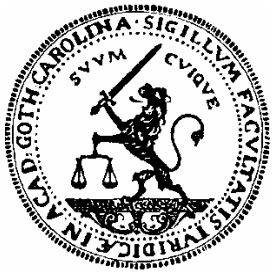

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REACH Regulation and the Environmental Liability Directive

-

The registrant's potential liability

Master thesis
30 credits

Annika Nilsson

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Contents

Summary

The main obligation under 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) is the obligation of registration. The company responsible for import and manufacture, as well as an only representative are registrants. To carry out the registration obligation means that the registrant generates information on the substance he registers. For CMR, R50/53, PBT or vPvB substance (substances of higher concern) above 10 tonnes, the registrant is obliged, as a part of the obligation, to perform a chemical safety assessment and generate exposure scenarios containing risk management measures to recommend the safe use of such substances. The system of registration means in effect, that substances of higher concern manufactured or imported in quantities above 10 tonnes per year are assessed and supplied with measures on how to reduce the risks of their use. The responsibility for registering substances of higher concern means that the registrant has the primary responsibility for registration and performing the chemical safety assessment and the generation of exposure scenarios containing adequate risk management measures. The downstream user shall provide the registrant with the appropriate information on his use in order to have his use covered by the registration, but is not involved in generating the exposure scenarios. The downstream user shall identify, apply and recommend such appropriate measures to adequately control risks identified in exposure scenarios attached to the safety data sheets supplied to him. The Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage (ELD) is built on the polluters pay principle and aims to make operators of dangerous activities liable for the environmental damage they cause. The Member States have been given possibilities in implementing the Directive and therefore the effect of the polluters pay principle will depend on the Member States implementing measures. The Directive's definition of occupational activities includes the use of a substance of higher concern. The registrant cannot be considered an operator and cannot therefore be held liable under the provisions of the Directive. However, there is a connection between the registrant's exposure scenario (including operational conditions and risk management measures) and occupational activity and environmental damage caused by such activity. It is possible that the registrants responsibility for correctly performed chemical safety assessment and adequate risk management measures of the exposure scenario will have significance when liable downstream users are invoking the defences provided for under the Directive, or a downstream user's right of recourse at the registrant following such downstream liability.

Sammanfattning

Den huvudsakliga skyldigheten under Europaparlamentets och Rådets Förordning (EG) Nr 1907/2006 av den 18 december 2006 om registrering, utvärdering, godkännande och begränsning av kemikalier (REACH), är registrering. Tillverkare och importörer som bär ansvar för importen eller tillverkningen av ett ämne anses vara registrant, och är skyldiga att registrera ämnen under förordningen. Registreringen av ett ämne innebär att registranten genererar information om det specifika ämnet. Registrering av ämnen som är cancerframkallande, mutagena, reproduktionstoxiska, ämnen som är långlivade, bioackumulerande och toxiska, samt ämnen som är mycket långlivade och mycket bioackumulerande (ämnen som föranleder betänkligheter) innebär att registranten skall utföra en kemikaliesäkerhetsbedömning samt exponeringsbedömning med framtagning av riskhanteringsåtgärder för att rekommendera en säker användning av dessa ämnen. Registreringskyldighetern i REACH har den effekten att ämnen som föranleder betänkligheter in mängder om minst 10 ton per registrant är försedda med åtgärder som reducerar riskerna förknippade med dess användning. Skyldigheten att registrera ämnen som föranleder betänkligheter innebär att registranten har det primära ansvaret för registreringen samt utförande av en kemikaliesäkerhetsbedömning och framtagande av exponeringsscenarier innehållande adekvata riskhanteringsåtgärder. Nedströmsanvändaren skall förse registranten med den nödvändiga informationen om användningnen, men har ingen roll i framtagandet av exponeringsscenarierna. Nedströmsanvändaren är skydlig att identifiera, tillämpa och rekommendera lämpliga åtgärder för att på ett adekvat sätt kontrollera risker som angivits i exponeringsscenariena som är fästa vid säkerhetsdatabladen registranten har försett nedströmsanvändaren med. Direktiv 2004/35/EG av den 21 april 2004 om miljöansvar för att förebygga och avhjälpa miljöskador bygger på principen förorenaren betalar och att det är verksamhetsutövare av en yrkesverkamhet som ska ansvara för orsakad miljöskada. Medlemsstaterna har givits möjligheter i dess implementering av direktivet, varför dess effekt av principen förorenaren betalar till stor del kommer att bero på den implementerande lagstiftningen i de olika Medlemsstaterna. Direktivets definition av yrkesverksamhet innefattar verksamhet där ämnen som föranleder betänkligheter används. Registranten kan inte anses vara verksamhetsutövare i direktivets bemärkelse och kan därför inte hållas ansvarig för nedströms miljöskada orsakad av sådan verskamhet som innefattar användning av ämnen som föranleder betänkligheter. Däremot finns det ett samband mellan sådan verksamhet och exponeringsscenarier framtagna av registranten. Det är möjligt att dessa exponeringsscenarier har betydelse då en miljöansvarig nedströmsanvändare åkallar de försvar mot ansvar som direktiver erbjuder. Det är också möjligt att nedströmsanvändaren till följd av sådant miljöansvar kan använda registrantens ansvar för kemikaliesäkerhetsbedömningen och framtagning av adekvata

riskhanteringsåtgärder som grund för dennes regressansvar mot en miljöansvarig nedströmsanvändare.

Preface

Det här examensarbetet innebär slutet på juristutbildningen. Första dagen på termin ett är idag över sex år sedan, men känns som mycket närmare än så. Åren har gått fort. Jag vill tacka mina vänner Ingrid och Emma som gjort dessa år i Lund fantastiska på alla sätt och vis. Tack också familjen: Mamma, Pappa, Anna, Lars och Marit som varit närvarande trots avståndet.

Relativt sent i skrivprocessen tog uppsatsen en helt annan riktning än den från början tänkta. Trots vändningen, och trots att jag därtill befunnit mig i ett annat land under skrivtiden, vill jag tacka min handledare Annika Nilsson som bidrog med goda synpunkter och förslag till förbättringar.

Tack också till alla partners på REACHLaw Ltd. i Esbo, Finland för den lediga tiden under tre veckor i april 2009 då jag sammanställde uppsatsen.

Sist men inte minst vill jag tacka Matti, för allt.

Esbo, Finland
1 Juni 2009

Abbreviations

CFI	Court of First Instance
CLP	Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic and Reprotoxic
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EEB	European Environmental Bureau
ELD	Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage
PBT	Persistent, Toxic, Bioaccumulative
R50/53	Very toxic to aquatic organisms, may cause long-terms effects in the aquatic environment
REACH	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
SVHC	Substances of Very High Concern
Substances of higher concern	CMR, R50/53, PBT and vPvB substances
TBT	Technical Barriers to Trade
vPvB	very Persistent, very Bioaccumulative
WTO	World Trade Organisation
WWF	World Wildlife Foundation

Introduction

The REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation (EC No. 1907/2006) was adopted on 18 December 2006 and entered into force on 1 June 2007. It was the outcome from years of negotiations between the Commission, the European Parliament, the European chemical industry, and environmental NGO's urging to revise the regulatory treatment of chemical substances in the European Union.[1] REACH is a notoriously complex and comprehensive piece of legislation. Partly based on previous directives and regulations, REACH regulates market access through its main regulatory pillars; registration, evaluation, authorisation and restriction. The obligations under REACH are imposed on a set of legal roles assigned to actors in the supply chain of chemicals. These roles are determined through looking at an actor's professional activity with regard to the substance concerned. The registration obligation require that legal entities, which are manufacturing and importing chemical substances, shall gather information on the substance and evaluate the risks resulting from their use. These legal entities have the role of registrants under the Regulation, and have now the burden of proving that chemicals placed on the market are safe. This is a new element compared with previous legislation.[2]

The registrant under REACH is the manufacturer, importer and the only representative appointed by a non-Community manufacturer. They are, as registrants, legally responsible for their registration dossier and its contents. In case of substances of higher concern manufactured or imported in quantities over 10 tonnes per registrant per year, the registration obligation includes the generation of risk management measures to ensure the safe use of such substances. These risk management measures are communicated in safety data sheets down the supply chain to the downstream users, who are obliged to identify, apply and recommend appropriate measures to adequately control the risks identified by the registrants in the safety data sheets.

Directive 2004/35/EC on environmental liability with regard to the prevention and remedying of environmental damage (ELD) aims at preventing and minimising the risks of environmental damage. Its fundamental principle is that an operator whose activity has caused the environmental damage shall be held liable. Liability under ELD is not dependent on whether the environmental good belongs to someone's property, and its definition of environmental damage is pure ecological impairment of nature caused by certain occupational activities. The registrant's responsibility for registering substances of higher concern and ensuring the safe use of such substances is particularly interesting

[1] A report of the European Environmental Bureau, *REACH: Environmental issues for the Second reading*, Publication 2006/007, p. 3.
[2] SCADPlus: Regulatory framework for the management of chemicals (REACH).

considering the ecological impairment of nature that substances of higher concern may cause. The registrants responsibility for its registration and risk management measures ensuring the safe use of such substances inevitably leads to the question on the registrant's potential environmental liability under ELD.

1.1 Purpose and main questions

The main purpose of the thesis is to identify the registrants' responsibility under REACH with regard to the registration and safe use of substances of higher concern, and his potential exposure to environmental liability under ELD.

In reaching its purpose, this thesis will firstly attempt to outline the contents of the registration obligation under REACH. It will examine the REACH requirements when registering substances of higher concern, and the responsibilities that apply to registrants of such substances. The purpose is to examine the actors' responsibility for the safe use of chemicals. Thereafter one can move on to the examination of the registrant's potential environmental liability under ELD.

The conclusions on the registrant's responsibility for the registration and downstream use of substances will serve as a base for the assessment of a registrant's potential environmental liability under ELD. Understanding the possibilities given to the Member States when implementing the Directive, and legal scholars' critique of the Directive is essential to understand how it could potentially fail to realise the polluters pay principle. The intention of the final analysis is firstly to address the registrant's responsibility with regard to substances of higher concern. Thereafter, the purpose is to identify the connections between REACH and ELD, and a potential inclusion of the registrant in the definition of the operator.

In reaching the above stated purpose, the questions guiding my work in this thesis are therefore:

- What does the registrant's responsibility consist of when registering and ensuring the safe use of substances of higher concern?
- Can such responsibility make the registrant liable under ELD for downstream environmental impairment caused by the hazardous substances he has registered?

1.2 Delimitations and clarifications

This thesis has been delimitated in a number of aspects to preserve its focus on the key issues.

First, I am throughout the text using the term “substances of higher concern”. It is important to have an initial understanding of the meaning of this term. When using the term, I am referring to those substances which are classified “hazardous” in accordance with Directive 67/548/EEC, and those substances identified to have PBT and vPvB properties under Annex XIII of REACH. Hazardous substances are those substances classified as Carcinogenic, Mutagenic and Reprotoxic (CMR) and very toxic to aquatic organisms causing long-terms effects in the aquatic environment (R50/53). PBT substances are those substances identified to have Persistent, Bioaccumulative or Toxic properties, or very Persistent and very Bioaccumulative properties. These substances are together the most dangerous substances on the EU market, and different obligations under REACH will follow when dealing with them.

I am also using the words “hazards” and “hazardousness” in order to describe how the intrinsic properties of a substance leads to the registrant’s decision in the chemical safety assessment that a substance is one of higher concern. Hence, the hazardousness of a substance determines if it is a substance of higher concern.

Second, the complex and comprehensive character of the REACH Regulation and the limited time and space granted to a master thesis, compels to a limitation of the material provisions of REACH. The material content of REACH is described only to the extent necessary for highlighting aspects of the registrant’s responsibility for the registration and safe use of substances. Third, environmental liability under ELD is particularly important with regard to substances of higher concern and possible impairment of nature resulting from their unsafe use. I have therefore focused on the REACH regulatory treatment of so-called substances of higher concern. For the same reason, I will mainly discuss occupational activities related to these substances as listed in Annex III of ELD. These activities I am referring to as ‘dangerous activities’.

Lastly, and with regard to the ‘joint’ element of the registration requirement in REACH, the risk management measures may emanate from a chemical safety report jointly compiled by the registrants of the same substance. It is not within the scope of my analysis to consider the consequences of potential exposure to environmental liability with regard to jointly compiled risk management measures.

1.3 Method and material

This thesis is written and built upon the dogmatic method of traditional legal analysis. Although the meaning of the method is debated, I am in this thesis presenting as well as systematically interpreting the applicable law. Within EC law, as a contrast to the Swedish method, preparatory work lacks legal significance. The text laid down in the Regulation, along with case law is of fundamental importance when presenting the applicable EC law. The

presentation of the applicable law is based on the legal text of the REACH Regulation, case law of the ECJ and textbooks and articles by reputable legal scholars.

The REACH Regulation entered into force on 1 June 2007, and the registration obligation in REACH one year later. This is the reason behind the lack of cases related to REACH lodged at the ECJ until this date. In fact, there is only one case pending at the ECJ, for which the Advocate General has recently issued an opinion.[3] The Guidance documents issued by ECHA will complement the work, despite their lack of direct legal significance. In addition, I am using opinions and articles by legal scholars, as well as practical solutions to REACH problems issued by an international law firm. These serve an auxiliary function for my analysis, as a tool for bringing clarity to some of the issues presented.

1.4 Disposition

The following chapter contains a brief introduction to the situation of EU chemicals regulation before REACH, and the reasons to why the regulatory treatment of chemicals was revised. The chapter presents the main objectives of the REACH regulation; its legal base and a somewhat deeper examination of the precautionary principle. Directive 67/548/EEC and its connection to REACH is also described.

In order to understand who the registrant in REACH is, the third chapter presents these actors and their different obligations. Thereafter, the following sections attempt to describe the REACH system of registration; the main building blocks of the registration obligation and the different requirements. The section on chemical safety assessments and following sections is narrowed down to mainly focus on what the REACH requirements when registering substances of higher concern. The chapter also examines the interplay between the registrant and its downstream user and demonstrates how the registration affects the downstream use of substances. The chapter ends with the assessment on the previously presented system and what effects it may have, and a section describing the different capabilities of actors when carrying out their obligation ends the chapter.

The fourth chapter outlines the environmental liability directive (ELD). First, it describes the main objective of the Directive and how it attempts to make operators liable. Thereafter it examines the different definitions and their interpretations. The chapter points out the different possibilities of Member States when implementing the Directive, and how a Member State may turn the Directive's provisions into a paper tiger.

[3] Opinion of AG Kokott delivered on 10 March 2009: Case C-558/07, *S.P.C.M. and Others*, 10 March 2009.

The last chapter intends to analyse the registrant's responsibility for his registration and the downstream, safe use of substances of higher concern. The chapter presents how the registrant's obligation under REACH, notably the chemical safety assessment with its exposure scenario (including operational conditions and risk management measures) is connected to ELD. The registrant's potential environmental liability for downstream, environmental damage and connection to such damage is examined through the registrant's responsibility for the registration and the impact of exposure scenarios on occupational activity as defined by ELD.

2 Introduction to REACH

2.1 Revision of chemicals regulation

The rapidly growing knowledge on the adverse impact of chemicals in EU was the base of three years of intense political discussion and environmental concerns leading to the proposal of revising the regulatory treatment of chemicals in EU.[4] In its White Paper 2001, the Commission presented the proposal on a future chemicals policy with the overriding goal of sustainable development. The proposal acknowledged the importance of knowledge about the impact of many chemicals on human health and the environment on substances, and underlined that the lack of this knowledge was a cause for concern.[5] It was stated that ”the future EU chemicals policy must ensure a high level of protection of human health and the environment as enshrined in the Treaty both for the present generation and future generations while also ensuring the efficient functioning of the internal market and the competitiveness of the chemical industry. Fundamental to achieving these objectives is the precautionary principle”.[6]

The existing chemicals policy before REACH was presented mainly by four legal instruments covering the regulatory treatment of chemicals in EU. The 1998 investigation of those instruments identified major problems. First of all, the system distinguished between ‘existing substances’, all substances declared to be on the market in September 1981, and ‘new substances’, those placed on the market since that date. Through the system, only new substances were subject to testing and assessment of risks, whereas existing substances which amounted to 99 % of the total volume of all substances on the market were not subject to the same requirements at all. Second, the allocation of the assessment responsibilities on authorities was considered inappropriate. In addition, the legislation did not require industrial users and formulators to provide information. There was a general lack of knowledge on the uses of existing substances. Third, the polluters pay principle in terms of environmental liability concerning chemical substances was by review identified as one of the major problems. As adequate test data on the effects of substances were not available, the causal connection between the cause and the resulting damage was considered problematic to prove.[7] Overall, the previous system often proved to be incapable of identifying risks posed by many chemicals and was slow to act when risks were identified.[8] The EEB stated that the situation was characterised by ‘toxic ignorance’, an

[4] A report of the European Environmental Bureau, *Op. cit.*, p. 3.
[5] White Paper COM(2001) 88 Final, *Strategy for a future Chemicals Policy*, p. 4.
[6] Ibid, p. 5.
[7] Ibid, pp. 5-6.
[8] SCADPlus: Regulatory framework for the management of chemicals (REACH) http://europa.eu/scadplus/leg/en/lvb/l21282.htm.

ineffective reporting and control system and hence by an ongoing in vivo experiment with man and nature.[9]

The weakness of the EU chemicals policy was revealed, and the report on the findings was adopted by the Commission in November 1998 and welcomed by the Council in December 1998.[10] The chemical industry and small and medium sized enterprises opposed REACH on grounds of competitiveness and cost, while environmental NGO's believed that the proposals do not go far enough to protect human health and the environment. Internationally the proposal was criticised for trade reasons. The final proposal was delivered in the Commission White Paper in 2003 and replaces some 40 existing Directives.[11] Despite the opposition during the debates, the final text was accepted unanimously.[12]

2.2 Legal base and objectives

The introductory article's first paragraph states:"The purpose of this Regulation is to ensure a *high level of protection* of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation."[13] This double objective has its goal of environmental concern as well as the free circulation of substances on the internal market. The REACH Regulation stipulates further in its introductory article, as well as in many of its recitals the fundamental objective that it aims to ensure, namely, a high level of human health and environmental protection through the application of the *precautionary principle*.[14]

REACH Regulation is enacted with Article 95 of the EC Treaty as its legal basis. Article 95.1 EC establishes that the Council is to adopt measures for the approximation of provisions laid down by law, regulation or administrative action in the Member States which have as their object the establishment and functioning of the internal market.[15] Article 95 is a 'residual provision' and is to be used only where other more specific Treaty provisions do not fit the subject matter of the measure. The article is very broadly framed, but shall be read in the light of Article 3.1.c and Article 14

[9] EEB first comments to the White Paper on the future EU Chemicals policy, Input to the Stakeholder conference on the Chemicals White Paper, 2 April 2001, p. 1.
[10] Commission Working Document SEC (1998) 1986 final.
[11] COM (2003) 644 Final, *Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}*, p. 11.
[12] Embrechts, Mark, *Compromise on chemicals*, Environmental Policy and Law, 2006, 36/1, p. 41.
[13] Article 1.1 REACH Regulation.
[14] Article 1.3 and Recital 1, 3, 4, 7, 9, 70, 71, 73, 87 REACH Regulation.
[15] Case C-380/03, *Germany v Parliament and Council*, para. 36.

of the EC Treaty, to improve the conditions for the establishment of the internal market. Measures enacted with the provision as its basis shall have genuinely as its object the improvement of the conditions for the establishment and functioning of the internal market.[16] The differences between the laws and regulations of Member States must be such as to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market, in order to justify its use as legal basis.[17] If the EC could rely on the smallest distortions of competition to justify using Article 95, it would contradict the principle of Article 5 by which the EC has only the powers specifically conferred on it.[18]

The 3rd paragraph of Article 95 states that the Commission shall, when passing measures under Article 95.1 relating to health, safety, environmental protection and consumer protection, to take as a base a high level of protection, taking into account in particular any new development based on scientific facts.[19] The legal base for environmental measures has been achieved with both Article 95 and Article 175 referring to Article 174 of the EC Treaty.[20] Both articles state that the legislation concerned is to be adopted with a "high level of protection", with the difference that Article 174 explicitly mentions the precautionary principle. Neither Article 95.3 nor 174 specifies however what a high level of protection is.[21] Neither does Article 95.3 stretch as far to require the provisions to be harmonised in accordance with the standards in the Member State with highest level of protection.[22]

Despite the environmental concern of the Regulation, the choice of legal instrument landed on Article 95. It was explained by the direct effect of regulations from which an expanding Community would benefit from homogenously applicable rules. Furthermore, the Commission explained that the harmonised requirements would allow the free movement of REACH-compliant substances on the internal market, which would reward the efforts required for complying with the high level of protection required by its provisions. It was thus considered more important that substances were imposed by homogenous rules and could circulate freely on the internal market.[23]

The REACH Regulation is further based on the principle of *industry responsibility* for the safe use of substances. The Commission discussed the issue already in its White Paper in 2001, and was included in its final proposal in 2003. There, it was considered one of the important features of the regulation in terms of proportionality, and would permit industry to apply risk reduction measures from an early point in the life-cycle of the

[16] Craig, Paul; De Búrca, Gráinne; *EU law Texts, cases and materials,* 2007, p. 616.
[17] Case C-380/03, *Germany v Parliament and Council,* para. 37.
[18] Craig, Paul; De Búrca, Gráinne, *Op.cit.*, pp. 615-616.
[19] Article 95.3 EC Treaty.
[20] Krämer, Ludwig, *EC Environmental law,* Sweet & Maxwell, London 2003, pp. 4-5.
[21] *Ibid*., pp. 10-11.
[22] Case C-233/94, *Germany v Parliament and Council,* para 48.
[23] COM (2003) 644 Final, *Op. cit.*, p. 11.

substance concerned, and thereby avoid negative impacts on downstream users and customers.[24] Hence, the Regulation relies upon the principle that it is for manufacturers, importers and downstream users to demonstrate, place on the market or use such substances that do not adversely affect human health or the environment.[25] This is carried out by means of the so-called reverse burden of proof.[26] It is crystallised in those *legal entities* that manufacture, import, place on the market or use substances in the context of their professional activities.[27] Moreover, the registration provisions are combined with the *access to market*. Registered substances should be allowed to circulate on the internal market.[28] The responsibility imposed on industry is a paradigm shift in the regulatory chemical policy. It provides different actors along the supply chain with an enormous self-responsibility compared with previous legislation, by placing a primary responsibility on those manufacturing and importing companies. These companies are usually well-informed about the processes occurring within the borders of their activity, but their knowledge on downstream processes decreases further down the supply chain. This is complemented through the central provisions on information up and down the supply chain.[29]

Finally, the Commission has insisted that the principle of non-discrimination and that avoidance of unnecessary obstacles to trade had been taken fully into account at the stage of REACH development and that the registration and authorisation requirements were not "overly restrictive and were workable in practice".[30] The question on whether REACH is World Trade Organization (WTO) - compatible has been discussed from the very beginnings of the negotiations on REACH between the WTO members in the Technical Barriers to Trade (TBT) Committee.[31] In its White Paper of 2001, the Commission underlined that a future chemicals policy should create no unnecessary barriers to trade and there must not be discrimination against imported substances and products.[32] REACH states in its preamble, that "the Regulation shall be applied in a non-discriminatory manner, whether substances are traded on the internal market or internationally in accordance with the Community's international commitments."[33]

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[24] *Ibid.*, pp. 11-12.
[25] Recital 18 and 19 REACH Regulation Preamble.
[26] Hansen, Bjorn and Blainey, Mark, *Registration: The Cornerstone of REACH,* Review of European Community and International Environmental Law, April 2008, Volume 17 Issue 1, p. 121.
[27] ECHA Guidance on Registration, May 2008, p. 13.
[28] Article 1.3, 5 REACH Regulation and recital 19 *á fin* REACH Regulation Preamble.
[29] Führ, Martin; Bizer, Kilian, *REACh as a paradigm shift in chemical policy – responsive regulation and behavioural models,* Journal of Cleaner Production 15, (2007), p. 331.
[30] Forbes, Reshad, *The long arm of REACH: How to navigate through the Compliance process,* European Energy and Environmental Law Review, February 2008, p. 49.
[31] Comments submitted by members of WTO's Committee on Technical Barriers to Trade on the EC notification notification to the TBT Committee: G/TBT/N/EEC/52; The Chinese representative in the WTO Committee on TBT, *Minutes of the meeting of 20 March,* G/TBT/M/44, June 2008, para. 41.
[32] COM (2001) 88 Final, *Op. cit.,* p. 7; COM (2003) 644 Final, *Op. cit.*, p. 55.
[33] Recital 3 REACH Regulation Preamble.

2.3 The precautionary principle

The precautionary principle has been elevated into a general principle of EC law. The ECJ laid down the foundations for the principle in the *BSE* case where it held that "where there is uncertainty as to the existence or extent of risks to human health, the institutions may take proactive measures without having to wait until the reality and seriousness of those risks becomes apparent."[34] The process continued with *Pfizer*[35] and *Artegodan*[36]. In the *Pfizer* case, CFI concluded that the principle is expressly mentioned in Article 174.2 concerning environmental policy. Thereafter, together with Article 6 and Article 3 of the Treaty, the CFI said that "the precautionary principle being a part of environmental policy, should also be a factor in other Community policies, and that the ECJ had in essence and at least very implicitly recognised the principle."[37] The definition and meaning of the precautionary principle is however controversial and open to broad interpretation.[38] According to Craig and De Búrca, the principle can be defined as requiring the competent authorities to act appropriately to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests. Since the institutions are responsible in all spheres of activity for the protection of environment and health, the precautionary principle can be regarded as an autonomous principle.[39]

There is no other public policy comparably dependent on science as the environmental policy. The need to tackle scientific uncertainties has been fostering the raise of the precautionary principle as an autonomous principle of law. The majority of the environmental directives and regulations now follow a precautionary approach.[40] An example is taking measures to ban or restrict the circulation of substances or products such as asbestos, cadmium and phthalates. Under Regulation 793/93, economic operators are obliged to produce a risk assessment for each of these products to find out whether the environment and human risk justifies restrictions. Applying the precautionary principle in this case would mean that measures could be taken without waiting for such a risk assessment.[41] In addition, the ECJ has departed from literal interpretation of obligations laid down in secondary law, and made extensive interpretations on legal concepts by relying explicitly or implicitly on the precautionary principle. The classic example is the difference between waste and product. Based on the precautionary

[34]Craig, Paul; De Búrca, Gráinne, *Op. cit.*, p. 567.
[35] Case T-13/99, *Pfizer Animal Health SA v. Council*.
[36] Cases T-74,76,83-85,132,137 and 141/00, *Artegodan GmbH v. Commission.*
[37] *Pfizer*, *Cit. op.*, paras. 114 and 115. and *Artegodan*, para. 183.
[38] Krämer, *Op. cit.*, p. 21.
[39] Craig, Paul; De Búrca, Gráinne, *Op. cit.*, p. 568.
[40] de Sadeleer, Nicolas, *The Precautionary Principle in EC Health and Environmental law*, European Law Journal, Vol 12 No. 2, March 2006, p. 144.
[41] Krämer, *Op. cit.*, p. 22.

principle, the concept of waste cannot be interpreted restrictively, and preventive action must be taken with regard to waste.[42]

2.4 Directive 67/548/EEC

One of the main horizontal instruments governing chemicals in the EU before REACH was Directive 67/548/EEC on classification and labeling of hazardous substances. The REACH proposal does not include rules for classification, labeling and packaging of hazardous substances. Classification is however a part of the obligations of registrants under the Regulation, which directly refers to Directive 67/548/EEC. Therefore, the relevant parts of the Directive will continue to apply. These rules will be taken over by the Classification, Labeling and Packaging (CLP) Regulation on 1 December 2010 which will fully repeal the Directive on 1 June 2015.[43]

The criterion in Directive 67/548/EEC for classifying substances of higher concern is used in different aspects of REACH. It is used for classifying substances that are carcinogenic, mutagenic and reprotoxic (CMR) or very toxic to aquatic organisms causing long-terms effects in the aquatic environment (R50/53) (hereafter called 'hazardous'). These phase-in substances have shorter deadlines for registration[44] and must be supplied with a safety data sheet.[45] In addition, if the first step of the chemical safety assessment concludes that the substance is hazardous the registrant must conduct an exposure assessment and generate exposure scenarios for the substance.[46]

Lastly, the same criterion in Directive 67/548/EEC is used partly for the identification of certain Substances of Very High Concern (SVHC's) and their possible inclusion on Annex XIV subject to the Authorisation procedure of REACH. SVHC's are substances which are classified hazardous under Directive 67/548/EEC or considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), and included on Annex XIV REACH. The toxicity criterion for PBT substances in REACH is fulfilled when the substance is classified as C, M or R (category 1 or 2) in accordance with Directive 67/548/EEC.[47]

[42] de Sadeleer, Nicolas, *Op. cit.*, p. 145.
[43] COM 2003 (644) Final, p.153.
[44] Article 23.1.a-b REACH Regulation.
[45] Article 31.1 REACH Regulation.
[46] Article 14.4 REACH Regulation.
[47] Art. 57.a-f and Annex XIII REACH Regulation.

3 REACH actors and the registration obligation

3.1 Actors' different roles in the supply chain

The responsibility for the management of the risks of substances lie with the natural or legal persons that manufacture, import, place on the market or use substances within their professional activities. REACH places legal obligations on 'actors in the supply chain'. The roles of actors in the supply chain are manufacturers, importers and downstream users,[48] of which the manufacturers and importers have a registration obligation. The different legal roles of a specific legal entity in the supply chain have specific definitions and meanings, which do not always correspond with how they may be interpreted within other areas of legislation.[49] In addition, the obligations under REACH apply to companies in relation to the business activity of each individual substance, which means that a company can have several roles depending on its activities, even for the same substance.[50]

3.2 The registrant

In the definition, the registrant in REACH is the manufacturer or the importer of a substance submitting a registration for a substance.[51] Each legal entity established within the EU, manufacturing or importing a substance is required to submit its own registration.[52] Within the definition of a manufacturer and importer, the legal concepts natural and legal person is used. Company law is not harmonised in EU, whereas the definitions are determined in accordance with the company law of the Member State as applicable.[53]

In the definition of a registrant the only representative is not explicitly mentioned, but ECHA lists the actors in the supply chain with registration obligations as manufacturers and importers of substances and only representatives established in the EU appointed by a manufacturer, established outside the EU to fulfill the registration obligations of importers".[54]

[48] Article 3.17 REACH Regulation.
[49] ECHA Guidance on registration, *Op. cit.*, p. 17.
[50] ECHA Guidance for downstream users, *Op cit.*, p. 20.
[51] Article 3.7 REACH Regulation.
[52] Article 6.1 REACH Regulation.
[53] ECHA Guidance on registration, *Op. cit.*, p. 19.
[54] *Ibid.*, p. 18.

3.2.1 The importer

Under REACH, the importer is any natural or legal person established within the EU who is responsible for import. Import of a substance is the physical introduction into the EU customs territory[55]. The importer is considered a registrant if it is *responsible* for the physical introduction of a substance into the European Economic Area (EEA). According to the legal definition of "placing on the market", import is considered to be placing on the market.[56] According to ECHA, a so-called 'sales agency' simply facilitating the order from one legal entity to another, cannot be considered an importer. The responsibility for the physical introduction into the customs territory depends on different factors such as who orders, who pays, who is dealing with the customs formalities, and who is taking the ownership of the goods. The shipping company is not to be mistaken for the importer, nor is the non-EU manufacturer. ECHA mentions exceptions to this if there are specific contractual arrangements where the shipping company is established in the EU and if it is responsible for the introduction of the substance in the EU. [57] According to an international law firm, the role of an importer may be achieved by taking on the responsibility for the import in different ways. This is a part of a strategy recommended to multinational company groups trying to achieve the most suitable control of the registration process of their substances. To avoid dependence on the independent EU based importers registration, the role of an importer may be taken by an EU-based company belonging to the group. The required responsibility for the import would be acquired through simply re-arranging the supply chain and thereby act as importer for the whole non-EU group.[58]

3.2.2 The manufacturer

The manufacturer is any natural or legal person established within the Community who manufactures a substance within the Community. Manufacturing means production or extraction of substances in the natural state.[59] As stated above, REACH is concerned with the legal entity *responsible* for the manufacturing activity. To determine whether the activity manufacturing within the meaning of REACH, the activity shall be addressed case-by-case to establish which steps of the synthesis of the end product lead to a substance which need to be registered.[60] An actor may contract a third party ('sub-contractor') to carry out an activity on his behalf. In cases where sub-contractors manufacture the end substance subject to registration, they will have the obligation to register. The nature of the obligations is determined by the activity agreed upon by both parties in the

[55] REACH apply in EEA EFTA-states (Norway, Iceland and Liechtenstein).
[56] Article 3.10-12 REACH Regulation.
[57] ECHA Guidance on registration, *Op. cit.*, p. 21.
[58] McDermott Will & Emrey, *REACH Update: Importer or Only Representative Options of (pre-)registration of multinational groups*, August 2008, pp. 3-5.
[59] Article 3.8 and Article 3.9 REACH Regulation.
[60] ECHA Guidance on registration, *Op. cit.*, p. 17.

contract. This is consistent with the concept of toll manufacturing in Directive 67/548/EEC.[61]

3.2.3 The only representative

The non-Community manufacturer of substances has no obligations under REACH and cannot register substances. This manufacturer may, by mutual agreement, appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers.[62] The non-Community manufacturer only may appoint *one* only representative per substance, but on the other hand may cover by a single registration all imports into the Community.[63] The appointment will relieve the importer within the same supply chain of his registration obligation, since through the appointment the importer will be regarded as a downstream user for the purposes of REACH.[64] An importer is responsible for registering all the substances he imports with an exception to those quantities of the substance that is covered by the only representative's registration.[65]

The only representative shall have sufficient background in the practical handling of substances and the information related to them. The meaning of this requirement or the level of "sufficient background" is not further specified. The purpose is that the only representative shall possess the requirements needed to be able to fulfil the obligations of importers.[66] It is suggested that the intention of the provision is that substances are handled adequately and that sufficient risk management measures are taken. Therefore, a general knowledge of substances, such as possessed by a chemist, should be sufficient for this purpose.[67] According to Flück et al., the only representative as a legal concept *sui generis*. He acts on empowerment by a non-Community manufacturer and cannot dispose autonomously out of his legal position. Therefore, he does not act entirely in his own right as an independent importer as he is simply a 'vehicle' of the non-Community manufacturer. The only representative is creating a level-playing field in the Community by means of complying with the obligations of importers in the form of a representative of a non-Community manufacturer.[68]

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[61] ECHA Guidance for downstream users, *Op. cit.*, p. 22; see also European Chemicals Bureau, *Manual of decisions for implementation of the sixth and seventh amendments to Directive 67/548/EEC on dangerous substances (Directives 79/831/EEC and 92/32/EEC)*, Updated version July 2006, p. 113.
[62] Article 8 REACH Regulation; see also ECHA Guidance on registration, *Op. cit.*, p. 21.
[63] ECHA Guidance on registration, *Op. cit.*, p. 22.
[64] Article 8.3 REACH Regulation.
[65] ECHA Guidance on registration, May 2008, p. 22.
[66] Article 8.2 REACH Regulation.
[67] Fluck, Jürgen et al., *Op. cit.*, note 32.
[68] *Ibid.*, note 16; see also Fischer, Kristian, *Legal Opinion on the Only Representative*, May 2008, p. 10.

The scope of the representation is *"all obligations on Importers under this Title*".[69] The title concerned is Title II, and includes the obligations of registrants as listed in the next section.

3.2.4 The registrant's responsibilities

The registrant has the primary responsibility for the collection of data and the compiling of the registration dossier, as well as the next step for minimisation of risks.[70]

In summary, the responsibility of registrants consists of pre-registering phase-in substances; collect and share existing information, and generate and propose to generate new information on properties and use conditions of substances; prepare the technical dossier; prepare a chemical safety assessment and a chemical safety report including exposure scenarios and risk characterisation for each substance in quantities above 10 tonnes per registrant which are substances of higher concern; implement appropriate risk management measures of own use; submit registrations for substances in quantities above the annual 1 tonne per registrant; keep the information submitted in the registration up-to-date and submit updates to ECHA; classify and label substances and preparations that are placed on the market; notify and register classification of hazardous substances with ECHA for the classification and labeling inventory for all substances placed on the market; prepare and supply safety data sheets for substances and preparations as required by Article 31 and Annex II to downstream users and distributors; recommend appropriate risk management measures in safety data sheets; communicate exposure scenarios developed in chemical safety assessment as annex to safety data sheet for substances in quantities above 10 tonnes per year per registrant (the extended safety data sheet); prepare and supply information on non-classified substances as required by Article 32 to downstream users and distributors; respond to any decision requiring further information as a result of the evaluation process; comply with any restrictions on manufacture, placing on the market and use of substances as set out in Annex XVII; apply for authorisation for uses of substances listed in Annex XIV.[71]

3.3 The registration obligation

"The cornerstone of REACH is registration." [72]

The registration provisions are built on the idea that if sufficient information is available for a substance, then generally industrial actors must implement

[69] Article 8.1 REACH Regulation.
[70] Führ, Martin; Bizer, Kilian, *Op. cit.*, p. 332.
[71] ECHA Guidance on registration, *Op. cit.*, Appendix 2, (1) and (2).
[72] Hansen, Bjorn and Blainey, Mark, *Op. cit.*, p. 107.

sufficient risk management measures for the safe use of such substances. Also, it was considered inefficient and inappropriate for authorities to determine case-by-case what information industry needs to have available.[73]

The registration obligation requires information to be submitted at certain amounts based on the tonnage of a substance imported or manufactured per year. The higher tonnage, the more data shall be included in the registration dossier. In addition to the tonnage, the classification of a substance determines the deadline for the submission of the dossier.[74] The registration provision makes difference between so-called phase-in substances and non-phase in substances. This structure is inherited from the previous legislation, where 'new' and 'existing' substances were subject to different requirements. A phase-in substance in REACH is being either listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)[75]; or manufactured but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of REACH; or placed on the market before entry into force of REACH and was considered as having been notified in accordance with Directive 67/548/EEC.[76] For these substances, the registration dossier can be submitted by the deadlines foreseen by REACH, provided that the substance has been pre-registered before 1 December 2008.[77] Non phase-in substances are substances not fulfilling the criteria for phase-in substances, and must be registered without benefiting from the phase-in deadlines before they can be manufactured in, or imported into the EEA.[78] Before registering a non phase-in substance, the registrant must inquire at ECHA by means of an inquiry dossier, to find out whether the substance has already been registered by another registrant. If this is the case, data and cost sharing mechanisms apply to these registrants.[79]

There are several exemptions from the general registration obligation, but also complementary requirements.[80] Moreover, the registration dossier contains all 'identified uses'[81] of a substance in the whole supply chain.[82] This means that the substance registered can only be used for those uses identified in the registration dossier.[83]

[73] *Ibid.*, p. 111.
[74] Article 10, Article 12, and Article 23 REACH Regulation.
[75] This list is available at http://ecb.jrc.it/esis/.
[76] Article 3.20.a-c REACH Regulation.
[77] Article 23 and Article 28 REACH Regulation.
[78] ECHA Guidance on registration, *Op. cit.*, p. 47.
[79] Article 26 and Article 27 REACH Regulation.
[80] See for example Article 2.7.a-b, Article 6.2, Article 6.3 and Article 9 REACH Regulation.
[81] More on use and identified use, below.
[82] Article 10.a.iii REACH Regulation.
[83] Nilsson, Annika, *Reach och hållbar kemikaliehantering*, Koll på kemikalier, Ebbesson & Langlet, 2009, p. 3.

3.3.1 The registration dossier

The registration provisions in REACH require each legal entity responsible for the manufacture or import of a substance, in quantities of one tonne or more per year, to submit a registration to ECHA.[84] This is the general obligation to register a substance, and means in practice that these legal entities are under an obligation to generate data in the form of a registration dossier on the substances they manufacture or import. For substances of higher concern they are obliged use these data to assess the risks related to the substance. [85] The registration obligation applies to all substances, irrespective of their hazard classification if they are not explicitly exempted from registration.[86]

The provisions are built on a tonnage-based structure.[87] The meaning of the structure is that information requirements on the registration dossier (and the deadlines set for the registration of phase-in substances) are based on the average yearly tonnage manufactured or imported per legal entity.[88] The data to be generated is reduced at lower tonnages and the deadline for generating the data and submitting the dossier is shorter the higher the tonnage is.[89] The tonnage ranges are equivalent or more than 1 tonne, 10 tonnes, 100 tonnes and 1000 tonnes.[90]

Regardless of tonnage range, each registrant is required to submit a 'technical dossier', which includes the identity of the registrant, the identity of the substance and information on its manufacture and use, the classification and labeling of a substance, guidance on its safe use, study summaries of the information on the intrinsic properties of the substance and an indication as to whether some of the separately submitted information has been reviewed by an assessor. The technical dossier shall also contain proposals for further testing (if applicable) and for substances in 1-10 tonnages it shall contain exposure information defining main use categories, types of uses and significant routes of exposure.[91]

The information requirements are set out in the Annexes VI to XI of the Regulation. For the lowest tonnage level, the standard requirements are in Annex VII, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure.[92] This way the information requirements applicable for

[84] Article 6.1 REACH Regulation.
[85] ECHA Guidance on Registration, May 2008, p. 13.
[86] *Ibid.*, p. 27.
[87] Hansen, Bjorn and Blainey, Mark, *Op. cit.*, p. 116.
[88] ECHA Guidance on registration, May 2008, p. 48.
[89] Article 10, 12 and 23 REACH Regulation.
[90] Article 23 REACH Regulation.
[91] Article 10.a.i, ii, iii and x, Article 11.1 REACH Regulation and ECHA Guidance on registration, *Op. cit.*, p. 50.
[92] Annex VI, Guidance note on fulfilling the requirements of Annexes VI to XI, REACH Regulation.

substances in the 1000 tonnes category are all of Annexes VI-XI, including a chemical safety report.[93]

The registration dossier is generated in the following way: The registrant gathers all existing available test data on the substance to be registered, including literature search for relevant information and all other available and relevant information on the substance. This may include information from alternative resources which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests. This procedure shall be carried out jointly in accordance with the provisions on joint submission[94] between registrants of the same substance. Based on the tonnage, the registrants shall identify the information required to then compare with the information already available and identify where there are gaps. Where there is an information gap that needs to be filled, new data shall be generated in accordance with Annexes VII and VIII, or a testing strategy shall be proposed in accordance with Annexes IX and/or X.[95] REACH provides for the possibility to waive some of the testing. This is built into the text in several places. In each of the testing Annexes IX-X, column 2 sets out circumstances when testing is not needed. For example, when certain information requirements are already fulfilled, testing is unnecessary.[96]

The generation and submission of the registration dossier is based on the principle of joint submission of data. This means that all registrants of the same substance shall submit certain parts of the dossier together. This is called the joint dossier. The joint dossier consists of the classification and labelling of a substance, study summaries of the information requirements in Annex VI-XI and robust study summaries if required, test proposals as listed in Annex IX, as well as an indication as to which of the information submitted has been reviewed by an assessor. The guidance on safe use and the chemical safety report may be carried out individually or jointly.[97] The generation of the dossier is coordinated by means of a Substance Information Exchange Forum (SIEF), in which all registrants of the same substance agree on exchange of existing data and on the joint generation of new data.[98] The intention behind the joint dossier is that registrants will save money by co-operating on the preparation of the dossier, which will reduce the need for testing, in particular on vertebrate animals.[99] This way REACH does not generate unnecessary testing on vertebrate animals, which shall be conducted only as a last resort.[100] However, the registrants participating in a SIEF are individually obliged to submit the individual part

[93] Article 12.1.a-e REACH Regulation.
[94] More on joint submission below.
[95] Annex VI, Step 1-4, REACH Regulation.
[96] Hansen, Bjorn; Blainey, Mark, *Op. cit.*, p. 119.
[97] Article 11.1 REACH Regulation.
[98] Aricle 11, 27, 29 and 30 REACH Regulation.
[99] ECHA Guidance on registration, May 2008, p. 55.
[100] Article 25.1 REACH Regulation.

of the dossier for each of their substances, and the principle of 'no data, no market' applies to each actor individually.[101]

3.3.2 The chemical safety assessment

The chemical safety assessment is in effect a combined risk assessment and risk reduction strategy carried out by the registrant for all the identified uses of their substance and is required for substances in quantities of 10 tonnes or more per year per registrant.[102] The chemical safety assessment is to be considered the tool for realising the principle that it is for industry to manufacture, import or use substances in a way that human health and the environment are not adversely affected. The assessment includes determining the hazard classification. When the substance is a substance of higher concern (classified as CMR or R50/53, ('hazardous'), or assessed to have persistent, PBT or vPvB properties), the aim of the chemical safety assessment is to identify the conditions ensuring control of risks arising from manufacture and uses of a substance. The registrants may decide themselves if the chemical safety assessment shall be conducted jointly in the SIEF or individually by each registrant.[103]

The chemical safety report is the documentation of the chemical safety assessment and is then submitted to the authorities as part of the registration dossier. For substances of higher concern the process prepares a set of corresponding information on operational conditions and risk management measures to be communicated to the users of the substance. These are the conditions for manufacture and use for controlling the risks.[104] The goal of the assessment is not to establish whether or not there is a risk, but to identify and describe the conditions under which the risks are controlled.[105] Any registrant required to conduct a chemical safety assessment must keep his chemical safety report available and up to date.[106] The safety data sheet shall also be kept consistent with the information in the chemical safety assessment.[107]

The first step in the chemical safety assessment is for the registrant to collect and evaluate all available relevant information on the substance. As explained above, this is done jointly with other registrants of the same substance within the SIEF. Thereafter, the registrant shall compare the standard information of intrinsic properties as laid down in Annexes VII-X stating the information requirements. Based on the data gap, the registrant then generates new data and/or proposes a testing strategy. The information

[101] Article 5 REACH Regulation.
[102] Article 14 REACH Regulation; and Hansen, Bjorn; Blainey, Mark, *Op. cit.*, p. 112.
[103] ECHA Guidance on [...] chemical safety assessments, *Part A: Introduction to the guidance document, Op. cit.*, p. 7; and Article 11.1 section 4 REACH Regulation.
[104] More on operational conditions and risk management measures, below.
[105] ECHA Guidance on [...] chemical safety assessments, *Part A: Introduction to the guidance document, Op. cit.*, pp. 7-9.
[106] Article 14.7 REACH Regulation.
[107] Article 31.2 REACH Regulation.

made available under the steps above is used in the hazard assessment, which the first step of the chemical safety assessment. The hazard assessment aims to determine is the substance is a substance of higher concern with regard to human health hazard, physiochemical hazard, environmental hazard or considered to be a PBT or vPvB substance. If the substance is not a substance of higher concern, the chemical safety assessment can stop here. The results are documented in the chemical safety report.[108] If the registrant concludes that the substance indeed meets any of these criteria, an exposure assessment and risk characterisation shall be carried out and an exposure scenario shall be generated. The chemical safety assessment shall include the relevant exposure scenarios in an annex to the safety data sheet covering identified uses.[109] For the manufacturers and importers of substances in the tonnage range at 10 tonnes or more, the reverse burden of proof is specifically important. The manufacturer or importer must demonstrate in their chemical safety report that the use of the substance is safe when it is registered.[110]

3.3.3 The exposure assessment and exposure scenario

An exposure scenario is the set of conditions, including operational conditions and risk management measures that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate[111] As already explained, the exposure assessment and risk characterisation is performed as a part of the chemical safety assessment for substances for which the registrant concludes that the substance meets the criteria for a substance of higher concern.[112] Exposure scenarios are the core of the process to carry out a chemical safety assessment. The first step in the assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures.[113]

Operational conditions aim to specify the circumstances of use of a substance through describing the types of activity to which the exposure scenario relates. This includes the processes involved; the activities of workers related to the processes and the duration and frequency of their

[108] Article 14.3 REACH Regulation; and ECHA Guidance on [...] chemical safety assessments, *Part A: Introduction to the guidance document, Op. cit.*, pp. 10-11.
[109] Article 14.4.a-b REACH Regulation.
[110] Hansen, Bjorn; Blainey, Mark, *Op. cit.*, p. 121.
[111] Article 3.37 REACH Regulation.
[112] Article 14.4 REACH Regulation.
[113] Annex I, General provisions for assessing substances and preparing chemical safety reports, Section 5.1.1. REACH Regulation.

exposure to the substance; the activities of consumers and the duration and frequency of their exposure to the substance; the duration and frequency of emissions of the substance to the environment and sewage treatment systems and the dilution in the receiving environmental compartment. Risk management measures mean an activity or device that reduces or avoid direct and indirect exposure of humans and environment to the substance, including waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling.[114] The operational conditions and risk management measures are a part of the exposure scenario and are compiled into one or more exposure scenarios to be annexed to the extended safety data sheet.[115] The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation.[116]

The exposure assessment shall cover any exposure that could relate to hazards as identified in the hazard assessment. This includes the generation of exposure scenarios and exposure estimation. The first step of the exposure assessment is to assess how the substance is currently used throughout the whole supply chain. For the different routes of exposure in the current use, exposure estimation is carried out to estimate the concentration of the substance in different situations. The estimations shall correspond to the operational conditions and risk management measures as defined in the current use of the substance. The chemical safety assessment can be stopped and documented in the chemical safety report and the exposure scenarios can be communicated down the supply chain when the chemical safety assessment demonstrates control of risks for all exposure scenarios and when all information needed under Annex VII-X on intrinsic properties has been generated, or the relevant testing proposals have been described. If it is not possible to control the risks, the chemical safety assessment shall be refined in different ways. This means that the operational conditions and risk management measures are, in an iterative process, adjusted with the aim of finally arriving in a derived no-effect-level. This can be carried out, for example, through conducting additional testing or through the use of a higher tier tool to make a more precise estimate of the exposure levels, or narrowing down the range of uses or introducing additional measures to control the risk. The purpose of the risk characterisation of the substance is to finally conclude that the estimated exposures for all identified uses do not exceed these no-effect-levels.[117] The exposure scenarios, exposure assessment and risk characterization shall address all identified uses of the registrant.[118]

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[114] Annex I, General provisions for assessing substances and preparing chemical safety reports, Section 5.1.1. REACH Regulation.
[115] ECHA Guidance on [...]chemical safety assessments, *Part A: Introduction to the guidance document, Op. cit..*, p. 9.
[116] Annex I, General provisions for assessing substances and preparing chemical safety reports, Section 5.1.1. REACH Regulation.
[117] *Ibid.*, pp. 11-14.
[118] Article 14 REACH Regulation.

3.4 The downstream user

A downstream user is any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, in the course of his industrial or professional activities. The downstream user does not have registration obligations.[119] There are three main roles of downstream users: a formulator of preparations, a final user of substances in professional activities and an industrial user of substances which do not remain in the final product.[120] The consequences of a registration for a downstream user are that a registered substance will continue to be available on the market. The potentially changed classification and labeling of substances will create the obligation for downstream users to review their own classification and labeling and safety data sheets received with exposure scenarios will create additional obligations.[121] As a consequence of the principle 'no data no market', the substance cannot be used by the downstream user if it has not been registered. That is why ECHA recommends downstream users to communicate early with their supplier (if the supplier is not the registrant, the supplier shall forward the information to the next actor up the supply chain) to be able to provide the registrant with the information on use to prepare the registrations and to develop exposure scenarios.[122] ECHA underlines the importance for downstream users of understanding their own use when providing the relevant information to their supplier. It is the registrant's responsibility to determine if a substance meets the criteria for substances of higher concern. The existing safety data sheet should indicate this. According to ECHA, these substances shall be given high priority when a downstream user is assessing its uses.[123]

A downstream user of a substance shall prepare a chemical safety report for any use outside the conditions described in an exposure scenario or for any use his supplier advises against. A downstream user can also prepare his own chemical safety report in order to cover the use that one of his customers has made known to him. He may also forward this new use to his supplier who will take care of the drafting of a new chemical safety report. If the downstream user compiles his own safety report for a use that is not covered by the safety data sheet, he must inform ECHA.[124]

Downstream users have several information obligations and prerogatives, which are directed both up and down the supply chain. With regard to a substance of higher concern, the downstream user must pass on any new information on its hazardousness, and as explained above, in case he is a receiver of risk management measures he must pass on any information

[119] Article 3.13 and Article 6.1 REACH Regulation.
[120] ECHA Guidance for downstream users, *Op. cit.*, p. 22.
[121] *Ibid.*, p. 17.
[122] *Ibid.*, pp. 29-30.
[123] *Ibid.*, pp. 31-34.
[124] Article 37.4 and Article 38 REACH Regulation.

likely to raise doubts to the appropriateness of those measures contained in the safety data sheet.[125] Any actor in the supply chain are under a general obligation to communicate new information on hazardous properties to the next actor or distributor up the supply chain. New information on hazards may influence the supplier's recommendations on risk management measures.[126]

3.4.1 The extended safety data sheet

Any actor in the supply chain performing a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. A safety data sheet shall be kept up to date as soon as new information which may affect the risk management measures or new information on hazards becomes available or information with regard to authorisations or restrictions.[127]

The registrant shall place the relevant exposure scenarios in an annex to the safety data sheet covering the identified uses, if the substance is considered a substance of higher concern. The safety data sheet is called extended safety data sheet when an exposure scenario has been annexed to it, and thus contains the operational conditions and risk management measures.[128] If, as a result of the assessment, the substance is not however considered one of higher concern, the exposure assessment does not need to be carried out, and the safety data sheet will simply reflect the chemical safety assessment, thus supplied without any operational conditions and risk management measures.[129] The information in the safety data sheet shall allow the user to adequately control risks and shall be kept consistent with the information in the chemical safety assessment.[130] On the safety data sheet the registering company or undertaking shall be identified. This person shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.[131] Only representatives are not explicitly mentioned, whereas he therefore has to be referred to as importer there.[132]

3.4.2 Identified use

A use under REACH is defined as any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other

[125] Forbes, Reshad, *Op. cit.*, p. 38.
[126] Article 34.a-b REACH Regulation.
[127] Article 31.2 and Article 31.9 REACH Regulation.
[128] ECHA Guidance on [...] chemical safety assessments, *Part A: Introduction to the guidance document*, *Op. cit.*, p. 9.
[129] Article 14.2, Article 14.7 and Article 31.2 *é contrario* REACH Regulation.
[130] Article 12 and Article 37.5 REACH Regulation.
[131] Annex II, Section 1.3 REACH Regulation.
[132] Fluck, Jürgen et al., *REACH + Stoffrecht, kommentar, Stand: Grundwerk*, March 2008, Article 8 note 36.

utilisation.[133] A use is the professional activity of a downstream user with regard to a substance. An identified use is a use of a substance that is intended to be registered by an actor in the supply chain, including the registrant's own use, or a use that is made known to him in writing by an immediate downstream user.[134] Identified uses are all uses included into the registration dossier.

Any downstream user has the right to make a use known in writing to the manufacturer or importer with the aim of having his use included into the registration dossier of the registrant.[135] For phase-in substances, this request shall be made 12 months before the applicable registration deadline.[136] The amount of detail that is needed in order to include the use of a substance into the registration dossier depends upon the nature of the substance and what the information will be used for. As a starting point, a brief general description of use is required. More details on the use will be needed for substances of higher concern to prepare a chemical safety assessment and exposure scenarios.[137] A registrant is not obliged to include a use made known, in its registration dossier. Having assessed the use, he may consider the use unsafe and decide to advice against such use.[138]

As explained above, for substances of higher concern the registrant shall place the relevant exposure scenarios in an annex to the safety data sheet covering the identified uses. The identified use of a substance of higher concern will receive operational conditions and risk management measures in the exposure scenario annexed to the safety data sheet covering his use.[139] The downstream user is obliged to identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in the extended safety data sheets supplied to him. Each downstream user of a substance supplied together with an extended safety data sheet must ensure that his use conditions are covered by that scenario.[140] For substances in quantities between 1 – 10 tonnes, the exposure information is not detailed, and the uses are divided into main use categories, type of uses, and significant routes of exposure.[141] A receiver of risk management measures has the responsibility to communicate to the next actor or distributor up the supply chain any information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him. Risk management measures communicated via an exposure scenario may be compliance checked through comparing the conditions described in the exposure scenario with own practices. When doing this, three different cases may occur: the

[133] Article 3.24 REACH Regulation.
[134] Article 3.26 REACH Regulation.
[135] Article 37.2 REACH Regulation.
[136] Article 37.2-3 REACH Regulation.
[137] ECHA Guidance for downstream users, *Op. cit.*, p. 89; see also ECHA Guidance on [...] chemical safety assessments, *Part A: Introduction to the guidance document, Op. cit.*, p. 28.
[138] Article 37.3 REACH Regulation.
[139] Article 14.7 and Article 37.2 REACH Regulation.
[140] Article 37.5 REACH Regulation; ECHA Guidance for downstream users, *Op. cit.*, p. 44.
[141] Annex VI, Section 6, REACH Regulation.

downstream users use is covered by the exposure scenario, and he does not need to take any actions; the downstream users use differs from the exposure scenario and a more detailed compliance check should be carried out; the downstream users use is not covered by the exposure scenario. In such case the downstream user should either make his use known to his supplier with the aim of having it included into the registration dossier, or implement the conditions of use as they are provided, or substitute the substance with another which is not supplied with extended safety data sheets (i.e. not a substance of higher concern), or find another supplier who provides extended safety data sheets that cover the use of the downstream user.[142]

3.5 Effects of the registration system

Article 95 of the EC Treaty as a legal base requires the co-decision procedure in the European Parliament during the legislative process. After the 2003 REACH proposal, the Regulation underwent two readings in the Parliament. In its first reading, the contents of the registration dossier and its information requirements played a big role in the discussions. The debates finally ended in a reduction of information requirements for low volume substances.[143] As a result in the final text, the required safety information was radically reduced for two-thirds of the substances produced above one tonne.[144]

The deadlines for submitting a registration dossier for a phase-in substance follows the tonnage structure with an exception to substances considered hazardous. Hazardous substances (regardless of quantity) and substances exceeding 1000 tonnes shall be registered on 1 December 2010. Substances exceeding the 100 tonnes shall be registered on 1 June 2013, and substances exceeding 1 tonne shall be registered on 1 June 2018.[145] Thus, in case of a hazardous (CMR, R50/53) substance, the deadline is shorter although the tonnage only exceeds 1 tonne or more. The information requirements are however not increased.[146] The Commission proposal of a tonnage based structure was received with great criticism. Alternative schemes, such as a risk-based prioritisation were proposed. The Chemicals Industry Association (CEFIC) proposed a scheme (which was never realised), in which the timing of registering substances would depend on whether the substance posed a low or a high risk.[147] Initial PBT- testing of a substance has been discussed as an alternative to tonnage when determining the risk of

[142] Article 34.a-b REACH Regulation; ECHA Guidance for downstream users, *Op. cit.,* pp. 44, 55 and 99.
[143] Hansen, Bjorn; Blainey, Mark, *Op. cit.,* p. 112.
[144] A report of the European Environmental Bureau, *Op. cit.,* p. 4.
[145] Article 23.1-3 REACH Regulation.
[146] There is however an exception: substances registered between 1 and 10 tonnes that meets Annex III criterions must also be provided with information on the physicochemical properties of the substance in accordance with Annex VII. Article 12.1 REACH Regulation.
[147] Hansen, Bjorn; Blainey, Mark, *Op. cit.,* p. 113.

a substance. This type of system could however be difficult to manage from a regulatory perspective as it would need a great deal of input from the authorities in deciding what further information would be needed.[148]

In its second reading, the Parliament adopted with a broad majority the requirement of a chemical safety report of all substances manufactured and imported in quantities between 1-10 tonnes per year. The Parliament required that the chemical safety report or at least some form of risk assessment by producers, must apply to all substances covered by the reform, and not just those above ten tonnes per year.[149] This approach was not supported by the Council and not included into the final text of the Regulation. A chemical safety assessment means that the data provided for in the registration dossier is assessed. The assessment is initiated for all substances over 10 tonnes, but stops after the hazard assessment for substances which are not hazardous or considered a substance of higher concern. Exposure is thus only being fully assessed for the most hazardous substances manufactured or imported in quantities over 10 tonnes. Therefore, for most substances the assessment is not very extensive. The exposure related information for substances in quantities between 1 – 10 tonnes is reduced to exposure categories and main patterns of exposure.[150]

According to the European Environmental Bureau (EEB), two-thirds of the 30,000 substances on the EU market to be registered under REACH, manufacturers and importers submit only safety data which they already possess. It means that only 10% of the 100,000 chemicals on the EU market would be safety-assessed. If a chemical safety report would be mandatory for all registered substances, it would avoid creating a charnel house of unused data. It would provide a proper standard for the producer's responsibility and would considerably limit downstream users' liability.[151]

The question on whether REACH realises the precautionary principle has been subject to discussion. The answer would obviously depend on an extensive analysis of the different provisions and their effect. According to Løkke, REACH is characterised by explicit reference to precaution and attempts to make precaution a part of the implementation, but there are also signs showing the opposite.[152] According to Nilsson, REACH sets an insufficient but nevertheless important minimi-level of chemical safety thorugh requiring that substances cannot be used without the application of general safety measures. However, if the provisions of REACH are interpreted strictly in the light of its legal basis; to allow the free movement of goods (substances), the objective of the Regulation will suffer;

[148] Nilsson, Annika, *Op. cit.*, p. 5; see also Hansen, Bjorn; Blainey, Mark, *Op. cit.*, p. 115.
[149] A report of the European Environmental Bureau, *Op. cit.*, p. 10.
[150] Annex VI, Section 6 REACH Regulation.
[151] A report of the European Environmental Bureau, *Op. cit.*, p. 10.
[152] Løkke, Søren, *The Precautionary Principle and Chemicals Regulation*, Environmental science and pollution research, Springer Berlin / Heidelberg, Volume 13, Number 5 / September 2006, p. 6.

guaranteeing a high level of protection of human health and the environment.[153]

3.5.1 Risk management measures

The obligation to compile risk management measures in the chemical safety assessment for substances of higher concern is not supplemented with clear guidelines or criterions on how to instruct the safe use of those chemicals. Annex I simply refer to the information obtained from the exposure estimation when the registrant is implementing on its site, and recommending for downstream users, risk management measures. This information consists of three elements of the exposure estimation: emission estimation; assessment of chemical fate and pathways; and estimation of exposure levels.[154] ECHA has developed a standardised system to structure and describe risk management measures: a risk management library. It contains a first structured collection of available risk management measures for the different target groups and exposure routes. However, the content of the library, including the information on effectiveness of certain risk management measures has not been validated by ECHA. Therefore, ECHA states explicitly that the library cannot be quoted in the chemical safety report as providing scientific evidence on appropriateness of risk management measures related to a certain exposure scenario.[155] The registrant seems to have the freedom to independently decide the criterions for the development of risk management measures. The self-regulatory designation of these provisions create reasons to believe that the risk management measures will not contain measures recommending the user to reduce the dosage of the substance or measures aiming at substitution of the substance. It is more likely that the measures will be as simple and cost-effective as possible, in order to maintain the market position of the substance in the supply chain. The possibility of further institutional control or review of the risk management measures would guarantee the high level of protection of those measures.[156]

3.6 Dossier evaluation

ECHA may evaluate any of the submitted registration dossiers. The main purpose of this evaluation is to check whether a registrant is meeting his obligations. The examination will be carried out to verify a technical completeness in accordance with the information requirements; that the adaptations of the standard information requirements and the related justifications submitted in the technical dossiers comply with the applicable

[153] Nilsson, Annika, *Op. cit.*, p. 26.
[154] Annex I, Section 6.5 and Section 5: Step 2, REACH Regulation.
[155] ECHA Guidance on information requirements and chemical safety assessment *Part D: Exposure Scenario Building*, May 2008 (Version 1.1), p. 35.
[156] Nilsson, Annika, *Op. cit.*, p. 7.

rules; and that whenever there is a chemical safety report included into the dossier, that the report comply with Annex I the general provisions for assessing substances and preparing chemical safety reports, and that its proposed risk management measures are adequate. If the dossier is considered incomplete, the result of the check may result in a requirement on the registrant to submit more information. The registrant is obliged to react to such decisions. All dossiers will not be checked; ECHA must select at least 5 % of the submitted dossiers. The checked dossiers will be available to the Member State competent authorities.[157] ECHA will apply both random and non-random prioritisation criteria for the compliance check of dossiers.[158]

With regard to the compliance check of the chemical safety report and the adequateness of risk management measures, ECHA's objective is to check compliance with the general provisions for assessing substances and preparing chemical safety reports and that the proposed risk management measures are adequate. In the Guidance on dossier evaluation ECHA states that "within the compliance check of the chemical safety report, the information should be checked for quality and the adequacy of the risk management measures should be evaluated. However, a compliance check does not mean that a "new" chemical safety report should be produced by re-evaluating the data". ECHA should check the exposure assessment (including exposure scenario and exposure estimation) wherever the substance meets the criterion for being a substance of higher concern. Risk management measures are a part of the exposure scenario and checking the adequacy of risk management measures is an integral part of checking the chemical safety report.[159] ECHA has specified the compliance check of risk managment meaures by stating that the deriviates of the exposure estimate will be matched with the exposure scenario.[160]

In the legal text, the evaluation of dossiers is concerned with the verification of the information requirements in general. In there, no special attention is given the check of risk management measures.[161]

3.7 Capabilities of different actors

Actors along the supply chain have different obligations and different capabilities to reduce the risks of substances. The primary responsibility lies with the registrant.[162] In Case C-558/07 it was claimed that some of the obligations under REACH are discriminatory and places a much heavier

[157] Article 41.1-5 REACH Regulation; see also ECHA Guidance on dossier and substance evaluation, June 2007, p. 15 and 39.
[158] ECHA Guidance on dossier and substance evaluation, *Op. cit.,* p. 43.
[159] ECHA Guidance on dossier and substance evaluation, *Op. cit.,* pp. 49-50.
[160] ECHA: Lebsanft, Joerg , *"ECHA's first experiences with evaluation"*, presentation at ECHA 2nd Stakeholder day, 27 May 2009.
[161] Nilsson, Annika, *Op. cit.,* p. 8.
[162] Führ, Martin; Bizer, Kilian, *Op. cit.,* p. 331.

burden on importers, since importers in many cases need the support of external suppliers (non-Community manufacturers) before they can take any steps to register a substance. The Advocate General made comparison between importers and manufacturer which lead her to the conclusion that importers and manufacturers are in fact not affected equally by REACH. She also stated that they are not in a similar situation either. That importers are affected differently by the obligation of registration corresponds to that difference from the position of a manufacturer.[163]

Downstream users have more knowledge on the downstream processes, as well as certain emissions and exposures which is brought to the registrant's attention through the obligation to provide information up the supply chain. The downstream user is usually the link between the substance manufacturer and the wide public consumers of the substance. The downstream user has environmental liability as well as civil law liability directed against him. Any liability with regard to the substance is going to bring the downstream user to attention first, which means that his incentive to reduce risks with the substance is high.[164]

[163] Case C-558/08, *Op. cit.*, paras. 136-138.
[164] Führ, Martin; Bizer, Kilian, *Op. cit.*, pp. 331-332.

4 The Environmental Liability Directive

4.1 Objective and purpose

To improve the situation of data on the effects of substances and to make producers assume responsibility for their products, the Commission was indeed preparing the proposal for a scheme on environmental liability during the early preparations of the REACH Regulation.[165] On 23 January 2002 the Commission announced that it had adopted a liability scheme to prevent and repair environmental damage. Swedish Environment commissioner Margot Wallström said "*The idea is that the polluter must pay is a cornerstone of EU policy. […] The time has come for the polluter to pay.*"[166] The final legal text in Directive 2004/35/EC of the European parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage (hereafter 'ELD' or 'the Directive'), entered into force on 30 April 2004. Member States had to bring into force the provisions necessary to comply with ELD by 30 April 2007.[167] Until this date, ECJ has passed judgments on eight Member States that have failed to adopt those provisions necessary to comply with ELD.[168] The difficult and lengthy transposition of the Directive can be explained by some doubts in relation to several weighty elements of the regime that have been left in the hands of Member States to decide; the scope of the Directive, issues such as the defences, Member State subsidiary responsibility and the issue on mandatory financial securities. Depending on the transposition of these elements in the Member States, the effectiveness of the Directive may differ.[169] No judgments have been passed on the material contents of the Directive.

One of the arguments by the Commission on necessity for a regime on EC level was that without it, operators could exploit differences in Member State approaches by spinning-off risky operations to legally distinct and undercapitalised companies and moving front offices within the EC to exploit liability loopholes.[170] The Directive has been criticised by legal scholars' for not meeting the requirements of EC law, such as the principles of subsidiarity and proportionality. The Commissions arguments for a

[165] COM (2001) 88 Final, *Op. cit.,* p. 7.
[166]European Commission, Press release, *Making the polluter pay: Commission adopts liability scheme to prevent and repair environmental damage.* Brussels 23 January 2002.
[167] Article 19.1, ELD.
[168] Case C-417,418/08, *Commission v United Kingdom and Ireland;* Case C-402/08, *Commission v Slovenia*; Case C-329/08, *Commission v Belgium;* Case C-330/08, *Commission v France;* Case C-331/08, *Commission v Luxembourg;* Case C-368/08, *Commission v Greece;* Case C-328/09, *Commission v Finland.*
[169] Winter, Gerd, et al. *Op. cit.,* p. 170; see also De Smedt, *Op cit.,* p. 2.
[170] Bergkamp, Lucas, *European Community Law for the New Economy,* 2003, p. 337.

liability regime have been considered unpersuasive.[171] Others have claimed that some of the new elements of the regime are lacking in one or more Member State legal orders, and that this fact may be reason enough to introduce the rules on EC level.[172]

The fundamental principle of ELD should be that an operator whose activity has caused the environmental damage or the imminent threat of such damage is to be held liable, in order to induce operators to adopt measures and develop practices to minimise the risks of environmental damage so that their exposure to financial liabilities is reduced.[173] Article 1 of ELD states its purpose to "establish a framework of environmental liability based on the polluter pays principle to prevent and remedy environmental damage". ELD is a public law regime centering on the Member State's obligation to ensure that the polluter restores the damaged environment (or to take measures itself) and to recover the cost of prevention and remediation in case the operator does not act. Traditional damage, i.e. suffered by private persons is not covered.[174]

4.2 The polluter pays principle

The content of the polluter pays principle is difficult to determine. Who is actually the polluter and who is to pay? The polluter pays principle is to be understood as an economic principle where the environmental impairment caused shall not be rectified by taxes paid by society. The person causing the pollution shall bear the cost. There are indications of the polluter pays principle as a principle not recognised by law. First, the principle has not been invoked and no damages have been claimed based on the principle. Second, if the polluter pays principle was legally binding, Community measures would not have the tendency of funding Member State via state aid and subvention to clean-up measures of the environment. It is consistently seen as a task for the public authorities to carry out, which is not compatible with the polluter pays principle.[175]

[171] *Ibid.*, p. 327 *et seq;* see also De Smedt, Kristel, *The implementation of the Environmental Liability Directive – Is harminisation always effective?*, European Energy and Environmental Law Review, February 2009, p. 4.
[172] Winter, Gerd; Jans, Jan H; Marcrory, Richard; Krämer, Ludvig; *Weighing up the Environmental Liability Directive*, Journal of Environmental Law 20:2, 2008, pp. 163-191.
[173] Recital 2 of the ELD Preamble.
[174] Winter, Gerd et. al., *Op. cit.*, p. 164.
[175] According to Krämer *Op. cit.*, pp. 25-26, the principle *"has not been invoked, and no Community text contains provisions on who shall pay for what"*.

4.3 The provisions of ELD

4.3.1 Environmental damage

The White Paper aimed at excluding 'traditional damage' such as injury to persons and property from the scope of liability. Its definition of damage was 'environmental damage' and included both damage to biodiversity and damage in the form of contamination of sites. With regard to the environmental objectives in Article 174.2 of the EC Treaty, the White Paper aimed at specifically including certain dangerous activity in the scope of the liability.[176] The outcome was, that environmental damage in ELD is defined as damage to protected species and natural habitats as defined by the Member States in accordance with the Wild Birds Directive and Habitat Directive; water damage to water courses covered by the Water Framework Directive (Directive 2000/60/EC) affecting ecological, chemical and/or quantitative status and/or ecological potential; and land damage as a result of direct or indirect introduction of substances, preparations organisms or micro-organisms where there is a significant risk that human health is adversely affected.[177] Member States have a possibility to enlarge the scope of the natural habitats and protected species, in order to include also other protected species or areas designated by the Member States. If Member States does not take this possibility, the scope of the Directive is rather limited.[178]

4.3.2 Occupational activities

The occupational activities covered by ELD shall be identified in principle by reference to the relevant Community legislation which provides for regulatory requirements in relation to certain activities or practices considered as posing a potential or actual risk for human health or the environment. ELD foresees two types of such activities: occupational activities listed in Annex III ('dangerous activities') causing environmental damage (all types of damage as defined by the Directive); and occupational activities other than those dangerous activities ('other activities') causing damage to protected species and natural habitats, whenever the operator has been at fault or negligent.[179] This means that the Directive imposes strict liability on operators of dangerous activities, and fault liability on operators of other activities for biodiversity damage.[180] The dangerous activities should be identified, in principle, by reference to the relevant Community legislation which provides for regulatory requirements in relation to certain activities of practices considered as posing a potential or actual risk for

[176] COM (2000) 66 Final, *Op. cit.*, pp. 16-17.
[177] Article 2.1.a-c. and Article 3.1.a-b ELD.
[178] Article 2.3.c ELD; see also De Smedt, *Ibid.*, p. 7.
[179] Article 3.1.a ELD.
[180] Article 3.1.a-b ELD; see also De Smedt, *Op. cit.*, p. 2.

human health or the environment.[181] Dangerous activities are *inter alia*, "Manufacture, use, storage, processing, filling, release into the environment and onsite transport of hazardous substances as defined in Article 2.2 of Council Directive 67/548/EEC".[182] Other activities relate to the IPPC, waste, water pollution, water abstraction, air pollution and GMO-Directives.[183] Operators for other activities are liable only for damage to protected species and natural habitats in cases when the operator has been at fault or negligent.[184]

4.3.3 The operator

The definition of the 'operator' under ELD identifies the group of potentially liable persons as:

"'operator' means any natural or legal, private or public person who operates or controls the occupational activity or, where this is provided for in national legislation, to whom decisive economic power over the technical functioning of such an activity has been delegated, including the holder of a permit or authorisation for such an activity or the person registering or notifying such an activity."[185]

In the proposed directive in 2002, the definition of the operator was:

"(9) "operator" means any person who directs the operation of an activity covered by this Directive including the holder of a permit or authorization for such an activity and/or the person registering or notifying such an activity;"[186]

In the proposed text, the term 'directs' was used instead of 'controls'. This was criticised to extensively widen the scope of possible liable persons, and to include claims against not only the actual operator, but also against affiliated corporations deemed to be 'directing' the activities of their subsidiaries.[187] In addition, the definition of the operator by the proposed directive was included a person that has 'registered or notified such an activity'. As pointed out by Bergkamp in 2003 on commenting the proposed directive, without the relevant control, an actor who registers a substance, and transfers it to a third party has lost all control over it. Under the proposed definition of the operator, the registering actor would be exposed

[181] Recital 8 ELD preamble.
[182] Annex III, para. 7.a ELD.
[183] Directive 1999/45/EC, Directive 91/41/EEC, Directive 98/8/EC, Directive 94/55/EC, Directive 96/49/EC, Directive 93/75/EEC, Direvtive 84/360/EEC, Direvtive 90/219/EEC and Directive 2001/18/EC, and Regulation (EEC) No 259/93.
[184] Article 3.1.a-b REACH Regulation.
[185] Article 2.4 ELD.
[186] COM (2002) 17 Final – COD 2002/0021, *Proposal for a Directive of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage*, Article 2(9).
[187] Bergkamp, Lucas, *Op. cit.*, p. 349.

to liability for downstream damage caused by the chemical substance he registered.[188] In the final text of the directive however, the designation of the definition in this regard is combined with a relevant control over such activity: 'decisive economic power over the technical functioning of such an activity […] including the person registering […] such an activity.'[189] '

An implementing Member State may under Article 16 include additional activities subject to the obligations, as well as the identification of additional responsible parties.[190]

4.3.4 Operators' and Member States' responsibilities

The Directive foresees two types of primary obligations; preventive and remedial actions. The secondary obligation is that the operator shall bear the cost of own remedial actions taken, or having a claim from third parties or the state to bear the cost of their remedial actions taken.[191]

The operator shall, on his own initiative where environmental damage has not yet occurred but there is an imminent threat of such damage occurring, take the necessary preventive measures without delay. The competent authority may (but is not obliged), at any time itself take the necessary preventive measures. [192] When environmental damage has occurred the operator shall inform the competent authority of all relevant aspects of the situation and take all practicable steps to immediately control, contain, remove or otherwise manage the relevant contaminants and/or any other damage factors in order to limit or to prevent further environmental damage and the necessary remedial measures, in accordance with a common framework in Annex II, to choose the most appropriate measures to ensure the remedying of environmental damage. The obligation to identify the appropriate measures ensuring the remedying applies only in case the competent authority has not taken action.[193] The operator may however wait for orders from the competent authority before he takes any remedial actions.[194] The competent authority may (but is not obliged), in the same way as for preventive actions, at any time take all practicable steps to immediately control the damage.[195]

The main rule is that the competent authority shall require that both preventive and remedial actions are taken by the operator. In case the operator cannot be identified or is not required to bear the costs of the

[188] *Ibid.*, pp. 349-350.
[189] Article 2.4 ELD.
[190] Article 16.1 ELD.
[191] Winter et al., *Op. cit.*, p. 169.
[192] Article 5.1 and 5.3.d ELD.
[193] Article 6.1, Article 7.1 and Annex II ELD.
[194] Article 7.2 ELD.
[195] Article 6.2.b ELD.

preventive and remedial actions taken, the competent authority may take these measures itself. Directive thus offers the *possibility* for the competent authority to take preventive and remedial actions at any time.[196] Environmental NGO's suggest that word 'may' implies that ELD factually does not impose any obligations at all on the Member State to remedy environmental damage where the operator cannot do this himself.[197]

4.3.5 Defences

The secondary obligation and the main rule with regard to the cost for remedial actions, is that the operator shall bear the cost.[198] If the damage was caused by a third person or resulted from compliance with a compulsory order of a public authority the operator is exempted from liability.[199] An implementing Member State has yet again another possibility. The Member State may to allow the liable operator of dangerous activity not to bear the cost of remedial actions taken under the Directive where the operator demonstrates that he was not at fault or negligent, and that the environmental damage was caused by an emission or event expressly authorised by (the 'permit defence').[200] The Member State may also allow the liable operator of any activity (dangerous activities and other activities) who demonstrates that he was acting in accordance with the state of scientific and technical knowledge not to bear the cost of damage caused in the course of such activity (the ' state-of-the-art defence').[201]

As soon as a liable operator is found, there is a presumption of his negligence or fault. The burden of proof lies on the operator to demonstrate that he was not negligent or at fault.[202] The word 'demonstrate' has been criticised by Environmental NGO's for potentially leading to a lighter burden of proof than is required by using the word 'prove'.[203] However, sometimes it might be difficult for the operator to prove he was not at fault or negligent. The defence therefore seems to be narrow. The majority of the Member States allows for a permit defence, which obviously weakens the strict liability and turns it into a fault liability.[204] With regard to the cases where an operator invokes the permit defence, i.e. where the environmental damage is intended by permit, who is to deal with the damage? The Directive remains silent. According to Winter et al., in these situations "the authorising or instructing act must somehow be altered with a view to readjust its legalising effect".[205]

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[196] Article 5.4 and Article 6.3 ELD.
[197] BirdLife International and WWF, *The European Directive on Environmental liability – "Polluter Pays": From principle to practice?* July 2004, p. 24.
[198] Article 8.1 ELD.
[199] Article 8.3.a-b ELD.
[200] Article 8.4.a ELD.
[201] Article 8.4.b ELD.
[202] Article 8.4 ELD.
[203] BirdLife International and WWF, *Op. cit.,* pp. 21-22.
[204] De Smedt, Kristel, *Op. cit.,* pp. 8-9.
[205] Winter, Gerd et al. *Op. cit.,* p. 170.

The Member State subsidiary responsibility must be reviewed in the context of the permit defence. For cases where the operator may exempt himself from liability through one of the defences, it is important that Member States have the responsibility for clean-up. This may, on the other hand be recovered from a polluting operator, via security or other financial guarantees, the cost incurred on the competent authority for remedial actions taken under the Directive. In theory, strict liability could be a strong incentive for operators to take all possible risk-minimising measures and it could be a way of implementing the precautionary principle. Nevertheless, with regard to the possibility of a permit defence, it is doubtful whether the Directive can realise the polluters pay principle. Through the combination of a permit defence and absence of subsidiary state responsibility, it is not sure damage to the environment is restored.[206] Claiming compensation from a government for pollution caused by industry undermines the effect of the polluter pays principle. Direct recourse to the company causing the damage would do more to facilitate implementation of a 'polluter pays' approach.[207]

4.3.6 Causality

The Directive is based on a liability mechanism of which the damage should be concrete and quantifiable, and a causal link should be established between the damage and the identified polluters.[208] As suggested by De Smedt with reference to Wagner, the most problematic issue in liability regimes is indeed the causality requirement. A strict application of a full proof of a causal link between the damage and the operator might paralyse every liability regime.[209] Operators under ELD bear a primary responsibility to prevent, notify and manage environmental damage.[210] These actions require a causal relationship between the operators and the potential damage. Concerning the causality requirement, the Directive is not clear. The burden of proof for the causal relationship seems to lie on the authorities, as is commonly laid on the plaintiff. ELD does not require a causal link between the damage and *one* single operator as reference is made to 'operators'.[211] If more than one operator causes the damage, the cost of remedying the damage can be allocated among the operators in accordance with the domestic tort law of the Member State. Almost all Member States implementing the Directive, has taken the possibility given by ELD; to impose a joint and several liability mechanism if several operators are found liable. This way it is possible to ensure that the polluter pays principle would be indeed be guaranteed.[212]

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[206] De Smedt, Kristel, *Op. cit.*, pp. 8-10.
[207] Boyle, A.E., *Globalising environmental liability: the interplay of national and international law*, Journal of Environmental Law, 2005, Vol 17 No I, p. 8.
[208] Recital 13 the ELD Preamble.
[209] De Smedt, Kristel, *Op. cit.*, pp. 3 and 10.
[210] Article 5.1-2, and Article 6.1 ELD.
[211] Article 4.5 ELD.
[212] De Smedt, Kristel, *Op. cit,*. p. 8 *et seq.*

4.3.7 Financial guarantees

Although the Commission saw the risk of spinning-off risky operations to legally distinct and undercapitalised companies as a reason to introduce environmental liability on EC level, insurance for operators under ELD is not mandatory. The issue was controversial in the development process of ELD. Strict liability will only give incentives for prevention if the insolvency risk can be cured, and from a theoretical perspective a strict liability regime should not be introduced without financial guarantees, since insolvency might distort the deterrence and compensation or restorative function of strict liability.[213] From the Environmental NGO's point of view, strong rules on financial security are necessary to create a strong incentive to prevent environmental damage, as well as the effective remedy of environmental damage occurred. In the absence of rules on subsidiary state responsibility, this is particularly important.[214] During the negotiations of ELD, mandatory insurance was proposed for hazardous activities, but there was a clear reluctance among several Member States to implement the proposal. Under Article 14 this reluctance is obvious. Article states that the "Member States shall take measures to encourage the development of financial security instruments and markets by the appropriate economic and financial operators, including financial mechanisms in case of insolvency, with the aim of enabling operators to use financial guarantees to cover their responsibilities under this directive." The Commission has the task to review the situation by 2010, and to examine whether the regime should be revised.[215] The decision is left to the Member States, and the effect of the Directive is thus left dependent on this decision. A minority of the Member States have included a provision with obligatory financial guarantees[216], with an exception to Sweden, where an operator of a hazardous activity already pays a yearly contribution, from which compensation is paid when a liable operator is unable.[217]

[213] *Ibid.*, p. 11.
[214] BirdLife International and WWF, *Op. cit.*, p. 9.
[215] Article 14 ELD.
[216] De Smedt, Kristel, *Op. cit.*, p. 11.
[217] Förordning (1998:1473) om miljöskadeförsäkring och saneringsförsäkring.

5 Analysis

The purpose of this thesis was to clarify the registrant's responsibility when registering substances of higher concern in order to assess his potential liability for downstream, ecological impairment of nature caused by such substances. In this chapter, I will begin with addressing the registrant's responsibility under REACH when registering substances of higher concern. Thereafter, I am moving over to the discussion on potential connections between REACH and ELD, after which the assessment on the registrant's potential environmental liability under ELD is finalising the analysis.

5.1 The registrant

The registrant is the actor in the supply chain with the obligation to register the substances he manufactures or imports. In addition, an only representative validly appointed by a non-Community manufacturer is included into the group of registrants. Through the appointment the only representative is taking over the registration obligation of the non-Community manufacturer's EU- based importers.

The registration obligation is placed on those legal entities *responsible* for the manufacturing and importing activity. As seen from the definitions and interpretations, this responsibility and the registration obligation is placed on that legal entity which is considered responsible for the activity. If several entities are involved, the responsible entity must be identified. For importers, a certain level of responsibility for the physical introduction of substances in to the EEA must be attained in order to be considered the importer. For manufacturers, the entity actually being responsible for the production or extraction of the substance is considered the manufacturer, although he is responsible for the activity as a sub-contractor of another company. The only representative on the other hand, is responsible for the registration of those substances covered by the appointment by his non-Community manufacturer.

5.2 The registrant's responsibility

The registrant is legally responsible for its registration. Nevertheless, what does this responsibility consist of, notably the registration of substances of higher concern?

5.2.1 Low volume substances

The information requirements for low volume substances (1-10 tonnes) are reduced and a chemical safety assessment is not required. Regardless of their intrinsic properties, a hazard assessment will not be carried out for substances within this tonnage range. In addition, the exposure information provided in the registration dossier is built on categories and main routes of exposure. The actual, detailed use of a substance and its exposure to humans and the environment remains unknown. For low volume substances, the responsibility consists of gathering information on the intrinsic properties of a substance without an assessment on the risks of their use.

5.2.2 Responsibilities when performing the chemical safety assessment

For substances over 10 tonnes however, the registrant is obliged to perform the chemical safety assessment as a part of the registration obligation. In generating the dossier, the intrinsic properties of a substance are made available. This information is used in the hazard assessment. It is indeed the responsibility of the registrant to determine if the substance is one of higher concern (either jointly with the other registrants in a SIEF, or as a result of the PBT and vPvB assessment). If the registrant so determines, he is obliged to carry out the exposure estimation and generate the exposure scenarios for the substance.

The registrant is to carry out the exposure estimation of the manufacture and use of the substance throughout the whole supply chain. He will obtain information from his downstream users' processes on their individual manufacture and use of the substance. If the registrant decides to include downstream user's use in the registration, the exposure assessment cannot be carried out without communication with the downstream user. The registrant does not have knowledge on the downstream processes. Therefore, the downstream user must provide the registrant with detailed information on his use. In doing this, he shall pay particular attention to his use of substances of higher concern. The information shall be extensive enough to allow the registrant to estimate exposure. If the use contains any kind of exposure of the substance to humans or the environment, the registrant must generate a scenario for each such estimated exposure.

5.2.3 Compiling the exposure scenario

Based on the information obtained from the exposure estimation, the registrant develops the exposure scenario containing the operational conditions and risk management measures for the substance. The information is an estimation of emission, an assessment of chemical fate and pathways and estimation of exposure levels. The exposure estimation and the generation of risk management measures is a rather complicated process,

and cannot be fully understood without knowledge on the different tier tools used in the process. On a theoretical level, the registrant is responsible for the alteration of the operational conditions and risk management measures until the risks related to the use of the substance can be considered adequately controlled.

5.2.4 The downstream users' role and obligation

The registrant and the downstream user are performing different tasks under REACH. The downstream user's role is rather limited in the chemical safety assessment. He must certainly have a good understanding of his use, but simply provides this information to the registrant and cannot affect the registrant's work in the hazard assessment. The downstream user has an obligation to inform the registrant of information that could call into question the appropriateness of the risk management measures he has received. This is a way of indirect influence leading to a potential re-assessment, but I cannot see that is has a significant impact.

Under Article 37.5 REACH, the downstream user is obliged to identify, apply and where suitable, recommend appropriate measures to adequately control risks identified in the safety data sheet supplied to him. This obligation is not entirely clear. The purpose of the registration obligation is to generate information on substances to adequately control risks when using a substance. As pointed out by Hansen & Blainey, the chemical safety assessment and the subsequent generation of risk management measures is indeed a risk reduction tool for the registrant of substances of higher concern in quantities of 10 tonnes or more per year. The purpose of the chemical safety assessment is therefore to identify the hazards of a substance and under which conditions the hazards are controlled. The purpose is not to control the actions or use of a downstream user with regard to a substance. Therefore, the measures must be considered a recommendation only and certainly not an obligation for the downstream user to apply the risk management measures, or unconditionally and obligation to readjust his use to fit the operational conditions to his activity per se.

In the individual part of the registration dossier for each substance the registrant shall include information on the manufacture and uses of the substance, which are all the registrant's identified uses.[218] The registrant is under a further duty to update the registration dossier with any new identified uses.[219] This indeed point at the conclusion, that only those 'identified uses' of a substance are allowed under REACH. This is especially applicable for identified uses of substances of higher concern. For a downstream users use advised against for reasons of protection of human

[218] Article 10.a.iii REACH Regulation.
[219] Article 22.1.d REACH Regulation.

health or the environment, the registrant shall inform the downstream user and ECHA of the reasons for the non-inclusion of the use into the registration dossier.[220] These uses must be considered 'unsafe', i.e. a substance of higher concern used within these operational conditions is not according to the registrant 'adequately controlled' within the meaning of REACH, and the downstream user wishing to include such use in the registration dossier will naturally not receive any exposure scenarios for this particular use. The conclusion is that substances may thus only be used as identified in the registration dossier. The consequence is that the freedom of a downstream user with regard to substances of higher concern is indeed reduced to the uses the registrant decides to include into the dossier (the 'identified uses'). Nevertheless, this freedom cannot be considered limited to those operational conditions and the under the precautionary measures through application of the risk management measures generated by the registrant. Under the self-regulatory character of REACH, the downstream user has an individual responsibility to ensure the safe use of the substances he is using. If he considers the measures inadequate, he has the right not to apply them. On the other hand, he is most likely to be able to explain why he deviated from the recommendations received from the registrant.

A downstream user with a use outside the conditions set out in the exposure scenario (operational conditions) has a choice to implement the operational conditions of use in the exposure scenario to ensure the safe use of the substance. This would in practice mean, that the registrant's exposure scenario is directly influencing the conditions of a downstream user's professional activity with regard to the substance. In this case the registrant's exposure scenario has a direct impact on the occupational activity of a downstream user in which a substance of higher concern is used.

5.2.5 ECHA's evaluation

With regard to institutional control, ECHA has the responsibility for checking compliance of the registration dossiers. The relevant articles of the REACH Regulation stipulate that ECHA verifies that all the required information is submitted, and that the risk management measures are "adequate". The meaning of this adequacy control is not clear. In the guidance document on dossier evaluation issued by ECHA, the responsibility consists of an evaluation of risk management measures. However, it is also pointed out that a new chemical safety report is not produced by re-evaluating the data. In describing the evaluation procedure, ECHA repeats the word "should" which has a significantly different meaning than "shall", and therefore appears as a recommendation. Compliance check cannot result in new exposure scenarios being produced, and only 5 % of the dossiers are required to be checked. According to my understanding, the REACH Regulation does not provide for effective

[220] Article 37.3 REACH Regulation.

control of the risk management measures generated by the registrant for substances of higher concern. In addition, REACH sets up no criterions on the risk management measures. ECHA's risk management library as a tool for compiling measures is based on a collection of existing measures under previous legislation for the different target groups and exposure routes. The content of the library has not been validated by ECHA and cannot be quoted in the chemical safety report as providing scientific evidence on appropriateness of risk management measures related to a certain exposure scenario. The evaluation of risk management measures seems to be purely technical and does not therefore guarantee their adequacy. The responsibility for such adequacy is therefore entirely in the hands of the registrant.

5.2.6 Interim Conclusion

The above outlined responsibility of the registrant leads to the inevitable conclusion that the registrant has a detailed knowledge on how the substance behaves, its exposure levels and their intensity throughout the whole supply chain. He knows under which conditions the substance is exposed to humans and the environment. The specific exposures of the whole supply chain are therefore only fully known and understood by the registrant (in addition to the downstream user on his own use) who independently designs and recommends the measures needed to avoid the downstream, unsafe use of the substance.

In summary, it is the registrant's responsibility to decide on whether the substance is of higher concern and if the use of a downstream user shall be considering an identified use. The registrant further has the freedom to designate the criterions for the risk management measures for those substances. In addition, it is the registrant's decision on whether or not to readjust the measures after receiving information from the downstream user that may question the appropriateness of the measures. Consequently, it is the registrant's responsibility that a substance of higher concern is supplied with the appropriate measures to avoid negative impacts on the environment in downstream processes. Without effective institutional control and downstream user's limited influence on such measures, the freedom of the registrant in this regard is extensive. However, the individual responsibility of a downstream user under REACH does not make him legally tied to the measures as such as they shall be considered a recommendation only.

5.3 REACH and ELD

Before assessing the potential environmental liability of a registrant under ELD, I will clarify the connection between the two pieces of legislation. First, I want to point out that I will be using the term hazardous substances as a part of substances of higher concern, since dangerous activities in ELD does not cover substances with PBT and vPvB properties, only those

classified hazardous under Directive 67/548/EEC. Also, in the following sections I am using the term 'exposure scenario' when referring to operational conditions and risk management measures together as a part of the extended safety data sheet, or using the terms separately, as the case may be.

5.3.1 'Identified use' and occupational activity

The occupational activities in ELD are identified, in principle, by reference to the relevant Community legislation which provides for regulatory requirements in relation to certain activities or practices considered as posing a potential or actual risk for human health or the environment.[221] The purpose of REACH Regulation is not to identify occupational activities. REACH provides for the registration of substances and generation of risk management measures for the safe use of hazardous substances. However, REACH provides for certain requirements (exposure scenarios) in relation to certain activities, notably activities containing the manufacture and use of hazardous substances. As concluded above, these requirements are mere recommendations and the responsibility for the safe use of such substances applies to the individual legal entity. The recommendations cannot be considered having the same impact on the occupational activity as for example a permit issued for a specific dangerous activity.

The definition of 'use' under REACH is the downstream user's professional activity with regard to a substance. ELD specifies the dangerous activity in Annex III as the "use, storage, processing, filling, release into the environment and onsite transport of dangerous (hazardous) substances as defined in Directive 67/548/EEC". The hazardous substances as defined in both REACH and ELD are thus the same: substances classified hazardous through application of the same legal instrument. The use of certain substances of higher concern under REACH must therefore be considered to cover the group of dangerous occupational activity as specified by ELD, Annex III, 7.a. There is however doubts as to considering 'identified use' equivalent to the definition of dangerous activity as defined by ELD. In the following I shall address the potential connections between operational conditions and risk management measures and dangerous activity and demonstrate how such measures may impact and even set out the limits for the activity.

5.3.2 Operational conditions

In contrast to the meaning of use, operational conditions in the exposure scenario aim to specify the circumstances of use of a substance through describing the types of activity to which the exposure scenario relates. The connection to ELD is here to which extent these conditions apply to

[221] Recital 8 ELD Preamble.

dangerous activity. The operational conditions are part of the exposure scenario and describe how the substance is manufactured or used during its life-cycle. The operational conditions in Annex I REACH sets out the conditions of the use of a substance with regard to processes involved. My conclusion is therefore, that the operational conditions describe the occupational activity to the extent it is connected to the substance itself, certainly as a part of the the activity, but not the actual activity per se. The purpose of operational conditions is not to identify or regulate a whole activity. However, the occupational activity is intrinsically a part of and connected to these operational conditions, and therefore cannot be separated from them. To which extent the operational conditions and its processes are describing the activity as a whole naturally depends on the activity itself and which role the substance takes in this activity. The REACH operational conditions can be concluded to describe the occupational activity to the extent the activity is related to different exposures of the hazardous substance itself. Therefore, if a hazardous substance has caused environmental impairment as a result of a dangerous activity, the conditions under which the substance was exposed to the environment can be presumed to have a connection to the operational conditions under REACH since conditions of use outside of the operational conditions are considered unsafe under REACH.

5.3.3 Risk managenement measures

Risk management measures for an identified use set out the recommendations for controlling the risk of such substance. The substance shall not be used outside the anticipated exposure which means that the non- or misapplication of risk management measures is considered unsafe. Clearly, an activity or device that reduces or avoids direct and indirect exposure of humans and environment to the substance is an action which will affect an occupational activity. But again, the activity itself and which role the substance takes in this activity would determine the impact of the risk management measures on the activity.

A further analysis on the impact of the risk management measures on a downstream, dangerous activity could clarify this relationship. The registrant’s connection to a downstream damage caused by his registration and risk management measures of a substance of higher concern is not possible to establish in this thesis, and may vary from case to case. The impact of risk management measures with regard to downstream damage, and their legal significance in these situation is yet to be seen. However, in line with the previous section, a hazardous substance causing environmental impairment as a result of a dangerous activity can be presumed to have a connection to the mis- or non-application of risk management measures, since they are designed to recommend an adequate control of such substances. In their application, risk management measures may therefore in certain situations, affect and possibly even restrict the activity in certain ways.

5.3.4 Permits and exposure scenarios

An interesting issue in comparing REACH and ELD is to what extent a permit issued for a dangerous activity could be equivalent to the exposure scenarios' operational conditions and risk management measures under REACH. For example, a permit for a dangerous activity allowing conditions that are more extensive than recommended by exposure scenarios received for the activity, would create conflicting rules for the downstream user (operator). Here there is a direct connection between unsafe exposures not adequately protecting human health or the environment within the meaning of REACH, and permits for dangerous activity issued by national legislation within the meaning of ELD. In this regard, it is worth mentioning that an authority normally issues a permit, whereas individual registrants compile exposure scenarios. These scenarios thus lack the direct, authoritative order of a permit. However, since REACH is built on the latest available knowledge on the hazards of a substance, the exposure scenarios must be considered to have scientific value and thus legal implications in these situations.

5.4 The registrant's potential environmental liability

The registrant's responsibility for the registration, notably the chemical safety assessment and the generation of exposure scenarios does not automatically imply that he shall be liable for what downstream, occupational activity adhering to such measures may cause.

5.4.1 The operator

Firstly, does the registrant fit within the definition of the 'operator'? In the definition of the 'operator', the word 'directs' was replaced with 'controls'.[222] This change obviously restricts the scope of possible liable persons. Who is to be considered controlling an activity is obviously dependent on the special circumstances of the activity. It has been concluded above that the operational conditions and risk management measures may set boundaries to certain parts of the activity. But it must be excluded that the registrant is considered to be controlling the occupational activity of a downstream user through his exposure scenarios. But as concluded above, the purpose of the registration is not to control an activity.

Moreover, the operator may be a person controlling and "registering or notifying such an activity". It is here worth to bear in mind the differences between the two legislations in this respect. Under REACH the registrant registers a substance, not a use. The main obligation and cornerstone of the

[222] Bergkamp, Lucas, *Op. cit.*, p. 349.

REACH Regulation is generating information on the intrinsic properties of a substance, and providing downstream users on recommendations on the safe use of substances of higher concern. The purpose is that the downstream user shall receive the appropriate measures to manage such registered substance safely. REACH Regulation does not focus on the use of a substance as such, nor the activity related to such substance. The dangerous activity and its operator is on the other hand an important element in the objective of ELD: it is the activity in which the substance is used and its operator which is liable under the Directive.

To conclude the above discussion; even though there is a clear connection between REACH exposure scenarios and dangerous activities under ELD, the registrant is with regard to the above discussion, not an 'operator' of dangerous activities, nor is he controlling such an activity through 'decisive economic power over the technical functioning' of a downstream users identified use.

5.4.2 Potential scenarios

By not including the registrant into the definition of the 'operator', i presume that the downstream user is the legal entity generally exposed to environmental liability under ELD. The registrant's role and his exposure scenario are nevertheless of potential significance in other situations.

For example: a Member State offers the possibility of permit- and state-of-the-art defence. A downstream user is the 'operator' of dangerous activities in that Member State and is found liable for the environmental damage caused by a hazardous substance used in his activity. The downstream user invokes the permit defence and claims that his action was acting fully in accordance with the permit issued for his activity. The downstream user is now under the rules of ELD to demonstrate that he was not at fault. The downstream user has also received extended stafety data sheets containing exposure scenarios for his use by the registrant of the substance which caused the damage. The significance of exposure scenarios in this situation is interesting. The question is: will the exposure scenarios play a role in reviewing action in accordance with such permits? If so, would the Member State competent authority search of a potential fault through comparing the downstream user's activity with operational conditions of the exposure scenario, or if the application of precautionary measures of the activity in accordance with the permit was in line with the recommended risk management measures by the registrant? Or would the Member State competent authority even go far enough to search for a potential fault in the generation of such measures? In the latter case, and if the fault could be established, the environmental damage can be connected to the registrant's responsibilities under REACH.

On the other hand, if the downstream user invokes a state-of-the-art defense, there is no permit to review. It is possible that the Member State in this

situation turns to other measures that are setting the standards of an appropriate course of conduct within such activity. To be exempted from liability, the downstream user invoking the state-of-the-art defense shall demonstrate that his actions was not considered likely to cause environmental damage according to the state of scientific and technical knowledge at the time when the emission was released or the activity took place. The application of REACH is to be underpinned by the precautionary principle in order to ensure a high level of protection of human health and the environment. It is based on the available knowledge on the intrinsic properties of a substance, and potentially even based on new tests performed by the registrants together in the SIEF. In combination with the individual registrant's knowledge on downstream operational conditions (the 'identified use'), REACH must be considered to *at least* set a minimum level of precautionary actions to be taken with regard to a hazardous substance. Therefore, if the hazardous substance caused the damage in situations of invoking a state-of-the-art defense, operational conditions and risk management measures may play a significant role in reviewing action by the downstream user. If the measures are considered faulty or inadequate, the registrant's responsibility under REACH is a potential trigger for responsibility. Faults by the registrant in performing the chemicals safety assessment and the exposure scenario's causing downstream environmental impairment can therefore be traced to the registrant.

A fault in generating such measures could come into question in tort cases following a downstream user's environmental liability under ELD, in which he seeks recourse at the registrant for reliance on inadequate or faulty exposure scenarios. A registrant recommending simple and cost-effective measures without a reduction of dosage or measures aiming at substitution of the substance may be considered inadequate. The correct and adequate generation of exposure scenarios under REACH may be considered a standard for the registrant in demonstrating that he was performing the chemical safety assessment correctly and managing risk with all reasonable and usual skill and forethought, in order to avoid operators (downstream users) right of recourse for damages caused by environmental liability under ELD.

In addition, a Member State has the possibility to widen the scope of ELD through the identification of additional responsible parties. The impact of the exposure scenarios on downstream activity could serve as a causal connection to the damage. A fault in generating exposure scenarios could therefore, depending on the situation, create an imperative for the Member State to identify the registrant as a responsible party according to Article 16 ELD.

5.4.3 Conclusion

The registrant's responsibility and freedom when performing the chemical safety assessment and generating risk management measures is extensive. It is the registrant's responsibility that a hazardous substance is supplied with adequate risk management measures. ECHA's poor evaluation obligation and the downstream user's reduced influence on the work in the chemical safety assessment do not guarantee the adequacy of risk management measures.

The fundamental principle of ELD is a liability regime built on the polluter pays principle. Strict liability on operators of risky or potentially risky activities was indeed the starting point of ELD. In examining ELD, it is clear that the impact of the Directive and its realisation of the polluters pay principle is dependent on the legislation of the implementing Member State. If no operator is found liable or is allowed exemption without a mandatory financial guarantee, the competent authority is responsible, but not obliged to take remedial action. Not only is there a risk of situations of un-remedied environmental damages, it would also lead to the undermining of the polluters pay principle.

Establishing a connection between REACH exposure scenarios and downstream environmental damage caused by substances of higher concern, could create a stronger incentive for generating adequate risk management measures. This could indeed be a way of guaranteeing a high level of protection of human health and the environment.

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