Might the risk of the miniscule be sizeable? The UK Nanotechnologies Strategy, published in March 2010,\(^1\) would appear to work under his assumption. Of the three areas covered by the Strategy, two dwell on risk; one addressing potential health, safety and environmental impacts and the other on foreclosing this risk through the regulation of nanomaterials and products into which these are incorporated. In spite of mentioning opportunities in its sub-title, only one section of the Strategy is given over to innovation, and that focuses primarily on the commercialisation of nanotechnologies rather than the science base for technological development as such. This approach is curious for two reasons in particular. Firstly, the Strategy suggests that the global market for nano-enabled products will be worth $81bn by 2015.\(^2\) This is far less than the oft-quoted figure of $1 trillion expected by that date.\(^3\) Whatever the figure, however, one might expect that the seemingly infinite possibilities to develop and exploit the novel properties of nanotechnologies might be the dominant theme of a government strategy. That government should be so engaged by the need to assure the public of the safety of the enterprise suggests a significant need to address uncertainties attaching the potential impacts of emerging technologies in the manner which the Science and Trust Report,\(^4\) also of March 2010, emphasised.

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\(^2\) *Ibid* at p.6

\(^3\) M. Roco and W.S. Bainbridge, (eds), *Societal Implications of Nanoscience and Nanotechnology* (National Science Foundation, March 2001).

\(^4\) Science and Trust Expert Group *Starting a National Conversation about Good Science* (BIS, March 2010)
The second curiosity concerns the capacity of the UK Government in any case independently to control that risk, particularly when in relation to goods being placed on the market. A single European market means that for most products EU law drives harmonised procedures for product authorisation. The Strategy recognises this well enough since a key action in relation to regulation is “to monitor the success of implementation of upcoming amendments to novel foods and cosmetics directives with respect to nanomaterials.”

Every European member state faces uncertainties about the novel behaviour of nanomaterials and, when combined with the lack of agreed methods for testing associated environmental and health effects, this renders regulation problematic. As the multiplicity of uses to which nanomaterials may be put can make it difficult to locate appropriate regulatory regimes in Europe, it is chemicals’ policy that has the greatest potential (realisable or otherwise) for the substantive governance of nanosubstances. The Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals, commonly known as REACH, is overwhelmingly likely to take up much of the regulatory burden. This is for simple reason that the economic and technical capacity of industry to test nanomaterials easily outstrips current potential of the public sector in Europe.

REACH devolves chemicals testing to industry, but if it is to proceed to do so in relation to issues such as the fate or behaviour of nanomaterials, as these are developed, then regulatory clarity is paramount. This paper explores the capacity of REACH to accommodate nanomaterials within its regulatory compass. The paper
splits into three sections plus a conclusion. The first two sections can be briefly presented. The first section covers the absence of an explicit regulatory framework for nanosubstances within the EU\(^7\) and the second provides an overview of regulation under REACH. The third section compromises the vast majority of the paper by analysing the application of REACH to nanosubstances. This final section concludes by exploring possibilities for the substantive regulation of nanosubstances within REACH.

The paper suggests that although, in theory, REACH has great regulatory potential in relation to nanomaterials, it is beset by two main problems. The first is a coverage problem arising because of difficulties of definition, exclusion and thresholds. Among the concerns here are that only a small number of nanosubstances may fall within the main remit of the Regulation due to threshold criteria\(^8\) (despite indications that these thresholds may be amended at some, as yet undisclosed, future date\(^9\)). Coverage issues also arise out of difficulties in classifying nanosubstances (as existing or new chemical substances) and in making judgements about the equivalence of nanosubstances to existing, conventional counterparts.

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\(^7\) Hereafter, we largely use the term ‘nanosubstances’ to mirror the language of REACH which primarily refers to chemical substances as defined in Article 3(1). This is not, however, to dismiss the current debate on the appropriate nomenclature to use for substances at the nano scale, on which see: BSI (2005) PAS 71:2005 Vocabulary – Nanoparticles, ASTM E2456 - 06 Standard terminology Relating to Nanotechnology; and Desmoulin, S. (2008) “French and European Community Law on The Nanometric Forms of Chemical Substances: Questions About How the Law Handles Uncertain Risks”, *Nanotechnology Law & Business*, 341 – 351

\(^8\) The term “main remit” is used here as it is acknowledged that certain elements of REACH (for example, the authorisation and restriction processes) apply without threshold criteria. This is discussed in the main body of the paper.

The second problem concerns the operation of REACH in its main activities of registration (together with risk assessment) and the evaluation, authorisation and restriction, as necessary, of nanosubstances using REACH methodologies. In particular, the lack of consensus (within and without the EU) on the appropriateness and applicability of mapping existing chemical evaluation testing methodologies onto nanosubstances nanomaterials (and the potential for new methodologies to be devised in a near future time frame) limits control even where nanosubstances are captured by REACH.

The interplay of these two problems suggests that nanosubstances (through no fault of the nanosubstance registrant) may not be as thoroughly assessed under REACH as equivalent substances at the conventional scale. In short, the conclusion is that although REACH has the potential to regulate nanosubstances (even on a substantive level) this potential may not be realised. Despite this, the where and how of nanosubstance regulation under REACH is significant, especially in view of the lack of nanosubstance specific legislation in the Community and because: “without greater certainty as to the future of nanotechnologies under REACH, industry and consumer confidence in this revolutionary technology may be lost”\textsuperscript{10}.

**The Regulation of Nanosubstances within the EU**

Talking in big picture terms about the tiny, nanotechnology has been depicted as: “…the science of the small”\(^{11}\). For present purposes, ‘nanotechnology’ is taken to refer to the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanoscale, namely 1 – 100 nanometres (where a nanometre is on billionth of one metre)\(^ {12}\). In their report\(^ {13}\) for the (then) Department of Trade and Industry, Frater et al observed that:

Essentially, nanotechnology covers the techniques of building things from the bottom up, atom by atom, and molecule by molecule. This is generally contrasted with the traditional industry standard of building things from the top, with large chunks of traditional raw materials manoeuvred in place to construct specific products such as integrated circuits or an ocean liner.

Rather than pursue an in-depth discussion of the need for the regulation of substances at the nanoscale\(^ {14}\), it is suggested that certain nanosubstances, at least, may present risks to human health or the environment\(^ {15}\) and that the given value of “may” in this sentence is not yet fully known. We know that substances at the nanoscale have the

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\(^{12}\) For some sense of scale, a previously used example is that a strand of human hair is approximately 80,000 nanometres in diameter (see Stokes, E. (2009) “Regulating nanotechnologies: sizing up the options”, *Legal Studies*, 29(2), p 281 – 304)


potential to exhibit different characteristics to the same substances at the bulk scale\textsuperscript{16}: for example, gold in its bulk form is yellow and inert; in a 1 nanometre particulate form, it is blue with low reactivity; and at 3 nanometres, it is reddish and catalytic\textsuperscript{17}. At the same time, we can also accept that nanosubstances, as part of a broader field of nanotechnologies, have the potential for massive benefits to society\textsuperscript{18} and in a vast array of contexts, from new and potentially life saving medicines to perfectly straightened hair\textsuperscript{19}. Thus, as the European Commission puts it, “the regulatory challenge is therefore to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained”\textsuperscript{20}. This challenge is not only one of balancing between possibly competing goals (innovation on the one hand; risk control on the other) but also on regulating such a massively broad range of substances and products within an equally vast array of legal instruments:

“[The] current and foreseeable applications of nanotechnologies are so diverse that they fall within the remit of a very large number of legislative provisions”\textsuperscript{21}

Given this, we can also accept, for the purposes of this paper, that the seemingly endless application of nanotechnologies makes it all but impossible to introduce a

\textsuperscript{16} Excluding, here, for the sake of brevity, the characteristics of substances at the nanoscale which have no bulk equivalent (and which are sometimes labelled nanoengineered substances).


\textsuperscript{19} http://www.tresemme.co.uk/electrical-product.aspx?id=HD-salon-straight-nano-silver

\textsuperscript{20} Commission of the European Union, Regulatory Aspects of Nanomaterials, SEC(2008) 2036, p3
single regulatory framework at the level of the European Community and thus there will need to be an adaption of existing provisions from a plethora of laws to address nanosubstances\textsuperscript{22}.

There is some awareness of this issue within the E.U. where politics and opinions diverge between the Commission and certain Member States (in areas of definition and the ambit of guidance) and between the Commission and the Parliament (in terms of what may constitute appropriate regulatory action). This variance is driven by competing priorities as between product safety and innovation across the plurality of applications (from pharmacology to cat food) of nanotechnologies. While the European Commission had developed and disseminated its strategy on nanotechnology by 2004\textsuperscript{23} leading both to an action plan and work by the Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”) on methodologies, progress in general is thought to have been slow. Neither the appearance of a communication on regulatory aspects of nanomaterials\textsuperscript{24} or a code of conduct\textsuperscript{25} has satisfied the European Parliament. In the Spring of 2009, the Parliament expressed its dissatisfaction at the rate of progress Commission’s approach and demanded that the Commission review relevant European laws to assure the safety of all nanotechnology applications throughout their lifecycle.\textsuperscript{26}

\textsuperscript{21} Stokes, n. 4, p 283
\textsuperscript{24} European Commission, n.15.
\textsuperscript{25} European Commission (2008 III), Recommendation of 07/02/2008 on a code of conduct for responsible nanosciences and nanotechnologies research, COM (2008) 424.
The regulatory gap analysis by Frater et al (referenced above) concluded that while gaps did exist in the ability of the then existing regulatory framework to regulate nanosubstances, such gaps were not insurmountable. The question then becomes one of how well does the mapping of existing regulation onto nanosubstances match the specific contours of the substances being regulated? It is this question, in the context solely of REACH, to which we now turn.

REACH – An Overview

At its most basic, REACH requires the generation of data on the intrinsic properties of certain chemical substances (likely to be somewhere between 30,000 and 45,000 of the more than 105,000 substances currently on the market). In what has been described as a form of hybrid governance, data gathering falls upon the private sector in the form of manufacturers, importers and, in limited circumstances, downstream users of those substances and should be followed by the registration of such substances, together with the testing data, with a newly created EU regulatory

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27 Frater et al, n. 5. This finding was largely endorsed by the Royal Commission on Environmental Pollution ((2008) Novel Materials in the Environment: The case of nanotechnology, RCEP 27th Report) which called for a process of adaptive management of current regulatory structures.
28 This estimate is vague as the European Chemicals Agency has not performed any evaluation of the 145,000 substances pre-registered with them in 2008 as potentially falling within the remit of the Regulation (http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx#whatisthislisttheheader). It is likely that not all 145,000 substances which were pre-registered will go on to be registered and only time will tell the actual number of substances captured by REACH.
body, the European Chemicals Agency (“ECHA”)\(^{30}\). What data is required to be submitted, and by when, depends on two main factors: the volume of substance manufacture or import; and the intrinsic harmfulness of the substance (with high volume, highly harmful substances needing to register first and with a correspondingly higher amount of testing data). If no data is submitted for a substance subject to REACH, it can not longer be marketed within the European Community (the ‘no data, no market’ rule)\(^{31}\).

ECHA is tasked with providing guidance on the implementation and understanding of REACH, evaluating a limited amount of the data it receives and otherwise acting as a facilitator or intermediary between the private sector and the EU Commission (and Member States). Certain substances identified as particularly harmful to human health or the environment (either as a result of industry testing or via Member State nomination) will be banned, either in toto or in certain applications; others may be granted a time limited authorisation by the Commission to remain on the market if it can be proved that the risks from those substances can be adequately managed or where the use can be justified on socio-economic grounds and no suitable alternatives are available. European Member States have individual responsibility for enforcement of the regime.

This paper focuses solely on the application of REACH to nanosubstances, but it would be somewhat limited if a few words were not said on the broader expectations


of the Regulation and the challenges it faces. REACH represents the most radical overhaul of EU chemicals policy in four decades\(^{32}\). A number of environmental and consumer non-governmental organisations are looking for the Regulation to lead to a “toxic free world”\(^{33}\) in which a large number of chemicals are banned or their use severely restricted. The EU Commission is curious to know why the incidence of certain diseases, such as testicular cancer and allergies, have significantly increased in the last three decades and looks to REACH for some of the answers\(^{34}\). At the same time, industry groupings and EU Member States are keen to support the chemicals sector during a period of global economic instability (and to prevent any market impacts as a result of regulatory burdens which may place the EU chemicals sector at a competitive disadvantage to other chemical producers\(^{35}\)). On a more day-to-day level, REACH faces practical challenges, from the less than perfect information technology tools which are intended to support the registration system to difficulties in staffing ECHA\(^{36}\). It is in this context, of an extremely ambitious legal instrument seeking to pacify a large number of stakeholders with disparate aims, that we focus on the regulation of nanosubstances.

**Regulating Nanosubstances under REACH**

\(^{32}\) Since Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances was passed into law.

\(^{33}\) http://www.sinlist.org/


There is nothing specific in REACH about nanosubstances, or any linked nanoprefixed derivative (despite the best efforts of the Environment Committee of the European Parliament during the second reading of the Regulation to include targeted provisions). Nowhere in the 140,000 plus words that make up the Regulation does the term “nano” appear. Despite this, there seems little doubt on the part of the relevant regulators that REACH applies, as the following statements indicate:

“REACH does not contain provisions specific for nanomaterials, but that does not mean that nanomaterials are not covered by REACH”. Geert Dancet, ECHA Executive Director

“Substances in the nano-scale fall under the scope of REACH and their health and environment properties must therefore be assessed following the provisions of this Regulation.” DG Enterprise, EU Commission

“Do substances at nano-scale fall under the scope of REACH? Yes, they do and their health and environment properties must be assessed according to the provisions of the REACH Regulation.” ECHA FAQ Document

For the remainder of the paper, the key provisions of REACH in the context of nanosubstances will be evaluated, namely: applicability of the Regulation; substance identification; risk analysis; the mechanics of registration; and market access controls (bans and restrictions). Much of the discussion reviews and analyses issues detailed in a document prepared by the REACH Competent Authorities Sub-Group on Nanomaterials and published by the Commission in December 2008 (hereafter referred to as the “CA Document”), which looks specifically at the practical application of REACH to nanosubstances. While the CA Document is not binding (and, indeed, is partly contested by a number of Member States), the Commission comments that, “Stakeholders are invited to take note of the content of this document and follow its development.”

What’s in a name?

Broadly, REACH applies to “substances on their own, in preparations or in articles” where a “substance” is defined as “a chemical element and its compounds in the natural state or obtained by any manufacturing process.” The definition of “substance” does not depend on particle size: there is, for example, no distinction between a tonne of carbon and a carbon nanotube. Given this, for the purposes of definition at least, the nano form of a substance is as captured by REACH as its bulk.

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42 The sub-group is made up of the Commission, Member State representatives and other, undisclosed, “stakeholders”. See: http://ec.europa.eu/transparency/regexpert/detail.cfm?ref=2064&l=R
43 Commission of the European Union, Nanomaterials in REACH, 16 December 2008, CA/59/2008, 6th Meeting of the REACH Competent Authorities
44 http://ec.europa.eu/enterprise/newsroom/cf/newsbytheme.cfm?displayType=news&tpa_id=150
45 Article 5, REACH
46 Article 3(1), REACH
counterpart. As the CA Document puts it, “REACH deals with substances, in whatever size, shape or physical state”\textsuperscript{47}.

\textit{Exemptions and Exclusions}

Article 2 of REACH details various substances to which certain of the provisions of the Regulation do not apply. One category of exemption is for those substances which occur in nature, including minerals and ores, as detailed in Annex V. The documented reason for this is that it is thought that the risks from base elements are generally well enough known already\textsuperscript{48}. However, this may not be the case for the nanoforms of these substances. As noted above, gold is unreactive and stable at bulk levels, but highly volatile in certain of its nano forms. In addition to the Annex V exemptions, Annex IV to REACH contains a list of substances exempt from the Regulation because they are considered to be minimum risk\textsuperscript{49}. In October 2008, the EU removed carbon and graphite from the Annex IV list\textsuperscript{50} (allegedly because of concerns over the potential for carbon nanotubes to cause mesothelioma which were raised in a number of scientific journals\textsuperscript{51}). Two items of note can be taken from the above (to say nothing of the approach of the Commission in having carbon and graphite removed from the Annex IV list). The first is that, in not distinguishing between nano and bulk

\textsuperscript{47} Commission, n.38, para 1.1
\textsuperscript{48} Article 2(7)(b), REACH
\textsuperscript{49} Article 2(7)(a), REACH
forms of substances in Annexes V and IV, there are inherent, implicit (and inaccurate) assumptions in the Regulation that the risk of a substance is the same at whatever scale. Such an assumption could mean that an existing risk assessment of a substance at the conventional scale would be sufficient for REACH exemption or exclusion of the substance at the nanoscale. The second is that companies which currently manufacture or import the nano forms of substances in Annexes V and IV, and who may have thought they were exempt from certain of the provisions of REACH, may find themselves subject to obligations in the future if our scientific understanding of the intrinsic properties of nanosubstances increases and the above assumptions are displaced.

The Registration Obligation

The registration obligation under Article 6 of REACH is volume-based with a one tonne *de minimis* threshold. As a starting point, it thus appears that a manufacturer or importer of any nanosubstance in quantities greater than one tonne per year will be captured under the REACH registration provisions. Although production volumes of nanoscale substances may be currently low, certain companies have the capacity to annually produce metric tonnes of silver, copper and aluminium nanoparticles, among others.\textsuperscript{52} However, the actual number of those nanosubstance manufacturers or producers who fall under the registration provisions may be very low.\textsuperscript{53} Estimates of quite how low this number may be are hampered by the lack of a definitive inventory

\textsuperscript{52} Exact figures in this area are a matter of some commercial sensitivity and thus are not known.

of the types and uses of nanosubstances on the European market (or, indeed, elsewhere). The de minimis one tonne threshold for registration has been called “the most significant potential limitation affecting the application of REACH” to nanosubstances and there are various calls for this to be abolished or amended (with, perhaps, new threshold criteria introduced for nanosubstances). As Stokes observes, “Whilst the one tonne threshold reflects the fact that the safety of a substance is determined by the volume in which it is produced, it fails to account for particle size and surface area as key determinants of toxicity.” In this context, the CA Document comments that: “REACH…does not prevent companies from registering on a voluntary basis their substances if they are below the one tonne threshold.” While certain nanosubstance manufacturers may opt for non-obligatory registration under REACH (perhaps as part of a voluntary drive to publicly ‘prove’ nanosubstance safety), the associated costs could be very high (especially if the registration-linked nanosubstance testing raised concerns about the intrinsic properties of that substance and its impact on human health and the environment). It would thus seem that the numbers of nanosubstances that will be registered in their own right under REACH (as the Regulation is currently drafted) will be low, notwithstanding that registration

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54 In the United States, the Project on Emerging Nanotechnologies has inventoried more than 800 manufacturer-identified nanotechnology-based consumer products currently on the US market (see: http://www.nanotechproject.org/inventories/) but this figure has been questioned by various trade associations.


56 See, for example, the June 2008 resolution of the European Trade Union Conference (http://www.etuc.org/IMG/pdf_ETUC_resolution_on_nano_-_EN_-_25_June_08.pdf - accessed 27 May 2009) and a briefing paper by Friends of the Earth (http://www.vivagora.org/IMG/pdf/REACH_nano_briefing_final.pdf - accessed 27 May 2009). This was also one of the amendments proposed by the Environment Committee of the European Parliament during the second reading of REACH and has been further raised by unnamed stakeholders who are members of the REACH Competent Authorities Sub Group on Nanomaterials (Commission, n. 25, para 2.5). The call is further echoed in the European Parliament’s latest resolution on nanomaterials (n.21, above).
has been described as the ‘cornerstone’ of the regulation.\textsuperscript{59} However, the CA Document muddies the waters somewhat with the following commentary:

“The tonnage triggers for registration apply to the total volume of a substance manufactured or imported by a registrant. Thus, for substances which exist both in bulk form and in a nanoform, the total volume determines the need and timing for registration and the information requirements”\textsuperscript{60}.

From this, it would seem that if a manufacturer of carbon (who produces, for the sake of example, more than 1000 tonnes of carbon per year) also produces an amount of carbon nanotubes (“CNTs”), these CNTs would be registered \textit{along with} the (bulk form) carbon whatever their volume of manufacture. However, what the Commission fails to note in this part of the CA Document (and which is discussed in greater detail below) is that this ‘bulk substance + nano substance’ combination of volume for registration purposes should \textit{only} apply where the substances, in their different forms, are considered the “same”. If they are not, such addition would be a wholly inaccurate approach.

Under Annex VI of REACH, the registration dossier for a substance must include information on the manufacturing process(es) and “all identified uses”. In the context of risk assessment (discussed in more detail below), registration under REACH

\textsuperscript{57} Stokes, n. 4, p286
\textsuperscript{58} Commission, n. 38. para 2.6
\textsuperscript{60} Commission, n. 38, para 2
requires a set of physicochemical, toxicological and ecotoxicological information in
the technical dossier, which duly reflects the spectrum of all identified uses. In 2007,
at a nanotechnology conference in Helsinki\textsuperscript{61}, Geert Dancet, the Executive Director of
ECHA, commented that registration dossiers should always contain information on
identified uses, \textit{including} those at nanoscale levels. However, official guidance
produced by ECHA on the registration process\textsuperscript{62} does not include any reference
whatsoever to nanosubstances or the nanoscale uses of chemicals subject to REACH.
At the same time, following on from a REACH registration, the registrant is
responsible, to update, without undue delay, the registration dossier if relevant new
information is available\textsuperscript{63}. This includes, for example, new identified uses for which
the substance is manufactured. If this includes identified uses at nanoscale levels, we
may expect to see a large raft of updates to registration dossiers as technology in the
nanosubstance field advances and the number of uses of any given nanosubstance
increases. In this context, the Commission comments:

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“When an existing chemical substance, already placed on the market as
bulk substance, is introduced on the market in a nanomaterial form
(nanoform), the registration dossier will have to be updated to include
specific properties of the nanoform of that substance. The additional
information, including different classification and labelling of the
nanoform and additional risk management measures, will need to be
included in the registration dossier. The risk management measures and
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\textsuperscript{61} Dancet, n.34
\textsuperscript{63} Article 22(1), REACH
operational conditions will have to be communicated to the supply chain.\textsuperscript{64}

It remains to be seen whether or not such updating will happen, as a matter of practice. However, registrants should note that failure to update the registration dossier, where so required, is an offence\textsuperscript{65} and subject to sanctions detailed in the enforcement regimes of the relevant Member State.

For substances manufactured or imported in quantities greater than ten tonnes per annum, the registrant is required to submit a Chemical Safety Report ("CSR")\textsuperscript{66}. The level of data on the intrinsic properties of a substance required for a Chemical Safety Report is far greater than that needed for a substance manufactured or imported in quantities less than ten tonnes per annum and may include an exposure assessment and risk characterisation study\textsuperscript{67}. At the present, it is very unlikely that nanosubstances, in their own right, will be captured by this tonnage threshold as current production volumes are comparatively low.\textsuperscript{68} However, Article 138 of REACH sets out a timetable for reviewing the requirement for a CSR. By June 2019, the Commission will have determined whether the CSR ten tonne threshold should be reduced. For substances which are thought to be cancerous, mutagenic or toxic to reproduction, the review will take place some time before June 2014. Given other

\begin{thebibliography}{99}

\bibitem{64} Commission, n.38, p4
\bibitem{65} Article 22, REACH
\bibitem{67} See: http://guidance.echa.europa.eu/chemical_safety_en.htm
\bibitem{68} It may be that low production volumes may mean lower overall risk: see Robichaud, C.O.; Tanzil, D.; Weilenmann, U.; and Wiesner, M.R. (2005) Relative risk analysis of several manufactured nanomaterials: an insurance industry context, \textit{Environmental. Science and Technology}, 39(22), 8985 – 8994.
\end{thebibliography}
calls, highlighted in this paper, for a review of REACH to specifically address concerns from nanosubstances, it is perfectly plausible that the requirement of a CSR for all nanosubstance registrations might then be introduced.

_Phase-In or Non-Phase-In, That is the Question (of Equivalence)_

The following sections discuss, in the context of REACH, the broad question of whether substances at the nanoscale can be considered equivalent, under the Regulation, to their bulk counterparts and, if not, in which specific contexts and to what degree. We begin by looking at the distinctions made in REACH between certain classes of substance for the purpose of regulatory compliance deadlines.

The chemicals regime in the EU prior to REACH\(^69\) split substances into “new” substances (essentially, those put on the market after 1981) and “existing” substances (those already on the market prior to 1981). While REACH does not copy this approach, there is still a divide between “phase-in” and “non-phase-in substances” when it comes to certain matters, such as deadlines for registration. A phase-in substance is one which meets the criteria set out in Article 3(20) of REACH. In essence, phase-in status is awarded to substances which have been listed on the European Inventory of Existing Commercial Chemical Substances (“EINECS”)\(^70\) and thus were “existing” substances prior to the entry into force of REACH. Whether a nanosubstance is phase-in or non-phase-in is crucial, as a decision that a given


\(^70\) For the legal background to EINECS, see: Geiss, F.; Delbino, G.; Blech, G.; Norager, O.; Orthmann, E.; Mosselmans, G.; Powell, J.; Roy, R.; Smyrniotis, T.; and Town, W. G. (1992). The EINECS.
nanosubstance was non-phase-in would see its manufacturer or importer unable to take advantage of the staggered registration compliance deadlines which apply to phase-in substances\textsuperscript{71}. Nanosubstances which are considered to be non-phase-in (and which are manufactured or imported in quantities greater than one tonne per year) needed to be registered prior to 1 June 2008 before manufacture or import could continue. As ECHA have yet to evaluate more than a small handful\textsuperscript{72} of the 194 registration dossiers submitted to them by 1 June 2009\textsuperscript{73}, it is not known whether any nanosubstances which were considered as non-phase-in and which are manufactured or imported in quantities greater than one tonne per annum were so registered.

This issue of equivalence (whether, for example, carbon and carbon nanotubes can be said to be equivalent under REACH) in the context of whether a substance is phase-in or non-phase-in has obvious economic consequences, especially where nanosubstances are not considered as equivalent to their conventional counterparts and so the direct regulatory cost imposed by REACH becomes that much greater\textsuperscript{74}. However, and as noted above, the task of deciding on whether a nanosubstance is phase-in or non-phase-in rests with the nanosubstance manufacturer or importer, who may well be perplexed by a multitude of differing (supposedly, authoritative) views on the matter. In 2004, the Royal Society in the UK recommended that nanosubstances be treated as “new” substances under EU health and environmental

\textsuperscript{71} And which are detailed in Article 23 of REACH, running up to 2018
\textsuperscript{73} Personal communication of 28 May 2009 from Vaughan, S. to ECHA Communications team. Response on 16 June 2009.
\textsuperscript{74} Bowman, D. & Van Calster, G., n.2
legislation\textsuperscript{75} (and so, as a corollary, would be non-phase-in substances under REACH). This is a call which has been echoed elsewhere, most notably by an EU Commission Scientific Committee which suggested that nanoscale substances should be differentiated from their conventional counterparts through the assignment of a new Chemical Abstract Service (CAS) number\textsuperscript{76}. The CA Document is more nebulous and comments that, “…the decisive criterion whether a nanomaterials is a new or existing substance is the same as for other substances, that is whether or not the substance is included in \[EINECS\]\textsuperscript{77}. But this is not particularly helpful in any meaningful practical sense. Carbon is registered on EINECS with the number 7440-44-0. But this listing does not distinguish, for example, between carbon in a conventional form and carbon nanotubes. The CA Document goes on to comment that:

“In interpreting whether a concrete material is covered by a particular EINECS entry…historical criteria need to be applied. In other words, whenever the material was considered to be covered by a particular EINECS entry in the past, it should be considered to have phase-in status under REACH.”

\textsuperscript{75} Royal Society, Nanoscience and nanotechnologies: opportunities and uncertainties, 2004, p71
\textsuperscript{77} Commission, n. 38, para 2.1
Exactly what this means is not entirely clear\textsuperscript{78} and it has been reported\textsuperscript{79} that there is currently a delay in further guidance on substance identification being issued by the Commission due to a lack of agreement between them and the Member States on questions of equivalence\textsuperscript{80}. It is then perhaps no wonder that there has been a divergence in practice between nanosubstance registrants as to how they categorise their substances under REACH. It was reported in February 2009\textsuperscript{81} that Thomas Swan & Co, a speciality chemicals manufacturer in the UK, had pre-registered\textsuperscript{82} its CNTs as a separate substance from bulk forms of carbon and graphite. Unlike other EU manufacturers of CNTs potentially requiring registration under REACH, the company pre-registered its CNTs without an EINECS number on the grounds that none exists specifically for carbon nanotubes at the moment. It is not yet known how (or if) ECHA will approach this disparity in pre-registration. The potential consequences of such disparity are discussed below, although it is perhaps worth noting that by pre-registering a substance, a manufacturer or importer is (implicitly) stating that the substance pre-registered has phase in status. How Thomas Swan & Co. have reconciled this approach (namely, pre-registering a substance without an EINECS

\textsuperscript{78} For example, whose view counts when debating, from a historical point of view, whether any given substance was covered by a given EINECS entry?


\textsuperscript{80} In the United States, the Environmental Protection Agency faced similar identification issues in the context of nanosubstance regulation under TSCA. In a 2008 white paper (“TSCA Inventory Status of Nanoscale Substances – General Approach”), the EPA commented that that not all nanoscale substances will qualify as “new” substances subject to TSCA oversight, saying that the agency will determine such matters on a case-by-case basis.


\textsuperscript{82} Pre-registration ran between 1 June 2008 and 1 December 2008 and was (in essence) an optional reporting window for manufacturers or importers of phase-in substances. Where a phase-in substance was pre-registered in this timeframe (through submission of a minimal amount of information detailed in Article 28(1) of REACH) the manufacturer or importer would then be able to take advantage of the staggered registration deadlines for phase-in substances in Article 23. Failure to pre-register would have required the manufacturer or importer to register the phase-in substance by 1 June 2008 before continuing manufacture or import.
number when pre-registration presupposes the existence of such a number, thereby qualifying the substance for phase-in status) is not clear.

*Sameness and Substance Identification in SIEF Formation*

The important question discussed above of equivalence goes beyond the issue of phase-in or non-phase-in status. Let us say, for example, that a manufacturer of carbon nanotubes in quantities greater than one tonner per year has decided (on whatever basis) that their products meet the criteria for “phase-in” substances and has pre-registered them accordingly using the EINECS number for carbon. At some point post 1 January 2009, (s)he will then be allocated to what is known as a SIEF, a substance information exchange forum. Participation in the SIEF is mandatory (with limited exceptions) for all potential registrants, downstream users and third parties who have submitted information to ECHA on “…the same phase-in substance”83 (own emphasis added). In basic terms, the SIEF pulls together everyone who has informed ECHA that they intend to register the “same substance” and then obliges them to share existing vertebrate animal test data and to agree on the generation of new test data for the substance.84 Going forward, one entity from the SIEF then assumes the role of “Lead Registrant” and submits the registration dossier for the substance on behalf of all of the SIEF members (the ‘one substance, one registration’ principle).85 In our example, the CNT manufacturer will be nominally allocated to the carbon SIEF. The question then is whether this is or is not appropriate. Are the CNTs

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83 Article 29(1), REACH
the “same substance” as carbon? If they are, the CNT manufacturer will remain in the carbon SIEF and work with them on the sharing of existing test data and the generation of new information. If not, the CNT manufacturer will either have to undergo registration alone (which has obvious cost implications) or seek out CNT manufacturers with whom to create a CNT SIEF. Under REACH, the question of ‘sameness’ is one to be answered by the registrant. The ECHA Guidance on Data Sharing comments\(^86\) that, “…the REACH Regulation does not define "sameness" and it does not foresee any formal step to confirm the establishment of sameness and the formation of a SIEF.” The CA Document comments that, “In the case of substances at the nanoscale, it is possible that some substances which in the past have been identified by the same EINECS number may have to be considered as different substances for the purpose of REACH\(^87\). In this case, all substances which were covered by the original EINECS number retain phase-in status\(^88\). These comments are of little practical use for a nanosubstance manufacturer attempting to decide in which SIEF to participate. To answer the question of “sameness”, ECHA directs potential registrants to its Guidance on Substance Identification\(^89\) which is equally unhelpful with only one reference to nanosubstances:

The current developments in nanotechnology and insights in related hazard effects may cause the need for additional information on seize [sic] of the substances in the future. The current state of development is not

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\(^85\) On which, see: http://echa.europa.eu/sief/leadRegistrants_en.asp


\(^87\) This obviously goes against the other advice set out in the CA Document (discussed previously in the main body of this paper) which says that if, historically, two substances were considered to be covered by the same EINECS listing, they are both phase-in and can use such listing for the purpose of pre-registration. It would thus seem that historical criteria are only relevant for the question of whether or not a substance is phase-in and not for the purposes of SIEF formation.

\(^88\) Commission, n. 38, para 2.3
mature enough to include guidance on the identification of substances in
the nanoform in this TGD [Technical Guidance Document]90.

In pre-registering their CNTs without an EINECS reference, Thomas Swan & Co
(discussed above) have signalled their belief that their products are not the same as
their bulk counterparts. It may well be that there are other CNT manufacturers who
have pre-registered using the carbon EINECS entry and who take a different view91.
This, then, has the potential for disparity in the levels of substance testing (and
methods deployed) between the two groups of CNT manufacturers in two separate
SIEFs (and thus has wider implications for all nanosubstance registrations). This
potential for disparity is especially acute as ECHA is intending to only evaluate a very
small number of registration dossiers (on which, see below). It would, therefore, be
perfectly possible for two CNT manufacturers from two, separate SIEFS, to have
submitted two registration dossiers to ECHA containing different data on the intrinsic
properties of those CNTs. This is one area where an attempt at definitive guidance by
the Commission is urgently needed.

The Risk Assessment of Nanosubstances

Most chemical regulation assumes a relationship between volume of material and
exposure. For nanosubstances, however, toxicity is presumed to relate to surface area
and the number of nanosubstances. Dissecting a 1 centimetre cube of any given

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91 Ibid, p28
92 It is somewhat difficult to search the register of all pre-registered substances
(http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx#searchtheлистheader) for specific
substance into 1 nanometre cubes increases the total combined surface area some ten million times – nanosubstances thus have the potential to be much more reactive than larger volumes of the same substance. While health and safety concerns persist in relation to human exposure to nanosubstances, the extent to which these concerns are well grounded is itself a matter of uncertainty since the potential risks posed by nanomaterials are not fully understood. At the same time, the appropriate methodological approaches to assessing such potential risks are themselves uncertain.

In 2008, a report by the Royal Commission on Environmental Pollution in the UK\(^2\) concluded that the pace at which nanosubstances are being developed and marketed was beyond the capacity of existing testing and regulatory arrangements to adequately control the potential adverse environmental impacts. Sir John Lawton (Chair of the Commission) observed\(^3\) that, “There is an urgent need for more research and testing of nanomaterials. It will be necessary to extend the coverage within the European Union of the existing regulatory regime for chemicals (REACH). This must be taken forward as a matter of urgency”. However, in their latest report in January 2009\(^4\), the EU Commission’s Scientific Committee on Emerging and Newly Identified Health Risks (“SCENIHR”) took a less gloomy view. Building on initial conclusions from reports in 2006\(^5\) and 2007\(^6\) it reaffirmed the view that, “…the procedure for

\(^6\) SCENIHR. (2007a) Opinion on the appropriateness of the risk assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the
assessing the potential risks of manufactured nanomaterials is still under
development”97. For SCENIHR, it is not so much that testing methods do not exist, but rather that, as yet, we do not have the means to characterise the harmful effects of nanomaterials. There is, to put it simply, a lack of any appropriate framework in which assessment might occur. At the same time, this is not a static field and SCENIHR comment that there has been improvement in the means to assess the risks from nanosubstances since its reports in 2007. One of the issues goes the lack of appropriate standardised testing protocols. As Geert Dancet puts it: “to decide for legislative purposes whether a nanoscale particle is dangerous to human health requires not only adequate and internationally recognised test methods, but also internationally agreed criteria on which test results can be used to classify a substance as such”. 98

On a practical level, it appears therefore that, at the moment, current testing approaches will be required to bridge the methodological gap in the assessment of nanosubstances. The European Commission comments that, “Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to

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97 SCENIHR, n. 67, p9
98 European NanOSH Conference –Nanotechnologies: A Critical Area in Occupational Safety and Health, 3–5 December 2007, Marina Congress Center, Helsinki, Finland. This is essentially the same conclusion as that of the Dutch National Institute for Public Health and the Environment. In 2009, they attempted a “mock” registration of nanosilver to see how, in practice, REACH applied to nanosubstances. One of their main conclusions was that “…a relevant measure for expressing harmfulness and exposure [of nanosilver and other nanosubstances] is not yet known” (RIVM (2009), Nanomaterials under REACH: Nanosilver as a case study, Report 601780003/2009). Work in this area of testing methodologies is being driven, in part, by the International Organization for Standardization’s Technical Committee for Nanotechnologies (on which, see: http://www.iso.org/iso/iso_technical_committee?commid=381983).
already existing guidelines\textsuperscript{99}, although they do acknowledge the need for testing guidance produced by ECHA to be modified at some unspecified future date\textsuperscript{100}. For a CNT manufacturer who has pre-registered under REACH (and who should, in theory, currently be debating with his/her SIEF colleagues the extent of necessary testing for the purposes of registration), this is not of much practical use (nor is the ECHA Technical Guidance Document on Information Requirements and Chemical Safety Assessment\textsuperscript{101} which has only limited references to nanosubstance evaluation). Does that manufacturer: (a) wait and see what happens; or (b) attempt to graft existing approaches as best as possible to his nanosubstance (which runs the risk that the registration dossier will fail evaluation by EHCA, a matter to which we now turn)?

\textit{ECHA Evaluation}

The evaluation process under REACH is a means by which ECHA can call on those who have submitted registration dossiers to provide additional or better information on the substances registered\textsuperscript{102}. This is in two parts: (a) dossier evaluation; and (b) substance evaluation. Whereas dossier evaluation can, in many respects, be thought of as an administrative box-checking exercise, substance evaluation operates in much greater depth. As a first task in the substance evaluation process, ECHA (in co-ordination with the Member States), has to develop criteria for prioritising substances, on a “risk based” approach, with a view to further evaluation\textsuperscript{103}. These criteria (based on hazard information, exposure information and substance tonnage) will lead into a

\textsuperscript{99} Commission, n. 38, p 4  
\textsuperscript{100} Commission, n. 38, para 2.4  
\textsuperscript{101} http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm  
\textsuperscript{102} Title VI, REACH  
\textsuperscript{103} Article 44(1), REACH
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three year European Community rolling action plan (the first to be submitted by ECHA to the Member States by 1 December 2010) detailing the substances to be evaluated each year and which Member State has responsibility for evaluating which substance\textsuperscript{104}. With substance evaluation, the role of ECHA is one of co-ordination, with the active evaluation of the intrinsic properties of the substance undertaken by competent authorities in the Member States (or third parties appointed on their behalf)\textsuperscript{105}. Competent authorities in the Member States undertaking a substance evaluation have the ability to require the registrant to submit additional information to assist with the evaluation. The CA Document comments that:

> “Substances at nanoscale can pose specific issues relating to evaluation due to their specific properties and due to the fact that certain standard tests may not be sufficient or appropriate. It could be useful to prioritise a small number of nanomaterials, both for dossier and substance evaluation in ECHA, as this would allow the issues that are likely to occur to be raised, discussed and resolved as far as currently practical. This is turn could provide useful guidance to other registrants, Member State authorities and the Commission on what to do.”\textsuperscript{106}

If (or how) nanosubstances are prioritised for evaluation under REACH may give some indication of the future trend of regulation. Pro-active prioritisation of nanosubstances by ECHA and the Member States in the context of evaluation could

\textsuperscript{104} Article 44(2), REACH. It is worth noting that a Member State can put itself forward as the competent authority for evaluating a particular substance in accordance with procedures detailed in Article 44(2) and (3).

\textsuperscript{105} Article 45(1), REACH

\textsuperscript{106} Commission, n. 38. para 4
suggest a more general pro-active regulatory approach, in contrast to the somewhat laissez-faire approach set out by the Commission in their 2008 Communication\textsuperscript{107}. It might also lead to claims of the disproportionate application of the REACH regulatory burden on nanosubstances manufacturers or importers (although we offer no opinion on whether this would be the case were it to occur). Where nanosubstances are evaluated, this could lead to the operation of the authorisation or restriction procedures under REACH, as discussed in the following section.

\textit{Nanosubstance Bans?}

Each separate use of a ‘substance of very high concern’ ("SVHC") which is listed in Annex XIV of REACH will be subject to authorisation by the Commission\textsuperscript{108}. Without an authorisation (which will be, in any event, time limited), the SVHC cannot be placed on the EU market. It is commonly thought that the review process is expected to affect about 3,000 (bulk) substances. A number of substances are automatically considered as SVHCs (and thus could potentially require authorisation)\textsuperscript{109}. These fall into four broad categories\textsuperscript{110}: carcinogens, mutagens and reproductive toxins; those substances which are persistent, bio accumulative or toxic; substances which are very persistent or very bio accumulative; and finally, “other” substances which will be identified on a case by case basis.

\textsuperscript{107} European Commission, n.15
\textsuperscript{108} Article 56, REACH
\textsuperscript{109} Article 57, REACH
\textsuperscript{110} Article 57, REACH
The authorisation procedure under REACH is particularly relevant in the nanosubstance context as the regulatory triggers are not volume based: “Authorisation and restriction schemes apply regardless of quantities manufactured or placed on the market”\textsuperscript{111}. At the same time, and as the CA Document notes, “Authorisation is also independent of registration in the sense that substances do not need to be registered in order to be subject to authorisation”\textsuperscript{112}. Given this, REACH could operate to ban certain nanosubstances from the EU market irrespective of whether those substances also fall elsewhere within the regulatory compass of REACH. While this is so, there is still a chicken-and-egg situation. For a substance to be subject to the authorisation procedure under REACH, there must be evidence that that substance poses unacceptable risks. However, in the context of nanosubstances, we still await (as highlighted above) testing methodologies sufficient to adequately evaluate the potential risks of nanosubstances (as well as internationally accepted standards by which testing may occur). Without these, the potential for nanosubstance authorisation under REACH is somewhat limited\textsuperscript{113} (unless REACH competent authorities adopt a precautionary approach to restrict or ban nanosubstances in an absence of generally accepted scientifically robust data, an issue raised by Bowman & van Calster\textsuperscript{114}). The issue is touched on, albeit obliquely, by the Commission in the CA Document. They comment,

\textsuperscript{111} Commission, n.38, p5
\textsuperscript{112} Commission, n. 38, para 5
“The guidance on identification of SVHC recognised the possibility that ‘as yet unidentified substance properties can be captured under the consideration of equivalent concern, where there is scientific evidence (relating to probable serious effects) that these properties give rise to an equivalent level of concern to those of CMR cat 1 and 2, PBT and vPvB substances. It might be that other as yet unidentified aspects of a chemical’s behaviour in the environment or its impacts on organisms will lead to a change in the current paradigm for chemical hazard and risk assessment. Authorities are encouraged to employ the underlying principles behind the preceding sections in considering such aspects and properties in the future.’ This should be taken into account when considering the identification of relevant substances at nanoscale that do not meet the criteria for CMRs or PBTs per se.”

What this may suggest is that where there are indications that a nanosubstance may amount to a SVHC, but sufficient data is lacking for the nanosubstance to be classified with any certainty as carcinogenic, toxic, persistent etc., it may fall nonetheless within the “other” limb of the definition of SVHCs. For this to happen, there would still need to be “scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern”¹¹⁵. Given this, it is important to stress that the mere fact that this “other” limb exists for the categorisation of SVHCs does not eliminate the need for generally accepted appropriate testing methodologies for nanosubstances. For nanosubstance bans to be considered under REACH, someone, somewhere, must be in possession of “scientific

¹¹⁵ Article 57(f), REACH
evidence” that the substance is harmful. For this evidence to arise, appropriate and agreed testing methodologies are necessary.

In October 2006, the Environment Committee of the European Parliament proposed an amendment to the draft text of REACH in order to subject ‘nanoparticles’ to authorisation *irrespective* of their toxicological properties\textsuperscript{116}. Although this proposal was voted down, its content was echoed in a 2006 report by AFSSET, the French Agency for Environmental and Occupational Health Safety\textsuperscript{117}, in which AFSSET called for all nanomaterials to be considered as a special class of SVHC. To date, none of the substances thought to be SVHCs put forward by Member States and then compiled by ECHA into a ‘candidate list’ for authorisation are at the nano scale\textsuperscript{118}. This does, however, raise an interesting query. In the CA Document, it is made clear that if a nanosubstance is put forward by a Member State as being a SVHC which should be included in Annex XIV, the dossier which details the reasoning behind the Member State’s proposal should clarify that it is the nanoform of the subject which is thought to meet the SVHC criteria (and not the bulk form). This seems clear enough. However, there is no corresponding advice for when dossiers are prepared for substances thought to meet the SVHC criteria in their bulk form only. For example, anthracene, used for the artificial production of the red dye alizarin as well as in certain wood preservatives, appears on the candidate list. Nowhere in the linked SVHC Support Document\textsuperscript{119} is there reference to which form of anthracene is thought to be a SVHC. We might assume that this refers to the conventional form, but does

\textsuperscript{116} European Parliament, n. 21, Amendment 79
\textsuperscript{117} See: http://www.afsset.fr/upload/bibliotheque/13875094995592393640847724164/afsset-report-nanomaterials.pdf
\textsuperscript{118} http://echa.europa.eu/chem_data/candidate_list_table_en.asp
\textsuperscript{119} http://echa.europa.eu/doc/candidate_list/svhc_supdoc_anthracene_publication.pdf
this then mean that the nano form of a bulk substance identified as a SVHC is also considered a SVHC? If not, should this not be made explicit?

Article 60 of REACH sets out the necessary conditions for the authorisation (i.e. continued market presence) of a SVHC to be granted - either: (i) the risk from the substance subject to authorisation must be “adequately controlled”; or (ii) the socio-economic benefits from the substance must outweigh the risks and there must be no suitable alternative substances or technologies. However, Article 60(3)(a) details that what we might term the ‘adequate control authorisation’ in Article 60(2) does not apply to substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with section 6.4 of Annex I. Query whether, for nanosubstances, such Annex I thresholds are currently capable of being determined? If not, the ability to claim an authorisation on the ground of adequate risk control would be ipso facto denied to nanosubstances. If an authorisation cannot be granted under paragraph 2 of Article 60 (or for substances listed in paragraph 3 of Article 60), an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. Guidance by ECHA on how to assess socio-economic benefits has yet to be published. Given the dichotomy between the potential for nanosubstances to bring improvements to a variety of aspects of our lives and the environment and the potential for such nanosubstances to be intrinsically harmful, it is

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120 Section 6.4 of Annex I of REACH details 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: (a) the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and (b)
likely there will be some very interesting arguments when it comes to the socio-economic analysis of any given nanosubstance labelled a SVHC which seeks authorisation. There are also some very interesting issues here when it comes to the question of “suitable alternatives”. As noted above, if there are “suitable alternatives” for a SVHC which is on the Annex XIV list which cannot take advantage of the ‘adequate control authorisation’ in Article 60(2), those alternatives must be used. As ECHA put it, “If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how he intends to replace the substance by the alternative”\textsuperscript{122}. Article 60(5) of REACH details that when assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including: (a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment (taking into account the appropriateness and effectiveness of risk management measures); and (b) the technical and economic feasibility of alternatives for the applicant. This issue of “suitable alternatives” would seem to cut both ways when it comes to nanosubstances. For bulk SVHCs which are on the Annex XIV list, it may be that a suitable alternative substance is not another bulk substance, but instead a nanosubstance. If this is so, REACH may drive the development of nanosubstances as replacements for bulk SVHCs (although there would appear to be two instantly apparent problems which go to economic and technical suitability: namely, the cost of nanosubstance production and extant availability of an alternative). At the same time, for nanosubstances which are SVHCs on the Annex XIV list, how will a “suitable alternative” be assessed? There is, as yet, no guidance

\textsuperscript{121} Article 60(4), REACH
on this. Say, for example, a particular nanosubstance is produced and used on products, making them ten times lighter than they would be were conventional substances used. Say also that this particular nanosubstance is a SVHC on Annex XIV. In this situation, the obvious “suitable alternative” is the conventional substance, although this ignores the entire reasoning behind the production of the nanosubstance in the first place. Where there is a “suitable alternative”, the drafting of Article 60(4) of REACH prevents a socio-economic analysis of the SVHC. Suitability of the alternative is determined on the basis of the risk reduction of the alternative and its economic and technical feasibility. There is here no potential (as REACH is drafted) for any social benefits to be considered. As outlined above, this may have significant impacts when it comes to granting authorisations for nanosubstances.

**Concluding Thoughts**

Much of the preceding discussion on the application of REACH is on the potential, practical application of REACH and how it could, logically, map onto the broad field of nanosubstances. As van Calster puts it, “…it is clear that, while the cornerstone of the EU’s chemical legislation certainly in theory could be applied to nanotechnological applications, its application in practice is not geared towards nanotechnology”\(^{123}\). Given this, the REACH-nano debate is somewhat normative and, as a corollary, legal scholars working in the field tend to couch their opinions in suitably qualified language\(^{124}\). Nothing in this area is set in stone. As a bare

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123 Van Calster, n.6. p.242
124 See, for example, Desmoulin (n.27, p347): “… REACH should be an appropriate legal instrument for obtaining information on the potential toxic and ecotoxic effects of nanosubstances” (own emphasis added). The Royal Commission on Environmental Pollution (n.22, p62) comment that, “At least in
minimum, REACH should apply to nanosubstances and should generate an amount of information on their intrinsic properties while, at the same time, banning or restricting the use of nanosubstances of very high concern (irrespective of whether they have been through the registration process or not). As Bryden concludes, “…REACH will be the primary regulatory tool for gathering information on new nano-materials.” At the same time, REACH should not hit the same regulatory brick wall as other regimes (which are, in part, robbed of their regulatory potential by a lack of commonly agreed data on the intrinsic properties of substances); instead, it should drive the testing of nanosubstances and produce new testing methodologies acting, to some degree, as a stimulus for the regulation of nanosubstances in other areas (such as worker health or product safety).

The Commission has promised to carefully monitor the implementation of REACH in the context of nanosubstances, in light of which “…current provisions, including quantitative triggers and information requirements, may have to be modified.” The UK Strategy has stated that it will attempt, as an action point, to “influence changes made to … REACH in order to ensure (nanomaterials) are robustly covered.” In the Strategy, the Government expresses concern that the design of REACH without reference to nanomaterials may produce implementation issues.

"principle, it would appear that REACH is capable of meeting the criteria for effective governance [of nanosubstances]" (own emphasis).


126 Frater et al, n. 5

127 Commission, n.38, p5. It is also worth noting here that the Commission is scheduled to update its Communication on the “Regulatory Aspects of Nanomaterials” in 2011. It may well be that, in light of the practical application of REACH by that date, amendments are proposed to the Regulation to account for nanosubstance related issues. In addition, three projects to potentially amend and update REACH guidance to address specific nanosubstance issues were launched in January 2010 by the European Commission’s Directorate General for Environment (on which, see: http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&obj_id=9830&dt_code=NWS&lang=en ).

128 The Strategy at p.5.
This paper has demonstrated a wide variety of issues with the application of the Regulation in its current form to nanosubstances. The extent to which these issues will play out in practice (and the extent to which REACH does, rather than ‘should’, act as test bed for nanosubstance regulation) remains to be seen. It is not known (by the authors or by ECHA) how many nanosubstances were pre-registered in 2008, nor is it known how many of the registration dossiers already lodged with ECHA include details on the nano forms of the substances being registered. This is perhaps worthy of further study. It also remains to be seen whether any nanosubstances will be prioritised for evaluation under REACH (and whether any of these then go on to require authorisation or are eventually restricted). This is very much a time of ‘ifs’ and ‘maybes’ but it is understandable that, as with the UK in its Nanotechnologies Strategy, much faith is placed in REACH. The REACH system was intentionally drafted, as is indicated above, without particular reference to nanosubstances. Yet the task with which it was charged, in terms of the registration, evaluation, authorisation and potential restriction of bulk chemical substances in common usage, could well be described already as herculean. Adding to this the resolution of the additional uncertainties generated by nanotechnology development might be regarded as truly heroic.

129 A conclusion which is mirrored in findings of the Dutch National Institute for Public Health and the Environment in their attempt to ‘mock’ register nanosilver. Their report has the overall comment that “It is concluded that REACH is not sufficiently implementable for nanomaterials” (above, n.93).