that chemical and/or physical property lead to an adverse health effect.

The proposed rule also allows mechanistic evidence "alone" to "provide strong evidence of carcinogenicity."[11] Therefore, the proposed rule promotes future classification based merely on suggestive mechanistic evidence.

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[8] *Id.* at 29 of 121.
[9] *Id.* at 20 of 121.
[10] "Observation of only benign neoplasia may or may not have significance for evaluation under these cancer guidelines" and "observation of a benign tumor response alone may have no significant health hazard implications when other sources of evidence show no suggestion of carcinogenicity." EPA Cancer Guidelines, *supra* note 3, at 2-2.
[11] Initial Statement at 28 of 121.

Although the Initial Statement of Reasons states the "framework for each hazard trait . . . is loosely based on the framework used by the International Agency for Research on Cancer [IARC] for describing the available evidence on carcinogenicity,"[12] the Initial Statement cites a myriad of other governmental frameworks and nonregulatory documents to support one or another aspect of the hazard trait framework.[13] Thus, the benefit of the IARC framework may be undermined.

The draft regulation has no mechanism to determine the continuing validity or timeliness of various classification decisions. Limited resources usually prevent the rapid change in classification of substances that should follow when significant new data are available. Limited resources to populate the clearinghouse are also a serious concern.

THE EXAMPLES FOR "OTHER RELEVANT DATA" FOR RESPIRATORY TOXICITY SHOULD BE EXPANDED

The proposed rule defines a Respiratory Toxicity hazard "as an adverse change in the structure or function of the respiratory tract following exposure to a chemical substance, including respiratory tract injury or decreased ability of the lungs to function in gas exchange."[14]

OEHHA describes this hazard trait as including:

- "[M]aterials that are fibrous in nature, and respirable, such as asbestos, can deposit in the lung and cause damage along the respiratory tract. Chemicals that are gases tend to impact the upper airway if they are water soluble, and impacts can extend down to the lower airway and parenchyma if they are less water soluble;"[15]
- "Particle size and fiber dimension influences where in the respiratory system a particle phase chemical will deposit and influences the toxicity of the chemical. If the chemical substance has a long half-life in the lung, then the probability of adverse health impacts from toxicity increases;"[16] and
- "[A] series of *in vitro* assays demonstrating the potential for a compound to produce prolonged inflammation would be suggestive evidence for the respiratory hazard trait, among others."[17]

Respiratory tract toxicity is a very common endpoint and can be influenced by numerous factors identified in a broad array of assays and other data. The examples of "other relevant data" should be expanded beyond "water soluble," to include, for example, "biosoluble" (solubility in biologic fluids). Similarly, the "long half-life in the lung" example should be expanded to

[12] *Id.* at 6 of 121.
[13] Initial Statement at 16-17 of 121.
[14] § 69403.15(a) Respiratory Toxicity.
[15] Initial Statement at 88 of 121.
[16] *Id.* at 91 of 121.
[17] *Id.* at 93 of 121.

include broader hazard assays, concepts, and endpoints, such as those measuring biopersistence. The value of modestly expanding the examples can be seen in the biopersistence assays used by the European Union ("EU") to evaluate potential fiber toxicity.[18]

THE PROPOSAL MAY DISCOURAGE RESEARCH ON POTENTIAL HAZARDS SO PRODUCTS HAVE NO "HAZARD TRAITS" FOR THE CLEARINGHOUSE

The absence of meaningful scientific criteria becomes even more apparent when applied to well-tested materials. If no scientific data is available for materials, OEHHA's proposal encourages the DTSC to give preferential treatment to untested products. An untested product does not mean it is a safe product.[19] A system wherein untested products are treated as though they are safe and not regulated should not form the basis for a decision on whether a product is banned. The DTSC should avoid awarding preferential treatment to a product or substance simply because a particular product's manufacturer has neglected responsible product stewardship and refused or failed to test its product. Indeed, the failure of a particular product or substance to be adequately tested should be a critical factor in determining that a product is not an acceptable alternative.

Glass wool is currently listed on Proposition 65 under its "authoritative bodies" criteria. The current validity of that listing is discussed more fully below, but the relevant point here is that the listing on Proposition 65 could result in a ban on fiber glass because of the draft regulation's wording. This would be a ludicrous result. Consider the history of fiber glass insulation's product stewardship and the enormous benefits of energy efficiency and pollution reduction derived from the installation of these products.

Since its introduction into commerce nearly 75 years ago, fiber glass has become one of the world's most useful insulating materials, helping homeowners and industry increase energy efficiency, protect the environment, and reduce energy costs.

As OEHHA knows, properly conducted toxicological studies normally require testing at doses sufficient to find an effect, and thus proper testing will almost always result in a hazard trait under the proposal. The proposal may therefore discourage proper testing of substances. Fiber glass insulation has been evaluated by many first-rate toxicological, epidemiological, and other studies at leading independent laboratories in the United States and abroad. Indeed, glass wool insulation is the most thoroughly tested insulation type. In contrast, the manufacturers of some competing insulation types have not provided any data to evaluate their products. This is an example of how the proposed rule will, unfortunately (and probably unintentionally), discourage

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[18] European Union (Nota Q, Regulation EC No 1272/2008 (CLP Regulation)), available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF. "All mineral wool insulation products manufactured by EUCEB members . . . are not classified as dangerous in accordance with the European Union regulations on classification, labelling and packaging of substances and mixtures." *See* available at http://www.euceb.org/.

[19] J.M.G. Davis, "The need for standardized testing procedures for all products capable of liberating respirable fibres; the example of materials based on cellulose," *British Journal of Industrial Medicine* 1993; 50: 187-190.

the development of the data the DTSC needs for evaluation. OEHHA and the DTSC should consider how to reduce this bias against quality data inherent in the proposed system.

The weight of the scientific research shows no association between exposure to glass fibers and respiratory disease or cancer in humans. In October 2001, an international expert review by the International Agency for Research on Cancer ("IARC") re-evaluated the 1988 IARC assessment of glass fibers and removed glass, rock and slag wool fibers from its list of substances "possibly carcinogenic to humans." They relied upon the scientific data that had been developed as a result of the industry's sponsored research following the 1988 IARC assessment. All fiber glass and rock and slag wools that are commonly used for thermal and acoustical insulation are now considered not classifiable as to carcinogenicity in humans (Group 3). IARC noted specifically:

> Epidemiologic studies published during the 15 years since the previous IARC Monographs review of these fibres in 1988 provide no evidence of increased risks of lung cancer or mesothelioma (cancer of the lining of the body cavities) from occupational exposures during manufacture of these materials, and inadequate evidence overall of any cancer risk.

IARC retained its Group 3 classification for continuous glass filaments and the Group 2B "possible carcinogen" classification for certain special purpose glass fibers, which are about 1 percent of total glass wool fiber products and used by OEM manufacturers with established health and safety programs.

The IARC change is consistent with the conclusion reached by the U.S. National Academy of Sciences, which in 2000 found "no significant association between fiber exposure and lung cancer or nonmalignant respiratory disease in the MVF [man-made vitreous fiber] manufacturing environment."

IARC's comprehensive review of the extensive studies developed over the past 15 years indicates that some of the prior expert reviews now need to be updated. Many of these earlier reviews do not account for the new science. For example, the U.S. Department of Health and Human Services (HHS, Shalala 1994) included fiber glass on its list of possible carcinogens based primarily on the 1988 IARC classification. Similarly, the California listing of fiber glass as "known to the state to cause cancer" was based principally on the old IARC classification.

The Agency for Toxic Substances and Disease Registry's ("ATSDR") Toxicological Profile on Synthetic Vitreous Fibers confirms the need for historic lists to update and revise their current listings:

- "In 2002, the International Agency for Research on Cancer (IARC) considered all of the evidence regarding the possible carcinogenicity of synthetic vitreous fibers. Much of the

evidence was collected in the 1990s and was not available for earlier assessments made by the U.S. Department of Health and Human Services (DHHS)."[20]

- "The U.S. Department of Health and Human Services, National Toxicology Program (NTP 1998, 2000, 2002) classified glass wool (respirable size) as *reasonably anticipated to be a human carcinogen*, based on the sufficient evidence of carcinogenicity in experimental animals. This assessment was originally prepared in 1993-1994 for the *7th Report on Carcinogens* (NTP 1994), but has not been updated since then in the *8th, 9th, or 10th Reports on Carcinogens* (NTP 1998, 2000, 2001)."[21]

In 2002, NAIMA petitioned the National Toxicology Program ("NTP") to delist fiber glass insulation from its Report on Carcinogens ("RoC"). In what has been an extremely lengthy bureaucratic process, NTP is close to issuing its final decision. What has happened along the way is consistent with what IARC did in 2001. Specifically, in 2009, the NTP Expert Panel, a group of fiber experts selected by NTP for their special expertise in fiber toxicology and the absence of industry ties, unanimously recommended that fiber glass be delisted from the RoC. Approximately a year later, NTP issued its Draft Substance Profile on the Petition to Delist Fiber Glass, specifically concluding that the majority of glass fibers are not carcinogens. In fact, 99 percent of all glass fibers under consideration by NTP do not cause cancer, but a small 1 percent of special purpose fibers are classified as a possible carcinogen. A possible carcinogen is significantly different from a known carcinogen because the scientific evidence for "known" is definitive and conclusive whereas possible carcinogens, which include coffee, are open to debate and the evidence is not conclusive.

In June 2010, the Board of Scientific Counselors reviewed the Draft Substance Profile, and the minutes of that meeting provide further concurrence of IARC's 2001 decision with that recognition that 99 percent of the glass fibers reviewed by NTP are not carcinogens. Importantly, NTP senior staff explained to the Board of Scientific Counselors that they intended to follow the European Union's ("EU") approach of allowing fibers (individual fibers) to be exonerated. Under this scenario, many of the glass fibers are already exonerated under the EU criteria, so these fibers would not be considered a carcinogen by NTP.

The weight of the scientific evidence shows no evidence of carcinogenicity in glass wool insulation. This scientific evidence has been reviewed by the international scientific community and the most authoritative bodies. These bodies historically have been predisposed to classify and list substances as carcinogens on limited evidence, yet fiber glass has been determined to be a non-carcinogen by IARC, the National Academy of Sciences, the NTP's Expert Panel, and NTP senior staff. ATSDR and many other governmental bodies outside the United States have reached similar conclusions that fiber glass is not a carcinogen.

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[20] *Toxicological Profile for Synthetic Vitreous Fibers* (U.S. Department of Health and Human Services, Public Health Services, Agency for Toxic Substances and Disease Registry), September 2004, p. 7.
[21] *Id.* at p. 217.

NAIMA MEMBERS PRODUCE PRODUCTS ECONOMICALLY IMPORTANT TO CALIFORNIA

Virtually all of NAIMA's members' products are used or sold in California. More importantly, NAIMA's members provide important manufacturing jobs to the California economy. Specifically, Owens Corning operates a fiber glass building materials manufacturing facility in Santa Clara. According to public sources, Owens Corning's Santa Clara facility employs an estimated 400 employees (www.manta.com/c/mmcntlv/owens-corning-sales-inc). Johns Manville operates a fiber glass manufacturing facility in Willows, California. According to public sources, Johns Manville's Willows facility employs between 250 and 499 employees and generates annual revenue of $100 to $500 million (www.manta.com/c/mmcckzn/johns-manville-corp). CertainTeed Corporation operates a fiber glass manufacturing facility in Chowchilla, California. According to public sources, CertainTeed's Chowchilla facility employs between 250 and 499 employees and generates annual revenue of $50 to $100 million (www.manta.com/c/mmjhsbb/certain-teed-corp). Knauf Insulation operates a fiber glass manufacturing facility in Shasta Lake, California. According to public sources, Knauf's Shasta Lake facility employs between 100 and 249 employees and generates annual revenue of $50 to $100 million (www.manta.com/c/mm0tt3b/knauf-fiberglass).

California is losing manufacturing jobs – in both traditional and high-tech industries – to other states and nations. One of the key reasons for this exodus from California is the State's existing regulatory requirements and concerns about the future regulatory climate.[22] California's regulatory environment is challenging, time-consuming, complex, duplicative, and costly.

The regulation under discussion herein is a perfect example of a regulation that will further encourage companies to pull out of California and cripple the State's economy. As discussed in greater detail below, this regulation, as currently written, could ultimately result in fiber glass products being banned from the State of California. That outcome would needlessly shut down all fiber glass manufacturing in the State, ban the sale of products that contain fiber glass insulation, prevent it from being used to insulate homes and buildings, and raise serious issues about the impact of its presence in homes and buildings that have already been insulated with it, including their market value and the health and safety of the occupants of those buildings. Fiber glass insulation is the most used insulating material available today.

Thus, fiber glass insulation is an important contributor to the California economy, both through direct manufacturing and imports, and also for insulation installers, homebuilders and consumers. NAIMA members have a great interest in the proposal.

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[22] Ross C. Devol, Perry Wong, Armen Bedroussian, Candice Flor Hynek, and David Rice, "Manufacturing 2.0: A More Prosperous California," Milken Institute, June 2009, p. 9.

GLASS WOOL INSULATION PROMOTES ENERGY EFFICIENCY AND ENVIRONMENTAL PRESERVATION AND HELPS CALIFORNIANS MEET ENERGY EFFICIENCY GOALS

The most important environmental benefit of fiber glass insulation is its ability to make buildings more energy efficient. A thermally efficient building reduces the amount of energy required to maintain a comfortable indoor environment. A reduction in energy consumption conserves non-renewable fuel supplies and reduces air pollution and greenhouse gas emissions such as CO_2 and NOx. According to a Harvard University School of Public Health study, this reduction in emissions as a result of energy efficiency through the use of thermal insulation greatly improves public health and saves lives.[23]

Energy efficiency is a resource. Indeed, insulation products are resources. In fact, energy efficiency, including insulation, has been deemed the greatest untapped resource available to address the current energy crisis and climate change.[24] Unlike other energy efficiency measures, such as energy-efficient appliances or energy-saving light bulbs, insulation, once installed, requires no additional energy to save energy. Insulation is a one-time cost that lasts the life of the building and requires no further maintenance. Nationally, insulation saves over 600 times more energy each year than all of the compact fluorescent lights, Energy Star appliances and Energy Star windows combined.[25] Indeed, the California Air Resources Board has identified increasing the energy efficiency of existing buildings as the "greatest potential for GHG reductions in the building sector."[26]

CONCLUSION

NAIMA strongly urges OEHHA to abandon the proposed rule and retain the existing risk-reduction framework. In the alternative, OEHHA should undertake major revisions to the proposed rule on hazard traits to eliminate those provisions that undermine sound science, inadvertently reward untested substances, and ignore the assurance represented by effective product stewardship.

Sincerely,

Angus E. Crane

Angus E. Crane
Executive Vice President, General Counsel

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[23] Jonathan I. Levy, Yurika Nishioka and John D. Spengler, "The public health benefits of insulation retrofits in existing housing in the United States," *Environmental Health: A Global Access Science Source*, April 2003, 2:4.
[24] "Transforming Energy Efficiency." www.duke-energy.com/docs/CGI - Fact-Sheet.doc, September 27, 2007.
[25] U.S. Environmental Protection Agency, ENERGY STAR Homes. Calculations performed by B. McNary, October 2006.
[26] California Air Resources Board, "Climate Change Proposed Scoping Plan: A Framework For Change," October 2008, App. C, at C-146.