# Substitution of hazardous chemicals – in general and under REACH

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# Structure of the lecture

- Background /projects / references
- Legislation, demanding substitution as priority
- The substitution regulation under REACH
- Definition and main strategies
- Substitution in practice and examples of substitution
- Main research results about influence factors of substitution
- Conclusions for REACH

# Background /Projects /References

## Substitution Projects Cooperation Centre Hamburg

- **SUBSPRINT** Substitution of organic solvents by VOC-free high boiling vegetable oil-based esters in the printing industry
- **SUMOVERA** Substitution of Mineral-oil based mould release agents by vegetable oil based esters (DE, FI; PO, NL)
- **SPHERE+** Substitution Projects for Health and Environment **(12 Case studies in Europe**
- **MetalVOC** Introduction of VOC-free cleaning technologies in the metal industry (DE)
- **Topic Centre Dangerous Substances** Contribution of good Practice Cases for Substitution to EU-OSHA database
- **SubChem** Options for successful systems to replace dangerous substances, **7 Case Studies in Germany**
- **EU-Substitution** Substitution of Hazardous Chemicals in Products and Processes, **10 Case Studies in Europe**

# Background /Projects /References

## Case studies DE – German Project SubChem

| *Field of application* | *Conventional chemical* | *Compared Substitute/process* |
|---|---|---|
| Automotive series coatings | High solvent coatings | Low solvent coatings |
| Softeners in plastics | DEHP | DINP or DIDP |
| Mould releases (concrete separating agents) | Petrochemical products | Esters based on renewable vegetable oils |
| Fibres in automotive silencers | Conventional man-made mineral fibres | Biosoluble fibres |
| Mineral fibres in automotive catalytic converters | Ceramic fibres | Biodegradable fibres |
| Cutting fluids | Petrochemical oils and biocidal additives | Minimum quantity cooling lubrication |
| Industrial cleaning of metal surfaces | Water-based cleaners | Organo-halogen solvents |
| Cement | Chromate cement | Cement with additives to reduce skin diseases |
| Stripping agents | Methylene dichloride | MDC-free stripping agents |
| Printing inks in packaging | Solvents | UV-drying |

# Background /Projects /References

## Case studies EU – Contract with DG Env

| *Case study [by application]* | *Problematic Substance(s)* |
|---|---|
| 1 Metal parts cleaning | Organohalogen solvents |
| 2 Cleaning of façades | Strong acids, alkalis, solvents and detergents |
| 3 Textile dry-cleaning | Perchloroethylene |
| 4 Marine ant-fouling | Organotin compounds |
| 5 Wood preservation | PCP and lindane |
| 6 Flame retardants in circuit boards | Brominated flame retardants |
| 7 Loss lubrication in inland water ships and locks | Lubricants derived from mineral oil |
| 8 Mould-release agents | Mineral-oil based agents |
| 9 Rechargeable batteries | NiCd accumulators |
| 10 Plasticisers in toys | Phthalates in PVC |

# Background /Projects /References

## Current activities – Kooperationsstelle

**Working party TRGS 600 ‚Substitution'**
New guidance for industry to fulfil the substitution obligation under the revised German 'Gefahrstoffverordnung' incl. socio-economic criteria (Working party of Dangerous Substances Committee AGS)

**CLEANTOOL**
Database on metal surface cleaning assessing 260 processes under five criteria:

- Technology
- Quality
- Environment
- OSH
- Costs

**GISMET**
Development of substitution supporting product codes in the metal industry

# Legislation, demanding substitution as priority

- General substitution demands (without a substance list): IPPC, CAD, VOC-Directive, Waste directive
- General substitution demand (with a substance list): Water Frame Directive
- Detailed bans for certain substances: End-of-vehicles, VOC (for carcinogenic substances), Carcinogenic Substances Dir etc.
- Biocide Directive: Detailed substitution procedure
- REACH

# Legislation, demanding substitution as priority

**IPPC COUNCIL DIRECTIVE 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control**

*Annex IV:*
*Considerations to be taken into account generally or in specific cases when determining best available techniques, bearing in mind the likely costs and benefits of a measure and the principles of precaution and prevention:*

1. *the use of low-waste technology;*
2. *the use of less hazardous substances; …*

# Legislation, demanding substitution as priority

## Council Directive 98/24/EC on the protection of the H&S of workers from the risks related to chem. agents at work

Article 6 (1):
*The employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum.*
*(2) In applying paragraph 1,* ***substitution shall by preference be undertaken****, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or less hazardous to workers' safety and health …*

# Legislation, demanding substitution as priority

**REAL DECRETO 374/2001, de 6 de abril sobre la protección de la salud y seguridad de los trabajadores contra los riesgos relacionados con los agentes químicos durante el trabajo.**

Artículo 5. Medidas específicas de prevención y protección.

*El empresario garantizará la eliminación o reducción al mínimo del riesgo que entrañe un agente químico peligroso para la salud y seguridad de los trabajadores durante el trabajo. Para ello, el empresario deberá,* ***preferentemente, evitar el uso de dicho agente sustituyéndolo por otro o por un proceso químico que, con arreglo a sus condiciones de uso, no sea peligroso o lo sea en menor grado.***

***Cuando la naturaleza de la actividad no permita la eliminación del riesgo por sustitución,*** *el empresario garantizará la reducción al mínimo de dicho riesgo aplicando medidas de prevención y protección que sean coherentes con la evaluación de los riesgos.*

# Legislation, demanding substitution as priority

## Germany: Ordinance on Hazardous Substances, 1986 version

§16, Para. 2:
*The employer must check whether substances, preparations or products with a lower health risk than those he intends to introduce are available.* ***If it is reasonable for him to use such substances, preparations or products and if substitution is necessary to protect the life and health of employees, only they may be used.***

Remark: Still valid today in a similar wording.

# Legislation, demanding substitution as priority

## EU: DIRECTIVE 98/8/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 February 1998 concerning the placing of biocidal products on the market

Article 10, 5 (i) V:

*An entry of an active substance in Annex I and, where relevant, IA or IB may be refused or removed,*

*— if the evaluation of the active substance in accordance with Article 11(2) shows that, under normal conditions under which it may be used in authorised biocidal products, risks to health or the environment still give rise to concern, and*

*— if there is another active substance on Annex I for the same product type which, in the light of scientific or technical knowledge, presents significantly less risk to health or to the environment.*

# The substitution regulation under REACH

## WHITE PAPER - Strategy for a future Chemicals Policy

*Another important objective is to encourage the substitution of dangerous by less dangerous substances where suitable alternatives are available. The increased accountability of downstream users and better public information will create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use.*

COMMISSION OF THE EUROPEAN COMMUNITIES
Brussels, 27.2.2001 COM(2001) 88 final

# The substitution regulation under REACH

## Explanatory Statement of the REACH-Regulation

*(72) To by suitable alternative substances or technologies, all applicants support the aim of eventual replacement of substances of very high concern for authorisation should provide an analysis of alternatives considering their risks and the technical and economic feasibility of substitution, including information on any research and development the applicant is undertaking or intends to undertake. Furthermore, authorisations should be subject to time-limited review whose periods would be determined on a case-by-case basis and normally be subject to conditions, including monitoring.*

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),…

# The substitution regulation under REACH

## Explanatory Statement of the REACH-Regulation

*(73) Substitution of a substance on its own, in a preparation or in an article should be required when manufacture, use or placing on the market of that substance causes an unacceptable risk to human health or to the environment, taking into account the availability of suitable safer alternative substances and technologies, and the socio-economic benefits from the uses of the substance posing an unacceptable risk.*

*(74) Substitution of a substance of very high concern by suitable safer alternative substances or technologies should be considered by all those applying for authorisations of uses of such substances on their own, in preparations or for incorporation of substances into articles by making an analysis of alternatives, the risks involved in using any alternative and the technical and economic feasibility of substitution.*

# The substitution regulation under REACH

**Socioeconomic analysis + 'no substitutes available' makes an authorisation of not adequately controlled uses possible (ref to §60 (4):**

*"If not (i.e. no adequate control of the risk of the use) then it may also be granted if the socioeconomic benefits outweigh the risks and there are no suitable alternative substances or processes."* *

**Complete assessment of substitutes (cited from §60 (5)):**

*"When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:*

*(a) whether the transfer to alternatives would result in reduced overall risks to human health and the environment, … ;*

*(b) the technical and economic feasibility of alternatives for the applicant."*

* Quoted from 'REACH in brief'

# The substitution regulation under REACH

**Existing substitutes – application for authorisations***

*"If there are (suitable alternative substances or technologies), they must prepare substitution plans, if not, they should provide information on research and development activities, if appropriate." **

*(ref. to § 62 (4f)*

**Future Substitutes**

*"The Commission may amend or withdraw any authorisation on review if suitable substitutes become available." **

*(ref. to § 61 (2))*

***Quoted from 'REACH in brief'**

# The substitution regulation under REACH

**Introduction of alternatives by third parties (ref to 64 §(2 and 3):**

**§ 64 Procedure for authorisation decisions**

*2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.*

*3. The Committee for Socio-economic Analysis may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.*

# Definition and main strategies

## Substitution definition

**Substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures.**

Lohse J., Lissner L. et al (2003): Substitution of hazardous chemicals in products and processes, Revision 1. http://ec.europa.eu/environment/chemicals/pdf/substitution_chemicals.pdf

# Definition and main strategies

## Substitution Types

| Substitution Type 1: | Substitution Type 2: | Substitution Type 3: |
| --- | --- | --- |
| Replace hazardous by a less hazardous substance while maintaining technology / product functionality | Use a less hazardous or non-chemical solution by changing the technology / product functionality | Use a less hazardous or non-chemical solution by changing the work organisation / product use pattern |

# Definition and main strategies

## Types of substitution - plastic floor coverings

**Type 1 : Substitution by less toxic plastifyers**

**Type 2a: Substitution by less mobile plastifyers**

**Type 2b: Emission control by chemical containment**

**Type 3: Meet same functionality with alternative material**

# Definition and main strategies

## Major NON-Substitution-strategies for risk reduction

- **Reduction and elimination of emissions**
  Technology, hygiene, organisation

- **Protection of target media**
  Air soil, water, workers, consumers

- **Reduction of the concentration of a hazardous substance**
  Dilution, ventilation, non functional filler materials

**Advantages of these strategies:**
Quantifiable, measurable,
from one point to another on one path.
Substitution is an exception.

# Substitution in practice and examples of substitution

## Most enterprises do not follow the most simple rules

**HSE UK:**

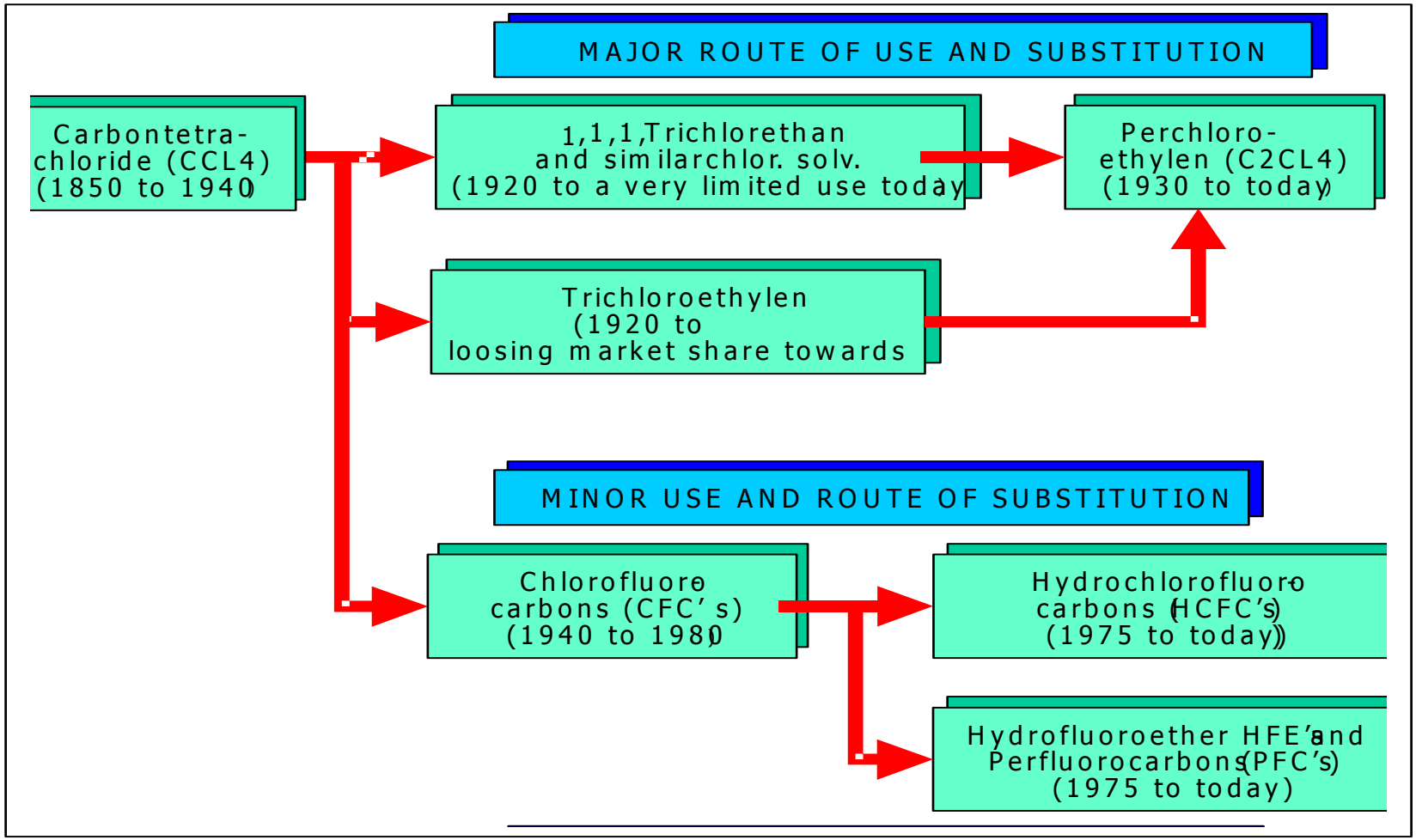
*"In approximately 1.3 million British companies chemicals are handled. When questioned, **only 16%** of these companies were able to state the applicable law for handling chemicals or the limit values for these substances at the workplace."*

**Ministry of Social Affairs – State of Hesse**

Between 60 and 70 % **do not (or cannot) observe** the statutory requirements of chemicals regulation: Instructions of employees, lists of dangerous substances, documentation of the substitution check.

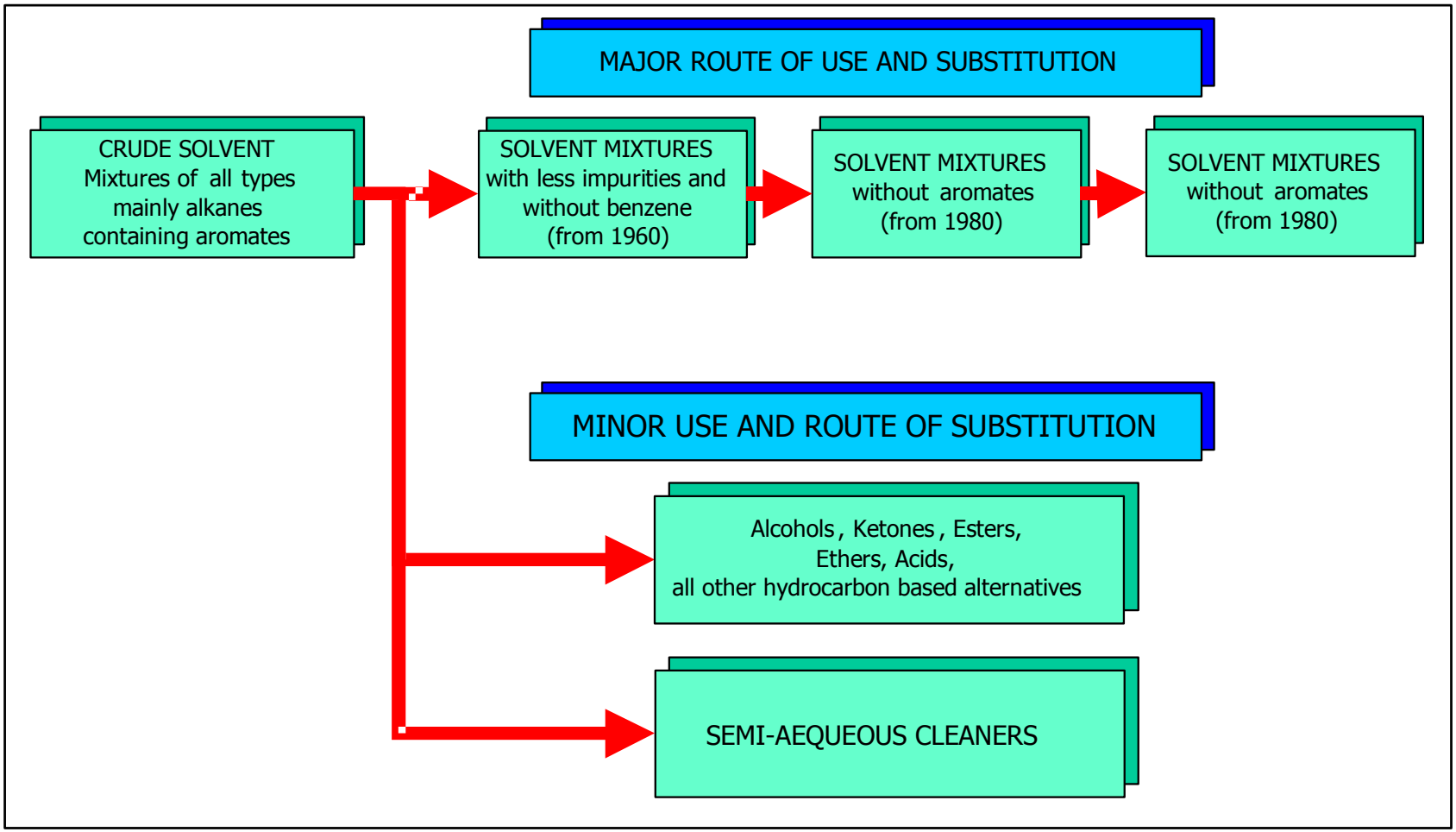
# Substitution in practice and examples of substitution

## History of organo-halogens substitution for metal cleaning



# Substitution in practice and examples of substitution

## History of petrochemicals substitution for metal cleaning



# Substitution in practice and examples of substitution

| Substitution from chlorinated solvents to organic solvents | | |
|---|---|---|
| **PRO SUBSTITUTION** | **CONTRA SUBSTITUTION** | **MAIN ACTOR** |
| | Cleaning efficiency | Industrial users, esp. producers of high quality products |
| Advanced equipment, to reduce the emissions acc. to stricter regulations | | Equipment producers |
| | Advanced and expensive cleaning equipment necessary against fire and explosion | Industrial users |
| Use of less cleaning agents through improved machinery design | | Industrial users, Cleaning equipment producers |
| Risks of spilling and soil contamination, storage obligations | | Industrial users, insurances, authorities |
| Prices for sludge, contaminated with chl. solv. | | Industrial users, authorities |
| Health hazards | | Less potential conflicts with authorities, workers, neighbours and the public |

# Substitution in practice and examples of substitution

| Substitution from hydrocarbons to water based cleaners | | |
|---|---|---|
| **PRO SUBSTITUTION** | **CONTRA SUBSTITUTION** | **MAIN STAKEHOLDER** |
| | Cleaning efficiency | Industrial users (technical and quality view) |
| | Drying problems (time, quality) | Industrial users technical and quality view) |
| Fire and explosion risk | | Industrial users |
| | More advanced and expensive waste water equipment | Industrial users (economic view) |
| | Difficult sharpening of the cleaning agent | Industrial users (process handling) |
| | Energy and water consumption | Industrial users (environmental view) |
| Less risks of spilling and soil contamination | | Industrial users (environmental view) |
| Less health hazards | | Authorities, workers, public, neighbours |

# Substitution in practice and examples of substitution

## Cleaning of facades - shift of risks and uncertain risk assessment

### Halogenated solvents vs. high pressurised water

**Risks of halogenated solvents**
Contaminated soil
Dangerous waste
Exposure of workers

**Risks of high pressurised water**
Risk of damages of the façade:
mechanical, wetness, oxidation, freezing
Construction standards
Standards by cultural heritage authorities
Waste water
Energy consumption
Accident risk due to high pressure
Investment into equipment

# Substitution in practice and examples of substitution

## Biodegradable loss lubricants (BLL) ` in inland and coastal water activities

### Costs and Quality

**Priority of state owned water authorities:**
Water protection
Long standing – high quality

**Priority:**
Price
Sufficient quality
Short term functioning
Water protection? - No legal obligation!


*www.ivam.llincwa.nl*

# Main research results on substitution

## Main factors not to substitute

### Uncertainty and 'Never change a running process'

- No priority neither at enterprises nor in practical governance
  Dealing with the current problems is already too laborious
  No additional problems by an unnecessary innovative approach (existing standards etc.)
- Uncertainty in risk assessment – Shift of risks
- Substitutes are less tested in practice
- Integration in the production chain makes an innovation beyond enterprise borders necessary
- Technological or economic difficulties

# Main research results on substitution

## Main factors to substitute

### Guiding principles ('Leitbilder') and market forces

- **Target oriented**: Health, Environment, Nature
- **Substance oriented** (general approach):
  Water based, biodegradable, clean, pure ….
- **Substance oriented** (scientific approach):
  Lowest toxic effect for humans and environment
- **Legal approach:** Not labelled as dangerous
- **No scandal substances** (marketing driven):
  No asbestos, no heavy metals, no PCBs, no TBT, no ...

# Main research results on substitution

**There is no simple 'Yes' or 'No' – Options are:**

- **Better - than the conventionally used chemical**
- **Equal …**
- **Better in certain applications - worse in others**
- **Equal in certain applications - worse in others ….**
- **Worse ….**

# Main research results on substitution

**A full calculation of the costs of one substance/preparation in comparison to the costs of an substitute is in most cases not available, even not inside the enterprise**

When comparing the current situation with a possible alternative situation, economic considerations should include factors as:

- Price / performance ratio
- Man hours connected with the use of the substance/ prep
- Investment costs for technical equipment
- Energy consumption
- Price of freshwater and waste water treatment
- Environmental protection costs (air, soil and water)
- Health and safety protection costs
- Waste management and disposal costs and
- Accident and fire protection incl. insurance costs.

# Conclusions for REACH

## What does this mean for substitution requirements under REACH?

**Proof of sufficient desk research**

- BREF-documents
- Branch-oriented databases as: Chemsource, GISBAU, CATSUB
- Substitution lists of large enterprise as Scania White list

**Advanced cost calculation beyond price per litre or kg**

**Consideration of different technological feasibility for different applications**

# Conclusions for REACH

## Types of substitution problems, regulatory options and possible results

| *Efforts dep. on the type of the substitution problem* | *Regulatory Option In general / under REACH* | *Intended result* |
|---|---|---|
| 1. Open innovative and demanding technolo-gical questions: R&D | Support, incentives, research; REACH – 6 years time limited authorisation | Development of a new preparation or of a completely redesigned process |
| 2. Adaptation of existing technologies necessary: DEVELOPMENT | Mixtures of incentives and command-and-control; REACH: detailed substitution plan and time limit | Adaptation of processes Medium-Term implementation |
| 3. Implementation of already widely spread reference processes: INFORMATION | Substitution has to be applied – exceptions only for certain applications | Introduction of an already practically tested solution |

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