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Department of Toxic Substances Control
Safer Products and Workplaces Program
P.O. Box 806
Sacramento, CA 95812-0806

Re: **Petition of HTIW Coalition for Modification of Candidate Chemicals List**

Dear DTSC Personnel:

Pursuant to Articles 2 and 4 of the Safer Consumer Products Regulations, (SCPR), the HTIW Coalition hereby petitions DTSC to modify the listing of Refractory Ceramic Fibers (RCF) on the SCPR Candidate Chemicals List. HTIW Coalition is an organization of manufacturers of RCF and other high-temperature insulation materials, dedicated to development and implementation of the industry's Product Stewardship Program (PSP) for RCF and other fiber products.[1]

The SCPR include a "list of authoritative lists" for identification of chemicals that have been designated by others as known or suspected human carcinogens. If a chemical appears on one of the lists, it is also listed in the SCPR, with the same carcinogen classification as in the original list. The problem with respect to RCF is that it appears on several of the lists referenced in the SCPR, and their classifications are not consistent. The stated basis for the RCF listing is that it is classified as 1B on the carcinogen list in EC Annex VI. Chemicals in EC classification 1B are "presumed to have carcinogenic potential in humans." However, RCF also has been listed by the International Agency for Research on Cancer (IARC) and the National Toxicology program (NTP). IARC has classified RCF as "possibly carcinogenic to humans." NTP has classified RCF as "reasonably anticipated to be a human carcinogen." These other classifications are significantly less stringent than the EC presumption.

For the following reasons, this petition requests DTSC to change the stated basis of the RCF listing in the SCPR from EC Annex VI to the IARC and/or NTP classifications:

(1) the EC listing is inconsistent with the IARC and NTP listings;

[1] Members of HTIW Coalition include Morgan Thermal Ceramics and Unifrax I LLC. Associate members include HarbisonWalker International and Nutec Fibratec. Additional information on HTIW Coalition, and a copy of the PSP and supporting documents, may be found on the HTIW Coalition website, www.htiwcoalition.org.

(2) the EC listing is not based on the best available evidence or on a rigorous scientific review process;

(3) the EC listing has not been replicated by other organizations on the DTSC list and is not consistent with the conclusions of other U.S. regulatory bodies;

(4) the EC listing is inconsistent with the classification of RCF under the OSHA GHS based Hazard Communication Standard program;

(5) revising the basis for the RCF listing will not result in any loss of protection for RCF workers or consumers in CA.

These issues are discussed in detail below, following the other information that SCPR Article 4 requires for listing petitions.

Petitioner Name and Contact Information

These are provided on the letterhead above.

Known Manufacturers and Importers

These include the HTIW members listed in footnote 1.

Product Description and Uses

RCF is a synthetic vitreous fiber first discovered in 1942 and commercialized in the 1960s. RCF is the smallest segment of the synthetic vitreous fiber industry, representing about 2% of total production, and is used primarily in industrial applications, rather than consumer products. Approximately 100 million pounds is produced annually in North America, with between 5-6% sold into California (representing approximately $9.4 million in annual sales). The total exposed population in the United States is approximately 26,000 workers, approximately 1,300 of which work in California end user plants.

RCF is an energy efficient insulation capable of very high temperature applications, up to 2800°F. RCF is an important product for furnaces, heaters, and reactors in the petroleum, petrochemical, chemical, fertilizer, steel, heat-treating, nonferrous metals, glass, ceramic, foundry, cement, and forging industries. Other uses are in fire protection, automotive catalytic converters, heat shields, air bags, aerospace, and defense applications. It is produced in a variety of forms, including bulk, blanket, modules, paper, felt, and textiles.

Globally, RCFs play an important energy efficient and environmentally friendly role by controlling high temperatures and reducing fossil fuel consumption. U.S. production of RCF is sold primarily into industrial furnace markets, saving an estimated 164 trillion BTUs annually, equivalent to 27.8 million barrels of oil, near $1.4 billion at $50/barrel, a huge impact on the US economy. As a superior energy efficient insulation product, RCF plays an important role for industry both in California's aggressive initiative under AB 32, as well as regional, national and international efforts, to reduce greenhouse gas emissions. For example, in a *single* 2,000 square foot batch (cycling) furnace, such as would be used in the metals processing or ceramic industries, RCF insulation would save $200,000 to $500,000 annually as compared to more traditional insulations, depending upon the fuel used for the furnace. In an environmental context the reduction in CO_2 emissions would range from approximately 1,100 to 1,600 metric tons annually; this savings would be equivalent to removing from 230 to 315 cars from the highway (RCFC, 2009).

RCFs are produced using a melt fiberization process, under highly controlled conditions, similar to processes for manufacturing other synthetic vitreous fibers (e.g., fiberglass and mineral wool). Primary fibers are produced in four plants in the United States not located in California and two in Mexico. Thus, the principal impact of the proposed PEL is on industries located in California that use RCF in critical applications. Those industries include:

- Petrochemical industry:
  - Most furnaces have been designed to use RCF products because it is far lighter than other refractory products (for example, RCF weighs 8-10 pounds a cubic foot, while denser refractories can weigh between 65-150 pounds per cubic foot).
  - If unable to use RCF in petrochemical furnaces, the impact would be very significant, particularly in terms of energy use since other refractories (with poorer insulation properties) require many more Btu's per hour because of the energy required to heat the furnace walls. Retrofit of a furnace to accommodate conventional refractories would virtually require a new furnace designed to accommodate heavy refractories.
- Forging industry
  - Most furnaces are lined with RCF and use natural gas to heat to high temperatures.
  - RCF is much lighter and has superior insulating properties. Furnaces can be cycled, and even idled; heating up for use takes as little as an hour and a half, while thermal shock is a real issue for other refractories thereby making cycling more difficult.
  - If forced to use firebrick or other denser refractories, the cost of natural gas and refractories themselves in a cycling furnace would skyrocket.

- Semiconductor industry

  - RCF is used in diffusion furnaces, where it supports the quartz tubes used to run gases such as argon through the furnace, to provide the appropriate thermal conductivity.
  - RCF is also used in vestibule block at the end of the furnace; the vestibule blocks are made from vacuum formed RCF and are also circumferentially encapsulated in RCF blanket.
  - While the amount of RCF used in the semiconductor industry is relatively small compared to the amount used in the petrochemical and forging furnaces, the impact on the marketplace in California would be substantial. Without the ability to use RCF in diffusion furnaces, numerous companies in Silicon Valley would be required to re-engineer this process at substantial cost.

- Emission control industry

  - RCF emission control products for diesel and other mobile source emissions play a vital role in providing the control devices essential for compliance with state and federal emission control regulations.

RCF Product Stewardship

Since the late 1980's, HTIW Coalition, its predecessor the Refractory Ceramic Fibers Coalition (RCFC) and their 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, as well as provisions addressing recommended exposure controls, work practices, worker training, respirator use, medical monitoring, product research, waste minimization, environmental responsibility, reporting, exposure monitoring and health studies.[2] Originally the integrated voluntary PSP was conducted as a cooperative program with USEPA, more recently this has been conducted with oversight by OSHA (see below).

Initially, the 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 the 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 in 1997 to 0.5 f/cc, as new workplace controls began to be

[2] The RCF PSP is described in detail in the Comments of Unifrax I LLC on the Notice of Proposed Rulemaking for Safer Consumer Product Alternatives, filed October 11, 2012. Additional information is also available on the Coalition's website. http://www.htiwcoalition.org/health.html

implemented and airborne concentrations began to decrease. Today the weighted average fiber concentrations at manufacturers and customers are approximately 0.2-0.3 f/cc (HTIW Coalition, 2015). These reductions were based primarily on levels attained in the majority of workplace scenarios with feasible engineering controls. Respirators are used for a small number of jobs or tasks likely to result in higher exposures, but the main reliance is on engineering controls.

As part of the PSP, the member companies also sponsored substantial animal and epidemiological research on the potential health effects of exposure to RCF, including a quantitative risk assessment. Various animal studies commissioned by the RCF manufacturers in the 1980s appeared to indicate that RCF was an animal carcinogen under certain test conditions, e.g., the "maximum tolerated dose" (MTD) of approximately 200 f/cc inhaled directly into the lungs. A later review of the MTD pathology indicated that the animals' lungs were "overloaded" because of large quantities of non-fibrous particles, and that this overload condition was likely responsible for the disease observed (see Brown et al., 2005 for details). Evaluation of the aerosol samples used confirmed the presence of significant quantities of particulate matter. In a subsequent multi-dose animal inhalation study at 25 f/cc, 75 f/cc, and 115 f/cc; a *no observed effect level* (NOEL) was found at 25 f/cc. This level is 50 times the industry recommended exposure guideline[3] of 0.5 f/cc for humans.

In addition to the animal studies, the RCF manufacturers engaged the University of Cincinnati (UC) to conduct a long-term medical surveillance study on RCF workers. This continuing study has been in progress for over 25 years, collecting data from respiratory questionnaires, lung function tests, chest X-rays, exposure monitoring, and worker mortality. The results of this study of RCF plant workers exposed from 1953 to the present have shown:

- No excess mortality related to all deaths, all cancers, or lung cancer
- No statistically significant increase in interstitial findings (fibrosis), and
- No mesotheliomas

This long term epidemiology study has demonstrated an absence of interstitial fibrosis, no increased mortality risk, and no decrement in lung function associated with current exposures (see Greim *et al.,* 2014; LeMasters *et al.,* 1998, 2003; Lockey *et al.,* 1996, 1998, 2002, 2012; Maxim *et al.,* 2015; McKay *et al.,* 2011; Utell and Maxim, 2010; Walker *et al.,* 2002, 2012 a, b).

Since there has never been human respiratory disease (e.g. lung cancer or mesothelioma) associated with exposure to RCF, a risk assessment based on cancer endpoints in humans is impossible. Accordingly, RCFC (the precursor of the HTIW Coalition) commissioned a risk assessment based on the bioassay data from the animal studies described above. *Sciences International Inc.,* a world renowned environmental consulting firm, conducted the risk assessment in 1998 based on the RCF animal studies. The risk assessment team was led by Dr.

[3] As discussed later, this is numerically equal to the Recommended Exposure Limit (REL) established by NIOSH in 2006 based on a careful review of the literature.

Suresh Moolgavkar and utilized the two stage clonal expansion model (*Sciences International Inc.,* 1998).

The model looked at fiber lung burden in the animals along with deposition and clearance in both humans and animals, allowing for estimates of risk based on lung burden only. The calculated risk for a 70 year old worker with 30 years of exposure to 1 f/cc was $3.7x10^{-5}$ (maximum likelihood estimate) for a nonsmoker and $1.5x10^{-4}$ for a smoker. Further work by Moolgavkar and coworkers has shown the importance of fiber biopersistence on carcinogenic potential (e.g., Moolgavkar *et al*., 2001 a, b). Fiber chemistry influences carcinogenicity primarily through its role in biosolubility. Using the Moolgavkar work, Turim and Brown 2003 summarized the 95% upper bound risk of excess lifetime lung cancer for nonsmoking workers as:

- 3×10^{-5} for a 1 f/cc exposure
- 1.5×10^{-5} for a 0.5 f/cc exposure
- 0.3×10^{-5} for a 0.1 f/cc exposure
- Separately, Fayerweather *et al*., (1997) extrapolated rat data to human data using a linearized multistage model and found at exposures of 1 f/cc, the excess lifetime risk of developing lung tumors was 3.8×10^{-5} (maximum likelihood estimate).

Subsequently others have modeled animal data yielding similar risk estimates.

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 manufacturer and customer 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 applauded the RCF PSP and were the first ever, under TSCA, in which manufacturers 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 (NIOSH, 2006). 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, known then 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. Again, by letter of July 2012 from Assistant Secretary Michaels to HTIW Coalition President Dell Hadden, OSHA commended the most recent version of the PSP, known as PSP 2012:

> PSP 2012 represents the third iteration of the industry's voluntary product stewardship program for RCF, and builds upon previous agreements in 2002 and 2007. OSHA believes that the specific commitments the HTIW Coalition has made in developing this Program are an important step towards further improving worker protection. The 0.5 fiber/cc exposure guideline recommended in the Program, and the emphasis placed upon engineering controls and work practices detailed in the Program, and the recognition that respiratory protection is appropriate in certain operations will help to reduce exposures of the workers who handle RCF products.
>
> We remain impressed that elements of the Program are addressed to both the manufacturers and the users of RCF materials, appropriate to their ability to efficiently reduce worker risks. Moreover, many of the provisions in PSP 2012 demonstrate the Coalition's determination to offer the best possible protections for workers. In particular, I point to the acknowledgement that "where feasible engineering controls can reduce workplace concentrations to levels below 0.5 *flcc,* HTIW Coalition recognizes that it is prudent to do so," and the provision that "where workplace concentrations have been reduced to levels below 0.5 *flcc,* HTIW Coalition recommends continued efforts to maintain the lowest levels consistently achieved."

In 2009, the California Occupational Safety and Health Standards Board adopted a state permissible exposure limit (PEL) for RCF of 0.2 f/cc. In adopting this PEL, the Board praised the RCF PSP:

> The Standards Board would like to note that it applauds the RCF industry's support of research on the potential hazards of RCF, and the product stewardship effort of RCF producers. The RCF industry has collected exposure data under a quality assurance project plan designed in conjunction with Federal EPA. These data have been shared with the Division as well as U.S. Department of Labor and other interested regulators. These data show that, with the help of RCF producers, users have achieved average TWA exposures well below the voluntary limit of 0.5 f/cc and in most circumstances at or below the proposed PEL of 0.2 f/cc. Therefore, in light of the totality of evidence cited by ACGIH and NIOSH on the potential for RCF to cause or contribute to respiratory disease, the Standards Board believes that a PEL for refractory ceramic fiber of 0.2 f/cc is feasible and necessary to protect workers.
>
> The Standards Board appreciates the concerns raised by RCFC that, although measurements of airborne exposure to RCF for some operations have averaged below 0.2 fibers/cc, the variability of the results indicates that employers cannot assume that a single sample on any particular day will always indicate an 8-hour TWA exposure that does not exceed this level. These employers will have the option of supplementing engineering controls with respirator use or finding ways to improve engineering controls.[4]

[4] Occupational Safety and Health Standards Board, "Final Statement of Reasons, Airborne Contaminants," p. 30 (Public Hearing March 19, 2009). A detailed discussion of RCF issues can be found on pp. 28-52 of this document.

Bases for Petition

Legal Requirements

Section 25257.1 (c) of the Green Chemistry statute requires that "the department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." Section 25252(a) provides that the list of chemicals of concern must be adopted "in accordance with the review process specified in Section 25252.5. That section, in turn, provides that evaluations "shall be based on the best available scientific data . . ." Section 25252(b)(2) also provides that "in adopting regulations pursuant to this section, the department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy."

The DTSC regulations adopted pursuant to these statutes define "reliable information" as follows:

> (57) "Reliable information" means a scientific study or other scientific information that meets the criteria in subparagraphs (A) and (B):
>
> (A) The study or other scientific information was:
> 1. Published in a scientifically peer reviewed report or other literature;
> 2. Published in a report of the United States National Academies;
> 3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
> 4. Conducted, developed, submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.
>
> (B) With respect to a scientific study, the study design was appropriate to the hypothesis being tested, and sufficient to support the proposition(s) for which the study is presented to the Department (emphasis added).

Section 69502.2(b)(3) of the DTSC regulations also provides that in revising the list of chemicals, DTSC "shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts and potential exposures. In evaluating the quality of the available information, the Department shall consider, as applicable, the factors specified in section 69503.2(b)(1)(C)." That provision reads as follows:

> The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. In evaluating the quality of the available information, the Department shall consider, as applicable:
>
> 1. The level of rigor attendant to the generation of the information, including, when relevant, the use of quality controls;
> 2. The degree to which the information has been independently reviewed by qualified disinterested parties;
> 3. The degree to which the information has been independently confirmed, corroborated, or replicated;
> 4. The credentials and education and experience qualifications of the person(s) who prepared and/or reviewed the information; and
> 5. The degree to which the information is relevant for the purpose for which it is being considered by the Department (emphasis added).

For purposes of this petition, several governing principles can be derived from these applicable legal requirements: (1) the listing decision must be based on the best available evidence, including rigorous scientific review processes; (2) listings published in a report of the United States National Academies are favored; (3) listings that are independently replicated are favored; (4) listings that are internally inconsistent and/or inconsistent with those of other U.S. regulatory bodies are disfavored. Each of these plays a role in the listing of RCF, for reasons to which we now turn.

Scientific Issues

IARC and NTP Listings. As discussed above, the CA regulations incorporate the IARC and NTP listings for known or suspected human carcinogens. RCF appears on both lists. In 1988 an IARC Working Group reviewed the available evidence for RCF and placed RCF in Group 2B (*possibly carcinogenic to humans)*. This classification was reaffirmed by a subsequent Working Group meeting in 2001 (IARC, 2002). Although additional studies on RCF have been published since 2001, *there is no study that would justify a revision in the IARC classification decision in favor of placing RCF in either Group 2A or Group1*. RCF also is listed in the 12th Edition of the Report on Carcinogens as *reasonably anticipated to be human carcinogens* based on sufficient evidence of carcinogenicity from studies in experimental animals.[5] The RCF industry did not challenge either of these classifications and continues to apply them as appropriate. .

EC Listing. The current listing for RCF in EC Annex VI is substantially more stringent than either the NTP or the IARC classifications. Under the previous labeling system used in

[5] See http://ntp.niehs.nih.gov/ntp/roc/twelfth/profiles/CeramicFibers.pdf.

Europe, known as the 1997 Dangerous Substances Directive, RCF was listed as a Category 2 carcinogen based only on animal studies. Category 2 substances were those which "should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of appropriate long-term animal studies."

The European RCF industry petitioned the European Union to reclassify RCF for scientific reasons discussed at length in Brown *et al*. (2005). The essence of the argument for reclassification is that while the RCC animal experiments certainly resulted in fibrosis and tumors, these could have been caused by lung overload (itself an artifact of a non-representative ratio of particles to fibers) and, therefore, the animal studies are of limited utility for assessing carcinogenicity. In addition, the assessment gave no credence to the results of the RCF epidemiological studies. To date the EC has never acted on the RCF petition.

In 2008, the EC began to phase out the Dangerous Substances Directive in favor of the new globally harmonized system. The phase-out process began with EC Regulation No. 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labeling and packaging (CLP) of substances and mixtures. This CLP regulation, as amended from time to time, is replacing step-by-step the older Dangerous Substances Directive. As part of the transition to the new CLP regulation, in 2009 the classifications under the Dangerous Substance Directive were 'translated' into the CLP globally harmonized system, a new scheme for classification and labeling. As a result of this proceeding, the old Category 2 Carcinogens were *automatically* classified as Category 1B carcinogens which are substances "presumed to have carcinogenic potential for humans, classification is largely based on animal evidence." Thus, the RCF classification became substantially more stringent in Annex VI than it had been under the previous directive, without any action on the RCF reclassification petition and with no opportunity for industry input on the new categorization.

The Statement of Reasons for the Safer Consumer Products Regulations includes a discussion of the EC procedures, concluding that "the classification of a chemical's hazard trait is harmonized through a transparent, public process to ensure that the classification of the chemical is agreed upon and to ensure adequate risk management throughout the European Union (p. 144)." While that may be true for other substances, it certainly has not been true for RCF. None of the procedures outlined in the Statement were followed in the automatic reclassification on RCF performed for Annex VI. The RCF classification in EC Annex VI not only conflicts with the IARC and NTP classifications, but also was performed without the scientific and procedural safeguards required by the CA regulations.

U.S. GHS Classification. The Global Harmonization System (GHS) is now being implemented in the United States by OSHA in its Hazard Communication Standard (the Final Rule became effective May 26, 2012). Unlike the EC system, the GHS requires manufacturers to address the appropriate carcinogen classification for their products. In 2014, Everest

Consulting Associates was retained to recommend a classification for RCF under the new GHS. In an updated Memorandum (ECA, 2015) dated October 19, 2015 (copy attached), Everest concluded:

> Our conclusion regarding proper classification is identical to that reached in 2006. There is no basis for placing RCF in Category 1A (known to have carcinogenic potential for humans) because the available epidemiological evidence, though limited, indicates that the members of the occupationally exposed cohort show no evidence of interstitial fibrosis, elevated lung cancer rates (compared to baseline rates), and no cases of mesothelioma. Thus, the logically possible choices for self-classification are reduced to Category 1B (presumed to have a carcinogenic potential for humans) and Category 2 (suspected human carcinogen).
>
> Selection of the most appropriate GHS category (between the categories 1B and 2) is ultimately a matter of judgment. In our judgment, it is appropriate to place RCF in Category 2. We are mindful that the IARC working group concluded on a weight of evidence basis, that the animal evidence provided sufficient, rather than limited evidence of carcinogenicity. However, this group also acknowledged that there was room for doubt. There is certainly abundant evidence that lung overload can lead to inflammation and tumors in laboratory inhalation studies of rodents. *Moreover, the applicable OSHA guidance document (Appendix F within the OSHA document) indicates that, even if RCF falls into IARC Group 2B, the correct match is GHS Category 2.* So our recommendation is fully consistent with applicable OSHA guidance.

This classification is now being implemented by the RCF industry in the U.S. Thus, the use of Annex VI to classify RCF in the CA regulations is not only inconsistent with the IARC and NTP listings, it is also inconsistent with the RCF classification used for regulatory purposes by OSHA in the U.S.

Conclusion

For the following reasons, HTIW Coalition hereby petitions DTSC to change the basis of the RCF listing on the Candidate Chemicals List from EC Annex VI to either the IARC or NTP listing:

(1) the EC listing is inconsistent with the IARC and NTP listings;

(2) the EC listing is not based on the best available evidence or on a rigorous scientific review process;

(3) the EC listing has not been replicated by other organizations on the DTSC list and is not consistent with the conclusions of other U.S. regulatory bodies, such as NTP;

(4) the EC listing is inconsistent with the classification of RCF under the OSHA GHS based Hazard Communication Standard program; and

(5) revising the basis for the RCF listing will not result in any loss of protection for RCF workers or consumers in CA.

Respectfully submitted,

November 16, 2015

References

Brown, R. C., Bellmann, B., Muhle, H., Davis, J. M. G., and Maxim, L. D., (2005). Survey of the biological effects of refractory ceramic fibres: overload and its possible consequences. *Ann Occup Hyg*, 49: 295-305.

Everest Consulting Associates, Inc. (ECA), 2015. Memo to Dr. Dean Venturin (Unifrax) from L. Daniel Maxim and Ron Niebo (ECA) re: GHS Classification of RCF. Memo dated October 19, 2015. Sent via email and attached to this submission.

Fayerweather, W. E., Bender, J. R., Hadley, J. G., and Eastes, W., (1997). Quantitative risk assessment for a glass fiber insulation product. *Reg. Toxicol. Pharm.,* 25: 103-120.

Greim, H., Utell, M. J., Maxim, L. D., and Niebo, R., (2014). Perspectives on refractory ceramic fiber (RCF) carcinogenicity: comparisons with other fibers. *Inhal. Toxicol.*, 26(13): 789–810.

HTIW Coalition, (2015). PSP 2012: A voluntary product stewardship program (PSP). Submitted to: The Occupational Safety and Health Administration (OSHA). Copy provided to: The National Institute for Occupational Safety and Health (NIOSH). Prepared for: HTIW Coalition, 1200 Seventeenth Street, NW, Room 09-59, Washington, DC 20036. Prepared by: Everest Consulting Associates (ECA), 55 Princeton Hightstown Road Suite 205B, Princeton Junction, NJ 08550, April 2015, HTIW Coalition, Washington D.C., 141 pp.

International Agency for Research on Cancer (IARC), (2002). *Man-Made Vitreous Fibres*. Vol. 81. Available online at: http://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf, accessed October 19, 2015.

LeMasters, G. K., Lockey, J. E., Yiin, J. H., Hilbert, T. J., Levin, L. S., and Rice, C. H., (2003). Mortality of workers occupationally exposed to refractory ceramic fibers. *J. Occup. Environ. Med*., 45: 440-450.

LeMasters, G. K., Lockey, J. E., Levin, L. S., McKay, R. T., Rice, C. H., Horvath, E. P., Papes, D. M., Lu, J. W., and Feldman, D. J., (1998). An industry-wide pulmonary study of men and women manufacturing refractory ceramic fibers. *Am. J. Epidemiol*., 148: 910-919.

Lockey, J. E., LeMasters, G. K., Levin, L., Rice, C., Yiin, J., Reutman, S., and Papes, D., (2002). A longitudinal study of chest radiographic changes of workers in the refractory ceramic fiber industry. *CHEST*, 121: 2044-2051.

Lockey, J. E., Levin, L., LeMasters, G. K., McKay, R. T., Rice, C. H., Hansen, K. R., Papes, D. M., Simpson, S., and Medvedovic, M., (1998). Longitudinal estimates of pulmonary

function in refractory ceramic fiber manufacturing workers. *Am. J. Respir. Crit. Care Med*., 157: 1226-1233.

Lockey, J., LeMasters, G., Rice, C., Hansen, K., Levin, L., Shipley, R., Spitz, H., and Wiot, J., (1996). Refractory ceramic fiber exposure and pleural plaques. *Am. J. Respir. Crit. Care Med*., 154:1405-1410.

Lockey, J. E., Roggli, V. L., Hilbert, T. J., Rice C. H., Levin, L. S., Borton, E. K., Biddinger, P. W., and LeMasters, G. K., (2012) Biopersistence of refractory ceramic fiber (RCF) in human lung tissue and a 20-year follow-up of radiographic pleural changes in workers. *J. Occup. Environ. Med*. In press

Maxim, L. D., Niebo, R., and Utell, M. J., (2015). Are pleural plaques an appropriate endpoint for risk analyses? *Inhal. Toxicol.*, 27(7): 321–34.

McKay, R. T., LeMasters, G. K., Hilbert, T. J., Levin, L. S., Rice, C. H., Borton, E. K., and Lockey, J. E., (2010). A long term study of pulmonary function among US refractory ceramic fibre workers. *Occup. Environ*. *Med*., 68: 89-95.

Moolgavkar, S. H., Brown, R. C., and Turim, J., (2001a). Biopersistence, fiber length, and cancer risk assessment for inhaled fibers. *Inhal. Toxicol.*, 13(9): 755–772.

Moolgavkar, S. H., Turim, J., Brown, R. C., and Luebeck, E. G., (2001b). Long man-made fibers and lung cancer risk. *Reg. Toxicol. Pharm.*, 33(2): 138–146.

National Institute for Occupational Safety and Health (NIOSH), (2006). Criteria for A Recommended Standard, Occupational Exposure to Refractory Ceramic Fibers. Department of Health and Human Services, Centers for Disease Control Prevention, National Institute for Occupational Safety and Health, Atlanta, Georgia, 203 pp.

RCFC, (2009). Comments of the Refractory Ceramic Fibers Coalition to Notice of Proposed Changes to Title 8 of the California Code of Regulations Title 8: Division 1, Chapter 4, Subchapter 7, Article 107, Section 5155 Of the General Industry Safety Orders Airborne Contaminants. Submitted March 13, 2009 by RCFC President Dean Venturin to the California Occupational Safety and Health Standards Board. RCFC, Washington D.C., 414 pp. Note – Appendix A contains illustrative energy calcualtions.

Sciences International, Inc. (SII), (1998). Quantitative risk assessment of refractory ceramic fibers in the occupational environment. Prepared for Refractory Ceramic Fibers Coalition. April 1998, Washington DC, 110 pp.

Turim, J., and Brown, R. C., (2003). A dose response model for refractory ceramic fibers. *Inhal. Toxicol*., 15(11): 1103-1118.

Utell, M. J., and Maxim, L. D., (2010). Refractory ceramic fiber (RCF) toxicity and epidemiology: a review. *Inhal. Toxicol*., 22(6): 500-521.

Walker, A. M., Maxim, L. D., and Utell, M. J., (2012a). Are airborne refractory ceramic fibers similar to asbestos in their carcinogenicity? *Inhal. Toxicol.*, 24(7): 416–424.

Walker, A. M., Maxim, L. D., and Utell, M. J., (2012b). Corrigendum: Are airborne refractory ceramic fibers similar to asbestos in their carcinogenicity?. *Inhal. Toxicol.*, 24(13): 928-929.

Walker, A. M., Maxim, L. D., and Utell, M., (2002). Risk analysis for mortality from respiratory tumors in a cohort of refractory ceramic fiber workers. *Reg. Toxicol. Pharm.*, 35(1): 95–104.