

THE USE OF DATA FROM THE NORDIC PRODUCT REGISTERS

Uppsala, 20-21 October 2004

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THE USE OF DATA FROM THE NORDIC PRODUCT REGISTERS

Uppsala, 20-21 October 2004

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

- | | |
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| 12.0 | Welcome |
| 12.15 | The development and usefulness of the Nordic Product Registers
<i>Margareta Östman (Swedish Chemicals Inspectorate)</i> |
| 12.45 | SPIN and aggregation of data from the Nordic Products Registers
<i>Poul Andersen and Sven Nielsen (Danish Product Register)</i> |
| 13.30 | Can the Nordic Product Register REACH the emission scenarios?
<i>Paul van der Poel (RIVM)</i> |
| 14.00 | How to derive easy-to-use emission estimation tools building on current TGD methodology?
<i>Silke Müller (UBA)</i> |
| 14.30 | Regulatory background of product information in Germany and impacts for practical work.
<i>Dr Axel Hahn (Federal Institute for Risk Assessment)</i> |
| 15.00 | Coffee |
| 15.45 | Identify chemical candidates for monitoring based on information in the Product Register.
<i>Stellan Fischer (Swedish Chemicals Inspectorate)</i> |
| 16.15 | Product register companies perspectives. Problems and Possibilities.
<i>Olof Holmer</i> |
| 16.45 | REACH and national supervision
<i>Barbro Sillrén (Swedish Chemicals Inspectorate)</i> |
| 17.15 | The day ends |

Program

21 October

- | | |
|-------|---|
| 09.00 | Towards a chemical Risk Index, data needs versus data availability
<i>Christian Heidorn (cec – Eurostat)</i> |
| 09.30 | Swedish environmental accounts
<i>Viveka Palm (Statistics Sweden)</i> |
| 10.15 | Presentation of working groups |
| 10.30 | Group work |
| 14.00 | Coffee |
| 14.30 | Summing up |

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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 registered.
- 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 registered. 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.

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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 is 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 their 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.

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The development and usefulness of Nordic Products Registers - Presentation at the Uppsala Workshop 20.10.2004

Margareta Östman
Swedish Chemicals Inspectorate

“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 90-ties 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. SHOW

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. SHOW BROSHYR

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 the 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 find 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 is 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

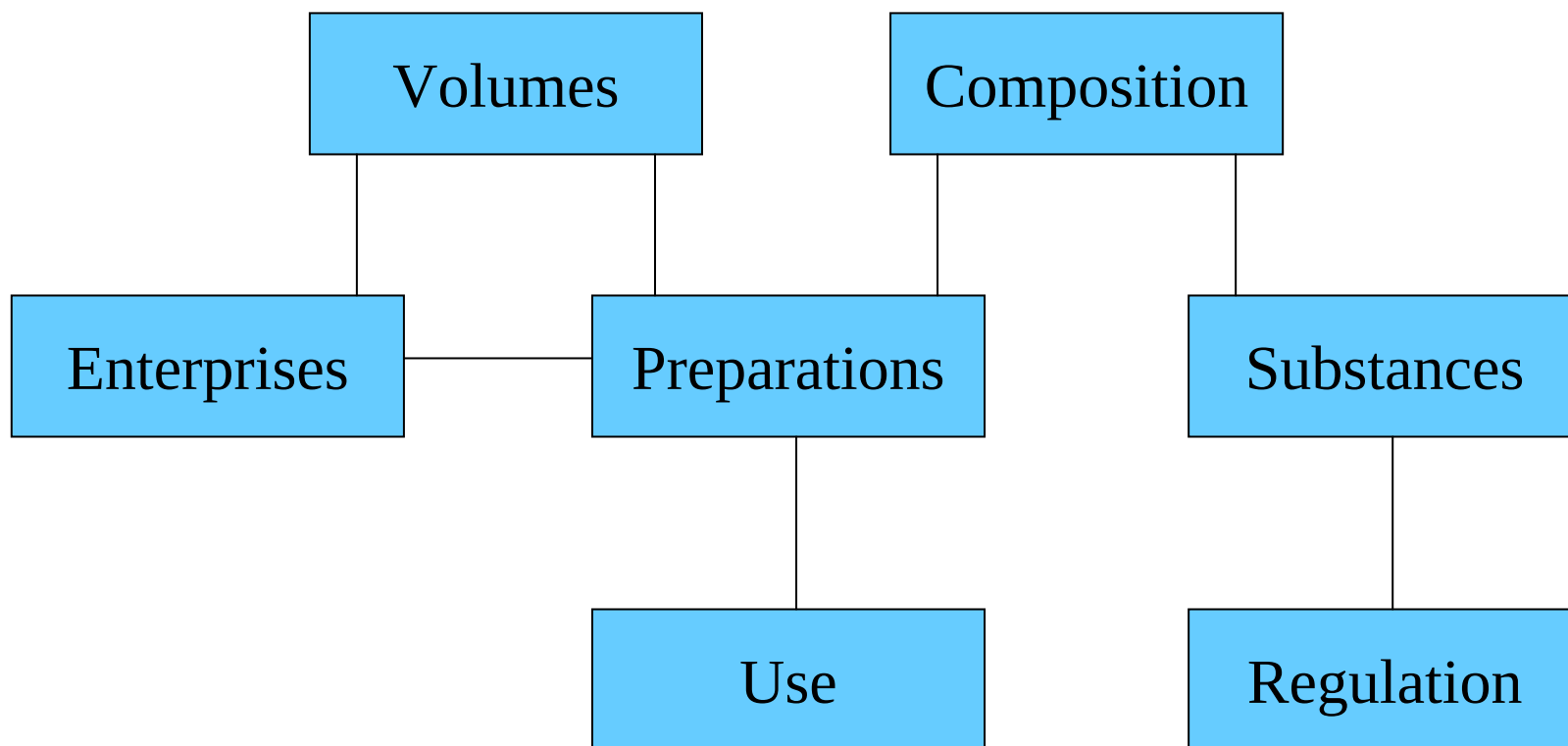
The Nordic approach to product registration and use of data

Poul Erik Andersen

Danish National Working Environment Authority

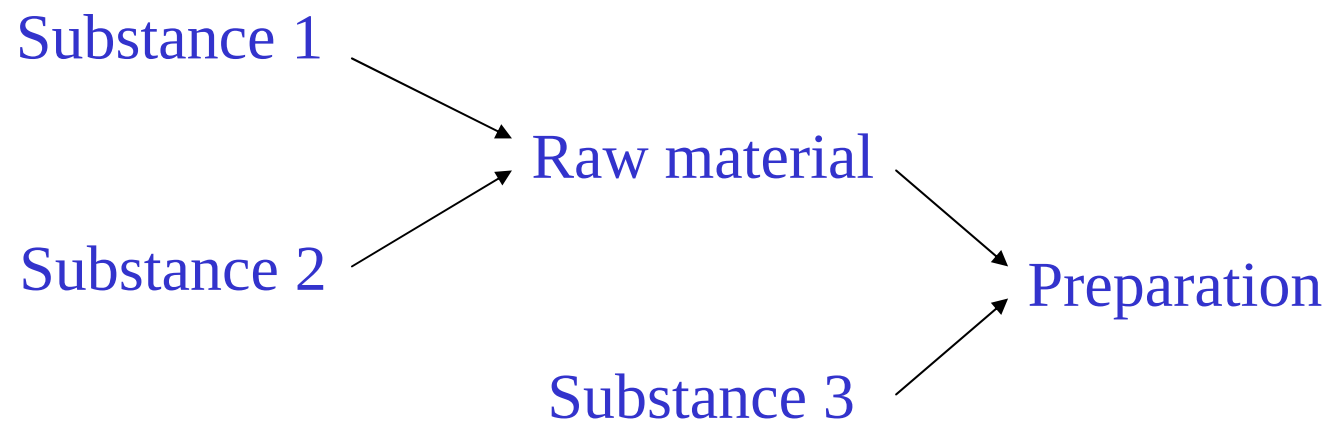


Logical file structure in PROBAS





Composition





Substance volume

$$M_{S1} = \sum_{x=1}^{x=n} M_{P_x} \times C_{S1x}$$

M_{S1} total volume of substance no. 1

M_{P_x} volume of preparation no. x

C_{S1x} concentration of substance no. 1 in
preparation no. x



SPIN - Microsoft Internet Explorer

Filer Rediger Vis Foretrukne Funktioner Hjælp

Tilbage Søg Foretrukne Medier

Adresse <http://www.spin2000.net/spin.html> Gå Hyperlinks >>



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

Internet



SpinUse Total - Microsoft Internet Explorer

File Rediger Vis Foretrukne Funktioner Hjælp

Tilbage Søg Foretrukne Medier

Adresse <http://195.215.251.229/FMPPro?-db=spinstof.fp5&-Format=spin/spinuset.html&-lay=spinuse&pid=&-Max=1&-Findall> Gå Hyperlinks



SPIN

Substances in Preparations in Nordic Countries

Help

Search mode	Show all	List			Guide	Reports	Exit
Main info	Total use	Industr. NACE	Industr. Nation	Use Cat. UC62	Use Cat. Nation	References	Technical

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

Nr. 1 of 18379

Total use					
Country	Year	# preparations	Tonnes	Consumer preparations	Confidential
FIN	2001	313	56926.6		
N	2001	518	40251.7	X	
DK	2001	2528	458.6		
N	2000	564	25488.8		
S	2000	1695	6963.0	X	
DK	2000	2151	522.8		
FIN	2000	335			

Internet



Industrial use (NACE) - Microsoft Internet Explorer

File Rediger Vis Foretrukne Funktioner Hjælp

Tilbage Søg Foretrukne Medier

Adresse p://195.215.251.229/FMPPro?-db=spinstof.fp5&-Format=spin/spinNACE.html&-lay=SpinIndustUse&pid=8-Max=18-Findall Gå Hyperlinks



SPIN

Substances in Preparations in Nordic Countries

Help

Search mode	Show all	List			Guide	Reports	Exit
Main info	Total use	Industr. NACE	Industr. Nation	Use Cat. UC62	Use Cat. Nation	References	Technical

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

Nr. 1 of 18379

Industrial use (NACE)

Country	Year	Code		# prep	Tonnes
N	2001	24	Manufacture of chemicals and chemical products	91	37266.5
FIN	2001	24	Manufacture of chemicals and chemical products	24	30974.7
FIN	2001	20	Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials	65	25430.2
N	2001	11	Extraction of crude petroleum and natural gas	10	1850.7
DK	2001	24	Manufacture of chemicals and chemical products	147	381.6
N	2001	26	Manufacture of other non-metallic mineral products	6	262.5
FIN	2001	26	Manufacture of other non-metallic mineral products	14	246.7

Internet



Use by category (UC62) - Microsoft Internet Explorer

Filer Rediger Vis Foretrukne Funktioner Hjælp

Tilbage Søg Foretrukne Medier

Adresse [tp://195.215.251.229/FMPro?-db=spinstof.fp5&-Format=spin/spinUC62.html&-lay=spincatuse&casno=&-Max=1&-Findall](http://195.215.251.229/FMPro?-db=spinstof.fp5&-Format=spin/spinUC62.html&-lay=spincatuse&casno=&-Max=1&-Findall) Gå Hyperlinks



SPIN

Substances in Preparations in Nordic Countries

[Help](#)

Search mode	Show all	List			Guide	Reports	Exit
Main info	Total use	Industr. NACE	Industr. Nation	Use Cat. UC62	Use Cat. Nation	References	Technical

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

N. 1 of 18379

USE CATEGORY (UC62)

Country	Year	Code		# prep	Tonnes
N	2001	A33	Intermediates	9	21381.8
N	2001	A02	Adhesives, binding agents	112	16160.9
N	2001	C39	Non-agricultural pesticides and preservatives	13	2578.3
DK	2001	A33	Intermediates	9	292.0
DK	2001	A02	Adhesives, binding agents	316	211.0
DK	2001	C39	Non-agricultural pesticides and preservatives	39	153.0
N	2001	A43	Process regulators	21	104.7
DK	2001	C12	Construction materials	85	21.0

Internet



Spin Technical - Microsoft Internet Explorer

File Rediger Vis Foretrukne Funktioner Hjælp

Tilbage Søg Foretrukne Medier

Adresse p://195.215.251.229/FMPro?-db=spinstof.fp5&-Format=spin/technical.html&-lay=SpinTechnical&casno=&-Max=1&-Findall Gå Hyperlinks

Main info Total use Industr. NACE Industr. Nation Use Cat. UC62 Use Cat. Nation References Technical

Cas no: 50-00-0 Name: Formaldehyde
EC no: 200-001-8 Nr. 1 of 18379

Technical

Molecular Formula CH₂O

Index no 605-001-00-5

SMILES C=O [Show structure](#)

Colour Index

CSD

Substance category		Main category (IUCLID)	
DES	Disinfectant	A13-03	Use resulting in inclusion into or onto matrix
HÆR	Curing agent	A13-02	Use in closed system
KON	Preservative, biocide	A13-01	Non dispersive use
MON	Monomer	A13-04	Wide dispersive use
OPL	Solvent		
RST	Residual monomer		
STA	Stabilizer		
URH	Impurity		

Internet



norden

Umwelt
Bundes
Amt 
für Mensch und Umwelt



Can the Nordic Countries Product Register REACH the emission scenarios?

rivm

National Institute
for Public Health and
the Environment

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

New
substances

Existing
substances

Biocides



Matrix of Emission Scenarios

Industrial categories, Processes

	X									X	X			
					X						X		X	
	X								X					
		X	X						X			X	X	
											X			
				X	X	X								
								X	X					
X														

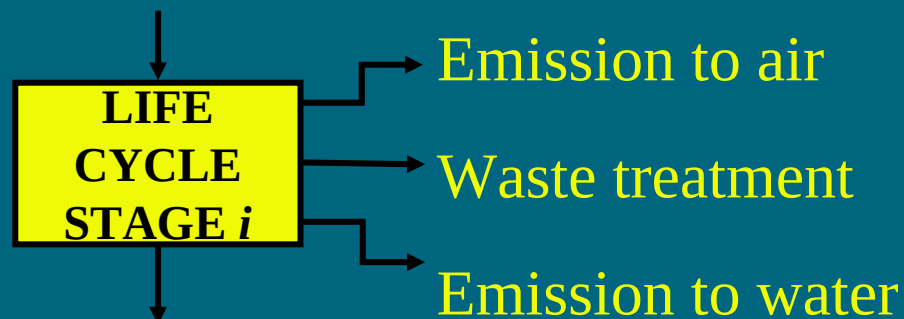
Life cycle stages, Process steps, Functions

Environmental Risk Assessment

- Every relevant life cycle stage

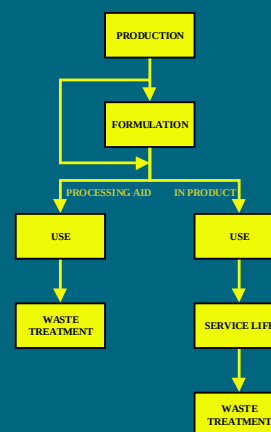
Local scale [1 point source]

Regional scale [area sources]

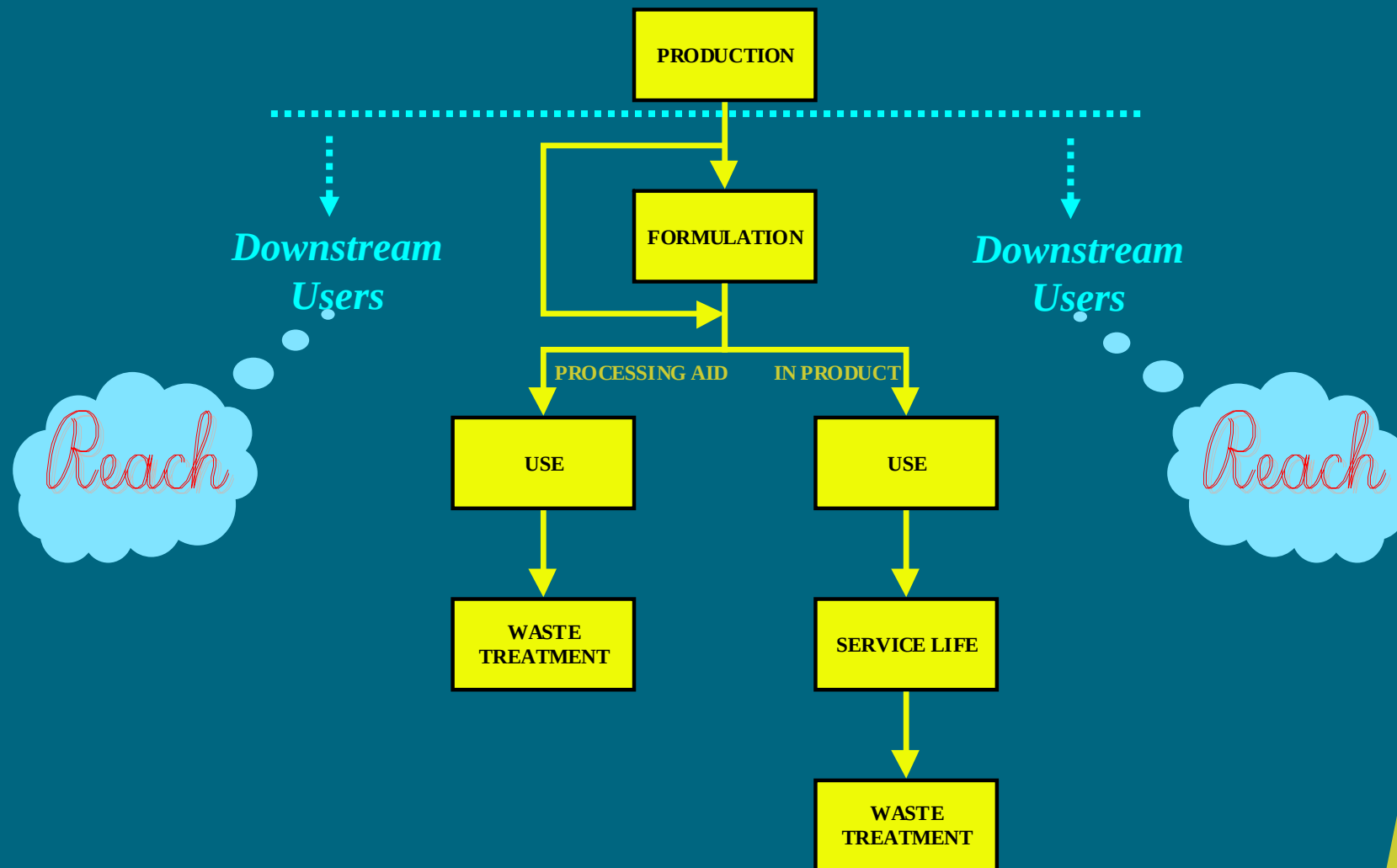


- Whole life cycle

Regional scale [all sources]



General Form of the Life Cycle of a Substance



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

Present

Authorities

```
graph LR; Authorities --> LocalScale[Local Scale]; Authorities --> RegionalScale[Regional Scale];
```

The diagram illustrates the flow of information from Authorities to the Local and Regional scales. A red line originates from the 'Authorities' label and branches into two arrows. One arrow points to the '1 Point Source (Main)' bullet point under the 'Local Scale' section, and the other points to the 'All Sources' bullet point under the 'Regional Scale' section.

Risk Assessment: REACH

Local Scale

REACH

Production

- All Point Sources

Site specific scenarios ← Producers

Relevant Life cycle stages DSUs

- Point Sources of DSUs

Generic scenarios ← Producers / Importers



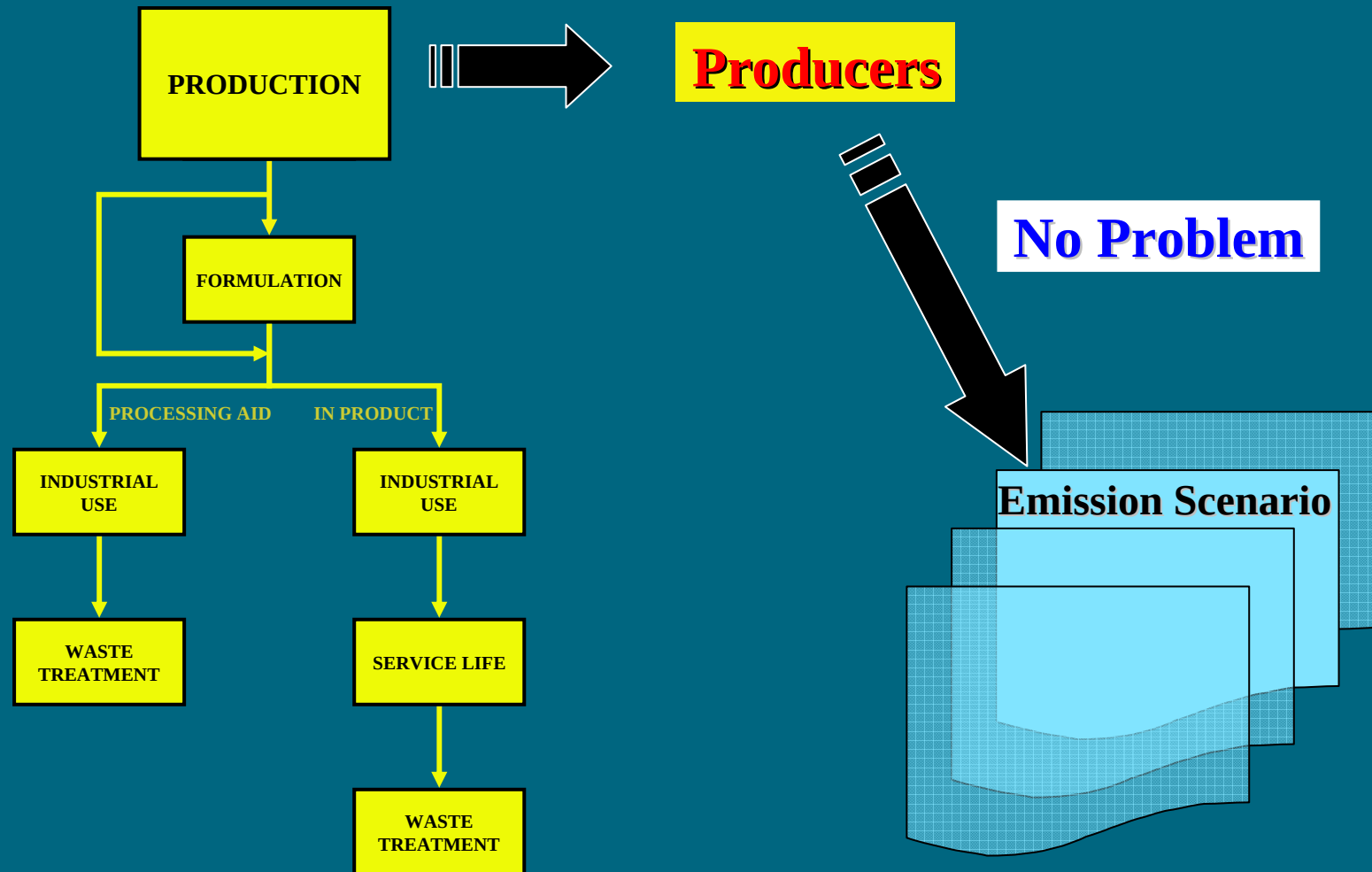
Site specific scenarios ← DSUs

Regional Scale

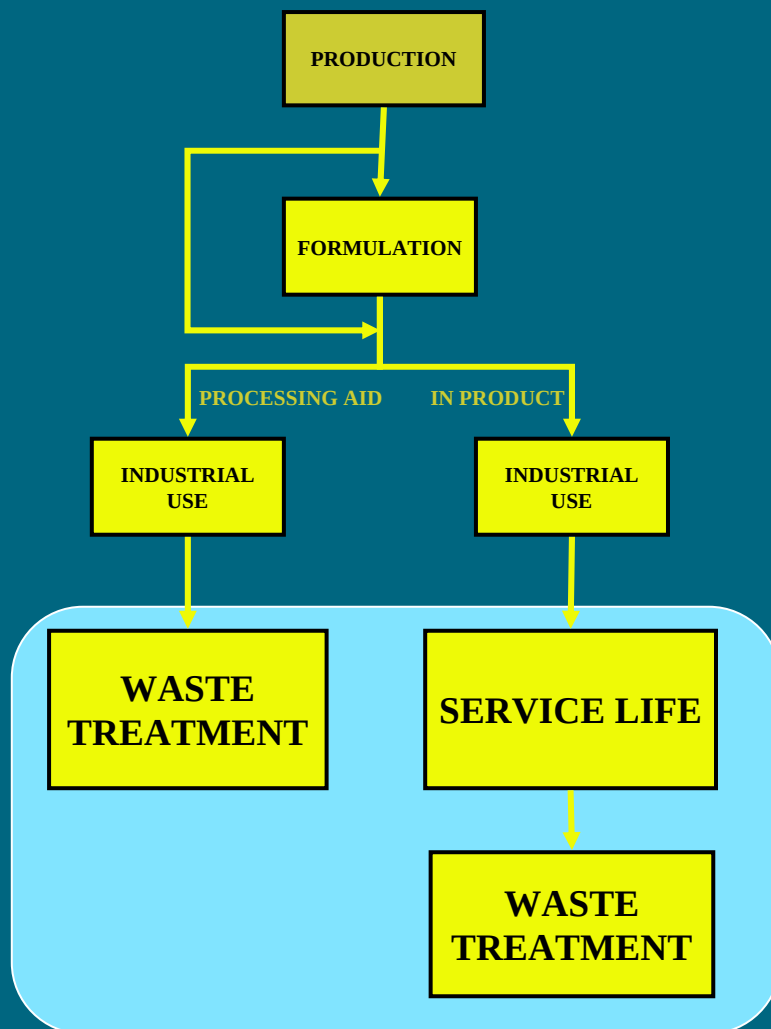
All relevant Life cycle stages

● All Sources ← Authorities

REACH and Life Cycle Stages



REACH and Life Cycle Stages

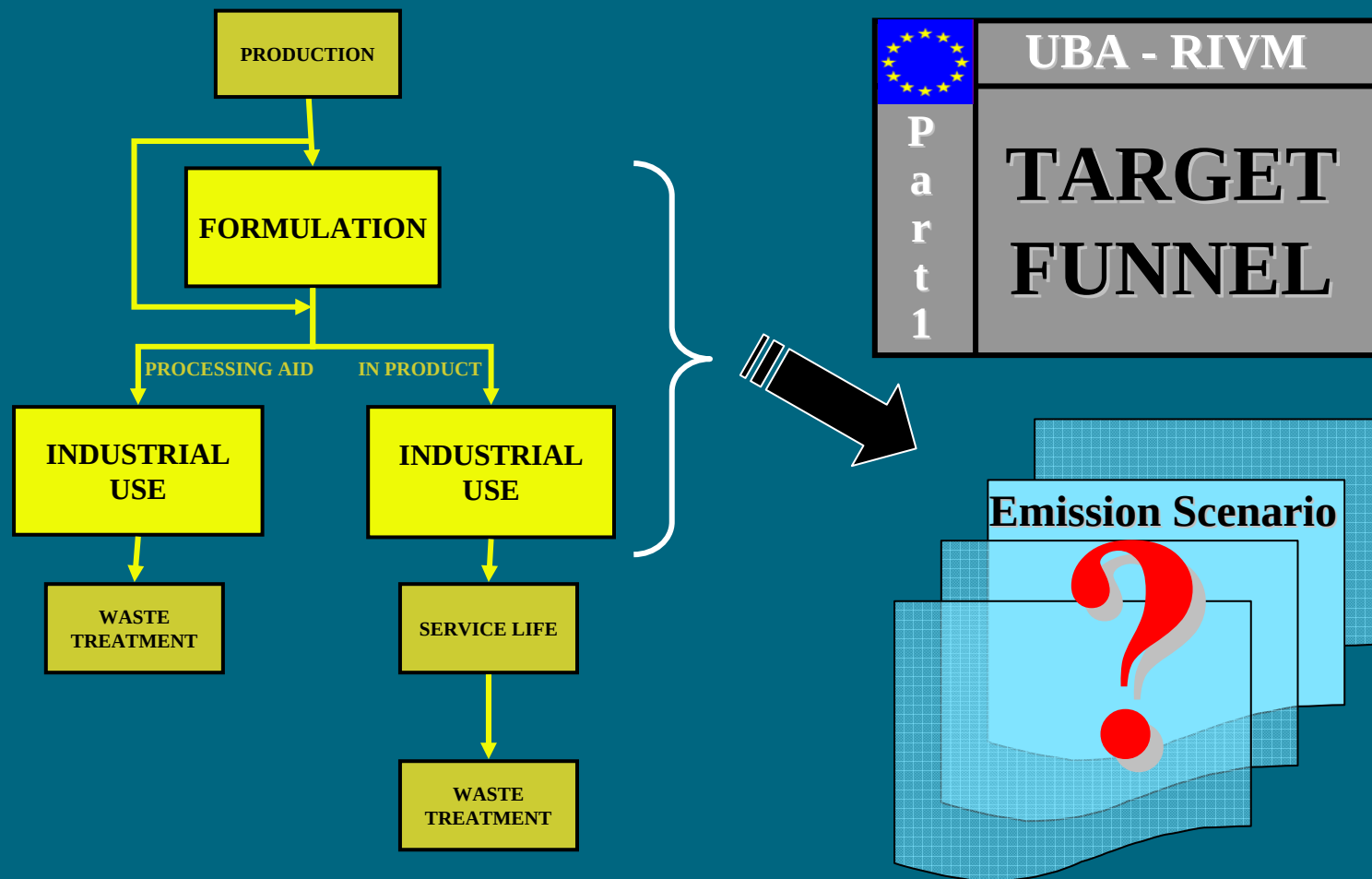


- Mainly Area Sources
(Diffuse Emissions)

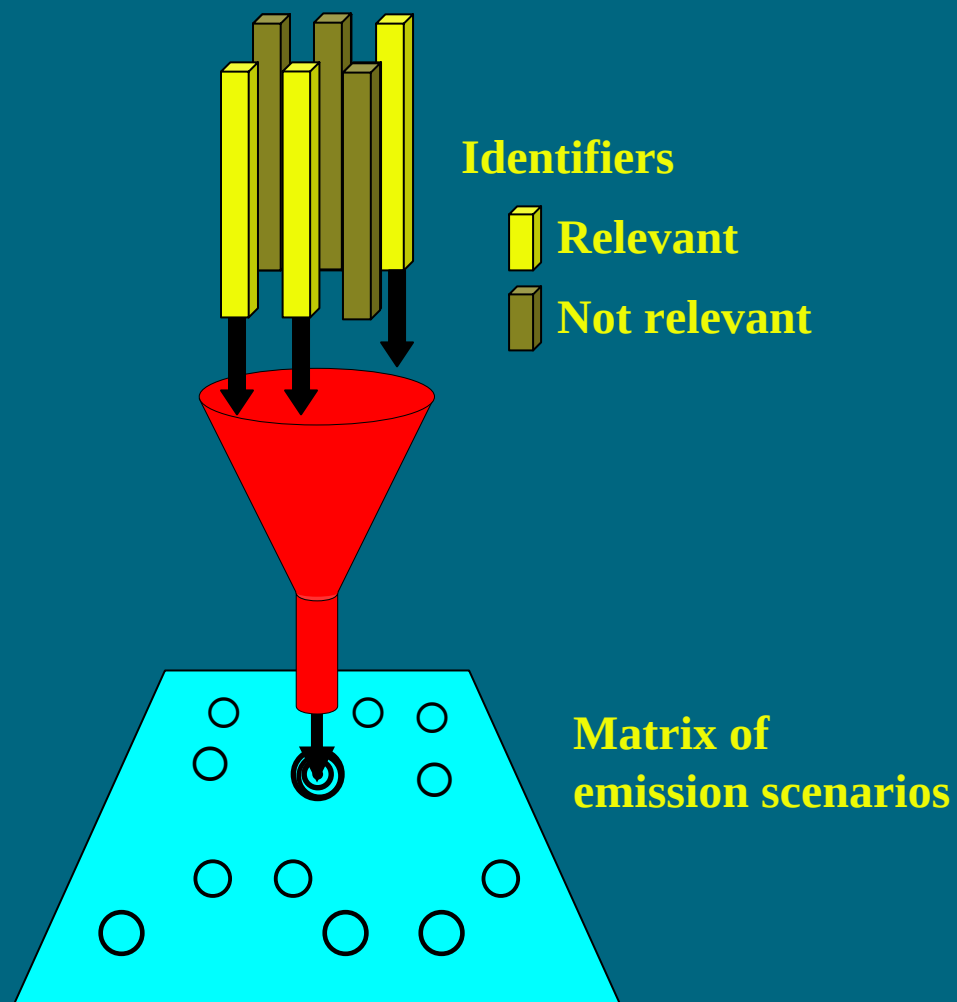
- Emission Scenarios
result from
Industrial Use

Outside Scope

REACH and Life Cycle Stages



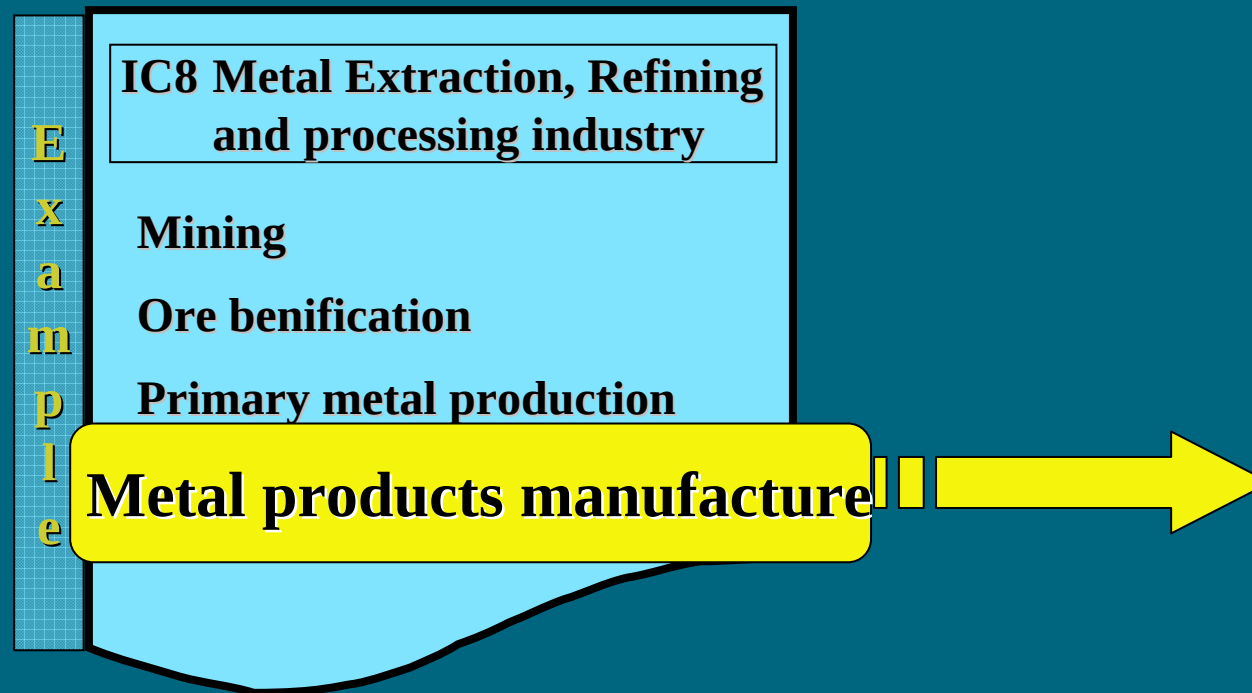
Target Funnel to Emission Scenarios



Target Funnel and Identifiers

1 Industrial Category (TGD)

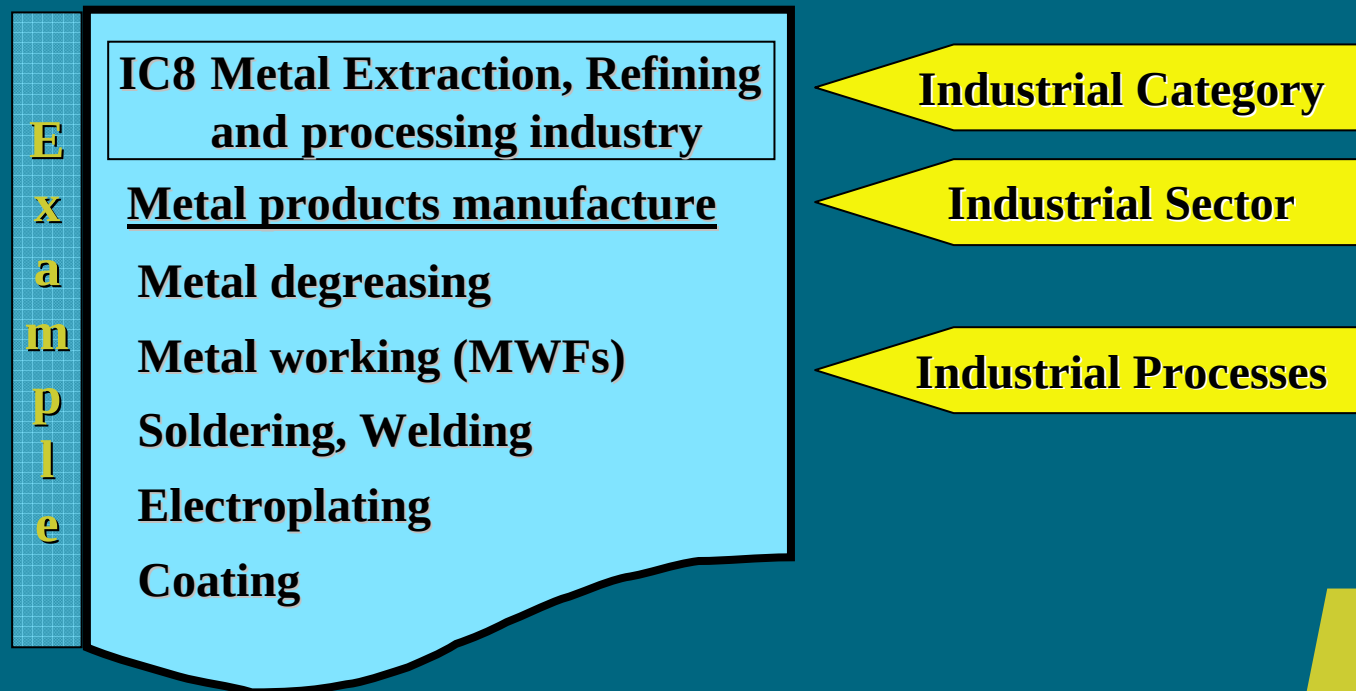
- Covered with number of emission scenarios



Target Funnel and Identifiers

1 Industrial Category (TGD)

- Covered with number of emission scenarios



Target Funnel and Identifiers

1 Industrial Category (TGD)

Industrial Proces: Textile processing

Proces step

E x a m p l e	IC 13 Textile Processing Industry	
	Pretreatment	
	Fibres and yarns treatment	
	Dyeing and printing	
	Finishing	

Target Funnel and Identifiers

1 Industrial Category (TGD)

Industrial Proces: Paint application

Proces type

E x a m p l e	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**

PRODUCTION

2 Chemical industry

FORMULATION

14 Paint industry

INDUSTRIAL
USE

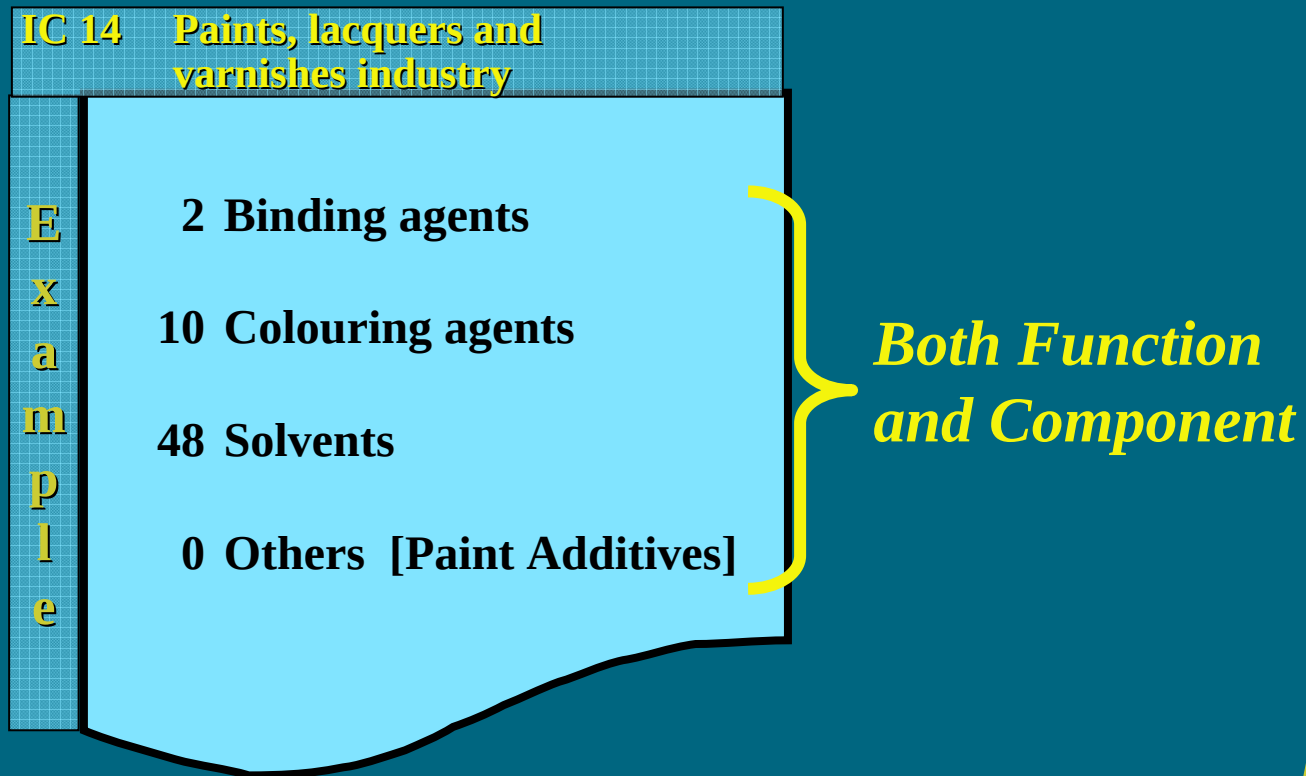
16 Engineering industry
Sector: Metal Products Manuf.
Process: Paint spraying

rivm

Target Funnel and Identifiers

2 Use Category (TGD)

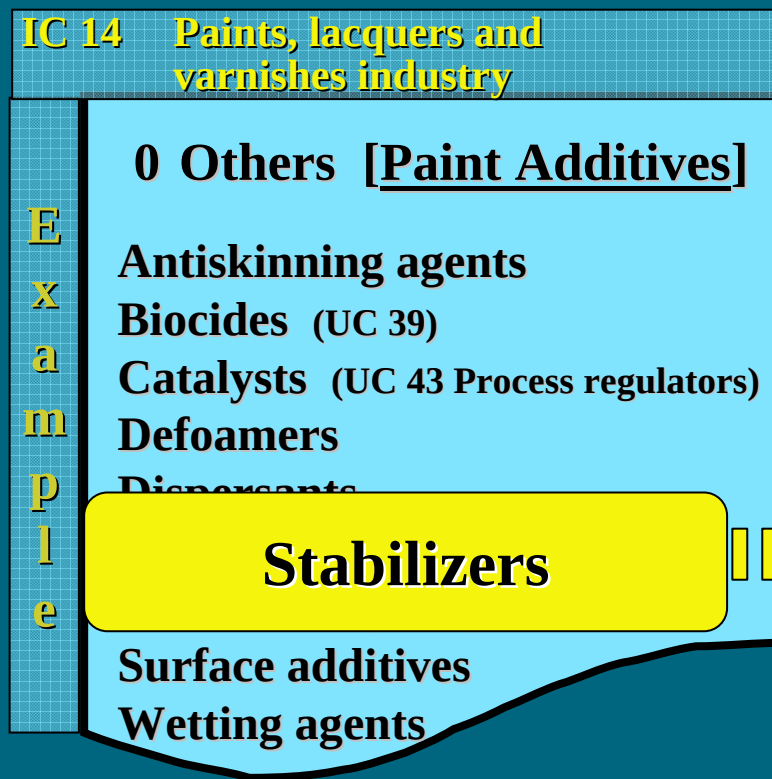
- Different level of detail



Target Funnel and Identifiers

2 Use Category (TGD)

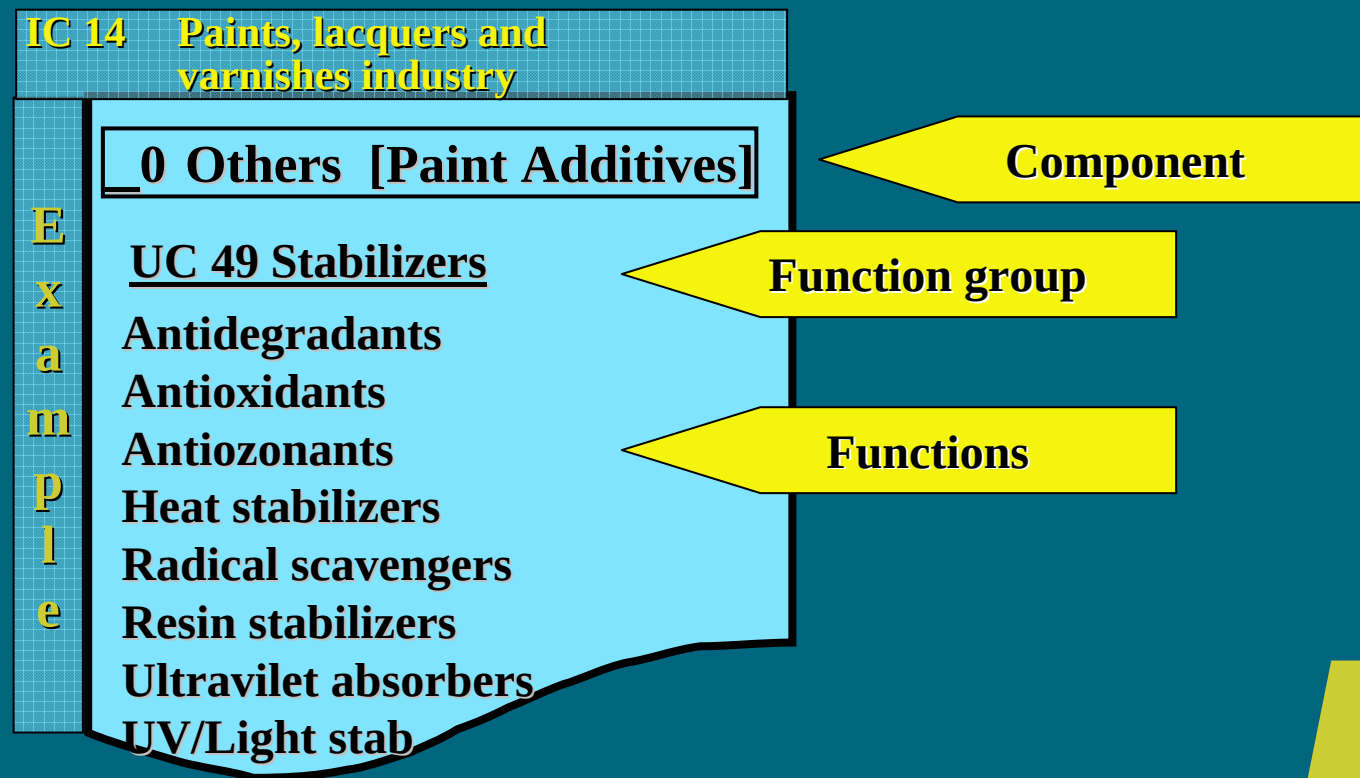
- ☞ 1 Component / Main function: ≥ 1 Function groups
- ☞ 1 Function group: ≥ 1 Function



Target Funnel and Identifiers

2 Use Category (TGD)

- ☞ 1 Component / Main function: ≥ 1 Function groups
- ☞ 1 Function group: ≥ 1 Function



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

Thou

Hund

Tens

Sever

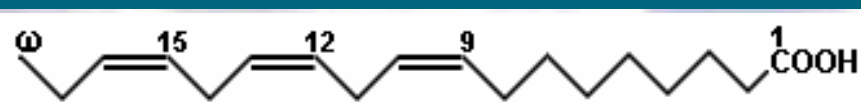
Mult

rivm



Components of Coating Products

1 Binding agents

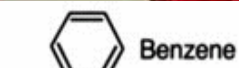


Alpha-Linolenic Acid (omega-3)

2

3

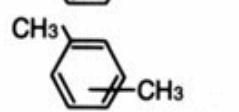
4 Additives



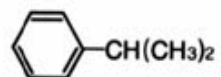
Benzene



Toluene



Xylene



Agro

C

Rubbl

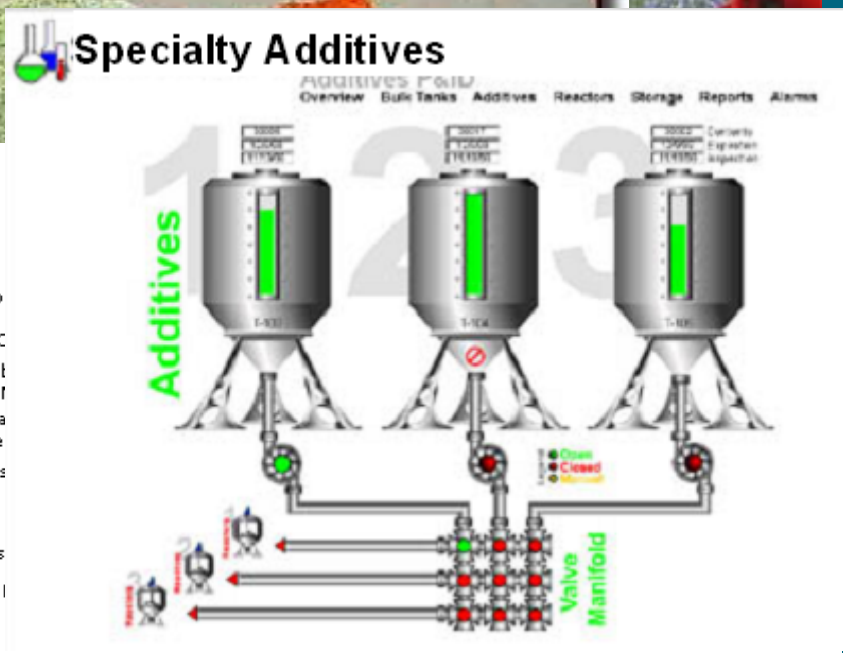
I

Meta

Cle

Hous

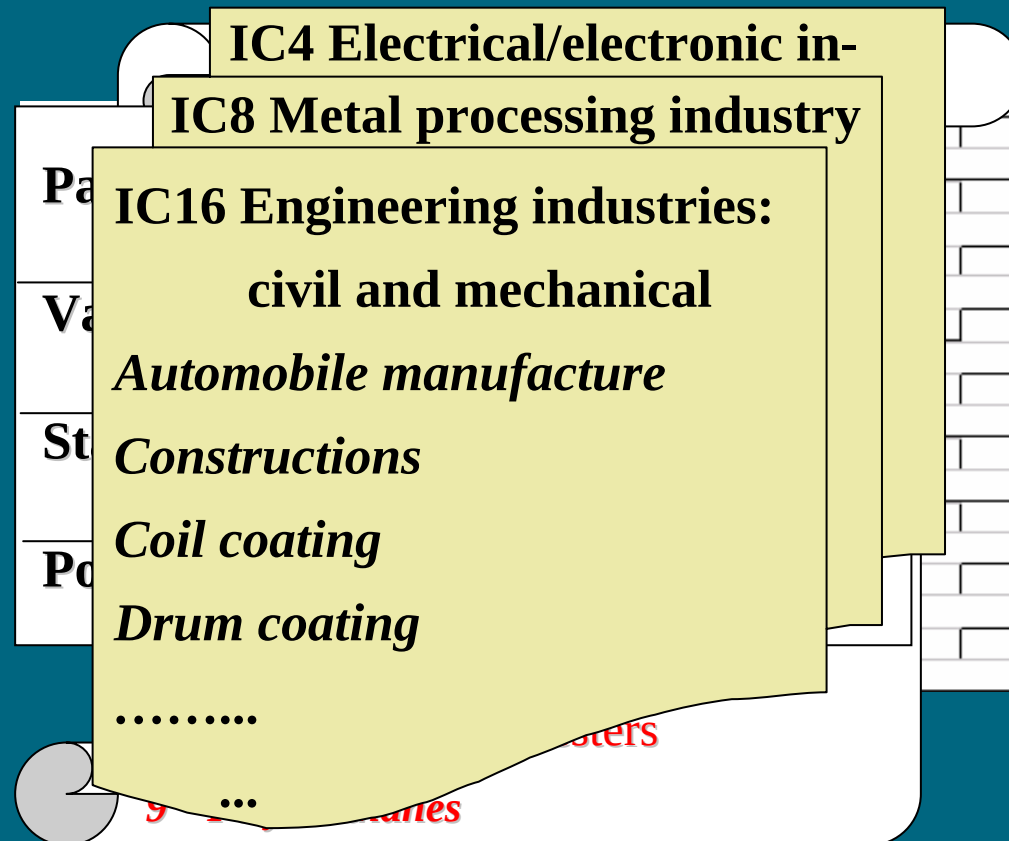
Cos



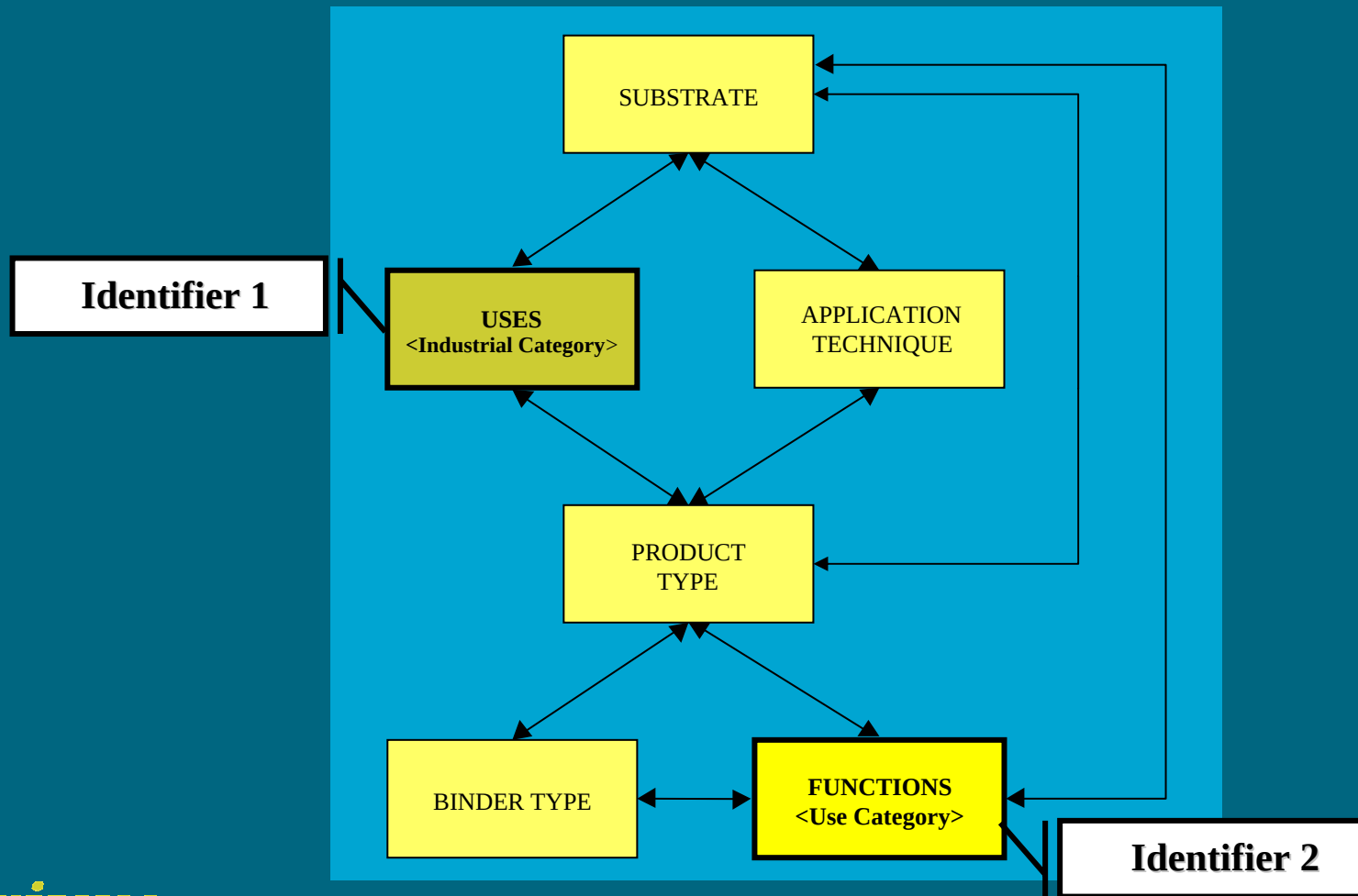
rivm

Paint Classifications and Functions of Substances

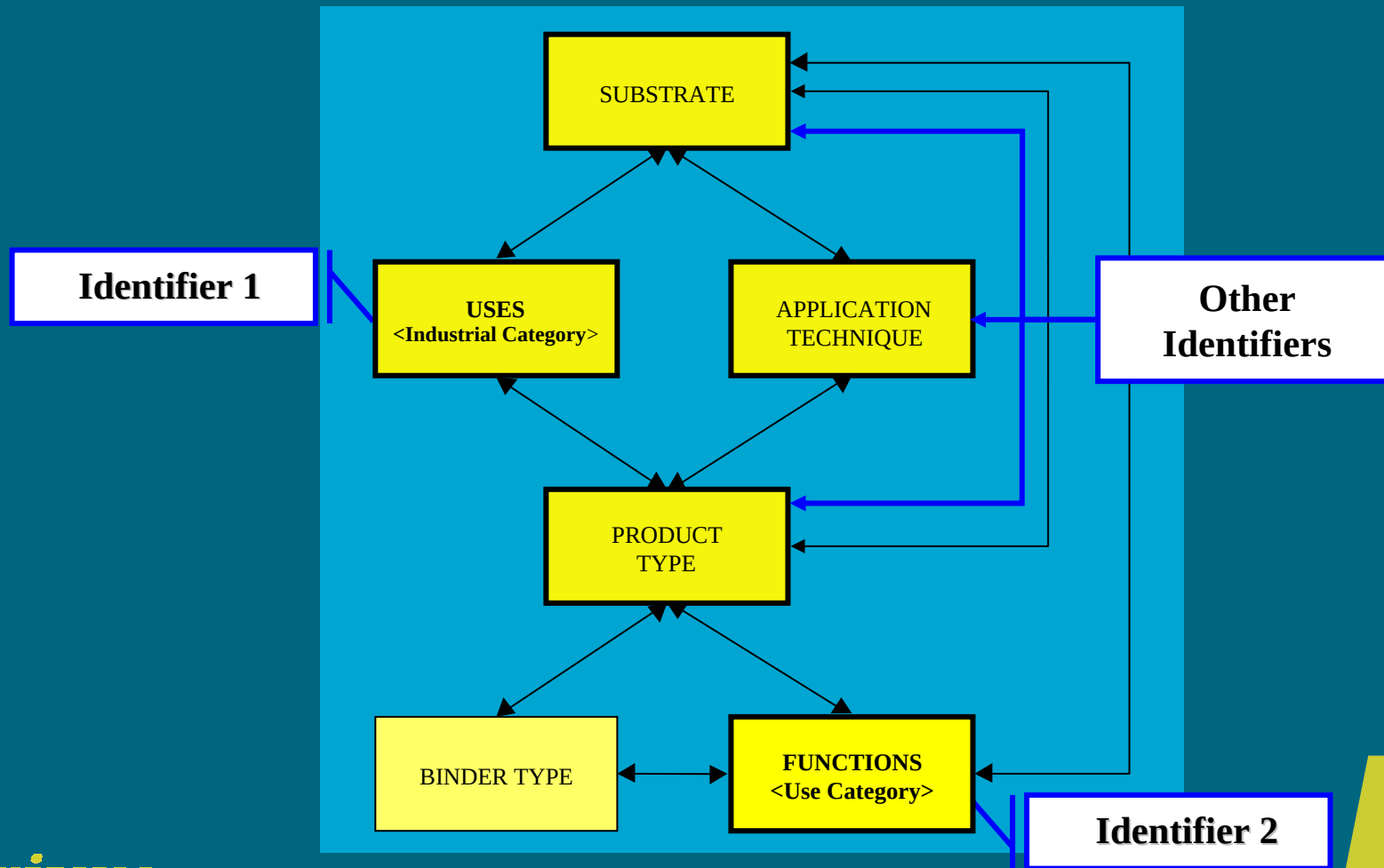
3 Industrial Paint (Industrial Sector)



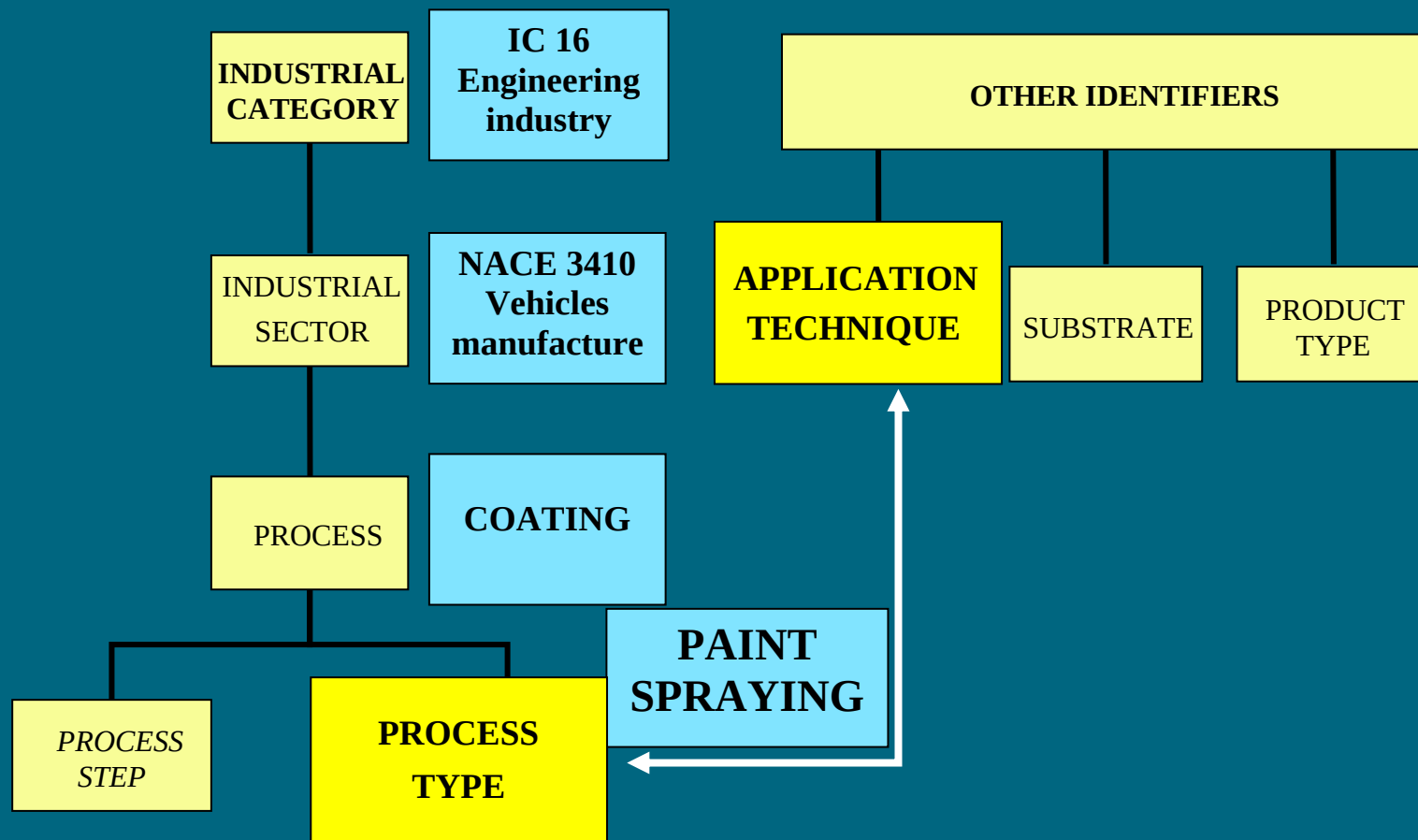
Relations between Classifications & Identifiers



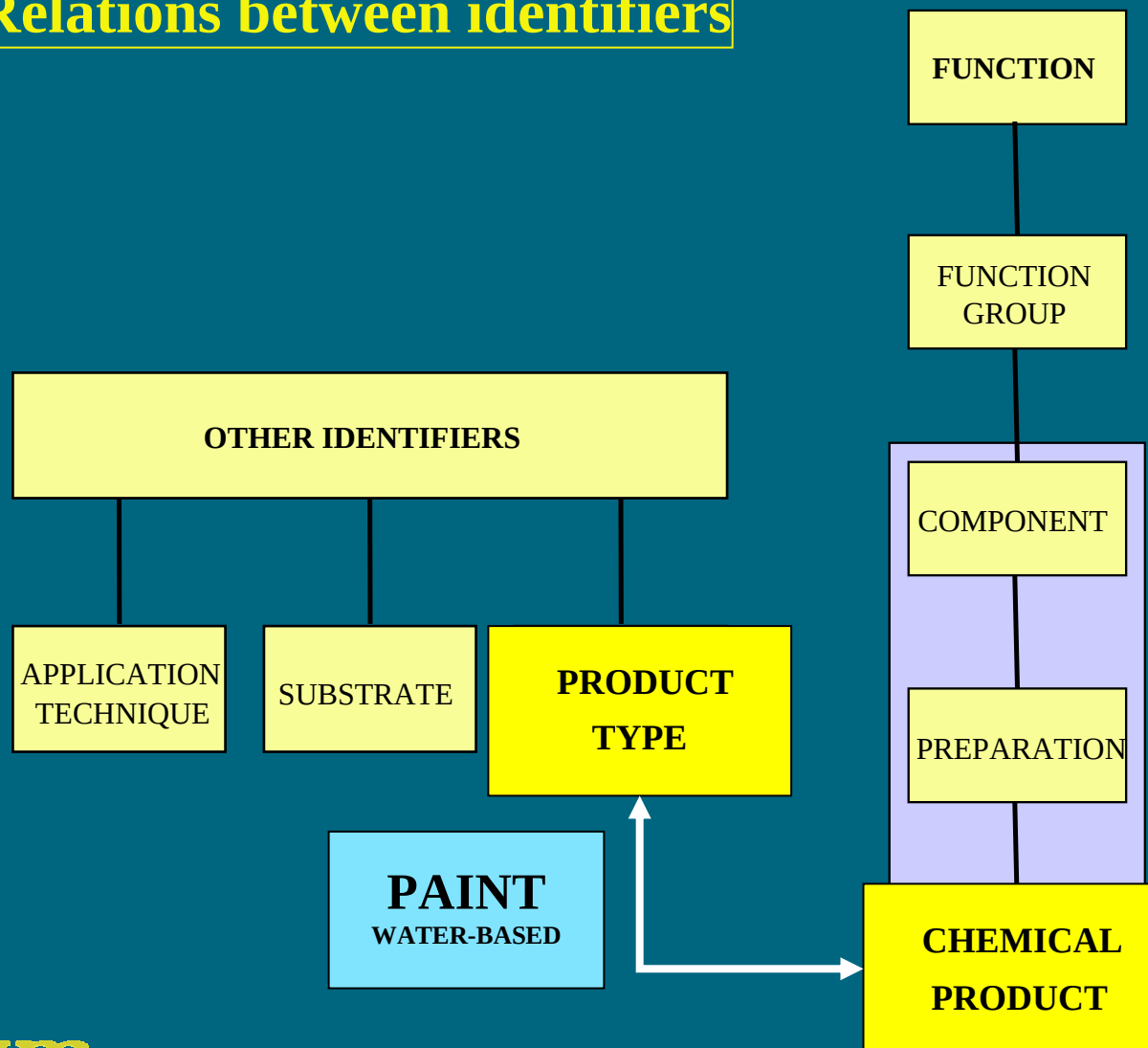
Relations between Classifications & Identifiers



Relations between identifiers



Relations between identifiers



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



Substances in Preparations
in Nordic Countries

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:

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

← **UC 7 TGD**

← **UC 2 TGD**

← **UC 47 TGD**

← **UC 22 TGD**

← **UC 10 TGD**

← **Colouring agents**

“ SPIN” Codes (Example: “Paint “)

2 Product types:

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

Pt 6 Biocidal Directive

Pt 7 Biocidal Directive

UC 39 TGD

“ SPIN” Codes (Example: “Paint “)

3 Chemical Preparations and Products:

Code	Description
F05250	Pigment pastes
M0500	Paint, lacquers and varnishes
M0570	Anticorrosive paints

Preparation

Products

“ SPIN” Codes & Other Identifiers

**Chemical
product**

**Product
type**

Function

**Field of
Application**

Code	Description			
M05131	Paint and varnish	Water based	Active corrosion inhibitor	Interior
M05132	Paint and varnish	Water based	Active corrosion inhibitor	Exterior
M05133	Paint and varnish	Water based	Active corrosion inhibitor	Industrial use
M05134	Paint and varnish	Water based	Active corrosion inhibitor	Other
	(including ship-, road-, art-,furniture-, autopaint)			

“ SPIN” Codes & Other Identifiers

Code	Description
M05213	Paint and varnish Volatile organic thinner Active biological/biocide function (e.g. anti-fouling) Industrial use

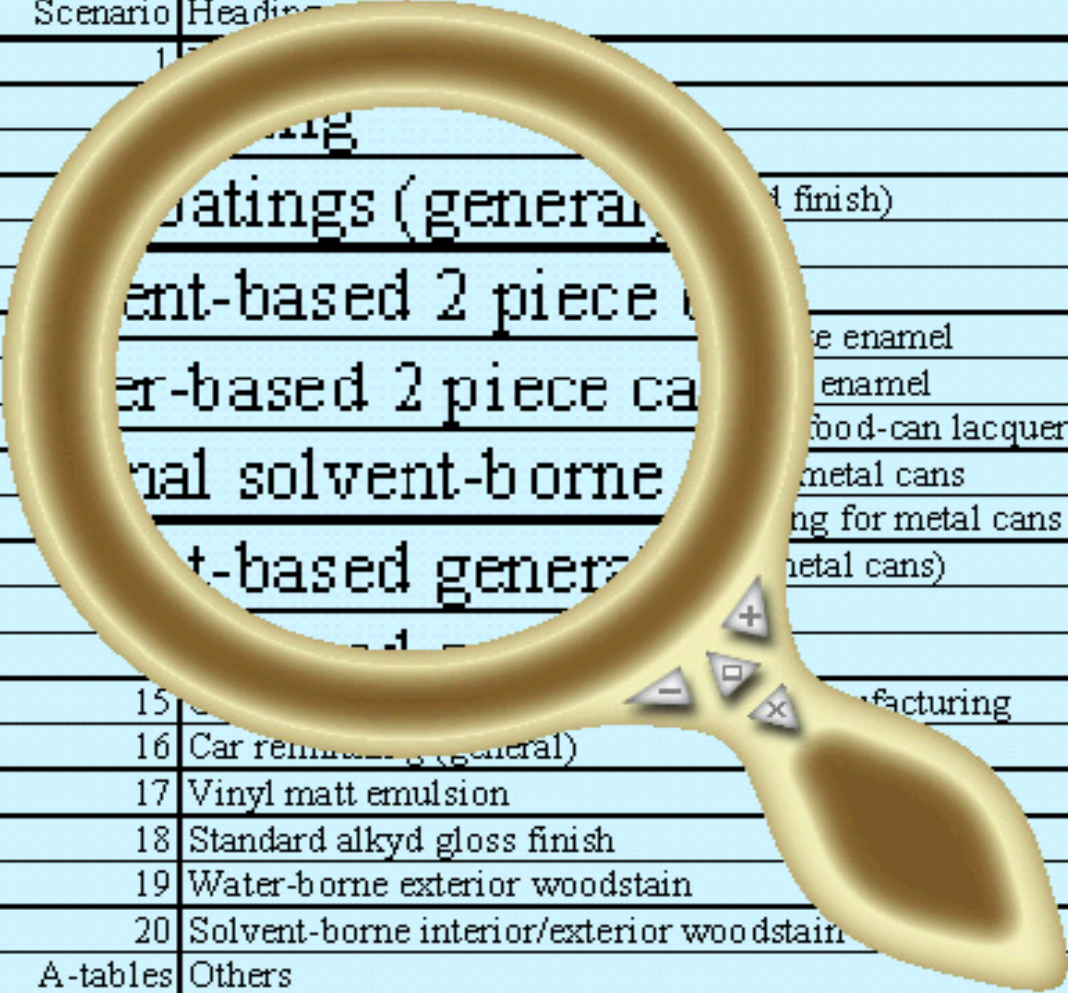
UC 39 Biocides:

Pt 6 In-can preservatives (SPIN B15310)

Pt 7 Film preservatives (SPIN B15320)

Pt 21 Antifouling products

Identifiers in EU Emission Scenarios “Paints”



Scenario	Heading
15	Coatings (general)
	Solvent-based 2 piece enamel
	Water-based 2 piece enamel
	Food-can lacquer
	Solvent-borne metal cans
	Water-based general (metal cans)
15	Manufacturing
16	Car refinishing (general)
17	Vinyl matt emulsion
18	Standard alkyd gloss finish
19	Water-borne exterior woodstain
20	Solvent-borne interior/exterior woodstain
A-tables	Others

Identifiers in EU Emission Scenarios “Paints”

15	Original equipment manufacturer car manufacturing
16	Car refinishing (general)
17	Vinyl matt emulsion
18	Standard alkyd gloss finish
19	Water-borne exterior woodstain
20	Solvent-borne interior/exterior woodstain
A-tables	Others

**All situations that no specific
Emission Scenario can be found**

Identifiers in EU Emission Scenarios “Paints”

IDENTIFIER



#	EMISSION SCENARIO	Substrate	App. Techn.
15	Original equipment manufacturer car manufacturing	X	
16	Car refinishing (general)	X	
17	Vinyl matt emulsion	X	
18	Standard alkyd gloss finish	X	
19	Water-borne exterior woodstain	X	
20	Solvent-borne interior/exterior woodstain	X	

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

Example of Substance

1 Siccative for paints and printing inks

Classification codes for Function:

Component 4	EU	EPA	KEMI	SPIN
Paint additives				M08100
Component Subgroup	EU	EPA	KEMI	SPIN
Driers		317		
Function	EU	EPA	KEMI	SPIN
Active driers				
Auxiliary driers				
Combination driers				
Co-ordinative driers				
Drying agents				T20100
Primary driers				
Secondary driers				
Siccatives				
Surface driers				
Trough driers				

Example of Substance

2 Corrosion inhibitor and EP-additive for lubricants

Classification codes for Function:

EU	EPA	KEMI	SPIN	Description
				Corrosion inhibiting additives
				Corrosion inhibiting agents
14	323	661		Corrosion inhibitors
			E20100	EP-additives
		1051		Extreme pressure additives
	195	1052		Lubricant additives
35				Lubricants and additives

Example of Substance

SPIN codes for Function in Data Base:

"UC62"	Description	
B14	Corrosion inhibitors	✓
B20	Fillers	?
B35	Lubricants and additives	✓
D59	Paints, laquers and varnishes	

Product

Example of Substance

SPIN codes for Function in Data Base:

"National"	Description
15	Dyestuff, pigments
23	Lubricants
470	Paints, varnishes
1050	Lubricants
1151	Caulking compounds
M0500	Paint, lacquers and varnishes
M0560	Primer
M0570	Anticorrosive paints
R2000	Anti-corrosion materials

Products

Example of Substance

SPIN codes for Industrial Sector in Data Base:

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

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.

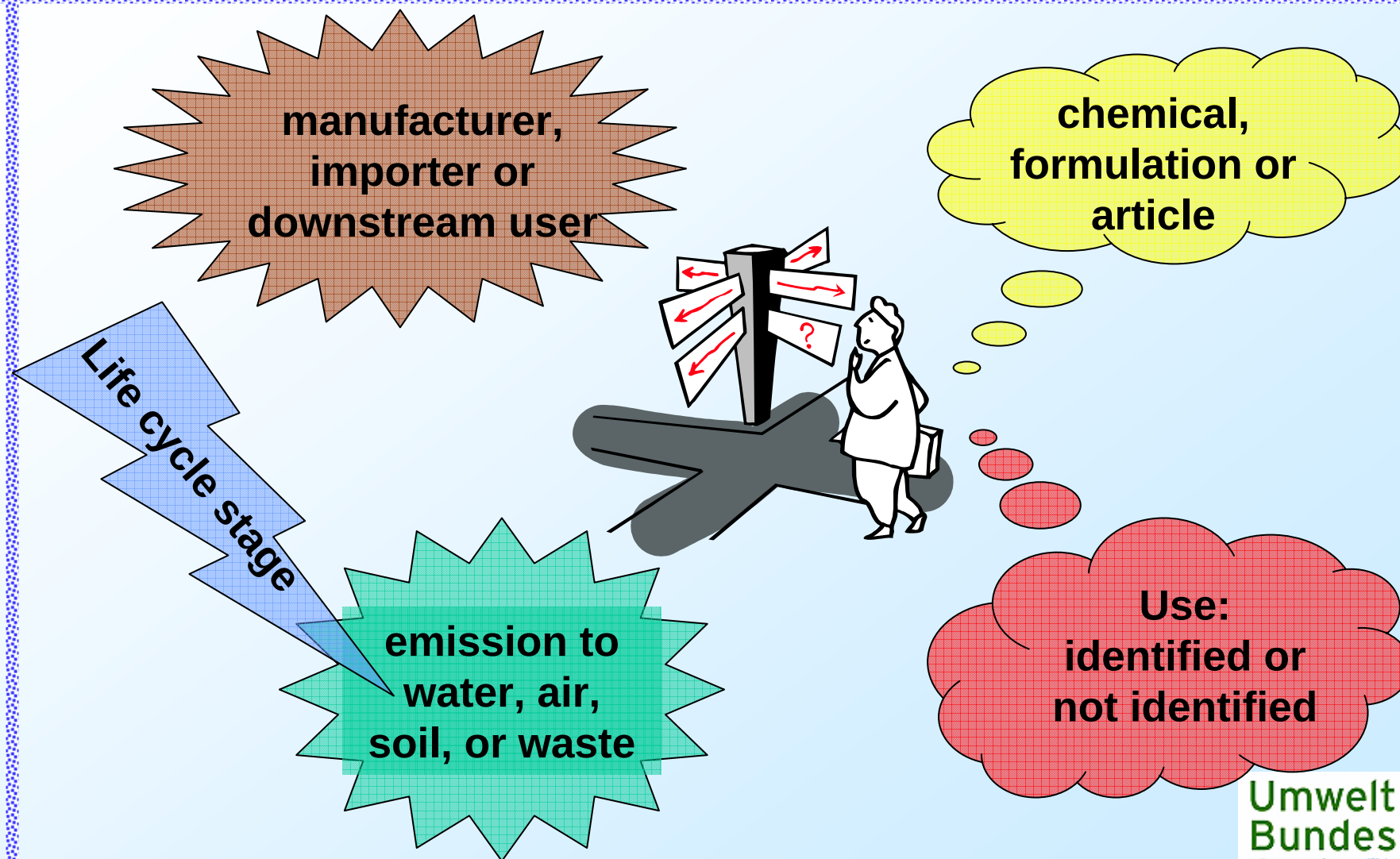
Current exposure estimation

- **EU Technical Guidance Document (2003):**
 - (1) estimation of local emissions → A-/B-tables, emission scenario documents (ESDs) → E_{local} in kg/d;
 - (2) degradation, transformation, distribution → various fate models → SimpleTreat, SimpleBox etc.;
 - (3) estimation of the predicted environmental concentration for each compartment → $PEC_{\text{compartment}}$ 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?



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:

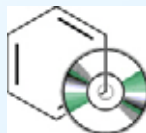


RIVM Expert Centre
of Substances

Project management:



Project B: Consortium



Chemie Daten



Steering group:

- OECD TFEEA
- Industry representatives
- Authority representatives



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.

Matrix

IC/ UC	ESD	Life cycle stages								Environmental pathway			
		<i>production</i>	<i>formulation</i>							<i>Wastewater</i>	<i>Air</i>	<i>Soil</i>	<i>Disposal</i>
1	Agricultural industry	EU A-/B-Tables											
2	Chemical industry: basic chemicals	EU A-/B-Tables	EU A-/B-Tables	EU A-/B-Tables						X	X	X	
3	Chemical industry: Chemicals used in synthesis	EU A-/B-Tables	EU A-/B-Tables	EU A-/B-Tables						X	X	X	
4	Electrical/electronic industry	EU A-/B-Tables	EU A-/B-Tables	EU A-/B-Tables						X	X	X	
5	Personal/domestic	EU A-/B-Tables	EU A-/B-Tables			EU A-/B-Tables				X	X	X	X
6	Public domain	EU A-/B-Tables	EU A-/B-Tables	EU A-/B-Tables						X	X	X	
7	Leather processing industry (Draft)	EU A-/B-Tables	EU A-/B-Tables	OECD ESD						X	X	X	
8	Metal finishing (release model)	EU A-/B-Tables	EU A-/B-Tables	OECD ESD				OECD ESD		X	X		X
9	Mineral oil and fuel industry			EU A-/B-Tables		EU A-/B-Tables							

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

$$E = \frac{Q_{product} * C_{chemical} * F_x * \sum_{j=1}^n (1 - F_{abatement})}{T_{emission}}$$

with

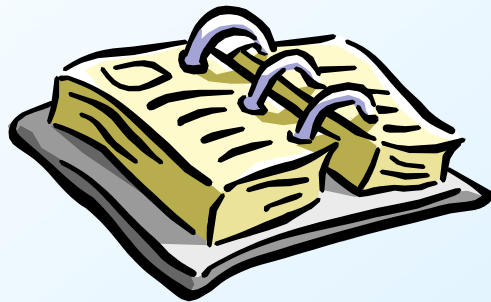
E	emission rate [kg a ⁻¹]
Q _{product}	the quantity processed or used per time [kg d ⁻¹]
C _{chemical}	the concentration of the chemical in the product [kg kg ⁻¹]
F _x	relevant emission factor [--]
F _{abatement}	any relevant emission factor for on-site abatement [--]
T _{emission}	the emission period [d a ⁻¹]

Generic and specific estimation

Input	M/I generic	DU 1 specific	DU 2 specific
Q_{product} [kg d ⁻¹]	1.000	500	1.000
C_{chemical} [kg kg ⁻¹]	0.2	0.2	0.5
F_x [--]	0.1	0.1	0.2
$F_{\text{abatement}}$ [--]	0	0	0.5
T_{emission} [d a ⁻¹]	365	365	250
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:

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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





Navigation was easy by following Viking-Ships and Götakanal Steamers

Part of the former Federal Health Office (BGA 1994, BgVV 2001)

- Staff ca. 600 Co-workers,
ca. 150 Scientists
- Headquarter Berlin
Branch Dessau
- Fields of Working
 - **Foods and other Commodities**
 - **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

- **German Chemicals Act**
- **German Toxicological Network**
- **Documentation of Products**
- **Documentation of Cases**
- **Risk Identification / Risk Assessment**
- **Output**
- **Conclusions**



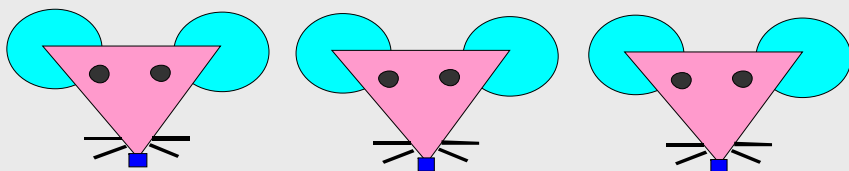
1982: Legislation in the Federal Republic of Germany laid the Foundation of the Chemicals Act in a systematical Assessment of

- 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:

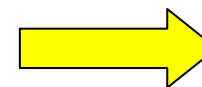
Not to rely only on Animal Data alone!



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 ...



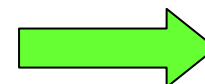
Product Data Base

- **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).



Case Data Base

- **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



Information from PCC

Co-operation between Federal Institute / 10 Poison Control Centres / Industry

Industry



Industrial Associations
Frankfurt / River Main

PCC Göttingen

BfR Berlin
Poison DocCentre

PCC Berlin 1

PCC Berlin 2

PCC Bonn

PCC Erfurt

PCC Homburg

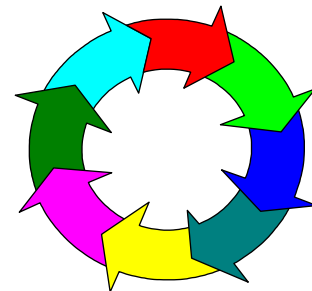
• **Heidelberg**

PCC Mainz

PCC Nürnberg

PCC Munich

PCC Freiburg



Product Data from Industry

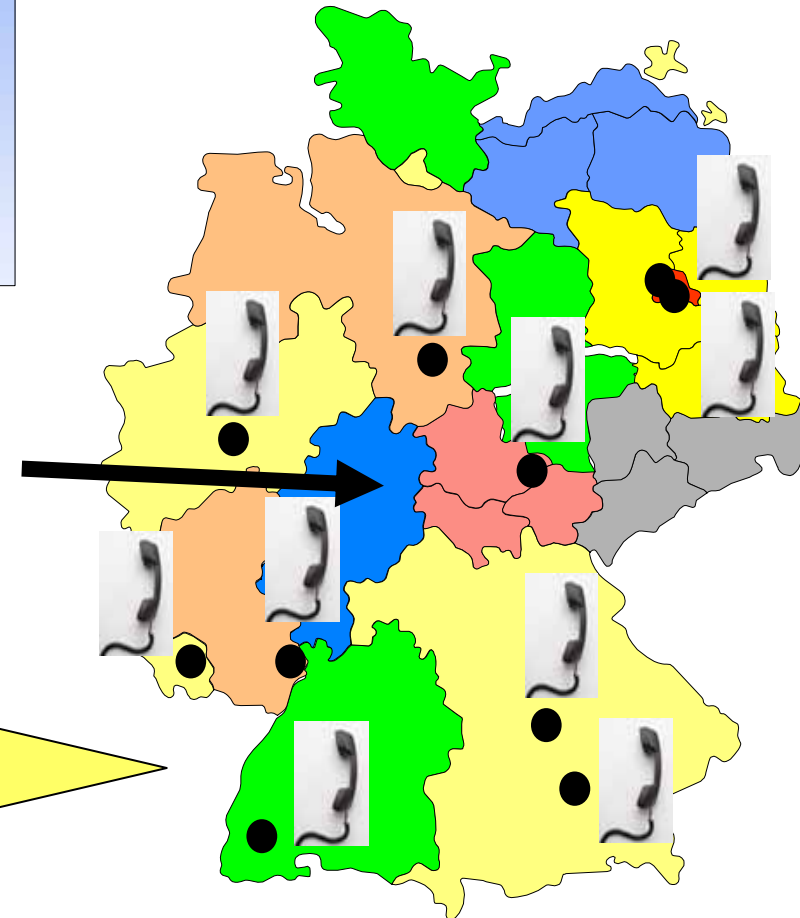


Notifications

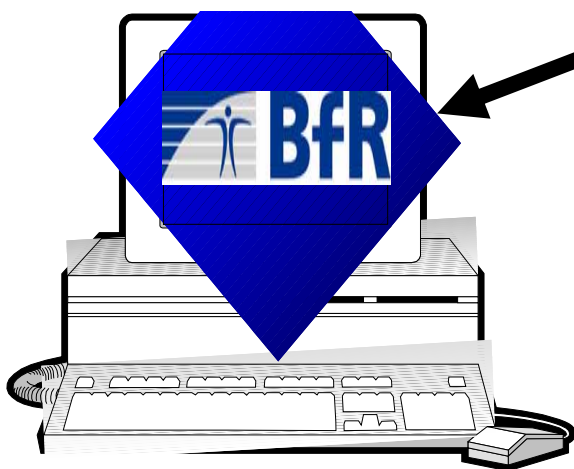
§ 16e
§ 5 d

Voluntaries

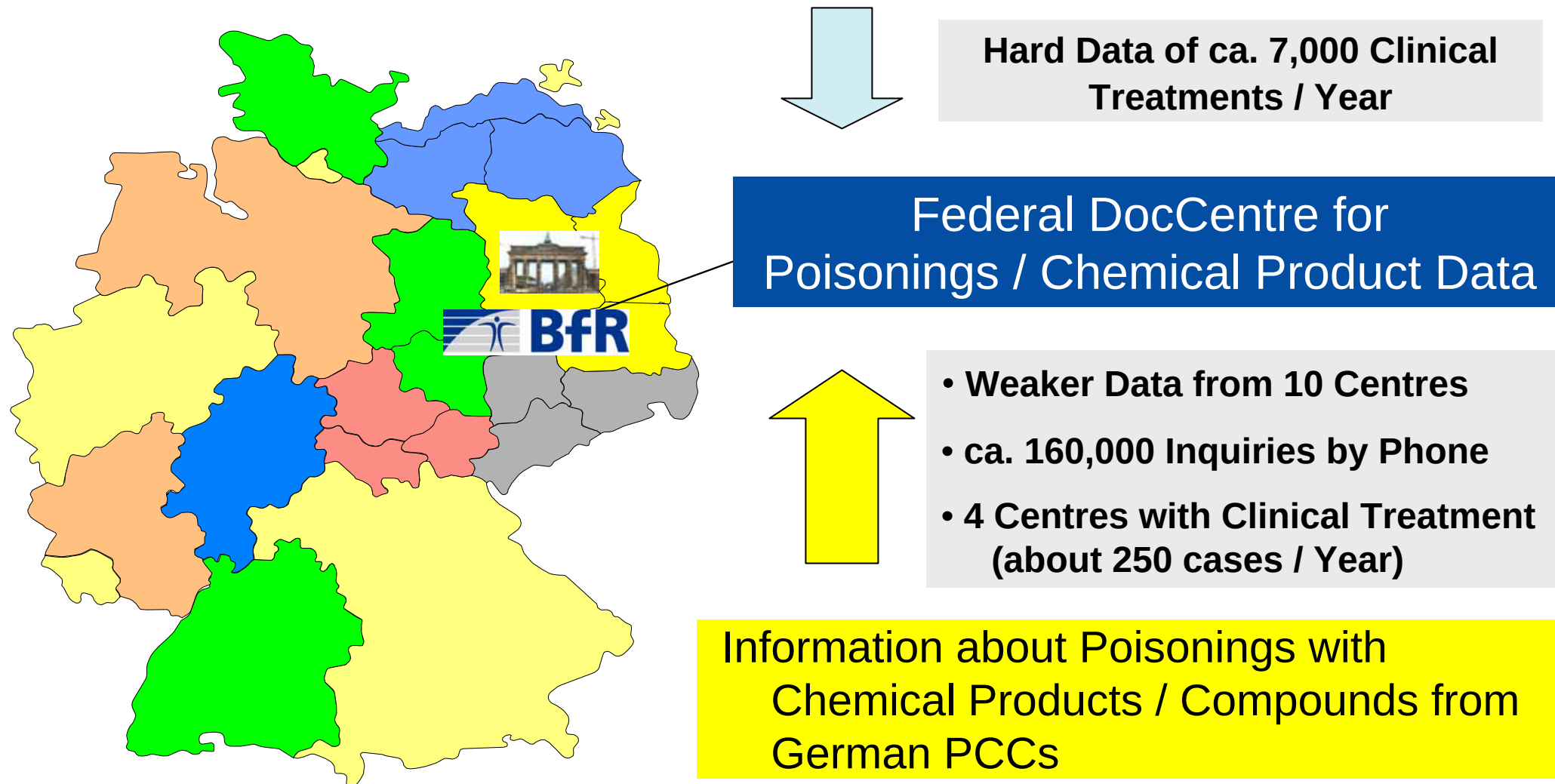
10 German PCCs



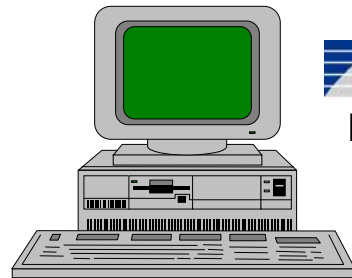
CD-EXPORT PCCs



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



Common Standards for Case Documentation (E.A.P.C.C.T. 1989)

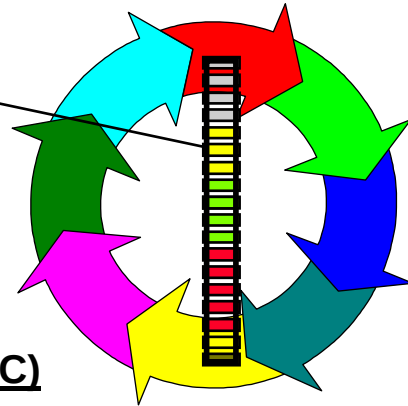


BfR
DoCCentre

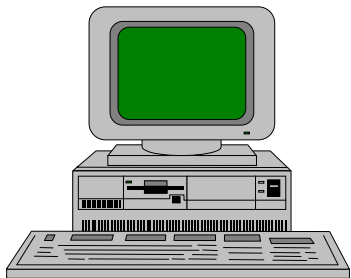
We learn by Exchange of 9,000
Standardized and Harmonized
Case Data Sets under Centralized
Data Maintenance

Standard Data Set

Cases

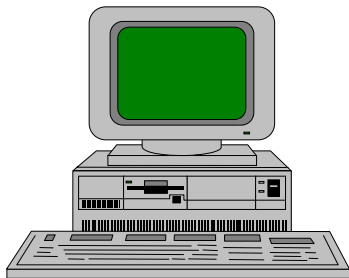


Poison Control Centres (PCC)



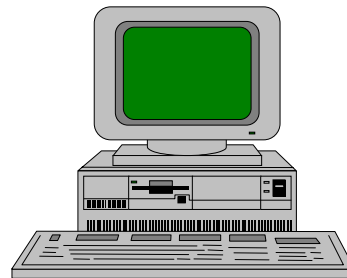
Berlin

50000 Calls /yr



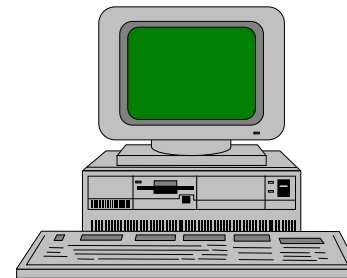
Mainz

24000 Calls /yr



Munich

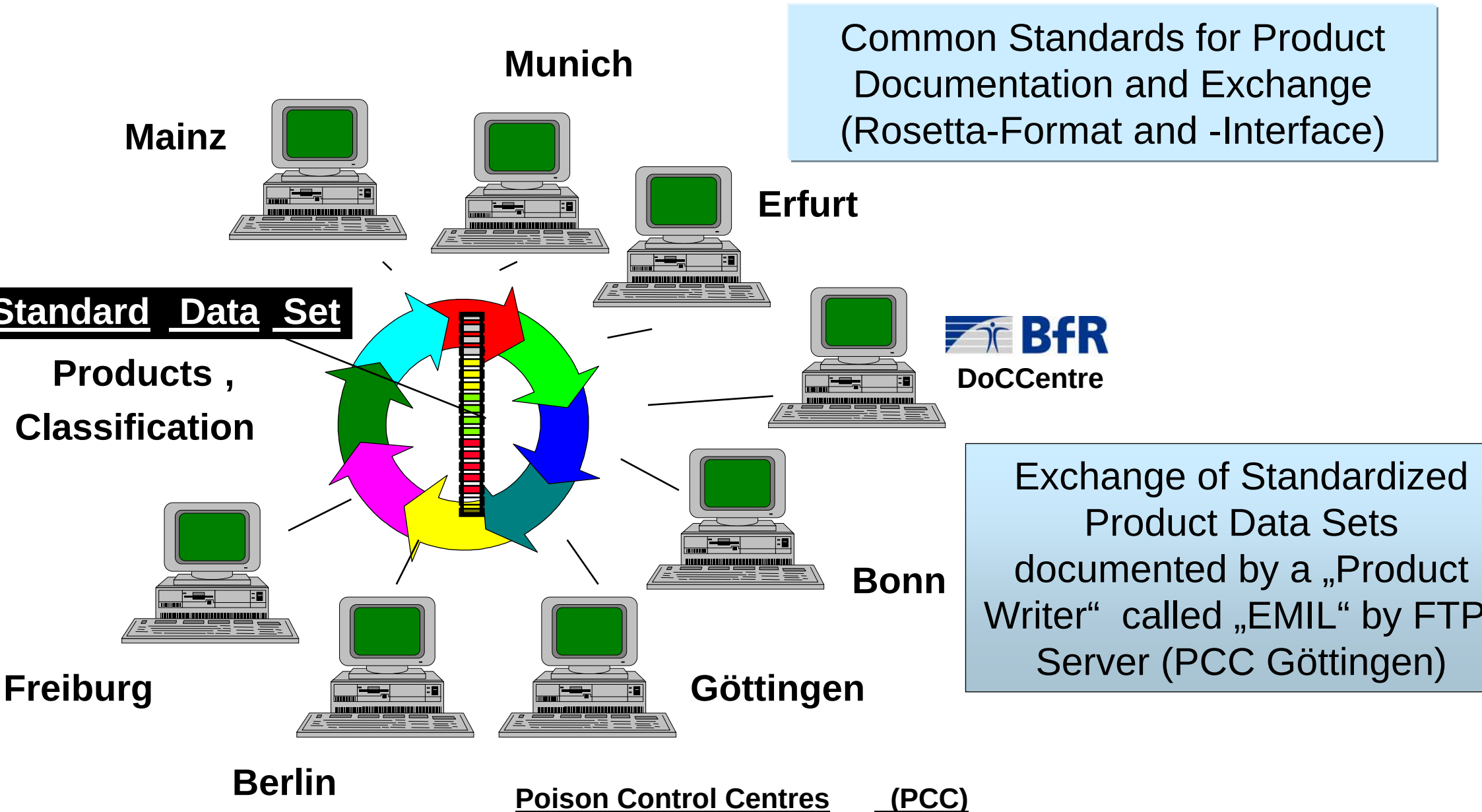
20000 Calls /Yr



Freiburg

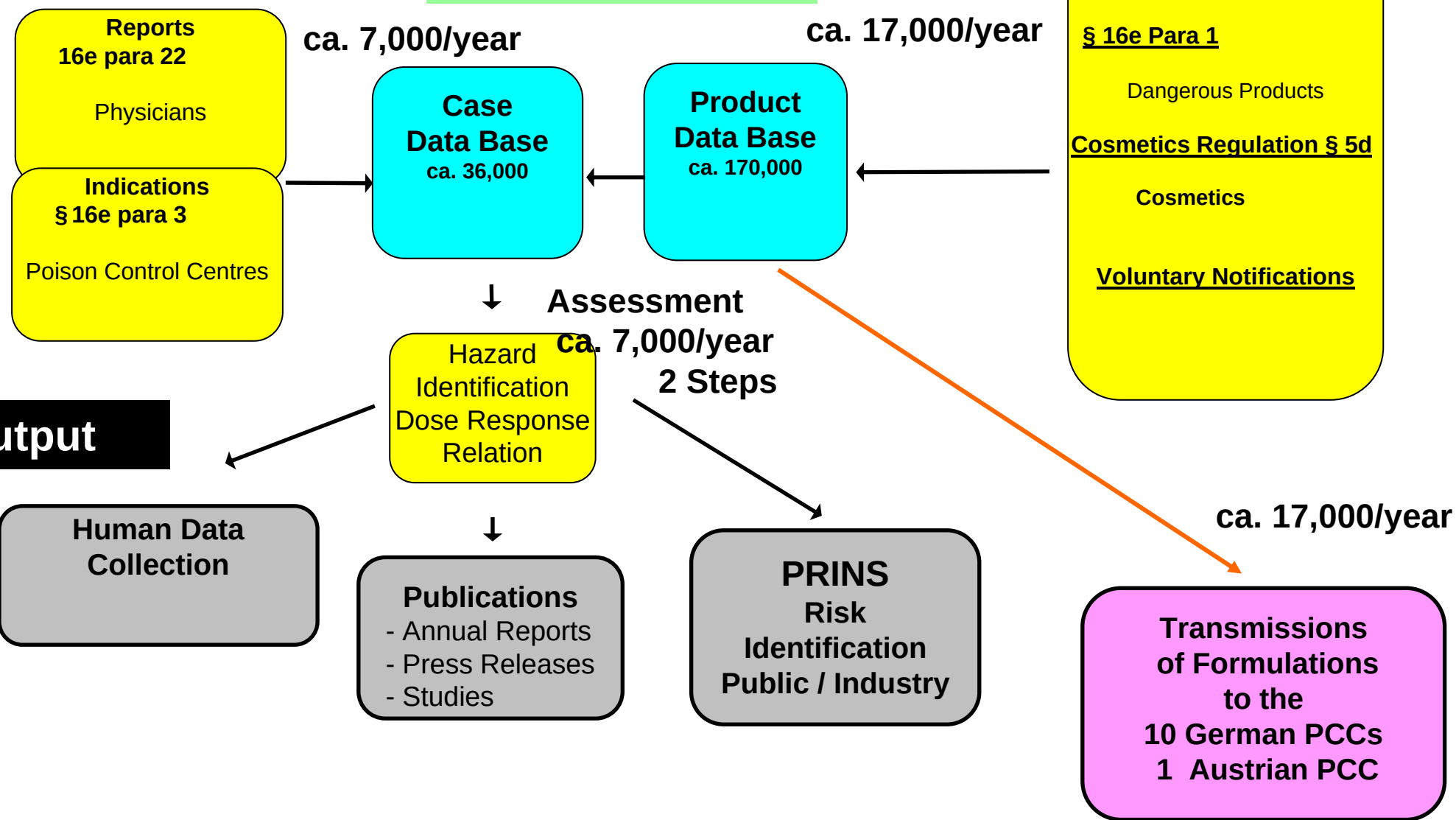
10000 Calls /Yr

Toxicological Documentation and Information Alliance



Input

Formulation Check!



Autoplus Öl Addit Mittelkarte NR. 18449
Reibungs- und Verschleißschutz

Hersteller LUBRICHEM Zubereitungsnummer: 00167530/01/0/1

Vertreib CH 1701 Fribourg

Beschaffenheit flüssig, grünlich Verwendung Motoröl Additiv
PN 2025

Anteil (in %)	Bestandteile (Angaben des Herstellers)	Stoffkarten des B G V V
3	Zinkdithiophosphat	In Vorbereitung
71,6	Mineralöl (150 Neutral)	Paraffinöle
20	Hitec 5757	
	* s. bes. z. beachten!	
5	Molyvan L	In Vorbereitung
	** s. bes. z. beachten!	
0,4	Covan 826	
	*** s. bes. z. beachten!	

Besonders zu beachten

* Hitec 5757: lt. SD-Blatt des Herstellers:
keine Angaben zu Inhaltsstoffen, LD50 oral Ratte: > 4000 mg/kg - 2 -

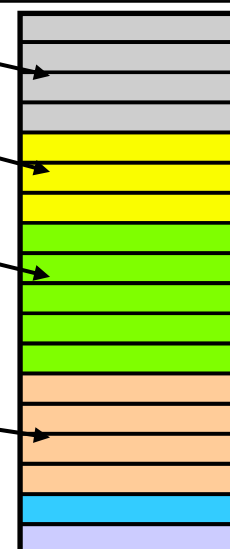
keine Haut- und Augenreizung zu erwarten

** Molyvan L: lt. SD-Blatt des Herstellers:
enthält Molybdäni(2-ethylhexyl)phosphordithioat (unlösliche Verbindung) gemischt mit Petroleumpräparat.
LD50 oral Ratte: 7350 mg/kg.

*** Covan 826: lt. SD-Blatt des Herstellers:
enthält 3,5-Dimercaptan-1,3,4-thiadiazolderivat
LD50 oral Ratte: > 5000 mg/kg

Vom BgVV an die GIZ. Nur für Ärzte! STRENG VERTRAULICH! Stand: 02.04.97

Product Data Set

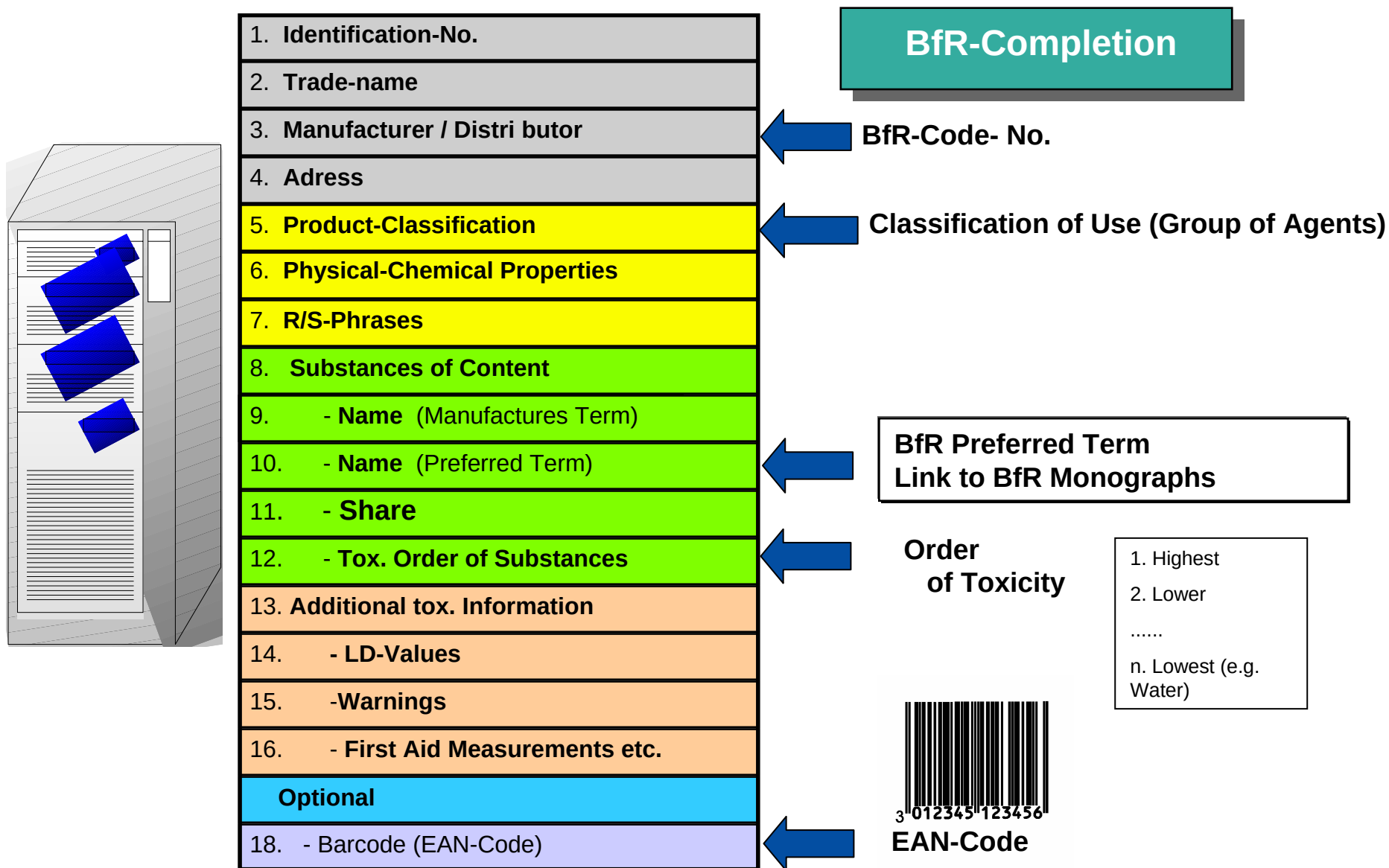


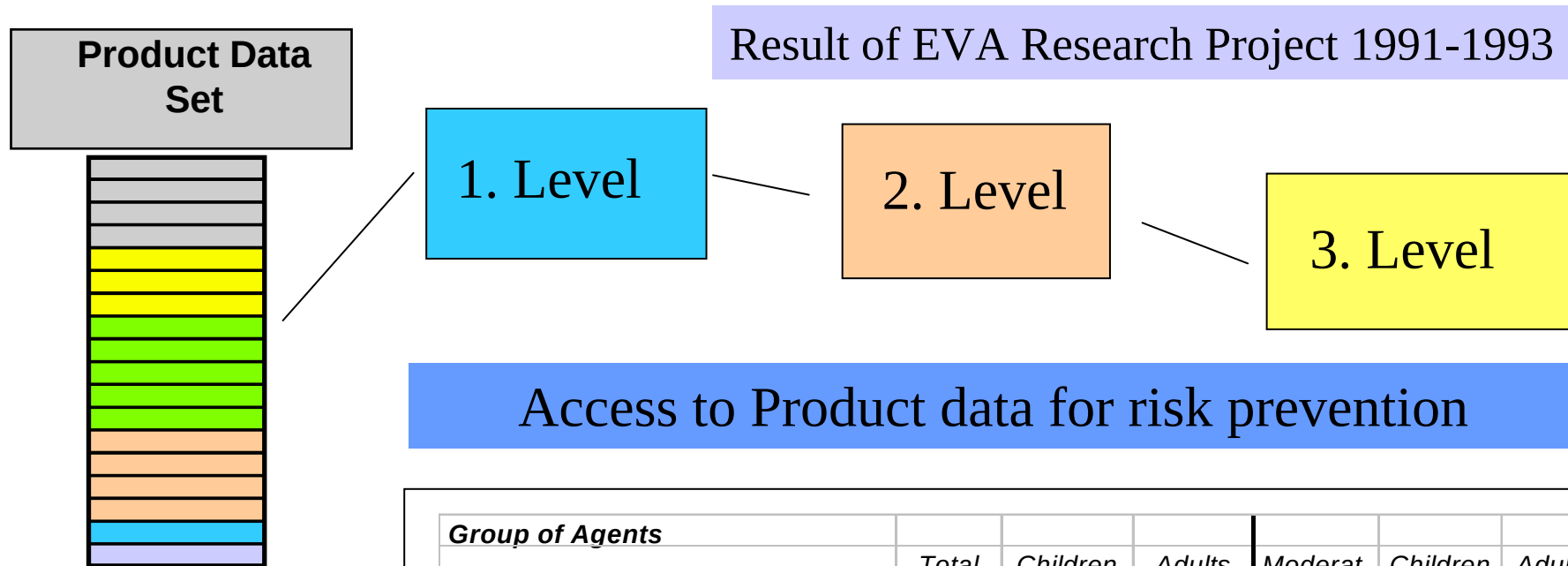
Identification

Classification

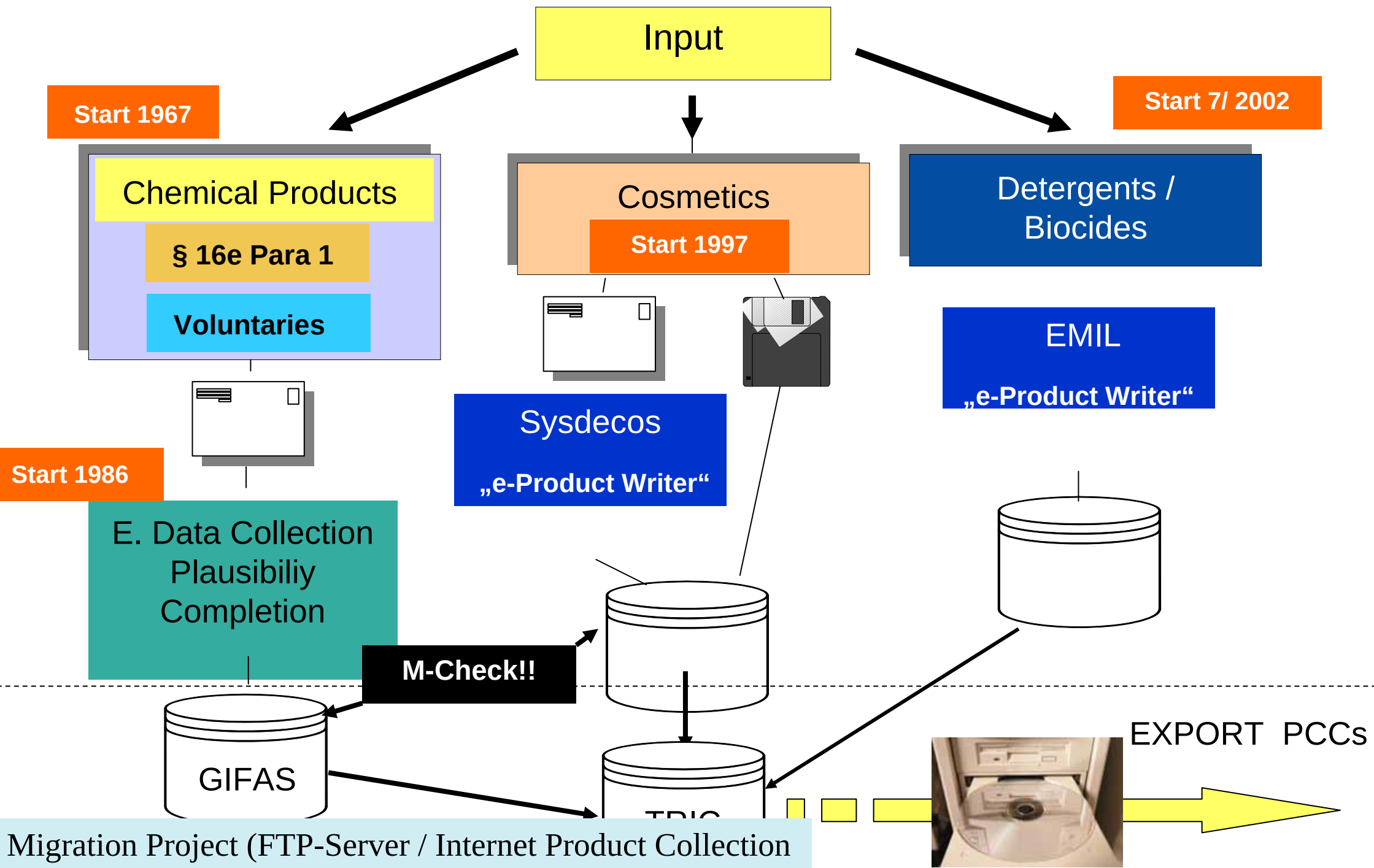
Composition

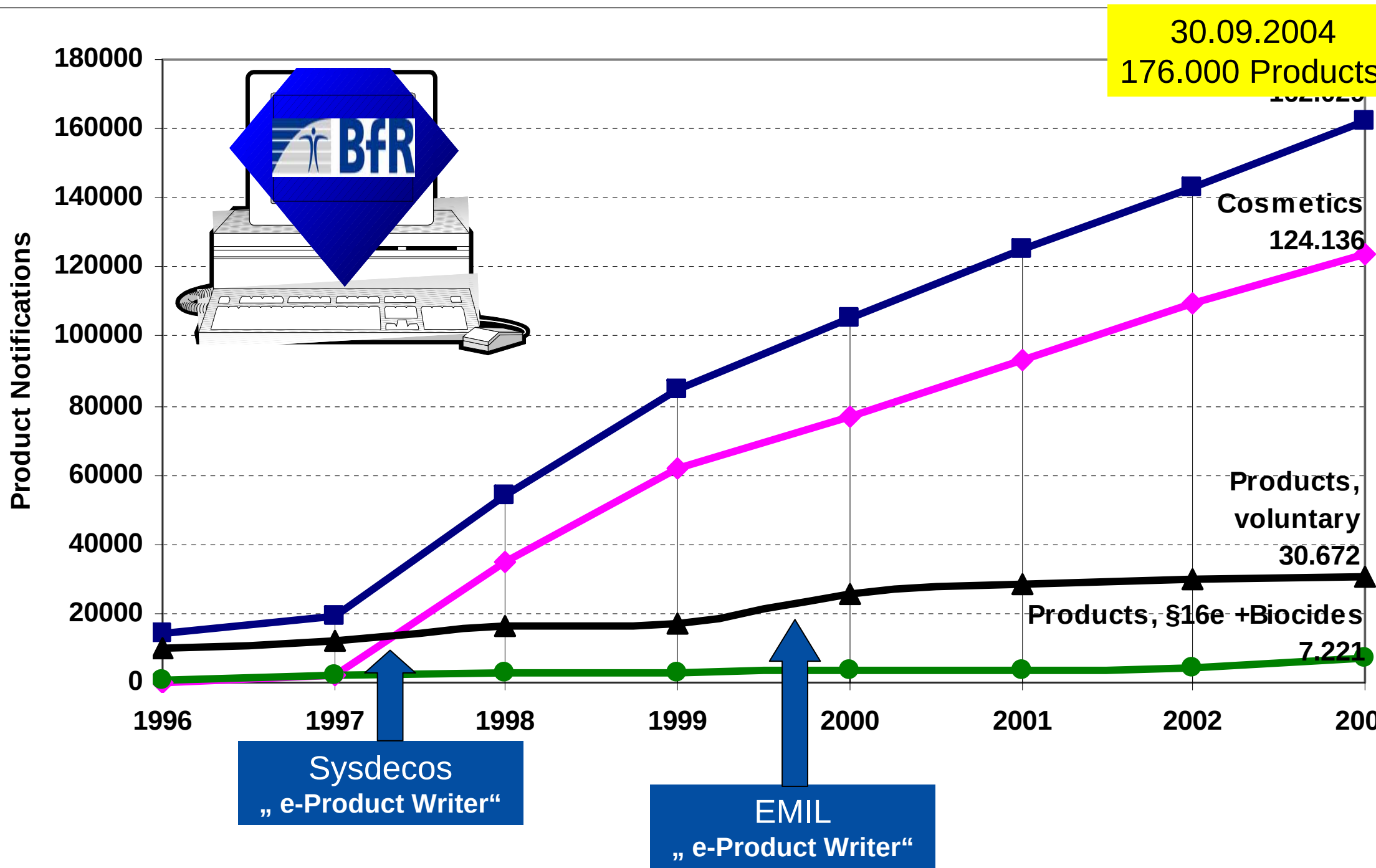
Tox. Information



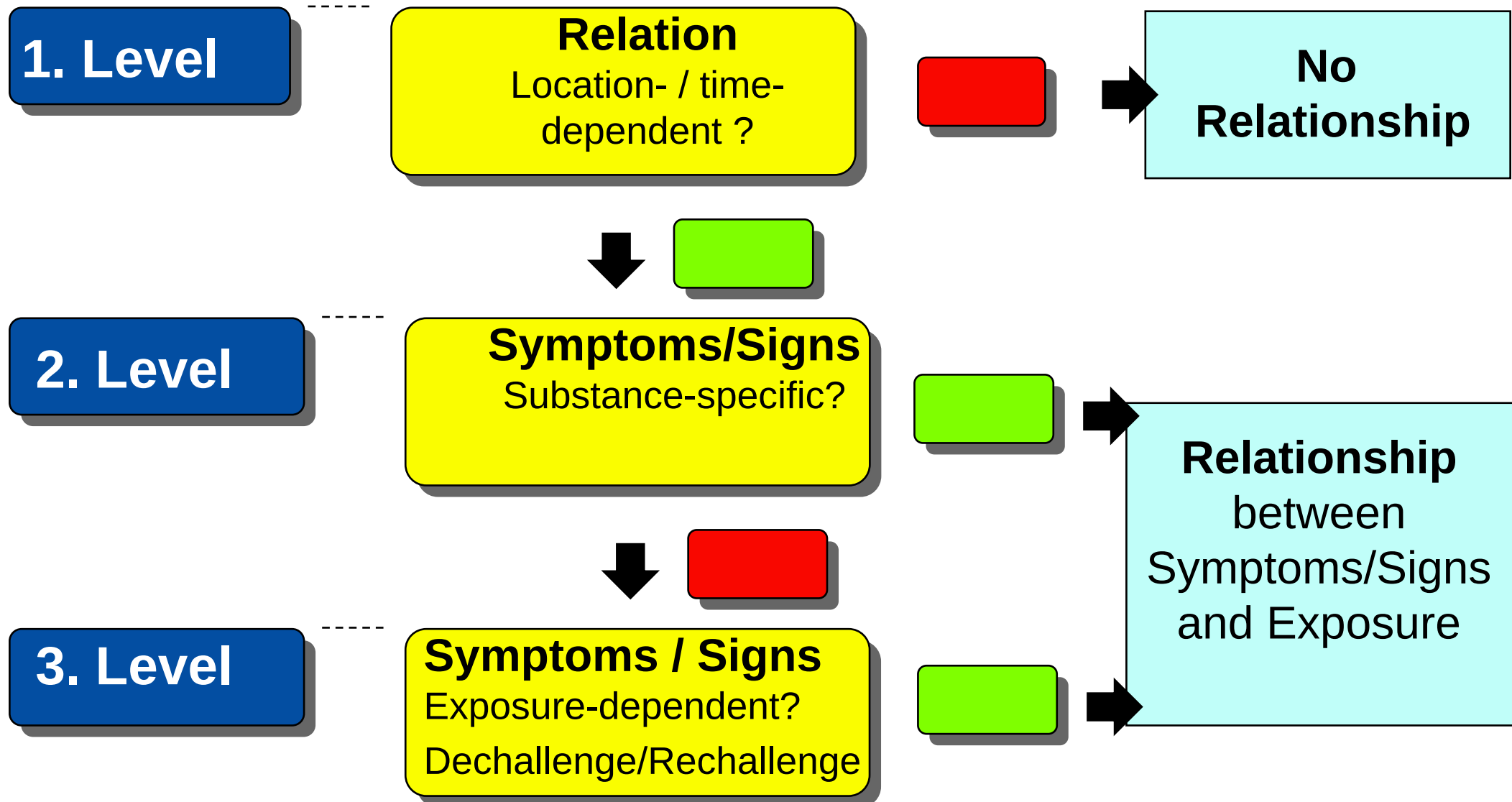


Group of Agents	Total	Children	Adults	Moderate/severe poisonings	Children	Adults
<i>First level</i>						
<i>Second level</i>						
<i>Third level</i>						
<i>I. Pharmaceutical products</i>	940	388	589	301	69	230
<i>II. Veterinary medicines</i>	10	6	4	3	2	1
<i>III. Chemical products</i>	1095	420	662	325	126	197
Paints and related products	127	32	94	44	5	38
Paint removers / strippers	5	5		4		4
Alkyd resin paints	3		3	2		2
Emulsion paints	1		1	1		1

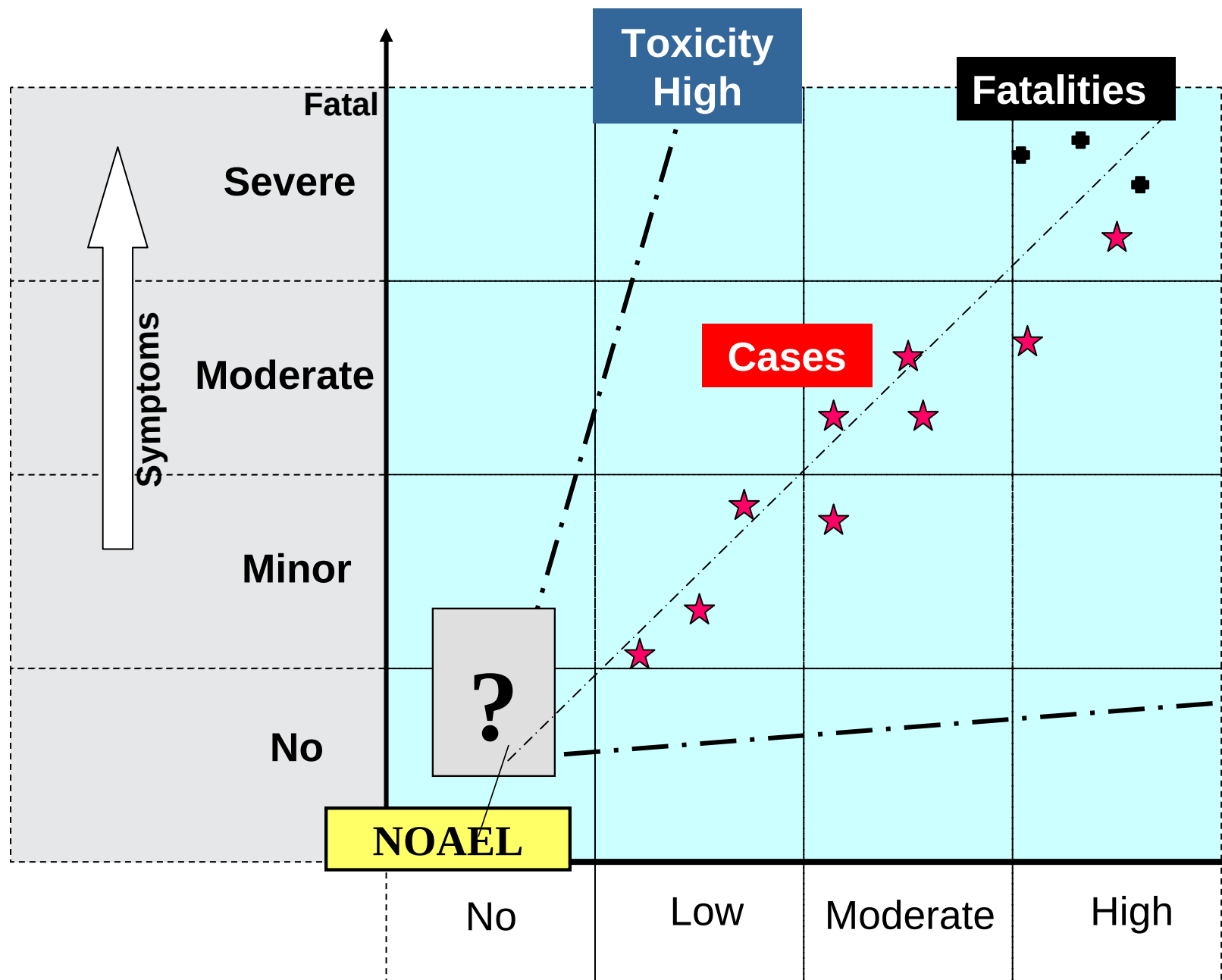




3 Level-Model for the „Substance of Main Toxic Relevance“



Degree: Severity of Health Disturbance (Tox. Score)



Old Paracelsus
(1493-1541)

Product / Case Data



Risk Identification

for

**Government, Manufacturers,
Distributors, Associations**

Immediate Reports

Criteria :
Serious Health Effects

Summarized Reports

Criteria :
Minor Health Effects



**Within 14 Days after
Completion of the Data**

Public Press Releases



**Annually: „Blue Letters“ for
Manufactures and Distributors in the
first two Months of each Year**

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

for Government, Manufacturers, Distributors, Associations

Year	Product	Substance of toxic relevance	Age Group	Outcome	Proposals BfR (P) and Results (R)
1998	Waterproofing Agent	Fluoridated HC	Adult	Death	V: Warnings R: Accepted
1998	Disinfectant	Quarternary Ammonia-Compound (Detergent)	Elderly	Death	V: Information, R: Labelling „Corrosive“ R: Accepted
1999	Draincleaner	Sodiumhydroxide	Adult	Burns	-
1999	Solvent	Naphta	Adult	Edama of the Lungs	-
1999	Depilation - Creme	Thioglycolic Acid	Adult	Scars	-
1999	Disinfectant	Quarternary Ammonia-Compound (Detergent)	Elderly	Death	P: Information, Labelling
1999	Industrial Cleaner	Sodiumhydroxide	Infant	Burns	P: Information
1999	Drug	Dimenhydrinate	Toddler	Death	P: Warnings
2000	Crème Bath	Detergent	Elderly	Death	P: Information
2000	Lamp Oil	Paraffine	Infant	Severe Pneumonia	P: Prohibition (coloured, perfumed) R: EC Prohibition Accepted Substitutes

for Government, Manufacturers, Distributors, Associations

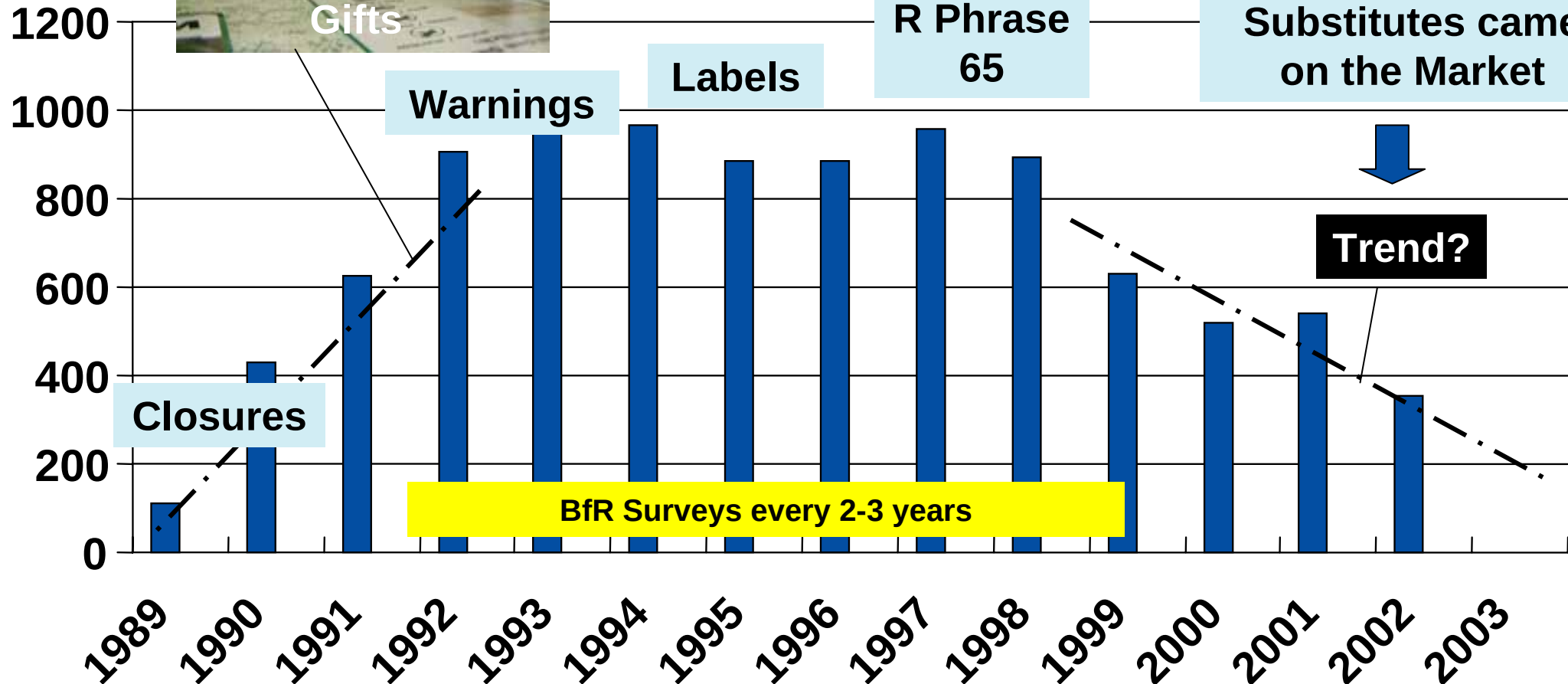
Year	Product	Substance of toxic relevance	Age Group	Outcome	Proposals BfR (P) and Results (R)
2001	Disinfectant	Alkylamine (Detergent)	Elderly	Death	P: Information
2001	Tea (Herbal Drug)	Atropa belladonna	Adolescent	Breath Depression	P: Information
2002	Sanitary-Cleaner	Detergent	Elderly	Burns	P: Information
2002	Mild Detergent	Detergent	Elderly	Death	P: Information
2003	Cleaner	Detergent	Elderly	Breath Depression	P: Information
2003	Dietary Supplement	Proteins	Adult	Severe Allergy	P: Information
2003	Gassing Product	Sulfuryldifluoride	Adult	Death	P: Information
2003	Drain Cleaner	Potassiumhydroxide	Child	Severe Burns	P: Information
2003	Disinfectant	Peracetic Acid	Adult	Breath Depression	P: Information
2004	Lamp Oils	Paraffine	2 Infants	Death	P: EC-Prohibition of all Lamp Oils

Risk Assessment / Mangement Steps



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

PCCalls



for Manufacturers, Distributors, Associations

Group of Use	2002	2003	Lower Levels	2002	2003
Pesticides	84	41	Insecticides	37	27
			Herbicides	34	10
Cosmetics	26	24	Skin Cosmetics	16	19
			Cremes/Lotions		8
			Bath oil/Bath pearls		5
Cleaners	161	112	Milk Machine Ccleaners	15	13
			Oven Cleaner	10	1
			Drain Cleaners		3
			General Purpose Cleaners	7	3
			Industrial Cleaners	24	9
			Sanitary Cleaners	14	12
			Dishwasher Detergents	7	7
Disinfectants	68	62			
Fuels, liquid	38	24	Lamp Oils	38	22
Construction materials	12	7			



AS Ultra

What is the real Trade- / Indexname for retrieval in a Product- Databases?

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



EC Standardization (CEN) 2006?

Bar-Code



Label

Product Identification Area

- **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!

Potsdamer Platz Berlin



Questions?



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

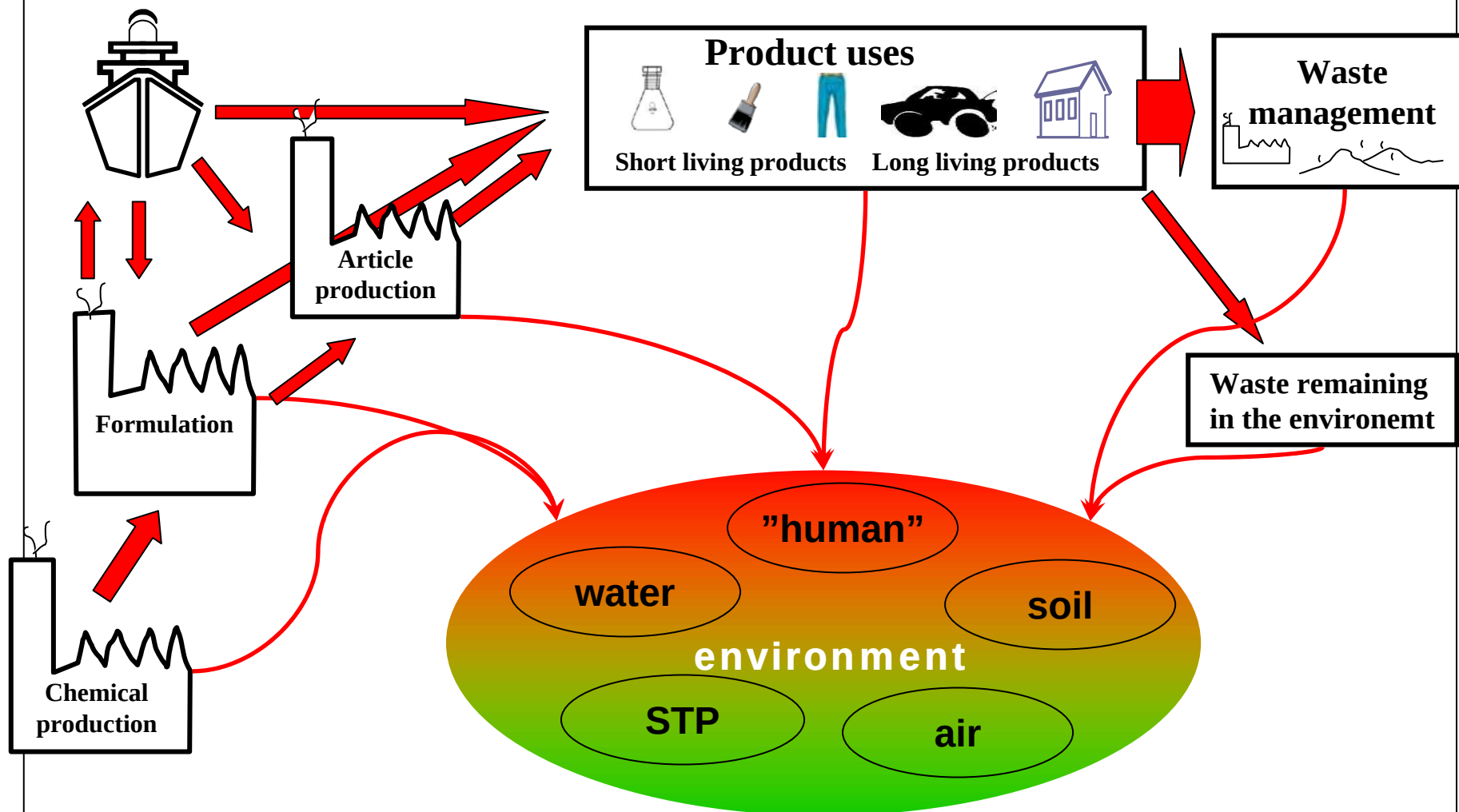
- National monitoring program:
 - Regulated and/or banned substances
- Request for new candidates:
 - Primary recipients for diffuse sources
- New criteria: Hazard → Risk:
 - Risk = Hazard * Exposure
 - Exposure: Quantity, Use pattern and others
 - Use pattern source: The Swedish **Product Register**

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



Pilot study 2002

- Database capacity check
- Correlation: use pattern $\leftrightarrow$ 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%)
(hazardous substances: <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

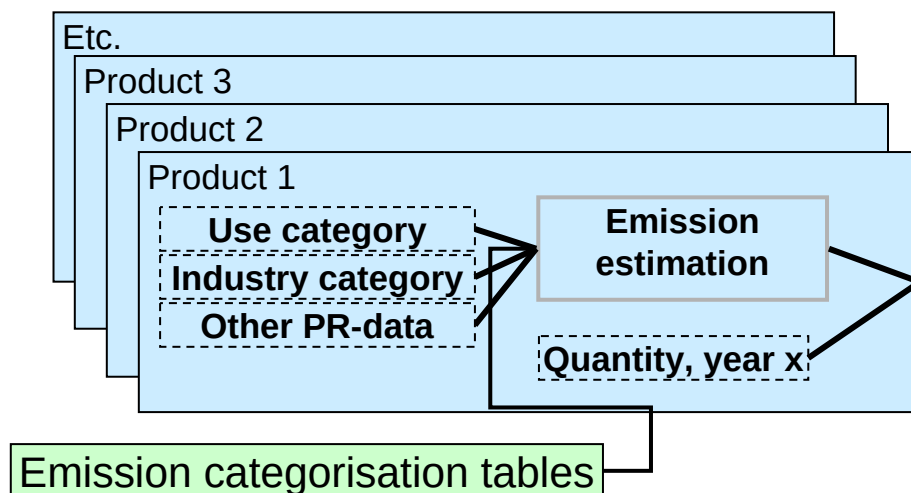
(urban areas)

- Air
- Soil
- Surface water
- STP
- “Human”

(sewage treatment plant)

(dermal, inhalation, ingestion etc.)

Emission estimation - product level

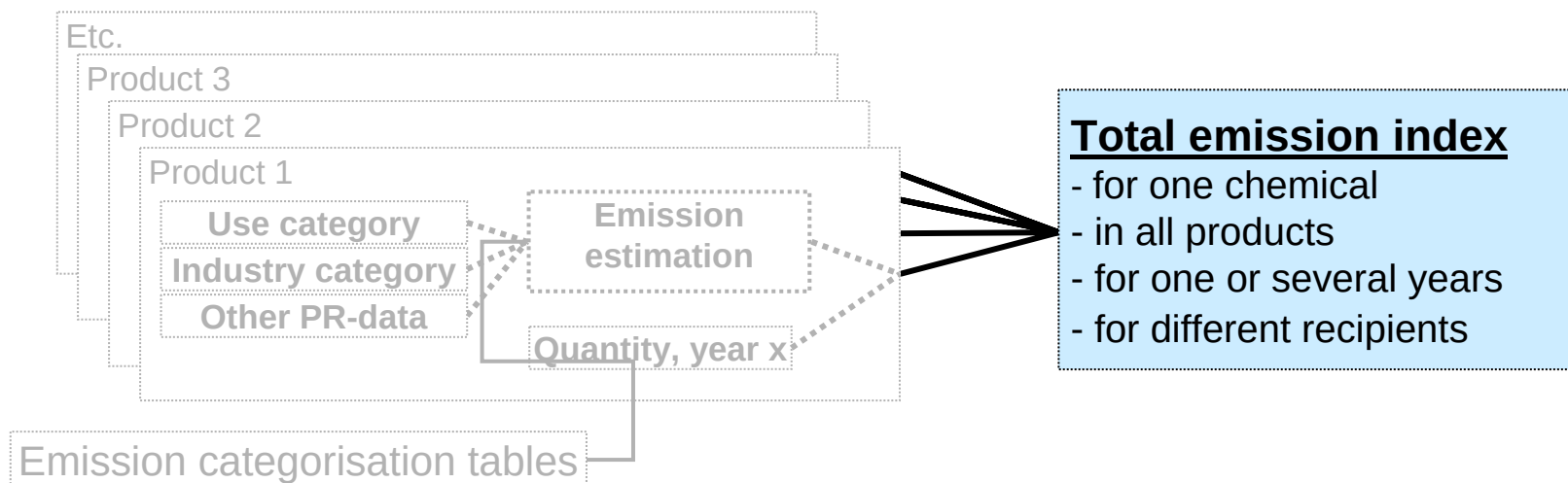


Emission categorisation tables, examples

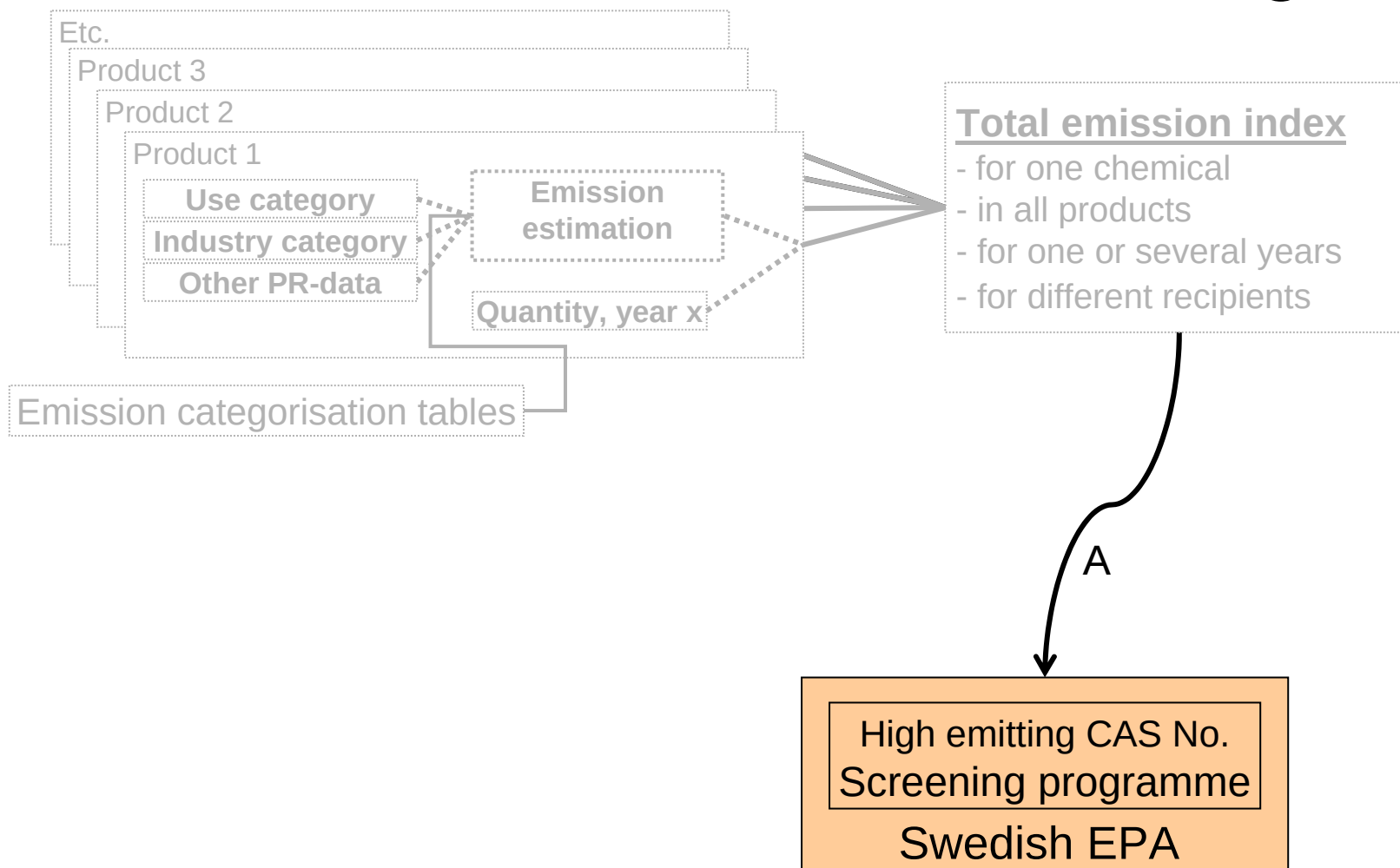
Use information		Emission potential low – medium – high				
		Recipients				
		Air	Surface Water	Soil	STP	"Human"
Use Category*:	Sealing materials	Medium	Low	Low	Medium	High
Use Category:	Fertilizers	Low	High	High	High	High
Industrial Category:	Washing and dry-cleaning of textile and fur products.	Low	Low	Low	Medium	Medium
Industrial Category:	Construction	Medium	Medium	Low	Medium	Low

* UC-Nordic

Emission estimation – per year



Candidates for monitoring



Candidates for monitoring

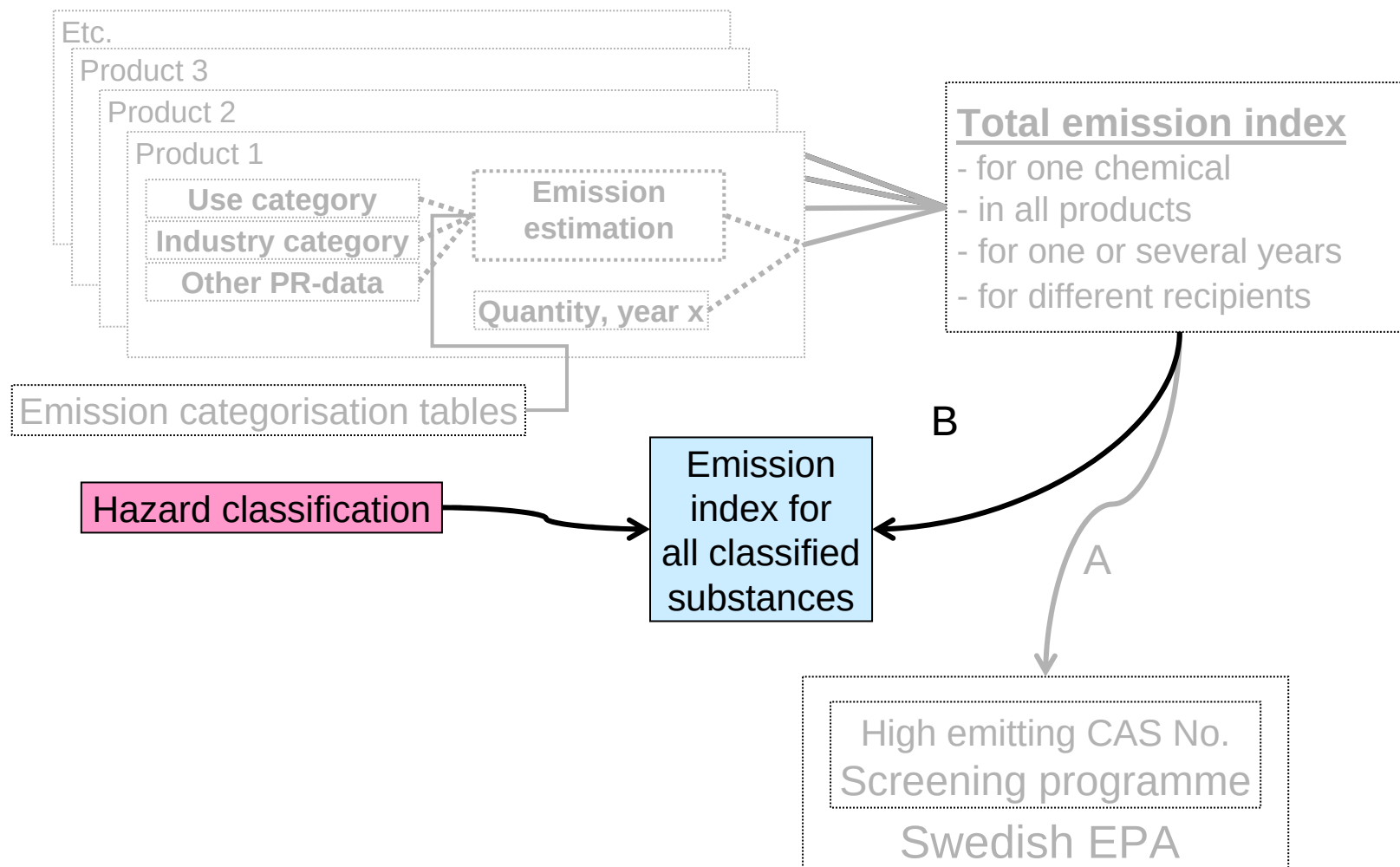
- “Screening program”
- Identify of substances with high emission estimation.
- Different primary recipients.
- Identify with substances with increasing trend.

Table of candidates

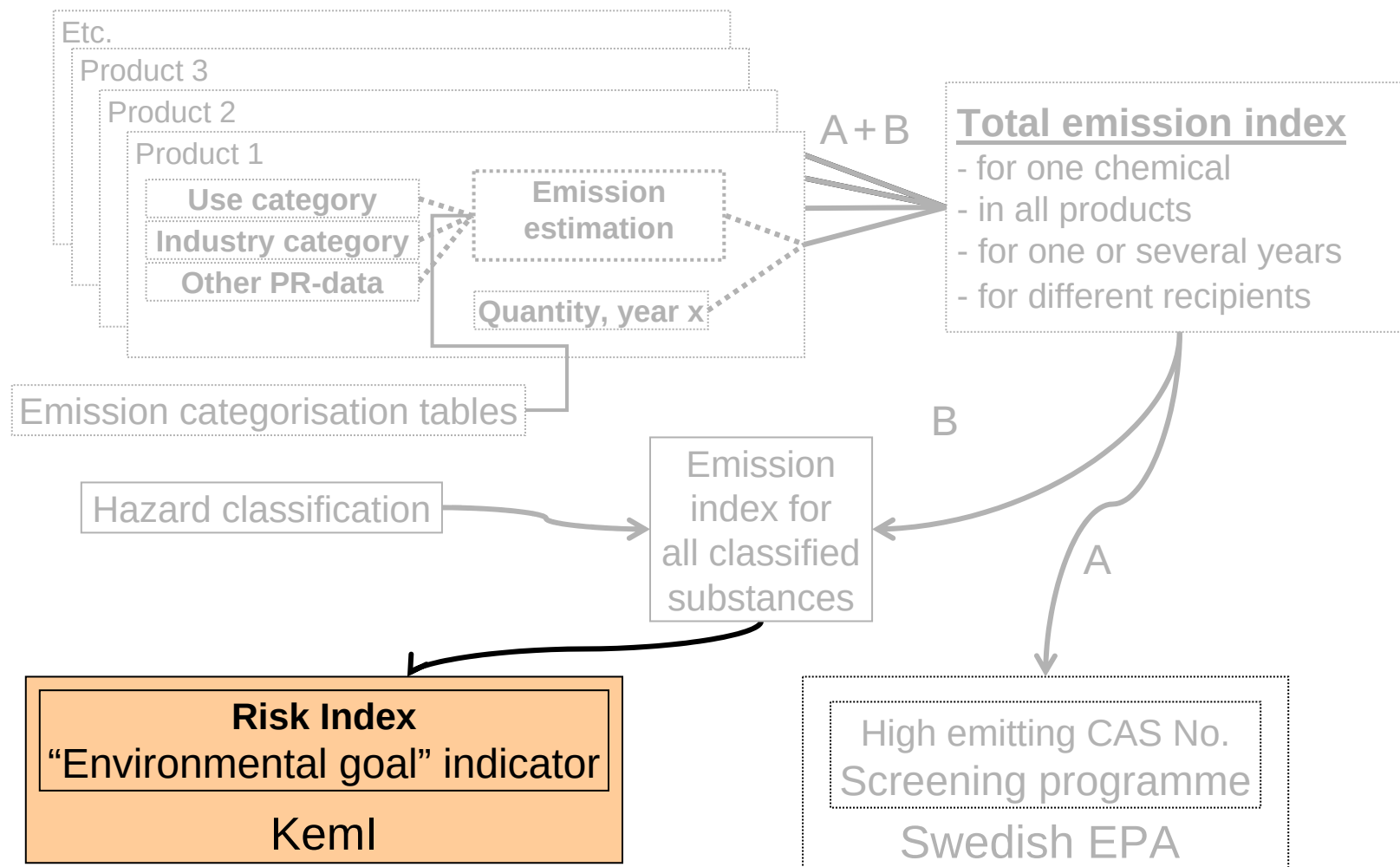
IDENTITY		DISTRIBUTION		USE PATTERN			QUANTITY
CAS No.	Name	Distribution Index	Time Trend *	Use Categories	Industrial Uses	Accumulation in the society	Category
		range 0 – 100	-, /, \	UC-Nordic (3 largest?)	NACE (3 largest?)	Yes= Y No = N	1-2-3
xx-xx-x	Aaaaa	99.6	-	G40100 H10100 F45200	G52.31 H D24.13	N	3
yy-yy-y	Bbbbb	93.5	/	Etc.	Etc.	Y, N	1
zz-zz-z	Ccccc	92.0	\	Etc.	Etc.	N	3
Etc.	Etc.	90.1	-	Etc.	Etc.	Y	2

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

Risk estimation



Risk indicator



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 annual trends for:
 - Human health
 - Environment

* Divided into Human health and Environment.

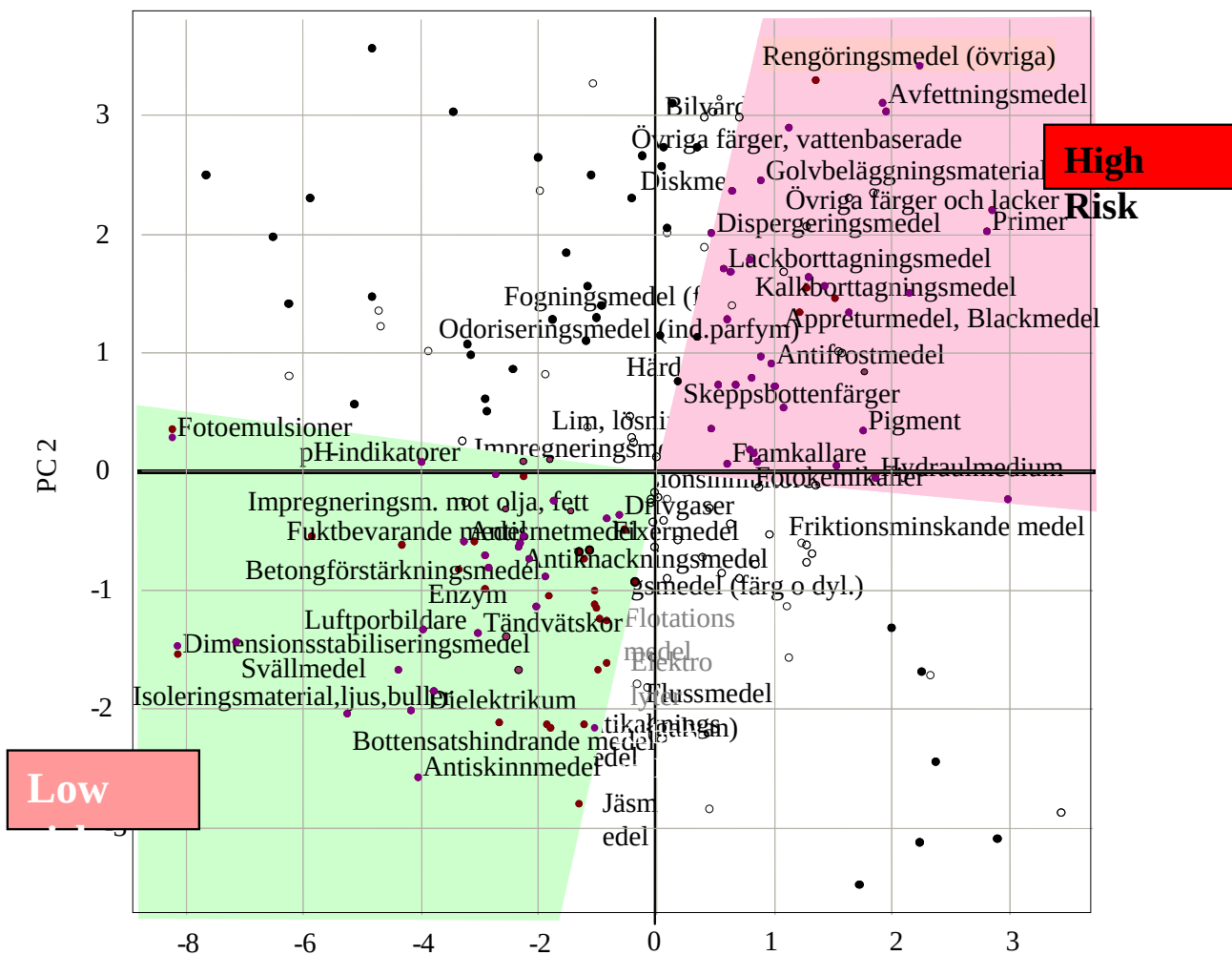
Difficulties

- Changes in the database structure:
 - New Use categories from 2002
- Time trends – significance
- Define recipients
- Double counts – raw materials
- Heterogeneity in Industrial and Use categories

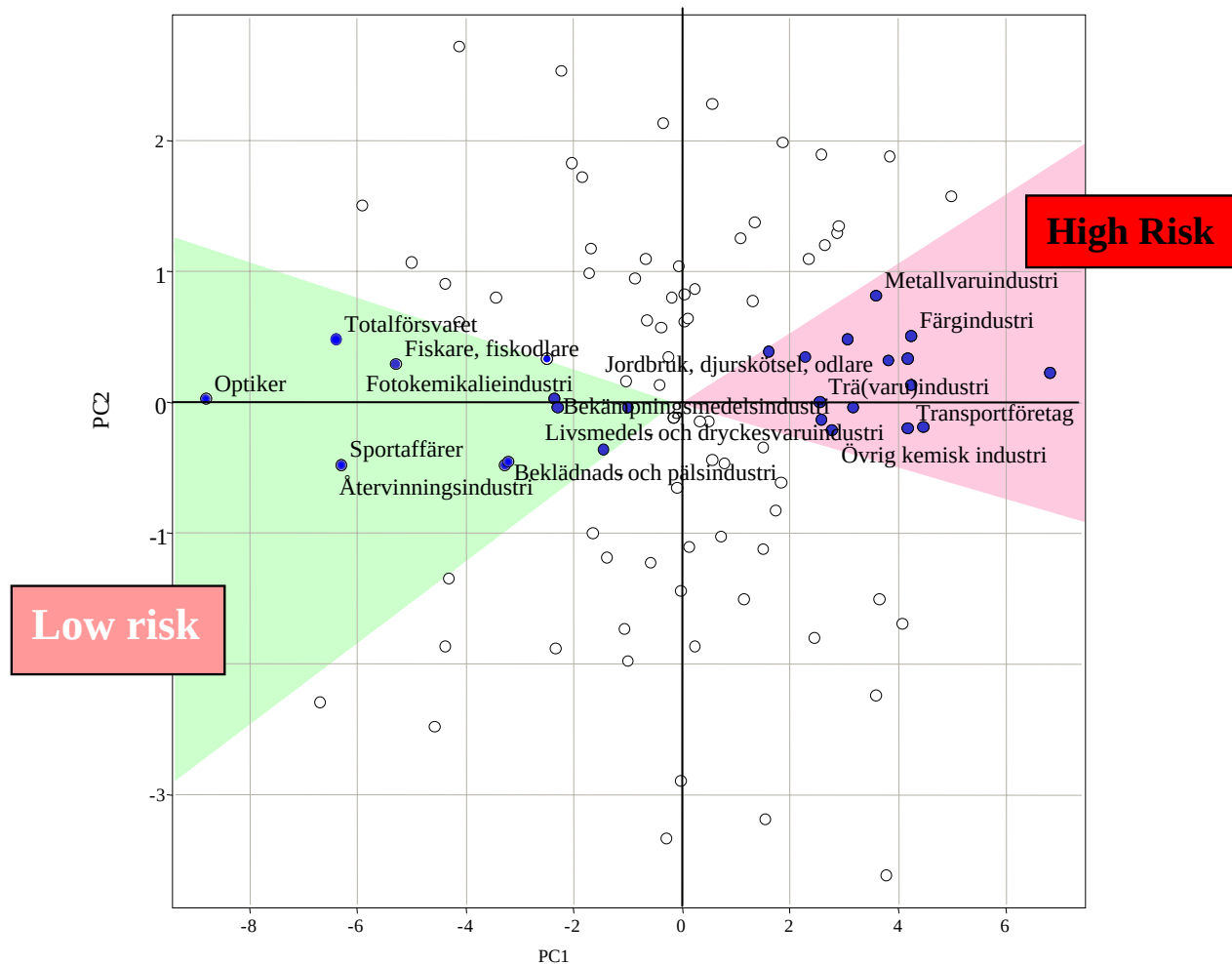
Multivariate analysis

- Part of the pilot study
- Visualize the structure

Multivariate analysis → Use categories with high risk



Multivariate analysis → Industrial categories with high risk





Lim.se
sveriges fog- och limleverantörers förening

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



för en giftfri miljö

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Flödesanalyser

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Publiceringsplan

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Giftfri miljö

Databaser

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Lagar och regler

Klassificering/Märkning

Bekämpningsmedel

Produktregistret

EU & Internationellt

Trycksaker

Ordbok

Länkar

Om Kemi

Om webbplatsen

Toxikologiska rådet

Statistik / Kortstatistik / Produkter och branscher / De tio vanligaste produkttyperna i störst antal 2001

Senast uppdaterad: 2004-08-15

De tio vanligaste produkttyperna i störst antal 2001

Produkttyper	Totalt antal produkter	Total kvantitet, ton
Färger och lacker	5 805	257 014
Smörjmedel	5 050	197 766
Färgämnen, pigment	3 388	195 988
Rengöringsmedel (övriga)	2 319	51 324
Råvara/plasttillverkning	2 160	1 570 616
Syntesråvara (övriga)	1 844	27 636 498
Bindemedel (färg,lim,etc)	1 763	338 872
Avfettningsmedel	1 154	25 962
Lim (övriga)	1 048	46 045
Bindemedel (övriga)	1 030	4 467 693

Källa: Kemi:s produktregister

Det finns många varumärken för olika användningsområden: speciella smörjmedel, färger, rengöringsmedel, avfettningsmedel och lim. De tillverkas i stor utsträckning inom landet och är både hushålls- och industriprodukter.

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

I Sverige fanns under 2001 totalt ca 65 000 kemiska produkter.

3



KEMI
KEMIKALIEINSPEKTIONEN

för en giftfri miljö

Sök

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Flödesanalyser

Kortstatistik

Överblicksstatistik

Statistiska meddelanden

Publiceringsplan

Mer statistik på Internet

Giftfri miljö

Databaser

Statistik

Lagar och regler

Klassificering/Märkning

Bekämpningsmedel

Produktregistret

EU & Internationellt

Trycksaker

Ordbok

Länkar

Om Kemi

Om webbplatsen

Toxikologiska rådet

Statistik / Kortstatistik / Produkter och branscher / De tio produkttyper som hanterades i störst mängd

Senast uppdaterad: 2004-08-15 

De tio produkttyper som hanterades i störst mängd

Produkttyp	Total kvantitet, ton	Totalt antal produkter
Syntesråvara (övriga)	27 636 498	1 844
Drivmedel (för förbränningsmotorer)	16 843 205	210
Uppvärmningsmedel	11 028 773	96
Bränslen, brännolja (övriga)	7 379 210	80
Bindemedel (övriga)	4 467 693	1 030
Svetsprodukter	1 890 049	96
Råvara/plasttillverkning	1 570 616	2 160
Oxidationsmedel	1 441 190	74
Blekmedel	1 328 183	117
Gödselmedel, gödningsmedel	1 006 611	311

Källa: Kemi:s 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:

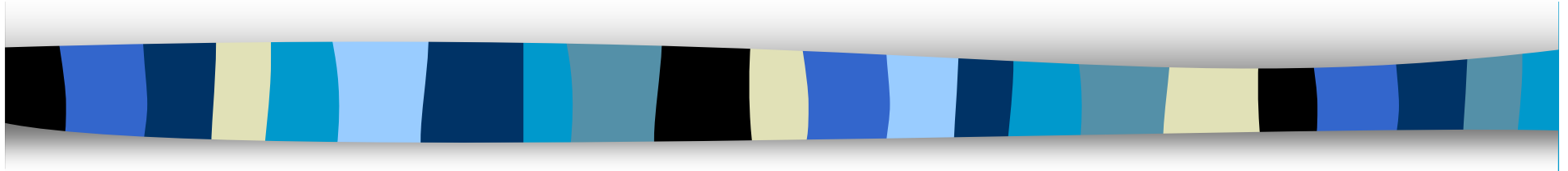
- Common Nordic general rules for product registers
- Common authority handling
- Same products to be reported
- Same level of content to be reported
- Same electronic report form

The Future for Nordic registers

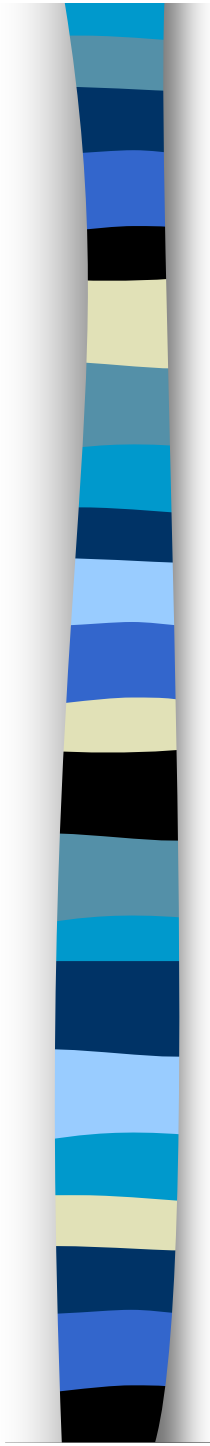
REACH

- 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



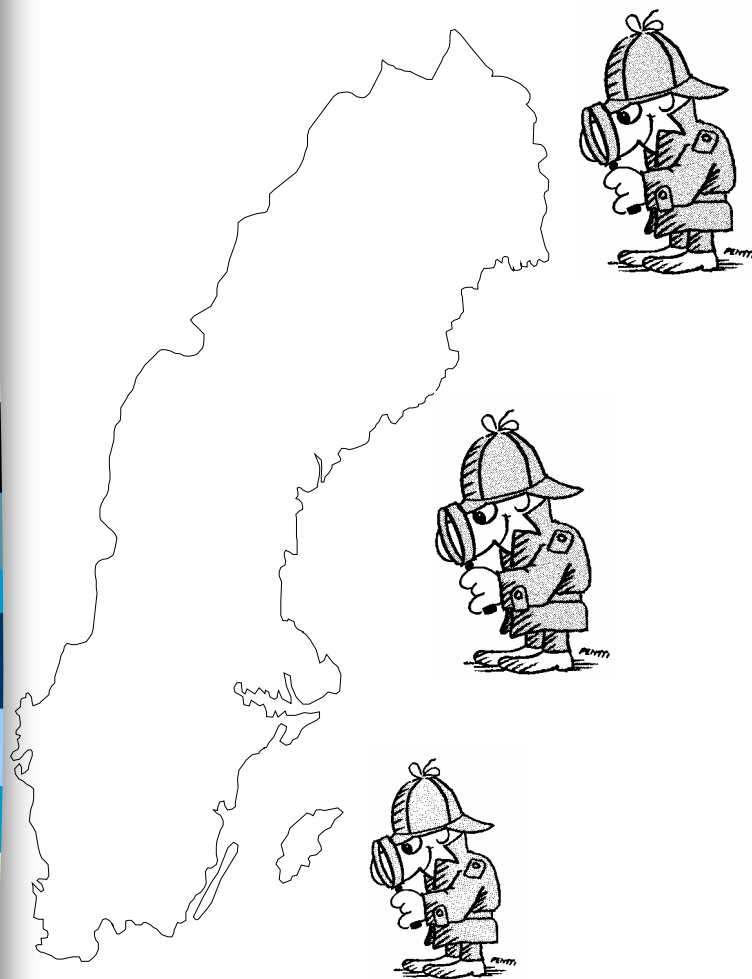
Barbro Sillrén



Use of data in supervision

- Inspections
- Use of Product Register – today
- Use of REACH register - tomorrow

Swedish Chemicals Inspectorate



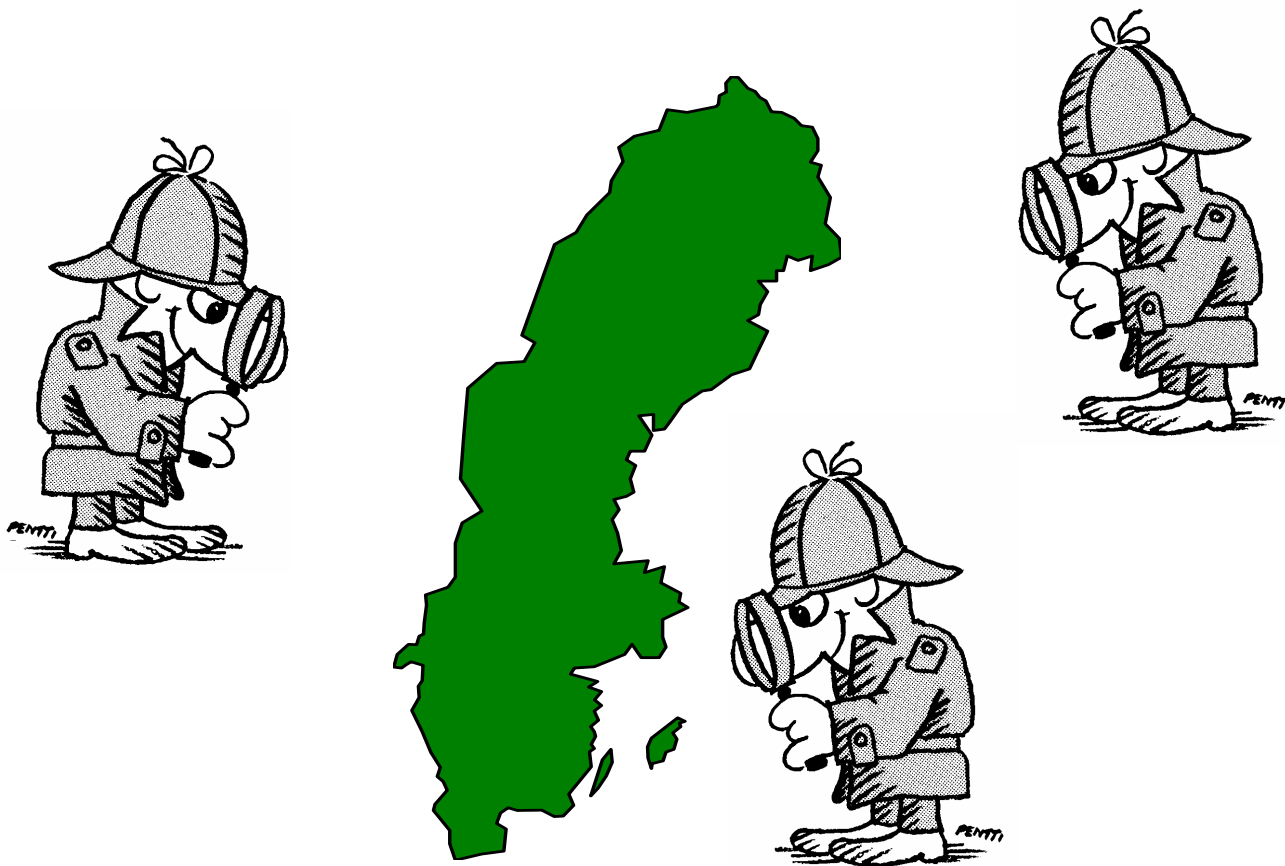
Central authority

From the products register

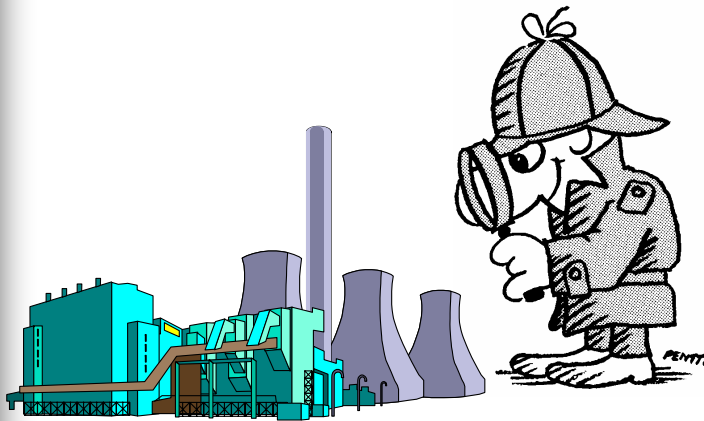
- 2.100 companies
Manufacturers and importers of
chemical substances and
preparations
- 64.000 preparations and
substances reported

Swedish Chemicals Inspectorate (KEMI)

Chemicals control



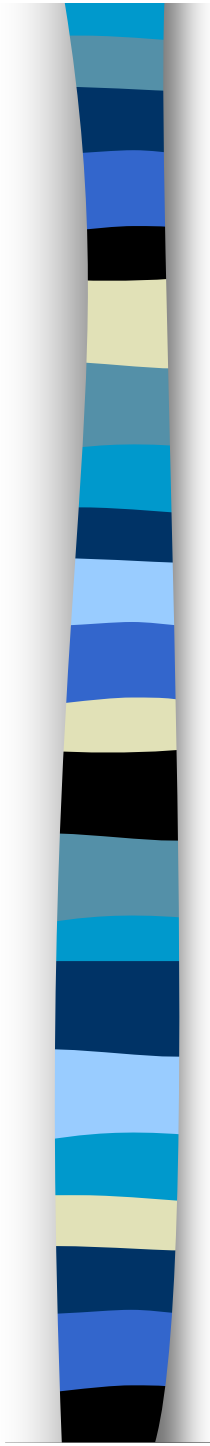
Inspections



The companies have the responsibility

Keml - Inspection unit

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



Inspections - strategy

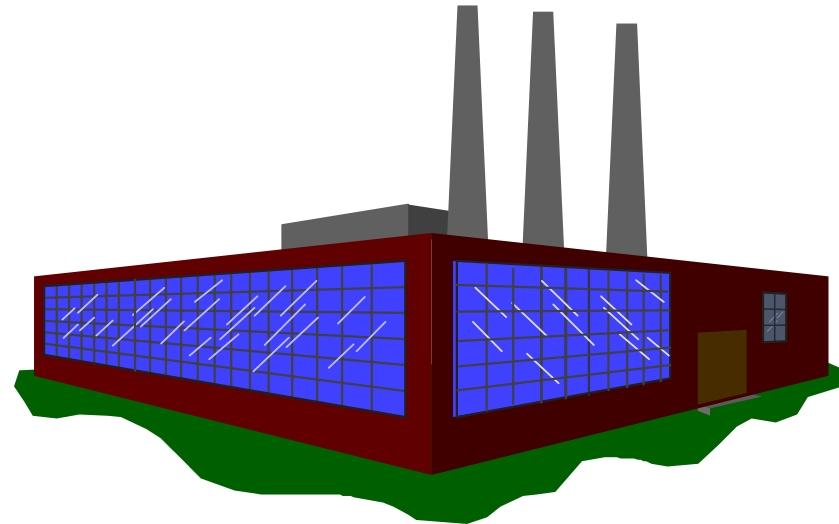
■ Types of products/Product groups

- 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)

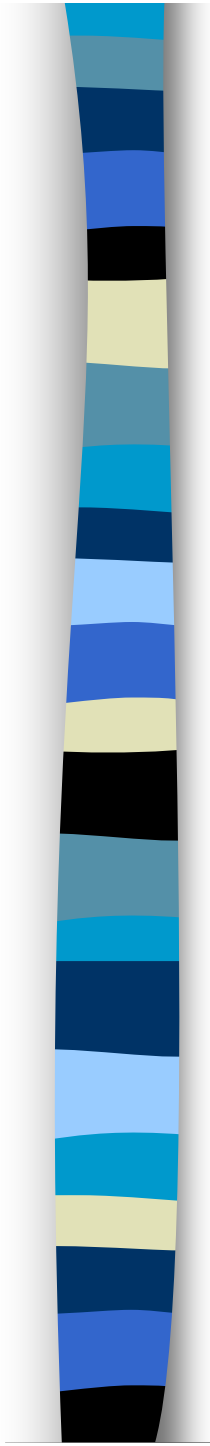
- Overall organization
- Policy for environment, health and safety
- Management system for environment, health and safety
- Organization
 - responsibilities
 - procedures
 - resources
- Competence



Inspection of companies (2)

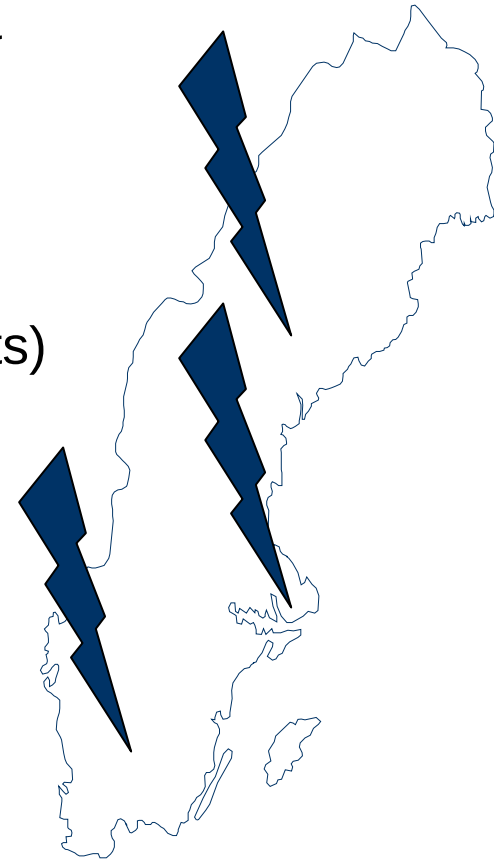
- Product investigation
 - health and environmental effects
 - protective measures, waste etc
- Product substitution
- Product information
 - MSDS and labelling
 - quality check

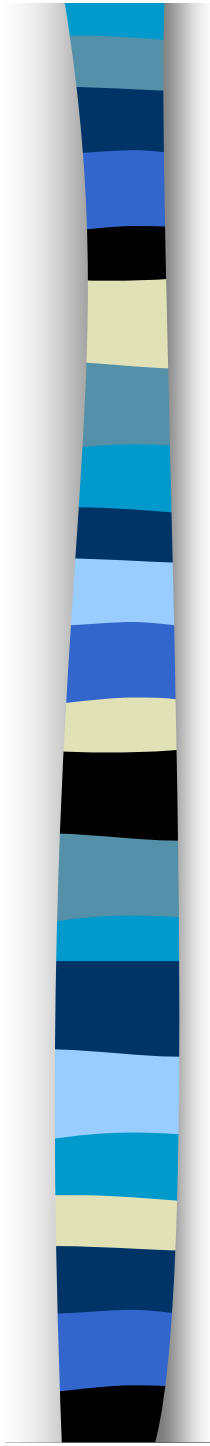




Regional Inspection Projects

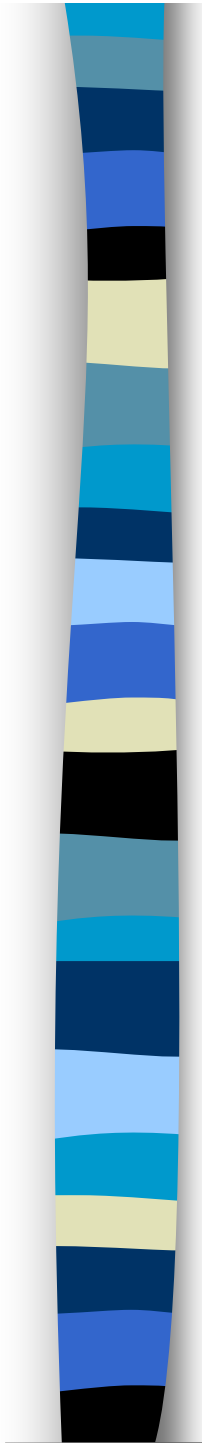
- Inspections of companies within a geographic area
- Selection factors:
 - Number of companies
 - Company size (by number of products)
 - Manufacturers/importers
 - Product-profile
- Time – approx. 2-4 months
- Form of Inspection
 - Visit or by letter





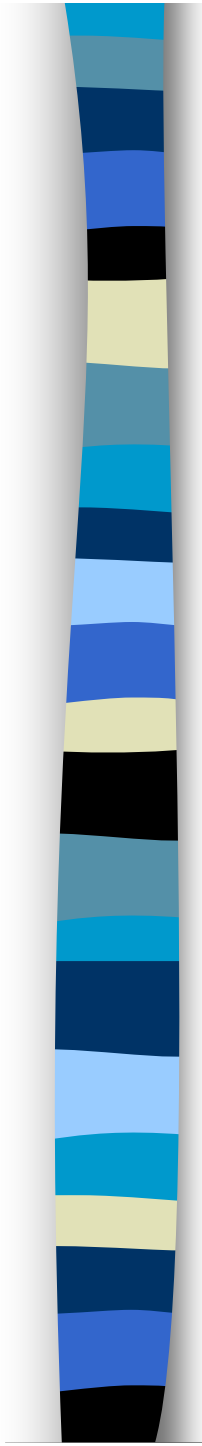
Use of Register - Today

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



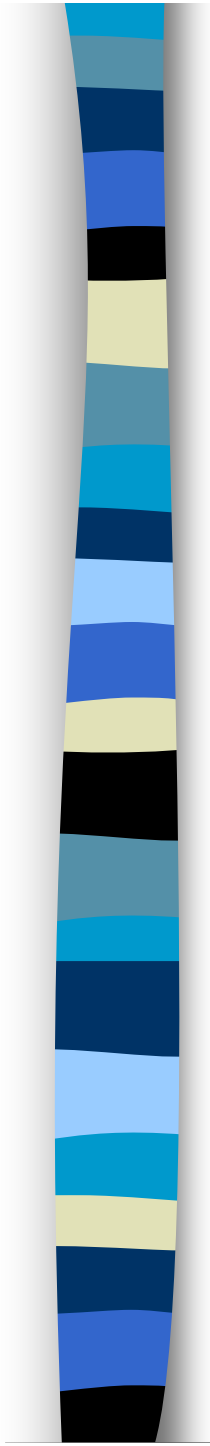
Use of Register - Today

- 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

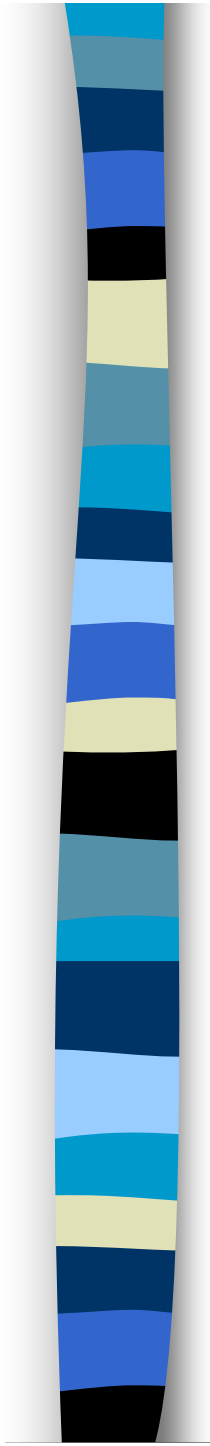
- National Product Register
- Register – Agency



Use of Register - Tomorrow

■ Information

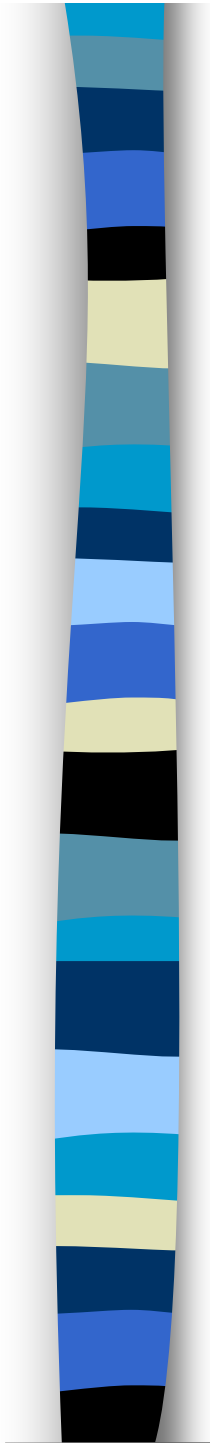
- registration numbers
- substances
- use of substances
- manufacturers/importers
- classification of substances
- authorisation
- restrictions



Use of Register - Tomorrow

■ Non confidential information:

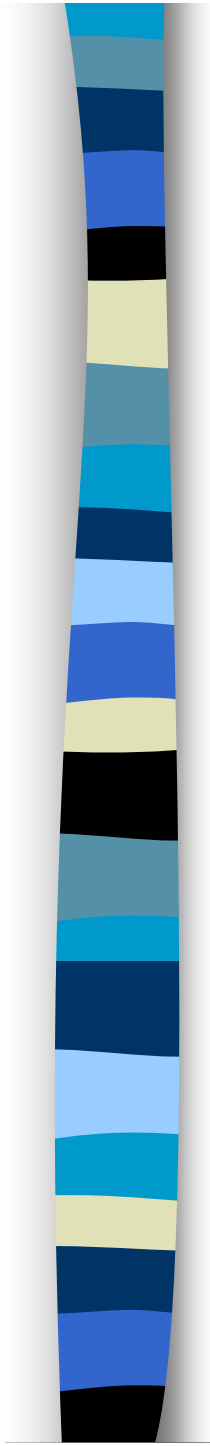
- name of substance
- physiochemical data
- tox/ecotox studies (result)
- classification/labelling
- guidance on safe use
- information in SDS
- etc



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 Agencys 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



Environment and Sustainable Development



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.”



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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:

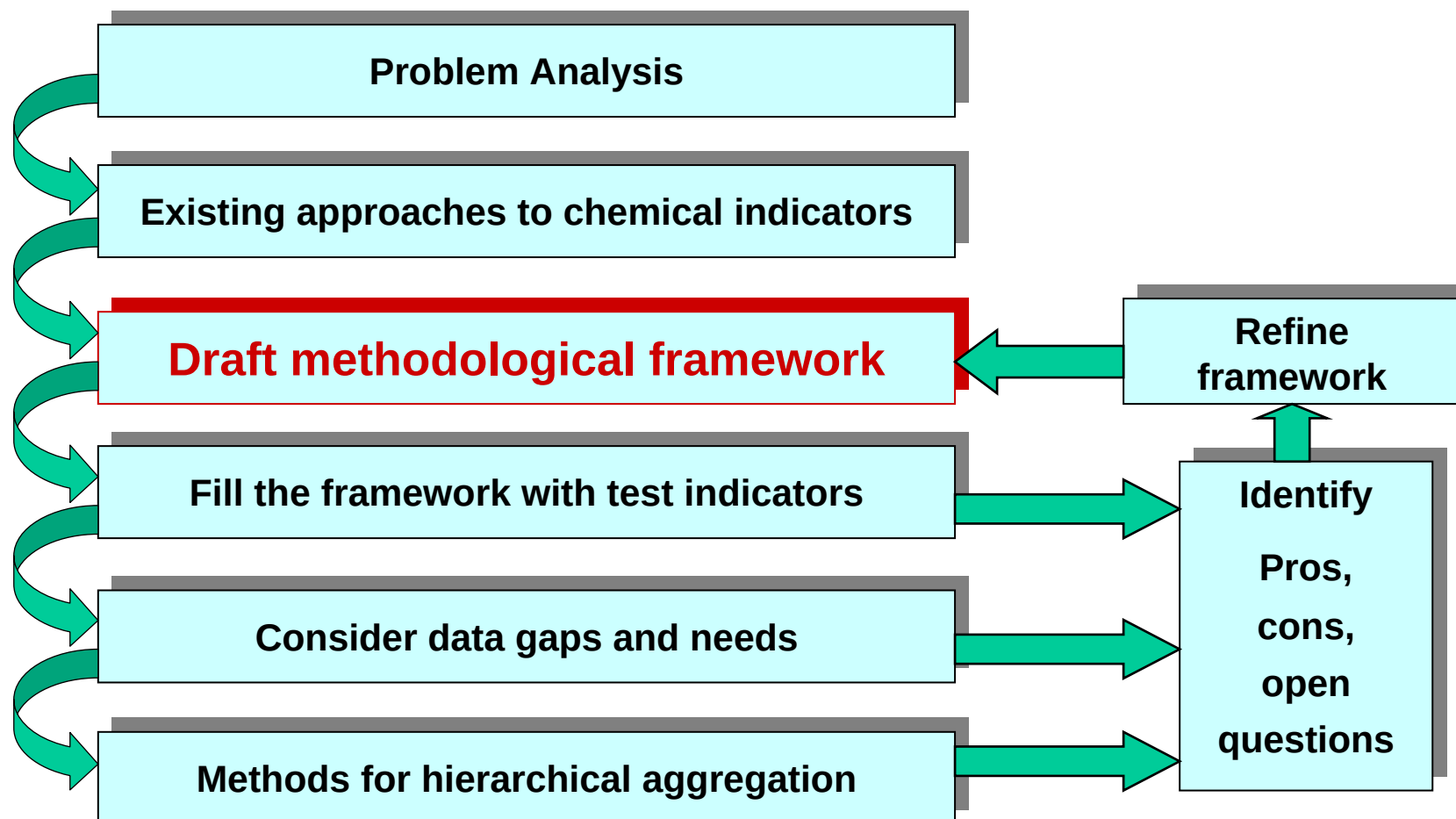
“source” “policy performance” “impact”



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Start with a framework, set boundaries



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;

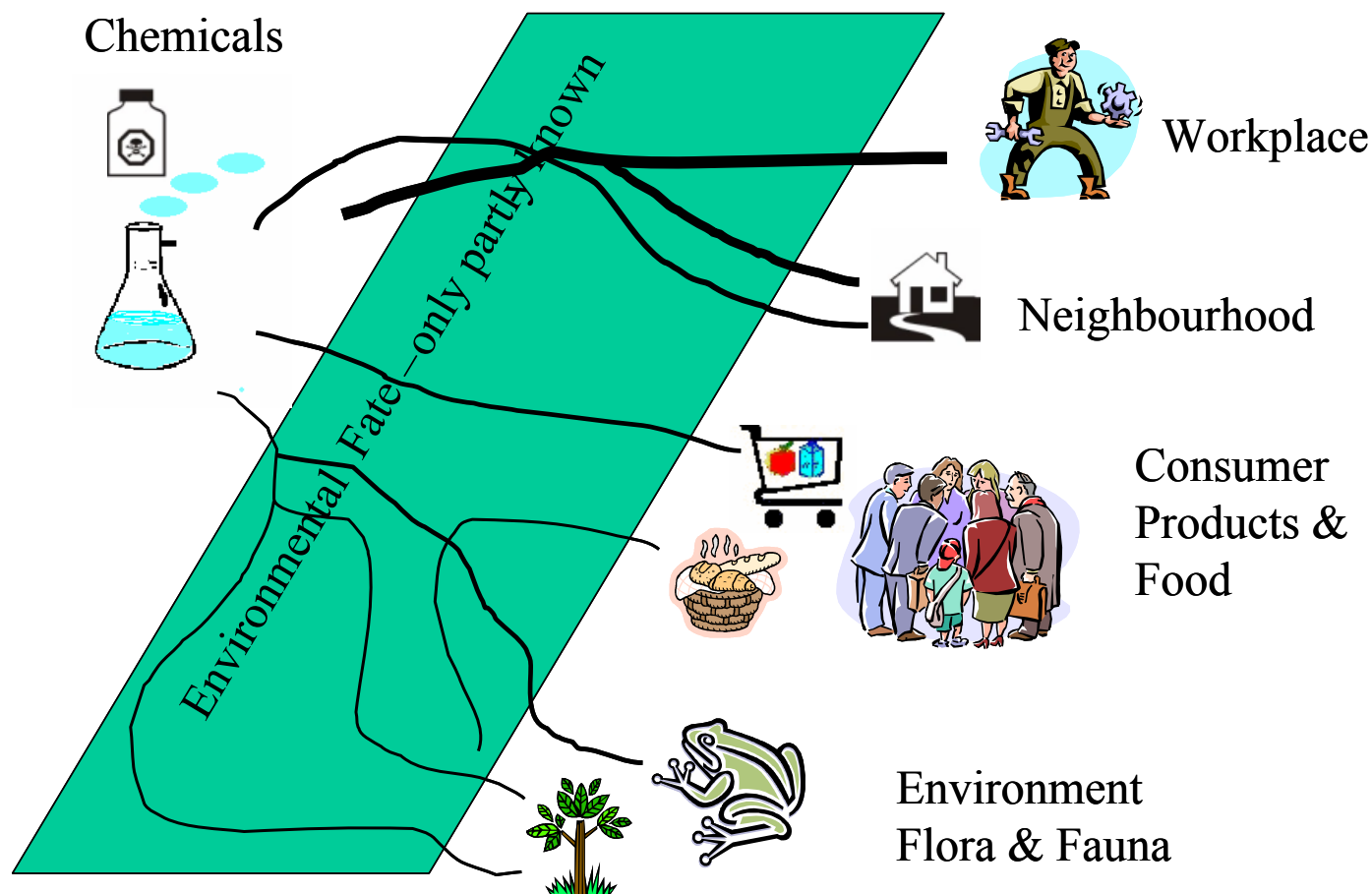
+ Existing approaches cover only partial aspects.



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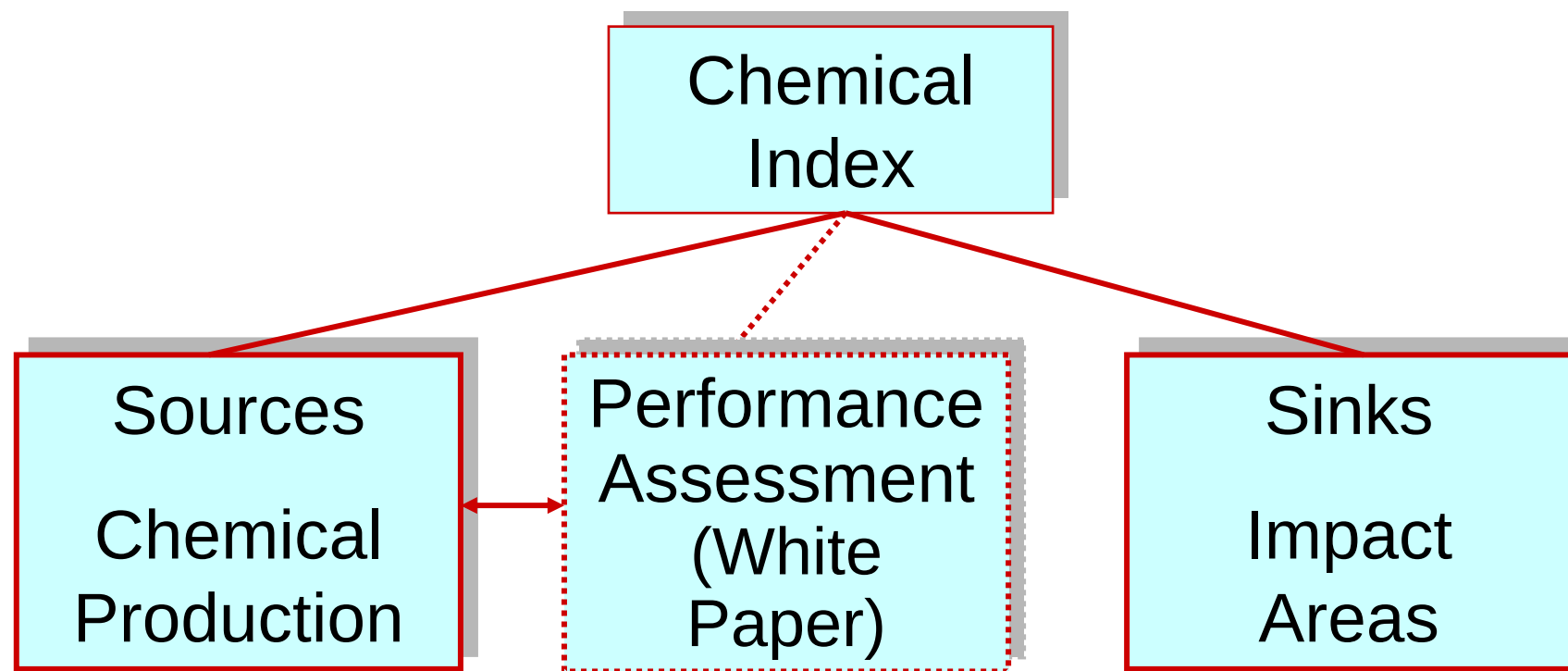
Knowledge on flow of chemicals



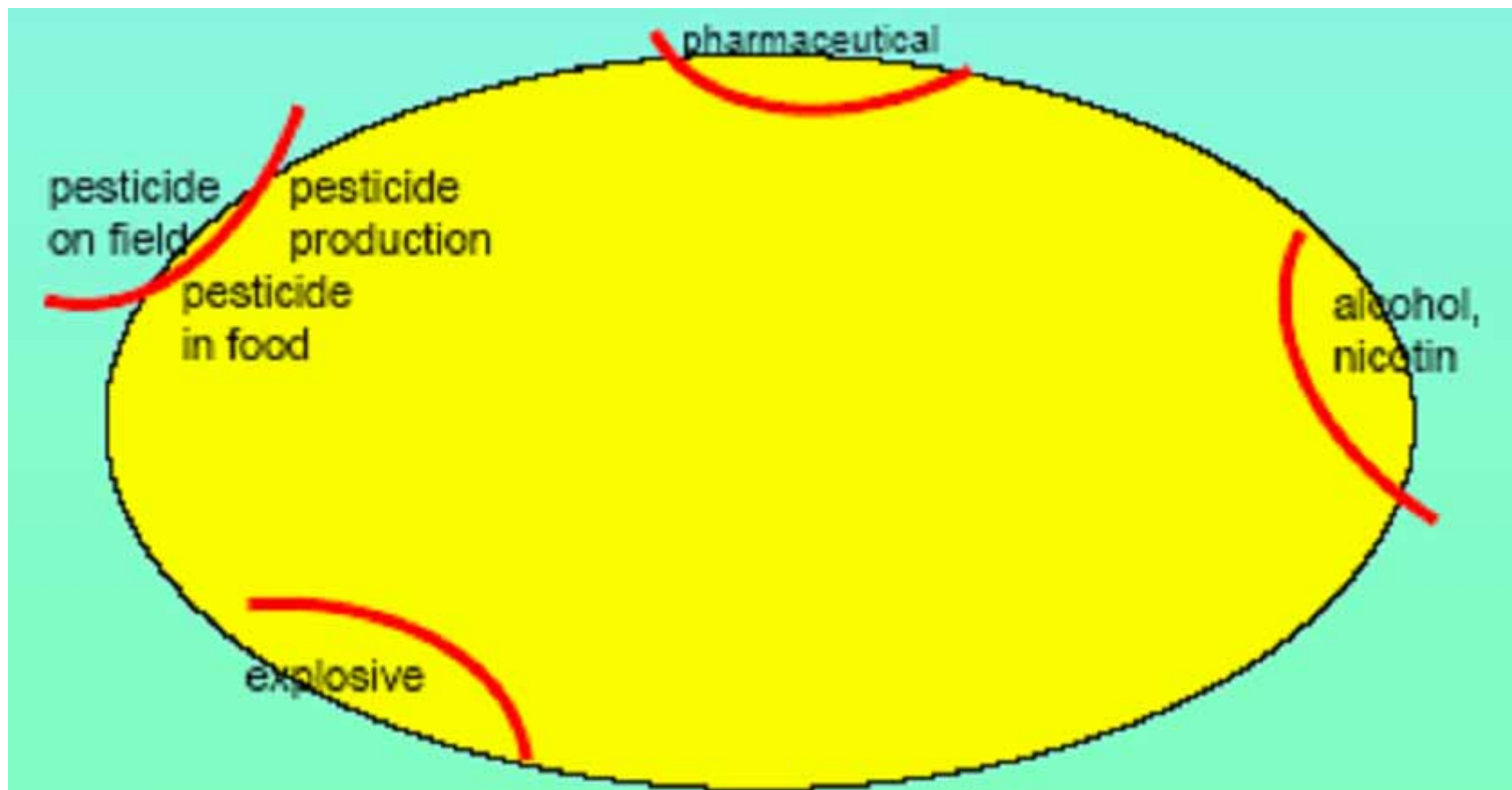
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Proposed scheme for a chemical index



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? → Define Impact Areas	How grave? → Define Risk Areas
- Working place - Neighbourhood - Consumer - Environment	- Known effects - Small 'Margin of Safety' - High hazard - Substantiated suspect - Unwanted exposure - Insufficient testing



Matrix of impact and risk areas

I_i	Workplace	Neighbourhood	Consumer	Environment
R_j				
Known effects				
Small MOS				
Hazards				
Substantial suspect				
Unwanted exposure				
Unassessed				

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

Impact I_i Risk R_i	→	Occupation	Neighbour- hood	Consumer direct	Consumer via environ- ment	Environ- ment	Aggregate risk indicators
Example: High hazard chemicals							indicator on damages by chemicals
							indicator on high risk chemicals
							indicator on high hazard chemicals
							indicator on substantiated suspect chemicals
Substantiated Suspect	▶	▶	▶	▶	▶	▶	indicator on substantiated suspect chemicals
Unwanted exposure	▶	▶	▶	▶	▶	▶	indicator on unwanted chemicals
Insufficiently tested	▶	▶	▶	▶	▶	▶	indicator on insufficiently tested chemicals



Vertical aggregation of impact areas

Impact I_i → Risk R_j ↓	Occupation	Neighbourhood	Consumer direct	Consumer via environment media	Environment
Known effects	▼	▼	▼	▼	▼
Example: Chemicals relevant to consumers' health				▼	▼
				▼	▼
				▼	▼
				▼	▼
				▼	▼
impact indicators	indicator: occupationally relevant chemicals	indicator: relevant chemicals for neighbourhood effects	indicator: relevant chemicals to consumers	Aggregated indicator: health relevant chemicals in environment	Aggregated 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”

Substances in Preparations in Nordic Countries Version 1.0

You are working on:

Help List Show All Search + all My list Load list + - Clear Save list Guide Reports Exit

Main info Total use Industrial use Use by category References Technical Found 1029

CAS no 71-43-2 Benzene
EC no 200-753-7

Total Use

Country	Year	# preparations	Tonnes	Consumer preparations	Confidential
FIN	2001	40	1239086.1		
N	2001	43	232902.8	X	
DK	2001	4359	21035.7		
N	2000	33	225029.7		
S	2000	145	52583.0	X	
DK	2000	3856	20475.1		
FIN	2000	39			
S	1999	152	55159.0	X	

$$I_{ConPot} = \frac{\sum PrepRisk}{\sum PrepTotal}$$



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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 ...)

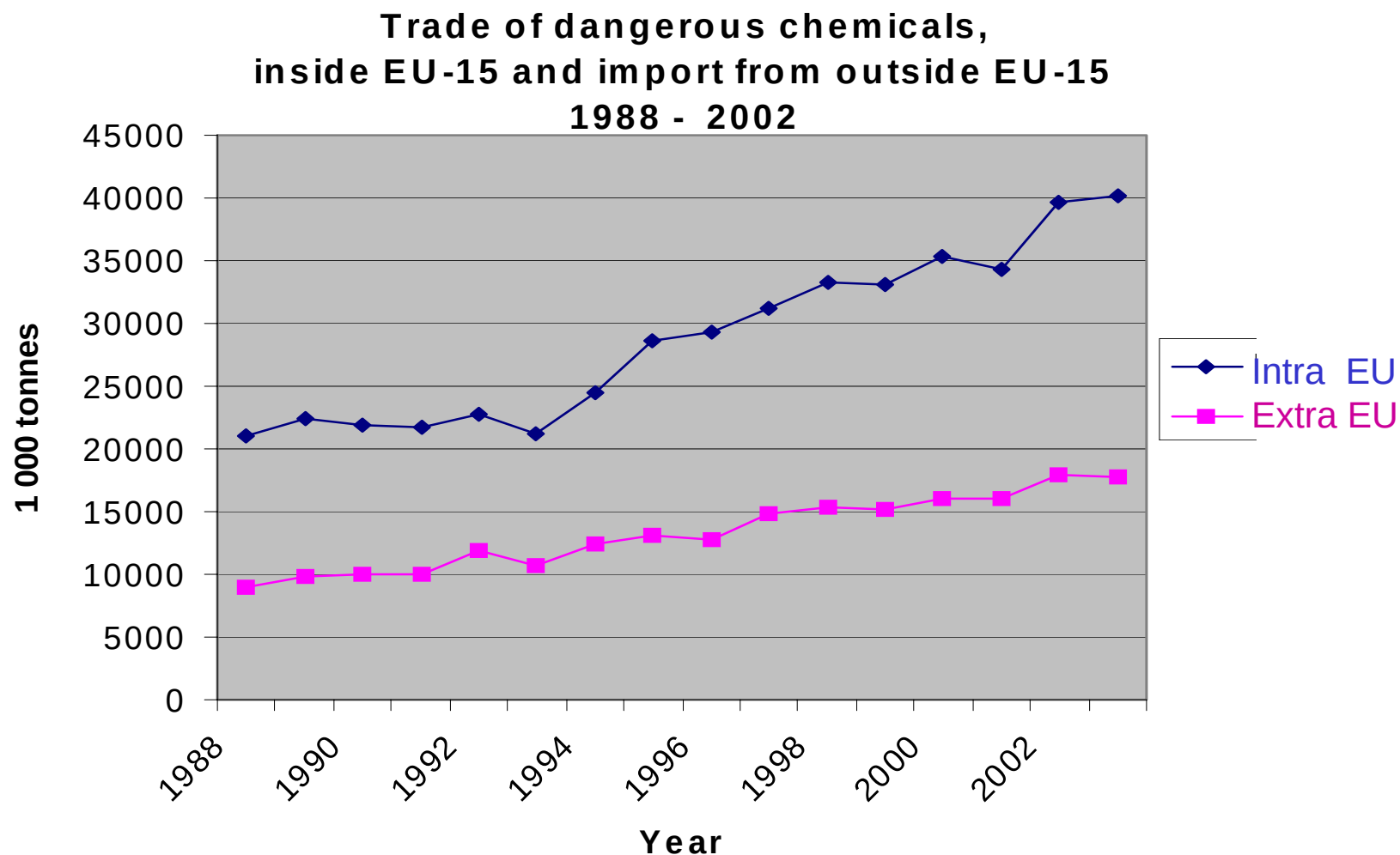


Source index

- + (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

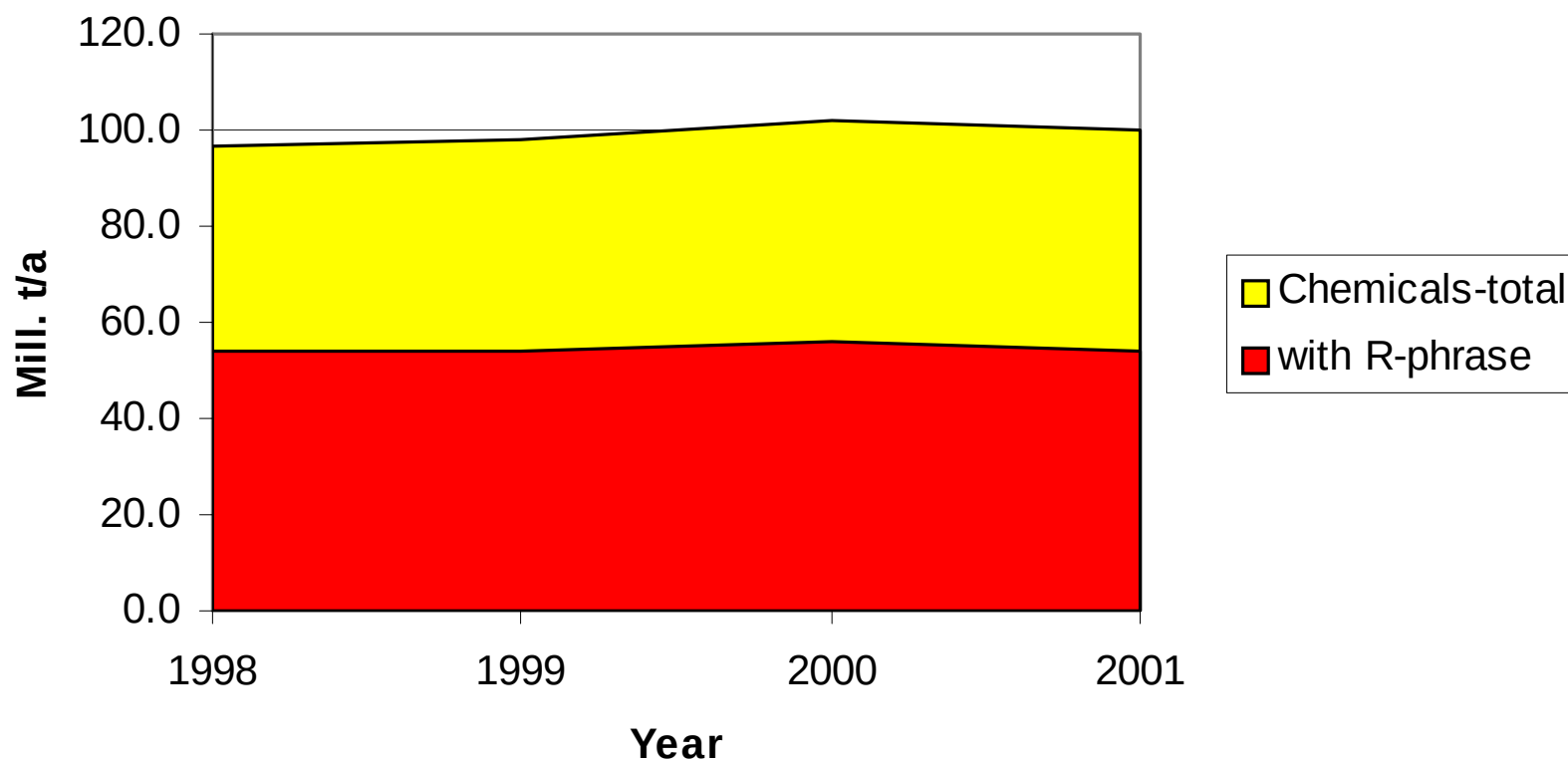


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First results (2): production statistics

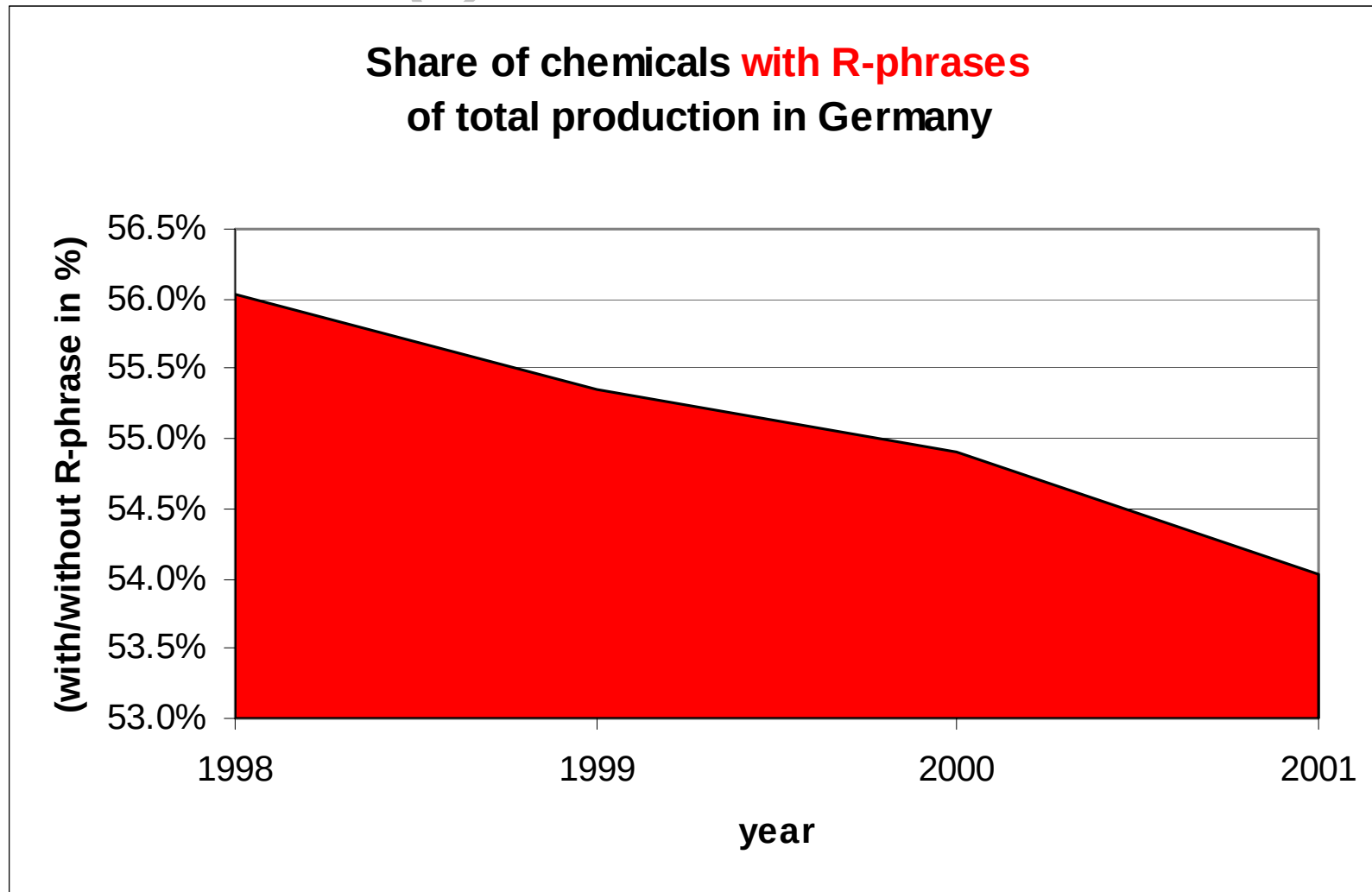
Production of chemicals (Total / with R-phrased) in Germany



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First results (3): share of “toxics”, but ...

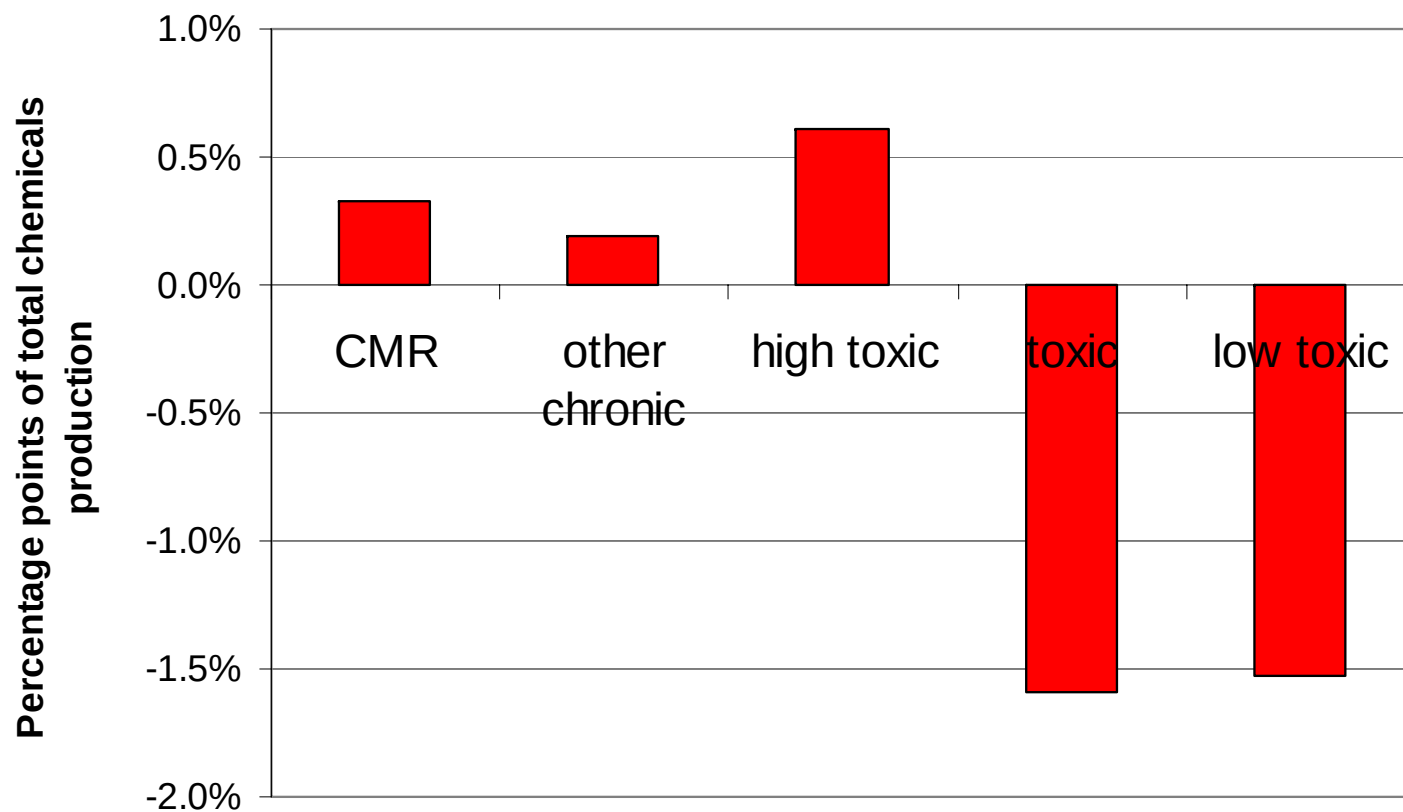


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... (4): *relative growth / toxicity classes*

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



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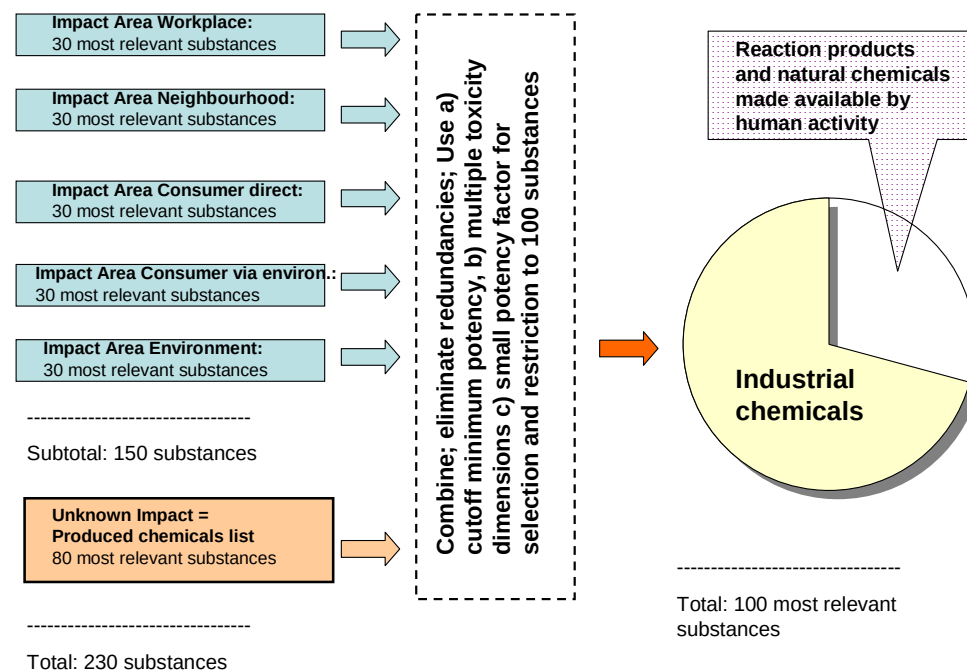


Source index, next steps ...

- 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)



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... next steps ...

- further work on the weighting factors:

$$I = \sum \text{amount} \bullet \text{hazscore} \bullet \text{potency_score} \bullet \text{multiplicity_score} \bullet \text{release_score}$$

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



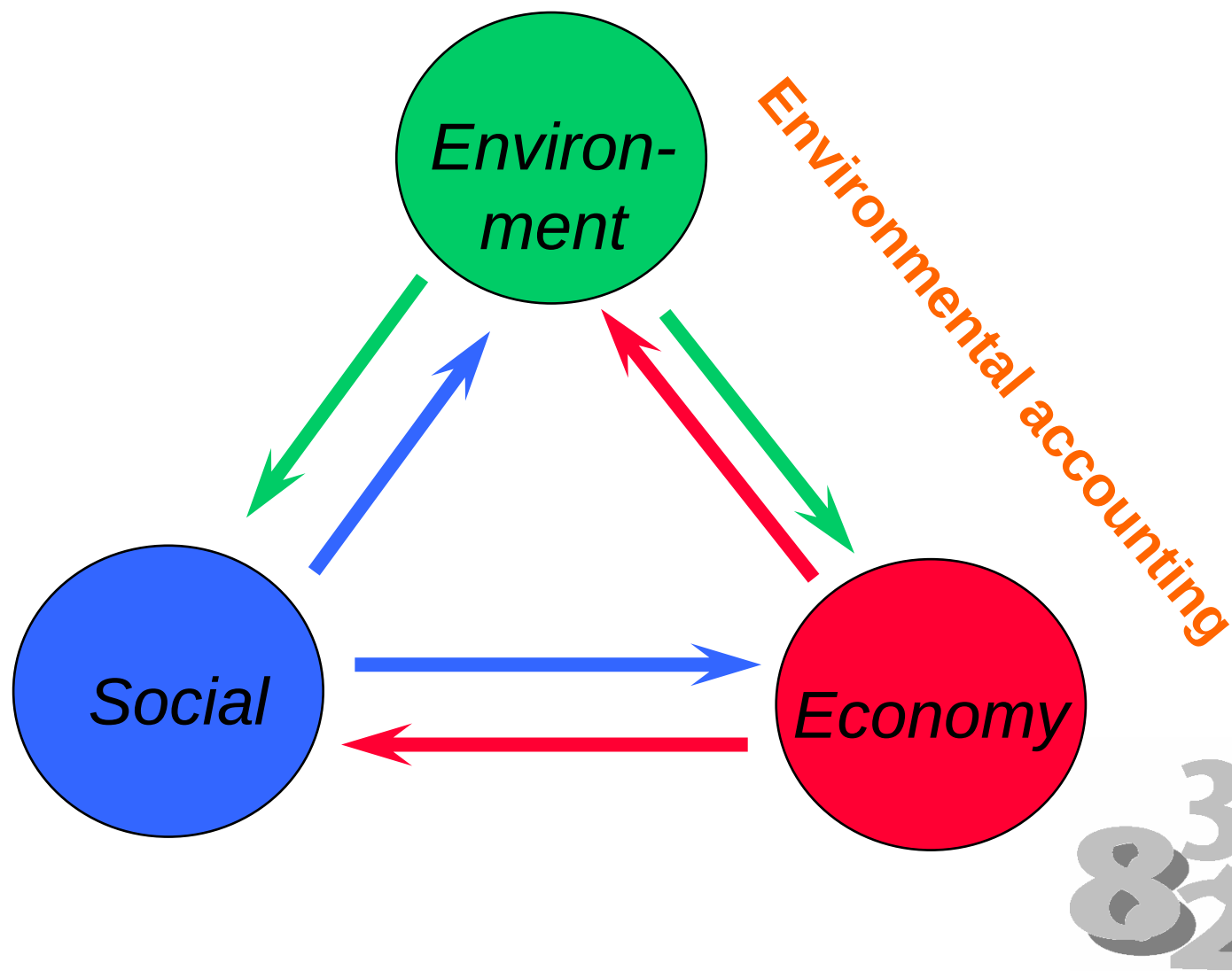
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Indicators for chemical product
input in different industries. Two
methods for including chemicals
in SEEA.

Viveka Palm, Statistics Sweden

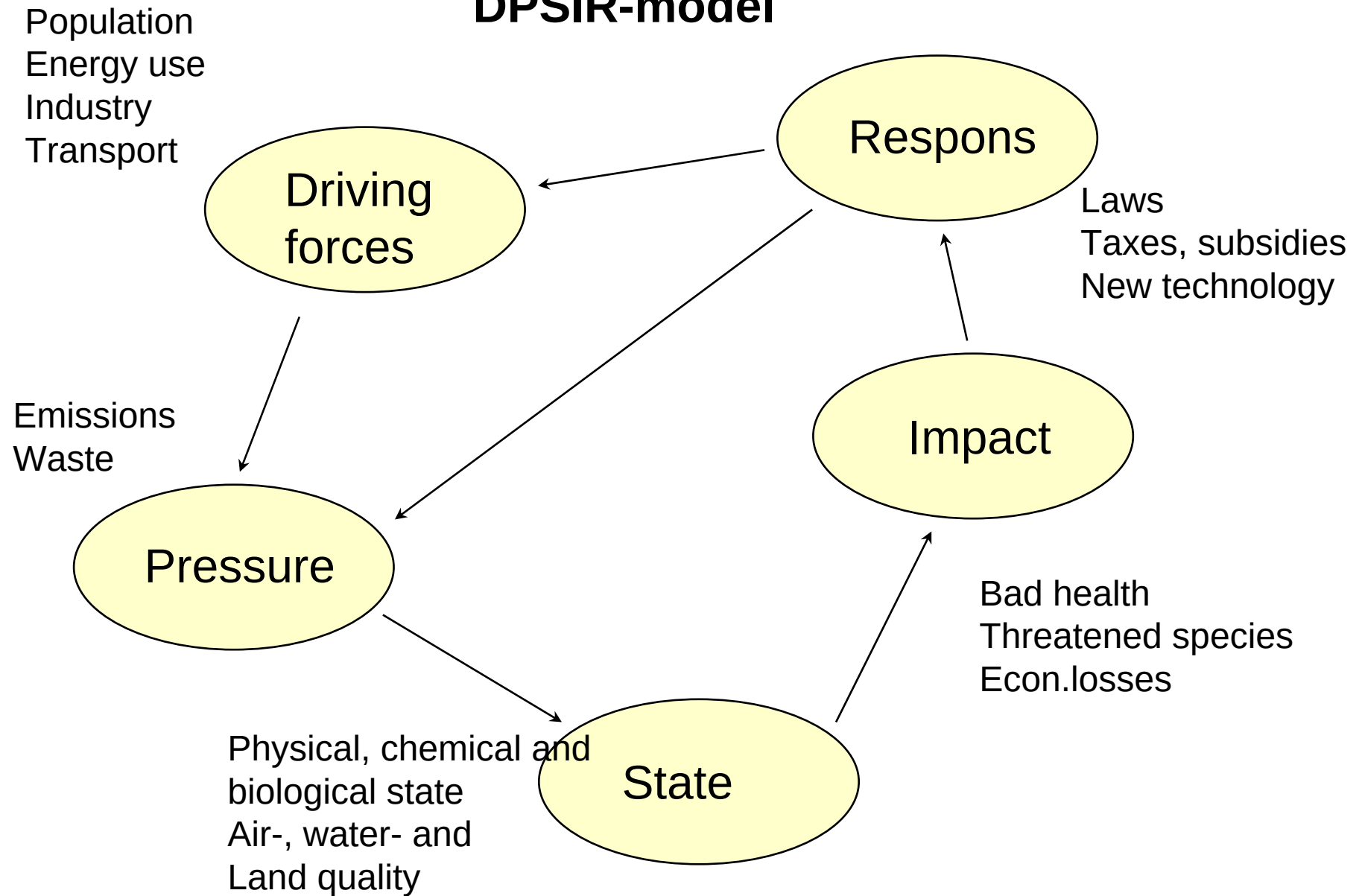
Sustainable development



Environmental accounts

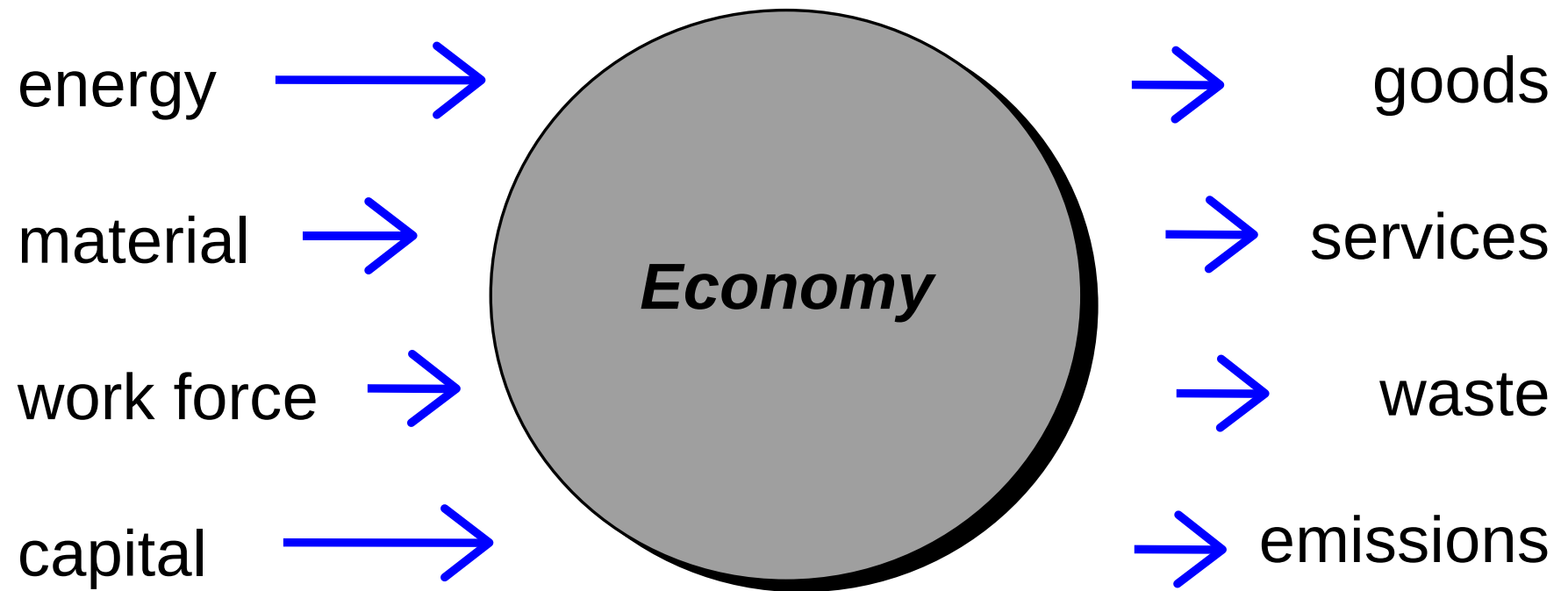
- Flows of materials (NAMEA)
- Economic variables (SERIEE)
- Natural resources: stocks, quality, value

DPSIR-model



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

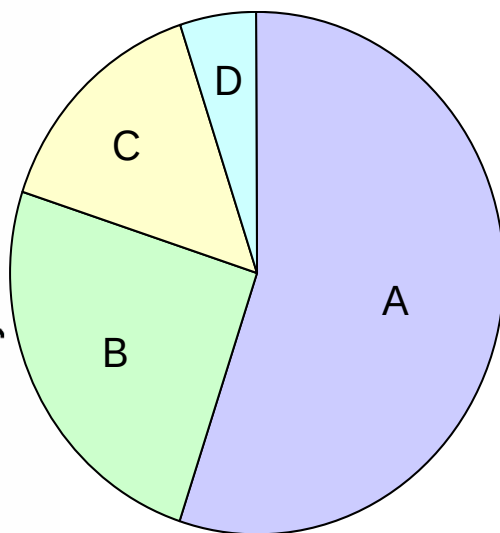




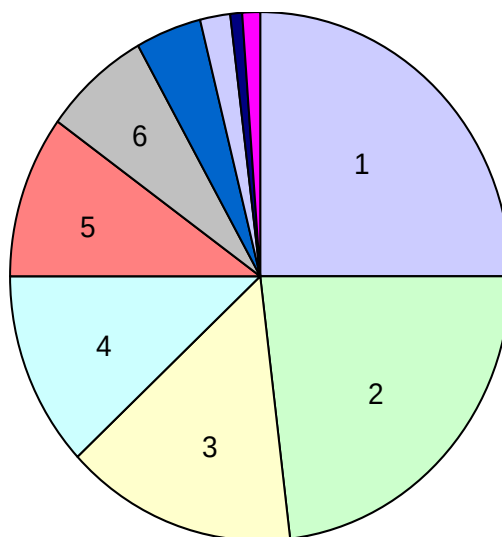
Sectors - Industries - Products

Statistiska centralbyrån Statistics Sweden

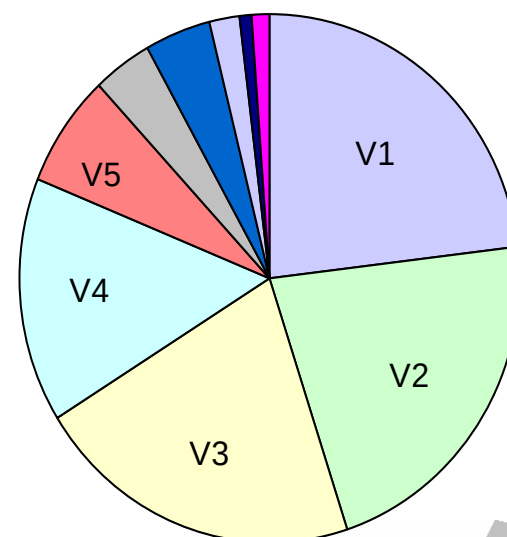
Sectors



Industries



Product/service



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+

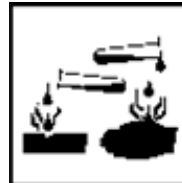
Very toxic



T
Toxic



C
Corrosive



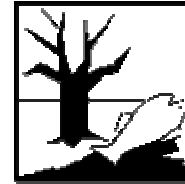
Xn

Harmful



Xi

Irritant



N

Dangerous for the environment

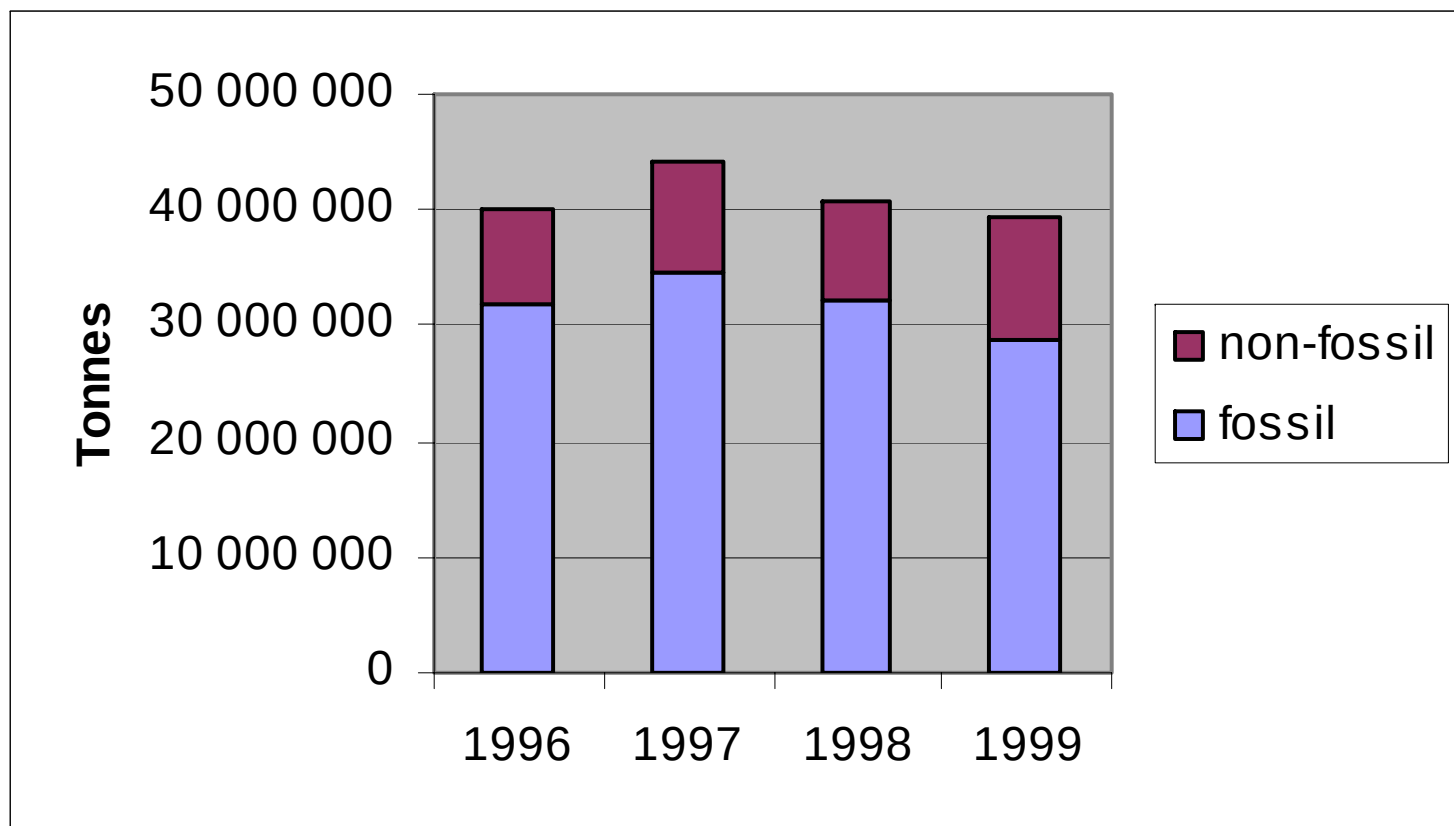
CSMR risk for diseases

- **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

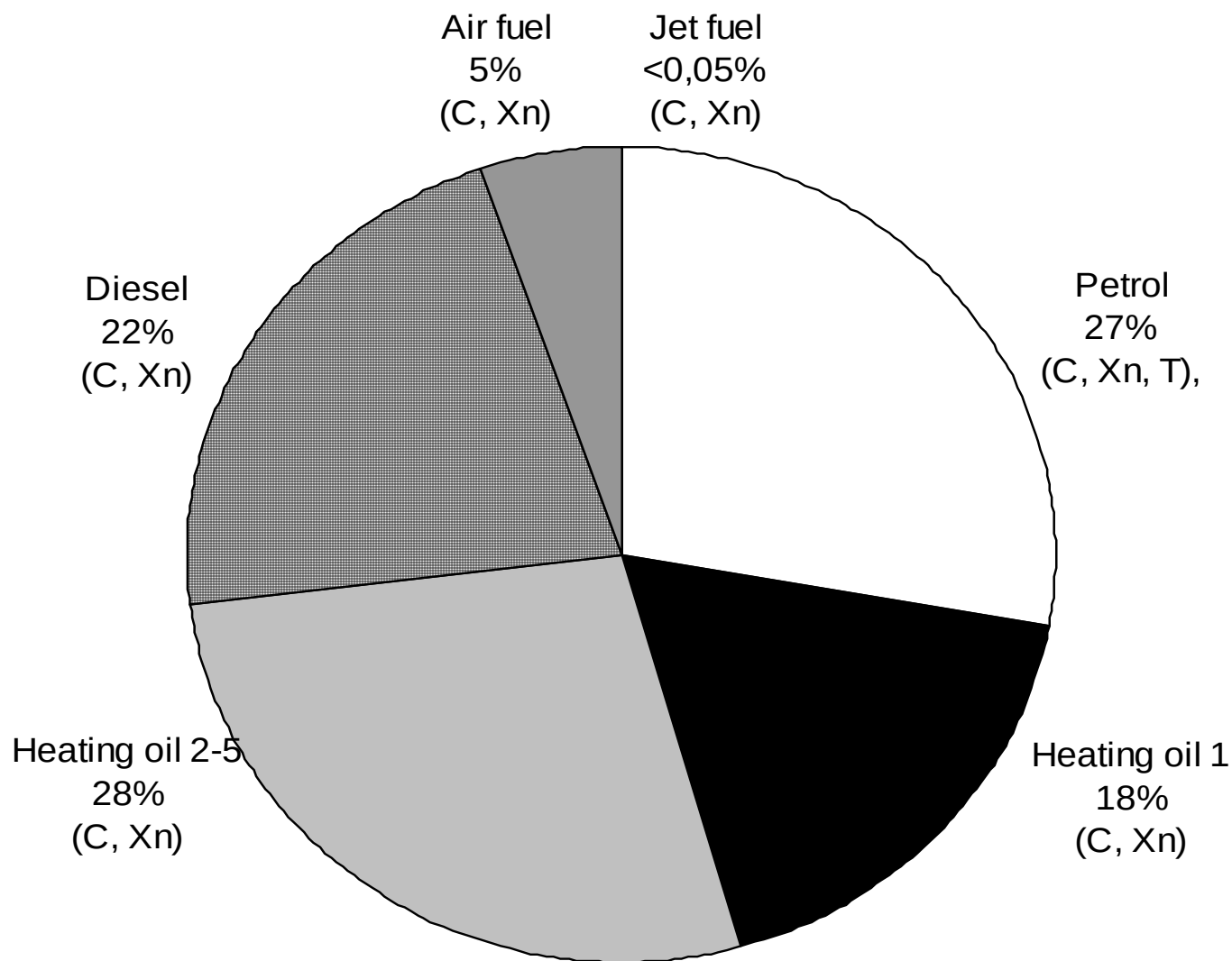
R 50 Very toxic to aquatic organisms

- **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

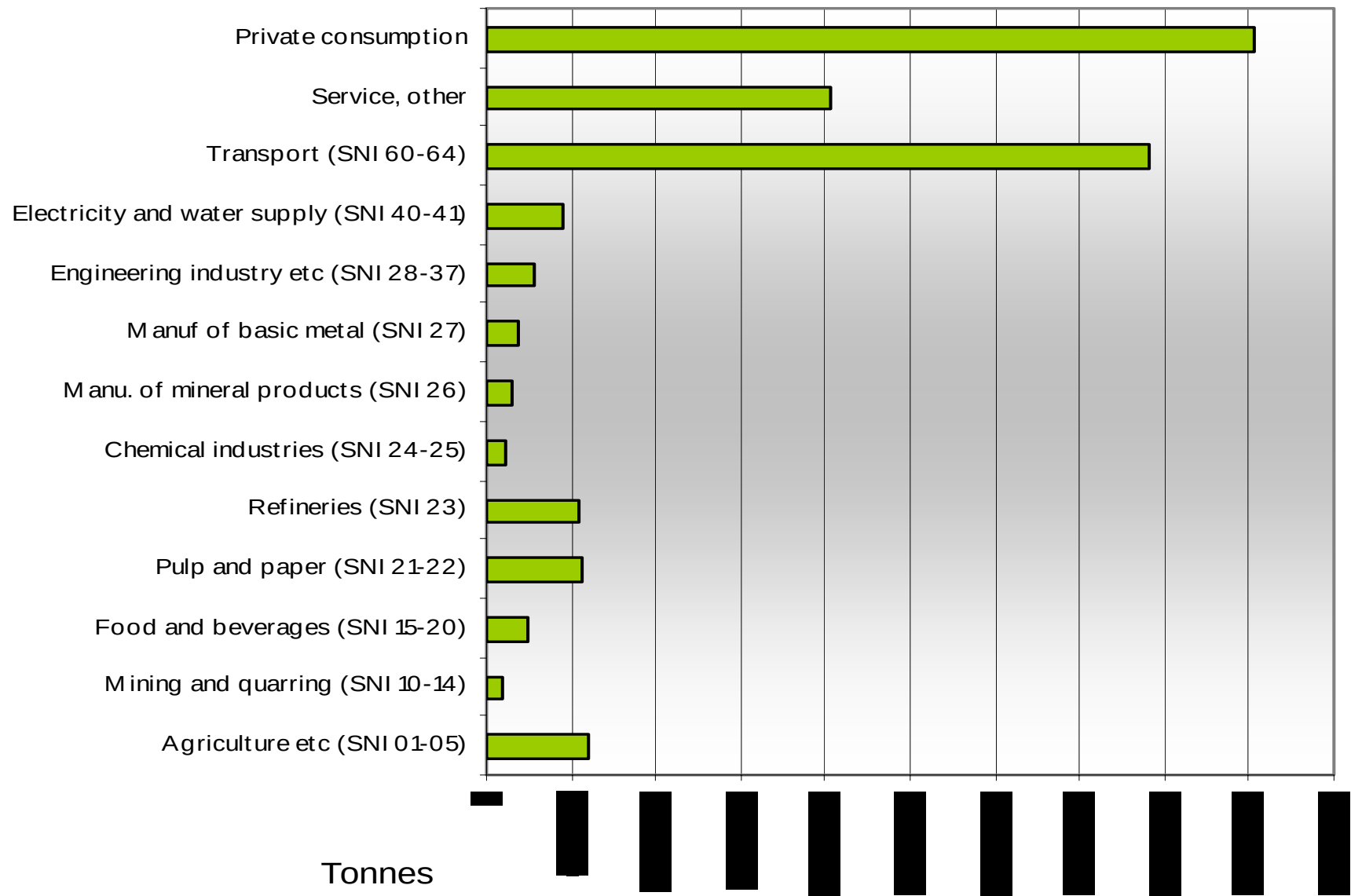


Totals of fossil fuels and non-fossil chemical products
1996-1999, labelled for inherent properties (lip)

Average distribution of fossil fuels by product



Use of classified fossil fuels in 2000



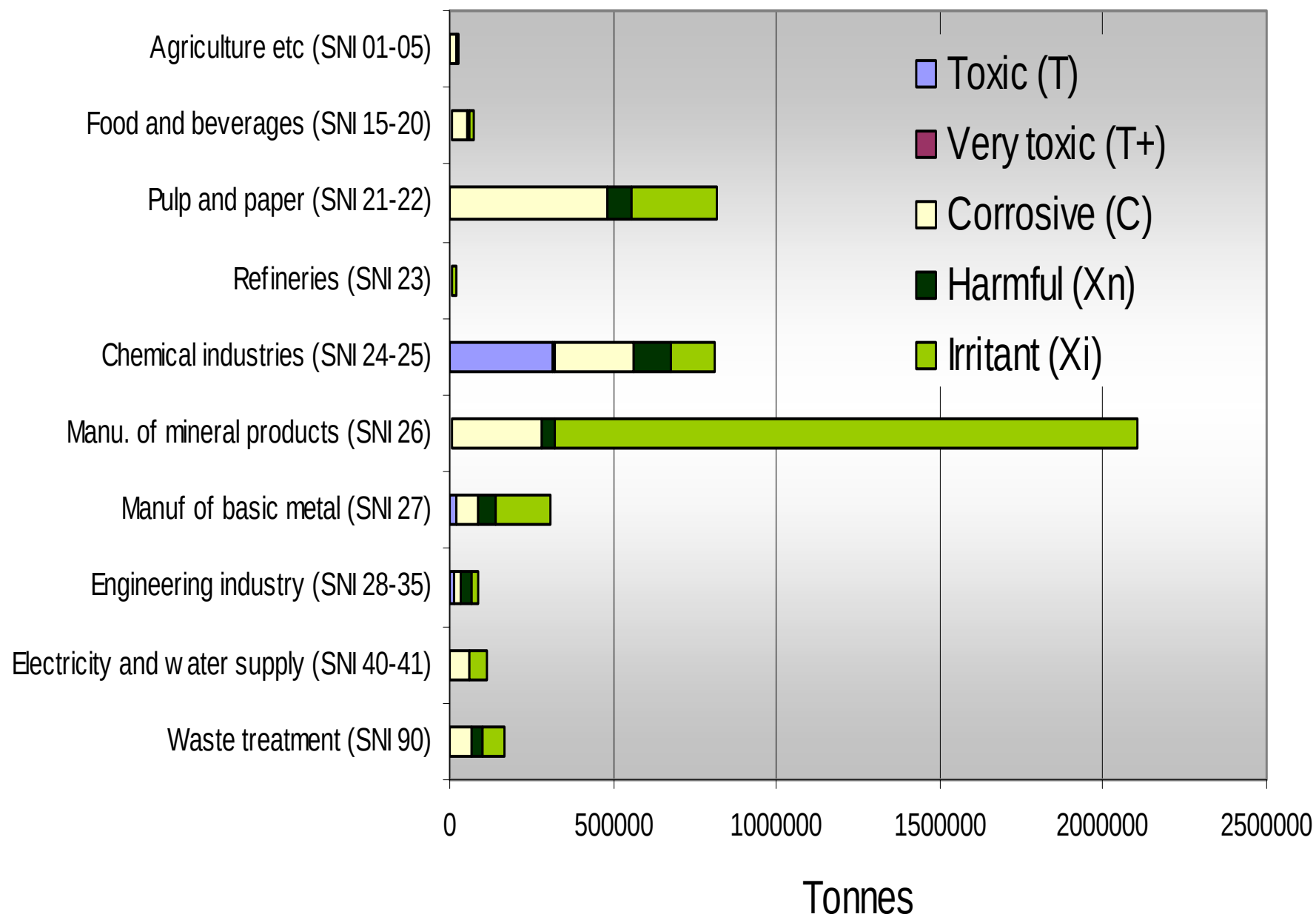
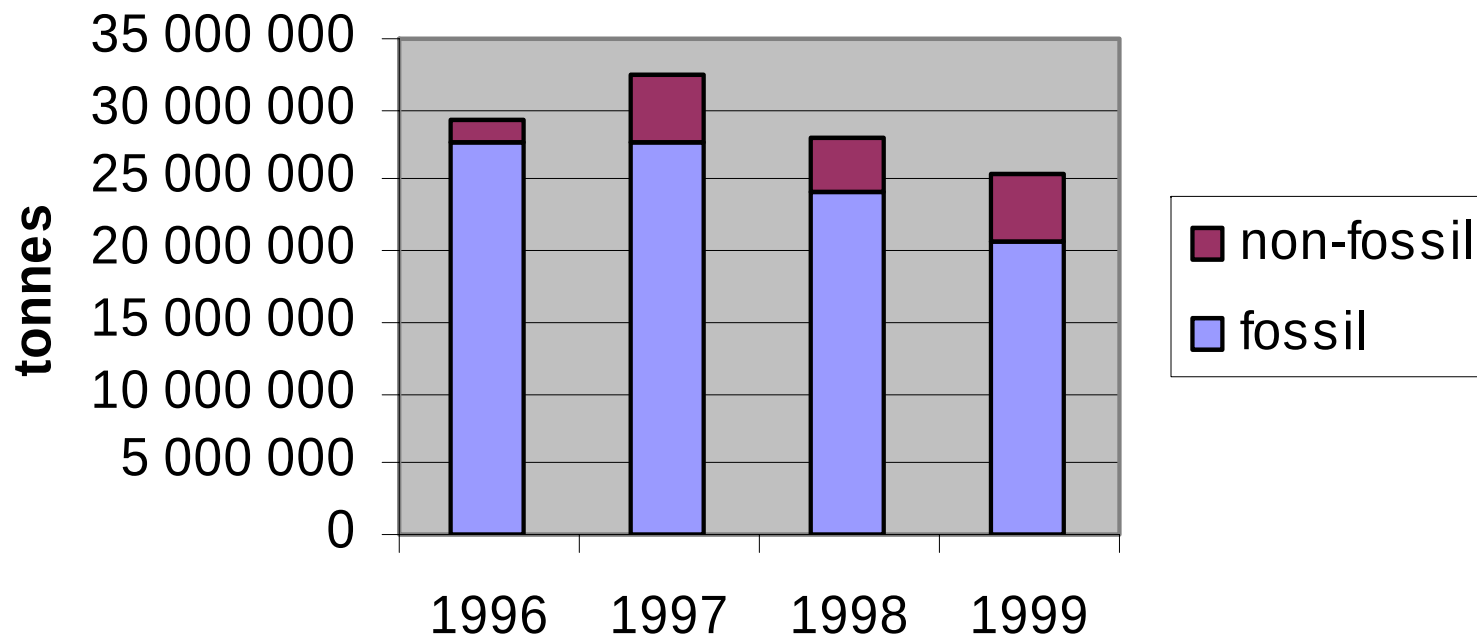


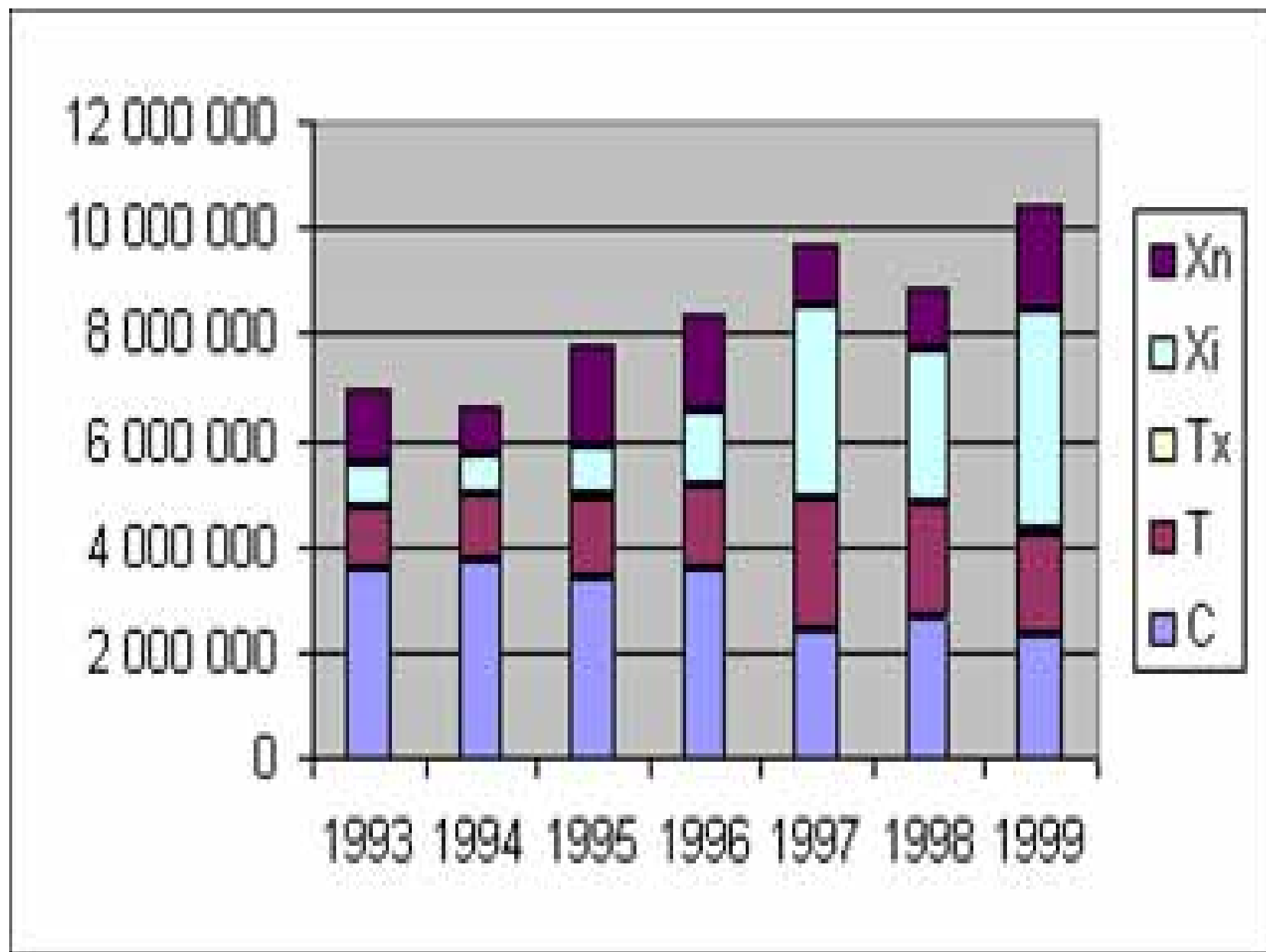
Table 1. Occurrence of unique risk phrases and their distribution among chemical products registered in the Product Register (including fossil fuels) (Brånvall, 2002).

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

csmr-labelled chem products



Totals of Non-fossil chemical products, lip, 1993-1999



Report: Chemical product indicators by industry – fossil fuels, cement and other chemical products classified as hazardous to health or environment 1996-2001.

Viveka Palm & Annica Carlsson.

[http://www.scb.se/Statistik/MI/MI1202/1996I01/
MI1202_1996I01_BR_MIFT0406.pdf](http://www.scb.se/Statistik/MI/MI1202/1996I01/MI1202_1996I01_BR_MIFT0406.pdf)

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.