The VECCO Case And Beyond, What Uses Can Be Exempted From Authorisation Under Article 58(2) Of The REACH Regulation

Case C-651/15 P, Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) and Others v European Commission [2017] ECLI:EU:C:2017:543

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I. Introduction

On 13 July 2017, the Court of Justice of the European Union (the 'European Court') confirmed the ruling of the General Court of the European Union (the 'General Court') in the *VECCO* case[1] regarding the conditions under which the European Commission (the 'European Commission' or 'EC') may grant an exemption from the authorisation process for certain uses or category of uses pursuant to Article 58(2) of the REACH Regulation.[2]

Through their respective rulings, the Courts outlined some of the conditions that must be met for this exemption to apply and in particular (1) that there is existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use or category of use in question and (2) that the risk is properly controlled 'on the basis' of such legislation. If those conditions are met, then the Commission may grant an exemption.

However, the Courts did not specify in that particular case how the concept of 'proper control' of the risk should be interpreted. This is unfortunate since several Annex XV dossiers are being submitted for which there is the potential scope for an exemption under Article 58(2) and for which therefore the Commission will have to decide whether or not such proper control exists.

The purpose of this article is to provide a reasonable interpretation of such terms in complement to the European Court interpretation in the *VECCO* Case.

In summary, this concept should not be read as requiring an absolute control of all possible aspects of the risks related to the use(s) being considered. It should rather be considered to be met in case the legislator, when adopting the legislation being considered, has intended to control the risk in a way that the likelihood of the effects is avoided. In doing so, full consideration should be taken to the 'proportionality principle' enshrined in Article 58(2). Moreover, Article 58(2) should also be available for non-threshold substances, for which 'a qualitative assessment of the likelihood that effects are avoided', should be used as the benchmark to assess the 'proper control' of the risk. Finally, Article 58(2) does *not* require that the existing specific Community legislation include provisions for substitution that are equivalent to those required by REACH authorisation.

In view of the above, when seeking an Article 58(2) exemption, a manufacturer or user of a substance should seek to demonstrate to the European Chemicals Agency ('ECHA') and the Commission that (1) specific Community legislation imposing minimum requirements exist that have considered the exposure

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1 T-360/13, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) and Others v European Commission* [2015] OJ C 389 (T-360/13 VECCO v Commission, hereafter); Case C-651/15 P, *Verein zur Wahrung von Einsatz und Nutzung von Chromtrioxid und anderen Chrom-VI-verbindungen in der Oberflächentechnik eV (VECCO) and Others v European Commission* [2017] ECLI:EU:C:2017:543 (C-651/15 P VECCO v Commission, hereafter).

2 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Autorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency , amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 200/21/EC OJ 2006 L 396.

routes identified as requiring proper control; (2) such specific legislation ensure the proper control of the risks of the use(s) of the substance in question either through binding limits, when applicable or, in their absence, when legislative measures were taken to minimise the likelihood of adverse effects to a satisfactory level; (3) so that subjecting the use of the substance at stake to authorisation would be disproportionate, in light of the second sentence of Article 58(2).

II. The Facts Of The Case

In 2010, Germany sent to ECHA a so-called 'Annex XV dossier' for the substance chromium trioxide, ie a dossier aimed at identifying that substance as a Substance of Very High Concern ('SVHC') in accordance with Article 59 of the REACH Regulation. Germany proposed such identification on the ground that chromium trioxide had been classified as carcinogenic (Category 1) and mutagenic (Category 2) in Annex VI to the CLP Regulation,[3] meaning that the substance allegedly satisfied the criteria for inclusion in the list of substances subject to authorisation (ie REACH Annex XIV) as per Article 57(a) and (b) of REACH.

Following a commenting period, the Member State Committee of ECHA accepted Germany's proposal and, accordingly, ECHA included chromium trioxide in the 'Candidate List', the list of substances for eventual inclusion in the list of substances subject to authorisation.

Following such inclusion, ECHA published on 15 June 2011 a draft recommendation to include, *inter alia*, chromium trioxide in REACH Annex XIV. This triggered the opening of a commenting period, during which some of the applicants submitted a proposal that provision be made for some specific uses of the substance to be exempted from the authorisation requirement as per Article 58(1)(e) and Article 58(2) of the REACH Regulation. In particular, the applicants proposed that provision be made for an exemption for the use of chromium trioxide as an active catalyst substance.

Following the issuance of the opinion of the ECHA Member State Committee, ECHA submitted in December 2011 a recommendation for the inclusion of chromium trioxide while not proposing to grant an exemption for any uses of that substance.

In accordance with Article 131 REACH, the European Commission adopted Regulation (EU) No 348/2013 (hereafter the 'Contested Regulation') including *inter alia* chromium trioxide in Annex XIV to REACH without providing an exemption for any of its uses.[4] The applicants brought an action in annulment of the Contested Regulation before the General Court. The applicants notably claimed that in adopting the Contested Regulation the European Commission had breached Article 58(2) of the REACH Regulation in not exempting the use of chromium trioxide as an active catalyst from the authorisation requirements.

The General Court dismissed the applicant's action in annulment in its Decision of 25 September 2015. On 4 December 2015, VECCO and 185 other applicants brought an appeal against the decision of the General Court before the Court of Justice, asking the latter to set aside the judgement of the General Court.

By its judgement of 13 July 2017, the Court of Justice dismissed the appeal and confirmed the decision of the General Court in that it considered that it has correctly held that no Article 58(2) exemption could be adopted.

III. The Ruling Of The Courts On Article 58(2) Of REACH

The decision to include a substance in Annex XIV is adopted by the Commission notably on the basis of the recommendation prepared by ECHA. This decision must state *inter alia* the uses or categories of uses exempted from the authorisation requirement, if any, and the conditions for such exemptions.

The conditions for use(s) exemptions are laid out in Article 58(2) of REACH which provides that:

> 'Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health *or* the envi-

3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008] OJ L 353.

4 Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Autorisation and Restriction of Chemicals (REACH) [2013] OJ L 108.

ronment for the use of the substance, the risk is *properly controlled*. In 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'.

In the view of the applicants in the *VECCO* Case, the risk stemming from the use of chromium trioxide as an active catalyst is properly controlled and the conditions set by Article 58(2) were met. The Commission, supported by ECHA, opposed such assertion.

In its decision, the General Court has examined whether the conditions of Article 52 REACH were met. In its ruling, the General Court has provided some details on the interpretation to be given to those provisions of the REACH Regulation.

More specifically, for an exemption of uses or category of uses to be granted under Article 58(2), the General Court ruled that it is necessary to examine:

(1) whether there is 'existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance', and, if that is the case,
(2) whether 'on the basis of that specific Community legislation the risk is properly controlled',
(3) lastly, and only if those two cumulative conditions are met[5], the Commission *may* grant exemption, enjoying a margin of discretion in that regard.

The General Court has further ruled that Article 58(2) constitutes a *strict exception* to the principle according to which SVHCs must, as a rule, be included in Annex XIV and be subject to the REACH authorisation procedure. As a consequence, a *restrictive interpretation* of Article 58(2) is necessary precisely because it constitutes an exception.[6]

The Court of Justice, while confirming the ruling of the General Court, further added that Article 58(2) of REACH allows for the exemption of certain uses or categories of uses from the authorisation requirement '(i) in order *to ensure coherence* between the authorisation scheme laid down in Title VII of the REACH Regulation and other EU legal provisions aimed at protecting human health and the environment'.

IV. Interpreting The 'Use Exemption Criteria' Of Article 58(2) Of The REACH Regulation

1. Existing Specific Legislation In Place

In the *Vecco* case, the General Court has further specified what qualifies as an 'existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' as provided in Article 58(2) of the REACH Regulation.

First, Community legislation is to be understood as 'a rule of law adopted by a European Union entity intended to produce binding effects.'[7] This would for example be the case of a Directive. By contrast, this is *not* the case of national measures, voluntary practices (for example the voluntary application of occupational exposure limit values), or Commission Communications.[8]

Moreover, the fact that the risks stemming from the various uses of the substance are, on other grounds, virtually non-existent, if not negligible or controlled by other means, is irrelevant since this would fail to establish a link between an existing specific Community legislation as explicitly required under Article 58(2).[9] Such control of risk could indeed be covered by an authorisation granted under Article 60 of REACH.

Secondly, a Community legislation is *specific* when the substance is referred to as such by that legislation.[10] If that is not the case, a category of substance could be considered subject to a specific legislation if that legislation none the less refers to a category that is clearly distinct from other substances. In that respect, 'the specific nature of legislation re-

5 See, C-651/15 P *VECCO v Commission* [2017] s 31.

6 ibid, s 32.

7 See T-360/13 *VECCO v Commission* [2015] s 33.

8 ibid.

9 ibid, para 64. On that, ECHA adds that a low level of risk or low tonnage associated to a use, voluntary measures implemented by industry, availability and suitability of alternatives, socio-economic benefits associated with continuing a use, is important but cannot be used as a basis for Art 58(2) exemption. See ECHA, 'Response to the comments received during the public consultation on its draft recommendation to include the Lead Compounds in Annex XIV of the REACH Regulation' (2015) <https://echa.europa.eu/documents/10162/13640/6th_axiv_rec_comref_acetic_acid_lead_salt_en.pdf> accessed 6 April 2018.

10 See T-360/13 *VECCO v Commission* [2015] s 40.

ferring to a category of substances must therefore be comparable to the specific nature of legislation which refers to one substance only.'[11] For example, according to the General Court, the mere reference to a category such as carcinogenic or mutagenic substances is not specific enough. Also, in so far as a Directive does not refer to a particular substance and is applicable generally to all chemical substances, it cannot be considered 'specific'.

The Court added to the General Court's ruling that 'the adjective 'specific' denotes that which is distinctive of a particular subset and distinguishes it from other subsets, thus it can be regarded as the opposite of 'general''[12]. For the judges, the concept of specific legislation 'must be interpreted as referring, *at the very least*, to any directive or regulation *laying down rules particular to the substance concerned*. That term is to be understood as *contrasting* with legislation governing either *a group of substances or categories of uses*, which are *defined generally and abstractly*'.[13]

Finally, Article 58(2) of REACH refers to the concept of *'minimum requirement*'. According to ECHA, this concept distinguishes specific legislation from those setting out only objectives: 'legislation setting only the aim of measures or not clearly specifying the actual type and effectiveness of measures required is not sufficient to meet the requirements under Article 58(2).'[14] According to the General Court also, in so far as a Directive lays down only a general framework for the duties imposed on economic actors, it cannot be considered as imposing minimum requirements.

The more difficult question is whether reference to 'minimum requirements' in Article 58(2) implies that a legislation that would include 'maximum requirements' would not qualify for an exemption. Both ECHA[15] and the General Court[16] explain that the concept must be understood as meaning that it constitutes a minimum standard in the interest of workers or other persons concerned, and that it allows the adoption or imposition of even stricter measures at national level. This is why the General Court also ruled that requiring occupational exposure limit values constitutes a minimum requirement possible within the meaning of Article 58(2) of the REACH Regulation.[17] Indeed, such limits establish a standard in the interest of the protection of human health or the environment while allowing still for the adoption of stricter measures if necessary.

However, other Community legislation imposing maximum limits with no possibility for the adoption of stricter measures also should qualify for an Article 58(2) exemption. For example, as also supported by ECHA, 'specific entries in Annex XVII (of REACH) under which a substance can be used can constitute an exemption from the authorisation requirement of that (those) use(s) within the meaning of Article 58(2) of the REACH Regulation for that particular substance.'[18] Annex XVII entries impose a ban or a restriction that are directly applicable in the Member States and do not allow them to adopt stricter measures.

2. Proper Control Of The Risk

Following an assessment of all the pieces of legislation claimed by the applicants to fulfil the standards of Article 58(2),[19] the General Court ruled that the

11 ibid, s 53. The Court added to the General Court's ruling that 'the adjective 'specific' denotes that which is distinctive of a particular subset and distinguishes it from other subsets, thus it can be regarded as the opposite of 'general'. For the judges, the concept of specific legislation 'must be interpreted as referring, at the very least, to any directive or regulation *laying down rules particular to the substance concerned*. That term is to be understood as *contrasting* with legislation governing either *a group of substances or categories of uses*, which are *defined generally and abstractly*'. See, C-651/15 P VECCO v Commission [2017] s 35.

12 See, C-651/15 P *VECCO v Commission* [2017] s 35.

13 ibid.

14 See, ECHA, 'General Approach For Defininig The Annex XIV Entries' (2009) 6.

15 ibid.

16 See, T-360/13 *VECCO v Commission* [2015] s 47.

17 ibid.

18 See, (n 14) 7.

19 In that case, the applicants claimed that the following legislation constituted 'existing specific Community legislation imposing minimum requirements': Directive 98/24 of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 83/391/EEC) [1998] OJ 1998 L 131; 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 (sixth individual Directive within the meaning of Article 16(1) of Directive 83/391/EEC) [2014] OJ 2004 L 158; Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC [2012] OJ 2012 L 197; Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution and control) [2010] OJ 2010 L 334. The General Court ruled that all those pieces of legislation did not meet the criteria of Art 58(2) of the REACH Regulation.

criteria of specific existing Community legislation were not met by any of them. As a consequence, an Article 58(2) exemption of use(s) or categories of use(s) was not possible.

On that basis, and following the principle of economy of means ('*économie de moyens*'), the General Court ruled on the case by dismissing the applicants' claim without providing much details on the other criteria of Article 58(2) of REACH, eg on the concept of the risk being properly controlled.[20] The European Court confirmed the approach of the General Court.

Nevertheless, the judges of Luxembourg have provided some, even if limited, guidance on the way this concept should be understood. This article further builds on such elements to propose the interpretation that should be given to the term 'properly controlled'.

a. The 'Risk' To Be Controlled

First, the courts remain silent as regards the 'risk' that should be properly controlled in order to enable the adoption of an Article 58(2) exemption by the European Commission.

It can be noted that Article 58(2) refers to the 'risk' in single rather than plural form. However, it would be difficult to build on that sole element that there could only be one risk to be controlled.

A more reasonable interpretation would be to consider that the risk or risks to be controlled would logically follow from the risk(s) stemming from the hazards justifying subjecting the substance to the authorisation process, such as its CMR or PBT properties, and relate to the 'uses' or 'categories of uses' that one would consider for an Article 58(2) exemption. Such interpretation would also be in line with the spirit of the authorisation process, since Article 60 which refers to the stage of the granting of an authorisation also refers to the control of '*the risk* to human health or the environment form the use of a substance *arising from the intrinsic properties* specified in Annex XIV (...)'.

This being said, it should be kept in mind that since Article 58(2) refers to risks and not hazards, accordingly exposure would also need to be taken into account. In that respect, ECHA stated in its Guidance Document on Annex XIV 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* (ie service-life of articles and waste stage(s), as relevant are covered in the existing legislation'.[21]

b. What Does Properly Controlled Entail?

The General Court has specified that given the wording 'on the basis of' in Article 58(2) of REACH, the control of the risk must be based on the existing specific Community legislation imposing minimum requirements.[22]

However, Article 58(2) nor the General Court provide much detail on how the 'proper control' of the risk is to be understood.

Other provisions of the REACH Regulation use the same wording of the risk being '*properly controlled*' that can help clarify the meaning of such terms. In particular Article 55 (which sets the aim of the REACH Authorisation regime), provides that 'the aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are *properly controlled* and that these substances are progressively replaced by suitable alternative (...)'.

Reference can also be made to Article 60 of REACH (which is specific to the stage of the granting of authorisation) which refers to the terms 'adequately controlled', when providing that 'an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is *adequately controlled* in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report'.

That Section 6.4 of Annex I to REACH (entitled 'General provisions for assessing substances and preparing Chemical Safety Reports') refers to the conditions upon which '(f)or any exposure scenario, the risk to human health and the environment can be considered to be *adequately controlled*, throughout the lifecycle of the substance that results from manufacture or identified uses'.

The question therefore is whether the concept of 'properly controlled' in the context of Article 58(2)

20 See, T-360/13 *VECCO v Commission* [2015], s 64.

21 ECHA, 'General approach for defining the Annex XIV entries, Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV' (2009) 6.

22 See, T-360/13 *VECCO v Commission* [2015] s 64.

exemptions should be understood to be aligned on that of 'adequately controlled' under Article 60 and Annex I Section 6.4 to REACH.

First, if the legislator has used a different terminology, it is because the two concepts are not identical. The 'umbrella' Article 55 uses the wording 'properly controlled' as in Article 58(2). By contrast, Article 60(2) as well as Section 6.4 of Annex I to the REACH Regulation refer to the 'adequate control'.

In fact, as further detailed below, considering that proper control of risk is identical to adequate control would imply that only the so-called 'threshold substances' could benefit from Article 58(2) exemption of use(s) or category of use(s). This is not foreseen by the REACH Regulation and such extensive interpretation of the letter of the Regulation would run contrary to the overall architecture of Authorisation under REACH.

By contrast, we submit that the concept of 'proper control of risk' is wider than that of 'adequate control' and should be interpreted so as to enable *inter alia* Article 58(2) of REACH to encompass both threshold and non threshold substances. The benchmarks to be applied by authorities for both kinds of substances are described below.

3. The Benchmark To Meet The Cumulative Conditions For Enabling An Article 58(2) Exemption

a. Section 6.4 Of Annex I As Benchmark To Evidence Proper Control Of Risk For Threshold Substances

Threshold substances are substances for which it is possible to determine a threshold under which the substance would have no effect (so-called Derived No-Effect Level or 'DNEL', and Predicted No-Effect Concentration or 'PNEC').

As mentioned above, in order to demonstrate adequate control of the risks, Article 60 refers to Section 6.4 of Annex I to REACH which details how such risks must be adequately controlled and such section specifies that 'for any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

- the exposure levels (...) do not exceed the appropriate DNEL or the PNEC (...),
- the likelihood and severity of an event occurring due to the physico-chemical properties of the substances (...) is negligible'.

This constitutes the benchmark to be applied when considering whether a specific legislation allows the adequate control of the risk stemming from a particular substance. Such criteria would for example be fulfilled in a situation where a legislation set out binding exposure limits. In that context, the demonstration of the proper control of risk would be satisfied by demonstrating adequate control.

b. Section 6.5 Of Annex I As Benchmark To Evidence Proper Control Of Risk For Non-Threshold Substances

By contrast, non-threshold substances are substances for which it is not possible to ascertain the proper control of risk, since it is not possible to determine a dose under which the substance would have no effect (DNEL or PNEC). Because of that, the test described in Section 6.4 of Annex I to REACH cannot be fulfilled and, in the context of an Application for Authorisation, Article 60(2) of REACH (ie the 'adequate control route') does not apply. This is confirmed by Article 60(3) of REACH.

Article 58(2) is silent on the fact that it would apply only to threshold substances and there is no reason that use(s) exemptions could not apply to non threshold substances. In fact, in the *VECCO* Case, the action in annulment concerned the substance 'chromium trioxide', which is a non-threshold substance. In that case, neither the General Court nor the Court have ruled that Article 58(2) could not apply to such substance on the motive that it was a non-threshold substance. Moreover, neither ECHA nor the Commission seem to have raised a plea that an Article 58(2) exemption could not have been granted for the substance on that ground. This implies that both the judges and the authorities recognise, rightly, that there is room for use(s) exemption for non-threshold substances.

With respect to non-threshold substances, we submit that, by analogy with the Section 6.4 test that applies to threshold substances, the criteria of Section 6.5 of the same Annex I should apply.

That Section 6.5 provides that 'for those human effects and those environmental spheres for which it was *not possible to determine a DNEL or a PNEC*, a *qualitative assessment of the likelihood that effects are avoided* when implementing the exposure scenarios shall be carried out'.

This is confirmed by Recital (70) of REACH which further provides that 'For any substance for which authorisation has been granted, and *for any other substance for which it is not possible to establish a safe level of exposure*, measures should always be taken *to minimise, as far as technically and practically possible, exposure and emissions with a view to minimising the likelihood of adverse effects*(...)'.

Therefore, it should be satisfactory for non-threshold substances to demonstrate that the risk is properly controlled by demonstrating that a specific EU legislation ensures that the likelihood of effects are avoided.

Following that line of interpretation, an existing specific Community legislation would ensure that the risk is properly controlled not only if such legislation (or several pieces of legislation) imposes enforceable/binding minimum requirements for the substance used, but also, for substance without threshold, when it ensures that the likelihood of effects are avoided.

4. The Commission's Margin Of Discretion In Deciding On An Article 58(2) Exemption

A proper interpretation of Article 58(2) also requires to review the margin of discretion which the Commission enjoys in taking Article 58(2) decisions and, in particular, how and to what extent such power must take into account the 'proportionality principle' embedded in the last part of such article, as well as the 'principle of substitution', which is referred to in other articles of REACH related to authorisation.

a. The Commission 'May' Grant An Exemption

Article 58(2) provides that, if the cumulative criteria described above are met, '(u)ses or categories of uses *may* be exempted from the authorisation requirements.'[23]

This means that, if all conditions are met, the Commission enjoys discretion in granting or not an exemption, as evidenced by the wording 'may' in Article 58(2) REACH. However, such margin of discretion is not be unlimited and the European Courts can control that the Commission exercised such discretion taking proper account of all the facts and circumstances of the case and that its decision is not arbitrary.

A contrario, if not all the conditions laid down in the first sentence of Article 58(2) are met, the Commission does *not* have any discretion with regard to the granting of an exemption and shall not grant.[24]

b. The Commission Should Not Replace The Legislator

As ruled by the Courts in the *VECCO* case, in the context of the adoption of an Article 58(2) exemption, the Commission is entitled to identify whether a specific EU legislation imposes some minimum requirements, ie whether the legislator intended to cover the risk by setting those requirements.

However, in our opinion it would be outside the competency of ECHA and the Commission to assess whether the minimum requirements set up in the said Legislation effectively and/or adequately ensure the proper control of risk. Otherwise ECHA/the Commission would be *de facto* substituting themselves for the legislator that intended to cover the risk.

Rather, we submit that the Commission should seek to determine whether the legislator had intended to control the risk in question. Therefore, upon identifying the existence of minimum requirements set up in a specific Community Legislation, the Commission shall presume the adequacy/effectiveness of those requirements to control the risk posed by a substance.

c. The Proportionality Principle

The second sentence of Article 58(2) provides that "(i)n the establishment of such exemptions, account *shall* be taken, in particular, of *the proportionality of*

23 See, Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [2006] OJ L 396, Art 58(2).

24 See, T-360/13 *VECCO v Commission* [2015] s 65.

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.'

No guidance exists on how to interpret that second part of Article 58(2). However, this sentence requires in plain language the Commission to use the proportionality principle when assessing the risks involved by the use(s) concerned.

This reference to the proportionality principle in Article 58(2) should be interpreted to mean that in the overall assessment of risk in the context of Article 58(2), *the Commission holds a margin of discretion* that it should be able to use *also in terms of the opportunity of granting an exemption* for a use. For example, where, after having conducted an assessment of the proper control of risk following the Annex I approach (Section 6.4 or 6.5, depending on the nature of the substance), the remaining level of risk is found by the Commission to be negligible or low but the full control of the risk on the basis of the EC legislation cannot be established (eg in absence of binding exposure limits), the Commission could still decide that it is not proportionate to submit that use to the authorisation regime and therefore grant an Article 58(2) exemption on the basis of other considerations related to the nature of the substance and of the risk it poses. This should be decided upon in light of all facts and circumstances of the case, including those related to the nature of the substance as provided in Article 58(2) of REACH.

Indeed, Article 58(2) of the REACH Regulation does not condition the granting of a use exemption to the 'full' control of the risk but rather to its 'proper' control. This wording provides some latitude to the European Commission to take into account, to some extent, other considerations than the sole risk posed by a substance.

d. Substitution Schemes As An Indicator But Not A Prerequisite

The final question is whether the application of Article 58(2) of REACH would require demonstration that the Community legislation imposing minimum requirements aim at achieving substitution in the same way as a REACH authorisation decision would. There is no legal basis to support such a suggestion.

Article 55 of REACH provides that the aim of Authorisation is to ensure that risks from SVHCs are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end, actors applying for authorisation shall analyse the availability of alternatives and consider their risk and the feasibility of substitution.

However, whereas Article 58(2) explicitly conditions an exemption of uses to a proper control of risk(s), *nothing in that Article* provides for any kind of requirements regarding substitution.

The second sentence of Article 55 REACH specifically addresses the issue of substitution at the stage of the application for authorisation. However, it cannot be inferred from Article 55 REACH that all provisions of Title VII, including those regulating earlier stage of the authorisation process are to be interpreted in light of the concept of substitution. Moreover, the listing of a substance on the authorisation list triggers no obligations towards substitution. It is later in the regulatory process that the issue of substitution is tackled by REACH. Consequently, the issue of substitution does not need to be addressed at the stage of the listing of a substance in Annex XIV or in the assessment the possible exemption of use(s) or category of use(s).

This being said, even if the existence of a substitution regime should not be imposed as a pre-requisite for the application of Article 58(2), the fact that a legislation being considered under that article does contain a substitution objective could certainly support or strengthen the validity of an exemption. This is the kind of fact that the Commission could also take into consideration in its proportionality assessment described above. However, whereas the existence of a substitution scheme could strengthen a case for an exemption, it may not be a prerequisite.