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July 13, 2009

Ms. Cynthia Oshita
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Dear Ms. Oshita:

Celanese Corporation appreciates the opportunity to submit comments in response to the June 12 *Request For Comments On Chemicals Proposed For Listing By The Labor Code Mechanism (Carcinogens)*. We are commenting in particular on the inclusion of vinyl acetate (CAS NO. 108-05-4) on the proposed list of chemicals.

Celanese is requesting by the attached comments that OEHHA:

- reconsider its proposed listing by the Labor Code mechanism,
- refrain from listing vinyl acetate as a chemical known to cause cancer, and
- work with Celanese and other interested parties in evaluating whether additional review of vinyl acetate is appropriate.

We also seek an opportunity to meet with OEHHA to further discuss the process and substantive issues prior to any final determination on the proposed listing.

Sincerely,



Dr. Edward E. Quick
Global EHS Director
Celanese Corporation

Celanese Corporation's Response to Request for Comments on Chemicals Proposed for Listing by the Labor Code Mechanism (Carcinogens)

Dated: July 13, 2009

Celanese International Corporation ("Celanese") submits these comments in response to the Office of Environmental Health Hazard Assessment's ("OEHHA's") "Request for Comments on Chemicals Proposed for Listing by the Labor Code Mechanism (Carcinogens)" dated June 12, 2009 ("Request"). Celanese is commenting particularly on the inclusion of vinyl acetate (CAS NO. 108-05-4) on the proposed list of chemicals to be added pursuant to the Labor Code mechanism under the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as Proposition 65).

EXECUTIVE SUMMARY OF COMMENTS

Celanese is requesting by these comments that OEHHA:

- reconsider its proposed listing by the Labor Code mechanism,
- refrain from listing vinyl acetate as a chemical known to cause cancer, and
- work with Celanese and other interested parties in evaluating whether additional review of vinyl acetate is appropriate.

At a minimum, Celanese requests an opportunity to meet with OEHHA to further discuss the process and substantive issues prior to any final determination on the proposed listing.

A foundation of these requests is the fact that vinyl acetate is not a "known" human or animal carcinogen and should not be listed as such under Proposition 65. Vinyl acetate is categorized by the International Agency for Research on Cancer ("IARC") as "2B" -- a "possible" human carcinogen. The classification of a chemical as 2B, by itself, is an insufficient basis for listing a chemical as "known" to cause cancer, even when applying the Labor Code listing mechanism. The question for OEHHA remains whether IARC has found "sufficient evidence" of human or animal carcinogenicity to warrant listing. *AFL-CIO v. Deukmejian*, 212 Cal. App. 3d 425, 437 (1989) ("*Duke I*").

In its monograph on vinyl acetate, IARC concludes that for vinyl acetate there is “inadequate evidence”¹ of human carcinogenicity, and “limited evidence”² of animal carcinogenicity, as opposed to “sufficient evidence” of animal carcinogenicity. Accordingly, vinyl acetate should not be listed using the Labor Code listing mechanism. This is true *regardless* of whether OEHHA is relying on Labor Code § 6382(b)(1) or (d) as the basis for listing. *Duke I*, 212 Cal. App. 3d at 437 (“same analysis applies” for listing based on both Labor Code subsections).

Neither the Labor Code mechanism nor the Superior Court decision in *Sierra Club v. Schwarzenegger*, No. RG07356881 (Alameda Super. Ct. Apr. 24, 2009), mandate the listing of *all* chemicals that IARC has classified as 2B. Since not all IARC 2B chemicals are “known” carcinogens for Proposition 65 purposes, OEHHA must exercise its discretion in choosing which 2B chemicals, if any, to list. At a minimum, any “ministerial” listing must take into account the *Duke I* requirement that only 2B chemicals for which there is sufficient evidence of human or animal carcinogenicity be listed. Either way, vinyl acetate should not be listed under the Labor Code references.

OEHHA must be allowed to exercise its responsibility to undertake a rigorous science-based review of vinyl acetate to determine whether it should properly be listed as “known” to the State of California to cause cancer. We would be surprised if OEHHA came to such conclusion, based on Celanese’s experience with recent governmental reviews of vinyl acetate around the world which have concluded that current consumer exposures to vinyl acetate present no health concerns. OEHHA implicitly recognized that vinyl acetate should not be listed without a more rigorous scientific review in an earlier Carcinogen Identification Committee (“CIC”) review of vinyl acetate. The CIC reviewed vinyl acetate in the mid-1990’s and decided it was not a high priority chemical for listing consideration.

There is no need for OEHHA to act precipitously in listing chemicals pursuant to the Superior Court decision in *Sierra Club v. Schwarzenegger*. That decision is not the final word from the California courts. A notice of appeal has been filed and will be pursued. The appellate courts’ resolution of the underlying legal issues associated with the scope of the Labor Code listing under Health & Safety Code § 25249.8(a) will impact how the chemicals proposed for listing will ultimately be considered under Proposition 65. OEHHA should wait for the already-instituted appeals process to run its course before adding any chemicals to the Proposition 65

¹ IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS, VOL. 63, 459 (1995).

² *Id.*

list in reliance upon the Labor Code listing mechanism. Moreover, nothing in the Superior Court decision requires immediate action by OEHHA.

Finally, there are a number of unintended negative impacts associated with the listing of vinyl acetate that should be considered. There would be environmental and public health impacts associated with the use of substitute chemicals that are more harmful and create greater emissions and wastes. There would be business and economic impacts that would be felt far beyond the borders of California. Many of these impacts would start upon the listing.

A BRIEF INTRODUCTION TO CELANESE

Celanese is an integrated global producer of value-added industrial chemicals. The company manufactures basic, intermediate and specialty chemicals, as well as emulsions, acetate products, technical polymers and food ingredients.

As the world's leading producer of vinyl acetate monomer ("VAM" or "vinyl acetate"), Celanese has been a consistent and active participant in the regulatory and technical evaluation of vinyl acetate around the world. Vinyl Acetate is an intermediate chemical that is manufactured using acetic acid, ethylene and oxygen. There are no direct consumer end uses of vinyl acetate. Celanese and its customers use vinyl acetate in the manufacture of emulsions and ethylene vinyl acetate performance polymers. These products in turn are used in medical devices, paints, adhesives, personal care products and high performance plastics.

VINYL ACETATE IS A WIDELY USED BASIC CHEMICAL WITH IMPORTANT ENVIRONMENTAL BENEFITS

For purposes of these comments and OEHHA's review, there is an important distinction to note between vinyl acetate *monomer* and the various *polymers* that are created using vinyl acetate. Vinyl acetate *monomer* is the chemical that is identified using the CAS No. 108-05-4 referenced in the Request. Vinyl acetate monomer is an industrial liquid substance that is only used in industrial/manufacturing polymerization processes in highly controlled environments. *Polymerized* vinyl acetate is not under consideration for listing pursuant to Proposition 65 -- nor should it be.³

³ There is no evidence that polymerized vinyl acetate is a carcinogen. IARC has categorized polyvinyl acetate and vinyl chloride-vinyl acetate copolymers -- two examples of vinyl acetate polymers -- as Group 3 chemicals. 19 IARC MONOGRAPHS, 341, 377 (1979), IARC MONOGRAPHS, Suppl. 7 (1987). Group 3 chemicals are "not classifiable as to [] carcinogenicity to humans." IARC MONOGRAPHS, Suppl. 7, 31 (1987).

Manufacturers either polymerize vinyl acetate or use polymerized vinyl acetate to produce a wide variety of consumer and industrial products. These include:

- medical related products: biopolymers and plastics (including FDA and EU-approved medical devices including both drug delivery and implant prosthetic applications)
- wood product adhesives (cabinetry, doors, windows)
- construction materials such as glues, self leveling flooring, paints and coatings
- safety and insulation glass liners
- white / wood glue, school glue, paint, caulk, carpet, cleaning wipes, laminates, spackling, wood filler, shoe soles
- personal care products such as mascara, eye liner, nail polish, hair spray resin
- packaging and food preservation products, such as in coatings on food (i.e. cheese, yogurt), package and envelope adhesives, inks and plastic wraps and containers (regulated by the FDA and similar authorities in the EU and Japan)

Exposures to vinyl acetate from these products will consist only of residual monomer at trace levels, if any. Exposure modeling has been conducted demonstrating that levels of exposure are multiple orders of magnitude below adverse effects levels (irritation).

Vinyl acetate polymers also provide environmental benefits, in addition to the useful products just discussed. Where there are potential substitute materials for vinyl acetate, those substitutes almost always involve greater environmental impacts. For instance, in paint and coatings applications, replacing vinyl acetate likely would result in an increase in VOCs from the replacement chemicals, an increase in CO₂ emissions from the processes associated with those other chemicals, and an increase in the disposal of solid waste. Replacement of vinyl acetate in a number of plastics applications would result in an increase in the use of PVC and phthalate plasticizers and their associated environmental issues.

THE LABOR CODE LISTING MECHANISM FOR CARCINOGENS SHOULD NOT APPLY TO VINYL ACETATE AND OEHHA SHOULD RECONSIDER THE PROPOSED LISTING

OEHHA is responsible for identifying and evaluating chemicals to be listed as known to the State of California to cause cancer or reproductive harm. This is an important gatekeeper function under Proposition 65, since the requirements and prohibitions under the Health & Safety Code provisions only apply to those chemicals that are formally listed. Health & Safety Code § 25249.8 describes the mechanisms for creating and maintaining the Proposition 65 list. Understanding these mechanisms is critical to the proposed listing in the Request.

Health & Safety Code § 25249.8(a) provides:

On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382 (d).

The cross-references in Health & Safety Code § 25249.8(a) to the Labor Code are often referred to as the “Labor Code listing mechanism.” Labor Code § 6382(b)(1) references substances listed as human or animal carcinogens by the International Agency for Research on Cancer (“IARC”). We will refer to this as the “IARC listing mechanism.” Labor Code § 6382(d) references the federal hazard communications standard (“HCS”) set forth in 29 CFR § 1910.1200. We will refer to this as the “HCS listing mechanism.” As an initial matter, there is significant ongoing litigation as to whether these Labor Code listing mechanisms apply at all once the initial list was promulgated.⁴ Celanese supports the Chamber’s efforts

⁴ The California Chamber of Commerce points out that Proposition 65 neither mandates nor authorizes ongoing automatic placement of any chemical identified by reference in Labor Code § 6382(b)(1) and Labor Code § 6382(d) on the Proposition 65 list after creation of the initial list. They argue that OEHHA has no authority to add chemicals to the Proposition 65 list unless they meet the criteria outlined in Health and Safety Code § 25249.8(b). Thus, OEHHA should not even be considering using the Labor Code Listing Mechanism to update the Proposition 65 list; the Labor Code listing mechanism pertains only to the initial list that was created upon passage of Proposition 65. While these comments focus on the application of the Labor Code listing mechanism to vinyl

and incorporates by reference those portions of the comments submitted by the Chamber detailing the arguments associated with conflict between the Labor Code mechanism and traditional listing mechanisms, as well as the timing considerations related to ongoing litigation. However, since the Request and proposed listing is based upon these mechanisms, we address them specifically.

A. The IARC Listing Mechanism

IARC does not maintain a single list of chemicals it has identified as carcinogens that can be readily imported into the state's list. Rather, IARC evaluates chemicals individually, and reports its analyses in monographs. In the monographs, IARC classifies chemicals into various "groups" depending on what is known of a chemical's carcinogenicity. "Group 1" chemicals are agents where there is "*sufficient evidence* of carcinogenicity to humans." IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS, SUPP. 7, 31 (1987) ("IARC Supp. 7"). "Group 2" chemicals are agents "for which, at one extreme, the degree of evidence of carcinogenicity in humans is almost sufficient, as well as agents for which, at the other extreme, there are no human data but for which there is experimental evidence of carcinogenicity." *Id.*

There are further subdivisions within the second category. Group 2A chemicals are "probably carcinogenic to humans." *Id.* Group 2B chemicals are "possibly carcinogenic to humans" *Id. at 32*. There are further subdivisions still within the subcategories. Group 2B chemicals range from those agents for which there is "limited evidence in humans" *Id.*, (emphasis omitted) to those for which there is "no data in humans but limited evidence . . . in experimental animals together with . . . other relevant data." *Id.*

B. The HCS Listing Mechanism

The federal hazard communication standard also does not present a simple, single list that can be ported over wholesale into the state's list under Proposition 65. There is no HCS list of carcinogens *per se*. The federal hazard communications standard makes subject to its requirements chemicals that are identified by a host of other bodies -- including IARC⁵ -- and agencies. Moreover, the hazard

acetate, OEHHA should not construe these comments to reflect any agreement by Celanese that the Labor Code mechanism should even be employed to update the Proposition 65 list.

⁵ Interestingly, the federal hazard communication standard treats IARC 2B chemicals differently from IARC 1 and 2A chemicals with respect to warning obligations. All IARC listed chemicals in Groups 1 and 2A must include carcinogenic warnings on both a Material Safety Data Sheet ("MSDS") and on a label. In contrast, the IARC status of Group 2B chemicals need be noted only on an MSDS. 29 CFR 1910.1200.

communication standard is not focused exclusively on carcinogens. It encompasses a wide variety of potential hazards and, significantly, more types of toxic endpoints than does Proposition 65. So, for instance, many non-carcinogenic substances are subject to the hazard communication standard. In addition, the precise hazards that have to be communicated are left up to the company using/producing the chemical. As with IARC's categorizations, HCS does not make a binary distinction between known carcinogens and non-carcinogens.

C. OEHHA is Not Engaging in a Purely Ministerial Exercise in Listing Vinyl Acetate

As the discussion of the IARC listing mechanism and the HCS listing mechanism demonstrates, deciding which substances are "known to [] cause cancer," Health & Safety Code § 25249.8(a), requires drawing a line between substances covered by the IARC and HCS listing mechanisms that are known carcinogens and substances that are not. OEHHA itself has observed as much, stating that:

It is critical to note that there is no single list or document that OEHHA can consult to determine if a chemical has been identified pursuant to [sections 6382(b)(1) and (d)] of the Labor Code. The provisions refer to a variety of sources that identify chemicals in different documents, in different manners, for different purposes, and for different endpoints. Therefore, OEHHA must review the various source documents in an effort to determine which chemicals have been identified as causing cancer or reproductive toxicity and must be added to the Proposition 65 list.

Defendants' Memorandum of Points and Authorities in Opposition to Motion for Summary Adjudication on Defendants' Duty to List Chemicals Identified in Labor Code Sections at 3:8-13, *Sierra Club v. Schwarzenegger*, No. RG07356881 (Alameda Super. Ct. Nov. 25, 2008).

As discussed below, this line-drawing exercise cannot be done on a ministerial basis with respect to vinyl acetate and many other IARC 2B chemicals. IARC specifically concluded that the available evidence for these chemicals was insufficient to classify the chemical as a known or probable carcinogen so there is

no foundation for a “ministerial” listing. Given the importance of the listing function, there needs to be transparency and clarity in the listing process.

OEHHA proposes to list vinyl acetate based solely on Labor Code § 6382(d). The same is true of six of the dozen chemicals proposed for listing as carcinogens. OEHHA proposes to list the remaining six chemicals -- four of which are IARC Group 2B -- under *both* Labor Code § 6382(b)(1) and Labor Code § 6382(d). Implicit in this distinction among the IARC 2B chemicals proposed for listing is an unarticulated standard in choosing which chemicals to list solely by reference to Labor Code § 6382(d). Below is a table showing the chemicals proposed for listing as carcinogens, IARC conclusions regarding those chemicals, and whether OEHHA is basing its listing on the IARC listing mechanism, the HCS listing mechanism, or both.

| Chemical | Type | Cancer Group | Evidence Human | Evidence Exp. Animals | Reference | Basis for Listing (Labor Code §6382) |
|---|-----------------|---------------------|----------------------------|---|--------------------------|---|
| Amsacrine | Drug | Group 2B | <i>inadequate evidence</i> | <i>sufficient evidence</i> | IARC (2000), Vol 76 | (b)(1) & (d) |
| Bleomycins | Drug | Group 2B | <i>inadequate evidence</i> | <i>limited evidence</i> | IARC (1987) Supplement 7 | (d) |
| Chlorophenoxy herbicides | Pesticide | Group 2B | <i>limited</i> | <i>inadequate</i> for 2,4-D and 2,4,5-T | IARC (1987) Supplement 7 | (d) |
| Diesel fuel, marine | Chemical | Group 2B | <i>inadequate evidence</i> | <i>limited evidence</i> | IARC (1989) Supplement 7 | (d) |
| Progestins | Drug | Group 2B | <i>inadequate</i> | <i>sufficient</i> | IARC (1987) Supplement 7 | (d) |
| Styrene | Chemical | Group 2B | <i>limited evidence</i> | <i>limited evidence</i> | IARC (2002) Vol. 82 | (d) |
| Toxins derived from <i>Fusarium moniliforme</i> | Natural product | Group 2B | <i>inadequate evidence</i> | <i>sufficient evidence</i> | IARC (1993) Vol. 56 | (b)(1) & (d) |

| Chemical | Type | Cancer Group | Evidence Human | Evidence Exp. Animals | Reference | Basis for Listing (Labor Code §6382) |
|-------------------------------------|-----------------|--------------|----------------------------|----------------------------|-------------------------------------|--------------------------------------|
| (<i>Fusarium verticillioides</i>) | | | | | | |
| Vinyl acetate | Chemical | Group 2B | <i>inadequate evidence</i> | <i>limited evidence</i> | IARC (1995b), Vol 63 | (d) |
| Wood dust | Natural product | Group 1 | <i>sufficient evidence</i> | <i>inadequate evidence</i> | IARC (1995a), Vol. 62 NTP (2002) | (b)(1) & (d) |
| Zalcitabine | Drug | Group 2B | <i>inadequate evidence</i> | <i>sufficient evidence</i> | IARC (2000) Vol. 76 | (b)(1) & (d) |
| Zidovudine (AZT) | Drug | Group 2B | <i>inadequate evidence</i> | <i>sufficient evidence</i> | IARC (2000) Vol. 76 | (b)(1) & (d) |

Chemicals that IARC has said only are “possibly carcinogenic to humans (Group 2B),” without more, are referenced as having been listed *solely* under Labor Code § 6382(d), the HCS listing mechanism. Such chemicals are *not* proposed for listing under the IARC listing mechanism, despite an IARC monograph providing the basis for listing.

In contrast, where chemicals are both (a) IARC classified as 2B, and (b) IARC has stated that there is “sufficient evidence” that the chemical is carcinogenic in experimental animals or there is “limited evidence” of carcinogenicity in humans, OEHHA is listing the chemical under *both* Labor Code § 6382(b)(1) and Labor Code § 6382(d).

Implicit in this distinction is that OEHHA is applying a different standard for listing under the IARC mechanism and the HCS mechanism. Moreover, OEHHA appears to be setting the bar lower for listing under the HCS mechanism, without explanation or analysis. Thus, it would appear OEHHA is proposing to list a chemical under the HCS listing mechanism in reliance on an otherwise-inadequate IARC monograph for listing under the IARC listing mechanism. This contradicts the “ministerial” nature of the determination. More importantly, these distinctions should be at the heart of the more rigorous review of the studies and science contemplated by the non-Labor Code listing mechanism under Proposition 65.

D. “Possible” Carcinogens are not Known Or Probable Human Or Animal Carcinogens and Should Not Be Listed

Not all IARC group 2 chemicals are “known [] to cause cancer” for purposes of Proposition 65 and the operation of the Labor Code listing mechanism. The California Court of Appeal examined the operation of the Labor Code listing mechanism in depth in *Duke I*, and the *Duke I* court explained when an IARC Group 2 chemical is “known to [] cause cancer” for purposes of that mechanism:

IARC Group 2 and supplemental category chemicals *as to which there is sufficient evidence that exposure causes cancer or reproductive toxicity in animals* are also known carcinogens. Just as “sufficient evidence” (fn. 3, ante) with regard to Group 1 chemicals means “known carcinogenicity,” so also it means “known carcinogenicity” in respect to Group 2 and supplemental category chemicals which must therefore be included in the initial list.

Duke I, 212 Cal. App. 3d at 437 (emphasis added). OEHHA seems to have taken this guidance to heart with respect to the IARC listing mechanism. OEHHA is apparently only proposing to list under the IARC listing mechanism 2B chemicals for which IARC has stated there is “sufficient evidence” of animal carcinogenicity. Vinyl acetate is not such a chemical, and OEHHA is not basing its proposed listing of vinyl acetate on the IARC listing mechanism.

Nonetheless, OEHHA appears not to follow the teachings of *Duke I* with respect to the HCS listing mechanism.

When the *Duke I* court turned to the HCS listing mechanism it said that:

The same analysis [as set forth for when a 2B chemical should be listed pursuant to the IARC listing mechanism] requires the initial list to include those carcinogens within the scope of the HCS. . . . [T]he HCS defines as a ‘carcinogen’ all substances listed by IARC in categories 1 and 2 as well as substances identified and listed by NTP as known or probable human carcinogens (on the basis of known carcinogenicity in animals) and certain additional substances listed by OSHA.

Id. (emphasis in original). Next, the *Duke I* court qualified the “all substances listed by IARC . . .” language, recognizing that:

It is true that “any substance within the scope of the federal [HCS]” (§ 6382, subd. (d)) includes chemicals other than known carcinogens. Section 25249.8, subdivision (a) and the Act itself, however, are concerned only with those substances that authoritative bodies have concluded are known to cause cancer or reproductive toxicity. Thus, the initial list, and subsequent lists published thereafter, need not include all substances listed under HCS *but only known carcinogens and reproductive toxins listed there.*

Id. at 438 (emphasis added).

OEHHA has erred in failing to properly implement the *Duke I* decision when making listings based solely on the HCS listing mechanism. As discussed above, OEHHA seems to be interpreting the HCS listing mechanism as allowing the listing of chemicals based on IARC monographs that fail to pass muster for purposes of the IARC listing mechanism. OEHHA’s decision to list chemicals under the HCS listing mechanism based on IARC monographs that do not identify sufficient evidence of either animal or human carcinogenicity eviscerates the standards that the *Duke I* court established for the use of IARC monographs as a basis for listing under the Labor Code mechanism.⁶

The *Duke I* court would not have expounded at length on which IARC 2B chemicals can be listed under the IARC listing mechanism had it intended for *all* IARC 2B chemicals to be listed under the HCS listing mechanism. Neither would it have expressly noted that OEHHA should limit the chemicals listed pursuant to the HCS listing mechanisms to “only known carcinogens and reproductive toxins listed there.” *Id.* OEHHA’s approach leads to the absurd result of an IARC monograph that cannot support a listing under the Labor Code section that

⁶ An obvious peculiarity of the HCS listing mechanism is that under any reading it renders the IARC listing mechanism redundant -- the HCS listing mechanism captures IARC carcinogens. And, indeed, every IARC 2B chemical that OEHHA has proposed for listing pursuant to the IARC listing mechanism is also listed pursuant to the HCS listing mechanism. See Request. However, in the view expressed in the OEHHA proposal, apparently, the converse is not true. There are six 2B chemicals that are proposed for listing solely under the HCS listing mechanism. In applying different standards for when an IARC monograph provides a basis for listing under the HCS listing mechanism versus the IARC listing mechanism that OEHHA acts inconsistently with *Duke I*.

expressly defers to IARC nonetheless supporting listing via the Labor Code section that references the HCS.

Accordingly, there is a single standard under Proposition 65 for when a 2B chemical is “known [] to cause cancer” for purposes of listing under the Labor Code mechanism. That is the standard set forth in *Duke I*: only the 2B chemicals “as to which there is sufficient evidence that exposure causes cancer or reproductive toxicity in animals are also known carcinogens.” *Id.* at 437.

Not all chemicals that IARC identifies as category 2B chemicals are “known” animal or human carcinogens under the standard articulated in *Duke I*. Group 2B encompasses chemicals for which there is a wide variance in the level of evidence of carcinogenicity. As IARC explains:

This category [2B] is generally used for agents for which there is limited evidence in humans in the absence of sufficient evidence in experimental animals. It may also be used when there is inadequate evidence of carcinogenicity in humans or when human data are nonexistent but there is sufficient evidence of carcinogenicity in experimental animals. In some instances, an agent for which there is inadequate evidence or no data in humans but limited evidence of carcinogenicity in experimental animals together with supporting evidence from other relevant data may be placed in this group.

IARC Preamble, *supra*, at 32.

Vinyl acetate exemplifies the weakest-case 2B listing described in the IARC monograph Preamble. As IARC itself recognized, this is not “sufficient evidence” of vinyl acetate leading to animal cancers. Were there “sufficient evidence” of animal carcinogenicity, IARC would have expressly said as much in its monograph, as described in the Preamble and as IARC did for several of the other IARC 2B chemicals proposed for listing. Instead, IARC concludes that for vinyl acetate there is “inadequate evidence”⁷ of human carcinogenicity, and “limited evidence”⁸ of animal carcinogenicity. This does not constitute a “known” carcinogen for purposes of listing under Proposition 65.

⁷ IARC MONOGRAPHS, VOL. 63, 459 (1995).

⁸ *Id.*

Neither the Labor Code mechanism nor the Superior Court decision in *Sierra Club v. Schwarzenegger* contravene *Duke I* and mandate the listing of *all* chemicals that IARC has classified as 2B. Since not all IARC 2B chemicals are “known” carcinogens for Proposition 65 purposes, OEHHA cannot on a “ministerial” basis list all 2B chemicals. At minimum, OEHHA must exclude from listing under the Labor Code mechanism chemicals for which IARC has not found “sufficient evidence” of human or animal carcinogenicity.

One way to look at the different levels of support for each Category 2B classification is to assign a numerical value to the weight of the evidence described in each IARC classification. In the following table we have ranked the weight of the evidence using the following arbitrary scale: inadequate = 0, limited = 1, sufficient animal = 3, sufficient human = 5. While one could argue about whether the numeric values should be compressed to 0-3 or spread over a wider range, there can be no question as to the order of the progression. Applying the 0-5 scale yields the following ranking for the relative weight of the evidence for the proposed Labor Code Mechanism substances. We note that vinyl acetate is in the group with the least weight of the evidence for its 2B classification.

| Chemical | Type | Cancer Group | Evidence Human | | Evidence Exp. Animals | | Rank |
|---|-----------------|---------------------|----------------------------|---|---|---|-------------|
| Wood dust | Natural product | Group 1 | <i>sufficient evidence</i> | 5 | <i>inadequate evidence</i> | 0 | 5 |
| Amsacrine | Drug | Group 2B | <i>inadequate evidence</i> | 0 | <i>sufficient evidence</i> | 3 | 3 |
| Progestins | Drug | Group 2B | <i>inadequate evidence</i> | 0 | <i>sufficient evidence</i> | 3 | 3 |
| Toxins derived from <i>Fusarium moniliforme</i> (<i>Fusarium verticillioides</i>) | Natural product | Group 2B | <i>inadequate evidence</i> | 0 | <i>sufficient evidence</i> | 3 | 3 |
| Zalcitabine | Drug | Group 2B | <i>inadequate evidence</i> | 0 | <i>sufficient evidence</i> | 3 | 3 |
| Zidovudine (AZT) | Drug | Group 2B | <i>inadequate evidence</i> | 0 | <i>sufficient evidence</i> | 3 | 3 |
| Chlorophenoxy herbicides | Pesticide | Group 2B | <i>limited</i> | 1 | <i>inadequate for 2,4-D and 2,4,5-T</i> | 1 | 2 |
| Styrene | Chemical | Group 2B | <i>limited evidence</i> | 1 | <i>limited evidence</i> | 1 | 2 |
| Bleomycins | Drug | Group 2B | <i>inadequate evidence</i> | 0 | <i>limited evidence</i> | 1 | 1 |

| Chemical | Type | Cancer Group | Evidence Human | | Evidence Exp. Animals | | Rank |
|---------------------|----------|--------------|----------------------------|---|-------------------------|---|------|
| Diesel fuel, marine | Chemical | Group 2B | <i>inadequate evidence</i> | 0 | <i>limited evidence</i> | 1 | 1 |
| Vinyl acetate | Chemical | Group 2B | <i>inadequate evidence</i> | 0 | <i>limited evidence</i> | 1 | 1 |

If OEHHA were to list vinyl acetate on a “ministerial” basis, OEHHA would be abrogating its responsibility to undertake a science-based review to determine whether vinyl acetate should properly be listed as “known” to the State of California to cause cancer.

E. The Use of the Labor Code Listing Mechanism Is Particularly Inappropriate for Vinyl Acetate

1. Vinyl acetate was already considered in 1996 by the OEHHA Cancer Identification Committee and a decision was made not to list vinyl acetate.

OEHHA’s Carcinogen Identification Committee (“CIC”) was presented with a draft data summary on vinyl acetate (among other chemicals) at a public meeting on July 22, 1996. The data summary on vinyl acetate and other chemicals was the subject of two rounds of public comment and a public workshop held on November 15, 1996. The IARC monograph for vinyl acetate underlying the current proposed listing was available at that time and was included in the CIC evaluation.

OEHHA did not propose at that time to list vinyl acetate. The ultimate outcome of the 1996 evaluation was that OEHHA placed vinyl acetate on its “category II” priority list.² As OEHHA explained:

Category II consists of those chemicals which are assigned a priority level of concern other than "high". No action is anticipated for Category II chemicals until all chemicals identified as posing a high hazard of concern have been identified from the tracking database, assigned to the Candidate List, and brought before the appropriate Committee of the Science Advisory Board.

² See OEHHA Website, *Availability of Final Data Summaries and Priorities for 33 Chemicals With Respect to Their Potential to Cause Cancer*, Sept. 19, 1997, available at http://www.oehha.org/prop65/docs_state/bat1crnr.html (last visited July 12, 2009).

OEHHA never brought vinyl acetate before the CIC for more detailed review, and vinyl acetate was never proposed for listing until June 12th of this year.

2. Listing of vinyl acetate is unnecessary given the low level of public risk from exposure to the chemical.

Vinyl acetate is polymerized into numerous polymers which are used extensively by the public. In-depth risk analyses have recently been conducted by the European Union and Canada which showed that there was no adverse risk to the public with these polymeric products when evaluating the broad range of consumer end-points, and finding all within acceptable risk tolerances.

In evaluating the appropriate regulatory classification for vinyl acetate, Health Canada and Environment Canada concluded in its Screening Assessment of Vinyl Acetate finalized January 2009¹⁰ that vinyl acetate does not meet the definition of “toxic” as set out in section 64 of CEPA 1999¹¹. Additionally, Health Canada concluded that vinyl acetate does not meet the criteria for persistence and bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000)¹².

The European Chemicals Bureau as part of its ongoing responsibility to review existing priority chemicals as mandated in European Council Regulation (ECC) 793/93, conducted a thorough risk assessment of all aspects of environmental and human exposure to vinyl acetate, including the broad range of consumer end uses. The overall conclusion regarding consumer exposures of the EU Comprehensive Risk Assessment Report of Vinyl Acetate was that “there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.” [page 184 EU RAR¹³]. Additionally, review by other EU expert committees on environmental risk, human health and labeling/classification ratified the EU RAR, concluding that there was no need for

¹⁰ See Environment Canada website, Screening Assessment for the Challenge Acetic acid ethenyl ester (Vinyl Acetate Monomer) Chemical Abstracts Service Registry Number 108-05-4, available at http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_108-05-4.cfm (last visited July 12, 2009).

¹¹ Canadian Environmental Protection Act, 1999 S.C., ch. 33 (Can.), available at <http://canadagazette.gc.ca/partIII/1999/g3-02203.pdf> (last visited July 12, 2009).

¹² *Persistence and Bioaccumulation Regulations* SOR/2000-107 (Can.), available at <http://canadagazette.gc.ca/partII/2000/20000329/pdf/g2-13407.pdf> (last visited July 12, 2009).

¹³ *Draft Risk Assessment Report, Vinyl Acetate, CAS 108-05-4*, May 4, 2005, available at http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/DRAFT/R059_0807_env_hh.pdf (last visited July 12, 2009).

additional labeling or warning with respect to carcinogenicity or reproductive toxicity¹⁴.

F. The *Sierra Club* decision is under appeal. Further action by OEHHA should be suspended until the final interpretation from the court has been reached.

It is premature and a misuse of public resources for OEHHA to proceed with the proposed listing. Celanese believes that the Court of Appeal will reverse the trial court in *Sierra Club*, and find that OEHHA should not use the Labor Code listing mechanism to update the Proposition 65 list. If OEHHA adds chemicals to the list using the Labor Code mechanism, it will be difficult, if not impossible, to subsequently unwind all of the effects of that decision. As discussed below, users of VAM and other listed chemicals will have to expend resources in response to a listing notwithstanding the pending appeal. Users of VAM may incur costs in evaluating and possibly switching to substitute chemicals, and so be unable to readily return to using VAM if the Chamber of Commerce's appeal is sustained. Certainly, Celanese and others will be forced to expend resources evaluating compliance issues and working with OEHHA to address potential regulatory issues. None of this will be necessary when the appellate court finds in favor of the Chamber of Commerce. OEHHA should defer listing any chemicals under the Labor Code mechanism until after appeals are exhausted.

NEGATIVE IMPACTS OF IMPROPER LISTING

The nature of this listing process has precluded any opportunity for a detailed, careful review of the science and data associated with vinyl acetate that would support a determination consistent with a number of other governmental authorities that vinyl acetate is not "known to cause cancer." Thus, the listing of vinyl acetate as a Prop 65 chemical will be a significant departure from the current characterization of the chemical and will improperly stigmatize the use of VAM.

Moreover, due to the large number of uses of vinyl acetate, any listing under Proposition 65 will result in a tremendous undertaking in terms of compliance evaluations and assessments. As OEHHA should well be aware, the structure of Proposition 65 places tremendous burdens on the regulated community in terms of assessing and complying with the requirements of the Health & Safety Code for listed chemicals. Since any detectable amount of a listed chemical triggers the

¹⁴ *European Commission, Scientific Committee on Health and Environmental Risks, Scientific Opinion on the Risk Assessment Report on Vinyl acetate, CAS 108-05-4, Human Health Part, Nov. 17, 2008, available at http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_108.pdf (last visited July 12, 2009).*

applicable provisions, an almost certain outcome of listing is that some VAM users will look for alternatives to VAM in order to avoid even assessing compliance with Proposition 65. In this case, the replacement of VAM will lead to numerous adverse consequences for California's environment and public health, California businesses, and California consumers. We provide a few examples of likely impacts in more detail below.

A. Environmental and Public Health Impacts

One example of how listing of vinyl acetate as a Prop 65 chemical will adversely impact the environment involves the paint and coating industry. Vinyl acetate copolymers generally allow paint manufacturers to use a lower amount of volatile organic compounds (VOCs) in their paints than when they use acrylic polymers, which would be the only substitute not listed under Prop 65. VAM thus allows for paint and coating manufacturers to cost-effectively¹⁵ reduce the VOC emissions associated with the product from levels compliant with California regulations to levels that are "super-compliant." Absent listing, Celanese would expect continued migration by manufacturers to VAM and to "super-compliant" status.

Listing vinyl acetate under Proposition 65 creates disincentives for paint manufacturers to further reduce the VOC content of their coatings. If we assume just 10% of California paint manufacturers would not continue to reduce (voluntarily) VOC levels of their flat and non-flat coatings from the lowest California required levels (SCAQMD Rule 1113) of 50 g/L to the SCAQMD defined "super compliant" level of 10 g/L, there would be a corresponding 1280 tons of VOC emission per year attributable to the listing of VAM.

VAM-based paints are also more durable than paints that replace VAM with acrylic polymer. In a study of the top six paints tested by Consumer Reports in 2009, it was shown that paint using vinyl acetate co-polymer resin provides a 62% stronger coating than the acrylic equivalent. The greater durability of VAM-based paints reduces VOC emissions by reducing the number of times items need to be repainted¹⁶ and reduces the solid wastes associated with repainting.

In addition to being harmful to public health in their own right, VOCs are a precursor to ozone formation and PM10. An increase in VOCs will make it more

¹⁵ Using acrylic polymer generally costs 45% more than the cost of a coating being made in compliance with California VOC regulations using VAM. Using acrylic polymers in a "super-compliant" product can cost twice as much as using VAM.

¹⁶ A conservative emissions estimate would be that if 10% of paint purchased in CA was used to re-paint each year due to lower durability, and the re-painter would use VOC-compliant (50 g/L) paint, then the resulting increase in VOC emission would be 1600 tons per year in California.

difficult for state and regional authorities to meet ozone standards, AQMPs, and State SIP obligations, and result in greater costs of compliance. Moreover, replacing just 10% of the vinyl co-polymer in California paints with acrylic polymers indicates a 68 ton/year increase in SO_x emissions and a 38 ton/year increase in NO_x emissions, per the 1999 “Eco-Profiles of Production systems for polymer dispersion” study¹⁷.

Substitution away from VAM would also detract significantly from California’s efforts to meet the carbon-reduction goals of AB32. VAM is derived primarily from natural gas, while acrylic polymers are derived primarily from a mixture of natural gas and oil. The resulting carbon footprints are much lower for VAM than for acrylic polymers. Based on the 1999 “Eco-Profiles of Production systems for polymer dispersion,” replacing just 10% of the vinyl co-polymer in California paints alone with acrylic polymers will result in increased carbon emissions of 10,000 tons/year of CO₂.

An additional benefit of vinyl acetate based polymers is that they are considered the safer public health and environmental alternative to certain existing materials. In 1999 Greenpeace sponsored a study at the University of Massachusetts to identify suitable alternatives to polyvinyl chloride (PVC) with a particular consideration of exposure routes to sensitive populations (children). ‘Soft’ PVC articles (e.g. toys, shower curtains, medical devices) can lead to exposure to both trace quantities of vinyl chloride and to phthalates which are used as a plasticizer in the articles to give them flexibility. That study, along with others, identified ethylene vinyl acetate co-polymers as a safer and cost effective plastic alternative. This has led to differing groups (e.g. Sierra Club, Center for Health, Environment and Justice, NYPIRG) calling for retailers to systematically reduce use of polyvinyl chloride plastic with an alternative being a safer PVC-free plastic, ethylene vinyl acetate (EVA). The proposed addition of vinyl acetate to the Proposition 65 list could curtail or reverse measures being undertaken voluntarily by retailers to provide safer PVC-free products.

B. Business and Consumer Impacts

While the listing of VAM will likely result in lost sales for Celanese as some users of VAM substitute alternative products in VAM’s place, the broader impacts on California business are just as significant. Regardless of whether customers decide to replace VAM or seek to comply with the requirements of Proposition 65, almost all of these businesses will expend significant funds evaluating compliance

¹⁷ Dr. I Boustead, *Eco-Profiles of production systems for polymer dispersion*, Report 17 (Nov. 1999).

obligations and/or alternatives to VAM. Users of VAM will be faced with evaluating additional litigation risk, potentially modifying or closing a business line, ceasing certain sales in California, and/or significant capital costs associated with substitution of chemicals. All of these options likely entail expenditures and job losses in California (and elsewhere) in the midst of the worst recession in decades.

By way of example, customers of Celanese in the medical supply industry that have put VAM-containing products through the 5-10 year FDA approval process (involving comprehensive clinical trials) will be evaluating the risk to their investment in those products. At a minimum, they will have to incur significant costs in evaluating compliance options and reformulation options -- assuming they can even develop some -- and processing those through the FDA approval process.

Higher costs and reduced product functionality will affect end-use consumers as well. Alternatives to VAM are typically more expensive and less effective in the roles now filled by VAM. Celanese estimates that increased costs for VAM users in the textiles, adhesives, building products, non-wovens, and paint sectors that likely would be passed through to end-users *in California* would be at least \$50,000,000. And the economic impacts are almost certain to expand outside of California's borders.

CONCLUSION

Celanese appreciates OEHHA's consideration of these comments. Celanese reiterates that OEHHA should not move precipitously in listing chemicals under the Labor Code mechanism. Before acting, OEHHA should allow the *Sierra Club* appeals to be resolved. OEHHA should also take up the issues raised in these comments with Celanese and other stakeholders. Celanese would appreciate having further discussions with OEHHA prior to any listing decisions being made.