



**Comments of Unifrax I LLC
on
Draft Stage 1 Alternatives Analysis Guide (September 2015)**

November 16, 2015

Introduction

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF), offers the following comments on the September 2015 Draft Stage 1 Alternatives Analysis (AA) Guide.

RCF is a high temperature insulation material that produces energy savings up to 40% or more in industrial furnaces in industries such as petrochemicals, metal forges and semiconductors, as well as other industries such as vehicle emission controls. In these times, it is particularly important to encourage use of such materials where they can be used safely. For over 20 years, Unifrax and other members of the industry association, known as the HTIW Coalition, have been commended for their dedication to product stewardship and workplace health protection. Since the late 1980's, HTIW and its member companies have developed and implemented a comprehensive Product Stewardship Program (PSP) to control potential workplace and other exposures to RCF. The RCF PSP has been endorsed by OSHA, NIOSH and EPA at the federal level. The California Occupational Health Standards Board has commended the PSP as well.

With respect to the Draft Stage 1 AA Guide, Unifrax believes that the final Guide should:

- (1) place more emphasis on the legal requirements to consider the benefits of the product and the feasibility of potential substitutes;



(2) clarify that voluntary industry programs, such as the RCF PSP, can be used as a substitute for AA, especially where approved by other regulatory agencies; and

(3) recognize that in some cases, “authoritative listings” developed by the EU do not constitute the “best available evidence” of potential product risk.

These points are discussed in detail below.

Product Benefits

Pursuant to Section 69505 of the CA regulations, the first step of a Stage 1 AA is “Identification of Product Requirements and Function(s) of Chemical(s) of Concern.” Unifrax also notes that several of the other factors specified in the statute for evaluation of alternatives are particularly applicable to RCF. These include:

- Product function or performance
- Materials and resource consumption
- Air emissions
- Production, in-use, and transportation energy inputs
- Energy efficiency
- Greenhouse gas emissions

Most of these factors, which address product benefits, are omitted from the draft Guide. Unifrax urges the Department to adopt a final Guide that states clearly that all of these factors are to be considered in the Stage 1 analysis.

Feasibility

Under the CA regulations, the feasibility of potential substitutes is considered largely in Stage 2 of the AA process. However, there is ample support for initial consideration of feasibility in Stage 1. For example, Section 69503.2(b) (2) of the final regulations provides:

(3) Safer Alternatives. When deciding whether to list a product-chemical combination as a Priority Product, the Department may also consider



whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

The final regulations include definitions of both technical and economic feasibility, described in the final Statement of reasons as follows:

Section 69501.1(a) (29) defines “economically feasible” to mean that an alternative product or replacement chemical does not significantly reduce the product manufacturer’s operating margin. This is necessary to make specific the use of the term “economic impacts” in the enabling legislation in Health and Safety Code section 25253(a)(2)(M). The term “economically feasible” is used in Articles 3, 5, and 6. This criterion includes the economic viability of the alternative that would allow the product to be profitable for the manufacturer. The responsible entity must consider the effect on the operating margin of the manufacturer. This factor reflects marketplace realities and business realities in determining whether there is an economically viable alternative to a Priority Product. Thus, this term is necessary to make clear that one of the considerations during the AA is whether the use of an alternative will significantly reduce the operating margin of a manufacturer. The purpose of this program is not to put companies out of business, but to ensure a fair and reasonable search for safer alternatives that may actually be used. (p.67)

Section 69501.1(a) (65) defines “technically feasible” to mean that the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement an alternative product or replacement chemical. This provision is necessary to ensure that there is a technical ability to develop and produce an alternative, and is referred to in Article 3, Article 5, and Article 6. As part of a determination of whether there is a readily available alternative, an alternative needs to meet the criteria for “functionally acceptable”, “technically feasible”, and “economically feasible” (see sections 69503.2(b) (3), 69505.4(b), 69505.6(a) (2) (C), 69506(a), 69506.5(b), and 69506.8). The term “technical feasibility” establishes the criteria to determine if there are resources available to achieve implementation of the alternative. This evaluation may, for example, consider the generation of knowledge about the product’s or process’s design, performance, production requirements, preliminary production costs, and level of resources needed and available.

The provisions of the regulations related to “technically feasible” ensure that an alternative is readily available (p. 98)



While the Draft Guide solicits input on some types of information relevant to feasibility determinations, it omits others and relegates to an Appendix a sentence indicating that the feasibility of potential alternatives must be considered. While consideration of feasibility is largely postponed until Stage 2, in some cases the feasibility analysis may be sufficiently clear that Stage 2 will not be necessary. The final Guide should solicit input on all relevant aspects of both economic and technical feasibility in Stage 1 to avoid the unnecessary expense of moving to Stage 2 in cases where major alternatives clearly are infeasible.

Voluntary Industry Programs

Section 69505.4 of the CA regulations provides for use of “alternative process” AAs prepared through procedures that differ from the specified regulatory process, provided that all of the regulatory requirements are satisfied. These are discussed at length in the draft Guide, but it makes no mention of voluntary industry programs, such as the RCF PSP, that could qualify as alternative process AAs. The final Guide should clarify that voluntary industry programs can be acceptable, particularly where they have been approved by other regulatory agencies.¹ This is also consistent with the statutory directive that the DTSC regulatory process should rely on other existing regulation where it is adequate.

Best Available Evidence

RCF is listed as a potential human carcinogen on three of the “authoritative lists” mentioned in the CA regulations: those compiled by the International Agency for

¹ The RCF PSP, and the various regulatory approvals it has received, are discussed in detail in past Unifrax Comments on the Green Chemistry regulations. They are also described in comments filed on this date with respect to the Department’s listing proposal, and in a listing petition filed with DTSC on this date by the HTIW Coalition.



Research on Cancer (IARC, the National Toxicology Program (NTP) and EC Annex VI. RCF was listed in CA on the basis of the listing in the EC Annex. However, 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 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. The essence of the argument for reclassification is that while the 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.

These issues are discussed in detail in comments and a listing petition filed with DTSC by the HTIW Coalition on this date. In accordance with those materials, the final AA Guide should make it clear that listings by other bodies, such as the EC Annex VI listing for RCF, should not be accepted if they are not based on the best available evidence.



Conclusion

For the foregoing reasons, the final Stage 1 AA Guide should:

- (1) emphasize the legal requirement to consider product benefits, particularly energy benefits;
- (2) require at least a preliminary screening analysis of the feasibility of potential substitutes;
- (3) clarify that voluntary industry programs can be used as a substitute for AA or significant portions, especially where approved by other regulatory agencies; and
- (4) recognize that in some cases, listing in EC Annex VI does not constitute the "best available evidence" of potential product risk.

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Dean E. Venturin". The signature is fluid and cursive, with a long horizontal stroke at the end.

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Unifrax I LLC

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