

# Environmental Protection

*European Law and Governance*

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# REACH: Combining Harmonization and Dynamism in the Regulation of Chemicals

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## 1. Introduction

Europe has a new Chemicals Agency. Its establishment is inextricably tied to the emergence in Europe of an ambitious new framework for the regulation of chemicals. This framework is known by the acronym REACH, and it concerns the Registration, Evaluation, Authorisation and Restriction of Chemical Substances.<sup>1</sup> The establishment of a *European Agency*, and the European-level *harmonization* of chemicals policy seems to mark an important step in the direction of a centralization of regulatory power. However, it is the argument of this chapter that reality is more complex, more subtle, and certainly more promising. The European Agency does not stand on high at the apex of a hierarchically organized system for the regulation of chemicals. It forms part of a system of governance which is intensely fractured. Power is shared among a multiplicity of actors, operating at different levels of government, and in the private as well as the public spheres. No single actor has autonomous decision-making power. Rather, each is empowered, in different circumstances and in different ways, to play a role in maintaining the dynamic quality of regulation in the face of information deficits and uncertain risks. Different actors can play a role in seeking to ensure the continuous generation of new and better information about risk and about the mitigation of risk, and in seeking to prompt regulatory decisions which are appropriately responsive to this. This fracturing of power creates a governance framework which is complex. But it is also a framework which seeks to combine,

\* Many thanks to John Applegate, Maria Lee, and Peter Oliver for very useful comments on an earlier draft. The students in the EUI Academy (2007) were outstanding in helping me get to grips with the intricacies of REACH. Many thanks to them also.

<sup>1</sup> Regulation 1907/2006. This both lays down the REACH framework and establishes the European Chemicals Agency.

harmonisation }  
dynamism }

uniformity }  
learning }

Introduction

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in a novel way, harmonization with dynamism, and uniformity with structures for regulatory learning.

History

In the year 2000 the Lisbon European Council framed an ambitious goal for Europe; in short, to become the most competitive and dynamic knowledge-based economy in the world. The chemicals sector is one in which Europe has achieved considerable economic success. Nearly half of the world's leading chemicals companies are based in Europe, and Europe enjoys a healthy and growing trade surplus in chemicals.<sup>2</sup> Nonetheless, until recently at least, Europe's chemicals regulation was not worthy of this success, representing an impediment to innovation, and an insufficient basis for sustainable growth. The reasons for this were many. But the pernicious bottom line was the incentive structure generated by the regulatory framework. There had grown up a regulatory gap in the treatment of old and new chemicals.<sup>3</sup> The regulatory burden attaching to new chemicals entering the market was such that it was easier and less costly to continue to use old chemicals which were largely exempt. The impetus to innovation was dulled and industry convenience came to prevail over safety. The EU's new chemicals regime represents an ambitious attempt to alter the incentive structure between old and new chemicals, and to do so in a manner which achieves a high level of protection of human health and the environment.

The volume and complexity of the Regulation is such that a lengthy book would be required to offer a full exposition and analysis. Running to 141 articles, 17 annexes, and 10 appendices, the densely printed Official Journal text amounts to 280 pages. At the heart of these 280 pages is a system for the regulation of old and new chemicals which makes the generation and dissemination of information about chemicals a priority. This information is intended to ensure that sensible decisions can be taken about which substances to focus investigative attention on, about when and how to restrict the use of chemicals, and about when to ban them completely. It is also intended to ensure that market transparency will create conditions in which chemical users—commercial users as well as consumers—will not only be properly informed about safe use, but will be able to exercise choices in favour of safer alternatives. When it comes to high-risk categories of chemicals, the availability of suitable and safer alternatives, will be a reason for the regulator to ban them.

In keeping with the theme of this volume as a whole, this contribution focuses upon the governance approach embodied in the REACH regulation, and upon

<sup>2</sup> For facts and figures on the European chemical industry see <[http://www.cefic.be/factsandfigures/level02/profile\\_index.html](http://www.cefic.be/factsandfigures/level02/profile_index.html)>.

<sup>3</sup> For this purpose old chemicals are known as existing chemicals and are those dating from before 1981. See Koch, L. and Ashford, N.A., 'Rethinking the role of information in chemicals policy: implications for TSCA and REACH', *Journal of Cleaner Production* 14 (2006) 31 at <<http://web.mit.edu/ctpid/www/tl/docs/Koch&Ashford1.pdf>> for a brief overview and critique of the EU's chemical regime. See also for an excellent outline of the main elements and legal issues arising, Molyneux, C.G., 'Chemicals' (2008), 8 *Yearbook of European Environmental Law* (2008).

certain key features ('core elements') which characterize this. The core elements pinpointed in this paper are industry responsibility, contestability, substitution, provisionality, and transparency. Three observations, flowing from the discussion which follows, may be usefully highlighted from the start.

First, and perhaps most important, REACH is concerned with product regulation, the regulation of chemical substances. Product regulation here, as elsewhere, bears heavily on trade in both the EU and the WTO. This trade dimension comes to the fore in the regulation. It is exhaustive in the harmonization which it achieves. It takes Article 95 as its legal basis, and contains a clear free movement clause. Member State recourse to the treaty-based free movement exceptions will be pre-empted. By contrast to much recent environmental law in the EU, the regulation is about harmonization not diversity, and offers reduced flexibility to Member States. But this surface impression does not tell the whole story. This is because the harmonization which it achieves is provisional and contestable. A wide range of mechanisms are established to allow for the contours of the provisional harmonization bargain to be contested, including in the light of experience in the individual Member States. At every turn, whether it is in relation to which substances are to be evaluated, which are to require authorization or restriction, or in relation to labelling requirements, Member States (and the Commission) are empowered, on the basis of clearly defined procedures, to seek to use their local knowledge to persuade the European Union as a whole, of the need to revise applicable norms, in order to ensure effective fulfilment of the Regulation's framework goals (high level of protection of human health and environment in particular). By contrast to the more traditional Article 95 EC Treaty opt-out, these procedures for contestation are multi-level and multi-actor, and eschew an approach which places the Commission on high, supposedly omniscient in its capacities to make judgments about regulatory right and wrong. Because of this, REACH offers an important lesson in thinking about governance in EU environmental law. By making harmonization provisional and contestable, and by creating mechanisms for contestation and regulatory learning, the EU has begun to articulate a model for regulatory federalism which seeks to respond to the imperatives of free trade and those of environmental/health protection.

Second, although in the form of a regulation, the implementation phase is all-important under REACH.<sup>4</sup> This becomes starkly clear by looking at the list of substances requiring authorization; empty at the time of enactment! The governance arrangements for the adoption of implementing decisions are varied and

<sup>4</sup> As John Applegate points out, it was at the implementation stage that the US chemicals regime in the form of the Toxic Substances Control Act, met its most pronounced failures. Careful scrutiny of implementation practices and decisions will be essential to any long-term evaluation of REACH. See Applegate, J. S., 'Synthesizing TCSA and REACH: Practical Principles for Chemical Regulation Reform', *Ecology Law Quarterly* forthcoming.

A)  
Product  
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harmonisation  
↓  
provisional  
+  
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arbitrary

B)  
Implementation

complex. As is typical, comitology procedures play an important part.<sup>5</sup> But on the whole the overall framework for decision-making is more inclusive than in the past.<sup>6</sup> This is not only a result of the enhanced role *sometimes* played by the European Parliament as a result of the new regulatory committee with scrutiny procedure.<sup>7</sup> It is also because interested third parties are given significant opportunities to participate in decision-making processes, and to have their viewpoints taken into account. In the discussion of substitution below, it is suggested that these opportunities for participation create a mildly adversarial mechanism, somewhat reminiscent of the kind that Wendy Wagner has in mind in her elaboration of a competition-based approach to the regulation of chemicals.<sup>8</sup>

Third, REACH places considerable emphasis upon information as a regulatory tool. At its heart, it is intended to mitigate the overwhelming data deficit which exists in relation to older chemical substances. REACH is also concerned with the communication of information, up and down the supply chain, and to consumers and to the public at large. As it stands, however, there exists an important gap. Labelling requirements relate only to chemical substances and preparations (mixtures of chemical substances). Consumer articles, such as textiles or furniture for example, containing chemical substances are not covered. Even where an article contains a chemical substance of very high concern (for example a carcinogenic substance) consumers will not be alerted to this by the presence of a label. Thus, to the extent that REACH seeks to harness the power of the marketplace to encourage innovation in the development of less risky alternatives, its labelling rules would seem to fall short.

The discussion which follows is often technical and dense. This is unavoidable when examining a regulatory regime of this volume and complexity. This should not be allowed to disguise either the intrinsic importance of the subject under discussion for environment and human health protection,<sup>9</sup> or the fascination of the governance forms which this regulation embodies. It is in the minutiae of law's construction of decision-making procedures and conditions for action that the politics of risk regulation are played out.

<sup>5</sup> For background to the concept of comitology see Craig, P. and de Búrca, G., *EU Law: Text, Cases and Materials* (OUP, 2007), pp. 118–23.

<sup>6</sup> See on this theme LSE Working Paper 07–2008, Heyvaert, V., 'The EU's Chemicals Policy: Towards Inclusive Governance?' at <[http://www.lse.ac.uk/collections/law/wps/WPS2008-07\\_Heyvaert.pdf](http://www.lse.ac.uk/collections/law/wps/WPS2008-07_Heyvaert.pdf)>.

<sup>7</sup> See again Craig and de Búrca, *supra* n. 5. For further details of the new regulatory committee with scrutiny procedure, see Article 5a Council Decision 1999/468. By 'sometimes', it is simply meant that this new procedure applies to some decisions to be adopted under REACH, but by no means all. Further details on this will emerge in the sections which follow.

<sup>8</sup> Wagner, W., 'Using Competition-Based Regulation to Bridge the Toxics Data Gap' at <[http://search.ssrn.com/sol3/papers.cfm?abstract\\_id=1090090](http://search.ssrn.com/sol3/papers.cfm?abstract_id=1090090)>.

<sup>9</sup> See, for a brief overview, chapter 1 of the Royal Society for Environmental Pollution's chemicals study at <<http://www.rcep.org.uk/chreport.htm>>.

comitology

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row

## 2. Core Element: Industry Responsibility

### A. Registration

#### 1. What does registration require?

REACH imposes an informational burden on industry. It does so through the introduction of a default rule: 'no data, no market',<sup>10</sup> generating a strong incentive for the information to be provided. Chemical substances manufactured or imported at or above a one tonne threshold must be registered with the new Chemicals Agency.<sup>11</sup> The Regulation establishes detailed rules for identifying substances requiring registration.<sup>12</sup> These include substances on their own, or in preparations (such as a detergent).<sup>13</sup> Also included are substances in articles, where the one tonne threshold is met, and where the substance is intended to be released under normal or reasonably foreseeable conditions of use.<sup>14</sup> Even where there is no intention that the substance be released, the Agency may require registration of substances in articles where it has grounds for suspecting that the substance is released and that this presents a risk to human health or the environment.<sup>15</sup> A number of substances enjoy total or partial exemptions under the regulation.<sup>16</sup>

<sup>10</sup> Article 5.

<sup>11</sup> Article 6(1). The threshold is determined at the level of an individual manufacturer or importer, and calculated on an annual basis. Note that in some situations a notification obligation will apply even in the absence of a registration requirement. This implies a much reduced informational burden but an informational burden all the same. See especially Article 9(2) in relation to the R & D exemption. See also n. 14 below in relation to notification of substances in articles under Article 7(2). Note also that the reference to 'notified substances' in Article 24 refers to a different concept. Here, notification under the old regime is being treated as registration for the purpose of the new one. On the Agency see Articles 75–111 and: <<http://echa.europa.eu/>>.

<sup>12</sup> The general definitions are provided in Article 3 where the concept of a substance is defined as a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

<sup>13</sup> Article 6(1). A preparation is defined in Article 3(2) as a mixture or solution composed of two or more substances.

<sup>14</sup> An article is defined in Article 3(3) as an object which during production is given a special shape, surface, or design which determines its function to a greater degree than does its chemical composition. Note a reduced obligation to notify (as opposed to register) the Agency of substances of very high concern in articles, where it is present above a concentration of 0.1% w/w, even where it is not intended to be released. The concept of substances of very high concern will be raised in the discussion below on authorization. This lesser notification obligation can only be excluded where the producer or importer can exclude exposure to humans or to the environment during normal or reasonably foreseeable conditions of use. See Articles 7(2) and (3). Registration would thus seem to rest on a subjective test (intended to be released), whereas notification rests upon an objective test.

<sup>15</sup> Article 7(5). This is still subject to the one tonne threshold. The Agency's decision is not subject to appeal by the Agency Board of Appeal (see Article 91) but it is susceptible to review by the Court of First Instance (see Article 94).

<sup>16</sup> See in particular Articles 2 and Annexes IV and V. Included among other things in Annex V are substances occurring in nature if they are not chemically modified or dangerous.

Prominent among these are polymers,<sup>17</sup> and certain intermediaries.<sup>18</sup> Likewise, substances manufactured or imported for the purposes of product or process oriented research and development are automatically exempted for five years.<sup>19</sup> This may be extended, upon request, by the Agency for a further five-year period; ten years in the case of medicinal products for human or veterinary use.<sup>20</sup>

The registration requirement took effect for new substances on 1 June 2007. Existing substances, known as phase-in substances, are able to benefit from transitional arrangements.<sup>21</sup> For these substances registration will proceed in stages, beginning in 2010 for very high volume substances and for certain risky substances, and ending in 2018.<sup>22</sup> Pre-registration is required for phase-in substances seeking to benefit from these transitional arrangements.<sup>23</sup> Upon submission of a registration document, the Agency will perform a completeness check. Where a registrant receives no indication to the contrary from the Agency within a three-week period, it may begin or continue to manufacture or import the substance in question.<sup>24</sup>

The intensity of the informational burden imposed by REACH is variable. First, and critically, the basic requirement rests upon an open-ended standard, rather than a detailed rule. This requires that each registrant must submit a technical dossier, and this must include all physico-chemical, toxicological, and

(self regulation?)  
<sup>17</sup> These are exempted from registration, although requirements may be extended in the future to polymers where a practicable and cost-effective way of identifying risky polymers is established. Polymers are large molecules consisting of repeated chemical units joined together. Plastics are polymers, for example.

<sup>18</sup> Intermediaries are chemicals used to make other chemical substances. On-site and transported isolated intermediaries are subject to limited registration requirements subject to the substance being rigorously contained during its whole life-cycle. Monomers used for this purpose do not fall within this. See Articles 17-19.

<sup>19</sup> Article 9.

<sup>20</sup> See Article 9(7) for the conditions which apply. Any decision taken by the Agency here will be subject to appeal.

<sup>21</sup> Article 23. See Article 3(2) for a confusing definition of the concept of phase-in substances. These include substances included in the European Inventory of Existing Chemical Substances (EINECS). Note that where an existing substance has been notified under the earlier regime under Directive 67/548, this will be regarded as a registration for the purpose of REACH. See Article 24. The aim of the regulation is to address the 'burden of the past' meaning substances not covered by the earlier regime.

<sup>22</sup> Very high volume means 1,000 tonnes or more here, and the risky substances to be registered by 2010 are those which are category 1 carcinogens, mutagens, or reproductive toxicants (CMRs) (no volume threshold) and those which are very toxic to the aquatic environment posing risks of long-term adverse effects (100 tonne threshold). See Article 23(1).

<sup>23</sup> Article 28. The relevance of this will become clear when talking about joint submission and data-sharing below.

<sup>24</sup> See Article 20(2) on the completeness check and Article 21(1) on timing. Note that the Agency has a three-month rather than a three-week period to respond in relation to phase-in substances registered within two months of the end of the transitional period. This is presumably due to concerns about the high number of last-minute registrations which will be submitted at this time, and reflects the fact that there are considerably more existing than new substances.

*Data*

ecotoxicological information that is *relevant* and *available* to the registrant.<sup>25</sup> This standard is accompanied by more specific rules setting out the minimum information to be included. In the main, the nature of this minimum will be determined by reference to volume.<sup>26</sup> For registered substances, more information is demanded as production volume increases. For the lowest tonnage level (up to 10 tonnes) the standard requirements in Annex VII will apply.<sup>27</sup> Every time a new tonnage threshold is reached (10 tonnes, 100 tonnes, and 1,000 tonnes) an additional annex will bite, imposing additional informational demands. Information on the intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met.<sup>28</sup> Indeed, wherever possible, information shall be generated by means other than vertebrate animal tests,<sup>29</sup> and all available *in vitro* data, *in vivo* data, historical human data, data from valid qualitative or quantitative structure-agency relationships ((Q) SAR), and from structurally related substances (read-across approach) is to be assessed first before new tests are carried out.<sup>30</sup> But as noted, such data will only be able to substitute for the results of the standard testing regime where they meet the requirements of Annex XI. These are expressed in open-ended, standard-based, terms; adequacy, reliability, and scientific validity for example. It will be for the Agency to evaluate registration documents to ensure that these requirements have been met.<sup>31</sup>

Two additional points may be usefully made in relation to the nature of the informational burden incurred by industry. First, Annex IX and X apply at the 100 tonne and 1,000 tonne marks respectively. In each case, the registration is to include testing proposals for the provision of the specified information, rather than the information itself; subject to the broad disclosure standard set out above.<sup>32</sup> It will be for the Agency to examine testing proposals, and to draft a decision accepting, rejecting, modifying, or supplementing the testing proposals.<sup>33</sup> Second, the 10 tonne volume threshold is of particular pertinence.

<sup>25</sup> Article 12(1). A guidance note on information requirements is set out in Annex VI, but does little to build upon this. It does make it clear that registrants have to be somewhat proactive in collating information by, for example, undertaking a literature search.

<sup>26</sup> There is one exception to this. More information has to be submitted for Annex III phase-in substances than non-Annex III phase-in substances. For the latter no toxicological or ecotoxicological information is required, but only physico-chemical information in accordance with s. 7 of Annex VII. Annex III substances include category 1 and 2 CMRs, as well as substances with dispersive or diffuse effects for which it is predicted that they are likely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548.

<sup>27</sup> Subject to the previous footnote for non-Annex III phase-in substances.

<sup>28</sup> Article 13(1). <sup>29</sup> Ibid.

<sup>30</sup> Annex VII, penultimate Recital.

<sup>31</sup> It will do so in the course of dossier evaluation to be discussed below. See especially Article 41 (1)(b) and the rubric to Annex XI.

<sup>32</sup> See Article 12(d) and (e) and Annexes IX and X.

<sup>33</sup> Article 40(3). Where any Member State proposes an amendment to the Agency draft decision, and where the Member State committee is not unanimous in its support, the final decision will be adopted by the Commission on the basis of a regulatory committee procedure.



It is at this stage that the obligation to conduct a chemical safety assessment and to submit a chemical safety report (CSR) kicks in.<sup>34</sup> This will require human health, environment, and physico-chemical hazard assessments, as well as an assessment of whether the substance may be characterized as persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative (PBT/vPvB). For dangerous substances and those which are PBT/vPvB, an enhanced CSR will be required, to include an exposure assessment and risk characterization.<sup>35</sup>

## 2. Industry accountability in registration

It has been suggested that REACH creates perverse incentives for industry. '[P]roducers have an incentive to underestimate risk in order to avoid outside intervention into self-regulation. This seems to be a key governance problem of REACH.'<sup>36</sup> It is then essential to consider the range of mechanisms put in place in an attempt to keep industry honest and forthcoming in its provision of information. Two principal mechanisms are put in place; one premised upon hierarchical oversight, and the other upon peer review.

Hierarchical control is largely predicated upon the concept of dossier evaluation<sup>37</sup> This involves two core elements, an examination of testing proposals and a compliance check of registrations.<sup>38</sup> Where, on the basis of compliance checking, the Agency concludes that the registration is not in line with the relevant information requirements, it may prepare a draft decision requiring the registrant to submit additional information.<sup>39</sup> For compliance checking, the Agency is required to examine at least 5% of registrations in each tonnage band.<sup>40</sup> It shall give priority, 'but not exclusively', to certain categories of registrations, namely those falling short in providing the standard Annex VII information, those concerning priority substances included on the Agency rolling action plan for substance evaluation, and those in respect of which specified information has

<sup>34</sup> See Article 14 and also Annex I containing general provisions for assessing substances and preparing chemical safety reports. Annex I, unlike the previously mentioned Annex IV, is not framed as a guidance note.

<sup>35</sup> Article 14(4) and Annex I, sections 5 and 6.

<sup>36</sup> Hey, C., Jacob, K., and Vokery, A., 'Better Regulation by New Governance Hybrids: Governance Models and the Reform of European Chemical Policy', Environmental Policy Research Centre paper at <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=926980](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=926980)> p. 13.

<sup>37</sup> Title VI, chapter 1.

<sup>38</sup> Compliance checking should be contrasted to the previously mentioned concept of a completeness check under Article 20. By contrast to compliance checking, the completeness check 'shall not include an assessment of the quality or the adequacy of any data or justifications submitted', and is more a tick-box exercise about the categories of information received.

<sup>39</sup> Article 41(3). The procedure for the final adoption of this decision is laid down in Articles 50 and 51. In essence, the Agency enjoys autonomy unless it receives a Member State proposal for the amendment of its draft decision. In this event, the Agency can only decide if it enjoys the unanimous support of the Member State committee, otherwise the Commission will decide acting on the basis of a regulatory committee procedure.

<sup>40</sup> Article 41(5). This percentage may be varied on the basis of a regulatory committee with scrutiny procedure. See Article 41(7).

been submitted separately rather than jointly by manufacturers and/or importers.<sup>41</sup> Also of practical assistance in assisting the Agency in concentrating its compliance checking efforts, is the fact that any technical dossier submitted upon registration must indicate, for certain key categories of information, where this has been subject to review by an assessor prior to submission.<sup>42</sup> While there is no requirement that any such assessor be independent, it is stated that he or she must have appropriate experience. It may well be in the interests of companies to flag up the existence of internal procedures for review, in a bid to obviate the need for time-consuming and costly external review.

One of the stated grounds for prioritizing registrations for compliance checking hints at the nature of the second, non-hierarchical, mechanism for promoting industry accountability in the provision of information. The regulation establishes a binding, but non-absolute, requirement that key information, including physico-chemical, toxicological, and ecotoxicological information be jointly submitted by manufacturers and/or importers, with one registrant acting as lead registrant for this purpose.<sup>43</sup> A registrant may offer a reasoned justification for separate submission of this information on specified grounds only. These are disproportionate cost, substantial commercial detriment caused by the commercially sensitive nature of the information, and disagreement with the lead registrant on the selection of information.<sup>44</sup>

The mechanics of joint registration are different in the case of non phase-in (new) and phase-in (existing) substances. For non phase-in substances, potential registrants have a duty to inquire from the Agency whether a registration has already been submitted for the same substance.<sup>45</sup> If several potential registrants have made an inquiry for the same substance, the Agency shall inform each about the other, thus facilitating joint registration. For phase-in substances seeking to benefit from the transitional arrangements, there is a duty to pre-register, and to participate in a substance information exchange forum (SIEF).<sup>46</sup> Among other things, this SIEF will facilitate the exchange of key information including the physico-chemical, toxicological, and ecotoxicological information to be jointly submitted.

<sup>41</sup> Article 41(5).

<sup>42</sup> This relates to physico-chemical, toxicological, and ecotoxicological information under Annexes VII–XI, as well as chemical safety reports and information on manufacture, use, and classification and labelling of a substance.

<sup>43</sup> See Article 11 referring to categories of information in Article 10. These categories of information are, in turn, spelt out in greater detail in Article 12. Certain additional categories of information *may* be jointly submitted at the discretion of the manufacturers/importers, including the chemical safety report, while others *must* be submitted separately, including specified information on manufacture, use, and exposure.

<sup>44</sup> Article 11(3).

<sup>45</sup> Article 26. This also applies to phase-in substances which are not making use of the Article 23 transitional arrangements.

<sup>46</sup> Articles 28 and 29.

Joint submission

It is possible to speculate that the concept of joint registration might promote industry accountability in the provision of information, by inculcating an ethos of peer review. Where a manufacturer or importer disagrees with the information to be submitted, that manufacturer or importer may justify remaining outside of the registration consortium. Any attempt on the part of a registrant to manipulate data, or to be less than forthcoming in sharing relevant (unreliable) data, runs the risk of being signalled to the Agency by an absence of cooperation between industry actors in registration. As noted, departure from the default position of joint registration serves to increase the likelihood of hierarchical, Agency, compliance control; the fact of individual submission being one of the factors according to which the Agency will concentrate its efforts in compliance checking. Needless to say, the accountability reinforcing potential of joint submission is, even at best, less than absolute. It would do nothing to prevent industry consortia from collectively withholding or manipulating data.

Along with joint registration, data sharing also emerges as a key feature of REACH.<sup>47</sup> This is intended in large part to avoid and reduce vertebrate animal testing.<sup>48</sup> It is interesting to ask whether it might serve also to facilitate industry accountability in the provision of information.

For registered substances, information submitted as part of registration will become freely available after twelve years.<sup>49</sup> Even during this period, previous registrants have an obligation to share information with potential registrants in so far as this information involves testing on vertebrate animals.<sup>50</sup> Even where a substance has not been previously registered, all potential registrants participating in a SIEF are obliged to request and share data involving testing on vertebrate animals.<sup>51</sup> Again, subject to rules on cost-sharing, any holder of such a study will be precluded from proceeding to registration until he provides the study in question.<sup>52</sup> If a relevant study involving tests (all tests, and not merely tests on vertebrate animals) is not available, only one such study will be conducted per

<sup>47</sup> See Title III, Articles 25–30. This will be facilitated by initiatives not formally part of the REACH framework. See for example the launch by OECD of eChemPortal: The Global Portal to Information on Chemical Substances. This Internet gateway provides free access to information on intrinsic properties of chemicals as well as hazard and risk assessments. It allows for the simultaneous search of multiple databases.

<sup>48</sup> See Article 13 and Annex XI establishing the range of data sources which can be used to provide information on intrinsic properties on substances, and adumbrating the circumstances in which this can be used.

<sup>49</sup> See Articles 26(3) and 27(1).

<sup>50</sup> Article 27(1). Previous registrants may choose to share other categories of information. Article 27 lays down the procedure to be followed where there is no agreement between previous and potential registrants. Subject to rules on cost-sharing, ultimately the Agency will disclose the relevant information. The Agency's decision will be subject to appeal.

<sup>51</sup> Article 30.

<sup>52</sup> Article 30(3).

information requirement within the SIEF for the benefit of all members, and the resulting information duly shared.<sup>53</sup>

While in some respects the regulation does anticipate disagreements between registrants (actual and potential) on data sharing,<sup>54</sup> it does not contemplate circumstances in which one registrant remains dissatisfied with the content or methodology of a study conducted by another registrant. Not only does it not impose an obligation on a registrant to repeat the study in these circumstances, but neither does it expressly permit it to do so. Yet from the point of view of industry accountability it is critical that received wisdom be susceptible to challenge. In view of this, the underlying premise that testing on vertebrate animals be undertaken only as a last resort, and that the duplication of other tests should be limited, must be read as leaving room for additional testing where the reliability of existing data has been credibly questioned. The concept of data sharing is an important one. It has the potential to strengthen arrangements for peer review between industry actors by increasing transparency and mutual oversight. At the same time peer review cannot function in a meaningful manner if earlier tests, and the results emanating from them, are treated as anything more than presumptively valid.

Sharing =  
peer review

## B. Applications for Authorization

Certain substances of 'very high concern' may not be placed on the market without authorization, even at very low volume, and below the one tonne threshold for registration.<sup>55</sup> These substances are to be listed in Annex XIV.<sup>56</sup> When seeking authorization, applicants must 'analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution'.<sup>57</sup> Applicants must likewise submit the specified information, including a chemical safety report where this has not been previously submitted as part of the registration process.<sup>58</sup>

Like registration, authorization imposes an informational burden on industry. But it does more than this. In most cases authorization will be granted where the risk to human health or the environment is adequately controlled. It will be for the applicant to document this in its CSR.<sup>59</sup> This will require the applicant to

controlled risk

<sup>53</sup> Article 30(2). The members of the SIEF shall take reasonable steps to reach agreement as to who is to carry out the test. If no agreement is reached, the Agency shall specify who is to perform it. Again, this is subject to cost-sharing requirements.

<sup>54</sup> See Articles 27(5)-(7) and 30(3).

<sup>55</sup> Article 55 for the terminology of very high concern. This applies to substances on their own, in preparations and incorporated into articles.

<sup>56</sup> We will look later, in the next section on contestability, at how the content of this list is to be determined. At the time of adoption of the regulation, the Annex was empty.

<sup>57</sup> Article 55 and Article 62(4)(e).

<sup>58</sup> See Article 62 specifying the information to be submitted, and especially Article 62(4)(d). Note Article 62(5)(a) leaving applicants the discretion as to whether to submit a socio-economic analysis.

<sup>59</sup> Article 60(2).

show that estimated exposure falls within the relevant exposure limits, and that the likelihood and severity of an event occurring due to the physico-chemical properties of the substance is negligible.<sup>60</sup> The relevant authorities will assess whether the applicant has made his case, taking expert advice, but it is plain that the burden of proof falls upon the applicant.<sup>61</sup>

There is perhaps more ambiguity about burden of proof for those substances made subject to different authorization conditions. For PBTs/vPvBs, and substances for which no exposure limits can be determined, authorization will only be granted 'if it is shown that socio-economic benefits outweigh the risk to human health or the environment', and where there are no suitable, less risky alternatives.<sup>62</sup> The regulation is not explicit in identifying who bears the burden of demonstrating this. While an analysis of alternatives must be submitted as part of the application package, it is up to the applicant to decide whether to submit a socio-economic analysis.<sup>63</sup> While the various information submitted by the applicant will represent an element to be considered in reaching a decision, ultimately the decision will take into account all available information on risk and on the availability of alternatives.<sup>64</sup> A positive authorization decision may in principle be reached on the basis of information not brought forward by the applicant. Still though, in essence, the role of the applicant will be to persuade the regulator that the conditions for authorization are met, and to refute available information which might suggest otherwise.

Authorization, like registration, places an information burden on industry. In the case of authorization, it does so by reference to substantive standards, such as that represented by the concept of adequate control. Information and arguments submitted by industry in the course of authorization will not be taken at face value. It will be evaluated by experts including, where they deem it appropriate, in the light of additional information submitted by third parties.<sup>65</sup> Equally though, the claims of the experts will not always go unchallenged, with applicants enjoying an opportunity to make further comments along the way.<sup>66</sup> For the

<sup>60</sup> Section 6.4, Annex I. The exposure limits are in the form of Derived No-Effect Levels for human health (the level of exposure to the substance above which humans should not be exposed. See sections 1.0.2 and 1.4 of Annex I); and Predicted No-Effect Concentrations for environmental effects (see sections 3.0.1 and 3.3.1, Annex I).

<sup>61</sup> Note that Article 61(1) provides that the applicant submit an updated CSR as part of the process for the review of authorizations '[i]f he can demonstrate that the risk is adequately controlled'. 'Demonstrate' clearly places the burden of proof on the applicant. It is suggested that 'document' does so also.

<sup>62</sup> Article 60(4). As we will see below, the suitability of alternatives implies an assessment of their technical and economic feasibility for the applicant.

<sup>63</sup> Recall Article 62(5).

<sup>64</sup> Article 60(4).

<sup>65</sup> The procedure for authorization will be considered more fully below. By experts what is meant here are the relevant committees on Risk Assessment and Socio-Economic Analysis. See generally Article 64, especially Article 64(3) and (4).

<sup>66</sup> Article 64(5) ensuring that the EU administrative law requirement of right to be heard is complied with.

alternatives  
analysis

CBA?

substances concerned, the default position is one of prohibition. It is not for the regulator to justify this, but for the potential user to challenge it. It is only when the potential user succeeds in making a prima facie case that the conditions laid down are met, that the regulator will incur a burden of justification to justify a ban.

flexibility  
proceduralisation

uniformity

product regulation } = all @ Int'l Market

### 3. Core Element: Contestability

One of the most intriguing, and potentially important, aspects of REACH is the way in which it combines harmonization with provisionality and contestability. The now dominant model of environmental regulation in the EU, premised upon substantive flexibility and proceduralization, is not well suited to product regulation in areas where uniformity is required in order to ensure the proper functioning of the European internal market. This presents a dilemma. Harmonization may be anticipated to come at the price of sacrificing the benefits of a more flexible approach. There is an upside to flexibility in that it is tolerant of regulatory diversity, and hence creates opportunities for regulatory learning on the basis of diverse Member State experience in implementation. Harmonization, on the contrary, by definition demands a singular response and would seem to exclude a role for Member States as laboratories for regulatory experimentation and learning. REACH, though, takes an imaginative step towards addressing this dilemma, and does so by inculcating the regime with the overlapping values of provisionality and contestability.

REACH takes Article 95 as its legal basis, and takes the form of exhaustive harmonization. Substances which comply with the regulation can be traded freely in the EU.<sup>67</sup> Recourse to the treaty-based free movement exceptions will be pre-empted.<sup>68</sup> But still, the Member States are not silenced. The regulation, and to a lesser extent the Treaty, preserve spaces for Member State contestation of the trade/regulation bargain struck. The contours of that bargain are provisional, and Member States are empowered in multiple ways to seek to destabilize it. There remains space for local knowledge to be integrated in a bid to provoke regulatory change. This local knowledge having been presented, the burden then falls on the EU decision-maker to justify its decision in relation to it, including from the point of the regulation's broad objectives, and in a manner which is compatible

<sup>67</sup> Article 128.

<sup>68</sup> Article 129. But note that, consistent with the case law of the European Court, recourse to these exceptions will be precluded only to the extent that the issue is covered by the harmonizing measure. This is apparent from Case 5/94 *Hedley Lomas* and reinforced by Article 128(2). So, for example, if a Member State wanted to restrict a chemical substance more strictly, for reasons not covered by REACH, it would remain free to do so, subject to the demands of other legislation, and with complying with the conditions in the Treaty-based free movement exceptions.

with the precautionary principle which underpins the regulation as a whole.<sup>69</sup> To this end, five particular points of entry are established in the regulation, and a further point of entry exists in the treaty. Each will be discussed in turn.

### A. Substance Evaluation

It is for the European Chemicals Agency (the Agency) to draw up a list of priority substances for evaluation by Member States.<sup>70</sup> It will draw up a three-year rolling action plan of substances to be evaluated. Using risk-based criteria developed in cooperation with Member States,<sup>71</sup> and on the basis of an opinion from the Member State committee,<sup>72</sup> the Agency shall include substances in respect of which there are grounds for considering that they constitute a risk to human health or the environment. A Member State may notify the Agency at any time of a substance not on the list, whenever it is in possession of information that suggests that it is a priority for evaluation.<sup>73</sup> The Agency has the final word, and its decision is not subject to appeal before the Board of Appeal.<sup>74</sup> But still there is room for Member State contestation, placing a burden of justification on the Agency to explain why it has rejected the Member State's suggestion. The Agency *shall* include substances where there are grounds in any appropriate source of information, including presumably in a Member State petition, that it presents a risk, and hence a refusal to add a substance at the behest of a Member State would be subject to judicial review before the courts.

### B. Substances Requiring Authorization

REACH establishes a prior authorization requirement for substances of 'very high concern'.<sup>75</sup> Unlike the registration requirement, this bites regardless of production volume. The regulation establishes definitively that this will apply to certain categories of substance. These include those which are category 1 or 2 carcinogens, mutagens, or reproductive toxicants.<sup>76</sup> It also applies to PBTs and vPvBs in so far as they meet the criteria set out in Annex XIII.<sup>77</sup>

Beyond this, however, the concept of a substance of very high concern remains open-ended. Additional substances may be subjected to this prior authorization requirement when they meet certain criteria and when they are added to the Annex XIV list.<sup>78</sup> The applicable threshold is a high one. It captures substances in

<sup>69</sup> See Article 1(1) for a statement of these objectives, and Article 1(3) for the inclusion of the precautionary principle.

<sup>70</sup> See Articles 44-48.

<sup>71</sup> These criteria shall consider hazard information, exposure information, and tonnage. See Article 44(1).

<sup>72</sup> See Article 44(2).

<sup>73</sup> Article 45(5).

<sup>74</sup> Article 93.

<sup>75</sup> Article 55.

<sup>76</sup> Article 57(a-c).

<sup>77</sup> Article 57(d-e).

<sup>78</sup> Article 57(f).

respect of which there is scientific evidence of probable serious effects to human health or the environment and which give rise to a level of concern which is equivalent to those of the other substances specifically listed.<sup>79</sup>

*Process*

The process for adding or removing substances to the Annex XIV authorization list is a complex one. It culminates in the adoption of a decision on the basis of the regulatory committee with scrutiny procedure, the new comitology procedure enhancing the powers of the European Parliament.<sup>80</sup> Along the way Member States are empowered to push in the direction of the inclusion of additional substances, by arguing in favour of their inclusion on a preliminary candidate list.<sup>81</sup> In particular any Member State may choose to submit a dossier for substances which it believes meet the various criteria laid down, to forward this to the Agency. Interested parties will be given an opportunity to comment on this. In the absence of any such comments from interested parties, or from the Agency itself, the substance in question will be added to the candidate list. Where comments are received the matter will go to the Member State committee. In the absence of unanimity in this committee, a decision to add the substance to the candidate list of substances requiring authorization will be taken on the basis of a regulatory committee procedure, namely the older procedure not involving the European Parliament to any significant degree.<sup>82</sup> Of course, inclusion on the candidate list at the behest of a Member State does not imply inevitable inclusion on the final list. What is less clear is whether inclusion on the candidate list is a prerequisite for inclusion on the final list. This is an important question given the different procedures which apply: regulatory committee for the candidate list and regulatory committee with scrutiny for the final list, reflecting a greater role for the European Parliament in respect of the adoption of the final list. The capacity of the European Parliament to use its veto powers to bargain for the inclusion of additional substances will be greatly curtailed if the final list may only include those previously included on the candidate list, in respect of the drawing up of

<sup>79</sup> Substances with endocrine disrupting properties, or PBTs and vPvBs not meeting the Annex XIII criteria are given by way of examples of the kind of substances which might meet this threshold.

<sup>80</sup> Article 58(1) and Article 58(8). This is the procedure referred to in Article 133(4) of the Regulation. It refers to Article 5a of Council Decision 1999/468, which was recently introduced by Council Decision 2006/512. A full discussion of the various comitology forms is outwith the scope of this chapter. Suffice it to note that under this new procedure the European Parliament, like the Council, can veto the Commission's draft decision, on the basis that it exceeds the implementing powers conferred by the basic instrument (REACH in this case), or that the draft decision is not compatible with the aim or content of that basic instrument, or does not respect the principles of subsidiarity and proportionality. This is an important constitutional development as it puts the Parliament on a more even footing with Council in the adoption of implementing (executive) acts, as is already the case in respect of legislative enactments in most areas under the EC Treaty.

<sup>81</sup> See Article 59 which lays down the opportunities and obligations of Member States in this respect, and the relevant decision-making procedure.

<sup>82</sup> That is to say that the candidate list will be adopted in this event by regulatory committee procedure, whereas the final list will be adopted on the basis of a regulatory committee with scrutiny procedure. The regulatory committee procedure is that referred to in Article 133(3) and this, in turn, refers to Article 5 of the comitology decision, supra n. 80.



which the European Parliament is not much involved. Also, in that the Member States' contestatory powers bite only in relation to the candidate list, the more preliminary authority enjoyed by this, the more influential their contestation may be anticipated to be.

To my mind it seems unlikely that the final list must draw exclusively from substances included on the candidate list.<sup>83</sup> Were this to be the case, priority substances included in an Agency recommendation for inclusion in the final list<sup>84</sup> would have to be ignored if that substance did not also appear on the candidate list for inclusion. It is notable in thinking about this, that the Agency does not enjoy an autonomous right of initiative in relation to the candidate list. Only the Member States and the Commission may set in train the process of seeking to have a substance included on this candidate list.<sup>85</sup>

### C. Restrictions

Annex XVII contains a list of restrictions concerning the manufacture, use or placing on the market of substances. This may be amended where there is an unacceptable risk to human health or the environment which needs to be addressed at Community level.<sup>86</sup> Member States may seek to contest the boundaries of Annex XVII by setting in train a procedure to consider its amendment, where it considers that the risk presented by a substance is not adequately controlled and needs to be addressed.<sup>87</sup> Where this demonstrates that action on a Community-wide basis is necessary, it shall submit this dossier to the Agency in order to initiate the restrictions process. The detail of the process for the adoption of new restrictions will be considered alongside the process for the adoption of authorization decisions below.

### D. Harmonized Classification and Labelling

The regulation provides for harmonized classification and labelling of certain substances, and specifically for CMR (categories 1–3) and for respiratory sensitizers.<sup>88</sup> These shall 'normally' be added to Annex I of Directive 67/548. Harmonized classification and labelling may also be provided for 'other effects' on a

<sup>83</sup> Although it is clear that this could be implied by the language of Article 59(1) which presents the role of the candidate list as being such as to identify which substances meet the Article 57 criteria.

<sup>84</sup> See Article 58(3) and (4).

<sup>85</sup> Article 59(2) and (3). When the Commission exercises its right to initiate this procedure, it will ask the Agency to prepare a dossier on its behalf. But the Agency cannot, independent of instructions from the Commission, move to the preparation of a dossier of this kind.

<sup>86</sup> Article 68(1).

<sup>87</sup> Also the Commission may request the Agency to prepare a dossier of this kind. The Agency will do so when it considers that there is a risk to human health or the environment which is not adequately controlled. See Article 69(1) and (2).

<sup>88</sup> Article 115.

case-by-case basis if justification is provided demonstrating a need for Community-level action. The competent authorities of Member States may submit proposals to the Agency to this effect.<sup>89</sup> The Agency committee for risk assessment will adopt an opinion on this proposal, giving the parties concerned the opportunity to comment, and the Agency shall forward the opinion and comments for the adoption of a decision under Article 4(1) of Directive 67/548.<sup>90</sup>

### E. Member State Safeguards

Article 129 establishes a Member State safeguard clause. This provides for the adoption of provisional (maximum 60 days) protective measures where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment. This is subject to an oversight procedure, whereby the Commission, acting on the basis of a regulatory committee procedure, will decide whether to authorize or approve the provisional measures. Where the provisional measure is approved, the Commission shall consider whether the regime as a whole needs to be adapted, and the Member State in question is required to initiate a Community-wide restrictions process as discussed above.

### F. Article 95 EC<sup>91</sup>

Whenever an EU legal act is based on Article 95 of the EC Treaty, certain 'opt-outs' are constitutionally guaranteed by Article 95(4) and 95(5). Though subject to a common procedure, the two sub-paragraphs differ in their scope. Article 95 (5) relates to the adoption by Member States of a new regulatory measure after the enactment at EU level of the harmonization measure in question. This is narrowly drawn, justifiable only on grounds relating to the protection of the environment or working environment, and even then only due to the emergence of new scientific evidence relating to a problem specific to that Member State. The Article 95(4) opt-out, by contrast, relates to the maintenance of national measures in place even before the enactment of the EU harmonizing act. The range of grounds on which Member States may rely is broader, including those specified in Article 30, as well as environment and working environment. Thus, for example, this would include public health.

<sup>89</sup> As with the candidate list for authorization and new restrictions proposals, the Member State shall submit an Annex XV dossier setting out the justification.

<sup>90</sup> Article 115(2). The formulation here in terms of participation is different, concerned as it is with 'parties concerned' rather than 'interested parties'.

<sup>91</sup> Note also Article 67(3) providing that Member States may maintain any existing and more stringent restrictions in force, relative to Annex XVII, until 1 June 2013, subject to their being notified according to the Treaty. The deadline for notification is not set out but it must be before 1 June 2009, as the Commission is required to publish an inventory of notified restrictions by this date. Many thanks to Peter Oliver for clarifying this point for me.

95 & 5  
(after)

95 & 4  
before

Under the Article 95 opt-outs, it is for the Commission to approve or reject the national provisions in question, usually within a six-month period. For this reason, Member States are obliged to notify their measures to the Commission. Any measure not so notified will be deprived of legal effects. In the course of reaching its decision, the Commission will scrutinize compliance with the various conditions, and verify also that the measure does not constitute a disproportionate obstacle to the functioning of the internal market.<sup>92</sup> As the recent Austrian case concerning genetically modified organisms shows, the Commission's decision will be susceptible to judicial review.<sup>93</sup> Where a Member State measure is authorized, it will be for the Commission to examine whether to propose an adaptation to the harmonizing measure in relation to which the Member State is opting out.<sup>94</sup>

GMO

The Article 95 opt-outs (or their predecessors) have been invoked nineteen times by Member States in relation to chemicals, with Member State measures receiving approval on thirteen occasions.<sup>95</sup>

Article 95 has something in common with the other channels for contestation in REACH; not least the fact that a successful Member State opt-out acts as a catalyst for the Commission to consider proposing an adaptation to the regulatory bargain for the Community as a whole. By contrast to the other mechanisms though, it is the Commission alone which is responsible for making a determination about whether to reject or approve the application in question. In this setting the Commission is unconstrained by either comitology or other consultation requirements.<sup>96</sup>

## G. Contestability: The Limitations

It is apparent from the above that the Member States enjoy multiple opportunities to contest the harmonized settlement represented by the regulation. They may do so by exploiting the opt-out possibilities established under Article 95 EC or by the safeguard clause in REACH. These possibilities are quite narrowly drawn. More particularly, and more unusually, Member States may also contest the boundaries of the regulatory settlement by setting in train a process of

<sup>92</sup> To preserve the useful effect of these opt-outs, the Commission read the 'no obstacle' requirement as meaning 'no disproportionate obstacle'.

<sup>93</sup> Joined Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Austria v. Commission* (judgment of 13 September 2007).

<sup>94</sup> So, for example, in relation to the Dutch example above, the Commission had proposed an amendment to the EU framework governing creosote and creosote-treated wood.

<sup>95</sup> See the list at: <[http://ec.europa.eu/enterprise/chemicals/legislation/derogations/index\\_en.htm](http://ec.europa.eu/enterprise/chemicals/legislation/derogations/index_en.htm)>.

<sup>96</sup> For a recent discussion of the limits to even the applicant Member State's right to be heard, see Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v. Commission*. Here the ECJ places emphasis upon the importance of achieving a speedy resolution of such issues, without time-consuming information exchange (para. 41).

reflection, according to which there will be detailed and reasoned contemplation of the need for change. Member States are accountable in making recourse to these procedures, not least through the frequent requirement that their bid for change be accompanied by a dossier which lays down the reasons for this and the evidence on which the conclusion of that Member State is based. The contours of such dossiers are set out in Annex XV.

Like the Member States, the Commission too enjoys certain opportunities to launch such processes. This is most apparent when it comes to the drawing up of the candidate list of substances requiring authorization, and in relation to the restrictions process.<sup>97</sup> That said, the Commission's powers are more circumscribed, notably in respect of the restrictions procedure.<sup>98</sup> Here, the conclusion of the Commission that a substance poses a risk will be examined by the Agency. The Agency will not automatically draw up a dossier upon request by the Commission but will do so only where it shares the Commission's view that the substance poses a risk which is not adequately controlled, and that action on a Community-wide basis is necessary.<sup>99</sup>

Still, this leaves the question of which other actors enjoy these formal opportunities to destabilize the settlement, and to contest the boundaries of the regulation. Two observations are pertinent here.

First, the Agency's autonomous capacity to do so is limited. While it is a central actor in all of the decision-making processes, regardless of where the initiative to contest originates, its powers to contest directly the regime's existing boundaries are constrained. Of course it enjoys considerable autonomy in drawing up the rolling action plan of substances to be made subject to evaluation.<sup>100</sup> And it is empowered to recommend substances for inclusion on the final list of those requiring authorization.<sup>101</sup> Beyond this it is an agent of the Commission, being made responsible for the preparation of a dossier, at the Commission's request, in respect of the candidate list of substances and the restrictions process. It is particularly significant that the Agency enjoys no independent right of initiative in seeking to launch a restrictions process.

Second, although interested parties are offered multiple opportunities to make their views known in the course of adopting implementation decisions, including

<sup>97</sup> See Article 59(2) and Article 69(1).

<sup>98</sup> The Commission does not enjoy the same powers to contest in respect of substance evaluation, harmonized classification and labelling, or the safeguard clause. Though recall the discussion above about the emergency powers of the Commission in the context of review of authorization decisions.

<sup>99</sup> Article 69(1) and (2). This is in contrast to the Commission's contestatory role in respect of authorization, where a Commission request to the Agency to draw up a dossier to consider a substance for inclusion on the candidate list will not be second-guessed by the Agency but carried out without question. See Article 59(2). This probably reflects the Agency's own role in recommending substances for inclusion on the final list under Article 58(3). This provides the Agency with the opportunity to make its own views known.

<sup>100</sup> See again Articles 44-48.

<sup>101</sup> Article 58(3).

in the course of drawing up the candidate and final lists of substances requiring authorization, and in relation to the restrictions process, such interested parties are not empowered themselves to set in train the various reflection processes. Neither industry actors or NGO voices, nor academics or other experts, are given formal recognition as catalysts for revision in the light of new information or better understanding. As noted, the boundaries of the regime are porous. But the range of actors which can seek to alter them is noticeably confined. It is to be regretted that other persons or organizations do not enjoy the capacity to bring forth evidence-based dossiers to launch formal inquiries about the need for change. It would be reasonable to think that the Agency might serve as an intermediary in this event, to examine dossiers submitted, in order to ensure that frivolous claims do not progress. In much the same way as the Agency will examine the credibility of the Commission's claims in seeking to launch an inquiry into the need for new restrictions, so too it could serve as a gatekeeper for attempts at de-stabilization brought forth by civil society actors.

## H. A Note on Authorization and Restriction Procedures and Criteria

It has been illustrated above that Member States enjoy multiple opportunities to contest the boundaries of the regulation. They enjoy very limited authority to impose stricter standards than those laid down in REACH, but they may in various ways set in train a procedure to consider ratcheting those standards up. Ultimately, decisions will be taken in accordance with the procedures laid down. Important differences exist between these procedures. This may be most starkly illustrated by reference to the distinct procedures for the adoption of authorization and restrictions decisions.

### 1. Authorization

#### (a) Procedure

The Agency committees shall issue draft opinions on an application for authorization.<sup>102</sup> The Committee for Socio-Economic Analysis shall take into account any information on alternative substances or technologies submitted by interested third parties.<sup>103</sup> Interested parties are not invited to comment more generally. However, the applicant is given an opportunity to comment, and the

<sup>102</sup> See Article 85 on the Committee for Risk Assessment and the Committee for Socio-Economic Analysis. These comprise members appointed by the Agency's Management Board from a list of nominees established by the Executive Director on the basis of Member State nominations. At least one nominee put forward by each Member State will be appointed, but not more than two. Members will be appointed for their role and experience in performing the Agency's task. The committees shall aim to have a broad range of relevant expertise, and to this end each committee may co-opt up to five additional members, chosen on the basis of their specific competence.

<sup>103</sup> Article 64(4)(b) and 64(2).

committees shall consider the comments, taking this argumentation into account when appropriate. It shall submit its opinions, with the written argumentation attached, to the Commission, the Member States, and the applicants.<sup>104</sup> The Commission shall adopt a draft decision and adopt its final decision on the basis of a regulatory committee procedure.<sup>105</sup>

### (b) Criteria

The Article 60, para. 2 criteria apply to authorizations for Annex XIV substances except where these are PBTs or vPvBs, or where it is not possible to establish a DNEC or a PNEC. In this case, authorization will be granted if it is established that the risk to human health and the environment is adequately controlled in accordance with section 6.4 of Annex I.

For other authorization substances, Article 60, para. 4 will apply. For these substances, authorization will only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment, and if there are no suitable alternative substances or technologies. In considering the availability of alternatives account will be taken of the overall risk profile of an alternative, and of its technical and economic feasibility for the applicants.<sup>106</sup>

## 2. Restrictions

### (a) Procedure

When a Member State or the Agency prepares a restrictions dossier demonstrating the need for a Community-wide restriction, interested parties will be given an opportunity to submit comments and/or a socio-economic analysis.<sup>107</sup> The Agency Committee on Risk Assessment shall draw up an opinion taking into account these comments (but not the socio-economic analysis).<sup>108</sup> The Agency Committee for Socio-Economic Analysis shall formulate a draft opinion, taking into account any socio-economic analyses submitted by interested parties. It will invite interested parties to comment upon this. It will adopt its final opinion taking into account earlier socio-economic analyses submitted, and subsequent comments received.<sup>109</sup> These committee opinions will be submitted to the Commission.<sup>110</sup> If the conditions for imposing a restriction are satisfied (see below) the Commission shall prepare a draft amendment to Annex XVII, taking its final decision in accordance with a regulatory committee with scrutiny procedure. Where its draft amendment diverges from the original proposal (put forward by the Member State or Agency), or does not take the opinions of the

<sup>104</sup> Article 64(5).

<sup>106</sup> Article 60(5)(b).

<sup>108</sup> Article 70.

<sup>110</sup> Article 72(1). In the absence of an opinion from either or both of the committees the Agency shall inform the Commission and state reasons for the absence.

<sup>105</sup> Article 64(8).

<sup>107</sup> Article 69(6).

<sup>109</sup> Article 71(1) and (2).

committees into account, the Commission shall annex a detailed explanation of the reasons for the differences.<sup>111</sup>

(b) **Criteria**

Restrictions will be imposed when there is an unacceptable risk to human health or the environment, arising from the manufacture, use, or placing on the market of substances, which needs to be addressed on a Community-wide basis.<sup>112</sup>

*3. Comparison of the authorization and restrictions procedure*

There are important differences in the procedures for the adoption of authorization and restriction decisions.

First, interested parties enjoy a broader right to submit comments under the restrictions procedure. Under the authorization procedure their right to intervene is restricted to the submission of information about alternative substances or technologies.

Second, authorization decisions are adopted by a regulatory committee procedure, whereas restriction decisions are adopted by regulatory committee with scrutiny. Thus the European Parliament is greatly empowered in the latter.

Third, an individual applicant enjoys a right to be heard under the authorization procedure.

Fourth, under the restrictions procedure the Commission is not obliged to take the Agency committee opinions into account. In this event it must offer a reasoned justification. While there is neither an obligation to take the committee opinions into account under the authorization procedure, nor any obligation to offer reasoned justification for departure, the case law of the European Court would seem to imply that both are necessary in any case. In each case the case law would suggest that departure from these expert opinions is circumscribed by an obligation to offer reasons and evidence for so doing. Where the committee offers scientific advice, departure is countenanced only where the Commission can offer scientific justification at a level which is commensurate with the committee opinion.

Taking the first two differences together, it is clear that there are opportunities for public participation, directly and indirectly through democratically elected representatives, enhanced in relation to the restrictions procedure, by comparison to the authorization procedure. Yet, particularly for the most risky substances requiring authorization under Article 60(4), the conditions for authorization are anything but purely scientific. Wide judgement is called for, in balancing costs and benefits, and in assessing the suitability of putative alternatives, including their economic feasibility for applicants.

<sup>111</sup> Article 71.

<sup>112</sup> Article 68(1) and Article 73.

Elsewhere, interested parties are given greater opportunities to comment, when the power of the European Parliament in comitology declines. Thus, in drawing up the candidate list for authorization, interested parties are allowed to comment, but the power of the European Parliament is diminished by recourse to the traditional regulatory committee procedure.<sup>113</sup> In drawing up the final list, by contrast, the European Parliament is involved by dint of the scrutiny procedure, but the individual right to comment is curtailed.<sup>114</sup> Both the restrictions and authorization procedures are unusual; the former by combining parliamentary involvement with direct public participation, and the latter by curtailing both.

#### 4. Core Element: Substitution

One consequence of REACH is that it will narrow, and ultimately close, the regulatory gap between new and existing chemicals. In the past the additional regulatory burden attaching to new chemicals has created a perverse incentive, favouring the continued use of existing chemicals, even where these existing chemicals are risky, and even where safer alternatives exist or could readily be developed. REACH seeks to alter this incentive structure. It does so most obviously by requiring the phased registration of existing chemicals. And it does so expressly when it comes to the authorization and restriction of risky chemicals.

As noted in the previous section, certain very risky substances will require prior authorization. Those applying for authorization are obliged to analyse the availability of alternatives and to consider their risks, as well as the technical and economic feasibility of substitution.<sup>115</sup> All applications for authorization are to include this analysis. This procedural obligation is combined with a substantive requirement that, for many of the substances requiring authorization, approval will only be granted if there is no suitable alternative substance or technology.<sup>116</sup> Suitability will be determined having regard to overall risks, as well as to the technical and economic feasibility of alternatives for the applicants.<sup>117</sup> It will be determined within the framework of the authorization procedure set out earlier in this paper. It will be for the Agency Committee for Socio-Economic Analysis to assess alternatives. It will do so having provided an opportunity for interested

<sup>113</sup> See Article 59.

<sup>114</sup> Article 58(1). Individuals do have an opportunity to comment on the Agency recommendation identifying priority substances. See Article 58(4).

<sup>115</sup> Article 55.

<sup>116</sup> Article 60(4). This requirement applies when para. 4 rather than para. 2 of Article 60 is applicable. This is the case for PBTs and vPvBs, and for other high-risk chemicals included on the final authorization list where it is not possible to determine a level of exposure threshold above which humans should not be exposed, or an environmental concentration threshold below which adverse environmental effects are not expected to occur. See Annex I, 1.0.1. and 3.0.1.

<sup>117</sup> Article 60(5).



third parties to submit information on alternatives, and having given the applicant a further right to submit comments following the publication of a draft opinion.<sup>118</sup> While the Commission is not bound by the Agency opinion, it is obliged to justify departure from it, including in relation to the suitability of alternatives.<sup>119</sup>

There is something here which is resonant of Wendy Wagner's proposal for 'competition-based regulation' in relation to chemicals.<sup>120</sup> According to this, the role of a regulator should be to adjudicate upon claims of environmental superiority, by inviting competitor companies to petition for certification of their product as superior, and for the restriction or banning of inferior products.<sup>121</sup> Superiority determinations should take shape within the framework of an adversarial procedure which is robust in its ability to guard against over-blown claims or misstatements of fact.

It might be argued that REACH creates just such an inclusive forum for adjudication on the suitability of alternatives, and for the banning of substances where a 'superior' alternative is shown to exist. The process of adjudication is mildly adversarial. The Agency does not take the word of the applicant as gospel, but invites the submission of rival information on alternatives from 'interested parties', including on the part of competitors. In certain respects, REACH goes further than Wagner proposes. For example, even more expensive alternatives may be deemed suitable, so long as they remain within the realm of economic feasibility. In other respects, however, REACH falls short of the Wagner paradigm. It applies only to high-risk substances, and not even to all of them.<sup>122</sup> Also, while, as noted in the previous section, there is some fluidity in what is to count as a high-risk substance, the initiative to expand the list rests in the hands of the Commission and Member States (and to a lesser extent the Agency). Competitors are not empowered to petition for a substance to be included on this list, and hence are not able to play a role in galvanizing the superiority adjudication.

This emphasis upon substitution is further reflected in relation to the restrictions process. Restrictions may be imposed where a substance presents an unacceptable risk to human health or the environment. Consistent with Wagner's suggestion in relation to the US Toxic Substances Control Act (TCSA),<sup>123</sup> here what counts as an unacceptable (unreasonable under TCSA) risk will be determined taking into account the socio-economic impact of a

<sup>118</sup> Articles 64(2) and (5).

<sup>119</sup> This obligation is inherent in the administrative law of the EU. See Case T-11/99 *Pfizer*.

<sup>120</sup> *Supra* n. 8.

<sup>121</sup> What counts as superior is stated at p. 22: 'If a company establishes that their product is significantly safer to public health or the environment than a competitor product for an identified set of uses, and is available at roughly the same price per application, then the product could be certified as competitively superior for those uses.'

<sup>122</sup> Recall the discussion above about the different conditions for authorization under Article 60(2) as compared to Article 60(4).

<sup>123</sup> Wagner, *supra* n. 8, p. 20.

restriction, including in the light of the availability of alternatives.<sup>124</sup> Once again, it is for the Agency Committee on Socio-Economic Analysis to draft an opinion on the proposed restriction. In so doing, it is obliged to take into account the analyses or information submitted by interested parties, including presumably information on the availability of alternatives.<sup>125</sup> While once again it is not within the gift of a competitor to set a restrictions process in motion, this process having been launched by a Member State or by the European Commission, a competitor is able to play an important role in providing information and in contesting received wisdom, including in relation to the socio-economic impact of putative restrictions, in the light of their knowledge of available alternatives.

The capacity of REACH to re-calibrate incentive structures in chemicals regulation, in favour of the development of 'green(er)' alternatives, will depend in large part on the way in which the substitution dynamic in authorization and restrictions plays out in practice. It will depend upon the willingness of the various political actors to use the vague language (suitable or available alternatives) to sanction the existence of workable alternatives, and upon the willingness of independent scientists and particularly competitor companies to come forward to play a role in the quasi-adjudicative process for certifying the existence of alternatives. REACH asks much less of competitor companies than Wagner would like. It merely asks them to engage in a process the impetus for which comes from elsewhere. It does not ask them, or indeed allow them, to instigate this process themselves. For a competition-based approach to regulation to work, competitors must be willing to succumb to a strategy of 'divide and rule' on the part of the regulator, and to be willing to attest formally to the superiority of their product relative to that of an industry rival. In an admittedly attenuated form, REACH may provide a test case for this. It will provide an occasion to assess the willingness of industry to participate in authorization or restriction processes concerning a competitor's product, and the willingness of industry to adduce evidence about alternatives in a bid to provoke a negative authorization decision or the imposition of restrictions in relation to that competitor's product. Time will tell.

## 5. Core Element: Provisionality

### A. Review of Authorizations

As will be discussed in more detail below, substances of very high concern will be subject to an authorization requirement, even at very low volume.<sup>126</sup> Where

<sup>124</sup> Article 68(1).

<sup>125</sup> Article 69(6)(b) and (71)(1) and (2).

<sup>126</sup> See Section B above.

authorizations are granted, these will be subject to a time limited review, and will normally be subject to conditions, including monitoring.<sup>127</sup> They will also be subject to the all-important proviso that the authorization holder will incur an absolute obligation to ensure that exposure is reduced to as low a level as is technically and practically possible.<sup>128</sup> This is somewhat reminiscent of the IPPC concept of best available techniques, a standard which gives rise to an evolving rather than an absolute obligation.<sup>129</sup> What is interesting here is that while socio-economic considerations will be directly relevant in the authorization process, and while the availability of substitutes will be subject to an economic feasibility test, this obligation to attain lowest exposure is not subject to any economic or cost-benefit balancing test. Admittedly it is only concerned with one element of the overall risk package—exposure as opposed to hazard—but even so it provides a strong instrument to the regulator in performing its review functions.

Authorization decisions will remain valid until they are amended or withdrawn subject to the obligation on the authorization holder to submit the review report discussed above, at least eighteen months before the expiry of the authorization time limit.<sup>130</sup> Review may be routine, associated with the time limit, or ad hoc. The Commission may conduct an ad hoc review at any time, if the circumstances of the original authorization have changed in such a way as to affect risk to humans or the environment, or if new information on possible substitutes becomes available.<sup>131</sup> Authorization may be withdrawn or amended, following a routine or ad hoc review, if under the changed circumstances it would not have been granted, or if suitable alternatives have since become available.<sup>132</sup> Where there is a serious and immediate risk for human health or the environment, authorization may be suspended pending the review.<sup>133</sup>

It is significant that review of authorization provides an opportunity to link REACH to other aspects of the EU's environmental programme. It is explicit in providing for the possibility of review in so far as IPPC environmental quality standards are not met or environmental objectives under the Water Framework Directive are not achieved.<sup>134</sup> In this way, REACH is somewhat parasitic for the attainment of its objectives, upon the monitoring regimes established by other instruments. The Water Framework Directive, in particular, lays down elaborate

<sup>127</sup> Article 60(8). The authorization will specify the time-limited review period and any monitoring arrangements.

<sup>128</sup> Article 60(10).

<sup>129</sup> Directive 96/61, Article 2(12).

<sup>130</sup> Article 61(1).

<sup>131</sup> Article 61(2).

<sup>132</sup> Article 61(3).

<sup>133</sup> Article 61(3). This is very much the Commission's equivalent to the Member State safeguard clause in Article 129 to be discussed below.

<sup>134</sup> Article 61(4) and 61(5). See also Article 61(6) which provides for the automatic withdrawal of authorization where the substance is subsequently prohibited or restricted under Regulation 850/2004 on persistent organic pollutants (POPs).

and detailed requirements on the monitoring of water status, and on the regular reporting by Member States of the results of this.<sup>135</sup>

### B. Reporting/Review/Revision

Along the way, in the lengthy course of the adoption of REACH, difficult and contested choices had to be made. It is striking, in the light of this, to note that the regulation is self-consciously provisional, in that it explicitly contemplates the circumstances for its own revision. It does so not merely in the abstract, or in general terms, but on the basis of carefully defined questions for inquiry, and in an institutional setting which confers specific review responsibilities on the Commission.<sup>136</sup> During the twelve-year period following the entry into force of the regulation, the Commission is charged at different points with reviewing specified elements of the regime, and with bringing forward proposals for reform.

In keeping with Article 131, amendments to the regulation's multiple and extensive annexes may be achieved by the Commission acting on the basis of a regulatory committee with scrutiny procedure. For amendments to the main body of the text, the Commission will be compelled to bring forward proposals for the adoption of legislative acts.

The range of questions to be addressed by the Commission is extensive, with nine specific tasks set out. The Commission is required to review the scope of certain obligations, including some which were among the most controversial during the enactment phase. Thus, for example, the Commission is to consider whether in the future to require a chemical safety report for substances produced at relatively low volume, below the current 10 tonne threshold;<sup>137</sup> or whether to modify the Annex XIII criteria for identifying PBTs and vPvBs.<sup>138</sup> The Commission will consider whether to extend the more rigorous authorization procedure to endocrine disrupting substances;<sup>139</sup> and whether to extend the duty to

<sup>135</sup> Directive 2000, Annex V. This might go some way to addressing concerns raised that REACH is not sufficiently committed to environmental monitoring as part of its approach to identifying and regulating against risk. See McEldowney, S., 'EU Chemicals Regulation: A Foundation for Environmental Protection or a Missed Opportunity?' Vol. 4 *Yearbook of European Environmental Law* (OUP, 2005).

<sup>136</sup> See Article 138.

<sup>137</sup> Article 138(1) to be carried out by 1 June 2019, except in so far as it relates to CMR (categories 1 and 2) substances in which case it is to be completed more quickly, by 1 June 2014. Looking at the precise wording, this would seem to include a review of this requirement for substances not currently subject to registration because they are manufactured or imported in quantities of less than one tonne.

<sup>138</sup> This is to be carried out more expeditiously, within one year of entry into force, by 1 June 2008.

<sup>139</sup> This is to be carried out by 1 June 2013. It will be recalled that Article 60 establishes two procedures for authorization under para. 2 and para. 4. At present Article 57(f) substances are subject to para. 2 except in the circumstances laid down in Article 60(3). As such they may be authorized so long as the risks are adequately controlled, and without being subject to an alternatives assessment, or a balancing of socio-economic benefits against risk.

communicate information on substances in articles to dangerous substances not currently included on the prior authorization list.<sup>140</sup>

In all but one case, the Commission's review obligations are one-off, to be carried out by the date specified. In the odd case out, there would appear to be a regular, recurring, obligation on the Commission to review the information requirements for substances produced at a volume of 1–10 tonnes.<sup>141</sup> This review obligation is explicitly linked to the Commission's obligation to produce a five-yearly general report on the operation of the regulation.<sup>142</sup> This general report will be issued following the submission of implementation reports by both Member States and the Agency.<sup>143</sup>

This regular reporting cycle also provides an important opportunity for reflection and review. Member State reporting is an endemic feature of EU environmental law. In practice, the Commission shapes the submission of information by Member States by issuing a questionnaire.<sup>144</sup> This serves to facilitate transparent comparison of Member State approaches, and of their achievements to date by the Commission in its synthesis report. It is early days with REACH, and as yet no such reports have been issued. There is, however, experience in other areas which is illustrative of the potential inherent in reporting and review mechanisms of this kind. Over the years, the scope of the Environmental Impact Assessment Directive has been extended, and its obligations sharpened. Many of the most important amendments introduced have their origin in lessons learned on the basis of Member State and Commission reports.<sup>145</sup> Member States come to constitute laboratories for experimentation in the implementation of often open-ended obligations. Experiences are then

<sup>140</sup> Article 138(8). This is to be undertaken by 1 June 2019, taking into account practical experience in implementing the article.

<sup>141</sup> Article 138(3).

<sup>142</sup> Article 117(4).

<sup>143</sup> Article 117(1) and 117(2). Under Article 117(3) the Agency also incurs a three-yearly obligation to submit a report on the status of implementation and use of non-animal test methods and testing strategies. This information will assist the Commission in performing its review function under Article 138(3) discussed above. The existence of a reporting obligation of this kind acquired a legal significance in the recent *Mangold* case (Case C-144/04). This was a factor cited by the Court in justifying its decision to conclude that the German law in question should be set aside as contrary to an EU directive, even though the deadline for implementation has not passed. In so doing, it relied upon the *Inter-Environnement Wallonie* doctrine (Case C-129/96), concluding that the regular reporting obligation incurred by states invoking a time-limited extension, implied the existence of a standstill obligation, whereby Member States were precluded from adopting measures which would make it impossible to achieve compliance at the end of the time-limited period.

<sup>144</sup> The Agency Forum (see n. 146 below) is responsible for establishing an electronic information exchange procedure. As with the Water Framework Directive, it is likely that this will result in informally agreed templates for the submission of information in reports, which will make it easier for the Commission, and others, to spot gaps, and compare performance across Member States. On the Water Information System for Europe (WISE) see, <<http://www.wise-rtd.info/>>.

<sup>145</sup> For a fuller discussion see Scott, J. and Holder, J. 'Law and New Environmental Governance in the EU' in de Búrca, G. and Scott, J. (eds.), *Law and New Governance in the EU and the US* (Hart Publishing, 2006).

pooled, allowing examples of good and bad practice to inform the revision of the overall regime. The reporting and review cycle provides an institutional framework for the integration of on-the-ground experiences in implementation, and for the organized and transparent participation of Member States in shaping the revised framework binding on all Member States.

125-126  
This remains important in the context of REACH, although it is in the form of a Regulation, and although, given its internal market focus, it promotes greater upfront harmonization across Member States than is frequently the case. Still, Member States enjoy sometimes substantial flexibility in implementation. This is notably the case when it comes to enforcement. Article 125 simply requires Member States to 'maintain a system of official controls and other activities as appropriate to the circumstances'. Article 126, in similarly enigmatic vein, provides that they 'shall lay down the provisions on penalties applicable for infringement... and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.' It is then hardly surprising that it is stipulated that Member State reports shall include sections on evaluation and enforcement, including the results of official inspections, the monitoring carried out, the penalties provided for, and other measures taken during the reporting period.<sup>146</sup> In this way, the reports serve an accountability as well as a learning function, rendering transparent and comparable Member State performance in areas characterized by open-ended norms and flexibility in implementation.<sup>147</sup>

## 6. Core Element: Transparency

### A. Information in the Supply Chain

A key premise of REACH is that effective risk management requires effective communication across the entire supply chain for chemicals. Communication should be two-way: down-stream to ensure the provision of up-to-date information necessary to facilitate safe use; and up-stream to allow for new,

<sup>146</sup> See also Article 127. This also states that the common issues to be covered in the reports shall be agreed by the forum. This is to be established by Article 86, and will be a successor to CLEEN, a chemicals enforcement network which has been in effective operation for over ten years. It shall comprise individuals selected by each Member State, an Agency representative, as well as representatives of the Commission, with stakeholders being invited to attend as observers. The forum may also co-opt up to a maximum of five additional members in a bid to ensure a broad range of relevant expertise among members.

<sup>147</sup> The activities of the Forum are laid down in Article 77(4) and include proposing, coordinating, and evaluating harmonized enforcement projects and joint inspections, identifying enforcement practices in enforcement, developing working methods and tools of use to local inspectors, developing an electronic information exchange procedure, and examining proposals for restrictions with a view to advising on enforceability.

on-the-ground, experience based information on risk and risk management to be fed back to the manufacturer or importer.<sup>148</sup>

At the core of the REACH system is the concept of the Safety Data Sheet (SDS). The requirements of this are set out in the Annex II 'guide', in a bid to ensure consistency and accuracy in the presentation of data. It is to include information on the intrinsic properties of substances; known uses; handling, storage, and disposal information; first aid, fire-fighting and accidental release measures; and exposure limits and control measures. These are designed 'to enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment'.<sup>149</sup>

The provision of an SDS is mandatory in only a limited range of situations. These concern the supply of substances or preparations which are dangerous, substances which are PBTs/vPvBs (meeting Annex XIII criteria), and substances included on the Article 59(1) candidate list for authorization.<sup>150</sup> Recipients may also receive, upon request, an SDS for certain preparations which contain substances which though not dangerous, pose human health and environmental hazards or which are PBTs/vPvBs not meeting the Annex XIII criteria.<sup>151</sup>

Outside of these situations, suppliers of substances on their own or in preparations still incur a duty to communicate specified information down the supply chain. This includes information about restrictions and authorization, but also more generally available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.<sup>152</sup>

The above is concerned with disclosure of information on substances on their own or in preparations. For substances in articles, controversially, different requirements apply.<sup>153</sup> Here, there will never be an obligation to prepare an SDS. For the most hazardous substances, identified on the basis of their inclusion on the Article 59(1) candidate list for authorization, there is instead merely a general, and relatively weak, disclosure requirement. This takes the form of a standard rather than a rule. It requires the disclosure of sufficient information to allow safe use. But it is subject to a proviso. Subject to an absolute obligation to provide information on the name of the substance, only information *available* to the supplier need be supplied.<sup>154</sup> The concept of availability is not defined.

<sup>148</sup> The discussion will focus here on downstream provision of information, but see Article 34 on the duty to communicate up-stream.

<sup>149</sup> Annex II, Recital 2. Where the relevant actor has been required to prepare a CSR as part of the registration or authorization process, it shall include the relevant exposure scenarios in an annex to the SDS. See Article 31(7). These only form part of a CSR for dangerous or PBT/vPvB substances.

<sup>150</sup> Article 31(1). The reference in Article 31(1)(c) to points (a) and (b) in the context of Article 59(1) is quite confusing. This refers back to (a) and (b) of Article 31(1) and not Article 59(1) and reflects the fact that some substances included on the candidate list will also be dangerous and/or PBTs etc.

<sup>151</sup> Article 31(3). This is subject to specified minimum concentration thresholds.

<sup>152</sup> Article 32(1). <sup>153</sup> Article 33.

<sup>154</sup> The concept of availability applies also under Article 32 concerning substances and preparations not requiring an SDS. But here the bottom-line disclosure requirement is more expansive, including information on authorization and restrictions.

More generally in thinking about the scope of obligations to supply SDS and other supply chain information requirements, it is important to contemplate the place of the final consumer. In thinking about this, it is crucial to be aware that information in the supply chain, including SDS, is to be supplied to recipients of substances on their own or in preparations. The definition of a recipient is given in Article 3(34) and is narrower than might otherwise be assumed. This means a down-stream user or distributor being supplied with a substance or a preparation. While it is plain that a consumer is not a distributor,<sup>155</sup> it transpires that neither does a consumer constitute a down-stream user for the purpose of the regulation. Only industrial or professional users are constituted as such.<sup>156</sup> Hence, when it comes to that part of the REACH package which is concerned with information in the supply chain (Title IV), consumer entitlement to receive information is somewhat lacking. Consumers are entitled to request such information as is necessary to allow for the safe use of an article containing a substance of very high concern, apart from information on the name of that substance, though this obligation is subject to the relevant information being 'available' to the supplier.<sup>157</sup>

It is then apparent that there are shortcomings or gaps in arrangements for the communication of information down the supply chain, and particularly in respect of consumers. These shortcomings are particularly pronounced in respect of substances in articles, where an SDS is never required. In view of these shortcomings, it is important to ask to what extent they are mitigated by other aspects of the REACH transparency package. To determine this, it is necessary to look at the rules laid down on harmonized classification and labelling on the one hand, and on public access to information on the other.

## B. Classification and Labelling of Substances

By contrast to information in the supply chain which is directed in the main at professional and industrial users, harmonization of classification and labelling of chemicals aims primarily at the protection of consumers and workers.<sup>158</sup> This is true both for the current EU system and for the Globally Harmonized System of

GHS

<sup>155</sup> See Article 3(14). A consumer does not store a substance and place it on the market for third parties.

<sup>156</sup> Article 3(13).

<sup>157</sup> See Article 33(2). This is also subject to a concentration requirement. See also Article 31(4) which may create an incentive to provide consumers with information. Where the ultimate user is a consumer and not a professional or industrial user, provision of this information to the consumer will mean that an SDS will only have to be supplied upon request. This is important as consumers will be able to receive, upon request, information on the presence of substances of very high concern in articles.

<sup>158</sup> But note Article 35 which provides that workers and their representatives shall be granted access by their employer to SDSs and other information on substances and preparations that they use or may be exposed to in the course of their work.



Classification and Labelling of Chemicals (GHS) which the EU is in the course of implementing.<sup>159</sup>

The core function of both the old and new system is to harmonize hazard classes for dangerous substances and preparations (so-called mixtures under GHS), to draw up a list of substances with harmonized classifications for specific hazard classes, and to regulate packaging,<sup>160</sup> and the provision of information to consumers and workers through labelling,<sup>161</sup> including hazard statements,<sup>162</sup> precautionary statements, and pictograms.<sup>163</sup> There are also rules on advertising, to avoid misleading customers. Where a substance or preparation is not subject to harmonized classification, it must be classified in accordance with established hazard classes by the supplier prior to it being placed on the market. The regime also provides for a publicly accessible classification and labelling inventory, containing the relevant information submitted to the Agency as part of the registration or notification process.<sup>164</sup>

A detailed evaluation of GHS is outside the scope of this paper. What is crucial for our purposes is that it provides a framework for the protection of consumers, in a way that the supply-chain information requirements do not. But equally it is plain that the scope of application of this framework is limited in that it applies only to substances on their own or in preparations (mixtures). With one exception, it does not apply to substances in articles, even where these are intended to be released or where it is reasonably foreseeable that they might be in the course of normal use.<sup>165</sup> When it is recalled that SDS are never required for substances in articles, and that consumers may only receive available information on request, including at a minimum the name of the substance, there does still appear to be a significant gap in the protective regime constituted by the

<sup>159</sup> To this end, the provisions of Title XI of REACH on classification and labelling will be moved to the new classification and labelling regulation. See COM(2007) 355 final for the proposal for a regulation on classification, labelling, and packaging of substances and mixtures, which will implement in the EU the international criteria agreed by the UN Economic and Social Council.

<sup>160</sup> See, for example, Annex II, Part III which provides for child-proof fastenings and tactile warnings.

<sup>161</sup> See Annexes II–V of the proposed regulation setting out the information to be included. Note that this includes in Annex II supplemental labelling provisions derived from the existing EU regime and not yet provided for by GHS. Similarly, in Annex III, additional hazard statements are required for hazards not currently part of GHS. Annex VI runs to more than 900 pages, comprising the list of substances with harmonized classifications.

<sup>162</sup> See Annex III. These provide information on the hazardous properties of substances. For example 'Explosives, Unstable Explosives' or 'Flammable Gases' or, more extreme, 'Reproductive Toxicity', 'Acute Toxicity', or 'Carcinogenicity, Hazard Category 1A, 1B'.

<sup>163</sup> See Annex V, reproducing the GHS hazard pictograms, such as flames, skull and crossbones, exclamation marks, a highlighted human chest, or fish in the environment.

<sup>164</sup> See Article 114 REACH, and Article 113 specifying the information to be included. At present the notification obligation under REACH applies both to the registered substances and preparations and to dangerous substances even when these are not subject to a registration obligation. Under the new proposal, registered substances will be treated as having been notified as the registration process already requires the submission of information on classification and labelling.

<sup>165</sup> The exception concerns flammable aerosols.

transparency requirements.<sup>166</sup> How significant depends in part upon how the ambiguous line separating articles from preparations will be drawn. Assistance should be provided in this regard by the REACH guidance document on substances in articles.<sup>167</sup>

Also, as has been seen, transparency is just one prong of a multi-faceted approach to the regulation of chemical substances. Restrictions may be imposed on the manufacture, placing on the market, or use of substances, including in articles. Already Annex XVIII includes restrictions designed to protect the general public, including through a range of prohibitions on sale to it. Requirements to provide information, including to consumers, do not appear to be a regular feature of the current restrictions laid down.

Moreover, substances of very high concern are subject to authorization, including for use in articles. Nonetheless, as outlined above, even for the most dangerous substances authorization may be granted where socio-economic benefit is deemed to outweigh risk, and where there is no suitable, technically and economically feasible, alternative. Thus even substances acknowledged to be of very high concern will remain on the marketplace, including for inclusion in consumer products. It is true that authorization may be made subject to conditions, and that there is no reason why the provision of consumer information could not form the basis of any such conditions. However, this remains an ad hoc, uncertain, case-by-case solution, to what seems to be a systemic weakness in the Regulation.

There are a number of reasons to think that REACH would be improved by incorporating more extensive requirements for the provision of information to consumers about substances in articles, especially substances of very high concern. This would enable consumers to make independent, informed, judgements about risk, in respect of substances over which there is uncertainty and disagreement among experts. It would also provide a push toward the substitution of dangerous chemicals by less risky alternatives, harnessing the power of the market to generate incentives for research and development, and for recourse to safer alternatives.<sup>168</sup>

<sup>166</sup> Recall though that when authorizing a substance, including for use in an article, conditions can be imposed and these could also take the form of consumer information requirements. Likewise, restrictions may limit the sale of articles containing hazardous substances to the general public. There are many examples of this in the existing Annex XVII.

<sup>167</sup> REACH Implementation Project (RIP) Working Group 3.8. For general information on RIP, and for the Guidance on the Requirements for Substances in Articles, see: <<http://ecb.jrc.it/reach/rip/>>. For the kind of debate this has stimulated see, for example, the submission by Edana (the International Association Serving the Nonwovens and Related Industries) concerning the status of impregnated tissue paper as an article rather than as a container with preparations. See <<http://www.europeantissue.com/Files/070307-EDANA+%20ETS%20Paper%20on%20Articles%20under%20the%20REACH%20Regulation.pdf>>.

<sup>168</sup> This argument gains strength when we look to experience in California in relation to 'Proposition 65'. See Applegate, *supra* n. 4, for an overview and further references. He observes that '[a]s California has found with its Proposition 65, pointed public information is a strong incentive to use only the safest chemicals'.

### C. Access to Information

The Chemicals Agency will be subject to the general EU law framework on access to information.<sup>169</sup> REACH, however, is proactive in indicating the accessibility of different categories of information. To this end, it establishes a traffic lights approach, laying down three lists which we call red, amber, and green.<sup>170</sup> Information included in the red list will not normally be accessible; it 'normally' being deemed to undermine the protection of commercial interests.<sup>171</sup> This includes details on the full composition of a preparation, the precise use of a substance or preparation, except in so far as this is required as part of the registration or authorization process, the precise tonnage of the substance or preparation, and information pertaining to links between a manufacturer or importer and his distributors or down-stream users. The Agency may, however, disclose this information where urgent action is essential to protect human health, safety, or the environment, including in emergency situations.<sup>172</sup> Information in the amber list will be available, except where a party submitting the information provides a justification at the time of registration as to why publication could be harmful to its or another party's commercial interests, and where this justification is accepted as valid by the Agency.<sup>173</sup> Information on the green list will be made publicly available.<sup>174</sup>

red

The categories of information listed on both the green and amber lists extend to information about substances on their own, as well as those included in preparations and in articles. On this basis, consumers will, invariably,<sup>175</sup> be able to obtain upon request to the Agency, information about the intrinsic properties of substances, including those in articles, details of human health and environmental thresholds (DNELs and PNECs), information about classification and labelling, and guidance on safe use. More often than not, and absent a justification to the contrary, they will also be able to receive summaries of tests and other activities undertaken to generate information for registration purposes, and information in the SDS.<sup>176</sup> All of this shall be made publicly available, free of charge, over the Internet.

green / amber

Given the focus on substances in articles above, it is important to consider how much information the Agency will hold on these as a result of the other dimensions of REACH. First, it will hold information on substances in articles where these must be registered.<sup>177</sup> Second, the Agency will hold a more limited

<sup>169</sup> Article 118 explicitly provides that Regulation 1049/2001 applies to it.

<sup>170</sup> Articles 118–119. <sup>171</sup> Article 118(1).

<sup>172</sup> Article 118(2). <sup>173</sup> Article 119(2).

<sup>174</sup> Article 119. <sup>175</sup> Article 119(1).

<sup>176</sup> Article 119(2).

<sup>177</sup> Recall Article 7(1) and (5), namely when the one tonne threshold is met and the substance is intended to be released under normal or reasonably foreseeable conditions of use, or the Agency suspects that it will be, thus presenting a risk to human health or the environment.

amount of information on substances in articles which are notified to it; namely substances of very high concern, included on the candidate list for authorization, where the volume and concentration threshold is met.<sup>178</sup> Third, the Agency will hold information on substances in articles, where these substances appear on the final Annex XIV list specifying substances requiring authorization.<sup>179</sup> Given the information to be supplied to the Agency under these various headings, it is apparent that the vigorous consumer would be able to ascertain which substances are used in articles, at least where the release condition is met or where the article appears on either the candidate or final list for authorization. For substances in articles requiring registration or authorization, copious other information on that substance will also be available. This is especially true of substances requiring authorization, which will entail the supply of a CSR and an analysis of alternatives. The availability of information on alternatives is of the utmost importance, as it will allow consumers and non-governmental actors to target their campaigns to situations in which substitution is feasible but economically costly.

Bringing these three sections on access to information together, especially in relation to information on substances in articles, there would seem to be a missing link. While the Agency will hold considerable information, and in the main give public access to this, neither the supply-chain information requirements, nor the labelling rules, are such as to alert consumers to the presence of substances in articles, even where these substances appear on the candidate or final list for authorization, and are thus acknowledged to be of very high concern. It would be an important step in the right direction, were the labelling rules to require the presence of such substances in articles to be highlighted on a label. Even if it were not required that the substances present be named individually on the label, it would be an important step to acknowledge the presence of such substances as a category and to provide details of where consumers might turn to receive further information.

## 7. Conclusion

The REACH package is complex and rich in its governance dimensions. Even in relation to these dimensions, this essay is far from being comprehensive. Other arrangements for collaboration between Member States in the implementation of REACH, including arrangements for networked norm elaboration through soft law, have not been examined here.<sup>180</sup> These arrangements, as well as the work of

<sup>178</sup> Article 7(2).

<sup>179</sup> Recall Article 62 identifying the categories of information to be submitted as part of the applications process.

<sup>180</sup> See *supra* n. 167. See Lee, M. and von Homeyer, I. in current volume for a discussion of the comparable process under the Water Framework Directive. Thus, for all the differences between REACH, with its emphasis on harmonization, and the Water Framework Directive, with its

the Agency Forum briefly touched upon above, require further investigation, to consider their contribution to effective and/or legitimate transnational governance in this area.

Even without these aspects though, the REACH package is interesting. It is about product market integration *and* environmental/health protection. While the former militates in the direction of harmonization, the latter militates against a complacent centre, convinced that it enjoys a monopoly on regulatory wisdom. In keeping with this, REACH is emphatic but tentative in the harmonization which it achieves. It is emphatic in that it leaves little room for unilateral Member State departure from it, as is exemplified by the free movement clause. At the same time, and in a manner which might seem contradictory but is not, REACH is tentative in the harmonization which it achieves. It constructs multiple channels which allow for the contestation of the regulatory bargain which it embodies. Far from being complacent, the EU centre actively institutes a multi-level and multi-actor dialogue about risk and about how best to respond to it.

emphasis upon appropriate flexibility, each of these has spawned a broadly similar process for norm elaboration. In the Water Framework Directive this is known as the Common Implementation Strategy, in relation to REACH (humorously or not) it goes by the acronym 'RIP', meaning the REACH Implementation Projects. See: <<http://reach.jrc.it/>> for an insight into the many activities being conducted under this rubric.