Unifrax I LLC hereby requests an exemption under REACH Article 58(2) for the professional and industrial uses of Aluminosilicate Refractory Ceramic Fibres (Al-RCF) and Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF). In requesting this exemption we rely on the control measures provided by Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (the Carcinogens Directive).

The following section (B) establishes that the Carcinogens Directive properly controls these uses of the substances in question and the granting of the exemption is proportional to the risk to human health and the environment posed by the physical nature of the substance.

First, however, we respectfully submit (in section A) our legal concerns with the interpretation of REACH Article 58(2) set out in section 5.1 of ECHA's June 2013 "General Approach" document (the Current Interpretation).[1] These legal issues call into question the validity of the Current Interpretation. We note also that in the context of the recent "REACH Review" the European Commission seems to share this concern over the use of the Article 58(2) exemption, stating that it "needs to be reviewed how these criteria are currently applied and to what extent they can be used for the exemption of uses covered by exemptions in specific sectoral legislation." [2] Therefore, we ask that ECHA refrain from applying the Current Interpretation and instead considers this exemption request according to a plain reading of Article 58(2) and in line with the European Commission established precedent for applying the provision.

A. LEGAL INTERPRETATION OF REACH ARTICLE 58(2)

Issue One: The Current Interpretation of REACH Article 58(2) departs from the plain text of the provision.

REACH Article 58(2) requires considering whether the Community legislation in question imposes "minimum requirements." However, the Current Interpretation adds the additional requirement to consider whether more stringent measures would have been "technically possible." This transforms the evaluation of Community legislation from one a review of minimum requirements to an exercise in second-guessing whether the legislation could have been more stringent. This interpretation goes beyond the text of Article 58(2), and is inconsistent with the principle of proportionality that is an explicit component of an Article 58(2) review (addressed in more detail below).

[1] ECHA, Preparation of Draft Annex XIV Entries for Substances Recommended to be included in Annex XIV General Approach (General Approach Document), 24 June 2013, Section 5.1.

[2] Commission Staff Working Document Accompanying the document General Report on REACH Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with Article 117(4) REACH and Article 46(2) CLP, and a review of certain elements of REACH in line with Articles 75(2), 138(3) and 138(6) of REACH, SWD(2013)25, (2013) p. 12.

The Current Interpretation also states that it can "be implied" from the REACH Regulation that "attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation."[3] Thus the Current Interpretation expands the control requirement in REACH Article 58(2) to cover all risks at all stages of the life cycle of a use. Such life-cycle considerations are not apparent from a literal reading of Article 58(2). Further, we are unaware of any existing Community legislation that deals with all risks associated with the full life cycle of a substance; it is unlikely that such a sweeping interpretation of "properly controlled" was intended. Moreover, this interpretation departs from the Commission's reasoning when granting an Article 58(2) exemption (discussed below), where there was no reference to life cycle concerns.

Finally, the Current Interpretation incorrectly requires legislative definitions to be the same. Under the Current Interpretation, when ECHA reviews existing Community legislation it must pay "special attention" to the definition of use in the legislation in question compared to the REACH definitions. While a review of definitions is reasonable, it is not reasonable to expect that different legislation enacted at different times will contain definitions that are similar to those contained in REACH. Moreover, the presumption or implication that different definitions suggest inadequate levels of control is without merit.

Issue Two: Divergence of the Current Interpretation from Commission Precedent

The Current Interpretation of REACH Article 58(2) is at odds with Commission precedent. In 2011, the Commission exempted three plasticizers (DEHP, BBP, and DBP) used in the immediate packaging of medicinal products from the Authorisation requirements. It is our understanding that this occurred after ECHA's inconclusive assessment of the possibility for exemption and request for the Commission's assistance.[4] The Commission responded by exempting the use of the plasticisers for the immediate packaging of medicinal products with adoption of Regulation (EU) No 143/2011.[5] Recital 17 of Regulation (EU) No 143/2011 explains the Commission's conclusion as follows:

> DEHP, BBP, and DBP are used in the immediate packaging of medicinal products. Aspects of safety of the immediate packaging of medicines are covered by Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. That legislation of the Union provides for a framework

[3] ECHA, Preparation of Draft Annex XIV Entries for Substances Recommended to be included in Annex XIV General Approach (2013).

[4] Recommendation of the European Chemicals Agency (the ECHA) of 1 June 2009 for the inclusion of substances in Annex XIV (the list of substances subject to authorisation) of Regulation (EC) No 1907/2006, Annexes I.E, I.F, and I.G.

[5] Commission Regulation (EU) No 143/2011 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH"), OJ L 44, 18.2.2011, p. 2–6.

> to properly control risks of such immediate packaging materials by imposing requirements on the quality, stability, and safety of the immediate packaging materials. It is therefore appropriate to exempt the use of DEHP, BBP, and DBP in the immediate packaging of medicinal products from authorisation under Regulation (EC) No 1907/2006.

According to the Commission, Directives that provide a sufficient "framework" for controlling the risks of the use of a substance qualify for the REACH Article 58(2) exemption. This indicates that EU legislation need not be overly prescriptive or specific (*e.g.,* expressly address "effectiveness") to meet the "properly controls" criterion of Article 58(2). This is logical in light of the principles of conferral and proportionality and the nature of Directives, which set out common goals and deadlines, but allow the Member States a certain amount of discretion – and autonomy – in the execution of the measure. Yet, according to ECHA's General Approach, "legislation setting only the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2)."

Indeed, according to ECHA, national legislation should not even be considered in the context of an Article 58(2) exemption request.[6] Yet, in certain areas, such as workplace health and safety,[7] the Commission may only legislate by means of a Directive, which by nature requires national implementing legislation. For example, Article 118a of the Treaty establishing the European Community is the legal basis for the Carcinogens Directive and dictates use of Directives as the legislative act for regulating workplace health and safety. Article 4 of the Carcinogens Directive clearly states that employers' are obligated to reduce and replace as far as technically possible. Article 5 clearly mandates a hierarchy of controls from purchase, storage and usage, through disposal "cradle to crave." Therefore, by interpreting "properly control" to mean that the "Community legislation" at issue must impose specific non-discretionary measures, and contain specific technical details on issues such as effectiveness, ECHA is implicitly concluding that Directives, the preferred and sometimes only permitted EU legislative vehicle, will generally not satisfy Article 58(2).

In light of Commission precedent, the nature of European Union law and the special role of the European Directive, it is our view that national legislation, such as that which implements the Carcinogens Directive, should be considered in relation to a REACH Article 58(2) exemption request.

Issue Three: Absence or misapplication of proportionality considerations

The Current Interpretation of REACH Article 58(2) fails to address the provision's "proportionality" criterion which states: "[i]n the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form." This sentence indicates that proportionality must be considered in an evaluation of a potential exemption. By its nature, such a proportionality consideration requires a case-by-case assessment of the actual risk associated with the use of a substance. The options should then be weighed to

[6] See, for example, Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for N,NDimethylacetamide (EC number: 204-826-4) p. 13.

[7] Article 153(a) and (b) TFEU.

determine which would achieve the objective while imposing the least burden. Review of earlier responses to exemption requests show a general absence of such considerations.[8]

Even when expressly considered, it is our view that proportionality is considered improperly. For example, consider an earlier exemption request for the occupational use of the substance DMAc. [9] The exemption was denied, apparently, in part because of the possibility that a stakeholder might later obtain permission to use DMAc under the Authorisation process. This is not a proportionality analysis in the context of a request for an exemption. Rather, it is simply a description of the Authorisation process. Such an interpretation renders the proportionality criterion in Article 58(2) meaningless.

Issue Four: Breach of the Principle of Effectiveness

Taken together, the legal flaws in the Current Interpretation of Article 58(2) create a situation where an exemption is seemingly unobtainable. Such an outcome violates the principle of *effet utile* (principle of effectiveness). This principle underpins the Court of Justice of the European Union (the Court) rejection of legislative interpretation that thwart the purpose and object of the legislation.[10] The Court labels such interpretations as "tantamount to rendering [a certain right] ineffective and nugatory."[11] More broadly, *effet utile* is also applied to protect a legal act from being "deprived of a not insignificant aspect of its effectiveness,"[12] "severely undermined"[13] or simply "impaired."[14] The Current Interpretation of REACH Article 58(2) arguably violates this principle by depriving stakeholders of a meaningful opportunity to obtain an exemption.

While we recognize the general, and accurate, proposition that the central purpose of REACH is to attain a high level of protection for human health and the environment. We do not think that it is correct to rely on this general purpose to fashion an interpretation of Article 58(2) that essentially renders it ineffective, and bears little resemblance to the text of the legislation itself.

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[8] See ECHA response to Submission 19, see also Submission 19 supplementary document, Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for N,NDimethylacetamide (EC number: 204-826-4), November 29, 2012.

[9] Submission 13, supplementary document, Responses to Comments Document (RCOM) on ECHA's Draft 4th Recommendation for N,NDimethylacetamide (EC number: 204-826-4), November 29, 2012.

[10] Stefan Mayr, Putting a Leash on the Court of Justice? Preconceptions in National Methodology v *Effet Utile* as a Meta- Rule, European Journal of Legal Studies, Volume 5, Issue 2 (Autumn/Winter 2012/13), p. 8-21.

[11] Case 157/86 *Mary Murphy and others v An Bord Telecom Eireann* [1988] ECR 673 para. 10.

[12] Joined cases C-68/94 and C-30/95 *French Republic and Société commerciale des potasses et de l'azote (SCPA) and Entreprise minière et chimique (EMC) v Commission of the European Communities* [1998] ECR I-1375 para. 171.

[13] Case C-450/06 *Varec SA v État belge* [2008] ECR I-581 para. 39.

[14] Case 106/77 *Amministrazione delle Finanze dello Stato v Simmenthal SpA* [1978] ECR 629 para. 20; Case C-213/89 *The Queen v Secretary of State for Transport, ex parte: Factortame Ltd and others* [1990] ECR I-2433 *Factortame* para. 21.

B. REQUEST FOR EXEMPTION OF INDUSTRIAL AND PROFESSIONAL USES OF AL-RCF AND ZR-RCF FROM REACH AUTHORISATION REQUIREMENTS

We request an exemption from the requirements for the professional and industrial uses of Al-RCF and Zr-RCF that are subject to the Carcinogens Directive.

As required by a plain reading of REACH Article 58(2) and in keeping with Commission precedent, the Carcinogens Directive properly controls the risks related to the industrial and professional use of Al-RCF and Zr-RCF because it requires Member States to establish minimum requirements for health protection by laying down exposure limit values as well as preventive measures. EU Member States have established specific workplace limit values for these substances, applicable at all workplaces and independent of the substance or article status of the material. When considering the risks related to the industrial or professional use of Al-RCF and Zr-RCF and the controls already in place through existing EU legislation, granting the exemption is the least burdensome option and should be chosen.

Alternative Request

In the event that this exemption request is refused, we ask that ECHA refrain from recommending Al-RCF or Zr-RCF for Annex XIV until conclusion of the current discussion on binding occupational exposure limit value (BOELV) which aims to harmonize specific minimum requirements across the EU via Annex III of Directive 2004/37/EC.