TABLE OF CONTENTS

Program 2
List of Participants 4
Supervision under REACH-group 6
  Answers to questions and discussion 6
Statistics-group 9
  Answers to questions and discussion 9
Assessment-group 12
  Answers to questions and discussion 12
The development and usefulness of Nordic Products Registers - Presentation at the Uppsala Workshop 20.10.2004 14
Can the Nordic Countries Product Register REACH the emission scenarios? 19
How to derive easy-to-use emission estimation tools building on current TGD methodology? 20
The Use of Data from the Nordic Product Registers - a summing up 22
Appendix – list of presentations 24
The aim of this workshop is to explore the possibilities how to use non-confidential data stored in the Nordic Products Registers with the aim to map and quantify downstream-use and exposure to chemicals.

Program

20 October

12.0 Welcome

12.15 The development and usefulness of the Nordic Product Registers
Margareta Östman (Swedish Chemicals Inspectorate)

12.45 SPIN and aggregation of data from the Nordic Products Registers
Poul Andersen and Sven Nielsen (Danish Product Register)

13.30 Can the Nordic Product Register REACH the emission scenarios?
Paul van der Poel (RIVM)

14.00 How to derive easy-to-use emission estimation tools building on current TGD methodology?
Silke Müller (UBA)

14.30 Regulatory background of product information in Germany and impacts for practical work.
Dr Axel Hahn (Federal Institute for Risk Assessment)

15.00 Coffee

15.45 Identify chemical candidates for monitoring based on information in the Product Register.
Stellan Fischer (Swedish Chemicals Inspectorate)

Olof Holmer

16.45 REACH and national supervision
Barbro Sillrén (Swedish Chemicals Inspectorate)

17.15 The day ends
Program

21 October

09.00 Towards a chemical Risk Index, data needs versus data availability
*Christian Heidorn (cec – Eurostat)*

09.30 Swedish environmental accounts
*Viveka Palm (Statistics Sweden)*

10.15 Presentation of working groups

10.30 Group work

14.00 Coffee

14.30 Summing up
## List of Participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
<th>Country</th>
<th>E-mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lona Olsen</td>
<td>Danish Environmental Protection Agency</td>
<td>Denmark</td>
<td><a href="mailto:lo@mst.dk">lo@mst.dk</a></td>
</tr>
<tr>
<td>Poul Erik Andersen</td>
<td>Danish Product Register</td>
<td>Denmark</td>
<td><a href="mailto:pea@at.dk">pea@at.dk</a></td>
</tr>
<tr>
<td>Sven Nielsen</td>
<td>Danish Product Register</td>
<td>Denmark</td>
<td><a href="mailto:sni@at.dk">sni@at.dk</a></td>
</tr>
<tr>
<td>Aive Telling</td>
<td>Chemical notification centre</td>
<td>Estonia</td>
<td><a href="mailto:aive.telling@sm.ee">aive.telling@sm.ee</a></td>
</tr>
<tr>
<td>Helen Vaheer</td>
<td>Chemical notification centre</td>
<td>Estonia</td>
<td><a href="mailto:helen.vaheer@sm.ee">helen.vaheer@sm.ee</a></td>
</tr>
<tr>
<td>Annette Ekman</td>
<td>National Product Control Agency for Welfare and Health</td>
<td>Finland</td>
<td><a href="mailto:annette.uk@sttv.fi">annette.uk@sttv.fi</a></td>
</tr>
<tr>
<td>Pia Korjus</td>
<td>National Product Control Agency for Welfare and Health</td>
<td>Finland</td>
<td><a href="mailto:pia.korjus@sttv.fi">pia.korjus@sttv.fi</a></td>
</tr>
<tr>
<td>Nina Lampinen</td>
<td>STTV, Product Register Unit</td>
<td>Finland</td>
<td><a href="mailto:nina.lampinen@sttv.fi">nina.lampinen@sttv.fi</a></td>
</tr>
<tr>
<td>Tapio Klemola</td>
<td>STTV, Product Register Unit</td>
<td>Finland</td>
<td><a href="mailto:Tapio.Klemola@sttv.fi">Tapio.Klemola@sttv.fi</a></td>
</tr>
<tr>
<td>Paul van der Poel</td>
<td>RIVM</td>
<td>Netherlands</td>
<td><a href="mailto:paul.van.der.poel@rivm.nl">paul.van.der.poel@rivm.nl</a></td>
</tr>
<tr>
<td>Sigurbjörg Gisladóttir</td>
<td>Environment and Food Agency of Iceland</td>
<td>Iceland</td>
<td><a href="mailto:sigurbjorg@ust.is">sigurbjorg@ust.is</a></td>
</tr>
<tr>
<td>Helene Magaud</td>
<td>ECB</td>
<td>Commission</td>
<td><a href="mailto:helene.magaud@jrc.it">helene.magaud@jrc.it</a></td>
</tr>
<tr>
<td>Aigars Hlopickis</td>
<td>Latvian Environment Agency</td>
<td>Latvia</td>
<td><a href="mailto:aigars.hlopickis@lva.gov.lv">aigars.hlopickis@lva.gov.lv</a></td>
</tr>
<tr>
<td>Sibilla Lerha</td>
<td>Latvian Environment Agency</td>
<td>Latvia</td>
<td><a href="mailto:sibilla.lerha@lva.gov.lv">sibilla.lerha@lva.gov.lv</a></td>
</tr>
<tr>
<td>Irena Veronika Vadeikiene</td>
<td>Ministry of Environment</td>
<td>Lithuania</td>
<td><a href="mailto:i.vadeikiene@am.lt">i.vadeikiene@am.lt</a></td>
</tr>
<tr>
<td>Viktortas Seskauskas</td>
<td>State Non Food Products Inspectorate</td>
<td>Lithuania</td>
<td><a href="mailto:viktortas.seskauskas@is.lt">viktortas.seskauskas@is.lt</a></td>
</tr>
<tr>
<td>Christian Heidorn</td>
<td>Eurostat</td>
<td>Luxembourg</td>
<td><a href="mailto:christian.heidorn@cec.eu.int">christian.heidorn@cec.eu.int</a></td>
</tr>
<tr>
<td>Einar Hovde</td>
<td>Produktregisteret</td>
<td>Norway</td>
<td><a href="mailto:einar.hovde@produktregisteret.no">einar.hovde@produktregisteret.no</a></td>
</tr>
<tr>
<td>Jan Kraft</td>
<td>Produktregisteret</td>
<td>Norway</td>
<td><a href="mailto:Jan.Kraft@produktregisteret.no">Jan.Kraft@produktregisteret.no</a></td>
</tr>
<tr>
<td>Mette Follostad</td>
<td>Produktregisteret</td>
<td>Norway</td>
<td><a href="mailto:mette.follostad@produktregisteret.no">mette.follostad@produktregisteret.no</a></td>
</tr>
<tr>
<td>Per Fjeldstad</td>
<td>Produktregisteret</td>
<td>Norway</td>
<td><a href="mailto:per.fjeldstad@produktregisteret.no">per.fjeldstad@produktregisteret.no</a></td>
</tr>
<tr>
<td>Beryl C. Nygreen</td>
<td>Statens forurensningstilsyn</td>
<td>Norway</td>
<td><a href="mailto:beryl@sft.no">beryl@sft.no</a></td>
</tr>
<tr>
<td>Geir Jørgensen</td>
<td>Statens forurensningstilsyn SFT</td>
<td>Norway</td>
<td><a href="mailto:gej@sft.no">gej@sft.no</a></td>
</tr>
<tr>
<td>Marianne Walding</td>
<td>Swedish Work Environment Authority</td>
<td>Sweden</td>
<td><a href="mailto:marianne.walding@av.se">marianne.walding@av.se</a></td>
</tr>
<tr>
<td>Astrid Breyne</td>
<td>BASF AB</td>
<td>Sweden</td>
<td>astrid.breynenordic.basf.org</td>
</tr>
<tr>
<td>Kjell Lässker</td>
<td>Becker Industrial Coatings AB</td>
<td>Sweden</td>
<td><a href="mailto:kjell.lassker@beckers-bic.com">kjell.lassker@beckers-bic.com</a></td>
</tr>
<tr>
<td>Carina Persson</td>
<td>Kemira Kemi AB</td>
<td>Sweden</td>
<td><a href="mailto:carina.persson@kemira.com">carina.persson@kemira.com</a></td>
</tr>
<tr>
<td>Anette Jakobsson</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:anette.jakobsson@kemi.se">anette.jakobsson@kemi.se</a></td>
</tr>
<tr>
<td>Carin Törner</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:carin.torner@kemi.se">carin.torner@kemi.se</a></td>
</tr>
<tr>
<td>Name</td>
<td>Organization</td>
<td>Country</td>
<td>Email</td>
</tr>
<tr>
<td>-----------------------</td>
<td>--------------------------------------------------</td>
<td>----------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Erik Djurlin</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:erik.djurlin@kemi.se">erik.djurlin@kemi.se</a></td>
</tr>
<tr>
<td>Eva Ljung</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:eva.ljung@kemi.se">eva.ljung@kemi.se</a></td>
</tr>
<tr>
<td>Gunilla Antvik</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:gunilla.antvik@kemi.se">gunilla.antvik@kemi.se</a></td>
</tr>
<tr>
<td>Heta Reipas</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:heta.reipas@kemi.se">heta.reipas@kemi.se</a></td>
</tr>
<tr>
<td>Inger Lindqvist</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:inger.lindqvist@kemi.se">inger.lindqvist@kemi.se</a></td>
</tr>
<tr>
<td>Magnus Åkerblom</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:magnus.akerblom@kemi.se">magnus.akerblom@kemi.se</a></td>
</tr>
<tr>
<td>Margareta Östman</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:margareta.ostman@kemi.se">margareta.ostman@kemi.se</a></td>
</tr>
<tr>
<td>Stellan Fischer</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:stellan.fischer@kemi.se">stellan.fischer@kemi.se</a></td>
</tr>
<tr>
<td>Ulf Rick</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:ulf.rick@kemi.se">ulf.rick@kemi.se</a></td>
</tr>
<tr>
<td>Åsa Almkvist</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:asa.almkvist@kemi.se">asa.almkvist@kemi.se</a></td>
</tr>
<tr>
<td>Alf Lundgren</td>
<td>Swedish Chemicals Inspectorate</td>
<td>Sweden</td>
<td><a href="mailto:alf.lundgren@kemi.se">alf.lundgren@kemi.se</a></td>
</tr>
<tr>
<td>Olof Holmer</td>
<td>Kemisk- Tekniska Leverantörsförbundet</td>
<td>Sweden</td>
<td><a href="mailto:olof.holmer@ktf.se">olof.holmer@ktf.se</a></td>
</tr>
<tr>
<td>Viveka Palm</td>
<td>Statistics Sweden</td>
<td>Sweden</td>
<td><a href="mailto:viveka.palm@scb.se">viveka.palm@scb.se</a></td>
</tr>
<tr>
<td>Dr. Boris Gödicke</td>
<td>C.S.B. GmbH</td>
<td>Germany</td>
<td><a href="mailto:goedicke@csb-online.de">goedicke@csb-online.de</a></td>
</tr>
<tr>
<td>Axel Hahn</td>
<td>Federal Institute for Risk Assessment</td>
<td>Germany</td>
<td><a href="mailto:a.hahn@bfr.bund.de">a.hahn@bfr.bund.de</a></td>
</tr>
<tr>
<td>Silke Muller</td>
<td>UBA</td>
<td>Germany</td>
<td><a href="mailto:silke.mueller@uba.de">silke.mueller@uba.de</a></td>
</tr>
</tbody>
</table>
Supervision under REACH-group
(10 persons)
Moderator: Barbro Sillrén, Reporter: Erik Diurlin

Answers to questions and discussion

1. What will be the main topic for supervision under REACH?

Registration

- It is essential that all the substances, which are dutiful for registration, should be registrated.
- It is essential to inspect/examine the safety data sheets SDS and its contents.
Control the number of unrecorded (unreported) cases

Authorization

- For example, harmful substances such as PBT, vPvB and CMR:s requires authorization (0 Kg).
- It should be possible to inspect authorisation cases “on the field”. For example, is the company using the substance/s in accordance with the authorisation?

Limitations of REACH

- Monomers:
According to REACH new monomers are dutiful for registration. However, it is a problem when the monomer already exists then the registration is not obligated.

- One interesting remark is the possibility for a company to create a new company and produce 9,9 more tons to get around the extra regulations, which involves chemicals beyond 10 tons.

- There are many exceptions in REACH and, for example, Annex 3 and the exemptions in Title VII Authorisations are exceptionally difficult to handle.

Classification and labelling
It is a fact that companies to day do not use the same procedures when it comes to self-classification. Harmonization is essential and the only conclusive regulations concerns substances with risk-phrase R42 and CMR-substances. Other chemicals are classified by the company them self. It could therefore happen that one substance ends up on two lists.
2. What need are there for new ways of presenting data already collected? (availability, updating, publishing on(?) Internet, distribution, “subscription” etc)

With regards to what has been written above (point 1.) concerning self-classification there is obviously a need for harmonising the self-classification of substances between companies. Complementary information regarding this issue needs to be provided the companies.

The National products register in Denmark has published the substances, which are targets for self-classification on their web site www.MSD.dk. This “Danish-way” could be something for other National Product Registers to imitate. However, in for example Sweden, the information regarding self-classification of substances provided by companies is usually not complete and the classification of the substance is only stored in the database as H (Harmful), M (environmental toxic), P (preservative), no risk-phrase is registrated. This would make it impossible, at this point, to create such a self-classification list.

3. Will the “REACH-register” affect National Product Register? Will we have one National register for products/substances and one EU-based for substances? Conflicts?

Whether or not the REACH register will affect the National Product Register is a difficult question to answer at this point. However, the “REACH register” is not a rivalry register to the National registers because it only deals with substances and not includes products. In addition, the National Products Register could have more detailed information regarding the distribution of some substances due to the limit of 100kg/a, the REACH register only have information of substances >1ton.

The question “could the “REACH register” grow and include products” was discussed. However, this would probably not happen because the names of a specific product may vary from country to country, which would make it impossible to compare data.

So could one use the National Product Register to provide the “REACH register” with data was one other question, which were discussed. This would most certainly be a good way to get usefulness of the National registers, however, the information provided by the registers may not be reliable enough. The information provided to the National Register had to be correct.

4. What information in the “REACH register” is available for enforcement authorities? (Confidential/Non-confidential/Agency website-where can we find the information and how? Non-confidential data on request-what does that mean?) What non-confidential Product Register data will be relevant for the supervisors.

There are plenty of arguments for having National Product Registers. One is the need for the supervisor to have access to relevant data regarding substances included in products. The National Product Register most provides the supervisors with classified data concerning the concentration of the components of the product and the tonnage used. With out this information it is not possible to make a classification of the substance/product.
In the group it seemed to be no question about what is non-confidential data according to REACH. It is not clear, however, which data are confidential for the enforcement authority.

The access to confidential data for the enforcement authority is limited in REACH. However, national legislations may manage this, leading to national variations in supervision.

5. How often will the “REACH-register” be updated? Problems? Updating is a problem today?

Today we know that it is a problem with the updating issues in, for example, the Swedish Product Register in the sense of making companies provide the register with accurate information annually. This means it could possibly be problem even for the “REACH-register”.

The role of the custom needs to be enforced. The custom tariff codes may not be enough to regulate this need thus they are not specific enough.

Participants:
Annette Ekman  National Product Control Agency for Welfare and Health, Finland
Barbro Sillrén  National Chemicals Inspectorate, Sweden.
Beryl C. Nygreen  Statens forurensningstilsyn, Norway
Carina Persson  Kemira Kemi AB, Sweden
Einar Hovde  Produktregisteret, Norway
Erik Diurlin  Products Register, National Chemicals Inspectorate, Sweden
Lona Olsen  Danish Environmental Protection Agency
Nina Lampinen  STTV, Product Register Unit, Finland
Sigurbjörg Gísladóttir  Environment and food agency of Island, Iceland
Victoras Sekauskas  State Non Food Products Inspectorate, Lithuania
Statistics-group
(10 persons)

Answers to questions and discussion

What is the aim of presenting statistics on chemicals on the EU level and for whom is the statistics presented?
For government and other authorities, e.g. occupational matter, for inspectors, for people in municipals sector, for media.
Statistics could sometimes be hard to understand for common people. It can be difficult to make links between statistics; it can also be borders between the statistics and the information part. More adaptation must be done to help people interpret so that statistics become information. In other words, to present the statistics in an understandable way special reporting for common people is needed
There is of course a lot of work to do it properly; there is need for a political will. In Germany for example the doctors use the statistics from the poison control centres to inform the public

People want to know what is dangerous or not, simple information like an index

Media tend to notice statistics only when it is dramatic, big changing in the figures, sometimes there can be a problem to get “normal” statistics out. Different journals, like scientific press, could be useful in getting the information out to the public.
It is important to remember how easy it is to present statistics in different ways, therefore it is very important to tell which figures are presented, what they represent. It is very easy to turn the figures “upside down” and lie with statistics.
Linking tables is good to use when you want to compare statistics.

It would be nice with a EU-evaluation of the possibility to create a EU level common database with product data. If it should be possible to collect such data a directive must set the rules.
A compilation of all Product Registers, PR, was done 1995 on EU level. The idea is now that the Nordic Products Registers Group shall update this. A workshop was also arranged in Tampere in 1995 by the commission. There the work of experience exchange and standard procedures for Products Registers made under the auspices of the Dublin Institute was discussed.

If we want to harmonize systems it is very important that we talk to each other, that we exchange information. For example we should be more practical and build something together that we can show is useful instead of “dreaming” of a common database on EU level.
Also some kind of indicators could be a way. Money will of course be needed for that, the output must be wanted by some stakeholder for sufficient resources to be raised. Perhaps it is useful that there are also other needs for statistics like market needs or demands that has nothing to do with the risk in the first place (productions and sales for example). But it can also be difficult to exchange data between authorities because of legislation.

The Mean hazard classification per Combined Nomenclature number could be nice to present.
Are there any statistics on chemicals at EU level?
On European level there is no statistics on chemicals except in trade statistics and there the statistics is mostly in economic terms. The statistical customs tariff number are the same for several single substances which make it difficult to use trade statistics to follow substances.
There is work done on connecting Cas-nr and Indexnumber and the connection to Statistical Customs number (or Combined Nomenclature) is found in the Customs database ECICS. In the work with a European Chemicals Indicator certain numbers in trade statistics have been used to find import figures for the substances.

How well is the Product Register data suited for use as EU statistics?
Can we use the Products Registers for information about the downstream users?
One opinion: - that is very difficult because the Safety Data Sheets, SDS, is changing all the time; one substance goes in so many different types of products. Therefore it is only possible to make estimation on the national level.
Other opinion: - it is exactly the opposite, to give information about downstream uses is what we can do in the Nordic PR database, to follow one substance to different products.
It would be interesting to find out how representative the Nordic market is for the European market. Perhaps a factor like the population number could be used to, out of the Nordic data, calculate how much is likely to be used in the European market.
In the Nordic countries we are downstream users

In Germany there are figures how/ where the products are sold, made by the industry, maybe that could be an instrument also in the European level. Also in Sweden there exist figures like that, statistics could be possible to find on the webpage of different trade organisations and institutes.

If we report to a central database what would be the most important parameters?
Trade name, risk phrases and so on for products.
All the substances, even the small amounts because it is important to know to find causes for health and environmental problems.
In EU a database could be in a form of more aggregated data, different codes but not the trade names or the company names. Then all could benefit from it even though not all countries are reporting, for example compare use of a substance. In that case more aggregated codes would be useful.
But perhaps it is better if every country have a product database of there one to be able to make national scenarios. Why make the codes cruder when we have more detailed data in the national registers?

What would make the Nordic registers more useful?
The web-address of other European Products Registers at the Nordic PRs website would be good as it would tell people that other product registers do exist.
In Norway and Denmark the companies have to say how much they sell of a product and how much they use for own sake and what is exported. That could perhaps be something for the other PRs as well?
In EU it could perhaps be useful to see how much the products are moving across the different borders, but it could be difficult outside the Nordic countries.
The aggregated data of the unique cosmetic database in Germany would be very interesting for others to see because the ingredients in the cosmetics are important for the impact on the environment. Also there is no other such database available. There is not yet any such aggregated information but perhaps it can be in the future, that would demand an permission from the industry. It can of course be complicated with the formulas.
In the Danish Products Register a wish is to get the information of consumer use of a product. The best would be if there could be a percentage combined with the information about consumer use. It could also be useful to know about the behaviour of people, what do they do with chemicals? A link to the behaviour of the people to the exposure scenarios is important. A start could be to register percentage for all NACE codes reported to the PRs.

**How could the aggregated information in SPIN be used for statistics?**

It should be possible to make more “user-friendly” data in the SPIN because data is available for 4 years now (for Sweden at least), like graphs and extract tables. It is not possible to see the risk phrases in SPIN but you can extract data from SPIN and connect it to other data like the classification list. Could we widen the information in SPIN to contain also aggregated data on products? Perhaps that should be in another database. Is it possible to get a “positive list” out of the PRs that tell us which products that does not contain that or that? Not in Norway or Sweden but in Denmark there has been some attempt to make such lists. In Norway they have started a voluntary website where the companies can put their SDS, www.PIB.no. In Germany they are looking for a link between the bar code and the SDS, maybe that could be helpful for SPIN, for calculations? That is something that could be done in many countries and then is useful in the comparison between the countries. Hopefully the companies will accept that because most of the SDSs are public already, but not all companies want theirs SDS to be public. Maybe the “Norwegian” way to make a website with voluntary information works better. It is meant to offer a place for a competition in turning in SDS. In REACH they say that the SDS are not for the public, only for the industry use. In Germany there is a special database with the barcode and the name of the products, perhaps that will be an international standard? Sweden at least is involved in this standardisation work with the barcodes. There exists common barcodes and companies that use their own barcodes. They have also tried to get a special bar code connected to the formulas but the industry did not agree on that because then everybody would see when they change the formulations.

**Messages from the group:**

- Make an update of the compilation of European Products Registers
- Co-operate to harmonize and translate codes and classifications
- Present statistics on chemicals that is understandable to non-experts
- Develop statistics on Downstream use and on consumer products
- Develop statistics out of the German Cosmetics Register, it is unique
- Encourage companies to present their SDS in an easily found place on the web
- Publish a SPIN-off database with aggregated data on chemical products
Assessment- group

*Answers to questions and discussion*

**Situation:** For downstream users there is a need for a more simplified code systems for defining use pattern (relative current system within EU). The situation is the opposite for some regulatory purposes.

**Recommendations:**

1) Use hierarchical code system (such as the NACE code). They are possible to use at different level of dissolution. Low dissolution for simple purposes and high resolution for more detailed situations.

2) Work for harmonisation of the use pattern codes within the EU chemical work. If possible extent the harmonisation to include also other sectors, such as trade statistics. Consider standardisation. Harmonisation/standardization on OECD/UN level can be the next step.

The waste directives will soon change the material flow within the society towards an increased recycling. To reduce the risk with contaminated materials there will be an increased need for identifies possible substances in different types of materials. Product register data can be an important source for such information. Change in the structure/interface should be considered to meet this need.

Classification according to Annex 1 is used for several statistical purposes. It is therefore important that the legal base for Annex 1 will not be changed.

The interfaces of SPIN are today designed as a substance database with the substance identification as the main input data. If SPIN will be used by downstream users they probably have an other way to enter a product register database. They are more familiar with use categories, industrial categories. Search functions and reports may need some changes to meet that need.

SPIN only contains non-confidential information. About half of product register data has to be excluded. The confidential data is available for national authorities. However, there is today a legal problem originating from the legislation of the different countries, even if the receiving authority can keep data confidential. In time, these problems could perhaps be solved. One important user of confidential product register data is the new European Central Agency (in Helsinki). For their work with “exposure scenarios” the connection between CAS-numbers, use categories, industrial categories, consumer products is of unique value. The most confidential part, quantities and concentrations, are of less importance. The group could, however, not agree on a recommendation on this point, mainly because the mandate for the workshop was limited to cover “non-confidential” data.

Reactive intermediates often are a highly toxic chemical group that represent large quantities in product registers. Since such chemicals mainly will be transformed into harmless materials and therefore not cause exposures outside the industry. It is therefore important that use codes for intermediates are handled in a proper way, both during registration and by the user of product register data. Wrong registered or handled can such intermediated seriously interfere in follow up statistics of chemical risks.
<table>
<thead>
<tr>
<th>Participants:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stellan Fischer (chairman)</td>
<td>Swedish Chemicals Inspectorate</td>
</tr>
<tr>
<td>Magnus Åkerblom (secretary)</td>
<td>Swedish Chemicals Inspectorate</td>
</tr>
<tr>
<td>Sven Nielsen</td>
<td>Danish Product Register</td>
</tr>
<tr>
<td>Pia Korjus</td>
<td>National Product Control Agency for Welfare and Health</td>
</tr>
<tr>
<td>Paul van der Poel</td>
<td>RIVM</td>
</tr>
<tr>
<td>Helene Magaud</td>
<td>ECB</td>
</tr>
<tr>
<td>Aigars Hlopickis</td>
<td>Latvian Environment Agency</td>
</tr>
<tr>
<td>Jan Kraft</td>
<td>Produktregisteret</td>
</tr>
<tr>
<td>Mette Follestad</td>
<td>Produktregisteret</td>
</tr>
<tr>
<td>Geir Jørgensen</td>
<td>Statens forurensningstilsyn SFT</td>
</tr>
<tr>
<td>Marianne Wadling</td>
<td>Arbetsmiljöverket</td>
</tr>
<tr>
<td>Astrid Breyne</td>
<td>BASF AB</td>
</tr>
<tr>
<td>Kjell Lässker</td>
<td>Becker Industrial Coatings AB</td>
</tr>
<tr>
<td>Gunilla Antvik</td>
<td>Swedish Chemicals Inspectorate</td>
</tr>
<tr>
<td>Heta Reipas</td>
<td>Swedish Chemicals Inspectorate</td>
</tr>
<tr>
<td>Inger Lindqvist</td>
<td>Swedish Chemicals Inspectorate</td>
</tr>
<tr>
<td>Dr. Boris Gödicke</td>
<td>C.S.B. GmbH</td>
</tr>
<tr>
<td>Silke Muller</td>
<td>UBA</td>
</tr>
</tbody>
</table>
“Help! We need our formulas back! Our plant was burnt out last night.”
That was the call from an extremely unhappy paint manufacturer I received one of the very first days at work at the Swedish products register in 1990. In those days it was a rare sign of trust that the full product composition had been sent to the register.
Back in the 70ties, when the idea of product registers for chemical products was first put forward the availability of full formulas in the register would have been a dream, or nightmare to some. And, yes, of course he got copies of his formulas and the brand is still on the market.

My name is Margareta Östman and I have been given the task to update us all on how the Nordic Products registers have been formed. I am also going to tell about the different parameters they are built of and how all this information is used.
Some of you are already very familiar with what I’m going to say but maybe it can be useful to bring us all to a common ground. To a great extent my examples will be taken from the Swedish products register but as the society is rather similar in the Nordic countries I’m convinced they will be examples also of what happens at all the product registers.

If anything is unclear or you want to get more into detail please feel free to interrupt and put your question.

The products registers in the Nordic countries are all children of the 70-ties. They are the result of lengthy investigations and committee works initiated by the governments in Denmark, Finland, Norway and Sweden.

The sharp economic growth in the 50ties and 60ties included a huge growth in use of chemicals both in industry and by common man. The benefits of this were obvious but around 1970 also the disadvantages began to show clearly in an increasing number of work place related sickness.

Damages to the environment could by then also be seen by anyone who had an eye for rivers or bird populations.

Immediate measures were taken, like introduction of more occupational exposure limit values and building of sewage treatment plants.

But the question remained –what will happen next? And where? The aim of the authorities in the different countries was to get a view of the total impact of the chemicals used in the country.
There are several ways to obtain such knowledge on chemicals; the debate was intensive on how to proceed.

Industry advocated targeted investigations on selected chemicals when needed whereas the authorities wanted to collect data on composition as well as use and emissions in advance.

Industry wanted a substance register; authorities went for a register with the products on the market, substances as well preparations. A leading industry representative expressed “It is absurd to be forced to provide the composition of every product”.

Authorities wanted the collected data on composition to be available to occupational health care officers whereas industry said it was given for the authorities use only.

But by and by, in Norway and Sweden in 1977 and in Finland and Denmark in 1979, the legal base for a national register for chemical products was created. The solutions and content were, and are, slightly different in the different countries but the aim is the same, to get a comprehensible picture of the risky uses of chemicals in the country. In all the countries, however, not the users of chemicals were to be the partners in building up national registers but the importers and manufacturers of chemicals.

Finland and Denmark attached the products register to their work environmental authorities; Sweden loosely to the environmental protection agency, only Norway made the products register a body of its own. But also in Norway the use by occupational health authorities was the predominant for a long time.

Already from the start in 1982 the central authorities in the occupational and environmental sectors were given direct on-line access to the register in Denmark and Norway. Finland followed in the middle of the 90ties by giving direct access to the Poison Information Centre. The Swedish register is thus the only one where the register staff does all on-line handling; no other authority had direct access to the Swedish products register.

In Finland and Sweden registration was to be associated with a fee rather early. In Finland it is a fee related to the actual registration whereas in Sweden it is a fee intended to finance the whole central chemicals control.

The Swedish fee is often seen as a fee for only the registration and is then of course out of proportion, a fact that has not enhanced the companies’ willingness to register. Each time there has been a change in the fee rates the number of registered products has changed as well.

In the middle of the 90ties also Norway introduced a fee based on product registration.

So, how did the ambitious, but empty, legal frame of the 70-ties transform in the rather stuffed registers of today? The way has been taken stepwise and has even been crooked sometimes, with evaluations and revisions every now and then. First was the choice of what products should be registered.

The aim was to find the dangerous substances so products classified as hazardous to health seemed a natural selection.
Finland and Denmark introduced the obligation to register all chemical products classified as hazardous to health and intended for occupational use, which means those where a Safety Data Sheet would have to be provided. Norway also chose this hazard approach and started their register by collecting reports on all toxic products. That included all products, not only the chemicals used at work places. When the toxic products were satisfyingly registered a successive extension with the products with less severe health effects followed.
The obligation to register also hazardous consumer products was introduced in Finland in 1989.

Sweden went another way by choosing to start with all chemicals of a certain kind, dangerous or not. The registration obligation was linked to the statistical customs tariff number. The collection started with names of all products under a great variety of statistical customs tariff numbers. The actual collection of data on chemical composition and use started with the products under the numbers for pure chemicals. This was done by the expectation that thus the supply of dangerous chemicals into the country’s manufacturing industry should be controlled.

In Denmark the products register has also been used to store the result of special investigations on groups of consumer available products e.g. cleaners. The possibility to voluntarily register also non-hazardous products has been applied in Norway. Those are ways to use the products registers as a multi-purpose place for storage of data that have been beyond the legislation.

Now the registers contain data of all the product names of dangerous products in the Nordic countries. Also all the non-classified products are in the Swedish register as well as many of them are reported voluntarily to the other registers. The contained substances with names/CAS-numbers and percentage are in. That means approximately one million information pieces of the combination substance-percentage that are in the active products on the Nordic market. Annually handled quantity is reported in three of the countries and makes it possible to calculate the amount of each single substance in chemical products within a minute. How the product is used is reported by use categories and by industrial categories. The about 500 Nordic use categories are now being harmonized. The industrial categories are the NACE codes used internationally for economic statistics. The statistical customs tariff numbers provide a possibility to compare with data from other sources. Health and environmental classifications give further help to target the searches.

*A comprehensive survey of the build of the Nordic registers was published 1999 by the Nordic Council of Ministers.*
The use of the registers has of course been dependent on what could be extracted. For the first decade that was almost exclusively information on one single product at a time. The registers were used for control by the authorities. Labelling and Safety Data Sheets were controlled and information on products found on work places could be checked. Help in emergency situations could be obtained and a particular substance in an investigation of occupational damage or diseases could be traced. Extractions of use data for a large number of substances were early done to form the basis for work with occupational exposure limits.

In Sweden the aim of the products register already from the beginning was to provide an overview of the use and flows of chemicals. In the late 80-ties the information in the whole register was processed in order to form such an overview. Tables on number of companies, substances and products were produced; a picture of how the dangerous products were used was formed. However the resolution was poor, the quantities were up till then reported in intervals, so were the percentages. The distribution over use and industrial category thus became rather crude and exported quantities were not possible to exclude. The first statistical processing clearly illustrated that more exact information was needed and in the beginning of the 90-ties the Swedish legislation was changed accordingly.

Already in the 80ties Denmark pronounced that their products register should be used also for contribution in international work. I think that this, making the world around us aware of the products register possibilities, has been very beneficial to all of us in later years.

Help has been provided to screen for use of High Production Volume Chemicals in the European substance risk assessment program.

Reports on single substance that are treated in the OECD programs on chemicals, such as at the SIAM meetings, have been supplied for many years.

In later years use data from the Nordic registers have been used in European risk assessments not only by authorities. We have had questions from large European producers about in what kind of products their substance is to be found. The possibility to single out substances in consumer available products has come to be much appreciated.

Targeting of environmentally dangerous substances became an issue in the Nordic countries in the end of the 80-ties. The really hazardous substances were already disposed of; at least on paper, and could rarely be found in the product registers. But as the knowledge grew on the environmental effects of many more substances came also the demands to use the registers for mapping where these substances could be found. The problem was that such substances and products are not always classified as dangerous to health and thus not reported to the registers. In the big Swedish phase-out project the register was search to find such uses that could be acted on to reduce use of environmentally dangerous substances.

The last decade many local authorities have used the register for the same reason. Unwanted substances are found in the sewage plant or in air and the local authority wants to know where in the community they should look for sources. They also want to know how to target information campaigns for instance to reduce hazardous waste from the household.
Similar questions on use pattern are also among the most common to the register from university students and researchers.

To include products classified as only dangerous to the environment in the registers and to trace such substances contained in low percentage has been the big challenge during recent years.

The responsibility for official statistics on chemicals in Sweden was 1994 put on the Swedish Chemicals Inspectorate. What could then be more natural than to use the total investigation in the house, the products register, as the main source? Comprehensive tables containing most parameters in the register are published on the web and so are flow analyses for many substances. To give also people who are not so much experts in chemistry a picture of what can be seen in the register simple charts and analyses are made for the topics of present interest.

The Norwegian products register publishes similar statistics.

Some of the statistics based on the register is used for follow-up of the political phase-out goals and other risk reduction measures. It can be in the form of indicators. Closely related to this is the assistance the product registers can offer in reporting to international conventions. This often requires elaborate work to be able to give as detailed information as possible without putting the secrecy rules aside. The European environmental legislation often implies more openness with also company specific information than the legislation ruling the registers. Use figures for CFCs, other F-gases and Volatile Organic Compounds are such frequent extractions for follow-up of international environmental goals.

If the 70-ties were the years of ideas the 80-ties were the years of debate and struggle. But when the legislation, also in the rest of Europe, had come so far that Safety data Sheets including the dangerous substances in the products become mandatory the acceptance of also the obligation to submit information to a product register grew markedly. So the 90-ties were the years of consolidation. The flow of information into the registers made it possible to provide better and better information. And the more used, the more accepted by stakeholders, including the reporting companies. The attitude of co-operation shown by the paint producer I told you of in the beginning is now more common.

Help with products lists, and even to look for a particular substance in the companies product compositions have been executed. As help in the preparations for Reach the registers could be used to organise every substances of each company in tonnage classes. That might be a welcome form of feedback. Addition of the reported uses categories for each substance would make it even more useful to the company.

I’m sure there are yet many ways to use the products registers. And that there are many benefits to be had from the slowly but steadily accumulated knowledge in them.
Can the Nordic Countries Product Register REACH the emission scenarios?

*Paul van der Poel* - RIVM

The present process of risk assessment is discussed in respect to the impact of REACH for the crucial phase of emission estimation. The part of the UBA-RIVM project directed at a system (“target funnel”) to select the correct emission scenario is described. This target funnel uses so-called identifiers, which help to select the correct emission scenario from the set of scenarios available. This system should work well for new substances and biocidal product types, but might give problems for low production volume chemicals and small-scale applications of high production volume chemicals. Therefore, the data in SPIN on substances used in chemical products might present a useful solution. A comparison is made between the EU TGD (Technical Guidance Document) and SPIN classifications. Both systems use classifications for functions and industrial categories (or industrial sectors). An example for paints and a paint additive is presented to show inconsistencies, overlaps, and occurrence of possible identifiers present in the descriptions of codes. Also, the emission scenarios of the TGD for paint application are considered for the applicability of identifiers. It seems that SPIN uses both single-function classifications and function classifications embedded in a description of product types and fields of application. The conclusion is that the SPIN codes might be useful for existing substances applied in chemical products. Therefore, harmonisation of classification codes is required and tuning with existing emission scenario documents (EDSs) should occur (probably leading to updating of ESDs). A prerequisite is that the identifiers needed for the various chemical products are incorporated in SPIN. A point of discussion will then be if extensive descriptions that include the identifiers should – as for paints and printing inks – be introduced or separate parameter choices for each identifier.
How to derive easy-to-use emission estimation tools building on current TGD methodology?

Silke Müller, Federal Environmental Agency, Germany,

While effects’ testing is harmonised worldwide through the OECD Test Guidelines, environmental exposure assessment, particularly emission assessment as the first step of an exposure assessment, is not transparent or fully harmonised. This problem stems from the fact that the functions of chemicals and the processes in which they are used are very diversified resulting in a variety of potential environmental pathways and release rates. The future European regulation on industrial chemicals REACH will stipulate manufacturers, importers, and, if necessary, downstream users to perform their own chemical safety assessment (CSA) which may comprise an exposure assessment and a risk characterisation (REACH regulation proposal, Art. 13, 29-33, 34-36).

Recently, several workshops and test runs according to REACH showed that industry is insufficiently prepared for conducting an exposure assessment. Thus, industry and authorities alike are interested in creating an easy to use and robust emission estimation tool accompanied with an instruction manual. This tool should allow manufacturers, importers, and downstream users to communicate within the supply chain about exposure assessment with a common methodology.

In 2004, the Federal Environmental Agency (UBA), Germany and the National Institute for Public Health and the Environment (RIVM), The Netherlands initiated a R&D project “Branch- and product-related emission estimation tool for manufacturers, importers, and downstream users within the REACH-system”. The project is supervised by the OECD Task Force on Environmental Exposure Assessment and is placed under the umbrella of the REACH Implementation Programme (RIP) No. 3 “Technical Guidance Documents and Tools for Industry” of the European Commission. The overall project is divided into two sub-projects: Sub-project A will be performed by RIVM, The Netherlands and sub-project B will be conducted by a consortium of three German companies.

Project A aims at the preparation of a technical guidance, which directs manufacturers, importers, and downstream users to an appropriate emission scenario that should be applied for the emission estimation to different environmental pathways. Paul van der Pool, RIVM will present first results of project A at this workshop.

Project B aims at the development of a technical guidance for emission estimations starting with an analysis of existing emission scenario documents (ESDs) and resulting in easy to use, well comprehensible, and robust manuals and software tools for emission calculations. First part of project B is linked to the so-called matrix project of the OECD Task Force on Environmental Exposure Assessment. I.e. a matrix is built up containing the 15 industrial and 55 use categories (IC/UC) of the EU TGD (2003) versus the relevant life cycle stages and emission routes of substances. Existing OECD and EU ESDs or the corresponding A- and B-tables of the EU TGD (2003) are allocated to the matrix cells indicating whether the respective industrial or use category, life cycle stage or emission route is represented by an existing emission estimation tool or not.
The second part of project B is an implementation of the matrix with stand-alone emission scenarios exemplified by two selected supply chains. The stand-alone emission scenarios are specified by a technical guidance for calculating local and, if needed, regional emission rates to wastewater, air, soil, and waste. The technical guidance consists of a short instruction manual and a robust stand-alone emission estimation software module.

The technical guidance should be used by the producer or importer as well as by the downstream user. The producer or importer applies a generic emission estimation module with default values for the parameters concerning the intended use of the respective chemical. The downstream user has the possibility to overwrite these default values with site-specific values for his plant, process, or article. The emission estimation algorithm will also contain correction factors for abatement techniques that the downstream user may apply, e.g. on-site wastewater treatment or air scrubbers.

The software modules will have an interface to EUSES or other fate models in order to complete the exposure estimation assessment.

The on-going work of the project will be published at the website of UBA under: http://www.umweltbundesamt.de/reach/index.htm.
The Use of Data from the Nordic Product Registers - a summing up

*Ulf Rick – Swedish Chemicals Inspectorate*

The Workshop was successfully held in Uppsala on October 20 to 21 2004. There were 44 participants from eleven countries representing authorities, industry and private firms. Hand-outs and presentations as well as minutes from the three working groups are available on CD-ROM and have been mailed to all participants.

I suggest that this group decides how much of this information should be published on the web and that all Nordic Product Registers present a link to that publication.

When first discussing this project the SPIN database had just been launched and the Swedish Products Register had been scrutinized from the view of using the register data as some kind of indicator for the goal of a Poison-less environment. The big question was how useful was the data aggregated in the registers and in SPIN. During the planning of this workshop there was a change: the REACH system began to take some concrete forms, the usability of SPIN-data was looked into and the search for good environmental indicators was enhanced.

The final conclusion was that from our first rather static views on the goals of this workshop developed a more prospective view: from What can we do with what we have? to What must we be able to do with what we have?

Three themes emerged: assessment under REACH, supervision under REACH and statistics. These themes were handled in three discussion-groups the minutes of which are presented in the workshop procedures. I suggest that the NPG look into these minutes to conclude which suggestions could be of use in its work. I want to stress some of the conclusions which I finds important, interesting and useful for NPG and the Nordic Registers:

1. Harmonization
   Already a big part of the NPG work the findings of the workshop underscores this theme. Anything done to harmonize the work of the registers, the data in the registers and the possibility to aggregate these data will be most useful in the development of good tools working with chemical legislation, chemicals and statistics.

2. Confidentiality
   This theme was not discussed as such but it might evidently present a problem not least when discussing common reports and data-sharing. It was also pointed out that on account of confidentiality there it a loss of information to be considered.

3. Up-dating the information on existing product registers
   Already a topic for the NPG underscored by the workshop.

I think this workshop has been worthwhile considering all the efforts put down by the participants both those having prepared a presentation and those sharing their opinions in the working-groups.
I think the participants, register keepers and register users, will make use of what was discussed in the workshop.

I think that the conclusion to be drawn by the NPG is that they are working with the right thing at the right moment.

_Ulf Rick_
Appendix – list of presentations

SPIN and aggregation of data from the Nordic Products Registers  
*Poul Andersen and Sven Nielsen (Danish Product Register)*

Can the Nordic Product Register REACH the emission scenarios?  
*Paul van der Poel (RIVM)*

How to derive easy-to-use emission estimation tools building on current TGD methodology?  
*Silke Müller (UBA)*

Regulatory background of product information in Germany and impacts for practical work.  
*Dr Axel Hahn (Federal Institute for Risk Assessment)*

Identify chemical candidates for monitoring based on information in the Product Register.  
*Stellan Fischer (Swedish Chemicals Inspectorate)*

Product register companies perspectives. Problems and Possibilities.  
*Olof Holmer*

REACH and national supervision  
*Barbro Sillrén (Swedish Chemicals Inspectorate)*

Towards a chemical Risk Index, data needs versus data availability  
*Christian Heidorn (cec – Eurostat)*

Swedish environmental accounts  
*Viveka Palm (Statistics Sweden)*
SPIN

Substances in Products in the Nordic Countries

The Nordic approach to product registration and use of data

Poul Erik Andersen
Danish National Working Environment Authority
Logical file structure in PROBAS
Composition

Substance 1 → Raw material → Preparation
Substance 2 → Raw material
Substance 3 → Preparation
Substance volume

\[ M_{S1} = \sum_{x=1}^{x=n} M_{Px} \times C_{S1x} \]

- \( M_{S1} \): total volume of substance no. 1
- \( M_{Px} \): volume of preparation no. \( x \)
- \( C_{S1x} \): concentration of substance no. 1 in preparation no. \( x \)
SPIN ON THE INTERNET
Substances in Preparations in Nordic Countries

SPIN provides data on the use of chemical compounds in Norway, Sweden, Denmark and Finland. The project is financed by the Nordic Council of Ministers, Chemical group and the data is supplied by the Product Registries of the contributing countries.

SPIN is available in two versions: As a program and database on CD and here on the Internet. The CD version gives some further possibilities when reporting and exporting the data.

SpinOn-line
Follow this link to get to the online version of the database. You can view data on the use of chemical compounds in each of the contributing countries, both as totals and in different industries and for different purposes.

Discussion and hints
Enter the discussion forum to read comments and hints from the administrators and other users and to write your own comment to other users.

Ordering the CD version
The CD version is available to when you fill out the agreement, that you find when following this link.

Download area
Users of the CD version can download updates to the database and new versions of the program.

National contact Points

Norway  Sweden  Denmark  Finland  Iceland
### Total use

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th># preparations</th>
<th>Tonnes</th>
<th>Consumer preparations</th>
<th>Confidential</th>
</tr>
</thead>
<tbody>
<tr>
<td>FIN</td>
<td>2001</td>
<td>313</td>
<td>56926.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>518</td>
<td>40251.7</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>2528</td>
<td>458.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>2000</td>
<td>564</td>
<td>25488.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>S</td>
<td>2000</td>
<td>1695</td>
<td>6963.0</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>DK</td>
<td>2000</td>
<td>2151</td>
<td>522.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FIN</td>
<td>2000</td>
<td>335</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# SPIN
Substances in Preparations in Nordic Countries

**Chemical Information**
- **CAS no:** 50-00-0
- **Name:** Formaldehyde
- **EC no:** 200-001-8

## Industrial use (NACE)

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Code</th>
<th>Description</th>
<th># prep</th>
<th>Tonnes</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>2001</td>
<td>24</td>
<td>Manufacture of chemicals and chemical products</td>
<td>91</td>
<td>37266.5</td>
</tr>
<tr>
<td>FIN</td>
<td>2001</td>
<td>24</td>
<td>Manufacture of chemicals and chemical products</td>
<td>24</td>
<td>30974.7</td>
</tr>
<tr>
<td>FIN</td>
<td>2001</td>
<td>20</td>
<td>Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials</td>
<td>65</td>
<td>25430.2</td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>11</td>
<td>Extraction of crude petroleum and natural gas</td>
<td>10</td>
<td>1850.7</td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>24</td>
<td>Manufacture of chemicals and chemical products</td>
<td>147</td>
<td>381.6</td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>26</td>
<td>Manufacture of other non-metallic mineral products</td>
<td>6</td>
<td>252.5</td>
</tr>
<tr>
<td>FIN</td>
<td>2001</td>
<td>26</td>
<td>Manufacture of other non-metallic mineral products</td>
<td>14</td>
<td>246.7</td>
</tr>
</tbody>
</table>
## SPIN
Substances in Preparations in Nordic Countries

**CAS no:** 50-00-0  **Name:** Formaldehyde  **EC no:** 200-001-8

### USE CATEGORY (UC62)

<table>
<thead>
<tr>
<th>Country</th>
<th>Year</th>
<th>Code</th>
<th>Description</th>
<th># prep</th>
<th>Tonnes</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>2001</td>
<td>A33</td>
<td>Intermediates</td>
<td>9</td>
<td>21381.8</td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>A02</td>
<td>Adhesives, binding agents</td>
<td>112</td>
<td>16100.9</td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>C39</td>
<td>Non-agricultural pesticides and preservatives</td>
<td>13</td>
<td>2578.3</td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>A33</td>
<td>Intermediates</td>
<td>9</td>
<td>292.0</td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>A02</td>
<td>Adhesives, binding agents</td>
<td>316</td>
<td>211.0</td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>C39</td>
<td>Non-agricultural pesticides and preservatives</td>
<td>39</td>
<td>153.0</td>
</tr>
<tr>
<td>N</td>
<td>2001</td>
<td>A43</td>
<td>Process regulators</td>
<td>21</td>
<td>104.7</td>
</tr>
<tr>
<td>DK</td>
<td>2001</td>
<td>C13</td>
<td>Construction materials</td>
<td>26</td>
<td>21.6</td>
</tr>
</tbody>
</table>
### Technical

<table>
<thead>
<tr>
<th>Molecular Formula</th>
<th>CH₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index no.</td>
<td>005-001-00-5</td>
</tr>
<tr>
<td>SMILES</td>
<td>C=O</td>
</tr>
<tr>
<td>Colour Index</td>
<td>Show structure</td>
</tr>
<tr>
<td>CSD</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance category</th>
<th>Main category (IUCrLD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES</td>
<td>A13-03 Use resulting in inclusion into or onto matrix</td>
</tr>
<tr>
<td>HAER</td>
<td>A13-02 Use in closed system</td>
</tr>
<tr>
<td>KCN</td>
<td>A13-01 Non dispersive use</td>
</tr>
<tr>
<td>MON</td>
<td>A13-04 Wide dispersive use</td>
</tr>
<tr>
<td>OPL</td>
<td></td>
</tr>
<tr>
<td>RST</td>
<td></td>
</tr>
<tr>
<td>STA</td>
<td></td>
</tr>
<tr>
<td>URH</td>
<td></td>
</tr>
</tbody>
</table>
Can the Nordic Countries Product Register REACH the emission scenarios?
Application of Emission Scenarios in Risk Assessment

1 No Measured Environmental Concentrations

2 No Data on Emissions

Then:

3 Emission Scenarios of Emission Scenario Documents

*If present, otherwise:*

4 A- and B-tables of TGD
### Matrix of Emission Scenarios

<table>
<thead>
<tr>
<th>Industrial categories, Processes</th>
<th>Life cycle stages, Process steps, Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>New substances</td>
<td>X</td>
</tr>
<tr>
<td>Existing substances</td>
<td>X X</td>
</tr>
<tr>
<td>Biocides</td>
<td>X X X X X X X X X X X X X X X X X X X X X X X</td>
</tr>
</tbody>
</table>
Environmental Risk Assessment

- Every relevant life cycle stage
  - Local scale [1 point source]
  - Regional scale [area sources]

- Whole life cycle
  - Regional scale [all sources]

LIFE CYCLE STAGE $i$

Emission to air
Waste treatment
Emission to water
General Form of the Life Cycle of a Substance

PRODUCTION → FORMULATION

Downstream Users

USE

WASTE TREATMENT

USE

SERVICE LIFE

WASTE TREATMENT

Downstream Users
Risk Assessment: Present

Local Scale
Every relevant Life cycle stage
- 1 Point Source (Main) Generic scenario

Regional Scale
All relevant Life cycle stages
- All Sources

Authorities
Risk Assessment: REACH

Local Scale

Production

- All Point Sources
  - Site specific scenarios
  - Relevant Life cycle stages DSUs

- Point Sources of DSUs
  - Generic scenarios
  - Site specific scenarios

Regional Scale

All relevant Life cycle stages

- All Sources

Producers

Producers / Importers

DSUs

Authorities
Mainly Area Sources (Diffuse Emissions)

Emission Scenarios result from Industrial Use

Outside Scope
REACH and Life Cycle Stages

- Production
  - Formulation
    - Industrial use
      - Waste treatment
    - Industrial use
      - Service life
        - Waste treatment

UBA - RIVM

Target Funnel

Emission Scenario
Target Funnel to Emission Scenarios

Matrix of emission scenarios

Identifiers
- Relevant
- Not relevant
Target Funnel and Identifiers

1 Industrial Category (TGD)

- Covered with number of emission scenarios

IC8 Metal Extraction, Refining and processing industry

- Mining
- Ore benification
- Primary metal production

Metal products manufacture
1 Industrial Category (TGD)

- Covered with number of emission scenarios

**Example**

- IC8 Metal Extraction, Refining and processing industry
  - Metal products manufacture
    - Metal degreasing
    - Metal working (MWFs)
    - Soldering, Welding
    - Electroplating
    - Coating

**Industrial Category**

**Industrial Sector**

**Industrial Processes**
### Target Funnel and Identifiers

#### 1 Industrial Category (TGD)

**Industrial Process: Textile processing**

<table>
<thead>
<tr>
<th>Proces step</th>
<th>IC 13 Textile Processing Industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretreatment</td>
<td>Fibres and yarns treatment</td>
</tr>
<tr>
<td>Dyeing and printing</td>
<td>Finishing</td>
</tr>
</tbody>
</table>
1 Industrial Category (TGD)

Industrial Process: Paint application

<table>
<thead>
<tr>
<th>Process type</th>
<th>Example</th>
</tr>
</thead>
</table>
| IC 14 Paints, lacquers and varnishes industry | Brushing  
Rolling  
Spraying (atomization)  
Spraying (electrostatic)  
Curtain coating         |
Target Funnel and Identifiers

1 Industrial Category

Paints and Coatings

Data Notification

1 Industrial Category
2 Use Category
3 Detailed Information on Envisaged Use

2 Chemical industry

FORMULATION

PRODUCTION

14 Paint industry

INDUSTRIAL USE

16 Engineering industry
Sector: Metal Products Manuf. Process: Paint spraying
2 Use Category  (TGD)

- Different level of detail

<table>
<thead>
<tr>
<th>IC 14</th>
<th>Paints, lacquers and varnishes industry</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Binding agents</td>
</tr>
<tr>
<td>10</td>
<td>Colouring agents</td>
</tr>
<tr>
<td>48</td>
<td>Solvents</td>
</tr>
<tr>
<td>0</td>
<td>Others [Paint Additives]</td>
</tr>
</tbody>
</table>
Target Funnel and Identifiers

2 Use Category (TGD)

- 1 Component / Main function: >= 1 Function groups
- 1 Function group: >= 1 Function

IC 14 Paints, lacquers and varnishes industry

Example:

0 Others [Paint Additives]
- Antiskinning agents
- Biocides (UC 39)
- Catalysts (UC 43 Process regulators)
- Defoamers
- Dispersants
- Stabilizers
- Surface additives
- Wetting agents

Nordisk Workshop October 2004 | Paul van der Poel
Target Funnel and Identifiers

2 Use Category (TGD)

☞ 1 Component / Main function: >= 1 Function groups

☞ 1 Function group: >= 1 Function

- Component
- Function group
- Functions

IC 14 Paints, lacquers and varnishes industry

0 Others [Paint Additives]

UC 49 Stabilizers

- Antidegradants
- Antioxidants
- Antiozonants
- Heat stabilizers
- Radical scavengers
- Resin stabilizers
- Ultraviolet absorbers
- UV/Light stab
Target Funnel and Identifiers

Main Identifiers

1 Industrial Category
  ➔ Industrial Sector ➔ Process (type / step)

2 Use Category
  ➔ Function Group ➔ Function
  ➔ Component ➔ Function group ➔ Function
Target Funnel and Identifiers

Other Identifiers

Other Identifiers depend on:

- Specific Characteristics of Industrial Processes
- Classification and Terminology of Industrial Sector

Example: Paints and Coatings
Coatings

Thousands of Coating Products

Hundreds of Applications

Tens of Application Techniques

Several Substrates
Components of Coating Products

1 Binding agents

2 Colouring Agents

3 Solvents

4 Additives
Paint Classifications and Functions of Substances

3 Paint Type (Industrial Sector)

IC16 Engineering industries:
- civil and mechanical
  - Automobile manufacture
  - Constructions
  - Coil coating
  - Drum coating

IC4 Electrical/electronic industry

IC8 Metal processing industry

Product type
- Paint
  - Paint Solvent-based
  - Aqueous
- Varnish
  - Varnish Solvent-based
  - Aqueous
- Stain
  - Stain Solvent-based
  - Aqueous
- Powder Coating

Intended use (Industrial Sector)
Relations between Classifications & Identifiers

Identifier 1

USES <Industrial Category>
APPLICATION TECHNIQUE
PRODUCT TYPE
BINDER TYPE
FUNCTIONS <Use Category>

Other Identifiers

Identifier 2
Relations between identifiers

INDUSTRIAL CATEGORY

IC 16
Engineering industry

OTHER IDENTIFIERS

NACE 3410
Vehicles manufacture

APPLICATION TECHNIQUE

PROCESS

COATING

PAINT SPRAYING

PROCESS TYPE

PRODUCT TYPE

INDUSTRIAL SECTOR

SUBSTRATE

PROCESS STEP

PROCESS TYPE
Relations between identifiers

- OTHER IDENTIFIERS
  - APPLICATION TECHNIQUE
  - SUBSTRATE
  - PRODUCT TYPE
  - PAINT WATER-BASED
  - CHEMICAL PRODUCT
- FUNCTION
- FUNCTION GROUP
  - COMPONENT
  - PREPARATION

PAINT WATER-BASED
New Substances versus Existing Substances

**New Substances**

Notification data:
- Industrial Category
- Use Category
- Details Envisaged Use

**Existing Substances**

Little data on LPVC and small scale applications of HPVC

Problem Area !!!
Data on Existing Substances in SPIN

**SPIN Data base:**

* Industrial Use

NACE Codes for Application Areas

* Use by Category
  ("use categories")

Extended List with 3 Main Types of Codes
Data on Existing Substances in SPIN

Industrial Use:
NACE Codes are at various levels in SPIN

Use Codes:
F: Codes?
S: KEMI Codes
DK, N, S: “SPIN Codes?”

1 Functions as in TGD (exact/comparable)
2 Product Types Biocides as in TGD
3 Chemical Preparations and Products
### “SPIN” Codes (Example: “Paint“)

#### 1 Functions:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A55100</td>
<td>Anti-static agents</td>
</tr>
<tr>
<td>B15310</td>
<td>In-can preservatives</td>
</tr>
<tr>
<td>B15320</td>
<td>Film preservatives</td>
</tr>
<tr>
<td>B20100</td>
<td>Binding agents for paints, adhesives etc.</td>
</tr>
<tr>
<td>B35100</td>
<td>Softeners for plastic, rubber, paint and adhesives</td>
</tr>
<tr>
<td>B45100</td>
<td>Flame retardants</td>
</tr>
<tr>
<td>F05110</td>
<td>Pigments to paint and printing inks</td>
</tr>
<tr>
<td>F45200</td>
<td>Extenders</td>
</tr>
<tr>
<td>O15100</td>
<td>Solvents</td>
</tr>
<tr>
<td>O25200</td>
<td>Dispersion agents (carriers)</td>
</tr>
<tr>
<td>O25300</td>
<td>Emulsifiers</td>
</tr>
</tbody>
</table>
### “SPIN” Codes (Example: “Paint”)}

#### 2 Product types:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A55100</td>
<td>Anti-static agents</td>
</tr>
<tr>
<td>B15310</td>
<td>In-can preservatives</td>
</tr>
<tr>
<td>B15320</td>
<td>Film preservatives</td>
</tr>
<tr>
<td>B20100</td>
<td>Binding agents for paints, adhesives etc.</td>
</tr>
<tr>
<td>B35100</td>
<td>Softeners for plastic, rubber, paint and adhesive</td>
</tr>
<tr>
<td>B45100</td>
<td>Flame retardants</td>
</tr>
<tr>
<td>F05110</td>
<td>Pigments to paint and printing inks</td>
</tr>
<tr>
<td>F45200</td>
<td>Extenders</td>
</tr>
<tr>
<td>O15100</td>
<td>Solvents</td>
</tr>
<tr>
<td>O25200</td>
<td>Dispersion agents (carriers)</td>
</tr>
<tr>
<td>O25300</td>
<td>Emulsifiers</td>
</tr>
</tbody>
</table>

**Pt 6 Biocidal Directive**  
**Pt 7 Biocidal Directive**  
**UC 39 TGD**
### “SPIN” Codes (Example: “Paint “)

3 Chemical Preparations and Products:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>F05250</td>
<td>Pigment pastes</td>
</tr>
<tr>
<td>M0500</td>
<td>Paint, lacquers and varnishes</td>
</tr>
<tr>
<td>M0570</td>
<td>Anticorrosive paints</td>
</tr>
</tbody>
</table>

Preparation

Products
### “SPIN” Codes & Other Identifiers

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Function</th>
<th>Field of Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>M05131</td>
<td>Paint and varnish Water based Actives corrosion inhibitor</td>
<td>Interior</td>
<td></td>
</tr>
<tr>
<td>M05132</td>
<td>Paint and varnish Water based Actives corrosion inhibitor</td>
<td>Exterior</td>
<td></td>
</tr>
<tr>
<td>M05133</td>
<td>Paint and varnish Water based Actives corrosion inhibitor</td>
<td>Industrial use</td>
<td></td>
</tr>
<tr>
<td>M05134</td>
<td>Paint and varnish Water based Actives corrosion inhibitor</td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(including ship-, road-, art-, furniture-, autopaint)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
“SPIN” Codes & Other Identifiers

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M05213</td>
<td>Paint and varnish Volatile organic thinner</td>
</tr>
<tr>
<td></td>
<td>Active biological/biocide function (e.g. anti-fouling)</td>
</tr>
<tr>
<td></td>
<td>Industrial use</td>
</tr>
</tbody>
</table>

UC 39 Biocides:

Pt 6 In-can preservatives (SPIN B15310)

Pt 7 Film preservatives (SPIN B15320)

Pt 21 Antifouling products
Identifiers in EU Emission Scenarios “Paints”

<table>
<thead>
<tr>
<th>Scenario Heading</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
<th>17</th>
<th>18</th>
<th>19</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Furniture (general)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UV curable wood lacquer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waterborne wood lacquer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrocellulose wood lacquer (sprayed finish)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coil coating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can white enamel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 piece white enamel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 piece can internal white enamel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal solvent-borne white enamel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal solvent-borne general can lacquer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal can lacquer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metal can lacquer for metal cans</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can internal solvent-borne white enamel</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can metal can lacquer</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Container coatings</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Original equipment manufacturer car manufacturing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Car refinishing (general)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vinyl matt emulsion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard alkyd gloss finish</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water-borne exterior woodstain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solvent-borne interior/exterior woodstain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-tables Others</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Identifiers in EU Emission Scenarios “Paints”

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Original equipment manufacturer car manufacturing</td>
</tr>
<tr>
<td>16</td>
<td>Car refinishing (general)</td>
</tr>
<tr>
<td>17</td>
<td>Vinyl matt emulsion</td>
</tr>
<tr>
<td>18</td>
<td>Standard alkyd gloss finish</td>
</tr>
<tr>
<td>19</td>
<td>Water-borne exterior woodstain</td>
</tr>
<tr>
<td>20</td>
<td>Solvent-borne interior/exterior woodstain</td>
</tr>
<tr>
<td></td>
<td>A-tables Others</td>
</tr>
</tbody>
</table>

All situations that no specific Emission Scenario can be found
## EMISSION SCENARIO

<table>
<thead>
<tr>
<th>#</th>
<th>EMISSION SCENARIO</th>
<th>IDENTIFIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Original equipment manufacturer car manufacturing</td>
<td>X</td>
</tr>
<tr>
<td>16</td>
<td>Car refinishing (general)</td>
<td>X</td>
</tr>
<tr>
<td>17</td>
<td>Vinyl matt emulsion</td>
<td>X</td>
</tr>
<tr>
<td>18</td>
<td>Standard alkyd gloss finish</td>
<td>X</td>
</tr>
<tr>
<td>19</td>
<td>Water-borne exterior woodstain</td>
<td>X</td>
</tr>
<tr>
<td>20</td>
<td>Solvent-borne interior/exterior woodstain</td>
<td>X</td>
</tr>
</tbody>
</table>
Example of Substance

Substance: Lead naphthenate (CAS-No. 61790-14-5)

Applications ¹):

1 Siccative for paints and printing inks

2 Corrosion inhibitor and EP-additive for lubricants

¹) Internet search
1 Siccative for paints and printing inks

Classification codes for Function:

<table>
<thead>
<tr>
<th>Component 4</th>
<th>EU</th>
<th>EPA</th>
<th>KEMI</th>
<th>SPIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paint additives</td>
<td>EU</td>
<td>EPA</td>
<td>KEMI</td>
<td>SPIN M08100</td>
</tr>
<tr>
<td>Component Subgroup</td>
<td>EU</td>
<td>EPA</td>
<td>KEMI</td>
<td>SPIN</td>
</tr>
<tr>
<td>Driers</td>
<td>EU</td>
<td>EPA</td>
<td>KEMI</td>
<td>SPIN 317</td>
</tr>
<tr>
<td>Function</td>
<td>EU</td>
<td>EPA</td>
<td>KEMI</td>
<td>SPIN</td>
</tr>
<tr>
<td>Active driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auxiliary driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combination driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Co-ordinative driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drying agents</td>
<td></td>
<td></td>
<td></td>
<td>T20100</td>
</tr>
<tr>
<td>Primary driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Siccatives</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surface driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trough driers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Example of Substance

### 2 Corrosion inhibitor and EP-additive for lubricants

#### Classification codes for Function:

<table>
<thead>
<tr>
<th>EU</th>
<th>EPA</th>
<th>KEMI</th>
<th>SPIN</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Corrosion inhibiting additives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Corrosion inhibiting agents</td>
</tr>
<tr>
<td>14</td>
<td>323</td>
<td>661</td>
<td></td>
<td>Corrosion inhibitors</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E20100</td>
<td>EP-additives</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1051</td>
<td>Extreme pressure additives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>195</td>
<td>1052</td>
<td>Lubricant additives</td>
</tr>
<tr>
<td></td>
<td></td>
<td>35</td>
<td></td>
<td>Lubricants and additives</td>
</tr>
</tbody>
</table>
### Example of Substance

#### SPIN codes for Function in Data Base:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;UC62&quot;</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>B14</td>
<td>Corrosion inhibitors</td>
<td>✔</td>
</tr>
<tr>
<td>B20</td>
<td>Fillers</td>
<td>?</td>
</tr>
<tr>
<td>B35</td>
<td>Lubricants and additives</td>
<td>✔</td>
</tr>
<tr>
<td>D59</td>
<td>Paints, laquers and varnishes</td>
<td>✔</td>
</tr>
</tbody>
</table>
### Example of Substance

**SPIN codes for Function in Data Base:**

<table>
<thead>
<tr>
<th>&quot;National&quot;</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>Dyestuff, pigments</td>
</tr>
<tr>
<td>23</td>
<td>Lubricants</td>
</tr>
<tr>
<td>470</td>
<td>Paints, varnishes</td>
</tr>
<tr>
<td>1050</td>
<td>Lubricants</td>
</tr>
<tr>
<td>1151</td>
<td>Caulking compounds</td>
</tr>
<tr>
<td>M0500</td>
<td>Paint, lacquers and varnishes</td>
</tr>
<tr>
<td>M0560</td>
<td>Primer</td>
</tr>
<tr>
<td>M0570</td>
<td>Anticorrosive paints</td>
</tr>
<tr>
<td>R2000</td>
<td>Anti-corrosion materials</td>
</tr>
</tbody>
</table>

*Products*
### Example of Substance

**SPIN codes for Industrial Sector in Data Base:**

<table>
<thead>
<tr>
<th>NACE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DJ280000</td>
<td>Manufacture of fabricated metal products, except machinery and equipment</td>
</tr>
<tr>
<td>DJ285100</td>
<td>Treatment and coating of metals on a fee or contract basis</td>
</tr>
<tr>
<td>DK290000</td>
<td>Manufacture of machinery and equipment</td>
</tr>
<tr>
<td>F</td>
<td>Construction industry</td>
</tr>
<tr>
<td>F0454410</td>
<td>Painting</td>
</tr>
<tr>
<td>G52.462</td>
<td>Paint stores</td>
</tr>
<tr>
<td>P0950000</td>
<td>Private households with employed persons</td>
</tr>
</tbody>
</table>

**Sectors relate to Application area of Chemical Products in which the Substance is applied**
Conclusions, Questions and Spin-off

- SPIN codes are at many different levels
- How do SPIN codes for Function and Industrial Sector relate?
- Are >1 SPIN codes assigned to one product (with the substance) which is registered?
- Present situation in EU classification for Functions and Emission Scenarios is also not consistent
Conclusions and Conditions for Spin-off

• Comprehensive SPIN codes - as for Paints and Printing inks - may be of great value for Risk Assessment of Existing Substances

• Therefore, SPIN and EU classification for Functions, Products, and Industrial Sectors should be harmonized

• In SPIN Identifiers for Emission Scenario Selection should then also be incorporated
Questions and Discussion
How to derive easy to use emission estimation tools building on current TGD methodology?

Silke Müller
Federal Environmental Agency,
Germany
Why are easy to use emission estimation tools necessary?

Who needs easy to use emission estimation tools?
The answer is: REACH

- REACH proposal, Article 1: stipulates manufacturers (M), importers (I), and downstream users (DU) to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment.

⇒ paradigm shift
Exposure and REACH

- REACH Proposal, Article 13:
  - demands **Chemical Safety Assessment** (CSA) and **Chemical Safety Report** (CSR) for substances produced or imported in quantities > 10 t/a;
  - CSA includes **human health**, **environmental hazard**, and **PBT/vPvB assessment**;
  - if substance is „dangerous“ or a **PBT/vPvB** substance, CSA comprises **exposure assessment** and **risk characterisation**;
  - results of CSA are summarised in a **Safety Data Sheet** (SDS).
Exposure and REACH

- Exposure Assessment:
  (REACH Proposal, Annex 1, No. 5)
  – The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration to which humans and the environment are or may be exposed.
  – Exposure assessment in two steps:
    Step 1: Development of exposure scenarios;
    Step 2: Exposure estimation.
Exposure and REACH

- **Step 1: Development of exposure scenarios**
  (REACH Proposal, Annex 1, No. 5.1)
  - for production and all identified uses;
  - for whole life-cycle;
  - description of processes and risk management measures for production and all identified uses;
  - description of waste management measures;
  - activities of workers and consumers;
  - duration and frequency of emission to environmental compartments.
Exposure and REACH

- **Step 1:** Development of exposure scenarios  
  (REACH Proposal, Annex 1, No. 5.1)

  Exposure scenarios  
  as wide-ranging or specific as necessary!

- **Step 2:** Exposure estimation consists of  
  (REACH Proposal, Annex 1, No. 5.2)

  1. emission estimation;
  2. chemical fate and pathways;
  3. estimation of exposure levels.
Exposure and REACH

- Communication in the supply chain
  (REACH Proposal, Article 13, 29-33, 34-36)
  - communication of Safety Data Sheet (SDS) in the supply chain;
  - duty of DU to check exposure scenarios of SDS conducted by M/I if the own uses are covered:
    → YES: DU follows the advices of SDS;
    → NO: DU indicates the own use to M/I to be covered in the SDS or prepares an own SDS.
Current exposure estimation

  1. estimation of local emissions → A-/B-tables, emission scenario documents (ESDs) → $E_{\text{local}}$ in kg/d;
  2. degradation, transformation, distribution → various fate models → SimpleTreat, SimpleBox etc.;
  3. estimation of the predicted environmental concentration for each compartment → $\text{PEC}_{\text{compartment}}$ in kg/l; kg/kg etc.

- OECD emission scenario documents (ESDs)
Advantages and disadvantages

- EU- and/or OECD-wide harmonised tools;
- ESDs harmonised with industry;
  - complicated and detailed;
  - difficult to manage without expert knowledge.

⇒ easy to use, well comprehensible, robust exposure estimation tools are necessary
- for REACH and
- for all actors in the supply chain.
Where to go? - How to perform?

- chemical, formulation or article
- manufacturer, importer or downstream user
- emission to water, air, soil, or waste
- Use: identified or not identified

KEMI-Workshop Uppsala *** 20.-21.10.2004 *** Silke Müller, UBA, Germany
Project „Emission estimation tool“

- initiated by UBA, D and RIVM, NL in 2004;
- timing: July/September 2004 – November 2005;
- supervised by OECD Task Force on Environmental Exposure Assessment (TFEEA);
- linked to the so-called matrix project of OECD TFEEA;
- linked to the REACH implementation project RIP 3 of the European Commission.
Project Structure

Project A: RIVM Expert Centre of Substances

Project B: Consortium

Chemie Daten

Project management:

Steering group:

• OECD TFEEA
• Industry representatives
• Authority representatives

KEMI-Workshop Uppsala *** 20.-21.10.2004 *** Silke Müller, UBA, Germany
Aim of project B

Project B aims at the development of a technical guidance for emission estimations:

- analysis of existing emission scenarios (step 1)
- development of easy to use, well comprehensible, and robust manuals and software tools for emission calculations (step 2).
Analysis and Documentation

- **Analysis** of existing emission estimation tools and related data sources
  - emission scenario documents of EU TGD and OECD;
  - A-/B-tables of EU TGD;
  - US EPA guidance documents for the TRI;
  - BREFs concerning IPPC Directive;
  - screening for other supplementary data sources.

- **Documentation** of emission scenarios
  - data sheets with a predefined structure for each emission scenario.
## Matrix

- **Structure** of the matrix:
  - starting point = 15 industrial and 55 use categories of EU TGD versus life cycle stages and environmental emission pathways.

- **Filling** of the matrix:
  - allocation of all identified emission scenarios to the respective matrix cells;
  - primary and secondary allocation.
<table>
<thead>
<tr>
<th>IC/UC</th>
<th>ESD</th>
<th>Life cycle stages</th>
<th>Environmental pathway</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>production</td>
<td>formulation</td>
</tr>
<tr>
<td>1</td>
<td>Agricultural industry</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>2</td>
<td>Chemical industry: basic chemicals</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>3</td>
<td>Chemical industry: Chemicals used in synthesis</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>4</td>
<td>Electrical/electronic industry</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>5</td>
<td>Personal/domestic</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>6</td>
<td>Public domain</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>7</td>
<td>Leather processing industry (Draft)</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>8</td>
<td>Metal finishing (release model)</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
<tr>
<td>9</td>
<td>Mineral oil and fuel industry</td>
<td>EU A-/B- Tables</td>
<td>EU A-/B- Tables</td>
</tr>
</tbody>
</table>
Anticipated outcome

- **overview** over existing emission scenarios:
  - uniform documentation of existing emission scenarios;
  - filled matrix;

- **further needs** of emission scenarios under REACH;

- **matrix as the link** between:
  - project A = where to go, what to choose and
  - project B = what exists, what is appropriate.
Stand-alone emission scenarios

- are the **implementation** of the matrix for each life-cycle stage and for each environmental pathway;
- are the technical guidance and consist of an **instruction manual** and a **stand-alone software module**;
- are exemplified conducted for **two supply chains**.
General emission estimation

\[ E = \frac{Q_{\text{product}} \times C_{\text{chemical}} \times F_x \times \sum_{j=1}^{n} (1 - F_{\text{abatement}})}{T_{\text{emission}}} \]

with

- \( E \) emission rate [kg a\(^{-1}\)]
- \( Q_{\text{product}} \) the quantity processed or used per time [kg d\(^{-1}\)]
- \( C_{\text{chemical}} \) the concentration of the chemical in the product [kg kg\(^{-1}\)]
- \( F_x \) relevant emission factor [--]
- \( F_{\text{abatement}} \) any relevant emission factor for on-site abatement [--]
- \( T_{\text{emission}} \) the emission period [d a\(^{-1}\)]
## Generic and specific estimation

<table>
<thead>
<tr>
<th>Input</th>
<th>M/I generic</th>
<th>DU 1 specific</th>
<th>DU 2 specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>$Q_{\text{product}}$ [kg d$^{-1}$]</td>
<td>1.000</td>
<td>500</td>
<td>1.000</td>
</tr>
<tr>
<td>$C_{\text{chemical}}$ [kg kg$^{-1}$]</td>
<td>0.2</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>$F_x$ [--]</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
</tr>
<tr>
<td>$F_{\text{abatement}}$ [--]</td>
<td>0</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>$T_{\text{emission}}$ [d a$^{-1}$]</td>
<td>365</td>
<td>365</td>
<td>250</td>
</tr>
</tbody>
</table>

### Output

| E [kg a$^{-1}$] | 0.055 | 0.028 | 0.20 |
First example

Manual prototype

Software prototype
Anticipated outcome

- easy to use, well comprehensible, and robust emission estimation tool based on current methodology;
- prototype in MS Excel, MS Access, or webapplication
- main calculation level = emission estimation;
- interface to EUSES, fate models to complete exposure assessment;
- pick-list with risk management measures.
- tiered approach, refinement cycles:
  - generic (M/I) → specific (DU);
  - if there is a concern (PEC/PNEC>1);
Use and exposure categories

- „Basic“ document:
  Shared evaluation of the Federal Government, VCI and of IG BCE of REACH proposal. August 2003 (only in German);

- Industry concept:
  VCI: Exposure categories - Targeted protection of humans and the environment. May 2004;

- Authorities concept:
  Concept of „use and exposure categories“ – Viewpoint of the German evaluation authorities BAuA, UBA, and BfR. September 2004 (only in German).
Use and exposure categories

- Definition acc. to authorities‘ concept:
  - summary of exposure situations that are characterised by comparable uses or activities and by a distinct set of parameters;
  - summary of comparable and specific exposure scenarios to an use and exposure category;
  - complete description of conditions that determines the exposure of substances.
Use and exposure categories

- **Parameter set** acc. to authorities‘ concept:
  - human and environmental pathway;
  - exposure period or frequency;
  - (point) source of exposure;
  - intrinsic properties of the substance;
  - substance quantity / emission factor;
  - activity or use;
  - expected exposure concentration (PEC);
  - acceptable exposure concentration (DNEL, PNEC);
  - risk reduction measures.

⇒ linked to **exposure scenarios** of REACH proposal.
Thank you for your attention!

- Contact:
  silke.mueller@uba.de
  burkhard.wagner@uba.de
  theo.vermeire@rivm.nl
  paul.van.der.poel@rivm.nl

- Website:
  http://www.umweltbundesamt.de/reach/index.htm
Regulatory Background of Product Information in Germany and Impacts for Practical Work

Axel Hahn

Bundesinstitut für Risikobewertung (BfR), Thielallee 88 - 92, D-14195 Berlin
Leaving Berlin with Potsdam is sight
Heading the Port of Stockholm

Navigation was easy by following Viking-Ships and Götakanal Steamers
Staff ca. 600 Co-workers, ca. 150 Scientists
Headquarter Berlin Branch Dessau
Fields of Working
- Foods and other Commodies
- Chemicals
- Cosmetics
- Veterinary Medicinal Products
- Zoonoses
- Plant Protection and Pest Control

German Documentation Centre for Poisonings and Products (BfR DoCCentre)
Hazard Identification

Exposure Assessment
- Releasing of Substances
- Entry from Environment
- Identification of exposed Persons
- Exposure in Relation to Path

Dose-Response-Relation
- Dose-Response-Relation
- Endpoint-specific Toxicity
- Risk-specific Dose

Risk Characterization
- Comprising Risk Information
- Uncertainty of the Data
Structure

• German Chemicals Act
• German Toxicological Network
• Documentation of Products
• Documentation of Cases
• Risk Identification / Risk Assessment
• Output
• Conclusions
1982: Legislation in the Federal Republic of Germany laid the Foundation of the Chemicals Act in a systematical Assessment of

- Old Compounds through an Advisory Board (German BUA-Board)
- New Compounds by Assessments based on Animal Data through German Federal Institutes

1990: Reports of Poisonings in Humans by attending Physicians were introduced through § 16e Chemicals Act.

The important Improvements are:

Not to rely only on Animal Data alone!

Start a systematical Collection of Human Data from August 1990 onwards
Para 1 Manufacturers/Distributors/Importers shall be required to inform the BfR of Trade Name, Details of Composition, Details of Use, Labelling, First Aid and Emergency Measures ...

Para 2 Any Physician consulted for the Treatment or Assessment of the Consequences of an Illness suspected of being ascribable to the Effects of Hazardous Substances must inform the BfR and submit the essential Data (Age/Sex of the Patient, Cause of Exposure, Amount, Symptoms established).

Para 3 The Information and Treatment Centres (Poison Control Centres -PCC-) shall report to the BfR of any Findings resulting from their Activities concerning Substance-related Illnesses.
Co-operation between Federal Institute / 10 Poison Control Centres / Industry

The German Toxicological Network

PCC Berlin
PCC Berlin 1
PCC Berlin 2
PCC Göttingen
PCC Bonn
PCC Erfurt
PCC Homburg
Heidelberg
PCC Mainz
PCC Nürnberg
PCC Munich
PCC Freiburg

Industrial Associations
Frankfurt / River Main

BfR Berlin
Poison DocCentre
Product Data from Industry

Notifications

§ 16e
§ 5d

Voluntaries

CD-EXPORT PCCs

10 German PCCs
Reports of Poisonings with Chemical Products / Compounds by attending Physicians (Ambulances, Hospitals, Accidents Insurances, Environmental Ambulances, Public Health Services etc.) even in suspected Cases

Federal DocCentre for Poisonings / Chemical Product Data

- Hard Data of ca. 7,000 Clinical Treatments / Year
- Weaker Data from 10 Centres
- ca. 160,000 Inquiries by Phone
- 4 Centres with Clinical Treatment (about 250 cases / Year)

Information about Poisonings with Chemical Products / Compounds from German PCCs

We learn by Exchange of 9,000 Standardized and Harmonized Case Data Sets under Centralized Data Maintenance.

Poison Control Centres (PCC)

- **Berlin**: 50,000 Calls /yr
- **Mainz**: 24,000 Calls /yr
- **Munich**: 20,000 Calls /Yr
- **Freiburg**: 10,000 Calls /Yr

**DoCCentre**
Toxicological Documentation and Information Alliance

Common Standards for Product Documentation and Exchange (Rosetta-Format and -Interface)

Exchange of Standardized Product Data Sets documented by a "Product Writer" called "EMIL" by FTP Server (PCC Göttingen)
Notifications
§ 16e Para 1
Dangerous Products
Cosmetics Regulation § 5d
Cosmetics
Voluntary Notifications

Input

Reports 16e para 22
Physicians
Indications § 16e para 3
Poison Control Centres

Output

Human Data Collection

Case Data Base ca. 36,000

Product Data Base ca. 170,000

Assessment
c. 7,000/year
2 Steps

Hazard Identification
Dose Response Relation

Publications
- Annual Reports
- Press Releases
- Studies

PRINS
Risk Identification
Public / Industry

Transmissions of Formulations to the
10 German PCCs
1 Austrian PCC

Formulation Check!
c. 7,000/year
c. 17,000/year
**Product Data Collection: Formula to BfR Product Data Set**

<table>
<thead>
<tr>
<th>Material</th>
<th>Identification</th>
<th>Classification</th>
<th>Composition</th>
<th>Tox. Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zincdiethylphosphat</td>
<td>*</td>
<td>**</td>
<td>***</td>
<td>*</td>
</tr>
<tr>
<td>Hevea 5777</td>
<td>*</td>
<td>**</td>
<td>***</td>
<td>*</td>
</tr>
<tr>
<td>Wollyan L</td>
<td>*</td>
<td>**</td>
<td>***</td>
<td>*</td>
</tr>
<tr>
<td>Covon 926</td>
<td>*</td>
<td>**</td>
<td>***</td>
<td>*</td>
</tr>
</tbody>
</table>

**Neue Angabe zu Inhaltsstoffen:**

- keine Haut- und Augenreizung zu erwarten
- Molyvan L: lt. EU-Blatt des Herstellers; enthalt 3,5-Dimercapt-1,2-thiazidätherivat; LD50 oral Ratte: > 5000 mg/kg
- Covon 926: lt. EU-Blatt des Herstellers; enthalt 3,5-Dimercapt-1,2-thiazidätherivat; LD50 oral Ratte: > 5000 mg/kg

**Hinweise:**

- keine Angaben zu Inhaltsstoffen, LD50 oral Ratte: > 5000 mg/kg  
- * z. Z. beachten
- ** z. z. beachten
- *** z. z. beachten

**Von BfR an die GIZ. Nur für Ärzte STRENG VERTRAULICH! Stand: 02.04.97**
# BfR Standard Product Data Set

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Identification-No.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>2. Trade-name</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3. Manufacturer / Distributor</strong></td>
<td></td>
</tr>
<tr>
<td><strong>4. Address</strong></td>
<td></td>
</tr>
<tr>
<td><strong>5. Product-Classification</strong></td>
<td></td>
</tr>
<tr>
<td><strong>6. Physical-Chemical Properties</strong></td>
<td></td>
</tr>
<tr>
<td><strong>7. R/S-Phrases</strong></td>
<td></td>
</tr>
<tr>
<td><strong>8. Substances of Content</strong></td>
<td></td>
</tr>
<tr>
<td><strong>9. - Name (Manufactures Term)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>10. - Name (Preferred Term)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>11. - Share</strong></td>
<td></td>
</tr>
<tr>
<td><strong>12. - Tox. Order of Substances</strong></td>
<td></td>
</tr>
<tr>
<td><strong>13. Additional tox. Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>14. - LD-Values</strong></td>
<td></td>
</tr>
<tr>
<td><strong>15. - Warnings</strong></td>
<td></td>
</tr>
<tr>
<td><strong>16. - First Aid Measurements etc.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Optional</strong></td>
<td></td>
</tr>
<tr>
<td><strong>18. - Barcode (EAN-Code)</strong></td>
<td></td>
</tr>
</tbody>
</table>

**BfR-Completion**

- BfR-Code-No.
- Classification of Use (Group of Agents)
- BfR Preferred Term
- Link to BfR Monographs
- Order of Toxicity
  - 1. Highest
  - 2. Lower
  - ......
  - n. Lowest (e.g. Water)

**EAN-Code**

3012345123456
Result of EVA Research Project 1991-1993

Access to Product data for risk prevention

<table>
<thead>
<tr>
<th>Group of Agents</th>
<th>First level</th>
<th>Second level</th>
<th>Third level</th>
<th>Total</th>
<th>Children</th>
<th>Adults</th>
<th>Moderant e/severe poisonings</th>
<th>Children</th>
<th>Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Pharmaceutical products</td>
<td>940</td>
<td>388</td>
<td>589</td>
<td>301</td>
<td>69</td>
<td>230</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II. Veterinary medicines</td>
<td>10</td>
<td>6</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III. Chemical products</td>
<td>1095</td>
<td>420</td>
<td>662</td>
<td>325</td>
<td>126</td>
<td>197</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paints and related products</td>
<td>127</td>
<td>32</td>
<td>94</td>
<td>44</td>
<td>5</td>
<td>38</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paint removers / strippers</td>
<td>5</td>
<td>5</td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkyd resin paints</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emulsion paints</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
20 10 2004 Workshop
Nordic Product Registers
Uppsala Sweden

BfR Product Data Base: Steadily Increasing Figures

30.09.2004
176,000 Products
162,029 Total

Product Notifications

Cosmetics 124,136

Products, voluntary 30,672

Products, § 16e + Biocides 7,221

Sysdecos "e-Product Writer"

EMIL "e-Product Writer"

30.10.2004, Workshop Nordic Product Registers, Uppsala Sweden
3 Level-Model for the „Substance of Main Toxic Relevance“

1. Level
   - Relation
     - Location- / time-dependent?
   - No Relationship

2. Level
   - Symptoms/Signs
     - Substance-specific?
   - Relationship between Symptoms/Signs and Exposure

3. Level
   - Symptoms / Signs
     - Exposure-dependent?
     - Dechallenge/Rechallenge
Product / Case Data

Within 14 Days after Completion of the Data

Public Press Releases

Immediate Reports
- Criteria: Serious Health Effects

Summarized Reports
- Criteria: Minor Health Effects

Risk Identification for Government, Manufacturers, Distributors, Associations

Toxicovigilance: Monitoring for suspected Health Impairments in Man to Substances like Medicines, Pesticides, Contaminants and other Chemicals

Annually: „Blue Letters“ for Manufactures and Distributors in the first two Months of each Year
<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>Substance of toxic relevance</th>
<th>Age Group</th>
<th>Outcome</th>
<th>Proposals BfR (P) and Results (R)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998</td>
<td>Waterproofing Agent</td>
<td>Fluoridated HC</td>
<td>Adult</td>
<td>Death</td>
<td>V: Warnings R: Accepted</td>
</tr>
<tr>
<td>1998</td>
<td>Disinfectant</td>
<td>Quarternary Ammonia-Compound (Detergent)</td>
<td>Elderly</td>
<td>Death</td>
<td>V: Information, R: Labelling „Corrosive“ R: Accepted</td>
</tr>
<tr>
<td>1999</td>
<td>Draincleaner</td>
<td>Sodiumhydroxide</td>
<td>Adult</td>
<td>Burns</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Solvent</td>
<td>Naphta</td>
<td>Adult</td>
<td>Edema of the Lungs</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Depilation - Creme</td>
<td>Thioglycolic Acid</td>
<td>Adult</td>
<td>Scars</td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>Disinfectant</td>
<td>Quarternary Ammonia-Compound (Detergent)</td>
<td>Elderly</td>
<td>Death</td>
<td>P: Information, Labelling</td>
</tr>
<tr>
<td>1999</td>
<td>Industrial Cleaner</td>
<td>Sodiumhydroxide</td>
<td>Infant</td>
<td>Burns</td>
<td>P: Information</td>
</tr>
<tr>
<td>1999</td>
<td>Drug</td>
<td>Dimenhydrinate</td>
<td>Toddler</td>
<td>Death</td>
<td>P: Warnings</td>
</tr>
<tr>
<td>2000</td>
<td>Crème Bath</td>
<td>Detergent</td>
<td>Elderly</td>
<td>Death</td>
<td>P: Information</td>
</tr>
<tr>
<td>2000</td>
<td>Lamp Oil</td>
<td>Paraffine</td>
<td>Infant</td>
<td>Severe Pneumonia</td>
<td>P: Prohibition (coloured, perfumed) R: EC Prohibition Accepted Substitutes</td>
</tr>
<tr>
<td>Year</td>
<td>Product</td>
<td>Substance of toxic relevance</td>
<td>Age Group</td>
<td>Outcome</td>
<td>Proposals BfR (P) and Results (R)</td>
</tr>
<tr>
<td>------</td>
<td>------------------</td>
<td>------------------------------</td>
<td>-----------</td>
<td>----------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>2001</td>
<td>Disinfectant</td>
<td>Alkylamine (Detergent)</td>
<td>Elderly</td>
<td>Death</td>
<td>P: Information</td>
</tr>
<tr>
<td>2001</td>
<td>Tea (Herbal Drug)</td>
<td>Atropa belladonna</td>
<td>Adolescent</td>
<td>Breath Depression</td>
<td>P: Information</td>
</tr>
<tr>
<td>2002</td>
<td>Sanitary-Cleaner</td>
<td>Detergent</td>
<td>Elderly</td>
<td>Burns</td>
<td>P: Information</td>
</tr>
<tr>
<td>2002</td>
<td>Mild Detergent</td>
<td>Detergent</td>
<td>Elderly</td>
<td>Death</td>
<td>P: Information</td>
</tr>
<tr>
<td>2003</td>
<td>Cleaner</td>
<td>Detergent</td>
<td>Elderly</td>
<td>Breath Depression</td>
<td>P: Information</td>
</tr>
<tr>
<td>2003</td>
<td>Dietary Supplement</td>
<td>Proteins</td>
<td>Adult</td>
<td>Severe Allergy</td>
<td>P: Information</td>
</tr>
<tr>
<td>2003</td>
<td>Gassing Product</td>
<td>Sulfuryldifluoride</td>
<td>Adult</td>
<td>Death</td>
<td>P: Information</td>
</tr>
<tr>
<td>2003</td>
<td>Drain Cleaner</td>
<td>Potassiumhydroxide</td>
<td>Child</td>
<td>Severe Burns</td>
<td>P: Information</td>
</tr>
<tr>
<td>2003</td>
<td>Disinfectant</td>
<td>Peracetic Acid</td>
<td>Adult</td>
<td>Breath Depression</td>
<td>P: Information</td>
</tr>
<tr>
<td>2004</td>
<td>Lamp Oils</td>
<td>Paraffine</td>
<td>2 Infants</td>
<td>Death</td>
<td>P: EC-Prohibition of all Lamp Oils</td>
</tr>
</tbody>
</table>
Risk Assessment / Management Steps

- Ban of coloured/scented Oils
  - Germany 01.1999
  - EC 06.2000
- Child Safe Burners 01/2001

PCCalls

1200
1100
1000
900
800
700
600
500
400
300
200
100
0


Labels
R Phrase 65
Substitutes came on the Market
Trend?

Gifts

Warnings

BfR Surveys every 2-3 years
<table>
<thead>
<tr>
<th>Group of Use</th>
<th>2002</th>
<th>2003</th>
<th>Lower Levels</th>
<th>2002</th>
<th>2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pesticides</td>
<td>84</td>
<td>41</td>
<td>Insecticides</td>
<td>37</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Herbicides</td>
<td>34</td>
<td>10</td>
</tr>
<tr>
<td>Cosmetics</td>
<td>26</td>
<td>24</td>
<td>Skin Cosmetics</td>
<td>16</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cremes/Lotions</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Bath oil/Bath pearls</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Cleaners</td>
<td>161</td>
<td>112</td>
<td>Milk Machine Cleaners</td>
<td>15</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Oven Cleaner</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Drain Cleaners</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General Purpose Cleaners</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Industrial Cleaners</td>
<td>24</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Sanitary Cleaners</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Dishwasher Detergents</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Disinfectants</td>
<td>68</td>
<td>62</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fuels, liquid</td>
<td>38</td>
<td>24</td>
<td>Lamp Oils</td>
<td>38</td>
<td>22</td>
</tr>
<tr>
<td>Construction materials</td>
<td>12</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
What is the real Trade- / Indexname for retrieval in a Product- Databases?
European Standardized Product Identification Area

Tradename with Reg. / Art.-No indicated by a Symbol

EC Standardization (CEN) 2006?

Product Identification Area

Bar-Code

Terpentin-Ersatz
Art. Nr. 321
5 l e

Brillux
48163 Münster
Tel. 0251 / 7188-0

Label
Conclusions

• The German Government give the main support for the Product Data Base

• A Product Data Base should be centralized. Producers / Distributors like to deal with one actor (Data Security/Data Maintenance/Data Responsibility)!

• Even in 2004 the productname is the most important link to the formula. Product Identification has to be improved

• It is impossible to handle a Product Data Base without a Classification System. There a need of international accepted standardizations!

• Exposures could not be assessed on the exact formular (often 10-20 single substances). They should be assessed on the basis of the substance of main toxic relevance!
Thank you!

Questions?

Potsdamer Platz Berlin
Identify chemical candidates for monitoring based on product register data

Stellan Fischer

The Swedish Chemicals Inspectorate
Uppsala workshop
October 2004
Content

- Emission – life cycle perspective
- Candidates monitoring
- Product register data
- Risk Indicator
- Multivariate analysis
Background

• National monitoring program:
  • Regulated and/or banned substances

• Request for new candidates:
  • Primary recipients for diffuse sources

• New criteria: Hazard $\rightarrow$ Risk:
  • Risk = Hazard $\times$ Exposure
  • Exposure: Quantity, Use pattern and others
  • Use pattern source: The Swedish Product Register
The Product register

2 029 Enterprises registered (2002)
72 594 Number of products* (2002)
13 000 Unique substances (2002)
5 - 6 Substances per product (average)

* defined by the CN-code
Flows and emissions

Product uses
- Short living products
- Long living products

Waste management

Waste remaining in the environment

Environment
- Water
- Soil
- STP
- Air

Formulation

Article production

Chemical production

“human”
Pilot study 2002

• Database capacity check
• Correlation: use pattern ↔ monitoring data
  • Fugacity calculation
  • Time trends
• Confidentiality check
• Limitations:
  • Chemicals in imported articles
  • Not included: cosmetics, pharmaceuticals
• Revise emission estimation
  • Use categories (function)
  • Industrial categories (branch)
• Revise primary recipients
Main study - Emission estimation

- CAS No.
- Use Category (UC-Nordic)
- Industry Category (NASE national)
- Conc. of constituents: (all constituents: >5%)
- Consumer products
- Quantity (tonnes/year)
- Corrections:
  - for export/import
  - for labelling (self classification)
  - Raw material (the chemical will disappear)
Primary recipients

Near diffuse source (urban areas)

• Air
• Soil
• Surface water
• STP (sewage treatment plant)
• “Human” (dermal, inhalation, ingestion etc.)
Emission estimation - product level

- Product 3
- Product 2
- Product 1
  - Use category
  - Industry category
  - Other PR-data
  - Emission estimation
    - Quantity, year x

Emission categorisation tables
## Emission categorisation tables, examples

<table>
<thead>
<tr>
<th>Use information</th>
<th>Emission potential</th>
<th>Recipients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>low – medium – high</td>
<td></td>
</tr>
<tr>
<td>Use Category:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sealing materials</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use Category*:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fertilizers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industrial Category:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing and dry-cleaning of textile and fur products.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industrial Category:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Construction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recipients</td>
<td>Air</td>
<td>Surface Water</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td></td>
</tr>
</tbody>
</table>

* UC-Nordic
Emission estimation - per year

Total emission index
- for one chemical
- in all products
- for one or several years
- for different recipients

Etc.
Product 3
Product 2
Product 1

Use category
Industry category
Other PR-data

Emission categorisation tables

Emission estimation
Quantity, year x
Candidates for monitoring

Swedish EPA

High emitting CAS No.
Screening programme
Swedish EPA

Total emission index
- for one chemical
- in all products
- for one or several years
- for different recipients

Emission categorisation tables

Use category
Industry category
Other PR-data

Emission estimation

Quantity, year x

Product 1
Product 2
Product 3
Etc.
Candidates for monitoring

- “Screening program”
- Identify of substances with high emission estimation.
- Different primary recipients.
- Identify with substances with increasing trend.
# Table of candidates

<table>
<thead>
<tr>
<th>Identity</th>
<th>Distribution</th>
<th>Use Pattern</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS No.</td>
<td>Name</td>
<td>USE PATTERN</td>
<td>QUANTITY</td>
</tr>
<tr>
<td></td>
<td>Distribution Index</td>
<td>Time Trend *</td>
<td>UC-Nordic (3 largest?)</td>
</tr>
<tr>
<td>range 0 – 100</td>
<td>-, /, \</td>
<td></td>
<td></td>
</tr>
<tr>
<td>xx-xx-x</td>
<td>Aaaaa</td>
<td>99.6</td>
<td>G40100 H10100 F45200</td>
</tr>
<tr>
<td>yy-yy-y</td>
<td>Bbbbbb</td>
<td>93.5</td>
<td>Etc.</td>
</tr>
<tr>
<td>zz-zz-z</td>
<td>Cccccc</td>
<td>92.0</td>
<td>Etc.</td>
</tr>
<tr>
<td>Etc.</td>
<td>Etc.</td>
<td>90.1</td>
<td>Etc.</td>
</tr>
</tbody>
</table>

* - = no change; / = Increase; \ = Decrease
Risk estimation

- Total emission index
  - for one chemical
  - in all products
  - for one or several years
  - for different recipients

Emission index for all classified substances

- Quantity, year x

Use category
Industry category
Other PR-data

Emission categorisation tables

Hazard classification

High emitting CAS No.
Screening programme

Swedish EPA
Risk indicator

Emission categorisation tables

Hazard classification

Risk Index
“Environmental goal” indicator

KemI

Total emission index
- for one chemical
- in all products
- for one or several years
- for different recipients

Emission index for all classified substances

Use category
Industry category
Other PR-data

Emission estimation

Quantity, year x

A+B

High emitting CAS No.
Screening programme

Swedish EPA

www.kemi.se
Risk index

1) For each classified substance...
   ... in each chemical product in the register for a single year:
   a) Calculate Emission Index*
   b) Hazard classification phrases → Hazard Index*
   c) Hazard number + Quantity → Risk Index.

2) Sum up the Risk Index for all substances in all products.

3) Plot the the annual trends for:
   → Human health
   → Environment

* Divided into Human health and Environment.
Difficulties

• Changes in the database structure:
  • New Use categories from 2002

• Time trends – significance

• Define recipients

• Double counts – raw materials

• Heterogenicity in Industrial and Use categories
Multivariate analysis

• Part of the pilot study
• Visualize the structure
**Multivariate analysis → Use categories with high risk**

![Graph showing categories with high and low risk]
Multivariate analysis → Industrial categories with high risk
Product register

Problems and possibilities
- the Industry perspective

Olof Holmer, Sveff, Lim, KTF and IIH 041020
Industry perspective

- The paint, varnish, printing ink, sealant, adhesive and cleaning agents manufacturers:
  - Vast number of products – relatively low volume
  - Heavy burden reporting for our companies
## De tio vanligaste produkttyperna i störst antal 2001

<table>
<thead>
<tr>
<th>Produkttyper</th>
<th>Totalt antal produkter</th>
<th>Total kvantitet, ton</th>
</tr>
</thead>
<tbody>
<tr>
<td>Färger och lasker</td>
<td>5 005</td>
<td>257 014</td>
</tr>
<tr>
<td>Smörjmedel</td>
<td>5 050</td>
<td>197 756</td>
</tr>
<tr>
<td>Färgämnen, pigment</td>
<td>3 388</td>
<td>196 986</td>
</tr>
<tr>
<td>Rengöringsmedel (övriga)</td>
<td>2 319</td>
<td>51 324</td>
</tr>
<tr>
<td>Råvara/plasttillverkning</td>
<td>2 160</td>
<td>1 570 616</td>
</tr>
<tr>
<td>Syntesråvara (övriga)</td>
<td>1 844</td>
<td>27 636 496</td>
</tr>
<tr>
<td>Bindemedel (färg,lim,etc)</td>
<td>1 763</td>
<td>338 872</td>
</tr>
<tr>
<td>Avfattningsmedel</td>
<td>1 154</td>
<td>25 962</td>
</tr>
<tr>
<td>Lim (övriga)</td>
<td>1 048</td>
<td>46 045</td>
</tr>
<tr>
<td>Bindemedel (övriga)</td>
<td>1 030</td>
<td>4 467 693</td>
</tr>
</tbody>
</table>

Källa: Kemis produktsregister


Resterande produkter ovan är kemiska produkter som utgör råvaror för industrin.

I Sverige fanns under 2001 totalt ca 65 000 kemiska produkter.
## De tio produkttyper som hanterades i störst mängd

<table>
<thead>
<tr>
<th>Produkttyp</th>
<th>Total kvantitet, ton</th>
<th>Totalt antal produkter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syntesråvara (övriga)</td>
<td>27 536 498</td>
<td>1 844</td>
</tr>
<tr>
<td>Drivmedel (för förbränningsmotorer)</td>
<td>16 843 265</td>
<td>210</td>
</tr>
<tr>
<td>Uppvärminsmedel</td>
<td>11 028 773</td>
<td>96</td>
</tr>
<tr>
<td>Bränslen, brännolja (övriga)</td>
<td>7 379 210</td>
<td>80</td>
</tr>
<tr>
<td>Bindemedel (övriga)</td>
<td>4 467 653</td>
<td>1 030</td>
</tr>
<tr>
<td>Svetsprodukter</td>
<td>1 890 049</td>
<td>96</td>
</tr>
<tr>
<td>Råvara/plastutverkning</td>
<td>1 570 616</td>
<td>2 160</td>
</tr>
<tr>
<td>Oxidationsmedel</td>
<td>1 441 190</td>
<td>74</td>
</tr>
<tr>
<td>Blekmedel</td>
<td>1 328 163</td>
<td>137</td>
</tr>
<tr>
<td>Gödselmedel, gödningsmedel</td>
<td>1 006 611</td>
<td>311</td>
</tr>
</tbody>
</table>

Källa: KemIs produktregister
Industry perspective

• "The use of data from the Nordic product registers"
  – "Shit in = shit out"
    • Quality of data linked to complexity for reporting companies
    • Comparability between the Nordic countries linked to the level of similarity in the Nordic registers

➢ Simplifying reporting procedures and harmonising approach in the Nordic registers gives more useful data
Industry Perspective

• Problems with today’s registers for our industries from a Nordic perspective:
  – Heavy work load and cost
  – Different general rules
  – Different products to be reported
  – Different level of content to be reported
  – Different report forms to be filled up
  – Same lack of possibilities to report by electronic means

✓ Same product codes in Sweden and Norway!
Possibilities
- a common interest:

Better data quality and better possibilities to compare in the Nordic and at the same time lesser burden for reporting companies by means of:

- Common Nordic general rules for product registers
- Common authority handling
- Same products to be reported
- Same level of content to be reported
- Same electronic report form
The Future for Nordic registers

REACH

– Will mean a lot of work for down stream users
– Will create EU register with:
  • All substances used in the EU
  • Volume for each substance
  • Intended use of all substances

➢ A replacement for Nordic product registers?
REACH and national supervision

Barbro Sillrén
Use of data in supervision

- Inspections
- Use of Product Register – today
- Use of REACH register - tomorrow
Swedish Chemicals Inspectorate

Central authority

From the products register
- 2,100 companies
  Manufacturers and importers of chemical substances and preparations
- 64,000 preparations and substances reported
Swedish Chemicals Inspectorate (KEMI)
Chemicals control
Inspections

KemI - Inspection unit

- Monitor companies’ compliance with legislation and regulations (manufacturers/importers)
- Inspections all over in Sweden

The companies have the responsibility
Inspections - strategy

- Types of products/Product groups
  - Number of products (large number, high priority)
  - Large volumes
  - Widely spread
  - Hazardous substances
  - Industrial as well as consumer use

  Cleaning agents, Paints, varnishes and fillers, Car-care products, Photochemicals, Hydrofluoric acid
Inspection of companies (1)

- Overall organization
- Policy for environment, health and safety
- Management system for environment, health and safety
- Organization
  - responsibilities
  - procedures
  - resources
- Competence
Inspection of companies (2)

- Product investigation
  - health and environmental effects
  - protective measures, waste etc
- Product substitution
- Product information
  - MSDS and labelling
  - quality check
Regional Inspection Projects

- Inspections of companies within a geographic area
- Selection factors:
  - Number of companies
  - Company size (by number of products)
  - Manufacturers/importers
  - Product-profile
- Time – approx. 2-4 months
- Form of Inspection
  - Visit or by letter
Use of Register - Today

- Reporting company - location
- Name of product
- TIN-type (manufactured, imported, “name changer”)
- Quantity.
- Use (function code description)
Use of Register - Today

- Product for own use/ transferred to another company
- Trade description (branch)
- Consumer use (yes/no)
- Risk phrase for cancer, allergy or reproductive disturbances.
- Classification (health) (T, C, Xn, Xi, -)
- Composition of the product.
Use of Register - tomorrow

- National Product Register
- Register – Agency
Use of Register - Tomorrow

- Information
  - registration numbers
  - substances
  - use of substances
  - manufacturers/importers
  - classification of substances
  - authorisation
  - restrictions
Use of Register - Tomorrow

- Non confidential information:
  - name of substance
  - physiochemical data
  - tox/ecotox studies (result)
  - classification/labelling
  - guidance on safe use
  - information in SDS
  - etc
Use of Register - Tomorrow

Confidential information:

- details of full composition of a preparation
- precise use/function/application of a substance or preparation
- precise tonnage
- links between manufacturer/importer and DU
- PPORD
Use of Register - Tomorrow

- Some information on Agency's website
- Non confidential information on request

Still unclear what information enforcement authorities have the right to see!!
Chemical Products
“Towards a chemical risk index, data needs versus data availability”

Christian Heidorn
European Commission - Eurostat

Workshop
“The use of data from the Nordic Product Register”
Uppsala 20 – 21 October 2004
Need for indicators on toxic chemicals ...

Motivation:

- 6th EAP: request new chemicals policy: Implementation to be monitored with suitable indicators;
- EU Sustainable development strategy;
- request from the Council for a (Structural-) Indicator on toxic chemicals.
Need for indicators on toxic chemicals ...

Motivation:
- 6th EAP: request new chemicals policy:

White Paper on a “Strategy for a future policy on chemicals” asks for indicators to monitor the implementation of new Legislation (REACH);

Registration, Evaluation, Authorisation of Chemicals

“Article 20 of the proposed Regulation sets the requirements for updating information of registered substances. This information, together with the original registration, would support the derivation of a chemical indicator.”
Development work at Eurostat ...

3 years project to develop Chemical Risk Index:
( ... started December 2001, shall end December 2004)

1st year: - definition of framework, boundaries, indicator types: ("policy-performance", "impact", "source")
- matrix of potential indicators presented;

2nd year: - feasibility: data availability:
in depth discussion with experts (workshop);

3rd year: - completion / presentation of workable indicators:
“source” “policy performance” “impact”
Start with a framework, set boundaries

Problem Analysis

Existing approaches to chemical indicators

Draft methodological framework

Fill the framework with test indicators

Consider data gaps and needs

Methods for hierarchical aggregation

Refine framework

Identify
Pros, cons, open questions

Environment and Sustainable Development
Problem analysis

100,000 existing chemicals, 30,000 > 1 tonne/year;

+ “Chemical pressure” on society:
  - is a complex function of volumes;
  - manifold intrinsic properties;
  - intricate behaviour and fate in the environment;
  - different effects in biota and humans.

+ Limited knowledge and data, various sources;
+ Political framework, REACH not adopted yet;
+ Existing approaches cover only partial aspects.
Knowledge on flow of chemicals

Chemicals

Environment
Flora & Fauna

Consumer Products & Food

Neighbourhood

Workplace

Environment and Sustainable Development
Proposed scheme for a chemical index

Chemical Index

Sources
Chemical Production

Performance Assessment (White Paper)

Sinks
Impact Areas

Environment and Sustainable Development
Boundaries, step by step exclusion
Impact indicators

- How to describe the burden of chemicals to society?
- Who or what is exposed to adverse effects or risks by chemicals? (Subgroups of the population, flora, fauna);
- How grave is the adverse effect or the risk? (e.g. risk of cancer, intoxications, sensitisation, damage to plants, un-assessed substances, …)
## Structuring the impact side, pragmatic approach

### Who and What?

- Working place
- Neighbourhood
- Consumer
- Environment

→ Define Impact Areas

### How grave?

- Known effects
- Small ‘Margin of Safety’
- High hazard
- Substantiated suspect
- Unwanted exposure
- Insufficient testing

→ Define Risk Areas
### Matrix of impact and risk areas

<table>
<thead>
<tr>
<th></th>
<th>Workplace</th>
<th>Neighbourhood</th>
<th>Consumer</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Known effects</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Small MOS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hazards</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Substantial suspect</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Unwanted exposure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Unassessed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Example Cell:** Known effects - Work place
Matrix of impact and risk areas, examples

Cell Indicator “Workplace – Known effects”
Statistics on occupational diseases caused by chemicals, number of accidents, relevant substances;

Indicators “Consumer/Food - all risk areas”
Information from monitoring data on breast milk, food analysis, human monitoring programmes;

Cell Indicator “Environment – all risk areas”
Data from European Pollutant Emission Register; National monitoring programmes etc.
### Horizontal aggregation of risk areas

<table>
<thead>
<tr>
<th>Impact</th>
<th>Occupation</th>
<th>Neighbourhood</th>
<th>Consumer direct</th>
<th>Consumer via environment</th>
<th>Environment</th>
<th>Aggregate risk indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Example:

**High hazard chemicals**

- Substantiated Suspect
- Unwanted exposure
- Insufficiently tested
### Vertical aggregation of impact areas

<table>
<thead>
<tr>
<th>Impact $I_i$, Risk $R_j$</th>
<th>Occupation</th>
<th>Neighbourhood</th>
<th>Consumer direct</th>
<th>Consumer via environment media</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Known effects</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
<td>▼</td>
</tr>
</tbody>
</table>

**Example:**

Chemicals relevant to consumers’ health

**Impact indicators**

- Indicator: occupationally relevant chemicals
- Indicator: environmentally relevant chemicals
- Indicator: chemicals that affect the consumer
- Indicator: health relevant chemicals in the environment
- Indicator: environmentally relevant chemicals
Conclusions on impact indicators so far ... 

+ “Impact” indicators: 
  (discussed with stakeholders at workshop in October 2003 ...)

- many indicators proposed, but only two appear to be feasible in the short term: 
  - European mothers milk Indicator
  - Bio-indicator marine environment
Conclusions on impact indicators so far …

+ “Impact” indicators:
  (discussed at stakeholder workshop in October 2003 …
  - development work has increased our knowledge:
    “we know better what we don’t know”
  - further harmonisation of data collections required;
  - need to further explore alternative data sources;
  … even for areas we expected to be well covered
  (occupational health) data are not comparable
  at European level.
Conclusions on impact indicators so far ...

+ “Impact” indicators: (recommendations ...)
- consideration of more data sources such as product registers (SPIN?)
e.g.: Risk area “Consumer direct”: “share of Consumer preparations containing CMR – substances”

\[
I_{\text{ConPot}} = \frac{\sum \text{PrepRisk}}{\sum \text{PrepTotal}}
\]
Conclusions on impact indicators so far ...

+ “Impact” indicators: (recommendations ...)
  - discussion on weighting factors:
    involve the OECD exposure working group, “Emission scenarios”;
  - discussion on priority substances;
  - chemicals monitoring programme of the EEA;
  ... more detailed recommendations in final report early 2005.
  + further research and development work required, however, we have to find ways to go ahead ...
Policy performance indicators

+ “Policy performance” indicators:

... measure the increase in our knowledge ...
- number of / share of substances assessed;
- quantitative volume of substances evaluated;
- number of authorised substances.

+ Feasible in the mid-term,
- but depend on the implementation of REACH

(“REACH independent”):
- no. of IUCLID updates;
- no. and production volumes of substances newly classified according to 67/548/EEC ... )
Source index

+ (Weighted-) index based on statistics on:
  - production
  - trade
    … of certain dangerous chemicals;
  - weighted with “toxicity and release / exposure scores”;
  - shall “bridge the gap” to more precise “impact” indicators.

+ Data sources:
  PRODCOM, COMEXT, other product registers?

(future: REACH)
First results (1): trade statistics

Trade of dangerous chemicals, inside EU-15 and import from outside EU-15
1988 - 2002

1 000 tonnes

Year

Environment and Sustainable Development
First results (2): production statistics

Production of chemicals
(Total / with R-phrase) in Germany

Year
1998 1999 2000 2001

Mill. t/a
0.0 20.0 40.0 60.0 80.0 100.0 120.0

Chemicals-total
with R-phrase

Environment and Sustainable Development
First results (3): share of “toxics”, but …

Share of chemicals with R-phrases of total production in Germany

(year with/without R-phrase in %)

1998 1999 2000 2001
... (4): relative growth / toxicity classes

Relative growth of chemicals with R-phrase from 1998 to 2001 in Germany

<table>
<thead>
<tr>
<th>Percentage points of total chemicals production</th>
<th>CMR</th>
<th>other chronic</th>
<th>high toxic</th>
<th>toxic</th>
<th>low toxic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.0%</td>
<td>-0.5%</td>
<td>1.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-0.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-1.0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-1.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-2.0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Environment and Sustainable Development
- calculate “light version” for EU-15 and EU-25, and consumption for 164 “Prodcom” substances (app. consumption = production + imports – exports)

- selection of priority substances by impact relevance:

(... work on impact areas was useful)
... next steps ...

- further work on the weighting factors:

\[ I = \sum \text{amount} \cdot \text{hazscore} \cdot \text{potency\_score} \cdot \text{multiplicity\_score} \cdot \text{release\_score} \]

Explanations see “Final Report Phase II”

- calculate weighted source index

(... if agreement on weighting factors can be reached).

Impact ...

- explore further data sources;
- discuss and refine methodologies
  ... in particular for aggregation;
- complete the matrix.
... next steps, outlook for 2005

- to have an in-depth discussion on quality criteria (e.g. for Structural Indicator);
- to present results to Commission services, involved stakeholders (EEA, OECD, KEMI, CEFIC ...);
- to develop a strategy for further development;
- to publish results (methodology and indicators).

... all reports are available under:
http://forum.europa.eu.int/Public/irc/dsis/pip/library?l=/indicators_chemicals
Indicators for chemical product input in different industries. Two methods for including chemicals in SEEA.

Viveka Palm, Statistics Sweden
Sustainable development

- Environment
- Social
- Economy

Environmental accounting
Environmental accounts

• Flows of materials (NAMEA)

• Economic variables (SERIEE)

• Natural resources: stocks, quality, value
Material Flow Statistics

- 1 Natural resources (TMR and similar)
- 2 SFAs for some metals and persistent substances
- 3 Chemicals indicators for large (and numerous) health hazardous substances
Economy

- energy → goods
- material → services
- work force → waste
- capital → emissions
Sectors - Industries - Products
The Products Register in Sweden

- Norway, Denmark and Finland have similar registers but with different scope and system boundaries (TemaNord 1999).
- Based on the customs tariff codes and apply to all chemical products (substances and preparations).
- Exempt products that come under legislation on foodstuffs and medical products.
- The duty to declare products to the product registers does not apply to cosmetic products in Sweden, Norway and Finland.
The Products Register in Sweden

• Constructed as a tool for superintendence of importing and manufacturing companies
• Contains data on components, quantities, classification and labelling of chemical products produced or imported
• The declaration requirements are based on the customs tariff codes
Two aggregation methods

- Method 1. Aggregation based on labelling of inherent properties
- Method 2. Aggregation based on labelling of risks for chronic diseases
- A separation is made between fossil fuels and other chemical products
Aggregation on labelling of inherent properties (lip)

- The first aggregation method, sorts out chemical products labelled as very toxic (T+), toxic (T), corrosive (C), harmful (Xn) or irritant (Xi), according to Directive 67/548/EC (Classification and labelling of dangerous substances).

- For health hazardous substances there are rules on how to label chemical products on the grounds of the content of a hazardous substance.

- The label ‘Dangerous for the environment’ is shown separately.
T+
Very toxic

T
Toxic

C
Corrosive

Xn
Harmful

Xi
Irritant

N
Dangerous for the environment
CSMR risk for diseases

- **R 40** Possible risks of irreversible effects
- **R 46** May cause heritable genetic damage
- **R 42** May cause sensitisation by inhalation
- **R 43** May cause sensitisation by skin contact
- **R 45** May cause cancer
- **R 49** May cause cancer by inhalation
- **R 340** Some risk of cancer cannot be excluded after frequently repeated exposure
- **R 60** May impair fertility
- **R 61** May cause harm to the unborn child
- **R 62** Possible risk of impaired fertility
- **R 63** Possible risk of harm to the unborn child
Risks for environment

- **R 50** Very toxic to aquatic organisms
- **R 51** Toxic to aquatic organisms
- **R 52** Harmful to aquatic organisms
- **R 53** May cause long-term adverse effects in the aquatic environment
- **R 54** Toxic to flora
- **R 55** Toxic to fauna
- **R 56** Toxic to soil organisms
- **R 57** Toxic to bees
- **R 58** May cause long-term adverse effects in the environment
- **R 59** Dangerous for the ozone layer
Totals of fossil fuels and non-fossil chemical products 1996-1999, labelled for inherent properties (lip)
Average distribution of fossil fuels by product

- Air fuel 5% (C, Xn)
- Heating oil 1-5 28% (C, Xn)
- Diesel 22% (C, Xn)
- Jet fuel <0.05% (C, Xn)
- Petrol 27% (C, Xn, T)
- Heating oil 1 18% (C, Xn)
Use of classified fossil fuels in 2000

- Private consumption
- Service, other
- Transport (SNI 60-64)
- Electricity and water supply (SNI 40-41)
- Engineering industry etc (SNI 28-37)
- Manuf of basic metal (SNI 27)
- Manuf of mineral products (SNI 26)
- Chemical industries (SNI 24-25)
- Refineries (SNI 23)
- Pulp and paper (SNI 21-22)
- Food and beverages (SNI 15-20)
- Mining and quarring (SNI 10-14)
- Agriculture etc (SNI 01-05)
Table 1. Occurrence of unique risk phrases and their distribution among chemical products registered in the Product Register (including fossil fuels) (Brånvall, 2002).

<table>
<thead>
<tr>
<th>Risk phrases</th>
<th>Number of products</th>
<th>Tonnes</th>
</tr>
</thead>
<tbody>
<tr>
<td>R340 - Some risk of cancer cannot be excluded after frequently repeated exposure</td>
<td>338</td>
<td>10 261 175</td>
</tr>
<tr>
<td>R40 - Possible risks of irreversible effects</td>
<td>2</td>
<td>300</td>
</tr>
<tr>
<td>R41 - Risk of serious damage to eyes</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>R42 - May cause sensitisation by inhalation</td>
<td>242</td>
<td>1 505</td>
</tr>
<tr>
<td>R43 - May cause sensitisation by skin contact</td>
<td>3 495</td>
<td>3 194 534</td>
</tr>
<tr>
<td>R45 - May cause cancer</td>
<td>289</td>
<td>28 038 955</td>
</tr>
<tr>
<td>R46 - May cause heritable genetic damage</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>R49 - May cause cancer by inhalation</td>
<td>19</td>
<td>161</td>
</tr>
<tr>
<td>R50 - Very toxic to aquatic organisms</td>
<td>16</td>
<td>1 306</td>
</tr>
<tr>
<td>R52 - Harmful to aquatic organisms</td>
<td>4</td>
<td>193</td>
</tr>
<tr>
<td>R53 - May cause long-term adverse effects in the aquatic environment</td>
<td>18</td>
<td>400</td>
</tr>
<tr>
<td>R59 - Dangerous for the ozone layer</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>R61 - May cause harm to the unborn child</td>
<td>70</td>
<td>3 628 048</td>
</tr>
<tr>
<td>R62 - Possible risk of impaired fertility</td>
<td>7</td>
<td>25</td>
</tr>
<tr>
<td>R63 - Possible risk of harm to the unborn child</td>
<td>40</td>
<td>92 617</td>
</tr>
</tbody>
</table>
Totals of Non-fossil chemical products, lip, 1993-1999

Viveka Palm & Annica Carlsson.

Conclusions I

• The magnitude of hazardous chemical products in Sweden lies between 30 and 40 million tonnes, approx 3 or 4 tonnes/capita and year.

• Major chemical product groups are petroleum-based products with between 25 – 30 million tonnes per year.

• The largest groups have carcinogenic and health hazardous properties, mainly petrol and diesel. Since all countries have statistics on oil consumption, it implies that information on a large part of the chemical product flow is already existing and thereby possible to use as indicators.
Conclusions II

• For the non-fossil chemical products, the information from the Swedish Product register is unique.
• The industries basic chemical production, non-metallic mineral production, and pulp- and paper industry dominate the non-fossil chemical products.
• By expressing the results as tonnes of non-fossil chemical product per value added in different industries, using the non-fossil chemical product results as a first estimate for other countries can be tested.