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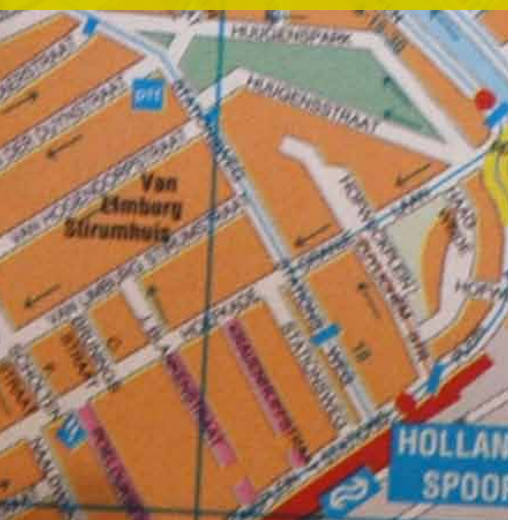
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Road-map quality standard setting

Interactions REACH and other chemical legislation

Setting of environmental quality standards



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Abstract

Interactions REACH and other chemical legislation

Setting of environmental quality standards

The new European chemical legislation REACH will gradually produce a large amount of information on the hazardous properties, use and exposure of chemicals. Other environmental policy frameworks, in particular those where environmental quality standards are used to safeguard environmental quality, will benefit from this accelerated generation of information. REACH will probably act as a very useful instrument to select and prioritise chemicals to be further addressed in, for example, the Water Framework Directive. The question is, however, whether the REACH 'risk limits' (PNECs and DNELs) will meet the requirements that authorities currently rely upon. Technical and conceptual differences between risk limits from REACH and other policy areas have been noticed, but also points of interest on quality control, timing and disclosure of background data. A number of general suggestions is given for an effective transfer of information from REACH to other chemical policy frameworks.

Key words: REACH, environmental quality standards

Rapport in het kort

Interactie REACH met andere wet- en regelgeving chemische stoffen

Normstelling

Via de Europese wet- en regelgeving REACH wordt aangetoond of het gebruik van chemische stoffen veilig is. De informatie die REACH oplevert is gedeeltelijk bruikbaar voor andere beleidskaders waar normen een rol spelen, zoals de Kaderrichtlijn Water (KRW), het Nederlandse stoffenbeleid en vergunningverlening. Dit blijkt uit onderzoek van het RIVM, in opdracht van het ministerie van VROM.

De REACH-gegevens die via de industrie beschikbaar komen, zijn aanvullend en daarmee waardevol om nieuwe normen af te leiden. Bovendien geeft REACH voorrang aan data voor de gevaarlijkste stoffen. De kwaliteit van gegevens wordt echter in REACH-kader niet voor alle stoffen door de overheid gecontroleerd. Ook zijn gegevens over de testen die de industrie uitvoert niet altijd openbaar. De onderbouwing van de risicogrenzen in REACH kent een andere grondslag dan de milieukwaliteitsnormen van de overheid. Daarnaast levert REACH bepaalde typen van risicogrenzen niet, die andere kaders juist wel gebruiken. Bovendien vallen biociden, bestrijdingsmiddelen en (dier)geneesmiddelen buiten het REACH-kader, terwijl het beleid regelmatig om normen voor deze stofgroepen vraagt.

Het rapport geeft suggesties om de aansluiting tussen REACH en andere kaders te vergroten. Zo kan een handleiding voor lokale overheden behulpzaam zijn bij het juiste gebruik van REACH-gegevens.

Trefwoorden: REACH, milieukwaliteitsnormen

Preface

Road-map quality standard setting

In 2009 the Ministry of Housing, Spatial Planning and the Environment (VROM) started the project '*Vernieuwde visie op normstelling*'. The reason was that the current framework of standard setting for chemicals lagged behind both the connection with new European chemical policy frameworks (*e.g.* REACH) and the shift of roles in responsibility between industry and authorities. The internal VROM strategy paper '*Op weg naar een vernieuwde visie op normstelling voor stoffen*' (June 2009) addresses ways to reach the goal, *i.e.* the realisation of an integrated set of standards that is joined with the relevant (inter)national policy frameworks. Within VROM interpretation will be given in 2009 and afterwards to a new set up of the national policy plan on chemicals and the position of environmental standard setting therein.

The *Road-map normstelling* (Road-map quality standard setting) is the long-range coordination scheme of the activities of RIVM to support the building of a new framework for standard setting. The products of this Road-map point the way to the VROM goals. The current RIVM report 'Interactions REACH and other chemical legislation- Setting of environmental quality standards' is one of these products. More information about the *Road-map normstelling*: charles.bodar@rivm.nl

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Summary

The new European chemical legislation REACH has entered into force on 1st June 2007. This Regulation, 1907/2006/EC for Registration, Evaluation, Authorisation and restriction of Chemicals aims to streamline and improve the former legislation on chemicals of the European Union. REACH places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment.

REACH will gradually produce a large amount of information on the hazardous properties, use and exposure of chemicals from which other, policy frameworks could benefit. Central topic of the current study is the interplay between REACH and those other (inter)national policy frameworks. In our study we focussed on other policy frameworks where environmental risk limits play a role as instruments to safeguard environmental quality (e.g. Water Framework Directive and local permits).

Within the next decade REACH will generate many data on important characteristics of a multitude of chemicals. The information will become available to the authorities and stakeholders (general public, non-governmental organisations and industrial partners). For most chemicals the registration dossier will also include Predicted No-Effect Concentrations (PNEC) and Derived No-Effect Levels (DNEL). These risk limits are an obligatory part of the Chemical Safety Assessment (CSA) irrespective if exposure scenarios and a risk characterisation have to be conducted. In principle, the other policy frameworks may thus take great advantage of these REACH outcomes.

REACH will generate data in various time 'batches'. It will bring forward the most relevant hazard data on the shortest notice. For a very large group of chemicals, however, REACH will only produce data after four or even nine years from now. REACH only applies to a limited extent to human and animal drugs, pesticides and biocides. For these substances the dossiers from other EU legislation will be accepted as a registration by REACH, but only for the purpose of the intended use of those chemicals (i.e. active ingredient or co-formulant). REACH will thus not generate any new data in those cases. The question is whether the REACH risk limits (PNECs and DNELs) will meet the requirements that authorities currently rely upon in the adjacent policy fields where they (still) have the responsibility. Various technical and conceptual differences were noticed between risk limits from REACH and other policy areas, but also points of interest on quality control and disclosure of background data. Stakeholders should be aware of these aspects in the course of decision making.

A number of suggestions is made to optimise the transfer of REACH information and to bring about realistic expectations, e.g. during the dialogues between industry and local authorities when granting permits.

1 Introduction and objective

The new European chemical legislation REACH has entered into force on 1 June 2007. This Regulation, 1907/2006/EC for **R**egistration, **E**valuation, **A**uthorisation and restriction of **C**hemicals (EC, 2006) aims to streamline and improve the former legislation on chemicals of the European Union (EU). REACH places greater responsibility on industry to manage the risks that chemicals may pose to human health and the environment. All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities of 1 tonne or more per year per company, manufacturers and importers need to demonstrate safe use of their chemical by means of a registration dossier, which shall be submitted to the European Chemicals Agency (ECHA). REACH also includes an authorisation system aiming to ensure that substances of very high concern are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance. In addition, chemical use can be restricted, varying from taking severe risk reduction managements to a complete ban of the chemical.

In principle REACH applies to all chemicals: not only chemicals used in industrial processes, but also in our day-to-day life, for example in cleaning products and paints as well as in articles such as clothes, furniture and electrical appliances (for exemptions see chapter 2).

REACH will gradually produce a large amount of information on the hazardous properties, use and exposure of chemicals from which other, policy frameworks could benefit. Central topic of the current study is the interplay between REACH and those other (inter)national policy frameworks, at present and in the future. The other policy frameworks are here limited to those where environmental risk limits (ERLs) play a role as instruments to safeguard environmental quality, in particular for water and air. How do the risk limits foreseen in the REACH process (PNECs, DNELs, DMELs; see section 2.2) relate to those needed in other policy frameworks? The focus is therefore on Dutch frameworks for environmental quality standard setting (INS¹ and WFD²), authorisation of crop protection products ('Regeling gewasbeschermingsmiddelen en biociden') and granting water discharge permits according to the Dutch Pollution of Surface Waters Act ('Wet verontreiniging oppervlaktewateren', Wvo). More detailed background on REACH and environmental quality standards is given in chapters 2 and 3. Other risk management elements, such as classification and labelling, emission reduction, or those for other protection goals, such as consumers or workers, are not addressed here or are already being covered in other studies. For example, a parallel RIVM study aims on the relevance of REACH for meeting emission reduction goals as laid down for Dutch priority substances (Van Herwijnen et al., in prep.).

The following main questions will be highlighted in the present study:

- To what extent will (inter)national policy frameworks that make use of ERLs benefit from the availability of substance information, including risk limits, from REACH?
- Which (groups of) substances will be involved in the data generation flow, which not, and when will the information become available?

¹Within the framework of INS ('International and national Environmental Quality Standards for Substances in the Netherlands'), environmental quality standards for substances are derived that are used as tools for the realisation of environmental policy objectives. INS is a cooperation between the ministries of Housing, Spatial Planning and the Environment (VROM), Transport, Public Works and Water Management (VenW) and Agriculture, Nature and Food Quality (LNV).

²WFD = Water Framework Directive. Within the project 'Standard setting for other relevant substances within the WFD' RIVM derives environmental risk limits for substances that are selected as relevant for the Dutch river basins.

- Can the information from the REACH dossiers be adopted or used directly into other policy frameworks ('cut and paste')?

The current study will attempt to answer these, and other related questions, and will demonstrate (basic ideas only) what steps are needed to yield an optimal output with a minimum investment for authorities and stakeholders.

This study is a follow-up activity of the workshop of the Confederation of the Netherlands Industry and Employers/The Netherlands Chemical Industry Association (VNO-NCW/VNCI) that was held on 1 October, 2008. During that workshop the participants, including policy makers of the Ministry of Spatial Planning, Housing and the Environment (VROM), emphasised the need for further discussions on the relationship between REACH and other regulatory frameworks on chemicals. The goal of this study is to give direction to these discussions. With that goal the study also contributes to one of the items raised in an internal VROM document on a revision of the structure of the national policy on substances, including the setting and use of environmental quality standards (VROM, 2009). Although this national revision process has just started, the interaction between REACH and quality standard setting in other frameworks should definitely be covered in the new approach. The document 'Handreiking consequenties van REACH voor vergunningverlening' (SenterNovem, 2008) also advocated for addressing this topic. A fundamental point in all these discussions is who will be held responsible for the derivation of environmental quality standards in future. If the responsibility is in the hands of industry what will then be the role of authorities and enforcement? This policy aspect of responsibility is outside the scope of this report, but it will definitely have a large influence on the interpretation of the results.

The subject is not an isolated national discussion point. Other EU member states also may address the interplay between REACH and, for example, the Water Framework Directive (WFD). Reference will be made to the outcomes of an international Berlin 2007 workshop entitled 'Consequences of REACH for other legal and administrative environmental instruments' held in 2007 (Hermann, 2007).

The underlying study is part of the so-called 'Road-map Quality standard setting', which is a series of contributions of RIVM to the development of a revision of the structure on standard setting in the Netherlands. Harmonisation with current international legislation is a prerequisite for the succeeding of that revision.

2 REACH

2.1 Introduction

This chapter will cover both a more detailed description of the REACH legislation (section 2.1) and technical information of risk assessment, and risk limits in particular, within the REACH process (section 2.2).

2.2 REACH legislation

The REACH Regulation (1907/2006/EC; EC, 2006) has come into force on 1 June, 2007. The main objectives of REACH are to protect man and the environment, to keep and improve competitiveness of the internal market, to improve transparency, to improve alternatives to animal testing and to harmonise EU obligations with the World Trade Organization (WTO). REACH thus has dual goals: to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market, while enhancing competitiveness and innovation. REACH distinguishes Registration, Evaluation, Authorisation and Restriction of Chemicals, each of which will be shortly explained. All chemicals fall under the scope of REACH, except for radioactive substances, substances subject to customary inspection, non-isolated intermediates, carriage of dangerous substances, waste and defence (up to individual Member State). For some chemicals, REACH only applies to a limited extent. For example, dossiers on human and animal drugs, food and feed additives, plant protection products and biocides, for which already a dossier exists in other legislation, will be accepted by REACH, i.e. only for the purpose of the intended use of those chemicals.

2.2.1 Registration

Registration of chemicals is mandatory for each chemical that is produced or imported in quantities above 1 tonne per year per producer or importer. Registration immediately applies to chemicals that are new on the market. For chemicals that were on the market before, industry has a right to register the chemical later, provided they pre-registered the chemical before 1 December 2008 to the European Chemicals Agency (ECHA). Currently, over 2.7 million pre-registrations have been submitted, covering over 150,000 individual substances by 65,000 individual companies. These outnumber previous estimates by a factor of 10-20. Each company that pre-registered the same chemical will be added to a SIEF (Substance Information Exchange Forum). The concept of the SIEF resulted from one of the aims of REACH to avoid unnecessary animal testing. Within a SIEF the different registrants of the same substance are to share test data (with the emphasis on vertebrate studies) among the registrants involved and to agree on the classification and labelling of the substance and, optionally, to agree on the chemical safety assessment.

Table 2.1 provides an overview of the three deadlines before which the pre-registered chemicals need to be registered.

Table 2.1. Overview of registration deadlines for chemicals that were on the market before and have been pre-registered. CMR = carcinogenic, mutagenic or toxic to reproduction; cat. 1 or 2 = category 1 or 2; R50-53 = substances classified as very dangerous to the environment; tpa = tonne per annum.

Substance with hazardous properties:	In tonnage	Registration deadline
CMR cat. 1 or 2	> 1 tpa	December 1, 2010
R50-53	> 100 tpa	December 1, 2010
Other	> 1000 tpa	December 1, 2010
Other	> 100 tpa	June 1, 2013
Other	> 1 tpa	June 1, 2018

Registration implies that a set of information on the registrant and on the supplier needs to be handed over to ECHA, in addition to a set of information on the substance. The information requirements are laid down in several annexes of REACH (i.e. Annex VII - X). All available information on the hazardous properties of the substances always needs to be included in the registration, while with increasing tonnage of the substance, more information is required. Information on hazardous properties is required on human health hazard assessment, physico-chemical hazard assessment, environmental hazard assessment, PBT (Persistent, Bioaccumulative and Toxic) and vPvB (very Persistent and very Bioaccumulative) assessment.

It has to be noted that if no adequate information is available for information requirements from Annexes IX and X, the registrant should ask ECHA for permission to carry out those tests by way of submitting a testing proposal. The purpose of this is to try and avoid unnecessary animal testing. Furthermore, if a chemical is produced or imported in quantities of more than 10 tpa and the chemical is classified as dangerous, or the chemical is a PBT or vPvB substance, an exposure assessment and risk characterisation needs to be performed (see section 2.2). Also, a Safety Data Sheet (SDS) needs to be made, if needed, amended with relevant exposure scenarios (ES). The ES provides downstream users with sufficient information on handling and use of the chemical in order to guarantee and communicate about safe use.

For some chemicals or some cases registration does not apply or applies only to a limited extent, i.e. for PPORD (Process and Product Oriented Research and Development), for which only a notification is needed, for plant protection products and co-formulants and active ingredients of biocidal products, as well as for (animal) drugs, food and feed additives, for which the registration in other legislation will do, and for some (on-site and transported) intermediates, for which a reduced registration applies. It must be noted that the information on e.g. registered actives of plant protection products will not as such be included in the REACH database at ECHA. The information will stay in place in databases for other legislation. It must also be noted that substances falling under the afore mentioned categories may have other functions as well, in which case they need to be registered for those uses in REACH.

2.2.2 Evaluation

Since individual companies are responsible for the registration of their dossiers and thus for the chemical safety reports, REACH includes two main types of evaluation for various aspects of quality assurance.

One type is dossier evaluation that actually comprises two elements: a) evaluating test proposals and b) compliance checks of the dossiers.

Ad a) ECHA is obliged to evaluate all testing proposals. ECHA's draft decision can result in an approval to carry out the test, in a rejection (since other appropriate information may be used), or to carry out the test and in addition to provide other information within the context of compliance.

Ad b) ECHA has to check at least 5% of the registration dossiers in each tonnage band on compliance. If the dossier is found to be non-compliant, ECHA can draft a draft decision in order to oblige the registrant to put the dossier in compliance. ECHA has also to check registration dossiers which are prioritised for substance evaluation (see next paragraph). These draft decisions by ECHA can be commented on by the European Member States.

The second type is substance evaluation. Member State Competent Authorities are to perform substance evaluation. However, this should be based on risks, and priorities should be set for selecting substances, resulting in a draft rolling plan. Following adoption of this plan, the substance evaluation should be finished within 12 months. The result of the substance evaluation is that registrants of the substance can be obliged to submit additional information that is relevant for improving the chemical safety assessment of the substance, which can be information on the hazards of a chemical, information on exposure, or both. When this information is submitted by the registrants to ECHA, this can either take away the concern over a chemical, or may lead to subsequent follow-up action, i.e. for example taking the dossier forward to authorisation, restriction, harmonised classification and labelling, or to other legislation.

2.2.3 Authorisation

The aim of authorisation as well as of restrictions is to ensure good functioning of the internal market, while assuring that risks are properly controlled, and where appropriate substances should be replaced by substitution. For authorisation, the rule is that once a substance is placed on Annex XIV of REACH, it can not be placed on the market, unless it is authorised. The scope for authorisation are Substances of Very High Concern (SVHC), i.e. CMRs (Carcinogenic, Mutagenic, Reprotoxic cat. 1 and 2), PBT, vPvB, or 'equivalent concern' substances. Authorisation follows a two-stage process, where first a substance must be identified as SVHC. It will then be placed on the candidate list, with implications that such substances in imported articles above 0.1% should be notified to ECHA and that an SDS should be made for these SVHCs. The next stage is that a selection is made of substances from the candidate list which will be proposed to be included for Annex XIV. This selection is based on priority conditions, such as PBT/vPvB, widespread use and high volume. Hitherto, 15 substances have been placed on the candidate list, while seven of them are proposed to be placed on Annex XIV. Once placed on Annex XIV, companies can ask for an authorisation to remain placing it on the market for specified uses, for which information on alternatives should be made available as well as a socio-economic analysis of the substance, if appropriate.

2.2.4 Restriction

Member States or the European Commission can initiate a restriction for a chemical. This can only be done when there is an unacceptable risk and where a community-wide action is needed. Within 12 months after making publicly known that a restriction will be drafted, it needs to be finalised. In the restriction proposal it needs to be very clear which restriction proposal is made and it is required to come up with clear documentation on the unacceptable risk. The proposal should also contain an analysis of different Risk Management Options and it may contain a socio-economic analysis. The type of restriction may vary from a complete ban, to setting requirements on environmental exposure, i.e. demanding that exposure should be below a certain risk limit.

2.3 REACH and risk limits

Within REACH the chemical safety assessment (CSA) forms an essential part of the registration file. For substances registered above 10 tonnes per year a CSA according to the format as allocated in Annex I of the REACH legislation is mandatory. As part of the hazard assessment of the chemical, the

Derived No Effect Levels (DNELs) for human health hazards and the Predicted No Effect Concentration (PNECs) for environmental hazards should be derived. For toxicological effects for which no safe level of exposure can be established, Derived Minimum Effect Levels (DMELs) should be derived instead of DNELs. The basis for the DNEL and PNEC derivation is (eco)toxicological data. By applying appropriate assessment factors (also called extrapolation or safety factors) a no-effect or safe level is being derived from critical test data (key study, i.e. the lowest or most critical no- or low-effect level with respect to a specific (eco)toxicological endpoint and a relevant exposure route from a sufficiently reliable test).

The human toxicological endpoints of interest are acute effects (acute toxicity, irritation and corrosivity), sensitisation, repeated dose toxicity and CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction), with workers, consumers and man indirectly exposed via the environment as human protection targets. DNELs should be derived for all relevant exposure routes (inhalation, dermal and oral). With respect to the environment, the protection targets of interest are the aquatic (including sediment), terrestrial and atmospheric compartment, including effects via food-chain accumulation and microbial activity of sewage treatment plants. For all environmental protection targets individual PNECs are derived.

Table 2.1 shows the information requirements on *ecotoxicological* endpoints based on REACH Annexes VII-X. It shows that the information requirements increase with tonnage levels. Exemptions or exposure-based waiving, etc. are not addressed here. With increasing tonnage levels, more information on additional taxonomic groups has to be made available to cope with uncertainties around interspecies variability, and more long term information is needed to extrapolate towards life-time exposure of ecosystems. Information related to other environmental compartments than water is requested as well. Accompanying PNECs can thus be based on different data sets and this is reflected in the magnitude of the assessment (or uncertainty) factor. With more data available, less residual uncertainty on the extrapolation towards field ecosystems is present, and therefore a lower assessment factor (10-1000) can be used in the PNEC derivation. In addition, for soil and sediment, at higher tonnage levels the PNECs can be based on actual test data for these compartments rather than solely applying the equilibrium partitioning method on water data. In general one could state that

		Invertebrate Fish	Invertebrate Plant Sediment (Birds)	<i>Long-term</i>
Plant (algae) Invertebrate (Daphnia) Water	Fish	Plant Invertebrate Micro-organism	Soil and sediment	<i>Short-term</i>
Annex VII ≥ 1 tonne	Annex VIII ≥ 10 tonnes	Annex IX ≥ 100 tonnes	Annex X ≥ 1000 tonnes	

Figure 2.1 REACH information requirements on ecotoxicology (short term and long term tests; Annex VII-X).

uncertainties in the PNEC decrease with larger data sets. It should be noted that the above-mentioned is focused on the minimum information requirements. For particular chemicals more data may be available than this minimum set, e.g. data from chronic tests, resulting in PNECs based on smaller assessment factors (lower uncertainty).

With increasing market volumes the *human* toxicological information requirements also gradually increase (see Figure 2.2), with more human toxicological endpoints to be covered. The information requirements range from the screening- or sub-acute level to a full or (sub)-chronic study reducing the uncertainty with respect to the derived endpoints that form the basis for the derivation of DNELs and DMELs. In addition, the more human toxicological endpoints are being covered the lower the uncertainty with respect to the derived over-all No Observed Adverse Effect Level (NOAEL) and thus DNEL.

		Developmental toxicity	Repeated dose toxicity (≥12 months)	<i>Chronic</i>
		Two-generation reproductive toxicity	Developmental toxicity Two-generation reproductive toxicity	
			Carcinogenicity	
(Acute toxicity (oral))	Repeated dose toxicity (28 days) Reproductive/developmental toxicity screening	Repeated dose toxicity (28 – 90 days)		<i>(Sub-)acute and sub-chronic</i>
Annex VII ≥ 1 tonne	Annex VIII ≥ 10 tonnes	Annex IX ≥ 100 tonnes	Annex X ≥ 1000 tonnes	

Figure 2.2 REACH information requirements on human toxicology ((sub)-acute, sub-chronic and chronic tests; Annex VII-X).

Within REACH the DNELs are being derived from the human toxicological endpoints as specified in Table 2.2. The REACH legislation, however, reports that the appropriate/relevant exposure routes have to be tested with respect to the human toxicological information requirements (oral, dermal and inhalatory). Guidance is given on which route is to be tested. This is based on substance properties, like vapour pressure and average size of a particle (can it be inhaled?) and the likeliness of exposure related to the use of the substance (will it be inhaled?). Sub-acute, sub-chronic and chronic studies with dermal and inhalation exposure are not always technically possible. Furthermore, the costs of these studies are an order of magnitude higher in comparison to the oral exposure route. It is therefore likely that most long-term studies will be performed with oral exposure resulting in a DNEL for that specific endpoint. DNELs will most certainly not be separately derived for all exposure routes even if they are relevant for a particular chemical. Instead, oral DNELs will be ‘route-to-route’ extrapolated to DNELs for the other exposure routes.

By making use of the appropriate assessment factors DNELs can subsequently be derived for the relevant protection targets (i.e. workers, consumers and man exposed via the environment).

Table 2.2 The various DNELs/DMELs as potentially being derived in REACH.

Exposure pattern	DNEL/DMEL (appropriate unit)	
Acute – inhalation, systemic effects	worker-DNEL acute for inhalation route-systemic	General population-DNEL acute for inhalation route-systemic
Acute – dermal, local effects	worker-DNEL acute for dermal route-local	General population-DNEL acute for dermal route-local
Acute – inhalation, local effects	worker-DNEL acute for inhalation route-local	General population-DNEL acute for inhalation route-local
Long-term – dermal, systemic effects	worker-DNEL long-term for dermal route-systemic	General population-DNEL long-term for dermal route-systemic
Long-term – inhalation, systemic effects	worker-DNEL long-term for inhalation route-systemic	General population-DNEL long-term for inhalation route-systemic ¹
Long-term – oral, systemic effects	Not relevant	General population-DNEL long-term for oral route-systemic ¹
Long-term – dermal, local effects	worker-DNEL long-term for dermal route-local	General population-DNEL long-term for dermal route-local
Long-term – inhalation, local effects	worker-DNEL long-term for inhalation route-local	General population-DNEL long-term for inhalation route-local

¹ DNEL/DMEL most relevant for environmental quality setting.

The information requirements as specified in Annex VII to X of REACH can be fulfilled in a ‘traditional’ way by performing tests. However, for particular physico-chemical or (eco)toxicological endpoints non-testing data should also be taken into account before executing a test, as specified in Annex XI of the REACH regulation (i.e. all existing information among which non-GLP studies and historical human data, data from (Quantitative) Structure-Activity Relationships (SAR or QSAR) and *in vitro* methods). Read-across can be considered, in addition to the question if testing is technically feasible or can be waived based on absence of exposure. It is up to the registrant to compile test and alternative data in a responsible and effective way.

When test data are submitted, a robust study summary (RSS) for at least the key-study should be provided in the registration dossier for each relevant endpoint using IUCLID (International Uniform Chemical Information Database, <http://iuclid.echa.europa.eu/>). While the toxicological endpoint will be made publicly available, some of the RSSs may be kept confidential by the registrant³, the full study report will not even be part of the registration dossier. Within 12 years after registration, vertebrate test data are to be shared mandatory between different registrants of the same chemical, for which the registrants should seek for financial arrangements. The study summaries of registrations will become publicly available after 12 years and can be used for the purposes of registration by other manufacturers or importers.

Only when substances are dangerous according to the rules laid down in Directive 67/548/EEC (EC, 1967) or when the substances are PBT or vPvB an exposure and risk assessment should be performed. Then, also exposure scenarios should be composed and added to the SDS. Consequently, only for dangerous substances or PBT/vPvB substances it needs to be established that a safe use (including risk reduction measures when needed) is demonstrated for production or import at the subsequent supply-chain for all relevant human and environmental protection targets.

³ Industry has the option to claim confidentiality. Requests towards ECHA should be underpinned with reasoning.

Although the aim of the SIEF is to share test data among the registrants involved and to agree on the classification and labelling of the substance, it should be noted that registrants can derive different DNELs or PNECs for the same substance, depending on the amount of available test and alternative data. It is the responsibility of the individual registrant to assess the validity, relevance, reliability and adequacy of all test and alternative data used for the registration and, in addition, to derive - with the most appropriate assessment factors – the most appropriate DNELs and PNECs. There is no general step within REACH to harmonise PNECs or DNELs other than the possibility of drafting a restriction, when community-wide risks are observed and where risk reduction can be achieved by obliging the registrants to keep exposure below a PNEC or DNEL. In addition, it should be noted that agreement on classification and labelling does have to be reached within the SIEF.

The REACH regulation does not address accidents, spillage or inappropriate use of the substance or waste disposal.

3 Environmental quality standards

3.1 Introduction

Environmental quality standards specify the concentration of a particular substance that should not be exceeded in an environmental compartment. These standards are numerical values, which are derived per compartment (e.g. ambient air, surface water and sediment). The standards are used as starting point for various implementing aspects, such as, the assessment of environmental quality, the phrasing of source-oriented policies and its prioritisation, the issuing of standards for plant protection products, the recalibration and formulation of government emission reduction objectives and the issuing of licenses.

The underlying study focuses on a limited number of regulatory frameworks in which environmental risk limits play a central role: 1) the setting of environmental quality standards, 2) the granting of discharge permits and 3) the authorisation of plant protection products and biocides. These frameworks can be regarded as supplementary to REACH as they cover other niches in chemical risk management. In contrast to REACH (see chapter 2) the responsibility of managing the chemical risks within these policy frameworks is in the hands of local and national authorities, although considerable efforts may be required from industry within the authorisation process.

Each of the regulatory frameworks generally goes through a series of steps, involving policy and science (Figure 3.1). In Step 1 a policy decision is needed to start the process of deriving an

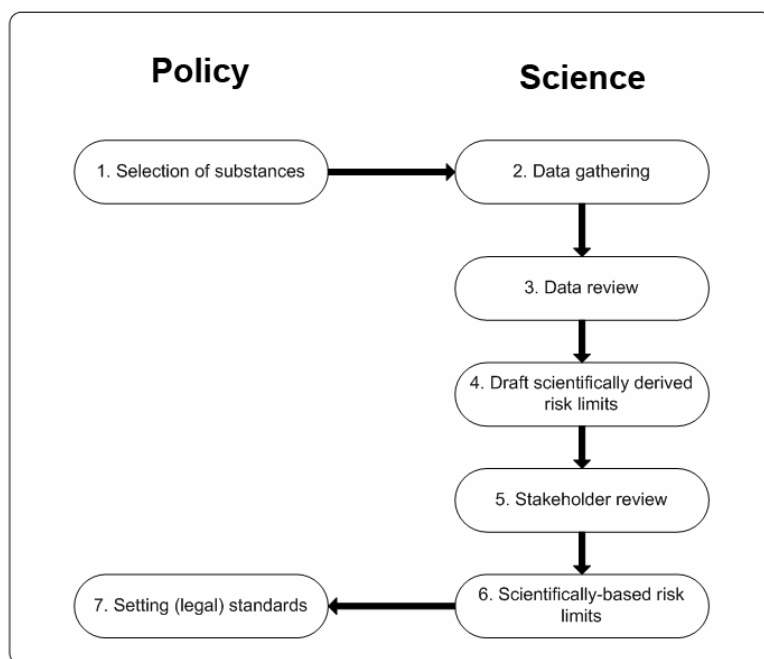


Figure 3.1 The various policy and science steps that are taken to initiate and to complete the process of setting legal or non-legal environmental quality standards.

environmental quality standard (standard). This can be based on concern over the observation of detectable concentrations of a substance in the aquatic, benthic or aerial environment or based on other types of concern. In the scientific part of the process, data will then be gathered on the substance (Step 2), which may include ecotoxicological and toxicological data, physico-chemical data as well as monitoring data, emission sources, et cetera. The quality and relevance of the data will then be reviewed in Step 3, which results in the underlying dataset from which an environmental risk limit can be derived. In Step 4 scientifically-based risk limits will be derived, following accepted guidance. In some regulatory frameworks, a stakeholder review (Step 5) is included to ask for scientific input from other parties. In Step 6 the stakeholder review is included and a scientific advice is handed over to policymakers who then decide to set environmental quality standards, if still needed in Step 7. The numerical value from the scientific advice may be taken over or may be adjusted, if needed. To emphasise the difference between a scientific advice and a formal (legislative) standard, the ‘term environmental risk limit’ (ERL) is used for the former while ‘standard’ is used for the latter. Below a description is given of important (inter)national regulatory frameworks, including the position of ERLs and standards in the individual process.

3.2 (Inter)national environmental quality standards for substances

The derivation of ERLs in the Netherlands takes place within the process of ‘International and national **environmental quality standards** for substances in the Netherlands’ (INS), in order to support environmental policy. The following four ERLs are distinguished:

- the negligible concentration (NC)
- the maximum permissible concentration (MPC)
- the serious risk concentration for ecosystems (SRC)
- the maximum acceptable concentration for aquatic ecosystems (MAC_{eco})

Detailed guidance on the derivation of ERLs within the context of INS is given by Van Vlaardingen and Verbruggen (2007). For the aquatic compartment, this guidance implements the methodology for standard setting within the context of the European Water Framework Directive (WFD; EC, 2000) as developed by Lepper (2005). The methodology for derivation of the MPC for the soil compartment is based on the Technical Guidance Document (TGD) used for the European risk assessment for new and existing substances, and biocides (EC, 2003). The methodology for derivation of the remaining ERLs is based on Dutch procedures. Since for the water compartment the ERL derivation according to the WFD methodology includes the derivation of an MPC protecting humans and predatory birds and mammals from adverse effects, this aspect has also been implemented in the derivation of risk limits for soil. Several physical, chemical and (eco)toxicological parameters are needed to derive ERLs. Detailed guidance is given in Van Vlaardingen and Verbruggen (2007) on the parameters needed and how data should be collected, evaluated and selected before the ERL derivation is started.

3.3 Water Framework Directive

In October 2000, the Water Framework Directive (WFD; 2000/60/EC) was adopted (EC, 2000). The WFD has consequences for water management in Europe. The WFD aims at ‘maintaining and improving the aquatic environment in the Community’. The ultimate aim is to achieve the elimination of priority hazardous substances. Under the WFD, member countries are obliged to draw up river basin management plans. These plans must contain a programme of measures to achieve the objective of at least a ‘good ecological status’ and a ‘good chemical status’ by defining and implementing the necessary measures within integrated programs of measures. Where good water status already exists, it

should be maintained. The plan must include measures to end the contamination of water by certain pollutants.

The WFD prescribes that prior permission is required for all process releases of significant quantities of pollutants and certainly for the substances of Annex VIII of the WFD (Steps 1 and 7, Figure 3.1). The basic measures must include release limits or comparable measures and **quality standards** laid down by current directives, as well as specific measures required by the European Commission to prevent the contamination of surface waters by individual pollutants or groups of pollutants, which cause an unacceptable risk to or via water. The Commission's priority list of 33 (groups of) substances will be adopted. Additional measures are still possible. Insofar as not mentioned in Annex VIII to the WFD, substances on the priority list will be added (Step 1, Figure 3.1). This is also valid for Annex III to the IPPC Directive 96/61/EC (EC, 1996).

For substances on the priority list, the European Commission will propose measures to be taken at the source (processes and products). Where possible, steps will be taken on an EU level to lay down process measures for each branch of industry. Moreover, measures at product level are being specified. The Commission will also make **quality target** proposals for these substances, with regard to water, sediment and organisms. If these are not defined at community level, the member countries must include **quality targets** for these substances in their river basin management plans for all the waters that are affected by discharge of these substances.

From the list of priority substances, so called hazardous priority substances will be selected by the European Commission (Step 1, Figure 3.1). For these pollutants measures shall be aimed at ceasing or phasing out discharges, emissions and losses within 20 years after the adoption of the measurements. The European Commission is also entitled to issue measures for all other substances in order to prevent water pollution, including pollution due to accidents. In other words, the European Commission may define measures for substances that constitute a risk to water at community level in order to protect the surface and groundwater against pollution. These measures may be either process-oriented or product-oriented. Process-oriented measures focus on the application of the latest techniques or compliance with emission limits and **water quality objectives**.

3.4 Dutch Pollution of Surface Waters Act

When granting a discharge permit under the Dutch Pollution of Surface Waters Act, the General Assessment Methodology (GAM) is used. The GAM for substances and compounds entails that a manufacturer or downstream user answers a limited number of specific questions on the properties of the substance/compound that may affect the aquatic environment. The potential environmental hazard posed by it can be assessed in this way. The higher the potential environmental hazard, the greater the effort needed to prevent or reduce it. For the sake of clarity, the GAM classifies substances/compounds into three categories. A 'desired decontamination effort' (A, B, or C) is linked to each GAM category:

- *A*: The aim is to approximate a 'zero discharge' as closely as possible. To achieve this, industrial processes must be adapted (using the best available techniques) or other substances/compounds must be used.
- *B*: The aim is to prevent discharge of the relevant substance/compound as far as possible through the use of the best practicable techniques. Process selection and internal operational management must also be optimally geared to this.
- *C*: The discharge of relatively harmless substances (such as sulphate, carbonate and chloride) must also be prevented as far as possible. To what extent action must be taken for this purpose depends on the water quality objectives.

Once the desired action has been taken, a *residual discharge* will nevertheless generally be involved. The question of whether this is acceptable is resolved via an *immission test*. In any event, conditions must be met in this context:

- residual discharge must not contribute significantly to failure to achieve the **water quality target** for the *aquatic system* (water and soil) into which the discharge is taking place.
- residual discharge must not lead to acute toxic effects on organisms living in the water or sediment *within the mixing zone*.

The CIW report entitled ‘Emission/immission - prioritisation of sources and the immission test’ (see: www.helpdeskwater.nl) deals with this subject. In general, the **MTR (MPC)** is used as the water quality target in the above described GAM process. The MPC is defined as the value derived following the INS approach (see section 3.2).

3.5 National Air Emission Guidelines

A number of activities or installations which are not covered by either IPPC directive (2008/1/EC (EC, 2008), formerly 1996/61/EC (EC, 2006)) or the Dutch Activity Decision have to be authorised using the National Air Emission Guidelines (NeR) which focus on specific activities. Emissions to air are granted using the methods laid down in the NeR. When issuing licenses it should be checked if these emission levels comply with statutory limit and guidance values (‘EU luchtkwaliteitseisen’) or non-statutory **environmental quality standards (MPC and NC)** for the atmospheric compartment. If not, this may be a reason for additional emission reduction measures or withholding.

3.6 Authorisation of plant protection products and biocides

The Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) takes decisions on the authorisation of plant protection products (PPPs) and biocides within the framework of the rules and legislation concerned. The basis of the authorisation process are EU-Directive 91/414/EEC (EC, 1991) and its successor Regulation 1107/2009/EC (EC, 2009), and Directive 98/8/EC⁴ (EC, 1998) The directives/regulations set out a frame for a two step evaluation procedure. The first step is the entry of the active substances onto a positive list (Annex I). The Annex I inclusion directives are based on risk assessment reports with associated lists of endpoints. Listing is granted when one safe use is demonstrated for a representative product. The second step is the national authorisation of proposed uses of products with that active substance. The environmental risk assessment should address the fate and distribution in the environment and the impact on non-target organisms on the acute and long-term time scale. The risk assessment for PPPs refers to specific organism groups (e.g. birds and mammals, aquatic organisms, honeybees et cetera) which are considered separately with their own assessment schemes. The biocides risk assessment is technically based on the TGD, in which compartment specific PNECs play a central role in the environmental risk assessment.

In the Netherlands, specific national items are addressed in the Regulation on plant protection products and biocides (‘Regeling houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden, Rgb’; Staatscourant (2007)). The Rgb connects the authorisation of plant protection products and biocide use with the general **environmental quality objectives** by using the **MPC_{soil}** and **MPC_{water}** as

⁴ The new EU PPP Regulation 1107/2009/EC came into force on 14 December 2009 and applies from 14 June 2011. A new biocide regulation will gradually be implemented during the coming years.

authorisation criteria. In the Rgb the MPC is specifically used when considering the persistency criterion and the risk assessment of aquatic organisms:

- Persistency (Article 2.8). When applying the uniform principles, the Ctgb decides that a plant protection product has no unacceptable effect on the environment if it is demonstrated that the concentration of the active ingredient, or a relevant metabolite, in the soil of the treated area, does not exceed the **MPC_{soil}** within a period of two years after the latest application of the plant protection product. The Ctgb calculates the MPC following the INS methodology (see section 3.2).
- Aquatic organisms (Article 2.10). An effect of a plant protection product on aquatic organisms is not considered as an unacceptable effect if it is demonstrated in a risk assessment that there is no exceeding of the **MPC** for aquatic organisms. The Ctgb calculates the **MPC_{water}** following the INS methodology (see section 3.2).

4 REACH and needs of other policy frameworks

4.1 Introduction

As noted in chapter 1 discussions have been started in the Netherlands on a revision of the structure of the national policy on substances, including the setting and use of environmental quality standards. Several outcomes of these discussions are possible, including a shift towards (more) responsibility for industry when setting environmental quality standards. A variety of other options may be possible as well, but up to now the ultimate direction remains rather open. It should be realised that this is a policy issue that is outside the scope of this more technical report. However, the outcome of that discussion will eventually have a large influence on the interpretation of the results of this study.

For the purpose of this study it is assumed that authorities will keep their responsible role in the derivation of environmental quality standards or in any case will have a role in the final approval of quality standards (Step 7, Figure 3.1).

As indicated in chapter 3 there are several (parts of) policy frameworks that are built on, or make use of, environmental quality standards. These environmental quality standards are set both at a national level (permits, INS, WFD in case of ‘other relevant substances’, plant protection products and biocides) or at community-wide level (e.g. WFD priority substances). It is expected that in the future environmental quality standards will still be needed as instruments to safeguard environmental quality. New or emerging substances will show up for which environmental quality standards will be lacking. This may stretch out to the full spectrum of chemical substances, from industrial chemicals to human and veterinary drugs or biocides. There may also be reasons to revise existing environmental quality standards. Furthermore the current legislation on plant protection products may trigger the derivation of environmental quality standards for either soil or water. Environmental quality standards also play a role in prioritisation programmes, i.e. making lists of priority chemicals for which special attention is needed. It can be concluded that several related policy or regulatory frameworks have a clear ‘need’ for environmental quality standards, although it is difficult to say for how many chemicals and for which specific chemicals. When there is a need for environmental quality standards, VROM (2004) clearly states to take as much advantage as possible from standards or risk limits as derived at EU level. Similarly, current EU legislation requires that information from other frameworks is used where possible (e.g. PPP dossiers should be used for authorisation of biocides with the same active ingredient, PPP and biocide dossiers should be considered within the context of the WFD). This in order to avoid duplication, but also for harmonisation purposes.

Within the next decade REACH will generate many data on relevant characteristics of tens of thousands of chemicals (see chapter 2). The information will become available to the authorities and other stakeholders (general public, NGOs and industrial partners). In this way many of the data gaps may be filled that are now identified when deriving risk limits (Step 2, Figure 3.1). The data flow related to hazard will consist of a set of basic entries on (eco)toxicological endpoints. In addition, for most chemicals the registration dossier will also include PNECs and DNELs. These risk limits are an obligatory part of the CSA (see section 2.3), irrespective if exposure scenarios and a risk characterisation have to be conducted. In principle, the other policy frameworks may thus take great advantage of these REACH outcomes. From another angle REACH may also ‘feed’ other frameworks as a tool to select or prioritise chemicals to be addressed at community-wide level (Step 1, Figure 3.1). For example, the conclusion of a restriction or substance evaluation dossier can be that further actions on that chemical should be addressed via the WFD (see section 4.2).

The first set of large numbers of REACH registration dossiers will only become available by the end of 2010. This implies that several conclusions in this study are based on assumptions. For example, it is unknown to what extent non-testing methods will be submitted as alternative for animal testing requirements. It remains also speculative whether or not indeed different PNECs or DNELs will show up for the same chemical due to incoherent registration dossiers. The same holds for the amount of information that registration dossiers will contain in addition to the minimum data requirements. Time will show what REACH will actually generate, but it is important to anticipate on a number of potential outcomes and pitfalls.

This chapter focuses more specifically on the match between the REACH outcomes on the one hand and the data needs and expectations of policy makers and authorities being active in other areas on the other hand. Section 4.2 systematically describes the various steps within the REACH process and roughly indicates how each stage relates to the scheme of environmental standard setting as applied in other policy frameworks (Figure 3.1). More details on the possibilities and the limitations of the use of REACH risk limits will be discussed in section 4.3. Aspects like the quality and availability of REACH data will be highlighted, but also technical differences and differences in protection levels between REACH and INS/WFD risk limits.

4.2 Support from REACH

Table 4.1 systematically goes through the various stages of the REACH process, i.e. registration, evaluation, authorisation and restriction. Based on the individual steps of the standard setting scheme as presented in Figure 3.1, it is indicated for each stage if other policy areas dealing with setting or using environmental quality standards may benefit from it.

Table 4.1 shows that in a number of stages REACH may support Step 1 'selection of substances', Step 2 'data gathering' and Step 3 'data review'. When other policy frameworks are selecting substances to be further addressed it is very relevant that they know about the 'status' of that chemical in the REACH process, e.g. is the chemical relevant at national scale only or will a restriction proposal on EU-level be drafted. This may have consequences for the ultimate selection or removal of that chemical in the further flow of the policy framework (Step 1). If selected, REACH will provide helpful information to be used in both data gathering (Step 2) and data reviewing (Step 3). The restriction stage of REACH may trigger a closer dialogue between REACH and other policy areas such as the WFD. Authorities more prominently come on the screen because of their drafting of a restriction proposal. Furthermore REACH restriction relates to chemicals for which community-wide actions are needed which explicitly brings chemicals at a higher policy attention level. In the case of authorisation, it is worth noting that once a substance is included in Annex XIV of REACH and industry applies for an authorisation, the application must show that the risk are controlled (below the PNEC or DNEL) in the case of substances with an (eco)toxicological threshold, or that a socio-economic analysis is included in the case of substances with a non-threshold, e.g. certain carcinogens. In all cases the Risk Assessment Committee (RAC) at ECHA will evaluate the risk assessment part of the application proposal. The closer involvement of authorities may imply that restriction and authorisation may converge with Step 7 'setting of (legal) standards'. The same holds for substance evaluation.

For chemicals on Annex XIV, where companies have obtained an authorisation, the authorities could check e.g. on site whether the conditions of the authorisation are met. For example, one of the conditions could be that emission is below a specific limit, which may be compared to an environmental quality standard. REACH refers to the WFD or one of its daughter directives. In Article 2(4) of REACH it is stated that REACH shall apply without prejudice to, among others, the WFD. Article 61(5) of REACH states that when the environmental objectives as referred to in Article

4(1) of the WFD are not met, the authorisations that are granted for the use of the substance concerned in the relevant river basin may be reviewed.

Step 4 ‘drafting scientifically based standards’, Step 5 ‘stakeholder review’ and Step 6 ‘setting scientifically based risk limit’ are not covered in Table 4.1. These steps are typical for the various policy frameworks and they are therefore not relevant in this context or they profit only to a lower extent from REACH. The stakeholder review (Step 5) with regard to setting the ‘environmental risk limit’ in terms of a PNEC is very limited or even absent for many REACH chemicals (internal industry review only). Caution is needed at Steps 4 and 6, because of a number of conceptual differences and limitations of the risk limits derived under REACH (see section 4.3).

Table 4.1 REACH stages and implications for other legislation related to setting/using environmental quality standards.

REACH stage REGISTRATION	Content	Comments	Implications for other frameworks involved in setting/using environmental quality standards
- pre-registration	<ul style="list-style-type: none"> ○ Enterprises that produced or imported chemicals on the market before REACH ('phase-in substances') could pre-register their chemicals before December 1, 2008, to access right to register at a later time. ○ Each producer or importer of the same substance is assigned to a Substance Information Exchange Forum (SIEF), to share data on animal testing and to harmonise classification and labelling, with options to opt out. 	Pre-registration has resulted in 2.7 million pre-registration on almost 150,000 individual substances by 65,000 individual companies.	<p>Check can be made on pre-registration list to find out whether or not the chemical of interest is likely to be produced in or imported into the European market, and when the anticipated deadline of registration is.</p> <p>Relevance for Step 1, 2 and 3 (Figure 3.1)</p>
- registration	<ul style="list-style-type: none"> ○ Chemicals new on the market ('non-phase in substance') require immediate registration to ECHA. ○ 'Phase-in substances' are to be registered within 3 deadlines (before 1 December 2010, before 1 June 2013, and before 1 June 2018) to ECHA. ○ Substances for research and development ('PPORDs') do not require registration, but should instead be notified to ECHA. 	<p>ECHA's database will gradually be filled with registrations of all chemicals on the European market in tonnage levels of > 1 tpa. The content of a registration depends on the tonnage level, the hazardous properties of the chemical and the use and exposure patterns. Each registration should include the steps in Annex I:</p> <ul style="list-style-type: none"> – assessing the toxicological hazards to human health – assessing the physical-chemical hazards to human health – assessing the hazards to the environment – assessing for PBT and vPvB <p>These steps include the derivation of PNECs and DNELs, where appropriate. If the chemical is in a tonnage band of > 10 tpa, and the substance is either dangerous or a PBT/vPvB, in addition an exposure assessment and a risk characterisation needs to be included in the registration.</p> <p>Each registration should contain information from at least Annex VI and VII, on:</p>	<p>Over time information on the hazardous properties of chemicals become available in the ECHA database. Part of it will become publicly available, e.g. results of endpoints, while other pieces of information will not become available, e.g. robust study summaries, confidential business information.</p> <p>Relevance for Steps 1, 2 and 3 (Figure 3.1).</p>

REACH stage REGISTRATION	Content	Comments	Implications for other frameworks involved in setting/using environmental quality standards
		<ul style="list-style-type: none"> - substance identity - use - classification and labelling - guidance for safe use and exposure - physico-chemical properties - toxicological information - ecotoxicological information. <p>There may be one or more registration dossiers for each chemical, with different information on the same chemical.</p>	

Table 4.1 (cont.)

REACH stage EVALUATION	Content	Comments	Implications for other frameworks involved in setting/using environmental quality standards
- dossier evaluation: compliance	<p>ECHA has the legal duty to check >5% of all dossiers within each tonnage band for compliance.</p> <p>The compliance check may vary from a targeted to a more comprehensive check, but is limited to a certain extent. The result may be that a company should provide more or better information.</p> <p>Member States and the European Commission are involved in the decision process.</p> <p>EU Member States can also perform compliance checks on a dossier on voluntary basis and may then inform ECHA the results of it. ECHA may then decide to pursue such a dossier.</p>	<p>Note: the check if a registration dossier is complete is part of the registration process.</p>	<p>Information on the compliance checks may provide quality assurance of the items of the dossiers that have been evaluated.</p> <p>Relevance for Steps 2 and 3 (Figure 3.1).</p>
- dossier evaluation: test proposal	<p>ECHA has the legal duty to perform an evaluation of each test proposal, within a limited time period following the registration. The objective is to avoid animal testing where possible. A public consultation period is foreseen to ask third parties whether there is relevant information.</p> <p>The result may be that a company is allowed to perform the testing, is not allowed to do so (because there is relevant information available) or that in addition other tests should be carried out or information be provided.</p> <p>Member States and the European Commission are involved in the decision process.</p>		<p>Relevance for Steps 2 and 3 (Figure 3.1).</p>
- substance evaluation	<p>If in the case a substance causes a community-wide concern for man or the environment, all relevant registrations of a substance can be integrated and evaluated. When appropriate,</p>		<p>Relevance for Steps 2, 3 and 7 (Figure 3.1).</p>

	<p>additional information can be asked from industry on the hazards, exposure or use.</p> <p>The process involves a formal procedure where first a substance needs to be identified and agreed upon, followed by appointing a Member State to perform the substance evaluation within a period of 12 months.</p>		
- PPORD	<p>A notification is required for substances for Product and Process Oriented Research and Development (PPORD). ECHA can provide conditions to ensure worker protection and environmental protection is guaranteed.</p>	<p>A notification includes much less than a registration. The notification is time limited. Member States may comment on the notification to ECHA.</p>	<p>May have little relevance for setting environmental quality standards.</p>

Table 4.1 (cont.)

REACH stage AUTHORISATION	Content	Comments	Implications for other frameworks involved in setting/using environmental quality standards
- general	A substance on Annex XIV is not allowed to be used or to be placed on the market, unless it is authorised. To bring a substance on Annex XIV, two steps are needed. Then, companies may get an authorisation, following a formal request.		
- identification of SVHC's	The scope of authorisation is limited to Substances of Very High Concern (SVHC). EU Member States and ECHA may identify an SVHC via an Annex XV SVHC dossier that will be discussed. If agreed upon by ECHA and the Member States, the substance will be placed on the 'candidate list'.	<p>Substances of Very High Concern are a) carcinogens, b) mutagenic substances, c) toxic to reproduction, d) Persistent, Bioaccumulative and Toxic (PBT), e) very Persistent and very Bioaccumulative (vPvB) and f) substance of equivalent concern.</p> <p>If a substance is on the 'candidate list', articles that are imported in the EU containing > 0.1% of the substance need to be notified to ECHA. In addition, a Safety Data Sheet needs to be made for such substances to communicate about these hazards.</p>	<p>The candidate list will provide a list of substances with known and agreed hazardous properties, some substances more relevant for human health and others for the environment.</p> <p>Relevance for Steps 1, 2 and 3 (Figure 3.1).</p>
- amending Annex XIV	From the candidate list, a select number of substances will be proposed by ECHA for amending Annex XIV. The selection will be primarily focussing on environmental concern, high tonnage substances with wide-spread use. The European Commission will take the decision to amend Annex XIV with information of the sunset date, the date after which the substance can no longer use or place on the market, without an authorisation.		Relevance for Step 1 (Figure 3.1).

<p>- granting of authorisations</p>	<p>Following inclusion of a substance in Annex XIV, companies who want to continue placing the substance on the market, need to apply for an authorisation, that may include information on alternatives, evidence that benefits outweigh the risks or that risks are not at stake. The request is evaluated by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) at ECHA, followed by an advice to the European Commission. The latter decides about granting or not granting the authorisation. If authorised, a regular review is included next to a detailed description of the authorisation. The RAC will likely review the quality of the relevant PNEC or DNEL.</p>		<p>Relevance for Steps 1, 2, 3 and 7 (Figure 3.1).</p>
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Table 4.1 (cont.)

REACH stage RESTRICTION	Content	Comments	Implications for other frameworks involved in setting/using environmental quality standards
- general	<p>A substance as such, in a preparation or in an article for which a restriction is included in Annex XVII may not be produced, imported or used, unless conditions tell otherwise.</p> <p>If a substance as such, in a preparation or in an article, is a carcinogen, mutagen or toxic to reproduction (CMR) and possibly be used by consumers, it is included in Annex XVII with a fast-track procedure.</p>		
- drafting of an Annex XV restriction proposal	<p>If a substance implies a risk for man or the environment that cannot be sufficiently controlled and requires community-wide action, then an Annex XV restriction proposal needs to be drafted. This proposal can be drafted by an EU Member State or by ECHA upon request by the European Commission. The proposal may include a socio-economic analysis together with a targeted or comprehensive risk assessment.</p> <p>The proposal is evaluated by the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC) at ECHA, followed by an advice to the European Commission. The latter decides about the restriction proposal and amending Annex XVII.</p>	<p>A restriction can be focussed on several issues, ranging from conditions to keep environmental concentrations below the PNEC/DNEL to a complete ban on production and use of the chemical.</p> <p>Within the proposal an evaluation of other Risk Management Options should be performed, which may include IPPC or WFD or a harmonised C&L under the CLP Regulation.</p>	<p>Relevance for Step 1, 2, 3 and 7 (Figure 3.1).</p>

4.3 Considerations on use of REACH risk limits in other policy areas

4.3.1 Introduction

In section 4.2 it is outlined that REACH may have a positive impact on the process of standard setting. Below an analysis is given on a number of considerations. The issues refer to various steps in the scheme of standard setting (Figure 3.1).

4.3.2 Quality, confidentiality and availability of data

Until now it is not foreseen that all the PNECs and DNELs that become available from the REACH registration dossiers will be structurally checked on validity by ECHA or any other authority, e.g. on the use of the relevant key studies, the correct assessment factor, et cetera. As stated in section 2.1 ECHA is obliged to perform a compliance check on at least 5% of the registration dossiers in each tonnage band. In addition, Member States' competent authorities, including inspection and enforcement authorities, also have the possibility to evaluate the registration dossier and to inspect the presence and quality of the underlying studies at the company (registrant) level, and subsequently to inform ECHA about these findings. A compliance check may, however, vary from a focussed evaluation of the quality of a study on a single ecotoxicological endpoint, to a more comprehensive evaluation of the registration dossier. Therefore, if a dossier is evaluated for compliance, this does not necessarily imply that the PNECs and DNELs will undergo a quality review.

In the case of a substance evaluation, restriction proposal and authorisation a more thorough evaluation of the registration dossiers may be involved (see section 4.2). The trigger for the restriction proposal is that there is a community-wide concern over the use of the substance and use should be more restricted. The concern or proposed restriction may, however, relate to either consumers, workers, the general public or the environment, but will not necessarily address all of these. Therefore, also the more thorough restriction proposal may be focussed and will not always evaluate all PNECs and DNELs for the substance of concern. The same may be true for authorisation and substance evaluation. It should further be realised that these stages may undergo a complex and lengthy process under REACH.

In section 2.3, the issue of publication and confidentiality of REACH data has been addressed. Article 119, paragraph 1 states that physico-chemical data concerning the substance and on pathways and environmental fate (119.1.d), the result of each toxicological and ecotoxicological study (119.1.e) and any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I (119.1.f) will be made publicly available over the internet. However, the study summaries or robust study summaries of the information referred to in paragraph 119.1(d) and (e) may not be available for the public. Only competent authorities have access to all underlying data (via IUCLID) or can request industry for further information.

In section 2.3 the point is raised that registrants depending on the amount of available test and alternative data can derive different DNELs or PNECs for the same substance. There is no general step within REACH to harmonise these PNECs or DNELs. Unless the particular chemical is adopted in a restriction dossier, where a harmonised PNEC or DNEL may be derived, this may raise difficulties. The potential differences in the contents of the various registration dossiers for the same chemical substance therefore makes a fluent transfer from REACH to other frameworks difficult. It is emphasised that such harmonisation of PNECs or DNELs has never been an objective of REACH.

Generally speaking, the higher the tonnage level the more data become available from the REACH process (Figure 2.1). The more data also implies that the derived PNECs/DNELs will have a more thorough basis (lower uncertainty, lower assessment factors to be applied). In other terms a PNEC from a chemical in the 10-100 tpa category may generally have a higher uncertainty than a PNEC from the > 1000 tpa category.

There will of course be deviations from this rule above, e.g. a low tonnage compound with a rich data set. From an information point of view, however, the REACH obligations are met if the dossier *at a minimum* contains the information requirements as prescribed in Annexes VII-X. Industry has the obligation to conduct literature searches, thereby disclosing ‘all’ relevant data on that endpoint, but there is no mechanism in REACH that evaluates this aspect. The Annex VI Guidance note on fulfilling the requirements of Annexes VII to XI states: ‘The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance. The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level.’ There is an entry in IUCLID 5 (E 12. Literature search) indicating which specific search profile has been used for the substance (time period, databases, key words). The entry is not obliged, however, and the intensity of the actual fulfilling of the broad REACH information requirements is therefore difficult to predict. Furthermore, it has to be noted that even if an extensive data set is generated for a substance, industry decides on selecting the key study from this data set. When deriving environmental risk limits, the data collection step (Step 2, Figure 3.1) is based on literature searches according to standardised search protocols. This to ensure that no relevant information is missing when establishing the risk limits for the chemical. The importance of this aspect was stressed by the former European Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE⁵) when concluding that it is of utmost importance to base a standard on a comprehensive and valid data base given the possible consequences of a legally binding quality standard in terms of health, environmental and economical aspects (CSTEE, 2004).

It should be realised that, although a DNEL is obligatory in the CSA (≥ 10 tpa), this does not mean that for all registered chemicals long-term DNELs, either systemic or local, become available for the general population and/or the oral or inhalatory exposure routes. The general population is the most relevant protection target for deriving environmental quality standards and the same is true for oral and inhalatory exposure as most relevant exposure routes (see Table 2.2). It is foreseen that in most cases only an oral test will be conducted and that other exposure routes, if needed at all, will ‘only’ be covered via route-to-route extrapolation. It is emphasised, however, that the route-to-route extrapolation step from an oral DNEL to an inhalatory DNEL may be associated with large uncertainties. This is particularly the case for specific substances causing systemic effects in lungs that may remain ignored when exposing via the oral route. There may be other reasons for not covering a priori relevant DNELs. For example, chemicals with a high vapour pressure may even not generate a DNEL for inhalation if it is demonstrated via exposure based waiving that exposure via air is not foreseen in the intended uses of the registrant. The result of the above may be that the number of DNELs that can be directly (MPC_{air}) or indirectly (MPC_{water}) used may be rather limited.

Non-testing methods, in particular (Q)SARs and in vitro techniques will in a number of cases be used by industry to fulfil the REACH information requirements (see section 2.3). For example, with an appropriate QSAR the acute toxicity for fish in terms of an LC_{50} can be estimated for a particular chemical. This value can subsequently be used for the derivation of the PNEC for water. Currently other frameworks like INS and WFD, are still much more restrictive in the use of QSAR data. Within these frameworks, QSAR estimates may be used to fill in non-critical data gaps for acute toxicity only.

⁵ The CSTEE is succeeded by the Scientific Committee on Health and Environmental Risks (SCHER)

They are thus not relied upon as equivalent or substitute for a sensitive taxonomic group, but may be used to decide on the appropriate assessment factor for PNEC derivation. It is difficult to anticipate on what scale and especially for which group of chemicals, non-testing methods will be actually used in the registration dossiers. It is also difficult to anticipate on what scale ECHA will grant the use of alternative methods during the process of dossier evaluation. The chemical classes for which reliable QSARs are available, whether the substance falls within the domain of the QSAR, and the reliability and regulatory applicability of the QSAR outcome all need to be specified (Annex XI, REACH). It is likely that QSARs will probably be used for the low tonnage chemicals (data poor chemicals), but also to a certain extent for high production volume chemicals. In addition to QSARs, REACH foresees using category approaches, where a single registration dossier may contain a number of related chemicals (a category) for which data gaps can be filled by performing experimental studies, by QSARs, or by read across, i.e. extrapolating or interpolating from other members of the category. This also will lead to generating (eco)toxicological data from non-testing sources, and thus PNECs and DNELs may in those cases also be based on non-testing data.

REACH sets strict time frames for the registration process. As indicated in Table 2.1 the registration deadlines are related to a combination of both tonnage level and hazardous properties. For chemicals with CMR characteristics, R50-53 chemicals at tonnage levels above 100 tpa, and chemicals with tonnage levels above 1000 tpa, the registration deadline is December 2010. For chemicals without CMR or R50-53 properties, and tonnage level above 100 tpa, the deadline is mid 2013. A registration deadline of mid 2018 holds for the rest group, i.e. no CMR or R50-53 and tonnage level above 1 tpa. The conclusion is that REACH will generate data in various time 'batches'. Chemicals with either the most stringent classification and labelling characteristics for man and environment and/or the highest tonnage level will be registered by the end of 2010. This deadline is sufficiently near to make the spin-off of the REACH data generation potentially relevant to other policy frameworks. However, for the other chemicals REACH will likely not generate data until 2013 or 2018.

One could speculate on the exact relationship between on the one hand the hazardous properties and tonnage level of a chemical and on the other hand the need for deriving/using risk limits in other policy frameworks (Step 1, Figure 3.1). However, prioritisation processes are often largely based on intrinsic hazardous properties of the chemical, advocating for a clear positive relationship between hazard and the need for control measures, including the derivation of risk limits. From that perspective REACH will indeed generate the most relevant data on the shortest notice. For the majority of chemicals REACH will generate data after four or nine years from now. Data generation will also be 'slower' for chemicals that do have CMR and/or R50-53 properties, but for which these characteristics only show up after the completion of testing programmes. It should be noted that there may already be well-founded environmental quality standards or risk limits, e.g. from WFD or former EC Regulation 793/93, for the first batch of chemicals facing restriction/authorisation under REACH.

For some chemicals, REACH only applies to a limited extent (see section 2.1). For human and veterinary drugs, PPPs and biocides, for which already a dossier exists in other EU regulatory frameworks, this dossier will be accepted as a registration by REACH, but only for the purpose of the intended use of those chemicals (i.e. active ingredient or co-formulant). REACH will thus not generate any new data in those cases. For other uses of the chemical, if relevant, REACH does apply and a registration under REACH is obliged. The question is then how the registration dossiers for these uses will be completed by industry. In the case of PPPs and biocides: will the registration dossier contain either the same, different or additional physico-chemical and (eco)toxicological data in comparison with the lists of endpoints? Will, for example, the PNECs from the biocide Competent Authority Report (CAR) be taken over in the CSA? And vice-versa, will any new information generated under REACH find its way back to the other frameworks?

In general the data requirements for pesticides and biocides are far more extensive than for industrial chemicals due to their intended use. Article 29 of REACH complicates the situation for biocides and pesticides. It states that even if the registration exemption applies (i.e. exclusively used in pesticides or biocides) producers of biocidal substances or pesticides are obliged to participate in SIEFs (see section 2.1) in which data-sharing is mandatory. Data protection provisions under the current Directive 91/414/EEC (PPPs) and Directive 98/8/EC (biocides) may thus conflict with the REACH goals on this important point. It should be noted that the proposal for the new regulation on biocides addresses several confidentiality provisions for a more effective exchange of information between REACH and the biocides framework. It is difficult to anticipate on how this will work in practice.

4.3.3 Technical differences

In general there is a major overlap in methodology (Steps 3 and 4, Figure 3.1) between REACH and INS/WFD as they are both mainly based on the EU TGD (EC, 2003). There is of course a conceptual difference between the basic assumptions of each: REACH relies on an integrated risk assessment approach, whereas INS/WFD focuses on determining environmental quality standards in specific compartments. Vos and Janssen (2005) made a comparison of the guidance documents in support of EU risk assessments (TGD) with those for the derivation of EU water quality standards according to the guidance prepared by the Fraunhofer Institute (FHI) within the context of the WFD (later revised by Lepper, 2005). They conclude:

‘Determination of EQSs in the FHI document was found to overlap with the environmental effect assessment of the TGD. Differences were partly technical; however, for certain substances the FHI method could lead to lower values of EQS for water compared to the derivation of safe water concentrations (PNECs) according to the TGD. Only one PNEC for water is derived following the TGD, whereas according to the FHI document, several EQSs for water are calculated from toxicity data for predators and human consumption of aquatic products.’

As an example of the consequences of the conceptual differences between REACH and the INS/WFD setting of environmental quality standards the case of CHEMICAL Y is given. (The example ignores that owing to its characteristics CHEMICAL Y will most probably be categorised as SVHC under REACH).

A (hypothetical) *REACH CSA* of CHEMICAL Y would yield a $PNEC_{\text{water}}$ of $2.3 \times 10^{-2} \mu\text{g/L}$. This value is based on a lowest LOEC of $2.3 \times 10^{-3} \text{ mg/L}$ for the insect *Chironomus tentans*. For man indirectly exposed via the environment the CSA would give a ‘DNEL for the general population-long-term for oral route-systemic’ of $1.5 \times 10^{-4} \text{ mg/kg}_{\text{bw}}/\text{d}$ (equal to TDI). The REACH CSA is based on the concept of the risk assessment and the DNEL is thus not re-calculated to a safe concentration in the water compartment (route: water→fish→man).

Deriving ERLs according to the *INS/WFD* methodology (Van Vlaardingen and Verbruggen, 2007) results in an $MPC_{\text{eco, water}} = 2.3 \times 10^{-2} \mu\text{g/L}$, being equal to the REACH PNEC that is also focused on the ecosystem as protection target. The WFD/INS methodology, however, additionally prescribes the derivation of a water concentration that safeguards man consuming fish, because several hazard triggers (R-phrases) are met for CHEMICAL Y. This $MPC_{\text{hh food, water}}$ is obtained by re-calculating the safe level of a chemical in fish (food) towards the water concentration. The $MPC_{\text{hh food, water}}$ for Y is calculated from the DNEL and amounts to $6.5 \times 10^{-4} \mu\text{g/L}$ (in-between calculation steps not shown here). The final MPC_{water} according to WFD methodology is set equal to the $MPC_{\text{hh food, water}}$ as it is lower than the $MPC_{\text{eco, water}}$ and thus becomes $6.5 \times 10^{-4} \mu\text{g/L}$. The idea behind is that the most critical route or protection target determines the overall value under WFD.

Conclusion: In those cases where triggers for addressing secondary poisoning or human health aspects (fish consumption and/or drinking water) are *not* met, the overall MPC_{water} as derived according to the WFD will equal the $PNEC_{\text{water}}$ obtained under REACH. The example above clearly illustrates, however, that a) risk limits from REACH dossiers cannot be automatically adopted to INS/WFD-proof

environmental quality standards (MPC level), and b) the transformation from REACH to WFD may have considerable numerical consequences (PNEC water \neq overall MPC_{water}).

4.3.4 Differences in protection levels

REACH aims at achieving safe use of chemicals through the supply chain, if appropriate by means of suggested risk reduction measures. The term ‘safe’ is defined here as the potential exposure being lower than the (environmental) risk limits. From a perspective of protection level the REACH risk limits (PNEC, DNEL, DMEL) equal the MPCs from the INS/WFD framework. REACH does not take into account the fact that ecosystems and man are being exposed to mixtures of chemicals. In principle, chemicals are individually registered and assessed under REACH (exemption: the group wise approach). The same is true for most other current EU chemical policy frameworks, including the WFD and PPP or biocides regulations. In the Dutch INS framework, however, an additional environmental quality standard is derived, *i.e.* the ‘target value’. The target value is, in principle, set at the level of negligible concentration (NC) and is the guideline for the long-term environmental quality to be achieved. The NC has been set to a factor 100 below the MPC, which defines a safety margin allowing for combination toxicity. For metals or other naturally occurring substances the NC is set at the natural background. The target value has a position in Dutch policy frameworks such as the setting of priorities for the emission policy.

The maximum acceptable concentration for ecosystems (MAC_{eco}) is a very important risk limit nowadays within the WFD framework. Water managers apply both the MAC and MPC in their evaluation of the water quality monitoring data according to WFD principles (for priority and ‘other relevant’ substances). The MAC is intended to protect the *aquatic* ecosystem ‘against adverse effects exerted by exposure to short-term peak concentrations’ or ‘against adverse effects of transient exposure peaks’. The derivation of the MAC is based on the PNEC_{intermittent} as defined in TGD and REACH, although additional guidance has been developed. In practice, however, it is anticipated that this PNEC_{intermittent} will only in a very limited number of cases be derived under REACH as it is related to a strictly defined short term exposure regime. Such exposure regime is only relevant for a small group of chemicals. Within the WFD framework, however, a MAC is to be derived for all chemicals, irrespective of their use scenarios. As a result, for the MAC there will be a discrepancy between WFD needs and deliverances of REACH. Since the MAC is based on acute toxicity data (e.g. L(E)C₅₀-values), the underlying data will be available in the REACH dossiers for classification and labelling purposes. The derivation of the MAC will, however, in most cases be lacking. The issues brought forward in section 4.3.2 on the completeness of the data set in the REACH dossier (extent of literature search, et cetera) are also relevant here.

The Serious Risk Concentration (SRC, see section 3.2) is used as a basis for the so-called Intervention Value. This is a standard for soil, sediment and groundwater, which is numerically higher than the MPC and which indicates the concentration level at which serious or imminently serious decrease will occur in structural or functional properties that may affect human health, plants and animals. The intervention values are related to the clean-up policy and apply to soil and sediment. Within the framework of REACH there is no equivalent risk limit. However, as for the MAC_{eco}, the data in the dossier may allow for derivation of the SRC.

From the above it can be concluded that REACH generates risk limits (PNECs, DNELs, DMELs) that are equivalent to risk limits according to the INS/WFD methodology, or can be used to derive such limits. The REACH risk limits do not taken into account combination toxicology as is pragmatically accounted for in the NC from the Dutch INS framework. Other environmental quality standards as used in Dutch policy frameworks and WFD, which have different protection levels, are also not generated from REACH, but may be derived using the data from the dossier.

5 Conclusions and recommendations

5.1 Conclusions

Chapter 1 raised the three main questions to be addressed in this study. This chapter attempts to give the answers.

To what extent will (inter)national policy frameworks that make use of ERLs benefit from the availability of substance information, including risk limits, from REACH?

1. Within the next decade REACH will generate many data on important characteristics of tens of thousands of chemicals. The information will become available to the authorities and other stakeholders (general public, NGOs and industrial partners). By this many of the current data gaps are assumed to be covered.
2. The data flow related to hazard will consist of a set of basic entries on (eco)toxicological endpoints. As a general rule REACH prescribes more information requirements with increasing tonnage levels for production, import and/or use. In addition, for most chemicals the registration dossier will also include PNECs and DNELs. These risk limits are an obligatory part of the CSA irrespective if exposure scenarios and a risk characterisation have to be conducted. In principle, the other policy frameworks may thus take great advantage of these REACH outcomes.

Which (groups of) substances will be involved in the data generation flow, which not, and when will the information become available?

1. All chemicals fall under the scope of REACH, except for radioactive substances, substances subject to customary inspection, non-isolated intermediates, carriage of dangerous substances, waste and defence. For some chemicals, REACH only applies to a limited extent. Registrations of human and animal drugs, food and feed additives, plant protection products and biocides, for which already a dossier exists according to other specific legislation will be accepted by REACH. Potential other uses of those chemicals do need an appropriate REACH registration. The question is then whether or not the registration dossiers for these uses will differ from the other dossiers. If the data package under REACH is different from e.g. the lists of endpoints prepared for biocide authorisation, this may lead to inconsistencies in the derived risk limits.
2. REACH will generate data in various time 'batches' (see Table 2.1). Chemicals with either the most stringent classification and labelling characteristics and/or the highest tonnage level will be registered by the end of 2010. REACH will thus bring forward the most relevant data on the shortest notice. For a very large group of chemicals, however, REACH will only produce data after four or even nine years from now. Data generation will also be 'slower' for those chemicals that do have hazardous properties, but for which these characteristics only show up after the completion of testing programmes.

Can the information from the REACH dossiers be adopted or used directly into other policy frameworks ('cut and paste')?

Issues related to the quality control of information:

1. Until now it is not foreseen that the PNECs and DNELs from the REACH registration dossiers (via CSA) will be structurally checked on validity by ECHA or any other authority (use of appropriate key study as basis, application of the correct assessment factor, et cetera).

2. There is no mechanism in REACH that systematically evaluates the completeness of the data for a particular endpoint. Industry has an obligation to collect 'all' relevant data on a particular endpoint, but it is not mandatory to present information on the methods that were used for data collection, such as the search profiles. It is thus hard to evaluate whether or not the dataset is incomplete. When deriving environmental risk limits, the first step is data collection based on literature searches according to standardised protocols. This to ensure that no relevant information is missing when establishing the risk limits for the chemical.
3. The REACH result of each (eco)toxicological study and any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) will be made publicly available over the internet. However, the study summaries or robust study summaries of the information may not be available for the public. Only competent authorities have or could get access to all underlying data.
4. The potential inconsistencies between the various registration dossiers for the same chemical (more than one PNEC or DNEL) hamper a fluent transfer of data from REACH to other frameworks.
5. Authorities will come more prominently on the screen for chemicals that will be addressed in the authorisation and restriction phase of REACH. This because Member States or the European Commission are intended to draft a restriction proposal for the specific chemical to be extensively discussed by ECHA (Risk Assessment Committee, RAC and Socio-Economic Analysis Committee, SEAC). Similarly, a thorough evaluation of industry's requests for authorisation by ECHA/Member States is foreseen. The closer involvement of authorities may imply that PNECs or DNELs for these chemicals will go through more serious quality control steps. On top of that REACH may bring forward the information on these chemicals on the shortest notice. Thus for the most critical chemicals the corresponding PNECs and DNELs may become available rather soon at the REACH time-scale and furthermore these PNECs and DNELs have passed the most stringent quality control scheme. It remains speculative, however, if this process will indeed have such advanced progress in practice. (Note: There may already be well-founded environmental quality standards or risk limits, e.g. from WFD or former EC Regulation 793/93, for the first batch of chemicals facing restriction/authorisation under REACH).

Issues related to intrinsic uncertainties:

1. The higher the tonnage level the more hazard data generally become available from the REACH process. The more data also implies that the derived PNECs/DNELs will have a more thorough basis (lower uncertainty → lower assessment factors to be applied). In other terms a PNEC/DNEL from a chemical in the 10-100 tpa category may generally have a higher uncertainty than a PNEC/DNEL from the > 1000 tpa category.
2. REACH will basically only require ecotoxicological test data for the terrestrial and sediment compartment at tonnage levels above 100 tpa. If reported, the PNECs for soil and sediment in lower tonnage dossiers will be based on a recalculation of the PNEC water (via equilibrium partitioning). If information on sorption is based on QSAR estimates instead of experimental data, this will produce additional uncertainty.
3. It should be realised that, although a DNEL is obligatory in the CSA (≥ 10 tpa), this does not mean that for all registered chemicals long-term DNELs, either systemic or local, become available for the general population and/or the oral or inhalatory exposure routes. These DNELs are identified as directly relevant for use in setting environmental quality standards. It is also emphasised that the route-to-route extrapolation step from, for example, an oral DNEL to an inhalatory DNEL may have large uncertainties.

Issues related to technical and conceptual differences:

1. REACH generates risk limits (PNECs, DNELs, DMELs) that are equivalent to risk limits according to the INS/WFD methodology, or can be used to derive such limits. The REACH risk limits do not taken into account combination toxicology as is pragmatically accounted for in the negligible concentration (NC) from the Dutch INS framework. Other environmental quality standards as used in Dutch policy frameworks and WFD, which have different protection levels, are also not generated from REACH (e.g. MAC, SRC).
2. In those cases where WFD-triggers for addressing secondary poisoning or human health aspects are not being met, the overall MPC_{water} derived according to the WFD-methodology will equal the PNEC_{water} under REACH. For chemicals that are bioaccumulative and/or (very) toxic the risk limits from REACH dossiers cannot be automatically be adopted as INS/WFD-proof MPCs.
3. Non-testing methods, in particular (Q)SARs and in vitro techniques will be used by industry to fulfil the REACH data requirements. Currently other frameworks like INS and WFD, are still more restrictive in the use of QSAR data.

The main conclusion is that complementary environmental policy frameworks, also those where environmental quality standards are used to safeguard environmental quality, may benefit from the accelerated generation of data from REACH. REACH will probably act as a very useful instrument to select and prioritise chemicals to be further addressed in, for example, the Water Framework Directive. The question is, however, whether the REACH risk limits (PNECs and DNELs) will meet the requirements that authorities currently rely upon in these adjacent fields where they (still) have the responsibility. Technical and conceptual differences between risk limits from REACH and other policy areas have been noticed, but also points of interest on availability, quality control, timing and disclosure of background data.

5.2 Recommendations

At an international level the Berlin workshop on ‘Consequences of REACH for other legal and administrative environmental instruments’ addressed some very useful ‘cooperation needs’ on a successful integration of REACH and other policy areas (Hermann, 2007). Subsequently in the Netherlands various national activities have already been undertaken to provide guidance to (local) authorities on how to position the REACH deliveries in policy frameworks like the Dutch National Air Emission Guidelines (NeR) and the Pollution of Surface Waters Act (Wvo) (SenterNovem, 2008; InfoMil, 2009).

Based on the present study the following suggestions are made to further optimise the transfer of REACH information and to bring about realistic expectations, e.g. during the dialogues between industry and local authorities when granting permits:

1. It would be useful to more structure and communicate the type of substance information that will be released from REACH. This should ideally be done at the level of the individual chemical. Based on (pre-)registration information it should be made clear which data will become available, within which time period and, very importantly within the current context, which quality control steps were taken. It is of equal importance to indicate which data will not (standard) be disseminated via REACH. For example, not every CSA will contain an inhalatory DNEL to be potentially used in the framework of National Air Emission Guidelines (NeR). The idea behind is that all parties can anticipate on REACH deliveries during the next decade and determine if, and if yes, what specific actions should be undertaken in their policy

framework. The current report provides a series of elements that can be used to elaborate on this action point.

2. Local authorities in the Netherlands being responsible for the implementation/execution of other policy frameworks, e.g. authorisation of permits, have already indirectly access to the REACH data for verification and validation purposes (via the Dutch Bureau REACH). Furthermore they have legal access to the underlying registration data for the specific company. Although this has been settled formally, further guidance may be given on the practical implementation. This study further points to the complex situation that more than one PNEC or DNEL may occur for the same chemical from various CSA. Solutions have to be found to circumvent this issue, not only the possibility to verify if other PNECs/DNELs may be present for the particular chemical, but also the decision on which value to be ultimately used.
3. More transparency should be given on the uncertainty associated with the risk limits generated from REACH. Not every single PNEC or DNEL is underpinned with the same amount of data and this is reflected in the 'power' of the value. Roughly speaking a PNEC or DNEL based on several testing data has a lower uncertainty than a value just based on one single test. In addition, it should be communicated that the PNECs and DNELs from the REACH registration dossiers will not be structurally checked on validity by ECHA or any other authority. This aspect is strongly linked with questions on the responsibility of setting quality standards in the near future. Risk limits from the restriction and authorisation phase of REACH are assumed to have passed more intense quality control steps.
4. A concise technical guidance or checklist should be made on the conversion of REACH risk limits to those needed in other policy frameworks (if compatible in terms of similar protection aims). It should be realised, however, that (equivalents of) certain environmental quality standards as being used in other areas (e.g. MAC in WFD) will not directly be available from the REACH registration dossiers.
5. The use of non-testing methods (QSARs, et cetera) is foreseen in the WFD methodology, but experience should be gained to implement this into the INS framework in a consistent way.
6. It should be made aware that REACH basic interpretation of safe use is scaled at the MPC level of individual chemicals, whereas INS has technical instruments that take into consideration the potential effects of mixtures, for example, by applying the Negligible Concentration.

References

- CSTEE. 2004. Opinion of the scientific committee on toxicity, ecotoxicity and the environment (CSTEE) on 'The Setting of Environmental Quality Standards for the Priority Substances included in Annex X of Directive 2000/60/EC in Accordance with Article 16 thereof'. Adopted by the CSTEE during the 43rd plenary meeting of 28 May 2004.
- EC. 1967. Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
- EC. 1991. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal of the European Union L 230, 19.8.1991.
- EC. 1996. Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control. Official Journal L 257, 10/10/1996 P. 0026 - 0040.
- EC. 1998. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. Official Journal of the European Union L 123, 24.4.1998, p. 1–63.
- EC. 2000. Directive 2000/60/EC of the European parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. Official Journal of the European Union L 327:1-72. Legal text available via http://ec.europa.eu/environment/water/water-framework/index_en.html.
- EC. 2003. Technical Guidance Document (TGD) in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. Edition 2. EUR 20418 EN/2. European Commission Joint Research Centre, Ispra, Italy.
- EC. 2006. Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Legal text available via http://echa.europa.eu/legislation_en.asp.
- EC. 2008. Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control. Official Journal of the European Union L 24/9.
- EC. 2009. Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
- Hermann A. 2007. Results of the International Workshop: Consequences of REACH for other legal and administrative environmental instruments. Evaluating the Environmental Effectiveness of REACH-EEE). Berlin, October 11-12, 2007.
- InfoMil. 2009. Digitale NeR. <http://www.infomil.nl/onderwerpen/klimaat-lucht/ner/digitale-ner/>.
- Lepper P. 2005. Manual on the methodological framework to derive environmental quality standards for priority substances in accordance with Article 16 of the Water Framework Directive (2000/60/EC). Schmallenberg, Germany: Fraunhofer-Institute for Molecular Biology and Applied Ecology.
- SenterNovem. 2008. Handreiking consequenties van REACH voor vergunningverlening. SenterNovem/InfoMil, september 2008 (in Dutch).

- Staatscourant.2007. nr. 188 28 september 2007; corrigendum Stcrt 2007, 211
- Van Herwijnen R, De Poorter LRM, Dang Z. 2010. Interactions REACH and other chemical legislation. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report 601783001 (in prep.).
- Van Vlaardingen PLA, EMJ Verbruggen. 2007. Guidance for the derivation of environmental risk limits within the framework of the project 'International and National Environmental Quality Standards for Substances in the Netherlands' (INS). Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report 601782001.
- Vos JH and MPM Janssen. 2005. Comparison of the guidance documents in support of EU risk assessments with those for the derivation of EU water quality standards. Bilthoven, the Netherlands: National Institute for Public Health and the Environment (RIVM). Report 601500001.
- VROM. 2004. Ministry of Housing, Spatial Planning and the Environment (VROM). (Inter)nationale Normen Stoffen (INS). <http://www.rivm.nl/stoffenrisico/newwordfiles/Werkwijze%20INS.pdf> (in Dutch).
- VROM. 2009. Ministry of Housing, Spatial Planning and the Environment (VROM). Internal paper 'Op weg naar een vernieuwde visie op normstelling voor stoffen'. (June 2009) (in Dutch).

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