Dragon, Karen E. (CDC/NIOSH/EID)

From: Kurt.Blase@hklaw.com
Sent: Thursday, September 22, 2011 1:55 PM
To: NIOSH Docket Office (CDC)
Subject: Unifrax Comments, Docket NIOSH-240
Attachments: Final Comments.pdf

Dear Docket Personnel,

Attached are the Comments of Unifrax I LLC for filing in Docket NIOSH-240, Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment, 76 Fed. Reg. 52664 (August 23, 2011). If you have questions regarding the comments or would like to discuss them further please contact me at this address or Dr. Dean Venturin as indicated in the Comments,

Sincerely,

Kurt Blase
Counsel for Unifrax I LLC

NIOSH Docket Office
Robert A. Taft Laboratories
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Re: Docket No. NIOSH-240, Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment

Dear Docket Personnel:

Unifrax Corporation, a manufacturer of Refractory Ceramic Fiber (RCF), submits the following comments in response to the NIOSH request for information concerning assessment of the NIOSH policies for carcinogens and recommended exposure limits (RELs)(76 Fed. Reg. 52664(August 23, 2011).

The request for information raises a number of questions for public response, including the following: (1) Should 1 in 1,000 working lifetime risk (for persons occupationally exposed) be the target level for a recommended exposure limit (REL) for carcinogens or should lower targets be considered; (2) What evidence should form the basis for determining that substances are carcinogens; and (3) In establishing NIOSH RELs, how should the phrase ''to the extent feasible'' (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted and applied. Unifrax answers these questions as follows:

(1) The 1/1,000 risk target should be retained;

(2) The determination of carcinogenicity should be based on substantial evidence drawn from the scientific record considered as a whole; and

(3) NIOSH should consider both technological and economic feasibility in establishing RELs.

These points are discussed in detail below, following a brief description of the product stewardship program (PSP) for RCF developed and implemented by Unifrax and other RCF manufacturers and endorsed by NIOSH in the Criteria Document for RCF.

THE RCF PSP

RCF is a high temperature insulation material that produces energy savings up to 40% or more in industrial furnace and other applications. In these economic times, it is particularly important to encourage use of such materials where they can be used safely. For over 20 years, RCFC and its members repeatedly have been commended for their dedication to product stewardship and workplace health protection. Since the late 1980's, RCFC and its member companies have developed and implemented a comprehensive Product Stewardship Program (PSP) to control potential workplace and other exposures to RCF. The PSP includes a recommended exposure guideline (REG) for workplace exposure to RCF, among other provisions.

Initially, our goal was to drive down exposures as this was the prudent thing to do regardless of the levels found in the workplace. In this way we would reduce any potential risk. First we had to train our users and measure actual exposures. As our efforts bore fruit and our measurements confirmed progress, we lowered our REG based on the fact that we had data that the new levels were feasible. Initially established at 3.0 fibers per cubic centimeter (f/cc), the REG was reduced, first to 1.0 f/cc and more recently to 0.5 f/cc, as new workplace controls began to be implemented and airborne concentrations began to decrease. These reductions were based primarily on levels attained in the majority of workplace scenarios with feasible engineering controls. As part of the PSP, the companies also sponsored substantial animal and epidemiological

research on the potential health effects of exposure to RCF, including a quantitative risk assessment. To date, the epidemiological studies have shown no excess disease in RCF workers, and the risk assessment concludes that potential risk at the 0.5 f/cc REG is well within the federal "significant risk" benchmark of 1/1,000. However, the REG has not been based directly on the RCF health studies or risk assessment, as experts consistently have advised that the health data are not suitable for sound assessment of quantitative risk. Rather, the REG has been based on the prudence of reducing workplace exposures to the lowest feasible levels.

As a direct result of the RCF PSP, the majority of workplace RCF exposures now are below the 0.5 f/cc REG. A major key to both attainment and evaluation of this progress has been the ongoing effort of the RCF producers to collect reliable workplace exposure data pursuant to the PSP and report it regularly to interested agencies. The industry began this effort voluntarily in the early 1980s, and it first became enforceable in a series of consent orders concluded with EPA, pursuant to the Toxic Substances Control Act (TSCA), in the early 1990s. The EPA RCF orders were the first ever, under TSCA, in which a manufacturer agreed voluntarily to conduct workplace monitoring at customer operations.

Subsequently, RCFC sought OSHA endorsement of the RCF PSP, including the 0.5 f/cc REG. Such endorsement was granted in February 2002. A letter of February 11, 2002 from OSHA head John Henshaw (at that time) to William P. Kelly, RCFC President, gives voice to OSHA's views as follows:

> OSHA believes that the commitments RCFC has made in developing this Program form an important step towards further improving worker protection. The 0.5 fiber/cc exposure guideline recommended in the Program, the specific engineering controls and work practices detailed in the Program, and the recognition that respiratory protection is appropriate in certain operations will help reduce exposures of the workers who handle RCF products daily. . . .

In 2006 NIOSH adopted a Criteria Document for RCF that essentially incorporates the PSP, including the 0.5 f/cc REG.[1] By letter of May 23, 2007 from OSHA head Edwin Foulke to RCFC President Dean Venturin, OSHA reaffirmed its commitment to the most recent update of the RCF PSP, now known as PSP-HTW. A principal feature of PSP-HTW is that it takes the workplace monitoring effort one step farther, to the operations of our customers' customers.

As noted above, the industry commissioned a comprehensive risk assessment for RCF workplace exposure, but the risk assessment has not been the primary basis for the RCF REG, which has been determined for the most part by feasible workplace exposure controls. However, the RCF risk assessment has played a major role in determining the potential need for the PSP and the effectiveness of the REG and the other PSP measures in protecting worker health at RCF operations. Equally as important, the successful industry effort to reduce potential RCF risk has not been derailed by inaccurate assessments of risk based on faulty or unrealistic assumptions. Unifrax attributes this to the preparation of a sound RCF risk assessment based on rigorous application of well-accepted scientific conventions, and to continued collection of the industry-specific exposure data that is essential for reasonably accurate assessment of potential risk.

Unifrax is proud of the RCF PSP and its successful track record of employee health protection. As discussed above, NIOSH, OSHA and EPA all have commended the PSP and have endorsed it as acceptable substitute for additional regulation of potential RCF exposures. However, if NIOSH were to revise the current 1/1,000 risk criterion or the manner in which feasibility is determined, a NIOSH REL consistent with the PSP may not be possible. Feasibility has been the primary basis for the measures addressed in the PSP, and

[1] NIOSH, "Criteria for A Recommended Standard: Occupational Exposure to Refractory Ceramic Fibers" (May 2006).

the various RCF risk assessments have served as useful confirmation of the absence of human disease demonstrated in the RCF epidemiological studies. If NIOSH decides to change its policies on significant risk or feasibility, the continued viability of our successful program would be jeopardized despite the absence of any evidence that such widespread change is required to protect employee health. We believe that NIOSH must continue to employ its current criterion for significant risk and must continue to consider feasibility fully in establishing RELs, for reasons to which we now turn.

SIGNIFICANT RISK

The Occupational Safety and Health (OSH) Act directs NIOSH to "develop such criteria as will effectuate the purposes of this chapter" (29 U.S.C. §669(a)(2)). The general purpose is "to assure *so far as possible* every working man and woman in the nation safe and healthful working conditions" (29 U.S.C. §651(b), emphasis added). With respect to NIOSH criteria,, this purpose is to be fulfilled "by providing medical criteria which will assure *insofar as practicable* that no employee will suffer diminished health, functional capacity or life expectancy as a result of his work experience" (29 U.S.C. §651(b)(7), emphasis added). In addition, the criteria are to "describe exposure levels that are safe for various periods of employment, including but not limited to the exposure level at which no employee will suffer impaired health or functional capacities or diminished life expectancies as a result of his work experience" (29 U.S.C. §669(a)(3)).

The courts have noted that "the statute directs NIOSH to develop criteria documents that describe safe levels of exposure, and [OSHA] is to promulgate standards that ensure that employees are protected. *The language employed by Congress in these two mandates is essentially identical . . .* " Industrial Union Dept., AFL-CIO v. Hodgson, 499 F.2d 467, 476

(D.C. Cir. 1974)(emphasis added).[2] With respect to the identical language governing OSHA standards, the Supreme Court has held:

> Relying on §6(b)(5)'s direction to set a standard "which most adequately assures . . . that no employee will suffer material impairment of health or functional capacity," the Government contends that the Secretary is required to impose standards that either guarantee workplaces that are free from any risk of material health impairment, however small, or that come as close as possible to doing so without ruining entire industries.
>
> If the purpose of the statute were to eliminate completely and with absolute certainty any risk of serious harm, we would agree that it would be proper for [OSHA] to interpret §§ 3(8) and 6(b)(5) in this fashion. *But we think it is clear that the statute was not designed to require employers to provide absolutely risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry. Rather, both the language and the structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of significant risks of harm.* Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 641 (1980)(emphasis added)("Benzene").

Since the Benzene decision, courts of appeals have considered this plurality opinion to have been adopted by a majority of the Court in American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490 (1981). See AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir. 1992)("PELs"). Following the PELs decision, OSHA must not only establish that a substance poses a significant risk at some level, it must show that existing workplace exposures present a significant risk of material health impairment or that the new standards eliminate or substantially lessen the risk (PELs at 980).

While the courts will generally not determine what level of risk is "significant," they have vacated regulations when OSHA merely issued findings that new limits will protect workers from a significant risk of some material health impairment without citing any specific studies. Mere conclusory statements have been found inadequate to support a

[2] The court went on to note that they are identical "except that [OSHA] must consider elements of feasibility" (*id.*). However, as discussed below, other portions of the statute require NIOSH to consider feasibility as well.

finding of significant risk of material health impairment (PELs at 976). In the PELs case, the Eleventh Circuit states:

> The lesson of Benzene is clearly that OSHA may use assumptions, but only to the extent that those assumptions have some basis in reputable scientific evidence. If the agency is concerned that the standard should be more stringent than even a conservative interpretation of existing evidence supports, monitoring and medical testing may be done to accumulate the additional evidence needed to support that more protective limit. Benzene does not provide support for setting standards below the level substantiated by the evidence. Nor may OSHA base a finding of significant risk at lower levels of exposure on unsupported assumptions using evidence of health impairments at significantly higher levels of exposure (PELs at 979).

The courts have also given some indication of the boundaries of what they consider to be "significant risk." For example, in Benzene, the Supreme Court stated: "if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it (Benzene at 655). In American Dental Ass'n. v. Martin, 984 F.2d 823 (7th Cir. 1993), OSHA was chastised by the Court for not segregating dental employees whose risks of contracting HIV and hepatitis could be distinguished from other medical professionals. The risk of contracting HIV from dentistry is less than 1 in 100,000, which "falls far short of establishing a significant risk," according to the court (*id* at 835).

It appears that OSHA consistently considers risk in the 1 in 1000 range to be "significant" and worthy of regulation. The following are risks that OSHA has found to be "significant":

> 8 - 160 deaths per 1000 workers (Benzene final rule, 52 FR 34460, 34463 Sept. 11, 1987);
>
> 186.2 - 266 deaths per 1000 workers (Cadmium proposed rule, 55 FR 4052, Feb. 6, 1990);
>
> 148 - 425 deaths per 1000 workers (Inorganic arsenic rule, 48 FR 1864, 1896, Jan. 14, 1983);

634 -1093 deaths per 10,000 workers (Ethylene oxide rule, 48 FR 17284, 17295, April 21, 1983; 49 FR 25,764);
6 - 30 deaths per 1000 (MDA proposed rule, 54 FR 20672, 20683, May 12, 1989);

164 deaths per 1000 (asbestos rule).

In spite of the apparent consensus regarding the "significance" of risks in the 1 in 1000 range, OSHA has allowed PELs to be set at levels leaving a residual risk in this range. For example, in the PELs case, the court notes that carbon tetrachloride was regulated to the 3.7 deaths in 1000 level, and that OSHA admitted that the residual risk "continues to be significant." Similarly, the vinyl bromide standard allowed a residual risk of 40 excess deaths per 1000: "clearly significant" according to OSHA (PELs at 976). Similarly, OSHA's ethylene oxide standards allow a "significant" risk of 12 -23 deaths per 10,000 workers, but were set at this level due to feasibility concerns. Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1502-03 (D.C. Cir. 1986).

As discussed above, the courts have found that the statutory schemes for OSHA and NIOSH are identical in this respect, and the Supreme Court's holding in Benzene therefore applies to both agencies with equal force. NIOSH apparently agrees, having adopted in September 1995 a new REL policy under which "NIOSH-recommended exposure limits (REL) will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measure by analytical techniques." The agency's Respirator Use Policy for Protection Against Carcinogens clarifies that "the effect of this new policy will be the development, whenever possible, of quantitative RELs that are based on human and/or animal data, as well as the consideration of technologic feasibility for controlling workplace exposures to the REL."

These principles, as applied in the OSHA proceedings discussed above, must be applied to the REL for RCF as well.

FEASIBILITY

As discussed above, current NIOSH policy requires consideration of technological feasibility in establishment of RELs. This is in accordance with the statutory language, also discussed above, that requires criteria documents to "assure *insofar as practicable* that no employee will suffer diminished health, functional capacity or life expectancy as a result of his work experience." The courts have held that congressional use of the term practicable "imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible." Biodiversity Legal Foundation v. Babbitt, 146 F.3d 1249, 1254 (D.C. Cir. 1998), quoting Fund for Animals v. Babbitt, 903 F. Supp. 96, 107 (D.D.C. 1995). Thus, as with the determinations of "significant risk," the statute effectively requires NIOSH to engage in the same feasibility determination that is required for OSHA standards. This requires determination of both technological and economic feasibility.

Technological feasibility. In determining technological feasibility, the courts have required OSHA to demonstrate, for each affected industry segment, that a typical firm will be able to install engineering and work practice controls that can meet the PEL in most of its operations. For example, in the PEL case the 11th Circuit held that feasibility must be determined on an industry-by industry basis, and concluded that OSHA's feasibility showing based on two-digit SIC Codes was invalid:

> [T]he undisputed principle that feasibility is to be tested industry by industry demands that OSHA examine the technological feasibility of each industry individually . . . OSHA primarily relied on the more general two-digit codes in its feasibility analysis. For most of the SIC Codes discussed, OSHA provided only a general description of how generic engineering controls might be used in a given sector . . . However, OSHA made no attempt to show the ability of technology to meet specific exposure standards in specific industries. Except for an occasional specific conclusion as to whether a particular process control could meet a

particular PEL, OSHA merely presented general conclusions as to the availability of these controls in a particular industry . . .

OSHA correctly notes that all it need demonstrate is "a general presumption of feasibility for an industry." However, as this quote indicates, "a general presumption of feasibility" refers to a specific industry-by-industry determination that "a typical firm will be able to install engineering and work practice controls that can meet the PEL in most of its operations." OSHA can prove this "by pointing to technology that is either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard's deadlines." Only when OSHA has provided such proof for a given industry does there arise "presumption that industry can meet the PEL without relying on respirators . . .

[I]t is clear that the concept of "a general presumption of feasibility" does not grant OSHA a license to make overbroad generalities as to feasibility or to group large categories of industries together without some explanation of why findings for the group adequately represent the different industries in that group (965 F.2d at 981-82, citations and footnotes omitted).

In a later decision, the court found similar problems with OSHA's cadmium standard:

Technological feasibility exists when the PEL can be met with engineering and work practice controls . . . Here, OSHA failed to meet this test from the start. In determining the technological feasibility of meeting the PEL in the dry color formulator industry, OSHA first determined the existing airborne levels of cadmium in the industry. However, the method OSHA employed in doing so was inadequate. Rather than analyzing the exposure levels in the dry color formulator industry, OSHA analyzed such exposures generically.

* * * *

In this case, OSHA lacks substantial evidence to demonstrate the accuracy of the pre-standard exposure levels it asserts.

* * * *

OSHA's analysis here relies on its determination of the starting exposure level. Its conclusion as to the feasibility of reducing these levels below the PEL is by method of a percentage reduction from the initial levels. For this reason, the initial levels are vital. In this case, the method of determining these initial levels was unreliable and insufficient, since the workers and plants to which the dry color industry was analogized were not shown to be sufficiently similar to justify such a comparison. OSHA employed the flawed and prohibited method of analyzing these pre-standard exposure levels generally, rather than specifically to the industry

> in question here. Color Pigments Mfrs. Assn. v. OSHA, 16 F.3d 1157, 1161-63 (11th Cir. 1994)(citations and footnotes omitted).

In accordance with these opinions, NIOSH RELs must be supported by findings that a typical firm in each of the affected industry segments will be able to install engineering and work practice controls that can meet the PEL in most of its operations.

Economic feasibility. The feasibility determination required for OSHA PELs and NIOSH RELs must examine economic as well as technological feasibility. PELs at 980. The analysis must "provide a reasonable assessment of the likely range of costs of its standard, and the likely affects of those costs on the industry . . . so as to demonstrate a reasonable likelihood that these costs will not threaten the existence or competitive structure of an industry . . ." PELs at 982. In the PELs case, the court reiterated that economic feasibility must be determined on an industry-by industry basis, criticizing OSHA for using industry "sectors" that were based on two-digit SIC Codes and in many cases were defined too broadly to suit the court:

> In this rulemaking, although OSHA ostensibly recognized its responsibility "to demonstrate economic feasibility for an industry, the agency nevertheless determined feasibility for each industry "sector" (i.e., two-digit SIC Code), without explaining why such a broad grouping was appropriate . . . Indeed, it would seem particularly important not to aggregate disparate industries when making a showing of economic feasibility. OSHA admits that its economic feasibility conclusions only "have a high degree of validity on a sector basis," as opposed to a sub-sector or more industry-specific basis . . . OSHA then stated that "[t]he costs are sufficiently low per sector to demonstrate feasibility not only for each sector but also for each subsector."
>
> However, reliance on such tools as average estimates of cost can be extremely misleading in assessing the impact of particular standards on individual industries. Analyzing the economic impact for an entire sector could conceal particular industries laboring under special disabilities and likely to fail as a result of enforcement. Moreover, for some substances, OSHA failed even to analyze all the affected industry sectors. We find that OSHA has not met its burden of establishing that its 428 new PELs are either economically or technologically feasible (965 F.2d at 982, emphasis in original, citations and footnotes omitted).

The court went on to note that while it was "not foreclosing the possibility" of analyses based on industry segments, OSHA would be required to show "that there are no disproportionately affected industries within the group" (id. n. 28).

The court then used OSHA's feasibility determination for perchloroethylene (perc) as an example of the potential for error inherent in OSHA's approach:

> OSHA's economic feasibility determination for perc cannot support either the new PEL of 25 ppm or the agency's decision not to set an even lower PEL. OSHA used the two-digit SIC code, SIC 72--Personal Services, to define the industries affected by the perc standard. This creates two problems. First, drycleaning is the only industry in SIC 72 affected by the perc standard. SIC 72 covers numerous other industries, including funeral services, shoe repairs, barber and beauty shops, and photography studios. Nevertheless, OSHA took the costs of compliance with the new perc standard, which would be borne only by the drycleaning industry subsector (SIC code 7216), and compared those costs to the profits and sales of the entire personal services sector (SIC 72). As a result, OSHA must have significantly understated the costs of compliance for the drycleaning industry. Indeed, petitioners claim that the actual economic impact on this industry would be more than ten times OSHA's estimate.
>
> Moreover, while the drycleaning industry received at least some feasibility analysis for perc, the other major user of that chemical, industrial degreasing operations, received none. This industry is not in SIC 72, which was the only industry sector reviewed for technological or economic feasibility for the new perc standard. Therefore, OSHA clearly has not fulfilled its duty to examine the feasibility of its perc standard for each affected industry (965 F.2d at 983, citations and footnotes omitted).

Two years later, the Eleventh Circuit reiterated and expanded upon this approach in invalidating the cadmium standard OSHA adopted for the dry color formulator industry. See Color Pigments Manufacturers Ass'n v. OSHA, 16 F.3d 1157 (11th Cir. 1994). In the cadmium case, OSHA had adopted "Separate Engineering Control Air Limits" (SECALs) for many industry sectors based on its determinations of feasible engineering controls for those sectors. The dry color formulators challenged OSHA's decision to subject their industry to the full effect of the 5 ug/m3 standard without a SECAL. Again, the court found that

OSHA's "grouping of the dry color formulator industry with other users of cadmium pigments and its failure to study any particular dry color formulators whatsoever show that OSHA proceeded generically rather than making the requisite specific findings for this identifiable industry segment" (16 F.3d at 1161). First, the court rejected OSHA's conclusions with respect to technological feasibility because the agency had not accurately determined pre-existing airborne exposure levels for the industry. The court then went on to detail related defects in the economic feasibility findings:

> Essentially, OSHA's economic feasibility findings here suffer from the same deficiencies as its findings of technological feasibility. If it is incorrect in its determination of the pre-standard exposure levels for the dry color formulator industry, then it will undoubtedly cost more for each firm to reduce exposures to the PEL, absent a SECAL.
>
> Any increase in cost not anticipated by OSHA must be absorbed somewhere in the industry. The data before this court shows the industry to be comprised of many small concerns, with minimum ability to absorb significant capital outlays, and with even less ability to spread such expenditures among its customers in the form of price increases. Of primary concern is the current existence of more cheaply priced imported colors from foreign dry color formulators. OSHA asserts, without support in either research or common sense, that customers of dry color formulators would prefer to pay more for their supply of colors from local, domestic formulators than pay less for imported products. Even if this is currently true as it relates to the relatively small price difference between domestic and imported colors, there is no reason to assume that these customers will be willing, or even fiscally able, to absorb the more substantial increase which may be necessitated by a large outlay in meeting the PEL.
>
> Additionally, there is evidence that the overall market for these cadmium pigment based colors has decreased by as much as 35% over the past several years, for both domestic and imported products. The lag in the market for these products will make the distribution of any capital outlays through cost increases significantly less feasible. Moreover, OSHA asserted in its own findings that "the targeted level of 5 ug/m3 will be difficult to achieve for many plants in [the dry color formulator] sector." Although OSHA found it feasible on balance, this estimate of difficulty will be exacerbated if it is shown that the pre-standard exposure levels employed by OSHA were inaccurate. Therefore, we hold that OSHA's analysis of the economic feasibility of the PEL in the dry color formulator industry is not supported by substantial evidence because it is predicated

> upon faulty assumptions and flawed methodology (16 F.3d at 1163, citations and footnotes omitted).

In the wake of these decisions OSHA has been increasingly careful to base its determinations of economic feasibility on precise definitions of the affected industry segments and detailed economic data for each segment. Examination of OSHA economic feasibility determinations suggests that as compliance costs approach 50% of the profits for a particular industry, the standard is more likely to be found economically infeasible. For example, OSHA's standard for cadmium contains the following statement as part of the discussion of economic feasibility: "No industry sector analyzed had a cost to profit ratio in excess of 0.5." For the reasons stated above, a similar analysis of economic feasibility for the affected industry segments is required to support NIOSH RELs.

EVIDENTIARY SUPPORT

OSHA findings of significant risk and feasibility must be supported by substantial evidence. PELs at 969-70. This is required by §6(f) of the Act, which provides for judicial review of OSHA standards under the "substantial evidence" standard of review.

The Act does not expressly provide for judicial review of NIOSH RELs, and therefore does not specify an applicable standard of review. In such cases, review is available under the more generic provisions of the Administrative Procedure Act, which specifies that the applicable standard of review is the "arbitrary and capricious" standard in cases where no hearing on the record is required by statute. However, that standard requires reversal of agency action that is "arbitrary, capricious, an abuse of discretion or not otherwise in accordance with law" (5 U.S.C. §706).

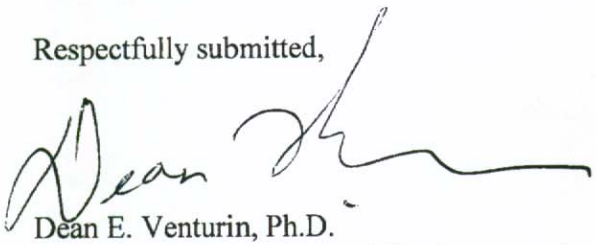
In this case, as explained above, Congress has provided identical substantive requirements for OSHA PELs and NIOSH RELs, strongly suggesting that NIOSH RELs also must be supported by substantial evidence. Further, even under the "arbitrary and

capricious" standard, the courts will reverse an agency's factual findings "if the agency's decision is not supported by substantial evidence." Kisser v. Cisneros, 14 F.3d 615, 619 (D.C. Cir. 1994), citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415-16 (1971). As the development of a NIOSH CD and associated REL are essentially fact- finding exercises, these actions must be supported by substantial evidence regardless of the applicable standard of review.

Conclusion

The applicable provisions of the OSH Act require NIOSH to demonstrate by substantial evidence that a REL is both feasible for the affected industry segments and necessary to reduce a significant risk from occupational exposure. The current risk criterion of 1/1,000 is well grounded in court decisions and administrative precedents. Any significant change would seriously jeopardize effective existing workplace programs, such as the RCF Product Stewardship Program, with little or no evidence that changes are necessary to protect employee health. For these reasons, Unifrax urges NIOSH not to revise its current policies for determining feasibility and significant risk in connection with RELs for potential carcinogens.

Respectfully submitted,



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