Risk and the Precautionary Principle in the Implementation of REACH

The Inclusion of Substances of Very High Concern in the Candidate List

*Christoph Klika**

The adoption of the REACH regulation, setting out to reform chemicals policy of the European Union (EU), was accompanied by intense controversy over the role of the precautionary principle. Analysing decision making on so called Substances of Very High Concern (SVHCs), this article demonstrates that despite legal underpinning, precaution plays a limited role in the implementation of the REACH authorisation procedure. Due to ambiguous legislative provisions, the controversies of the legislative process are carried over to the implementation process.

I. Introduction

After a lengthy and controversial legislative process, the REACH regulation was finally adopted in December 2006, setting out to reform chemicals policy of the European Union (EU).[1] The adoption of REACH was accompanied by intense controversy in which a business coalition and a green coalition were fighting over the general objectives of the regulation, the underlying principles and the technical details regarding its implementation.[2] Among the key issues in this controversy was the role of the precautionary principle. While the precautionary principle was not featured in the draft legislative proposal, various stakeholders referred to it to support their respective positions in the public consultation.[3] Subsequently, the principle was included in the legislative proposal and ultimately in REACH, which states in Article 1 that its provisions "are underpinned by the precautionary principle".[4] However, during the legislative process, the precautionary principle had "been reduced to a concept which is more or less devoid of practical meaning".[5]

This is of particular importance for so called Substances of Very High Concern (SVHCs), given that REACH states that these substances "should, in accordance with the precautionary principle, be subject to careful attention".[6] It is indeed difficult to derive practical meaning from such general formulation and scholars have raised the question as to whether the regulation of SVHCs will be based on precaution.[7] The article sets out to answer this ques-

* PhD Candidate at the Faculty of Arts and Social Sciences of Maastricht University. This article was made possible through a fellowship of the Centre for European Law and Governance at Cardiff University. The author is grateful to Stijn Smismans and Elen Stokes for commenting on earlier drafts of the article. The author also wishes to thank the two anonymous reviewers for their valuable comments.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, (…), OJ L 396/1.

2 Henrik Selin, "Coalition Politics and Chemicals Management in a Regulatory Ambitious Europe", 7 *Global Environmental Politics* (2007), pp. 63 et sqq.; Dieter Pesendorfer, "EU Environmental Policy under Pressure: Chemicals Policy Change between Antagonistic Goals?",15 *Environmental Politics* (2006), pp. 95 et sqq.

3 See e.g. KEMI, "REACH Regulation – response to the public internet consultation", 4 July 2003, available on the Internet at http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (last accessed on 15 February 2014).

4 See Regulation (EC) 1907/2006, *supra* note 1, Art. 1.

5 Søren Løkke, "The Precautionary Principle and Chemicals Regulation. Past Achievements and Future Possibilities", 13 *Environmental Science and Pollution Research* (2006), pp. 342 et sqq.; Veerle Heyvaert, "Guidance without Constraint: Assessing the Impact of the Precautionary Principle on the European Community's Chemicals Policy", in Thijs F.M. Etty and Han Somson (eds.) *Yearbook of European Environmental Law*, (Oxford: Oxford University Press, 2006), pp. 27 et sqq., at p. 57.

6 See Regulation (EC) 1907/2006, *supra* note 1, Recital 69.

7 Lars Koch and Nicholas Ashford, "Rethinking the role of information in chemicals policy: implications for TSCA and REACH", 10 *Journal of Cleaner Production* (2006), pp. 31 et sqq., at p. 40; Steffen Foss Hansen, Lars Carlsen and Joel A. Tickner, "Chemicals Regulation and Precaution: does REACH really incorporate the Precautionary Principle", 10 *Environmental Science and Policy* (2007), pp. 395 et sqq.

tion by analysing actual decisions on SVHCs after the adoption of REACH and by focussing on the role of precaution, I aim to examine controversies pertaining to decision making.[8] It will be demonstrated that precaution plays a limited role in this respect and that due to ambiguous provisions in REACH, the controversies of the legislative process are carried over to the implementation process.

Since the so called Candidate List of SVHCs is at the centre of these controversies, the analysis will be restricted to decisions made in order to include SVHCs in this list. The analysis is based on empirical evidence from 2008, when the implementation commenced, until 2013, when the European Commission released a roadmap on SVHCs identification and REACH implementation.[9] Although the implementation is an on-going process, this article is primarily concerned with the first years of implementing decision making. In this time span, important decisions have been made setting in motion developments that affect the role of precaution in the implementation process. The Commission roadmap marks a watershed in this process as it somewhat formalises such developments. The analysis draws on legislative texts, a wide range of policy documents, technical guidance and decisions as well as minutes of the respective decision making bodies. In order to increase the validity of the analysis, the documentary evidence is complemented by semi-structured, open-ended interviews with policy makers, experts and stakeholders. These interviews are based on qualitative research methodology and do not follow quantitative surveys in terms of representative selection of respondents. Instead, snowball-techniques for selecting interviewees and saturation regarding new information are employed as important measures to increase the reliability of such qualitative methods.[10]

II. The REACH Authorisation Procedure

The REACH regulation is a complex regulatory framework entailing various, inter-related instruments which are included in the acronym of the regulation: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Registration (and related evaluation) is based on the "no data, no market" principle and requires companies to submit a dossier on their substances used in industrial processes, including technical information but also reports on the safe use of these substances.[11] Apart from registration, the REACH authorisation procedure is a new regulatory instrument with a dual objective, namely to ensure the good functioning of the internal market and to control the risks of SVHCs, ultimately substituting them with alternative substances.[12] Whereas registration applies to all substances on the market, albeit with exemptions, authorisation and restriction are regulatory instruments that require decisions by regulatory authorities as to which substances should be subjected to the procedure. These decisions are also required because a large number of substances can potentially be subjected to the authorisation procedure. This is so because the procedure does not necessarily affect newly developed chemical substances, products or uses. On the contrary, the potential substances are so called existing substances which are already on the market and in use, if not regulated or banned otherwise.

This is so due to a regulatory gap in EU chemicals policy that existed before REACH. The substances brought on the market before 1981, i.e. existing substances, are less regulated than those brought on the market after 1981, i.e. new substances.[13] Since the majority of all substances on the market are existing substances, there is a large pool of potential substances. In December 2006, shortly before the adoption of REACH, the European Commission estimated that around 900 substances are known to be SVHCs.[14] Hence, the identification of SVHCs is a

8 For similar approaches see Noelle Eckley and Henrik Selin, "All talk, little action: precaution and European chemicals regulation", 11 *Journal of European Public Policy* (2004),pp. 78 et sqq.; also Les Levidow, Susan Carr and David Wield, "European Union regulation of agri-biotechnology: precautionary links between science, expertise and policy", 32 *Science and Public Policy* (2005), pp. 261 et sqq.

9 Commission Roadmap for SVHCs identification and implementation of REACH Risk Management measures from now to 2020, CA/2/2013, Brussels, 08/02/2013.

10 Robert S. Weiss, *Learning from strangers: The art and method of qualitative interview studies*, (New York et al.: The Free Press); Greg Guest, Arwen Bunce and Laura Johnson, "How many interviews are enough?: An experiment with data saturation and variability", *Field Methods* (2006), pp. 59 et sqq.

11 See Regulation (EC) 1907/2006, *supra* note 1, Art. 5.

12 See Regulation (EC) 1907/2006, *supra* note 1, Art. 55.

13 Veerle, Heyvaert, "Coping with Uncertainty. The Regulation of Chemicals in the European Union", Ph.D thesis on file at the European University Institute, (1999).

14 European Commission,"MEMO/06/488", Brussels, 13th December 2006.

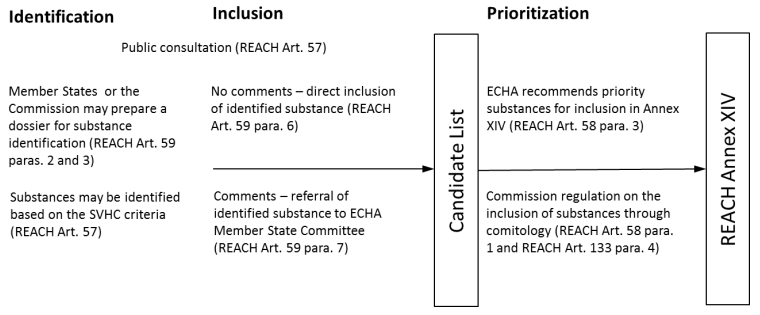

Figure 1

salient issue for regulatory authorities and members of the green and business coalition alike.

The authorisation procedure requires an intricate process that consists of two basic steps (see Figure 1). As a first step, SVHCs are included in the Candidate List. The Candidate List serves a dual purpose. First, the inclusion of a substance requires companies to release information about their products containing the substance.[15] Second, from all SVHCs included in the Candidate List, substances are further prioritised for inclusion in Annex XIV of REACH. After a substance is included in Annex XIV, companies wishing to use the substance have to apply for authorisation and, thereby, are required to conduct risk assessment.[16] Due to the resource-intensive application process, both for companies to apply and regulatory authorities to grant or reject authorisation, only a limited number of SVHCs will be included in Annex XIV.[17] Hence, the new authorisation procedure and restrictions, already in place before the adoption of REACH, differ considerably. In fact, the very existence of the authorisation procedure is intrinsically related to the failure to deal with substances of concern solely through restriction.[18] Restrictions require regulatory authorities to conduct risk assessment themselves in order to limit specific uses of substances.[19] The authorisation procedure through preceding inclusion in Candidate List and Annex XIV respectively reverses this process.[20]

REACH also brought about the establishment of a new EU agency by creating the European Chemicals Agency ECHA.[21] In order to include SVHCs in the Candidate List, respective substances have to be identified and proposed first by possibly each Member State and the Commission, asking ECHA to submit the respective dossier.[22] After a substance is proposed and put up for public consultation, it is included by ECHA's Member State Committee (MSC).[23] In the cases where no comments are received during consultation, the proposed substance is directly included in the Candidate List without passing through the committee. In the cases where comments are received, the MSC can decide on the inclusion of the proposed substance either through written procedure or committee deliberation. If no unanimous agreement is reached in the committee, the proposal is referred to the Commission for decision making.

III. Conceptual Framework

Answering the question of whether the regulation of SVHCs is based on precaution requires a clear conceptualisation of the precautionary principle. At a general level, the principle implies "that on some oc-

15 See Regulation (EC) 1907/2006, *supra* note 1, Art. 7 and 33.

16 Commission White Paper Strategy for a future Chemicals Policy, COM(2001) 88 final, Brussels, 27.2.2001.; also Lars Koch and Nicholas Ashford, "Rethinking the role of information in chemicals policy", *supra* note 7.

17 See Regulation (EC) 1907/2006, *supra* note 1, Recital 77.

18 See Regulation (EC) 1907/2006, *supra* note 1, Recital 9.

19 Ibid., Art. 68 and 69 regarding restrictions.

20 The intricate relation between restrictions and the new authorisation procedure, and decisions for one or the other instrument are not prescribed by law. Instead, decision making processes depend on a number of factors such as type and use of targeted substance, as well as resources and goals of the regulatory authorities; see ECHA, "Workshop on the Candidate List and the Authorisation as Risk Management Instruments", 21-22 January 2009.

21 See Regulation (EC) 1907/2006, *supra* note 1, Art. 75.

22 Ibid., Art. 58.

23 Ibid., Art. 59. The MSC is comprised of representatives of the Member States, usually staff of ministries or national regulatory agencies dealing with chemicals policy.

casions, measures against a possible hazard should be taken even if the available evidence does not suffice to treat the existence of that hazard as a scientific fact".[24] Given that the principle is an elusive concept due to a variety of definitions, I aim to operationalise the concept by drawing on Sandin who derived four dimensions of the principle: 1) threat dimension, 2) uncertainty dimension, 3) action dimension and 4) command dimension. [25] These four dimensions can then be utilized to form an ideal-type decision rule in relation to SVHCs inclusion in the Candidate List.[26] This decision rule serves as a benchmark or indicator of precautionary decision making.

A threat (1) can be understood as an adverse effect or an "undesired possible state of the world".[27] In the context of the REACH authorisation procedure, such adverse effects relate to three different types of SVHCs: a) carcinogenic, mutagenic and toxic for reproduction (CMRs); b) persisting, bioaccumulative and toxic (PBTs); c) substances of equivalent concern (ECs).[28] In REACH, the notion of SVHCs is hazard-based because a threat is derived from the intrinsic properties of a substance. In contrast, a risk-based approach derives a threat not only from the substances' intrinsic properties, but also from actual exposure to a substance, given that only then adverse effects can actually occur.[29] Whereas a risk-based approach is better able to differentiate the severity of threats, it also requires exposure information, resources and expertise as well as a common understanding of acceptable risk. Given that the balance between hazard- and risk-based approaches requires a number of political and economic trade-offs, it is hardly surprising that controversies in chemicals regulation often materialise along these lines.[30]

While the threat dimension relates to adverse states of the world, the uncertainty dimension (2) relates to the (lack of) knowledge regarding these states, and therefore states how plausible a threat must be in order to trigger precaution.[31] The threat and uncertainty dimension are closely related because the way adverse effects are defined by legal provisions requires different levels of knowledge regarding these effects. For the three different types of SVHCs this means that although they are all considered as having adverse effects, the uncertainty regarding these effects varies considerably. In case of CMRs, there is no uncertainty regarding the adverse effect, because the adverse intrinsic properties of CMRs have been established as such by way of harmonised classification at the EU level. Prior to the adoption of REACH, thousands of hazardous substances have been classified and listed in technical annexes of the respective legislation.[32] According to REACH, these CMRs can be identified as SVHC with a reference to their entry in the respective annex listing all classified substances.[33] In contrast, PBTs cannot be identified as SVHC in the same way. While CMRs are de facto already identified as having SVHC properties according to REACH, PBTs need to meet specific testing results showing that they can be identified as PBTs according to REACH.[34] Since PBTs imply adverse effects on the environment, scientific uncertainty is elevated and, moreover, these substances do not have the same regulatory history as CMRs. Hence, regulatory authorities cannot rely on codified

24 Per Sandin et al., "Five charges against the precautionary principle", 5 *Journal of Risk Research* (2002), pp. 287 et sqq., at p. 288.

25 See Per Sandin, "Dimensions of the Precautionary Principle", 5 *Human and Ecological Risk Assessment: An International Journal* (1999), pp. 889 et sqq.

26 In his discussion of these four dimensions, Sandin forms if-clauses, linking certain threats with subsequent action. By drawing on Sandin's dimensions, I form similar clauses, yet I prefer to speak of decision rule.

27 Per Sandin, "Dimensions", *supra* note 25, at p. 891.

28 See Regulation (EC) 1907/2006, *supra* note 1, Art. 57. Among the latter type of ECs are endocrine disrupting or respiratory sensitisers for instance.

29 Bjorn G. Hansen and Mark Blainey, "REACH: A Step Change in the Management of Chemicals", 15 *Review of European, Comparative & International Environmental Law* (2006), pp. 270 et sqq; Tom Gebel, Eva Lechtenberg-Auffarth and Christine Guhe, "About hazard and risk assessment: Regulatory approaches in assessing safety in the European Union chemicals legislation", *Reproductive Toxicology* (2009), pp. 188 et sqq.

30 Ragnar E. Lofstedt, "Risk versus Hazard – How to Regulate in the 21st century", *European Journal of Risk Regulation* (2011), pp. 149 et sqq.

31 Per Sandin, "Dimensions", *supra* note 25, at p. 893.

32 Harmonised classification of substances is the most important hazard-based instrument in EU chemicals policy and continues to be an important regulatory instrument complementary to REACH. See Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353.

33 See Regulation (EC) 1907/2006, *supra* note 1, Art. 57 (a-c).

34 Ibid., Art. 57 (d,e); also Annex XIII.

lists of PBTs similar to the annex listing substances classified as CMR. This uncertainty is further elevated with regard to ECs, because substances such as endocrine disruptors are at the forefront of scientific discovery. Hence, REACH does not provide for definite identification criteria, but states that ECs for which "there is scientific evidence of probable serious effects" have to be identified on a case-by-case basis.[35]

In order to deal with threats, regulatory decision making implies some kind of action (3) in order to respond to adverse effects, whereas the command dimension (4) relates to the question of whether this action is actually prescribed as mandatory. Since the authorisation procedure was introduced to deal with SVHCs, their inclusion in the Candidate List, as a necessary step towards Annex XIV inclusion, and therefore authorisation, can be taken as default action. Since SVHCs are defined as such based on their intrinsic properties, a hazard-based approach would require that the inclusion of all SVHCs in the Candidate List becomes mandatory, given that the mere fact that a substance fulfils SVHC criteria is deemed a threat.

Hence, based on the four dimensions of the precautionary principle, an ideal-type decision rule in relation to SVHCs inclusion in the Candidate List can be derived as follows: If (1) there is threat stemming from a Substance of Very High Concern, which is (2) uncertain, then (3) include this substance in the Candidate List (4) mandatorily. Applied in this way, the hazard-based SVHC criteria of REACH can be described as the "embodiment of the precautionary principle" given that actual adverse effects of SVHCs, hence risk-based, do not have to be validated scientifically in order to be included in the Candidate List.[36] As a result, this ideal-type decision rule is the most precautious interpretation with regard to the Candidate List and resembles propositions by members of the green coalition, which are usually proponents of the precautionary principle. These propositions call for the inclusion of hundreds of substances that are known to have SVHC properties.[37] The rationale of these calls is not only geared towards eventual inclusion of these substances into Annex XIV, but also to the release of information about consumer products containing SVHCs. A similar rationale with regard to workers' protection is maintained by trade unions that have also released lists of substances with SVHC properties that should be included.[38] However, the ideal-type decision rule does not only serve as an indicator of precaution. The systematic operationalisation of the precautionary principle enables the examination of controversies in the implementation process of REACH authorisation by analysing deviations from the ideal-type.

IV. The Inclusion of SVHCs in the Candidate List

Whereas the recitals of REACH state that SVHCs should be dealt with in accordance with the precautionary principle, the respective provisions of the authorisation procedure are not directly underpinned by the principle.[39] During the legislative process, the leading committee in the European Parliament (Environment, Public Health and Food Safety) unsuccessfully attempted to amend the regulation so that all known SVHCs *shall* be listed in the Candidate List.[40] This amendment would have laid down the ideal-type decision rule in the legal provisions and, thus, would have led to the inclusion of all SVHCs in the Candidate List. The Council, however, refused to accept these amendments.[41] Accordingly, REACH states that SVHCs *may* be included in the Candidate List.[42] In the actual implementation process, SVHCs are targeted step-by-step with only a limited number of substances included in different rounds of inclu-

35 Ibid,, Art. 57 (f).

36 Koch and Ashford, "Rethinking the role of information in chemicals policy", *supra* note 7.

37 The so called SIN list (Substitute It Now), for instance, contains over 600 substances that according to the green coalition should be included in the Candidate List; see ChemSec, "SIN List 2.1 update: new information from REACH registrations extends the SIN List", 14 February 2013, available on the Internet at: http://www.chemsec.org/images/stories/2013/Press_release_SIN_2.1_update.pdf (last accessed on 20 February 2014)

38 Tatiana Santos, Dolores Romano and Rafael Gadea, "Trade Union Priority List for REACH Authorisation", Version 2.0, June 2010, available on the Internet at: http://www.etuc.org/sites/www.etuc.org/files/TUListREACH.pdf (last accessed on 20 February 2014)

39 European Parliament Report on the proposal for a Regulation of the European Parliament and of the Council concerning (…) (REACH), establishing a European Chemicals Agency, A6-0315/2005 FINAL, Amendment 214.

40 Ibid., Amendment 215 and 216.

41 Council Common Position (EC) No 17/2006 adopted by the Council on 27 June 2006 with a view to adopting Regulation (EC) No …/2006 of the European Parliament and of the Council of… concerning (…) (REACH), establishing a European Chemicals Agency, (…) (2006/C 276 E/01).

42 See Regulation (EC) 1907/2006, *supra* note 1, Art. 57.

Table 1 - Number of SVHCs included in the Candidate List, 2008 to 2013

Round	Date		No. of SVHCs proposed	No. of SVHCs included	Cumulative No. of SVHCs in the Candidate List
1	October	2008	16	15 (14)	14
2	January	2010	15	15 (13)	27
3	June	2010	8	8 (8)	35
4	December	2010	11	8 (8)	43
5	June	2011	8	8 (8)	51
6	December	2011	20	20 (20)	71
7	June	2012	13	13 (13)	84
8	December	2012	54	54 (54)	138
9	June	2013	10	6 (6)	144
10	December	2013	7	7 (7)	151
			S 162	S 154	

Note: The number of SVHCs proposed equals the number of decisions regarding the inclusion in the Candidate List (S 162). Since not all substances proposed were included the Candidate List, this number is higher than the number of SVHCs included (S 154). The discrepancy between inclusions and the cumulative number of the Candidate List stems from the fact that some substances have been proposed for a second time in later rounds; these substances are listed as being included at the second date, even though they had been included before. The numbers in brackets are therefore lower in some rounds. In the second round, one substance was formally included in March.

sion, usually twice a year (see Table 1). Instead of the hundreds of substances called for by environmental NGOs and trade unions to be included, only 151 substances have been included in the Candidate List as of December 2013.

Note: The number of SVHCs proposed equals the number of decisions regarding the inclusion in the Candidate List (S 162). Since not all substances proposed were included the Candidate List, this number is higher than the number of SVHCs included (S 154). The discrepancy between inclusions and the cumulative number of the Candidate List stems from the fact that some substances have been proposed for a second time in later rounds; these substances are listed as being included at the second date, even though they had been included before. The numbers in brackets are therefore lower in some rounds. In the second round, one substance was formally included in March.

It is noteworthy that almost all substances proposed as SVHCs, 154 out of 162, were eventually included in the Candidate List. In eight cases, the Member State Committee (MSC) unanimously agreed not to include the proposed substance; all of these cases concern PBTs in which the SVHC criteria could not be met.[43] Although, the MSC is the ECHA body in charge to include substances, in a third of all cases, the committee was not concerned because no comments were received on the proposed substance, which was then included directly in the Candidate

43 The evidence presented in this paragraph is derived from the minutes of the Member State Committee and ECHA decisions on SVHC inclusion.

List. Based on the 162 cases of decision making on proposed SVHCs, the MSC reached agreements in a third of all cases by written procedure and by committee deliberation respectively. The largest share of cases included directly or by written procedure concerns CMRs. Since a majority of these substances has received harmonised classification regarding the adverse properties, a proposal of one of the substances as SVHCs cannot be contested in the committee; once it is proposed as SVHC according to the REACH criteria, the substance is de facto included in the Candidate List, even though it might be referred to the committee due to comments received in the consultation. In contrast, substances proposed as SVHCs due to their equivalent level of concern, which have to be identified and included on a case-by-case basis, are inevitably referred to the committee.

V. Discussion: Precaution in the Implementation of the Authorisation Procedure

As mentioned above, environmental NGOs and trade unions call for the inclusion of all SVHCs in the Candidate List, primarily, but not exclusively CMRs, because the substances fulfil the hazard-based criteria laid down in REACH. Being classified as such, these substances can be easily proposed and, as the empirical evidence shows, are indeed in many cases directly included without concerning the Member State Committee (MSC). In line with the ideal-type decision rule, the rationale of these calls is to include SVHCs mandatorily due to the uncertain threats of these substances stemming from consumer products and industrial applications. However, the Member States and European Commission, both being entitled to propose SVHCs, do not follow this hazard-based rationale. Instead, the step-by-step inclusion of Member States and the Commission is risk-based.[44] This risk-based rationale is arguably less precautious because the uncertainty related to a threat is not dealt with by including the substance in the Candidate List, but by determining the actual threat stemming from SVHCs.

Hence, the risk-based approach not only takes into account the intrinsic properties of a substance, although this would be legally sufficient to include a substance as SVHC, but also information on substances' volumes, uses and exposure. [45] While this might reduce the uncertainty regarding the actual threat of a substance, risk-based SVHC identification requires extensive information, time and expertise.[46] In order to facilitate the identification, Member States' experts have created a list of known SVHCs which, based on risk-related information, should be prioritised for inclusion in the Candidate List. Although this information will eventually be used for risk-based prioritisation for Annex XIV, the green coalition criticises that identification and inclusion, in line with a precautionary approach, should be purely hazard-based.[47] The risk-based approach implies that substances known to have SVHC properties might not be considered for the Candidate List, in case the substance is used in negligible volumes for instance.

These controversies relate to the general role of the Candidate List and the issue of substituting SVHCs with alternative substances.[48] Proponents of Candidate List inclusion argue that it facilitates the substitution, even though the listing of a substance does not require its substitution.[49] In contrast, the Candidate List, and also SVHC lists compiled by NGOs, is regarded as black lists by companies.[50] In some cases the inclusion of substances has been appealed unsuccessfully before the Court of Justice of the EU.[51] This resonates with the controversies during the legislative process. For members of the green coalition, the substitution of hazardous substances is intrinsically related to the precautionary principle, whereas for companies it is regarded as dispropor-

44 Unsurprisingly, this risk-based approach is heavily criticized by the green coalition. ChEMTrust et al., "First REACH hazardous chemicals list is a drop in the ocean", Brussels 22 October 2008; European Parliament, "Question for Question Time in committee 2008/8 under Rule 187 of the Rules of Procedure by Satu Hassi", Notice to Members, 19 November 2008.

45 ECHA, "Guidance on inclusion of substances in Annex XIV", August 2008.

46 Most of the proposals are lengthy and elaborate documents and only a limited number of Member States is responsible for a large share of all submitted proposals.

47 Interview with a member of the green coalition.

48 See Regulation (EC) 1907/2006, *supra* note 1, Art. 55.

49 Commission Staff Working Document, General Report on REACH, SWD(2013)25 final, at p. 118.

50 Kristina Nordlander, Carl-Michael Simon and Hazel Pearson, "Hazard v. Risk in EU Chemicals Regulation", 1 *European Journal of Risk Regulation*, pp. 239 et sqq.

51 Action brought on 4 January 2010 – PPB and SNF v ECHA (Case T-1/10), OJ C 63/48.

tionate.[52] During the legislative process, the green coalition aimed to strengthen the goal of substitution by amending the respective REACH article on the objectives of authorisation.[53] However, similar to the precautionary principle, this was rejected by the Council in its common position.[54]

However, despite the risk-based identification of SVHCs, according to REACH, proposed substances are included by the MSC solely based on their intrinsic properties.[55] This means that if a known SVHC is proposed, mostly CMRs, single Member States cannot influence the inclusion of the proposed substance and the committee has de facto no other choice than to include it. Since Member States and the Commission are entitled to initiate both procedures, SVHCs were included in the Candidate List for which restrictions were initiated as well.[56] The identification of specific SVHCs has been an issue since the very first round and some substances cause controversy in the MSC. The controversies relate to the uncertainty dimension, i.e. the actual threat of the proposed substance, as well as to the economic implications should the proposed SVHC end up in the Candidate List or Annex XIV. Hence, coordinating SVHC identification is not possible in the MSC due to its strictly defined mandate, which prescribes the hazard-based inclusion of SVHCs.

Although authorisation and restriction are complementary regulatory instruments of REACH, with different requirements and repercussions for regulators and industry, the legal provisions of REACH do not specify under which conditions one or the other instrument should be applied to deal with SVHCs. Therefore, a workshop was convened by ECHA after the first round of identification, attended by representatives of the Member States and the Commission, in order to clarify questions pertaining to the implementation of REACH.[57] One result of the workshop was the introduction of the Risk Management Options (RMO) analysis. The rationale of the RMO analysis is to enhance coordination among Member States and the Commission regarding the identification of SVHCs and the choice of regulatory instruments. Similar to the introduction of the risk-based prioritization of known SVHCs, this introduction deviates from the ideal-type decision rule. In contrast to this rule, the authorisation procedure is not the default regulatory instrument for SVHCs, but only one among other options such as restriction for instance.

Similar to risk-based identification, the invention of the RMO analysis is perceived with criticism by the green coalition. Not only might known SVHCs be discarded due to risk-related information, but the RMO also includes regulatory and economic implications with regard to authorisation and restriction, thus extending the command dimension by explicitly comparing both instruments. Although the requirement of full-fledged risk assessment still lies with the company applying for authorisation after Annex XIV inclusion, risk-based identification and RMO analysis place a considerable share of the work on the regulatory authorities.[58] The respective information requirements for SVHC identification, according to these criticisms, increasingly resemble restrictions, whereas REACH states that in comparison to chemicals policy before REACH, more needs to be done to protect human health and the environment in accordance with the precautionary principle.[59] Given that authorisations have been likened to restrictions in the implementation process, the green coalition argues that the implementation repeats this failure, whereas it was introduced to rectify it.[60]

Since the RMO analysis is not mentioned in REACH, all details regarding its implementation had to be worked out during the implementation process. While Member States agree that not all known SVHCs should be identified, disagreement prevails over the format of RMO, information requirements and decision making.[61] In contrast to the legal pro-

52 See Charlotte de Roo, "BEUC response to the consultation document concerning (…) (REACH)", 2003, available on the Internet at http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (last accessed on 15 February 2014); CEFIC, "Consultation Document concerning (…) (REACH), Volume 1, Cefic Comments", 8 July 2003, available on the Internet at http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (last accessed on 15 February 2014).

53 See European Parliament Report, *supra* note 39.

54 See Council Common Position, *supra* note 41.

55 See Regulation (EC) 1907/2006, *supra* note 1, Art. 59; also ECHA, "Guidance on inclusion", *supra* note 45.

56 ECHA, "Co-ordination of activities related to the preparation of Annex XV dossiers", CA/10/2010, Helsinki, 20/01/2010.

57 ECHA, "Workshop on the Candidate List", *supra* note 20.

58 Interview with a Member State representative.

59 See Regulation (EC) 1907/2006, *supra* note 1, Recital 9.

60 Interviews with various members of the green coalition; see also EEB and ClientEarth, "Identifying the bottlenecks in REACH implementation", October 2012.

61 ECHA, Format for Risk Management Option (RMO) analysis, CA/29/2010, Helsinki, 18/1/2010.

visions of REACH, the RMO analysis is not legally binding and SVHC identification can appear as incoherent and arbitrary. The absence of binding rules has led to situations in which a substance is not identified by one Member State due to the outcome of the RMO analysis, yet it is picked up by another Member State to be identified for authorisation.[62] Although the Commission is a stern advocate of RMO analysis, in 2012 it requested ECHA to identify 37 SVHCs without RMO analysis. The identification of this relatively large number of SVHCs was due to promises made by the Commission two years earlier, amidst criticism regarding limited SVHC inclusion in the Candidate List, to include another 100 or so substances by the end of 2012.[63] Hence, this request was primarily motivated by political considerations.[64] It is ironic that these SVHCs, all CMRs, were identified with mere reference to their harmonised classification and without additional information on volumes and uses, thus adhering to the continuing demands of the green coalition.

The RMO analysis is problematic for another reason. The inclusion of SVHCs in the Candidate List is preceded by public consultation, stakeholders are observers in the Member State Committee and the minutes of the committee meetings are published. Hence, Candidate List inclusion, in accordance with the provisions of REACH, provide for stakeholder access and transparency. In contrast, RMO analysis is based on coordination among Member States' experts for which no binding rules exist and some Member States that transparency would lead to politicisation, while they prefer an informal exchange of experts.[65] Both the green coalition and industry have criticized this lack of transparency regarding RMO analysis.[66] This makes it difficult for NGOs to trace the decision making processes of substance identification, while companies seeking planning reliability depend on domestic contacts with national authorities. As the Commission roadmap states, the RMO analysis is not meant to be made public and consultation is foreseen; it is up to the Member State to consider if it wants to consult with stakeholders or publish the results.[67] Although communication with stakeholders and transparency are considered important, the implementation process regarding the roadmap is not fully accessible. While identification of PBTs and EDs is open to stakeholder experts, CMR identification is not; in the latter case, the identification is considered a "practical" process whereas the former relies on technical and scientific expertise.[68]

VI. Conclusions

The requirement of authorisations is usually seen as a precautionary regulatory instrument because products remain off the market unless their safety is proven.[69] Yet, the REACH authorisation procedure has, so far, targeted mainly existing substances which are already on the market. Hence, a key issue during the legislative process was the role of precaution regarding the identification of known SVHCs and their inclusion in the Candidate List. Although REACH states that its provisions are underpinned by the precautionary principle, the respective provisions remain ambiguous due to the controversies during the legislative process. Hence, this article set out to analyse the inclusion of SVHCs in the Candidate List by drawing on an ideal-type decision rule derived from four dimensions of the precautionary principle. It was demonstrated that precaution plays a limited role in the implementation of the authorisation procedure, measured by deviations from the ideal-type decision rule.

These deviations alter the decision rule which, in the actual implementation process, has become more qualified.[70] While such alteration does increase the accuracy of the threat dimension, and perhaps the proportionality in terms of action, it also implies a partial reversal hazard- and risk-based approach. Due to the fact that RMO analysis is informal and not legally binding, decision making has appeared as incoherent and lacking transparency. This issue has

62 Interview with a Member State representative.

63 European Commission, "Chemicals: New European Commission determined to make REACH a success", 25 March 2010, IP/10/360.

64 Interviews with Commission officials.

65 Interview with a Member State representative.

66 Chemical Watch, "Industry and NGOs want greater transparency on SVHC roadmap. Availability of RMO information and lack of consultation worry stakeholders", 14 February 2013.

67 Commission Roadmap for SVHCs identification, *supra* note 9.

68 ECHA, "SVHC Roadmap to 2020 Implementation Plan", 9 December 2013.

69 Veerle Heyvaert, "Guidance without Constraint", *supra* note 5, at p. 42.

70 As pointed out by one of the anonymous reviewers.

been addressed through the implementation of the Commission roadmap on SVHC identification and REACH implementation.[71] However, the implementation of REACH is an on-going process which deserves further scholarly scrutiny.[72] While the legislative process of REACH has spurred a vast literature, the implementation of the regulation has received relatively little attention. This article provides empirical evidence on decision making pertaining to SVHCs inclusion in the Candidate List from 2008 until 2013 to facilitate a better understanding of these on-going processes of REACH implementation.

71 ECHA, "SVHC Roadmap", *supra* note 68.

72 Regarding the legitimacy of the authorisation procedure see Christoph Klika, "The Implementation of the REACH Authorisation Procedure on Chemical Substances of Concern: What Kind of Legitimacy?", 3 *Politics and Governance* (2015), forthcoming.