





# The Nordic Product Registers and the future REACH substance database

Comparison of the registration systems and options for  
future developments

*Andreas Ahrens and Antonia Reihlen*  
Ökopol GmbH

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**Nordic Council of Ministers**

Store Strandstræde 18  
DK-1255 Copenhagen K  
Phone (+45) 3396 0200  
Fax (+45) 3396 0202

**Nordic Council**

Store Strandstræde 18  
DK-1255 Copenhagen K  
Phone (+45) 3396 0400  
Fax (+45) 3311 1870

[www.norden.org](http://www.norden.org)

**Nordic cooperation**

*Nordic cooperation* is one of the world's most extensive forms of regional collaboration, involving Denmark, Finland, Iceland, Norway, Sweden, and three autonomous areas: the Faroe Islands, Greenland, and Åland.

*Nordic cooperation* has firm traditions in politics, the economy, and culture. It plays an important role in European and international collaboration, and aims at creating a strong Nordic community in a strong Europe.

*Nordic cooperation* seeks to safeguard Nordic and regional interests and principles in the global community. Common Nordic values help the region solidify its position as one of the world's most innovative and competitive.

# Preface

The European Commission launched on 29 October 2003 its proposal for a new chemical legislation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). In 2006 the Nordic Chemicals Group granted funds to the Nordic Product Register Group (NPG) to start a joint Nordic project on *The Nordic Product Registers and the future REACH substance database. Comparison of the registration systems and options for future developments*. The report has been made by Andreas Ahrens and Antonia Reilen at Oekopol GmbH.

The objective of the project was to clarify the extent of overlap between REACH substance database and the Product Registers and characterize the added value of the Nordic Product Registers.

The conclusions presented in this report are expressions of the authors' opinions and do not necessarily reflect the views of the Nordic Council of Ministers.

*NPG members:*

Lona Olsen and Poul Andersen, Denmark  
Heikki Salonen and Nina Lampinen, Finland  
Sigurbjörg Gísladóttir, Iceland  
Geir Jörgensen and Jan Kraft, Norway  
Stellan Fischer and Eva Ljung, Sweden

*Project group:*

Geir Jörgensen, Jan Kraft and Einar Hovde, Norway



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# List of abbreviations

CAS	Chemicals Abstract System
CBI	Confidential Business Information
CMRs	Carcinogenous, mutagenous substances, or substances toxic to reproduction
CFCs	Chlorinated Fluorinated Carbons
CSA	Chemicals Safety Assessment
CSR	Chemicals Safety Report
DU	Downstream User
EINECS	European INventory of Existing Commer- cial Chemicals Substances
ELINCS	European LIst of Notified Chemical Sub- stances
ESR	EU Existing Substance Program under Di- rective 793/93
EU	European Union
EC	European Community
IC	Industry Category
IUCLID	International Uniform Chemical Informa- tion Data Base
IUPAC	International Union if Pure and Applied Chemistry
NLP	List of substances regarded <u>N</u> o <u>L</u> onger <u>P</u> olymer in the EU (substances not exemp- ted as polymers from duty to be registered)
NPRs	Notation for the four Nordic product regis- ters collectively
NACE	General Nomenclatura of Economic Activi- ties in the European Community
OECD	Organisation of Economic Cooperation and Development
RIP	REACH Implementation Projects
SPIN	Data base on “Substances in Preparations in the Nordic Countries”
SIDS	Screening Information Data Sets
SMEs	Small and Medium Sized Enterprises
TGD	Technical Guidance Document
UC	Use category
UCN	Use Category Nordic
VOC	Volatile Organic Compounds



# Summary

A new European Chemical Legislation will enter into force in summer 2007. The requirements on Registration, Evaluation and Authorisation of Chemicals (REACH) will be directly applicable in all Member States of the EU. Under the REACH system, manufacturers and importers of substances (as such or in preparations) will have the duty to submit a registration dossier to the Chemicals Agency in Helsinki and to update the information in case relevant changes occur.

Companies placing chemical products (= substances or preparations) on the Nordic markets (Denmark, Norway, Finland, Sweden) are already today obliged to register to the Nordic Product Registers (NPRs). With REACH entering into force it may be felt that reporting to the Nordic Product Registers and to Chemicals Agency is duplication of work and hence reporting under the NPRs should be ceased. In order to clarify the extent of overlap between the two systems and characterise the potential added value of the NPRs, the *Nordic Product Register Group* initiated a study to Oekopol.

There are significant differences between the two systems with regard to both, the purpose of the system and the information content of the related data bases. The REACH registration process will not generate information on volumes and uses of substances similar to what is available from the Nordic Product Registers. Thus replacing the NPRs with a future REACH substance register would lead to a significant loss of information essential for targeting and balancing chemicals policy.

While REACH is a system to register single substances only, in the NPRs substances and preparations are registered. Hence, the overlap between the information being available in the NPRs and the future REACH data base is limited to the identity of substances, the identity of companies manufacturing or importing substances and to the generic use of a substance as anticipated by the substance manufacturer. Information related to single preparations on the market or single preparation makers like available in the NPRs will not be part of the REACH substance data base. Also, it will hardly be possible to obtain relevant time trend information on market volumes and shifts in the use patterns of substances from the future REACH data base.

The added value of the NPRs during the implementation phase of REACH and after REACH has entered into full operation can be summarized in three items:

- Product registers of the NPRs- type can be used as a tool to support and enforce the implementation of REACH at the level of preparation makers and preparation importers. The functioning of the REACH system very much depends on whether the downstream user requirements will really work in practice. Based on the NPRs information the inspectorates can directly follow up the response of formulators receiving the extended Safety Data Sheets under REACH.
- Based on the NPRs information substances can be traced down to single preparations. Thus, a reality check can be performed to which extent the registered use pattern under REACH and market reality match each other. Such market surveillance mechanism is not part of the REACH system, however REACH requires the EU Member States to ensure enforcement of REACH. In this respect the NPRs could be seen as a means to comply with the obligation of the EU member states.
- The REACH data base will enable trend analysis on market volumes and use patterns of substances only to very limited extent. This is due to the fact that abandoned uses do not have to be notified, and that changes in market volumes are only to be notified if i) one of the five relevant tonnage thresholds is passed or ii) production/import has stopped. Mass flow analysis will not be possible at all, since registrants will not have the duty to include a break down of the total substance volume into uses. Compared to that, the NPRs allow to link annual trends in substance volumes and use patterns to information from economical statistics. Also mass flow analysis is possible, since the volume of single products and the corresponding percentage of substances in these products are reported to the product registers. Trend and mass flow analysis is one of the pre-requisites to monitor policy performance and progress towards sustainable development.

The SPIN data base is an instrument to enable public access to substance related information in the NPRs on a regular basis. The managers of the SPIN data base have to struggle with same confidentiality issues like the managers of the future public part of the REACH data base may encounter. However, even under these constraints, the added value lies in the fact that aggregated volumes and use patterns of substances (based on UCN and NACE classification) can be retrieved from SPIN. In the REACH system only the corresponding volume band of a substance and information on use as far as contained in the safety data sheet will become publicly available.

The added value of the Nordic product registers and the SPIN data-base can be clearly demonstrated. However it is important to integrate as much as possible the related requirements with the work to be carried out under REACH. Acceptance in trade and industry would increase if the

documentation work at company level could serve the two systems in one go. It is even likely that the established routines with the NPRs can help the importers and formulators in the Nordic countries to cope with the challenges of REACH. In order to mobilize synergies, it is however necessary to further harmonise the registration requirements among the NPRs and to make adjustments to REACH.



# Introduction

A new European Chemical Legislation will enter into force in June 2007. The requirements on Registration, Evaluation and Authorisation of Chemicals (REACH) will be directly applicable in all Member States of the EU. Under the REACH system, manufacturers and importers of substances as such or in preparations will have the duty to submit a registration dossier to the Chemicals Agency in Helsinki and to update the information in case relevant changes occur.

Users of dangerous substances as such or in preparations (= chemical products) as well as manufacturers or importers of articles containing substances of very high concern<sup>1</sup> will have to send a notification to the Agency if certain conditions are met:

- If the use of a substance as such or in a preparation is not covered by the exposure scenario in the supplier's safety data sheet, the user of the chemical has to notify this to the Agency, if he intends to maintain such unregistered use.
- If a substance in articles exceeds the amount of 1 t/a per company, and the substance has not been registered for that use by anyone else, and the manufacturer or importer cannot exclude exposure, he is obliged to notify this to the Agency.

Companies placing substances as such or preparations (= chemical products) on the market in the Nordic countries (Dk, Nor, Se, Fin) have been obliged since the 80ies to register to the Nordic Product Registers (NPRs). With REACH entering into force it may be felt that reporting to the Nordic Product Registers and to the Chemicals Agency is duplication of work and hence reporting under the NPRs should be ceased.

The current document aims to explain and compare the two systems in order to establish the extent of overlap and to characterise the potential added value of the NPRs compared to the future REACH substance register.

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<sup>1</sup> Substances meeting the criteria of being carcinogenous, mutagenous or toxic to reproduction (CMRs); substances meeting the criteria of being persistent, liable to bioaccumulate and toxic (PBTs); substances meeting the criteria of being very persistent and very bioaccumulative (vPvBs); substances being of an equivalent level of concern.



# 1. Benefits from NPRs<sup>2</sup>

The following chapter provides a systematic description of practical benefits gained from well developed and up-to-date products registers. Each of the benefits is illustrated by an example. The source of these examples is a compilation of cases made available by the Swedish Chemicals Agency (KemI).

## 1.1 Rapid reaction on risks identified

In summer 2005, an increasing number of calls were received by the Poison Information Centre as well as by KemI from local inspectors about seals of barbecue starter fluids that didn't work. Thus children were prone to drink petroleum solvents as these products are common consumer products, also often used under quite relaxed circumstances. The importers and manufacturers of the use category "starter fluids" could be found in the products register as well as the composition to tell if the product contained substances requiring child resistant seal. Without a products register detailed enough to find the starter fluids, inspectors would have had to physically visit shops and start a time consuming investigation work.

Another type of rapid reaction to risks has been reported from the Finnish product register: An important use of the Finnish register is that rescue services and the Criminal Investigation Department use the register frequently to identify the substances involved in a case. If, for example the fire brigade only knows the trade names of different chemicals, the product register can provide the names of the substances inside the products. This can be a key information to take the appropriate measures in handling emergency situations. The register can also help when investigating the cause of fires.

## 1.2 Starting dialogues with trade and industry

During the last 20 years quite a number of hazardous substances were discovered in the environment, in human tissues or in the working or housing environment of people, and thereby became an issue of public concern. This applies e.g. to nonylphenol ethoxylates in the effluent of municipal waste water treatment systems, brominated flame retardants in

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<sup>2</sup> based on a background document prepared by KemI, 2006-08-21

breast milk or glycol ethers (toxic to reproduction) in preparations for professional and consumers. In all such cases the product register could identify products and related companies, and enable authorities to start an early dialogue (long before legal action is taken) on how to solve the problem and to find less hazardous alternatives.

### 1.3 Dangerous substances in consumer products

Since registrants under the product register are requested to indicate for each single product whether it is marketed for consumer use or not, it can be quickly established in which consumer products a certain dangerous substance occurs. This helps to effectively respond to new information on hazardousness of substances or to systematically identify dangerous substances in consumer products.

Product register data indicating use in consumer products are interesting to both companies and intergovernmental organisations, when a risk assessment is done. For example, each compilation of a Screening Information Data Set (SIDS) in the OECD risk assessment program for high volume production chemicals includes a check of data from the products registers. Of special interest is the information on presence of a substance in consumer available products and the concentration ranges in such preparations. The most recent case was an amine of which the data in the products register said it was present in consumer available products although industry preliminary claimed the opposite.

Without a product register many of the consumer uses would never be identified. This is partly due to the fact that suppliers of raw materials, semi-manufactured products, and imported products report compositions directly to the register, and that the register can link this information to the customers and their markets in the supply chain. The registering preparation makers further down the supply chain often do not know all substances in their products, and the raw material suppliers at the top of the chain, do not know enough about the markets of their customers. Thus, the product register bridges the missing information link. The availability of such sensitive business information in the product register is the result of many years building of trust between the companies and the register and would be hard to obtain from elsewhere.

### 1.4 Emission information under international reporting

Environmental emission statistics and reporting only cover a handful of well known single substances. And even here only large sources are taken into account. Thus, it is not possible for example, to report national NMVOC (Non Methane Volatile Organic Compounds) emissions under

the Kyoto Protocol or under the EU VOC Directive based on emission statistics. The alternative used most frequently is to derive solvent emission from production, import- and export statistics. This, however, is only possible for pure solvents. “Hidden” solvent streams as part of chemical products can only be estimated. Also, from the production and import statistics no information on the type and conditions of use (which determine the emission factor) can be derived. Thus targeting measures and monitoring progress is very difficult in these approaches. Also, the Kyoto Protocol figures will be the base for economic transactions and hence the methods to derive the basic figures must be very robust.

Due to this background, Sweden based its VOC reporting for solvents under the Kyoto protocol on products register information. Mass flows of VOC substances, their carbon content and the break down into use areas can be established based on the product register information. The emission is calculated based on emission factors assigned to each single area of use. This can also be used to establish time trends.

### 1.5 Linking economic growth to risk related information

In Sweden, data on the amount and the number of different hazardous chemical products distributed to each industrial branch has been extracted from the products register and incorporated into the national green accounts for 5 years now. As the industrial category classification is the same in the products register as in Statistics Sweden, it is possible to compare between economic data and use of hazardous chemicals. This can be seen as a vital part to find out whether the country is on its way towards a sustainable society (economic growth without increase of chemicals risks).

### 1.6 Support to policy impact analysis

The product register contains constantly updated information of companies acting in the chemicals field which can be linked to economical data, e.g. annual turn-over and number of employees. This includes the quantity of all imported and manufactured substances (as such or in preparations).

In 2004 a study for Nutek, the Swedish Agency for Economic and Regional Growth, on the number of companies that would have to register substances in the REACH system was performed. The study was done by Statistics Sweden in cooperation with KemI. Companies importing or manufacturing substances in the quantity intervals that trigger the different registration obligations in REACH were extracted, and their organisation-numbers were connected with economic and trade data in the com-

pany register of Statistics Sweden. Table 1 provides an overview on the number of companies importing substances in a sector break down. This table illustrates the advantage of registering chemicals based on classifiers also used in economical statistics. Please note that this overview also includes substances imported from EU countries<sup>3</sup>, and that the same substance may occur in more than one sector and more than one tonnage band. According to the Swedish Chemicals Industry Federation, about 73% of imported substances originate from EU countries.

**Table 1: Number of companies per sector importing substances, 2002<sup>4</sup>**

Sector	<1t	1-10 t	10-100 t	100-1000 t	>1000 t
Construction, wholesale and retail trade	294	215	147	97	37
Chemical industry	119	113	103	81	57
Wood, paper and graphic industry, refineries	28	22	17	17	24
Industry for non-metals and mineral products	21	18	16	12	10
Manufacture of machinery	27	17	13	4	1
Rubber and plastic industry	22	13	11	10	3
Agriculture, mining, food industry	12	9	8	7	4
Steel and metal production	11	10	9	5	5
Metal ware industry	16	9	8	6	1
Manufacture of office machines and computers	14	12	6	4	0
Education and other community services	15	6	4	2	2
Group not reported to Statistics Sweden	12	7	4	2	0
Manufacture of transport equipment	10	8	4	2	0
Remaining sectors	11	8	4	0	0
Remaining manufacturing sectors, electricity, hot water supply	7	5	4	1	1
Manufacturing of precision instruments	6	2	1	1	1
Manufacture of tele communication equip.	5	2	2	0	0
Manufacture of textile, textile and leather ware	4	1	1	1	0

The total number of companies in Sweden synthesising substances is about 60, 28 of these without importing chemicals from abroad. The total number of companies importing substances > 1 t/a (EU and Non-EU) is about 700. The REACH relevant share of non-EU-importers in this could however not be identified at the time when the NUTEC study was performed. KemI expects around 100 importing companies to register under REACH. The order of magnitude of this estimate is supported by figures from the Danish Product register (270 importers from sources outside EU, EC and Switzerland).<sup>5</sup>

By using the products register, a more realistic view of the proportion of work the regulation will mean to Swedish industry can be obtained.

<sup>3</sup> Unfortunately, it is not reported to the products register whether a product is imported into Sweden from inside EU or from external EU. This results in an overestimation of companies that would have to register imported substances.

<sup>4</sup> Source: Swedish Products Register 2002

<sup>5</sup> Personal comment Arbedstilsynet, 16.11.06

This will help industry and authorities to target and plan their work with help-desks etc. Also, it could be used to send reminders to companies to meet the deadlines for registration under REACH. Such reminders of new notification obligations were sent to all companies manufacturing products that contained substances without EINECS numbers before Sweden joined the EU in 1995.

Without the facts of the products register, estimation of REACH impact on industry would have to be very much based on ad hoc information compiled by industry, with all the difficulties experienced in the various REACH impact studies at EU and national level (strategic communication, confidentiality issues, lack of well organised information in the companies). The possibility to add up quantities per substance and company is unique!

## 1.7 Monitoring policy performance

Monitoring substances and use pattern in the Swedish products register is done constantly. Much of the statistics published on the KemI webpage is of this kind, both as an interactive database where you can monitor any substance you like and as more or less analysed statistics. Update is made annually and summarised statistics on policy relevant chemicals are published e.g. for chlorinated paraffins, nonylphenol ethoxylates, phthalates, CMRs, allergenic substances, solvents, "CFC"s and others. This work is done by KemI and the aim is to provide comprehensive information on chemicals to as many different users as possible.

By providing updated, extensive data on chemicals, their uses, their hazards and the companies involved, the products register can answer most questions of the chemical pattern of Sweden in very short time, if no secrecy problems are present. This ensures easy and quick access to relevant information for policy makers and the wider public.

Without the products register there would be very little statistics on chemicals as is apparent when compared to other countries. The information derived from trade and production statistics is not very comprehensive and is of very little use when dangerous substances and uses are to be identified and monitored. Thus single substance studies (including update to follow the market dynamic) would be necessary, requiring considerable resources. With an estimated cost of 100 000 €(100 working days) per substance for an annual questionnaire (including data processing and analysis), monitoring of only 7 substances would already cost the whole budget of the Swedish products register with its 13 000 substances.

## 1.8 Support to effective market surveillance

Every year national and regional inspectorates carry out inspection projects on chemical products on the market: Product information is checked for companies in a certain region. A list of all companies in such a region, manufacturing, importing or re-branding chemical products, is compiled. From this list a selection may be done depending on different criteria. For every company a list of chemical products is obtained from the product register. In inspection projects concerning a special group of products this group can easily be picked out in the products register. The product register provides easy access to addresses of all companies that may be selected for supervision.

Without the products register the inspectors would have to use other sources like the yellow pages, internet and media as well as contacts with branch organisations and local authorities in order to find the addresses. The inspectors would have to demand lists of products from the company with explanations on use and composition. This would be very time-consuming both for the inspectors and for the companies.

## 1.9 Access to information on single products

The possibility to obtain correct and sufficient information about a product in the market can be vital for prevention of risks and provides for transparency of the chemicals market. Much of this information can be passed on request without revealing any sensitive business information. However, the product registers also see it as their mission to direct questions to the relevant respondent in the market and thereby facilitating direct communication between business partners and stakeholders. The register is a giant catalogue over the chemical products that have been on the market for the last twenty years and is often used to connect buyers and sellers.

## 2. The Product Registers

### 2.1 Characterisation of the NPRs

The NPRs are central registers that keep information on chemical substances and products. National legislation requires manufacturers and importers to declare chemical substances and products to the product registers. The registration obligation does not apply to foodstuffs, cosmetics and medicinal products. Also quantities of less than 100 kg/a per company are not to be reported.<sup>6</sup>

The number of active registered products is between 25.000 (Norway) and 70.000 (Sweden). In Sweden, the 70.000 active products contain about 13.000 different substances. The number of active products is driven by differences in the design of registration obligation and differences in the market structure. While for example in Sweden all<sup>7</sup> chemical products (dangerous or not) manufactured or imported > 0.1 t/a are registered, the Danish register is targeted to dangerous products for industrial and professional use only. Norway and Finland register dangerous products for consumer use in addition to dangerous products for industrial and professional use. In Finland and Denmark this includes non classified products containing dangerous substances in a concentration > 1%.

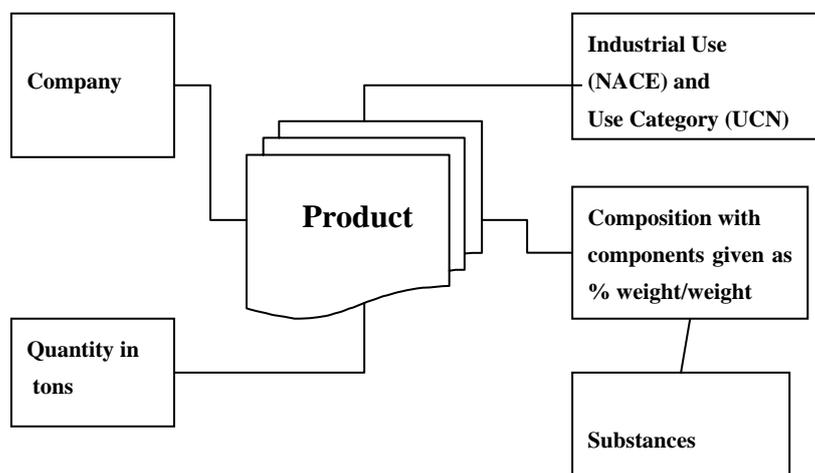
All the NPRs contain information about the company placing a product on the market and the identity of such products. Data in the registers include information on technical function of the chemical, industrial area of use, hazard classification, composition of the chemical products, the quantities in which the chemical product is placed on the market, etc. Figure 1 provides an overview of the core data in the Nordic Product Registers.

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<sup>6</sup> This general cut-off does not exist in Finland.

<sup>7</sup> Chemical products to be registered are defined as product categories annexed in annex 1 to the Ordinance on Chemical Products and Biotechnological Organisms (1998:941).

**Figure 1: Core data in Nordic Product Registers (Source: Nordic Product Register Group, 2006)**



The registers have established a regular, obligatory updating routine, however the frequency and the type of updated information slightly differs between the four countries, Norway and Sweden with most complete updating routines including the use patterns of substances.

There is in principle no requirement to register articles (e.g. textiles, chipboard) even if they contain dangerous substances. However, registration of preparations includes information on the areas where the preparation is used and hence indirectly information on types of articles. For example, if softeners (UC 47<sup>8</sup>, UCN B35100) are used in plastic industry (IC 11<sup>9</sup>, NACE code 25.2), it is likely that they end up in soft plastic articles.

The national authorities and Poison Information Centres use the registers as supporting tools to prevent injury to health and environmental damage resulting from chemicals. Data in the registers is used as support for risk assessments, statistical calculations, substance flow analyses and supervision activities (site inspections and market surveillance).

The secrecy in the registers is handled according to national regulations, which means that quantities of single products and supplier-customer relationships are usually kept confidential. This also applies to detailed information on the composition of chemical products.

<sup>8</sup> Use Category (UC) according to TGD 2003

<sup>9</sup> Industry category (IC), according to TGD 2003

## 2.2 Harmonization of the Nordic Product Registers

The Nordic product registers use the NACE codes<sup>10</sup> to indicate the branches of industry where the products are used. However until recently all four countries used a different coding system for classifying the type of chemical product. In 2002 a new set of harmonized product type codes, UCN (Use Categories Nordic) was developed by Norway, Sweden and Denmark. The codes are documented in the guide for the SPIN database. Compared to the current EU system of use categories (developed for newly notified substances), the UCN system allows for more specific classification of uses.

Today all three countries are using these codes and only Finland still classifies the product type by using the EU system of use categories in a slightly modified form.

The *Nordic Product Registers Group* sees many advantages from using the same set of identifications for information exchange (between industry and product register and between product registers). Also, industry is urging for a total harmonization of the product registers. A subgroup in the *Nordic Product Registers Group* is currently working on harmonization. This group wishes to develop a set of standardised data, together with representatives from industry, for reporting to product registers. This includes:

- a set of recommended data for registration supporting better leverage when proposing adjustments to the regulations.
- a common application, which creates specified XML files, to be sent to each country.

## 2.3 The SPIN Data Base<sup>11</sup>

SPIN is the result of a common Nordic initiative to gather non-confidential, summarised information from the Nordic product registers on the use of chemical substances in different types of products and industrial areas. The name SPIN stands for “Substances in Preparations In the Nordic Countries”.

The intention behind the database SPIN is to make available to the public as much data as possible from the registers. Often aggregation of volumes or use patterns is a solution to make an information non-confidential. For the time being, each of the four product registers feeds its non-confidential information into the SPIN database. Thus confidentiality needs are checked for each product register separately. Total quanti-

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<sup>10</sup> Statistical classification of economic activities in the European Community which was also embodied in the EEA Agreement by the EFTA countries.

<sup>11</sup> [www.spin2000.net](http://www.spin2000.net)

ties, the total number of products and the use pattern have not been reported to SPIN if the substance is contained in less than 4 products and is reported by less than 3 companies<sup>12</sup>. Thus sometimes substances registered in the Nordic Product Registers are mentioned in SPIN only by their name.

The SPIN data base only contains the names and identity codes of substances, but no specific product names can be found among the data. All the data is summarised and no references can be made to specific concentrations of any given substance in any kind of product. The total number of substances in the SPIN database is 22,000 (21560 CAS names). More than half of these substances are not contained in the EU information system on existing substances (ESIS). This is mainly related to the fact, that SPIN covers substances below 10 t/a. In addition SPIN covers polymers, a group of substances not registered elsewhere in Europe and also exempted from REACH.

The substance related information contained in the SPIN data base are listed in Table 2 and 3:

**Table 2: General substance information in SPIN<sup>13</sup>**

CAS-number
Name(s)
Molecular formula
Lists (international or national bans, IARC, etc.)
Index-number (Annex I to the Directive 67/548)
Colour Index Number (C.I.-number)
EC-number (EINECS, ELINCS, NLP)

**Table 3: Summarised information on use of substances in SPIN**

Use categories (technical or functional type of product) of the chemical products in which the substances are found.
Main category-codes (IUCLID) indicating whether the substance is i) used in closed systems, ii) manufactured into an article matrix c) used in single industrial processing sites or iv) used by a high number of users outside industrial sites (dispersive use).
Industry codes, indicating in which sectors chemicals are used (NACE).
Summarised substance volumes (tons per year) <sup>14</sup>
Use of substances in aerosol products and preparations (yes or no).
Use of substances in consumer products and preparations (yes or no).

<sup>12</sup> Presence of a substance in less than 4 single products or used by less than three companies lead to the concern that publication of volumes, number of products or use codes could lead to a disclosure of confidential business information. The confidentiality thresholds are based on a rule of thumb which is also applied to IUCLID data under the ESR.

<sup>13</sup> Some data are collected from other sources than the NPRs and some data are only collected from one of the registers

<sup>14</sup> Volume = produced volume + imported volume - exported volume

Due to confidentiality reasons, the information listed is not available for all substances.

- Information on aggregated volumes is only publicly accessible for 30% of the substances.
- Information on areas of use (industry sector or function of chemical) is only publicly accessible for 25% of the substances.

These figures may give an indication on the extent of current confidentiality problems related to public access to information on the use pattern of chemical products.

A possible strategy to make more information on total volumes of substances and use pattern publicly available would be the aggregation of the data from all four Nordic Product Registers. Thereby, the number of manufacturers and products within a certain use or industry category would increase. As a result, public access to more information on a greater number of chemical substances would be possible. This is for example the number of products containing a certain substance, the annual tonnage, industrial categories and use categories, the annual tonnage within these categories and the presence or absence of the substance in consumer products. However, whether aggregation over all national registers is really possible is not yet clear, since it would include transfer of confidential data to a third party. It would also include a quite laborious check of secrecy as many companies could be the sole supplier to the total Nordic market and publication of data would then be impossible anyway.

Whether the confidentiality issues with *products* as described above are to the same extent relevant to use patterns of *substances* in a substance register (as under REACH) should be further investigated. Under REACH the substances are not registered via registration of preparations but as substances with a certain generic pattern of use. This cannot lead to disclosure of CBI related to a single preparation or a single preparation maker.

In Norway, the product register publishes the trade name of preparations together with the UCN classification and the NACE classification. The manufacturers of the preparations are asked beforehand whether there are CBI concerns. Only 0.5–0.8% of the companies make a claim for confidentiality. Thus also at the level of preparation making there seems to be no relevant confidentiality concerns with regard to information on the use patterns of these products.

For those substances, for which use information is accessible, the average number of uses per substance is 5–8 by NACE and 3–5 by UC 62. About 90% of substances with use information have less than 12 uses by NACE code and less than 8 uses by UC 62 (based on distribution in

Norway and Denmark). About 50% of use-indications are related to 7 product groups:

- Paints and varnishes
- Cleaning and washing agents
- Adhesives and binding agents
- Surface treatment of metals (e.g. chromatising agents, hardeners, rust removers, metal staining) and other materials (e.g. paper and cardboards, etch of electronic, etch of glass)
- Colouring agents
- Lubricants and additives
- Fillers

About 25% of the substances covered in SPIN are contained in consumer products.

In conclusion, these figures seem to suggest, that the majority of substances has a limited number of uses. However, note that this conclusion is possibly biased by the fact, that use-information is only available for substances and preparations with a broad use pattern.

This rough characterisation of SPIN may give an idea how a future REACH data base accessible over the internet may look like on the use side. It also indicates the limitations of such systems, taking into account that SPIN is based on a well developed system of product registers where the use information has been collected and controlled for many years.

## 3. How does REACH work?

### 3.1 Use-related information to be registered

All manufacturers and importers of substances > 1 t/a have to submit use and exposure related information with their registration dossier. According to annex VI of REACH the following data is required.

**Table 4: Use related information in the REACH registration dossiers**

	Substances 1-10 t/a	Substances > 10 t/a	Dangerous substances
Overall amount manufactured or imported		X	
Tonnage for own use		X	
Form substance is made available to downstream users <sup>15</sup> (substance, preparation, article)		X	
Concentration in preps made available to downstream users <sup>16</sup>		X	
Amount of substance made available to downstream users in articles <sup>17</sup>		X	
Brief, general description of identified uses		X	
Short title for exposure scenarios			X
Use category by function (in SDS)			X
Uses advised against			X
Main use category by user group (3 classes) and process type (4 classes) <sup>18</sup>	X		
Significant route of exposure	X		
Frequency and duration of exposure	X		

Further information needed to carry out a safety assessment for dangerous substances > 10 t/a will be contained in the CSR but not in a form suitable to be retrieved and stored in a data base.

For substances > 10 t/a, REACH does not specify by which descriptors a *brief, general description of use* is to be made. A system of descriptors is one of the expected deliverables from the REACH Implementation Project (RIP) 3.2.2<sup>19</sup>. For substances < 10 t/a, REACH specifies a minimum information roughly indicating the exposure potential, including the “main category” of use. This information is needed to determine

<sup>15</sup> Note, based on REACH definition, consumers are no downstream users. Hence, the current annex VI seems to suggest that the substance manufacturer is not obliged to submit information on the form the substance is made available to consumers.

<sup>16</sup> See previous footnote.

<sup>17</sup> Note, based on REACH definitions, industrial or professional recipients of articles are no downstream users. Hence the current annex VI seems to suggest that the substance manufacturer is not obliged to submit information on concentration ranges in consumer products.

<sup>18</sup> Industrial, professional, consumer use; closed system use, industrial use (non dispersive), dispersive use, use resulting in inclusion into a matrix. Note: The industrial use and the use resulting in inclusion into a matrix are not exclusive, hence, these four process type categories are not completely consistent.

<sup>19</sup> First results expected to become available in February 07.

whether the registrant has to generate new data on substance properties, or whether he can register based on the existing knowledge.

### 3.2 Information access via the internet

REACH contains a number of rules related to access the collected information. The following details are only related to information to be made available over the internet and not to the rules for getting access to information on a case by case basis.

According to article 117<sup>20</sup>, disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:

- details of the full composition of a preparation;
- the precise use, function or application of a substance or preparation;
- the precise tonnage of the substance or preparation manufactured or placed on the market;
- links between a manufacturer or importer and his downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.

According to article 118(1)<sup>21</sup>, electronic public access is foreseen for the following information:

- the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;
- if applicable, the name of the substance as given in EINECS;
- the classification and labelling of the substance;
- physicochemical data concerning the substance and on pathways and environmental fate;
- the result of each toxicological and ecotoxicological study;
- any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
- the guidance on safe use provided in accordance with sections 4 and 5 of Annex VI;
- analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

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<sup>20</sup> Changed to article 118 in final REACH text

<sup>21</sup> Changed to article 119 in final REACH text

According to article 119 (2), the following information on substances shall be made publicly available over the Internet, except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

- if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
- the total tonnage band (i.e. 1–10 tonnes, 10–100 tonnes, 100–1000 tonnes or over 1000 tonnes) within which a particular substance has been registered;
- the study summaries or robust study summaries of the information on substance properties;
- information, other than that listed in paragraph 1, contained in the safety data sheet, e.g. the use of the substance (by technical function of the substance) or the title of the exposure scenario;<sup>22</sup>
- the trade name(s) of the substance;<sup>23</sup>
- the name in the IUPAC Nomenclature, for dangerous non-phase-in substances within the meaning of Directive 67/548/EEC;<sup>24</sup>
- the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC if exclusively used as intermediate or for research and development purposes.<sup>25</sup>

According to these requirements, the only use-related information for public assess foreseen under REACH is i) the volume band and ii) use related information contained in the safety data sheet for dangerous substances.

Annex II of REACH describes the use related information in the Safety Data Sheet under REACH: *Indicate the uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common uses need to be listed. This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.*

This can be interpreted in a way that the technical function of the substance (e.g. based on UC 62) should be described.

Where a Chemical Safety Report is required (dangerous substances > 10 t/a), according to Annex II of REACH, the Safety Data Sheet shall contain information on all the identified uses relevant to the recipient of the Safety Data Sheet. This information shall be consistent with the identified uses and exposure scenarios set out in the annex to the Safety Data

<sup>22</sup> No examples given in the REACH text, added by the authors of the study.

<sup>23</sup> Shifted from paragraph 1 to paragraph 2 in the final REACH text of December 2006.

<sup>24</sup> Amendment in the final REACH text of December 2006.

<sup>25</sup> Amendment in the final REACH text of December 2006.

Sheet. This requirement relates back to the “general, brief description of use” contained in the registration dossier (see REACH annex VI).

In summary, the only use related information under REACH open to public access and comparable with the NPRs information is

- the most common technical functions of a dangerous substance < 10 t/a and
- all identified uses (descriptors not yet defined) of dangerous substances > 10 t/a.

## 4. Comparisons

### 4.1 Comparing the information to be registered

There are a number of significant overlaps and differences in the type of information reported, processed and stored in the two systems.

**Table 5: Differences and overlaps in information to be registered**

Information type	Both systems	REACH	NPRs
Identity of substance manufacturer	X		
Identity of substance or preparation importer from non EU (M/I) <sup>26</sup>	X		
Identity of substance	X		
Annual volume of substance per company manufacturing or importing	X		
Identified use of substances	X		
Volume fractions supplied to these uses		Only the split between own use by manufacturer and amount placed on the market	X
Concentration of substance in single preparation		Only generic ranges for preparation types	X
Identity of preparation maker (by mixing substances)			X
Identity of preparation			X
Composition of preparation			X
Volume of preparation			X
Identified uses of preparation		Indirectly, as part of the substance' general description of use	X
Volume fractions supplied to these uses			X

### 4.2 Comparing the opportunities of both systems

#### 4.2.1 Tracing substances in single chemical products and their producers

The NPRs data bases contain information on the identity and composition of single preparations and the identity of the single preparation maker. Under the REACH system, companies importing or manufacturing substances > 1 t/a have to register their substances. There is no obligation to register i) the manufacture/import of preparations as such and ii) the identity of preparations (plus related information) under REACH. The identity of preparation makers will only be stored in the system, if the company notifies a so far unidentified use of a substance, or if it has to register non EU imports of substances. Thus, the identity of single preparation

<sup>26</sup> In the NPR it has been so far not possible to distinguish between imports from EU and from non EU.

makers, the identity of their products and the composition of these products will not be traceable under REACH.

#### *4.2.2 Identifying use patterns of substances*

The registrant under REACH is obliged to register all identified uses, given he can demonstrate under which conditions the use is safe. However, there will be relevant uncertainties to which extent the registrant under REACH will have registered all uses relevant in the market and to which extent those uses not identified by the registrant will be made known to the Agency by downstream-user-notification. In the NPRs the uncertainty is smaller since the preparation maker (the customer of the substance manufacturer) is obliged to register, and he knows pretty well to which markets he sells his product.

#### *4.2.3 Monitoring the mass flow of dangerous substances in the market*

Both systems will contain or do contain information on the use pattern of chemical substances as such or in preparations. The level of detail to which the uses of substances will be characterised in the REACH registration dossier is still open. The NPRs give oversight over specific substances on the national market; national volumes and national use patterns (branch and product types). Since the volume of single preparations, the volume fractions marketed for different uses, and the percentage of single substances in the preparation is registered, mass flow analysis is possible. The REACH data base will not provide for such an option.

#### *4.2.4 Tracing substances of concern in articles*

The REACH data base is likely to contain generic information on the use pattern of substances in articles. This will possibly be based on the industry category (IC) and an additional descriptor for article types where needed.<sup>27</sup>

In the NPRs, manufacture of substances into articles can be traced via the NACE code of a sector to which a preparation is supplied. Some of the NPRs include information on the type of material into which the preparation is manufactured, however, no information on article types. This is related in particular to construction material (UCN: K35300 and K35500) and electric and electromechanical components (UCN: E07100 to E07900).

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<sup>27</sup> First results of the corresponding work under RIP 3.2.2 expected to become available in February 07.

#### *4.2.5 Monitoring trends in single substances' market*

Updating information is a duty of the registrants in both systems. All NPRs have active updating of all products initiated by the registers. Finland, Sweden and Norway update all products each year – Denmark every second year. The products in the registers are representative for products actually on the market. Products no longer on the market are de-registered. This updating is supported by the financial incentive to save the registration fees for de-registered products. Due to the annual updating routines, the data in NPRs allows for detailed “time trend analysis”. Compared to that, the REACH data base will not provide for such an option: The updating obligation under REACH article 22 does not require the registrants to report on market changes unless the market development results in changes with regard to the registrant’s identity, the composition of substance, the volume band (including cessation of production or import), new identified uses or new uses advised against. A regular updating routine is not foreseen (and not supported) under REACH. Thus keeping the registration files up-to-date is largely left to the companies and corresponding compliance checks by the national authorities. As a consequence, changes in market volumes within a tonnage band or above 1000 t/a, or cessation of identified uses of substances are not likely to be reported at all. Hence in-time monitoring of market trends in mass flows of dangerous substances will hardly be possible based on the REACH data base.

#### *4.2.6 Supporting market surveillance with regard to preparations*

Different than the REACH data base, the NPRs data bases support market surveillance related to preparations. It is possible to control the correctness of classification and labelling of preparations and if restricted substances are included in single preparations.

#### *4.2.7 Public information access*

The only use-related information under REACH open to regular public access and comparable with the NPRs information is i) the most common technical functions of a dangerous substance < 10 t/a (= UCN code) and ii) all identified uses (descriptors not yet defined) of dangerous substances > 10 t/a. Whether or not the descriptors for identified uses under REACH will at all be comparable with the UCN and NACE based information in SPIN will depend on the outcome of RIP 3.2.2.

### 4.3 Comparing the benefits potentially to be gained

Based on the illustrative descriptions of benefits from NPRs the potential benefits through the REACH registration data can be evaluated. As it turns out, the REACH registration is not suitable to generate most of the benefits illustrated for the NPRs. For some areas, the extent of potential benefit still depends on the further development of the REACH regulation and the tools to implement it. In particular the required level of detail in the brief, general description of use will determine the added value of the use-related information in the REACH data-base.

**Table 6: Benefits related to NPRs also possible via the REACH registration data base**

Benefit based on NPRs	Supported by REACH registration data base	Explanation
Rapid reaction to risks related to chemical products	No	Single preparation makers are not identifiable through REACH.
Starting dialogues between authorities and formulators	No	Single preparation makers are not identifiable through REACH.
Identification of dangerous substances in consumer products	Possibly yes	For substances < 10 t/a yes; for other substances refinement of annex VI may be needed related to products available to consumers (see table 4)
Availability of emission information	No	No break down of production volume into use sectors required in REACH registration dossier
Linking economic growth to related risks	No	No break down of production volume into use sectors required in REACH registration dossier
Support to regulatory impact analysis	Depends	Quantitative impact analysis at level of manufacturers and importers; possibly qualitative analysis at users level, depending on descriptor system for the brief general description of use
Monitoring of chemicals policy performance	Depends	Volume trends at M/I level not updated; qualitative identification of impact areas at users level possible, depending on descriptor system for the brief general description of use
Access to information on composition and hazard of single preparations	No	Preparations and articles not registered under REACH
Market driven surveillance system in Norway: A customer can check whether the preparation he buys from their supplier has been registered.	Partly	Preparation maker may look into the REACH substance register to establish whether his raw materials (if single substances) have been registered. He can't however check this related to raw materials in form of preparations.

### 4.4 Comparing types of registrants

The duty to register at the NPRs is on manufacturers/importers of substances and preparations. This leads to a high share of SMEs among the registrants due to the fact that companies manufacturing and importing preparations are often SMEs. In Sweden, for example, the share of SMEs among the companies importing chemicals to Sweden is about 88%. The

number of companies importing chemicals to Sweden is more than ten times higher than the number of companies synthesising substances.<sup>28</sup>

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<sup>28</sup> Information KemI, November 06, referenced to information from Statistics Sweden.



## 5. Discussion and future options

The rough comparison shows that there are significant differences between the two systems with regard to both, the purpose of the system and the information content of the related data bases. REACH registration even in combination with the DU notification requirements will not generate information on the uses of substances comparable to the NPRs and the SPIN database. Due to the differences in the basic set-up of the systems, the REACH data base cannot deliver the same informational support to chemicals policy as the NPRs do. Even more, the SPIN data base may be a valuable source for registrants to identify the uses of their products in the market. Replacing the NPRs through a future REACH substance register would lead to a significant loss of information essential for targeting and balancing chemicals policy.

Based on this conclusion, a number of future functions of the NPRs under the REACH framework can be described.

### 5.1 Feed experience into the REACH process

The current ESIS (EU Substance Information System) does not provide public access to relevant information related to the uses and market volume of substances. This is partly due to confidentiality reasons and partly due to the fact that not much information on uses exists at all in the IUCLID data base. Compared to that, the Nordic SPIN database informs about total substance volumes broken down into technical functions and industrial area of use, as well as the number of preparations a substance is used in. Some data however, are also claimed confidential in SPIN. The experience of setting up and operating the SPIN database will be useful for setting up the REACH data base.

The identifiers for description of substance use in REACH are still under development. The Nordic Product Registers work with different coding systems and hence the experience could be fed into the RIP process.

Registration of substances in imported preparations works in the Nordic countries since the formulators directly supply their data to the Register but not to their customers. Experience gained here can be probably used for third party mechanisms to be established under REACH.

In order to keep the information in the system up-to-date an incentive is needed to make registrants report market changes. In particular disappearance of company names from the market, split and mergers of companies, decreasing market volumes of substances and abandoning certain

uses tends not to be reported. Since the REACH updating obligation are limited, normal market fluctuation will not be detectable in the REACH data-base which may lead to rapid outdateding after registration (see experience in current IUCLID and some of the Nordic product registers).

## 5.2 Tool for monitoring and enforcing of REACH

Under REACH, it will be the responsibility of the Member States to enforce REACH. This includes monitoring to which extent

- substances are registered in compliance with the tonnage band they are manufactured/imported in;
- the substance flows in the market really follow the use pattern as defined in the registration dossier;
- the downstream users comply with the requirement of notifying uses not foreseen by the manufacturer and consequently carry out an own CSA;
- substances are used in prohibited uses;
- the downstream users comply with the requirement of notifying the use of substances subject to authorisation.

In this context, the NPRs systems will work as a tool for inspection and enforcement under REACH at national level. Other member states do not have such tools yet in place. They still need to develop the appropriate means for inspection and enforcement, in particular at the level of formulators (= companies mixing substances for the purpose of marketing).

In the long term, the REACH system will function as a substance-register providing substance-by-substance information on i) the total amount imported or manufactured per company, ii) the qualitative use pattern and iii) the hazard information. However, even in a fully developed REACH system, no information will become available on the identity of single preparations and single preparation makers, except for those cases where formulators identify themselves in notifying particular uses not covered by the substance manufacturer's registration. Thus, national or local registers on companies formulating preparations are needed as a complementary instrument for inspection and control related to the implementation of the REACH downstream user requirements.

## 5.3 Source of information for registrants under REACH

Under REACH, the manufactures are obliged to cover all identified uses in their registration. For multi-purpose chemicals, the manufactures often know little on the final uses of their product in the market. In this respect,

the SPIN data base will be one potential information source for registrants to identify actual uses in the market. This is however limited to those 25% of substances in the SPIN data for which the use pattern is not regarded confidential. Also, the picture will only be representative for the consumer sector. The industrial use of substances will be influenced by the special Nordic industry profile with e.g. many pulp/paper industries, oil industry in Norway and a small base chemical sector. Nevertheless, SPIN may also provide useful information on examples for possible industrial uses of substances, even very far down the supply chain (e.g. substances in construction material).

## 5.4 Adjustments to REACH

In whatever function and period of time the product registration is maintained as a complementary system to REACH, harmonising of formats of registration for those companies who would have to register under both systems is needed. Otherwise, acceptance in trade and industry would be very low. This also applies to some harmonisation needs between the Nordic registers. In particular:

- Companies should be obliged to report if the product is imported from a non-EU country.
- Companies in the Nordic countries falling under the REACH registration requirement should be able to easily import the relevant parts of their REACH registration documents (and the relevant chapters of the IUCLID file) into the information package required under the Nordic register. This in particular regards substance identity, company identity, total volume and the coding system for the use pattern.
- The use identification system should be as far as possible compatible with the system used under REACH. This does not necessarily mean identical in all details, but at least consistent in structure and hierarchy levels. Since the industry category (by sector of economy) and the use category (by technical function of substance or preparation) are the backbone of use description in the current EU system (for new substances) and the NPRs, it is likely that basic compatibility is ensured. It would be nevertheless useful to contribute to the development of use descriptors within the RIP 3.2 process in order to inform about the experience made with transforming the current UC 55 system used in the EU into the UCN code system, and the experience made using NACE codes instead of the 16 ICs used in the EU.

Some of the routines already established to register to the NPRs will provide a good starting point for companies to comply with the REACH requirements. This applies in particular to the procedures

- to register imports of substances in preparations and
- to classify i) the type of chemical product sold to the customer and ii) the type of economical activity the customers carries out with the substance.

## 6. Conclusions

The data from the NPRs are available now, whereas the information in the REACH register will only be available with a fairly total picture in yet 15 years. During this period of time, the information from the NPRs is needed anyway to further implement policies towards sustainable development, including chemicals safety.

While REACH is a system to register single substances only, in the NPRs substances and preparations are registered. Hence, the overlap between the information being available in the NPRs and the future REACH data base is limited to the identity of substances, the identity of companies manufacturing or importing substances and to the generic use of a substance as anticipated by the substance manufacturer. Information related to single preparations on the market or single preparation makers available in the NPRs will not be part of the REACH information. Also, it will hardly be possible to obtain relevant information on volume trends and shifts in the use patterns of substances from the future REACH data base. Based on this, the added value of the NPRs during the implementation phase of REACH and after REACH has entered into full operation can be summarised in three items:

- Product registers of the NPRs type can be used as a tool to support and enforce the implementation of REACH at the level of preparation makers and preparation importers. The function of the REACH systems very much depends on whether the downstream user requirements really deliver in practice. Based on the NPRs information the inspectorates can directly follow up the response of formulators receiving REACH extended Safety Data Sheets.
- Based on the NPRs information substances can be traced down to single preparations. Thus a reality check can be performed to which extent the registered use pattern under REACH and market reality fit to each other. Such market surveillance mechanism is not part of the REACH system. However, REACH requires the EU Member States to ensure enforcement of REACH. In this respect the NPRs could be seen as a means to comply with this obligation.
- The REACH data base will enable trend analysis on market volumes and use patterns of substances only to very limited extent. This is due to the fact that abandoned uses do not have to be notified, and that changes in market volumes are only to be notified if i) one of the five relevant tonnage thresholds is passed or ii) production/import has ceased at all. Mass flow analysis will not be possible at all, since registrants will not have the duty to include a break down of the total

substance volume into uses. Compared to that, the NPRs allow to link annual trends in substance volumes and use patterns to information from economical statistics. Also mass flow analysis is possible, since the volume of single products and the corresponding percentage of substances in these products are reported to the product registers. Trend and mass flow analysis is one of the pre-requisites to monitor policy performance and progress towards sustainable development.

The SPIN data base as an instrument to enable public access to substance related information in the NPRs has to struggle on a regular basis with the same confidentiality issues like the future public part of the REACH data base will have. The added value lies in the fact that aggregated volumes and use patterns of substances (based on UCN and NACE classification) can be retrieved. In the REACH system only the corresponding volume band of a substance and information on use as far as contained in the safety data sheet will become publicly available.

The added value of the Nordic product registers and the SPIN database can be clearly demonstrated. However it is important to integrate as much as possible the related requirements with the work to be carried out under REACH. Acceptance in trade and industry would increase if the documentation work at company level could serve the two systems in one go. It is even likely that the established routines with the NPRs can help the importers and formulators in the Nordic countries to cope with the challenges of REACH. In order to mobilize synergies, it is however necessary to further harmonise the registration requirements among the NPRs and to make adjustments to REACH.

## References

- Anderson, P. [Arbejdstilsynet, Copenhagen]: Explanation on the comparison between IUCLID listed substances and SPIN listed substances; received per email on November 16, 2006.
- ECB (2003): Technical Guidance Document on Risk Assessment. European Commission, Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau. 2006.
- European Council (2006): Common position adopted by the Council with a view to the adoption of a REGULATION (EC) No .../2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), June 2006.
- KemI [Swedish Chemicals Agency] (2006): Compilation of cases demonstrating the benefits generated by making use of information collected in the Swedish Product Register. August 2006, unpublished.
- Nielsen, S. [Arbejdstilsynet, Copenhagen]: Substances in SPIN data base not listed in the EU IUCLID database; received per email on August 30, 2006.
- Nielsen, S. [Arbejdstilsynet, Copenhagen]: Distribution of substances on number NACE-codes and UC-codes per substance in SPIN 2004, 18.10.2006; received per email on October 23, 2006.
- Nielsen, S. [Arbejdstilsynet, Copenhagen]: Distribution of NACE-codes and UC-codes on number of substance per code, 10.8.2006; received per email on August 29, 2006.
- Nordic Product Register Group (2006): The Nordic Product Registers. A detailed presentation of the product registers of Denmark, Finland, Sweden and Norway. June 2006 unpublished.
- Nordic Product Registers Group (2006): Compilation of answers to a list of questions related to experience with SPIN asked by Ökopol; 29.8.2006; received by email August 29, 2006.
- Nordic Product Registers Group (2006): Table of key figures for SPIN version 2002-2005; 29.8.2006; received by email August 29, 2006.
- Östman, M. [Swedish Chemicals Agency]: Information with regard to the number of chemicals importing companies in Sweden that may have a registration duty under REACH; received by email November 7, 2006.



# Sammendrag

En ny europeisk kjemikalie lovgivning vil tre i kraft sommeren 2007. Kravene for registrering, evaluering og autorisering av kjemikalier (REACH) vil bli innført i alle EUs medlemsland. Når REACH systemet er innført vil produsenter og importører av kjemikalier (som kjemikalier eller i blandinger) ha en plikt til å sende inn et registreringsdossier til Kjemikaliebyrået i Helsinki og å oppdatere informasjonen dersom relevante endringer inntreffer.

Firma som plasserer kjemiske produkter (enkelstoffer eller blandinger) på det nordiske markedet (Danmark, Norge, Finland, Sverige) må allerede i dag registrere produktene til produktregisteret i det aktuelle landet. Når REACH treffer i kraft kan det synes at å rapportere til de nordiske produktregistrene og til Kjemikaliebyrået er dobbelt arbeid og at en derfor burde nedlegge produktregistrene. For å klargjøre graden av overlap mellom de to systemene og beskrive tilleggsverdien av produktregistre fikk Nordisk Produktregister Gruppe Ökopoll til å lage denne rapporten.

Det er signifikante forskjeller på de to registreringssystemer både med hensyn til hensikten med registreringen og informasjonen som blir samlet inn. REACHs registreringsprosess vil ikke generere informasjon om volum og bruk av stoffer av samme type som hva som er tilgjengelig fra produktregistrene. Ved å erstatte produktregistrene med det kommende REACH stoffregister vil en få et signifikant tap av informasjon som er essensiell for målrette og balansere kjemikaliepolitikken.

REACH er et system for å bare registrere enkeltstoffer, mens i produktregistrene er både enkeltstoffene og stoffblandinger registrert. Dermed er overlappen mellom informasjonen tilgjengelig i produktregistrene og i det framtidige REACH begrenset til navnet på stoffer, identiteten på firma som produserer eller importerer stoffer og den av produsent forventede bruk av stoffene. Informasjon om enkelt sammensetninger på markedet eller enkelt produsenter, som er tilgjengelig i produktregistrene, vil ikke være tilgjengelig i REACH stoff database. Det vil heller ikke være mulig å få relevant tidstrend informasjon om mengder på markedet eller skifte i bruksmønstre for stoffer fra den kommende REACH databasen.

Tilleggsverdien av produktregisterinformasjon i implementeringsfasen av REACH og etter at REACH er fullt operativt kan oppsummeres i tre punkter:

- Produktregister kan være et verktøy for å støtte og håndheve implementeringen av REACH med hensyn på oppgaver som kjemikalieprodusenter og -importører får. For at REACH systemet skal fungere er det helt nødvendig at kravene til nedstrømsbrukeren blir oppfylt. På bakgrunn av informasjon i produktregistrene kan tilsynsmyndighetene direkte følge opp responsen fra tilvirkere som mottar det utvidede sikkerhetsdatabladet i REACH.
- Basert på informasjon i produktregistrene kan stoff følges inn i enkeltsammensetninger. Dermed kan en utføre en virkelighetsanalyse for å se i hvilken grad bruksmønster registrert i REACH stemmer med det reelle bruksmønsteret. En slik markeds overvåkningsmekanisme er ikke en del av REACH, men REACH pålegger medlemstatene å forsikre seg om at REACH krav blir oppfylt. Sett i dette lyset kan produktregistrene være et hjelpemiddel for å kontrollere at forpliktelsene i REACH blir oppfylt av medlemslandene.
- REACH-databasen vil bare i svært liten grad muliggjøre trendanalyser på markedsvolum og bruksområder av stoffer. Dette fordi at det ikke er krav til å melde at et bruksområde opphører, og at endringer i markedsvolum bare skal meldes dersom i) et av de relevante vektbandene passerer eller ii) produksjon/import har opphørt. Massestrømsanalyser vil ikke bli mulig i det hele tatt siden de som registrerer ikke vil ha plikt til å inkludere en oppsplitting av den totale mengden på de ulike bruksområder. Produktregistrene gjør det mulig å sammenligne årlig utvikling i mengder og bruksområder med informasjon fra økonomisk statistikk. Også massestrømsanalyser er mulig, siden mengden av enkelt produkter og tilhørende prosentdel av hver enkelt komponent, meldes til produktregistrene. Trend- og massestrømsanalyser er et av de viktigste verktøyene for å måle effekten av politiske grep og framskritt mot en bærekraftig utvikling.

SPIN databasen er et verktøy for å gi publikum adgang til oppdatert stoffrelatert informasjon i produktregistrene. De som styrer SPIN databasen, sliter med de samme konfidensialitetsproblemene som de som skal styre den framtidige åpne delen av REACH databasen kan komme bort i. Men selv med disse begrensningene, er det en tilleggsverdi i det faktum at sammenslåtte mengder og bruksområder av stoffer (basert på UCN og NACE klassifisering) kan tas ut fra SPIN. I REACH vil bare det korresponderende vektbandet til et stoff og informasjon om bruk så langt dette er oppgitt på databladet bli tilgjengelig for publikum.

Nytteverdien av de Nordiske produktregistrene og SPIN databasen kan tydelig demonstreres. Allikevel er det viktig å integrere så mye som mulig med de tilsvarende rapporteringskravene som skal oppfylles under REACH. Forståelsen i forretningslivet og hos industrien vil øke dersom dokumentasjonsarbeidet i firmaene kan oppfylle begge systemene med samme data. Det er sannsynlig at de etablerte rutinene med hensyn til de

Nordiske produktregistre kan hjelpe importører og produsenter å takle utfordringene vedrørende REACH-registrering. For å mobilisere disse synergieffektene er det nødvendig med en videre harmonisering av registreringskravene i produktregistre og å gjøre tilpassninger til REACH.