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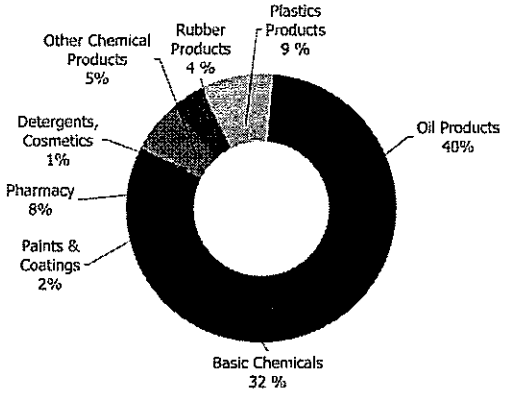
二、參訪機關簡報資料

11 billion

Chemical Sector Exports 2017

Chemical Industry Federation of Finland

Finnish Chemical Sector Exports by product group



2017 Total EUR 11,396 milj.

Source: Board of Customs

Chemical Industry's big impact on Finnish economy

20

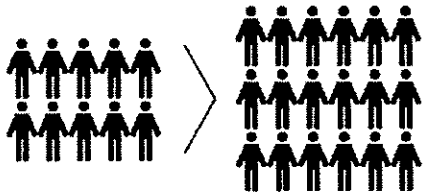
Of exports of goods 19%
Of manufacturing 18%
Sales EUR 20 billion

Operating principle

We promote the competitiveness and operating conditions of our members as well as cooperation between our members and stakeholders.

Nearly 100 000 jobs!

10 jobs in chemical sector creates 18 for other sectors
3 jobs in chemical sector creates 4 jobs for services!



Source: KPMG, Kemianteollisuuden taloudelliset vaikutukset Suomessa, 2017

A trade association for the chemical industry and its closely related sectors

nearly 400 company members

13 association members

Finnish **Bioindustries** FIB
The Finnish **Boatbuilders** Employers' Association
The Finnish **Cosmetic, Toiletry and Detergent** Association
The Finnish **Crop Protection** Association
Association of Finnish **Environmental Industries and Services YTP**
Employers' Association of Finnish **Goldsmiths**
The Association of Finnish **Leather and Shoe** Industries
Pharma Industry Finland
Association of the **Glass and Ceramic** Industry
The **Oil Product** Association
The Association of Finnish **Paint** Industry
Finnish **Plastics** Industries Federation
The Finnish **Printing Ink** Association
The **Rubber** Manufacturers' Association of Finland

We are in the frontline in Sustainability

- Chemical industry's responsibility program, in Finland since 1992
- Covers **80%** of production, **60%** of personnel, approx. **100** companies
- Practical and target oriented cooperation, Companies are committed to continuous improvement
- From energy efficiency to wellbeing at work
- Coordinated by Chemical Industry Federation of Finland, **collaboration** together with Industrial Union, Pro ja YTN
- **Great Results!**

RES PON SIBLE CARE 25

Areas of operation 2016–2018

Member services

Education, expert assistance and solutions, network building, member communications

- Training, counselling and expert assistance services to member companies
- Internal committee work
- Member communications, events and projects
- The Responsible Care programme
- Supportive networks, the best industry for occupational well-being by 2020
- Settling disputes, representing member companies in courts
- Negotiating collective agreements for the chemical industry
- Cooperation platforms for youth and educational institute communications

Interest representation

Regulation, agreements, taxation, permit processes and public funding

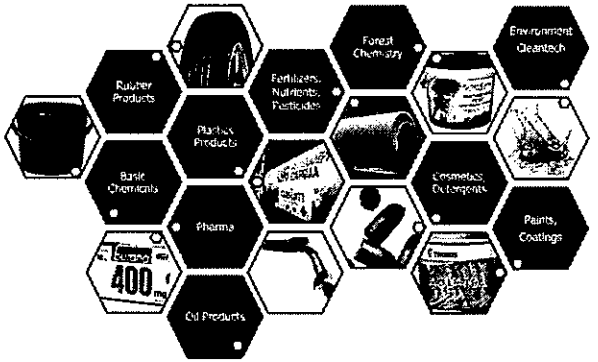
- Bioeconomy and circular economy
- Energy, climate, the environment and logistics
- Educational systems
- Research and development, innovation systems
- Industrial Relations
- Occupational, process and product safety

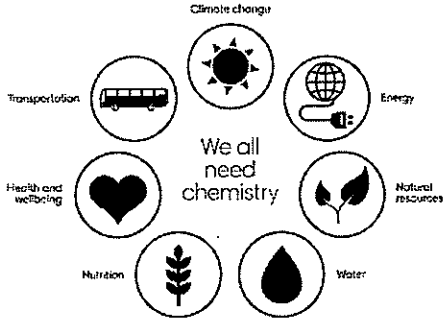
Industry communications

Awareness, reputation and perception

- Media and Public Relations
- Industry brand
- Industry reviews
- Youth communications and cooperation with educational institutes

From process chemistry to lipsticks





Chemical Industry Federation Organization

The Board

Director General
Mika Aalto

Administration
Arja Puikkonen

Industrial Relations
Jyrki Hollmen

Terms of employment; Collective bargaining and Workplace consultation, Labor law, Competence and Education, Educational Institution Relations

Responsibility
Sami Nikander

Bio and Circular economy, Energy and climate, Logistics, Environment, Safety, Product Stewardship, Responsible Care

Public Affairs
Susanna Aaltonen

Communications and Public Relations, Industry facts and brand, Innovations, Renewal

Chemistry enables Circular Economy and Bioeconomy

- The basic principle of the Circular Economy is to keep products, components and materials in the society at their highest utility and value for as long as possible: "One man's trash is another man's treasure".
- Circular Economy is a path to a more sustainable development and a great economical opportunity that also renews business models.
- The development of Bioeconomy and Circular Economy requires cross-sectoral co-operation on many fronts, e.g. in R&D&I, administration and business.
- The Chemical Industry of Finland is a forerunner in Circular Economy. Industrial symbioses within the sector are in full operation, e.g. in the towns of Kokkola and Porvoo, and side and waste streams from other companies and sectors are being utilised.

Chemical Industry and Circular Economy in Finland

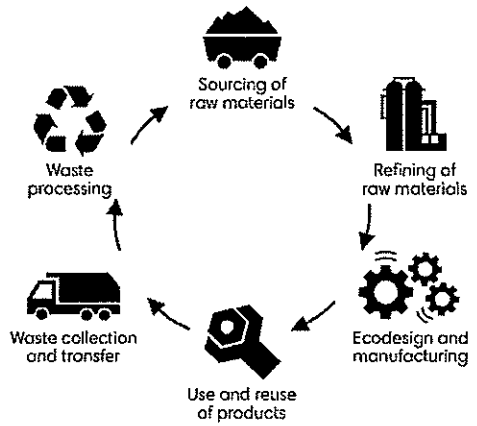
Ms. Pia Vilenius, The Chemical Industry Federation of Finland

Strengths of the chemical sector in Circular Economy and Bioeconomy

- **Mastering the molecular level.** Enables the smart use of both primary and secondary raw materials. The aim is not only recycling but upcycling. Chemistry plays a crucial role, as its core competence is to create value for different material streams.

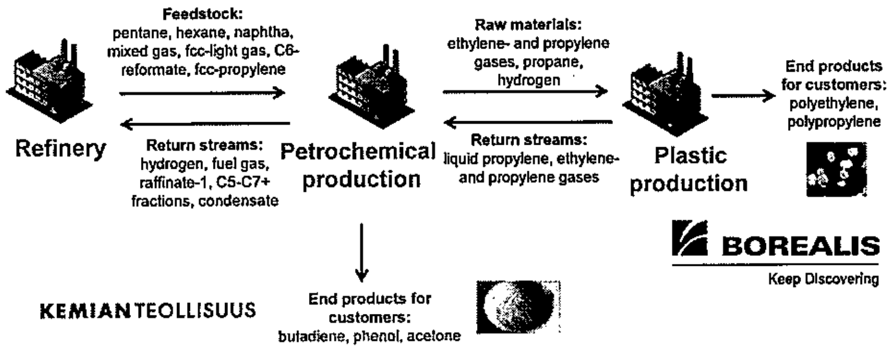
- **Boosting connectivity**: the chemical sector is connected to almost all other sectors by providing them with materials and sustainable solutions. It is difficult to find a value network within the manufacturing industry in which chemistry is not involved. Ecosystems and smart added value use of raw materials will be of increasing importance, and in this, chemistry will play a key role.

Chemistry enables Circular Economy



Borealis is part of industrial symbiosis: utilizes sidestreams in production

- Production chain from crude oil to plastics in Kilpilahti, Finland: **refinery, petrochemical & plastic production**
- Utilizes streams unsuitable for fuel and lubricant production from Neste's refinery
- Borealis returns streams back to the refinery to be used e.g. as gasoline components.



BOREALIS
Keep Discovering

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A few Circular Economy examples from the industry

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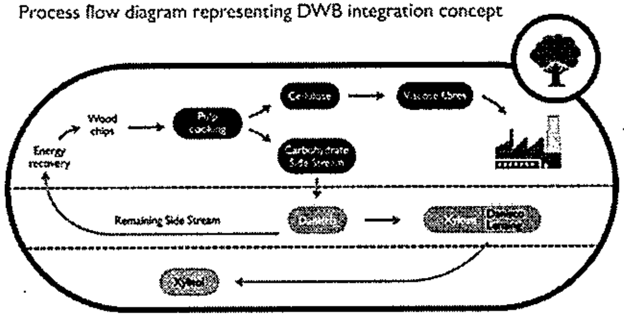
5

DuPont Nutrition & Health: Xylitol with health benefits from pulp and paper industry side streams

- Xylitol is manufactured with hydrogenation technology from xylose purified from pulp and paper industries' side streams. The carbon footprint of the product is ca. 90 % lower than that of xylitol produced by Chinese competitors using corn cobs as raw material.
- DuPont N&H is world's leading xylitol producer: the largest xylose plant in the world is located in Austria and the world's largest xylitol plant in Kotka, Finland. Xylitol is used as a tooth-friendly sweetener: it has been clinically proven to decrease tooth decay (EFSA approval).

Process flow diagram representing DWB integration concept



XIVIA
DUPONT

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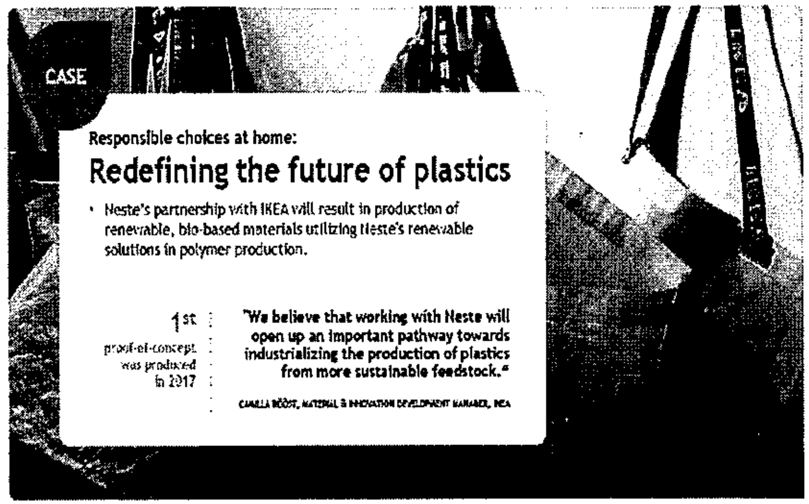


NESTE

Yara: gypsum obtained as a process by-product decreases effectively the loss of phosphorus

- **Gypsum ($CaSO_4$) is a by-product** from the phosphoric acid production at Yara Siilinjärvi plant
- Gypsum is spread to clay soils rich in **phosphorus (P)**, 4 tonnes/ hectare. The impact will last approximately 5 years.

Gypsum amendment reduces the loss of P from fields to watersystems:

- The amount of dissolved reactive P by 30 %, the amount of soil particulate P by 60 % and the he amount of dissolved organic carbon by 50 %

Gypsym amendment is a promising method for reducing the P load from agriculture to the Baltic Sea

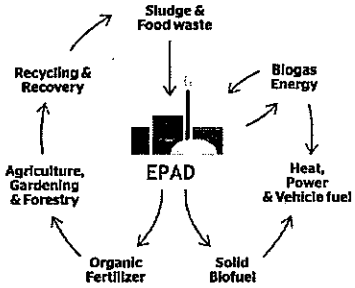


YARA

KEMIANTEOLLISUUS

Envor Protech Oy: EPAD-biogas technolgy for paper&pulp sludges

- EPAD is globally the first biogas technology to utilize forest-based slurries from pulping process as the feedstock
- Potential technology to both existing paper and pulp mills as well as the next generation bioproduct mills
- Case: EcoEnergy SF Oy biogas plant in the area of MetsäFibre Bioproduct Mill in Äänekoski, Finland
- Biogas plant shall process the wastewater slurries of the Bioproduct Mill, and turn those into biogas for transportation, carbon dioxide for pulping process as well as fertilizers and solid biofuel for boiler plants



EnvorPROTECH

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Neste: Innovative NEXBTL technology for the production of renewable traffic fuels

- Almost any oil or fat can be refined into Neste's renewable products. Raw materials include e.g. animal fat from food industry waste, waste and residues from vegetable oil refining, as well as vegetable oils.
- The **share of waste and residues** of all renewable raw materials **is already ca. 80 %**, with an aim to further increase the share
- The use of the product is **expanding** from traffic fuels also **to production of other chemical products such as plastic raw materials**



NESTE

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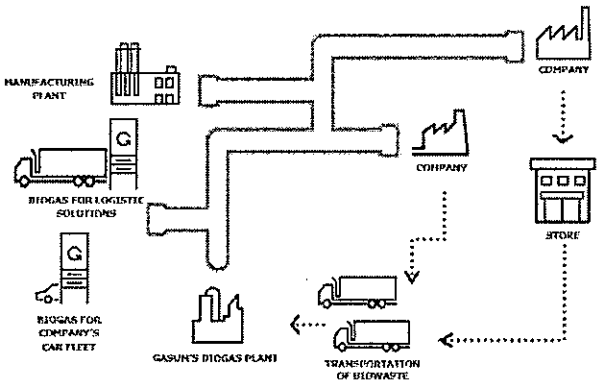
Gasum unites waste & energy and brings recycled biogas in the market



- **Gasum's innovative concept offers companies the opportunity to produce biogas from their own biodegradable waste**
- **The produced and upgraded biogas can then be used in logistics, to fuel the company's own car fleet and as a source of renewable energy in the production processes of new products**

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Gasum

St1 Biofuels: Traffic biofuel from waste and residues

What are the raw materials of bioethanol?

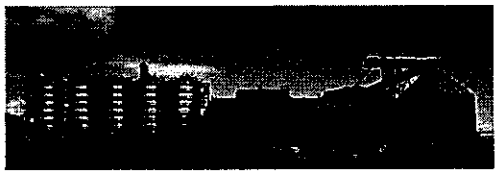
- Side streams and waste of food industry and household biowaste
- Saw mill residues like sawdust and chips

Where is bioethanol produced?

- In five plants in Finland and in one plant in Sweden
- First plant using saw dust as feed stock is under construction in Finland
- Production technology is developed by St1

Where is the produced bioethanol used?

- To replace imported fossil fuels



Further information
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www.st1biofuels.com

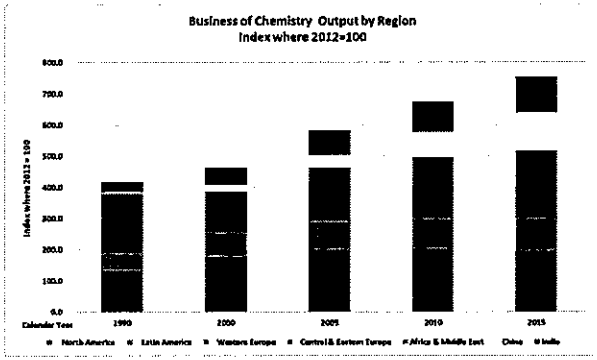
Currently ongoing in Finland on Circular Economy

- A Large survey "A review of potential economic instruments for circular economy" released in June
- A National Roadmap on Plastics is being drafted (deadline September): a large group of different stakeholders, work lead by the Parliament
- The National Roadmap on Circular Economy is under renewal, lead by Sitra; stakeholder groups involved; deadline January 2019
- The Circular Economy/Waste legislation package; national implementation work starts in June
- A lot of different programs for creating and developing business in Circular Economy; Sitra and Business Finland

Promoting corporate social responsibility in industry

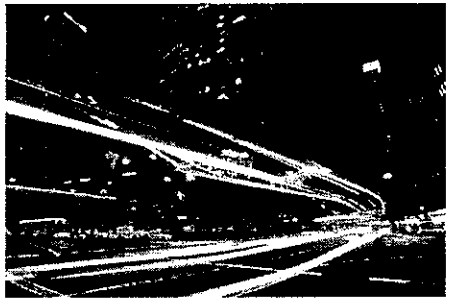
A brief introduction

Global Chemistry Output



Responsible Care

- Responsible Care is the global chemical industry's initiative to improve
  - Health
  - Environmental performance
  - Enhance security
  - Enhance stakeholder dialogue
- The program was launched in Canada 1985
- A common program but adapted to the national needs



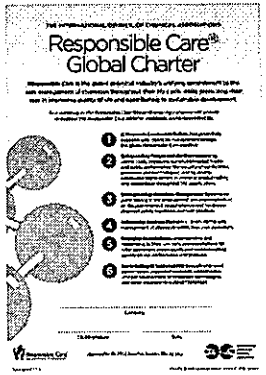
A common understanding of the concept

- Corporate Social Responsibility is a **universal concept** that represents the good, **desirable business behaviour**
- This requirement is seen to extend **beyond the legal responsibility** to comply with legislation and sees organizations freely taking more steps
- "Corporate Social Responsibility is the continuing commitment by business to behave ethically and contribute to economic development while improving the quality of life of the workforce and their families as well as of the local community and society at large." –Sustainable business council

Responsible Care in Finland

- About 100 companies
- 80% of the production in Finland
- 60% of the personnel
- Launched in Finland 1992
- In cooperation with the trade unions
- The companies commit to constant improvement

Responsible Care Global Charter



1. A Corporate Leadership Culture
2. Safeguarding People and the Environment
3. Strengthening Chemicals Management Systems
4. Influencing Business Partners
5. Engaging Stakeholders
6. Contributing to Sustainability

Where are we today?

-88 %
Lost time injuries frequency rate** from 1988

-21 %
Energy consumption* from 1995

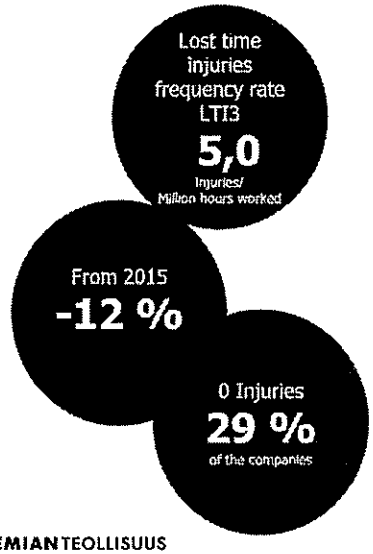
-60 %
Water consumption* from 1995

-27 %
Greenhouse gas emissions* from 1999

*Proportional to the volume of production
** LTI3

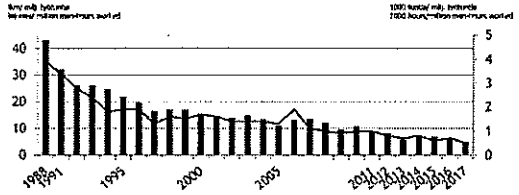
Our contribution to the SDGs – how we position ourselves to the global discussion

Responsible Care
Our commitment to sustainability



Developing safety at work

Työstä poissaoloon johtaneiden tapaturmien lukumäärä miljoonaa työtuntia kohden sekä menetetyt työtunnit miljoonaa työtuntia kohden.
Lost time injuries frequency rate and work hours lost per million man-hours worked



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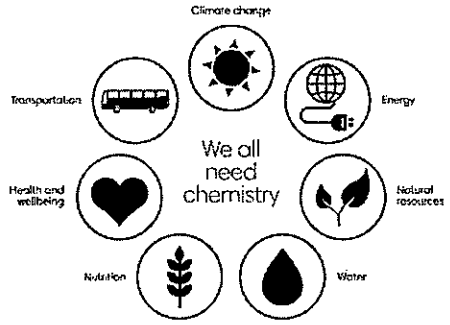


01 SUBSTANCE EVALUATION

☐ Ask for more Information

1. What sorts of further information may be requested?

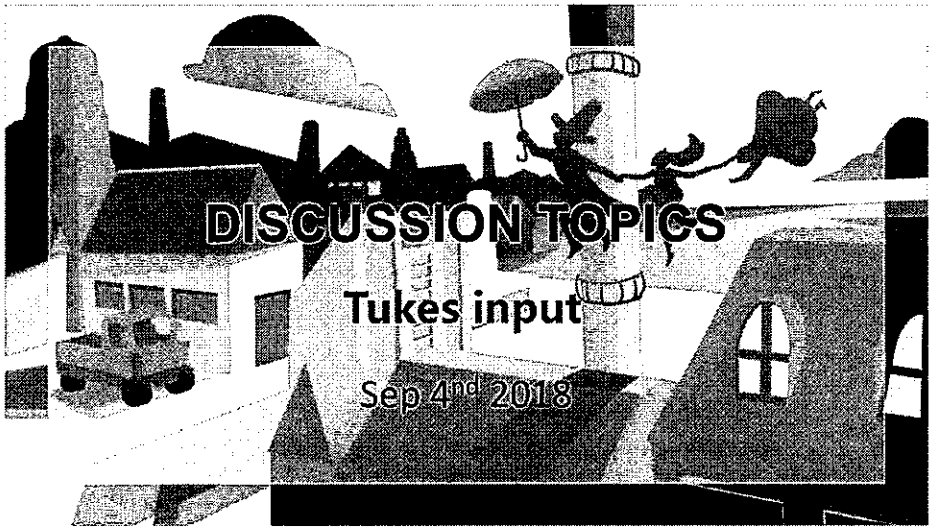
Tukes:

Substance evaluation concerns basically evaluation of the intrinsic properties of a substance, but it focuses on improving risk management.

To request additional information under SEv, the agency must be able to demonstrate inter alia*:

1. A potential risk to human health or the environment
   - Proof of a real risk is too high
   - Risk is combination of hazard and exposure information
2. That the potential risk identified needs to be clarified
   - SEv is intended to assess risks that may occur in reality and not only theoretically
3. That the information requested has a realistic possibility of leading to improve risk management measures

*ECHA, Board of Appeal



01 SUBSTANCE EVALUATION

☐ Ask for more Information

1. cont... What sorts of further information may be requested?

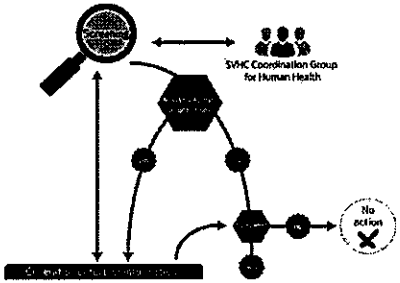
Tukes:

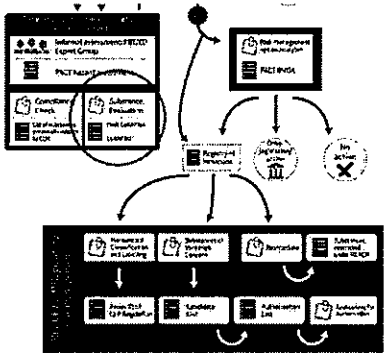
Typical endpoints for information requirements based on substance evaluation, e.g.:

- Endocrine disrupting properties (effects on health and/or environment)
  - OECD No. 150 Guidance document on standardised test guidelines for evaluating chemicals for endocrine disruption
- Information on persistence, bioaccumulation and/or toxicity to verify PBT/vPvB assessment
- Information on carcinogenic, mutagenic or reprotoxic (CMR) properties if not comprehensive in the registration dossier
- etc.

Test methods: usually based on OECD test guidelines

Activities and regulatory processes under EU REACH





● Information on regulatory processes and activities
● Substance flows

01 SUBSTANCE EVALUATION

☐ **Use information**

1. What is the way to get more comprehensive use information for article management, such as conducting post-market inspections or implementing regulations on articles/products?

Tukes: Enforcement: articles are covered by SVHC information requirements and some restrictions in REACH. In enforcement we can request information from the company and/or test articles for a specific substance.

01 SUBSTANCE EVALUATION

☐ **Ask for more Information**

2. If the further information requirements are not mandatory under REACH, what the approach to get the information?

Tukes:

- Information requirements in REACH regulation, Annexes VII-X, are mandatory in registration phase.
- SEv decision with further information requirements is also legally binding when needed to clear a concern.

SEv process:

Phase 1

Evaluation (eMSCA) → SEv report and Draft decision, if further information is needed (eMSCA) → REGs' comments → Response to comments (eMCSA) → Other MSCAs' and ECHA's comments → Response to comments (eMSCA) → REGs' comments → Final decision (ECHA) → to REG

Phase 2

Submission of required information (REG) → Evaluation of the new information (eMSCA) → SEv conclusion

02 ENFORCEMENT

☐ **Implementation**

- Do you have any post-market actions to check and validate compliance to regulations?

Tukes:

- Yes. We have a unit concentrating only to enforcement issues of several different chemicals related legislations. We do both proactive and reactive enforcement, which means that we plan our own enforcement projects, or participate to EU- or Nordic common projects. And we react to notifications from other authorities, consumers and competitive companies on possible non-compliant situations. We try to act risk based and we have adopted a strategy on risk based reactions to non-compliances of different legislations. Every year several projects are carried out; in 2017 our enforcement targeted about 1400 products and 580 company visits

01 SUBSTANCE EVALUATION

☐ **Exposure information and assessment results from Registrants**

1. How do Tukes confirm/ensure the reliability of the exposure information and subsequent assessment results submitted by registrants?

Tukes: Enfocement: we can enforce the exposure scenario in safety data sheet and its distribution in the supply chain. In 2017 an EU wide ECHA Forum enforcement project REACH-EN-FORCE-5: Exposure Scenarios, extended SDS, RMM and OC was conducted. Its results are not yet ready.

In assessing the correctness of the information the task is also in occupational health and environmental protection authorities

03 COMPLIANCE SUPPORTING MEASURES

- **Supporting measures**
  - How do you initiate and plan a supportive program? What are key elements you would consider while developing supporting service?

Tukes:

Finnish helpdesk's support to companies

- Web pages on chemicals: Information on scope of regulations, procedures, obligations,...
- News on current topics
- FAQs and Fact sheets on hot topics
- Special E-mail and phone campaigns
- Communication on social media via Tukes channels
- Face to face meetings
- Phone service and web form for questions

Communication activities and support material take account of

- proceedings/deadlines/transitional periods related to the implementation of REACH
- amendments to REACH
- ECHA's news and communication campaigns
- often asked questions.

02 ENFORCEMENT

- **Implementation**
  - What are your major implementation strategies? (Including selection of inspection targets, different regulating subjects, etc.)
  - How do you collaborate with the customs on enforcement of the import of chemicals? Is inspection taking place in cooperation with other authorities?

Tukes: risk based prioritization and actions case by case. See slides

- We use regularly the EU Commission's Rapex-system where all EU enforcement authorities gather information on products on the EU market that cause severe risk to human health or the environment.
- Cooperation on a regular basis. A network of Finnish enforcement authorities meeting twice a year and changing information on different topics relating to enforcement. The Customs provide us their decisions when products are banned from entering the Finnish market, and we provide them our decisions when the company is importing the non-compliant product to other EU countries.

03 COMPLIANCE SUPPORTING MEASURES

- **Difficulties and challenges**
  - What are the difficulties and challenges the SMEs commonly face? How do you help them to overcome those difficulties and meet requirements?

Tukes:

Topics of enquiries

- Registration of substances
  Do I have to register? Scope? How to register?
- Safety Data Sheets
  In what language should the SDS be supplied? Who has to supply the SDS? Who has an obligation to translate the SDS? When does the SDS need to be updated? When does the registration number has to be included in the SDS?...
- Obligations of importers
  What do I have to do when I start importing chemicals from outside the EU?

02 ENFORCEMENT

- **Difficulties and challenges**
  - According to your experience, what are the difficulties and challenges to improve the compliance of regulations in your country?

Tukes:

- Usually lack of knowledge and resources in companies to be able to follow chemicals legislation. We have the chemicals helpdesk working very well and companies can ask their questions. Still there are many companies who are not aware of their duties and do not even know what they could ask from the helpdesk.

03 COMPLIANCE SUPPORTING MEASURES

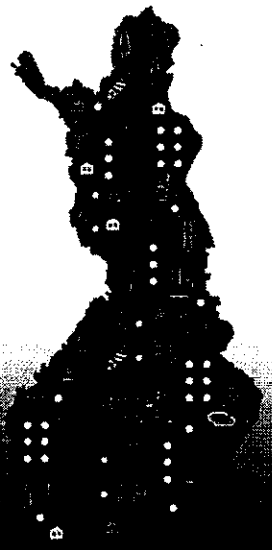
☐ **Difficulties and challenges**

- What are the difficulties and challenges the companies commonly face while communicating along the supply chains and applying "Use Map"?

Tukes:

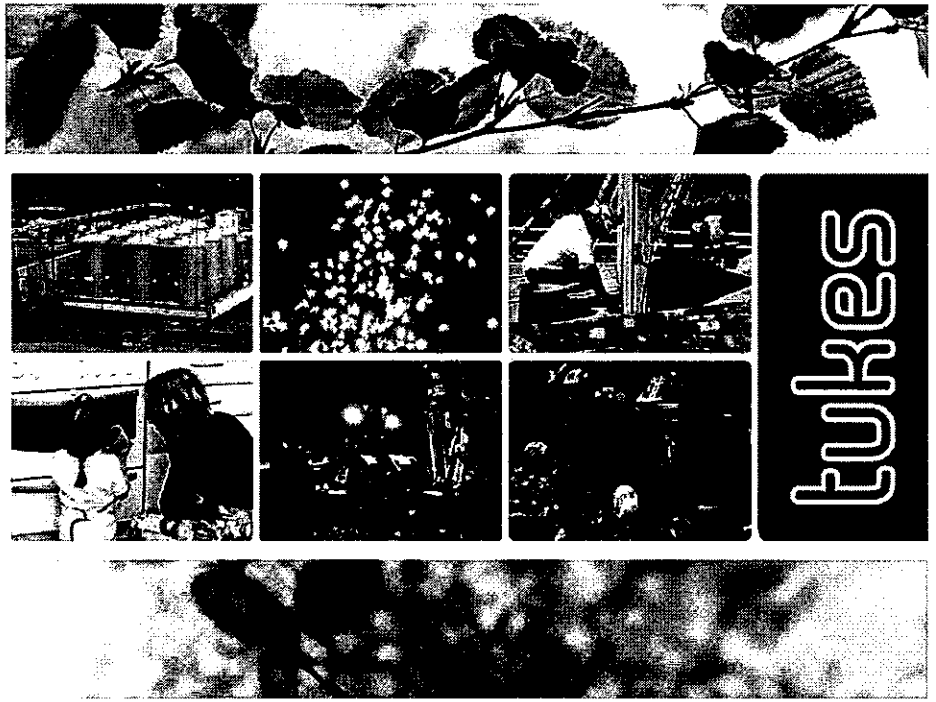
Thank you for your attention!

OPERATIONAL PRINCIPLE



We PROMOTE the operational SAFETY of products, services and industrial operations and their reliability

SUOJAN TUOJA. tukes



OUR VALUES

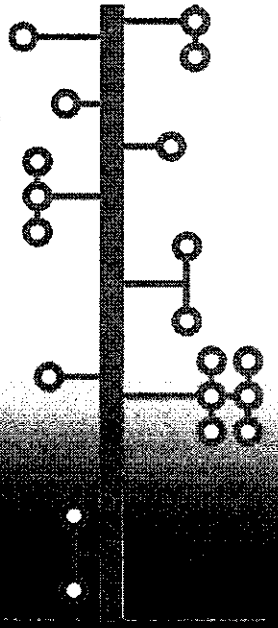
WORK TOGETHER WITH EXPERTISE

– Experiment boldly and reform innovatively

SUOJAN TUOJA. tukes

TUKES VISION 2022

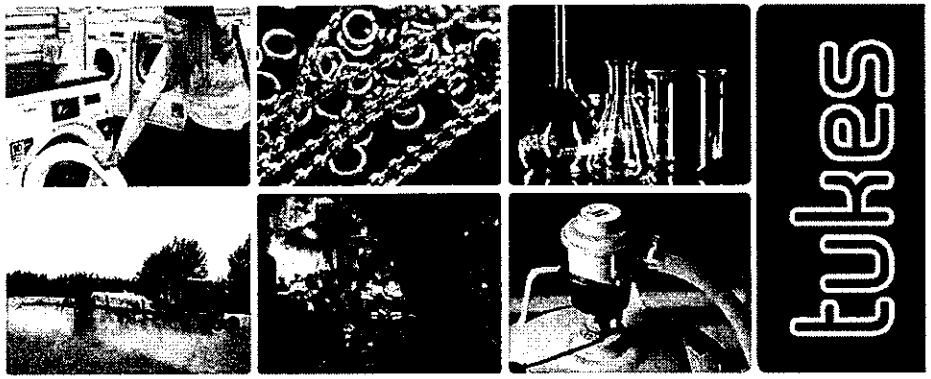
- This is how our operations affect Finnish society



VISION

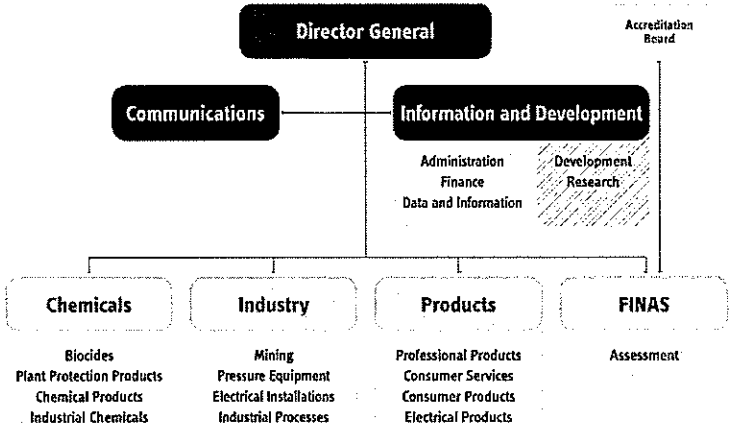
Responsible, safe and COMPETITIVE Finland – Tukes is a builder of cooperation

SUOJAN TUOJA. tukes



Surveillance

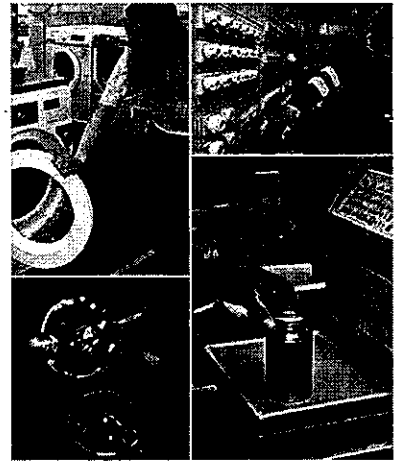
Our organisation



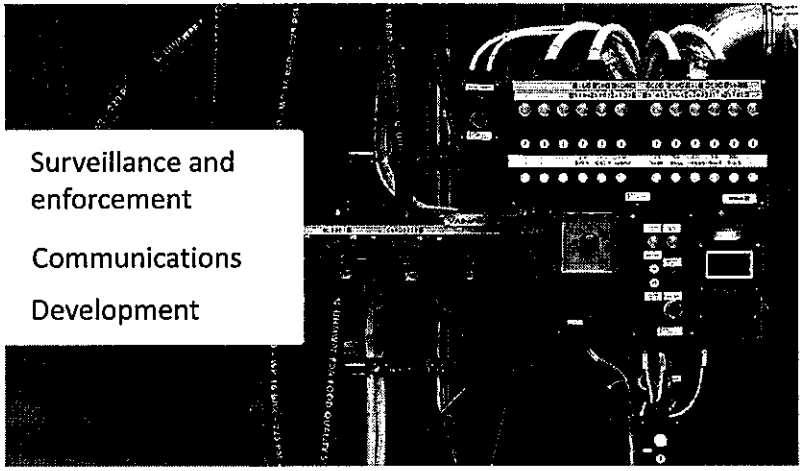
1. Products

Professional products
Consumer products
Consumer services
Electrical products

Responsibility for the surveillance of product safety, technical reliability and consumer safety.



Tukes' core duties



Surveillance and enforcement

Communications

Development

Communications

2. Industry

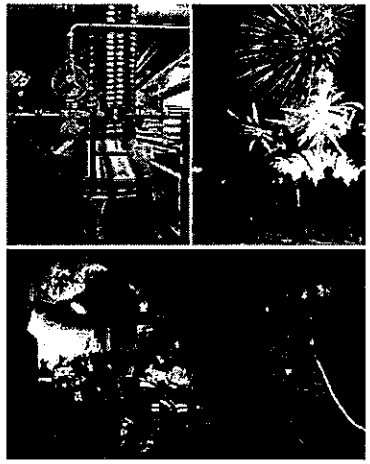
Industrial processes

Pressure equiments

Electrical Installations

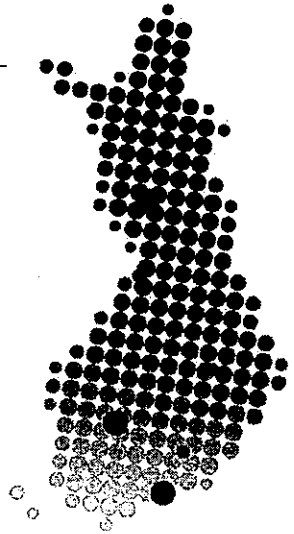
Mining

Responsibility for the surveillance of production plants and mines, installation business and inspection services.



Tukes in brief

- Core duties: surveillance and enforcement, communications and R&D
- Founded in 1995/2011
- FINAS Accreditation service 1.1.2015 ->
- Main offices in Helsinki, Tampere and Rovaniemi
- 268 employees (person-years)
- Budget: expenditure €27.4 million (gross), income €6.6 million



3. Chemicals

Consumer chemicals

Industrial chemicals

Biocides

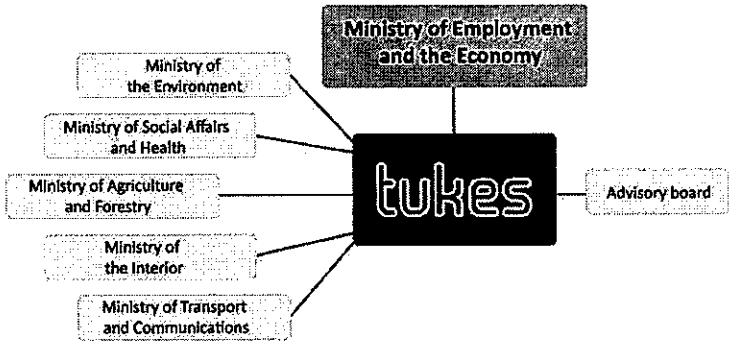
Plant protection products

Responsibility for the enforcement and surveillance of chemicals legislation.

Administrative position

Tukes operates within the administrative branch of the Ministry of Employment and the Economy.

Steering ministries (multi-ministry steering)



Responsibilities of Chemicals Department - legislation covered

- **Enforcement** in addition to the above
  - Plant protection products
  - RoHS
  - Packaging Waste Directive
  - Batteries and accumulators
  - Labelling of explosive precursors
  - Persistent organic pollutants (POP)
  - Precious metal products (national legislation)
  - Volatile organic compounds (VOC) in paints and varnishes

tukes

Collaboration with ECHA - Implementation and enforcement of EU chemicals legislation

Role and duties in the implementation of EU chemicals legislation

➢ Tukes is **appointed**
  - Competent Authority (**CA**)
  - National **helpdesk** (www.kemikaalineuvonta.fi)
  - National Enforcement Authority (**NEA**)

➢ Tukes **experts** are nominated to
  - **ECHA committees** (BPC, MSC, RAC, SEAC) and the **Forum**
  - **ECHA expert groups:** ED, Nano, PBT, RIME

Responsibilities of Chemicals Department - legislation covered

Assessment of hazards and risks and safe use of chemicals – purpose high level of protection of human health and the environment.

- European legislation – responsibility of the Unit:
  - Classification, labelling and packaging of chemicals - **CLP**
  - Registration, evaluation, authorization and restrictions of chemicals – **REACH**
  - Biocidal Products Regulation - **Biocide regulation**
  - Biodegradation of surfactants – **Detergents Regulation**
  - Serious undesirable effects of cosmetics SUE – **Cosmetics Regulation**

Competent Authority tasks – evaluating, commenting, preparing

- Authorisation process:
  - **Preparation of** proposals for **identification of a SVHC substance** (upon request by the Ministries, Art. 48) – **FI proposal:** terphenyl, hydrogenated
  - **Identification of SVHC substance** – priority!

Commenting proposals for identification:

Year	Proposals	Evaluated	Commented
2012	67	20	3
2013	10	10	9
2014	14	14	10
2015	9	9	9
2016	10	10	10
2017	11	11	11

Role and duties in the implementation of EU chemicals legislation

- **CA tasks** mentioned in the Regulations
  - evaluating, commenting and preparing

- Upon request by the Ministry of Social Affairs and Health and/or Ministry of the Environment, performing **tasks** allocated to **Member States**, such as preparing
  - proposals for identification of **SVHC** substances and
  - proposals on **restrictions** of manufacturing, placing on the market and use of specific dangerous substances

Competent Authority tasks – evaluating, commenting, preparing

- Restrictions:
  - **Commenting restriction proposals,** case by case
    - 2012: ***Phtalates commented***, Chromium (VI) in leather articles evaluated
    - 2013: Lead in consumer articles, Dichlorobenzene, NMP, evaluated
    - 2013: Nonylphenol and nonylphenol ethoxylates (monitoring data submitted)
    - 2014: ***Nonylphenol and nonylphenol ethoxylates, commented***
    - 2015: ***Methanol commented***, PFOA, D4&D5 siloxanes, DecaBDE evaluated
    - 2016: ***Phtalates and TDFAs commented***
    - 2017: ***Diisocyanates and Lead in PVC commented***

  - **Preparation of restriction proposals** (upon request by the Ministries)
    - 2014 Methanol in windscreen fluids, Co-op with PL

ECHA Committee work

MSC: 1 member 0.5-0.7 FTE, an alternate 0.2-0.4 FTE, supporting 6 CA experts
- Assessment of all draft decisions/identifications, where possible participating as rapporteur

RAC: 1 member 0.5-0.7 FTE; 3 advisors 1 FTE, supporting 4-6 CA-experts
SEAC: 1 member 0.5-0.7 FTE
- Assessment of all proposals and applications
- Participation in committee opinion making procedure as active rapporteurs

Performance indicators for year 2018

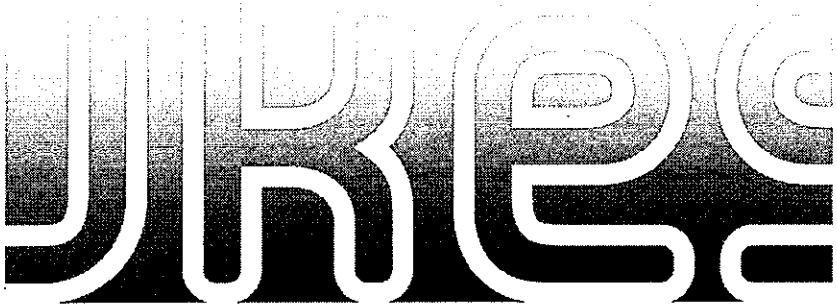
Increasing knowledge: REACH- and CLP- helpdesk	600
Influencing by information means: Media and internet notices, factsheets etc.	10
Increasing information available: Dossier evaluation decisions (DEv–CCH, Dev-TPE)	0
Increasing information available: Substance evaluation work (manual screening, Corap evaluation, SEvDD)	54
Increasing information available: Proposals for harmonised classification and labelling (CLH)	24
Risk management of substances of concern: Substances for authorisation process (SVHC identification, Draft REC and RMOA)	21
Risk management of substances of concern: Substances proposed for restriction process	7
CA outcome in total	106

Competent Authority tasks – evaluating, commenting, preparing

- **Classification and labelling of substances**
  - **Commenting** harmonised classification and labelling **(CLH) proposals** in public consultation, average target 20
  - **Preparation of CLH proposals** and participating in the follow-up activities (Art. 37): Priority for evaluated BS and PPP active substances
    - **2015:** hymexazol, propiconazole, (earlier CLH submissions: difenacoum, glutaraldehyde)
    - **2016** (hymexazole)
    - **2017** (hexytiazox, desmedipham, phenmedipham), peracetic acid
    - **2018** *hymexazole, hexytiazox, desmedipham, phenmedipham, peracetic acid, foramsulfuron*

Year	CLH-proposals	Evaluated	Commented
2013	31	23	16
2014	45	27	20
2015	41	14	14
2016	36	15	13
2017	63	29	22

Thank you for your attention!



Chemical risks – prioritisation approach

- **ECHA work programme** - availability of high quality data used to identify and address chemicals of concern, chemicals that matters most
- **National programme on Dangerous Chemicals:** objective to ensure that chemicals pose no risk to the environment or human health hazards in Finland in 2020; Circular economy, 7th EU Environment Action Programme, Agenda 2030
- **Tukes focus** – substances *on the Finnish market/used* in Finland/FI registrant (the Product Register), *use categories* (consumer use, cosmetics), *National Programme on Dangerous Chemicals* (PBT, ED, nanomaterials), *BS/PPP active substances*.
  ECHA Committee work: *sharing the burden* (ongoing tasks and rapporteurships of FI Committee Members taken into consideration)

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Welcome

General introduction to ECHA

Jenny Holmqvist
Coordinator of International Affairs

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Visit of Taiwanese Delegation

4 September 2018

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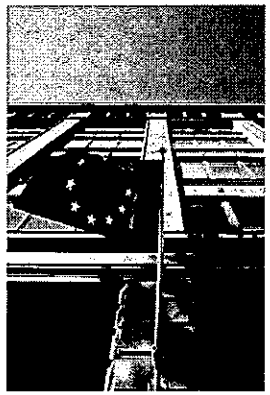
ECHA key facts

- Established 1 June 2007
- Responsible for industrial chemicals and biocides
- Staff (ca. 600) from EU and EEA countries
- Lean and agile organisation
- Excellent track record in delivering targets



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Programme

14:00—14:10	Welcome Jenny Holmqvist, Coordinator of International Affairs
14:10—14:20	Introduction to Taiwan chemical management scheme Taiwan TCSB
14:20—14:50	REACH 2018 deadline and future challenges Tiago Pedrosa, Regulatory Officer, Dossier Submission & PIC Unit
14:50—15:20	Topical issues in the dossier compliance check process. Addressing groups of substances and ECHA screening of compliance check candidates Hannu Braunschweiler, Senior Scientific Officer, Evaluation II Unit
15:20—15:40	*Break*
15:40—16:40	REACH evaluation and regulatory risk management – restriction and authorisation processes Jukka Peltola, Scientific Officer, Risk Management Implementation unit
16:40—16:50	Closing of the meeting

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Principles of REACH

Industry responsible for safe manufacture and use

Deal with the 'burden of the past' with a systemic program for registration of old chemicals

Get adequate information on hazards while minimising the use of experimental animals and the costs

Targeted activities by ECHA, Member States and the European Commission to get maximum effect

Enforcement at national level

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What do we do?

REACH	CLP	BPR	PIC
Registration Evaluation Authorisation All chemicals ≥ 1 tonne per year	Classification Labelling Packaging All chemicals and mixtures United Nations standards	Biocides Active substances and biocidal products	Prior Informed Consent Import/export of certain hazardous chemicals Rotterdam Convention

We...

- Manage high volume regulatory processes
- Disseminate information on chemicals
- Develop scientific IT tools
- Provide regulatory assistance to industry (helpdesk and guidance)
- Advise EU institutions and Member States on chemical safety and assist EU's international activities
- Work closely with 111 Accredited Stakeholder Organisations (ASOs)

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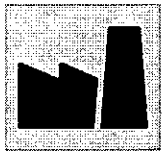
Key processes of REACH & CLP



Registration
Industry gathers information on their chemicals, ensures management of risks and document in a registration dossier submitted to ECHA.

Evaluation
ECHA and Member States control and request further information whenever needed
Member States enforce the legislation.

EU-wide risk management
Commission, with support of ECHA and Member States, applies community wide risk management measures, e.g., authorisation or restriction of certain uses.

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REACH adopted in 2006

- **R**egistration of chemicals
- **E**valuation of selected registered substances
- **A**uthorisation of (certain) Chemicals
- Restriction of (certain) **Ch**emicals

Aims of REACH:

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances on the internal market
- Enhance competitiveness and innovation

Currently on our website...

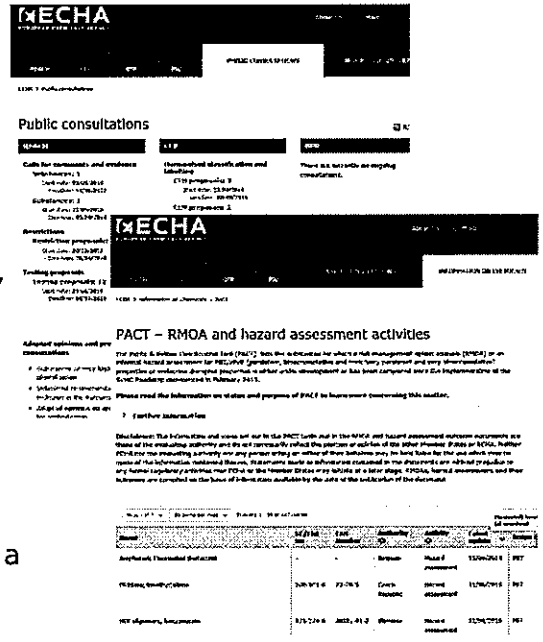
181	Substances of Very High Concern
580	Risk management proposals
1 600	Dossiers for HPV chemicals checked for compliance
21 000	Substances registered under REACH
142 000	Substances classified with GHS
>2 million	Study summaries on properties and effects of chemicals

Our approach to transparency

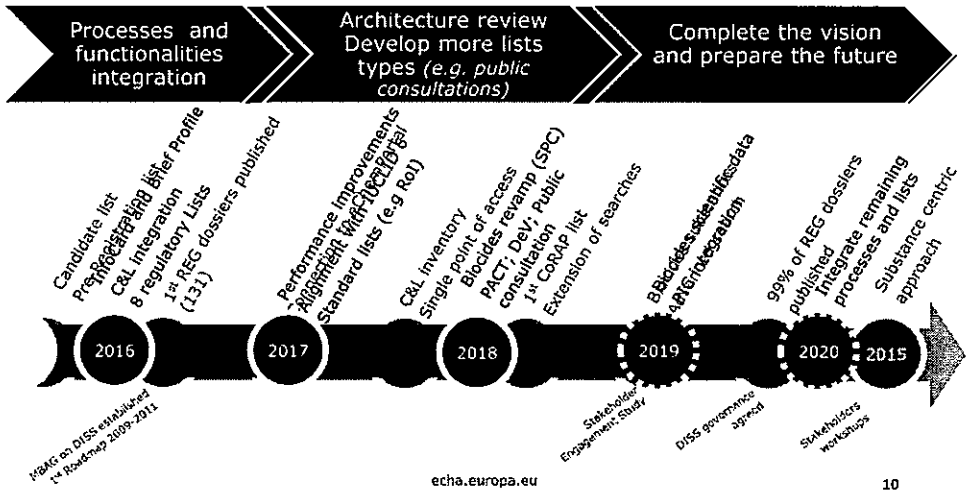
1. Maximise the availability of (non confidential) information on ECHA website
   - REACH
   - Biocidal products
   - Classification, Labelling & Packaging (CLP)
   - Export & Import of Hazardous chemicals (PIC)
2. Adapt available information to different audiences from layman to more scientific content
3. Be transparent on regulatory decision making processes including how and when stakeholders can interact
4. Be predictability for registrants by early indications of regulatory action

Transparent decision making process

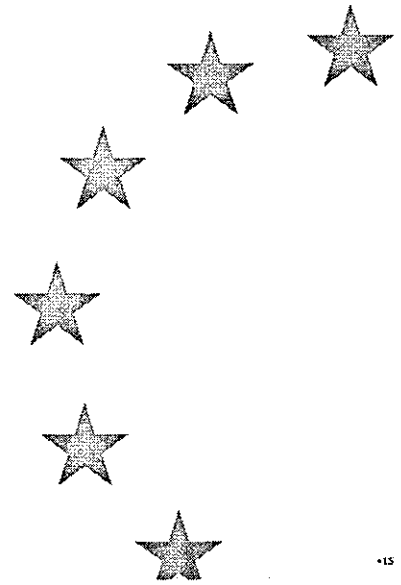
- Activities and regulatory processes explained clearly
- Open decision making
- Indication of when and how stakeholders can interact
- Information available in a timely manner
- Public Activities Coordination Tool (PACT)



Dissemination • *Next steps*



Looking ahead



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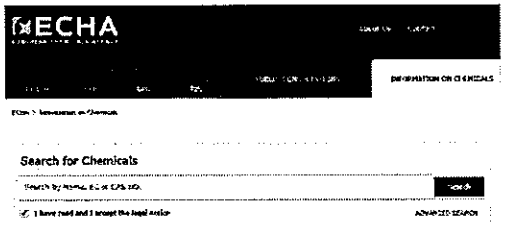

ECHA's dissemination website

Tailored access to all information on chemicals contained in ECHA databases in **one single point of access** to

- Provide meaningful and relevant information on chemicals
- Increase the transparency
- Promote quality of data
- Promote the safe use of chemicals for consumers
- Assist citizens to make informed decisions on the safe use of chemicals

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Examples of new work areas

- **Poison Centres:** Central portal for receiving/making available to national bodies industry notifications on emergency health responses
- **European Union Observatory for Nanomaterials**
- **Persistent Organic Pollutant (POPs)**
- **EU Chemicals legislation finder:** Information on how a chemical is regulated at EU level. Holistic view to break silos
- **Occupational Exposure Limits (OELs)**
- **...**

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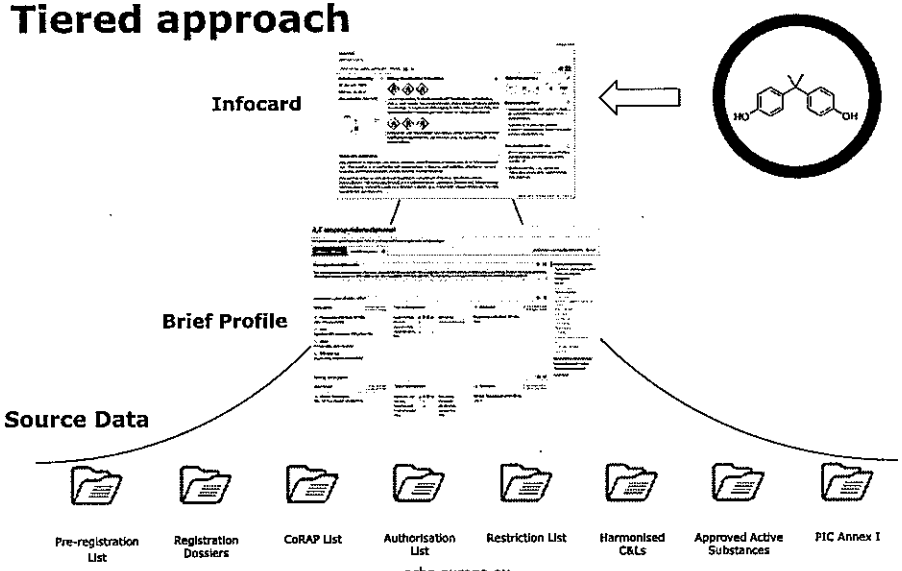
Tiered approach



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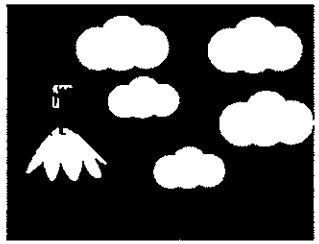
Where do we want to go?



Drivers defining ECHA's future work:

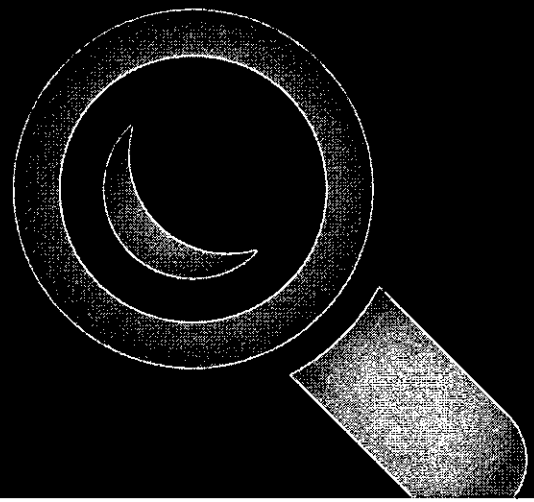
create **synergies**, achieve **consistency** and optimise **interlinkages** (e.g. water framework directive)

ECHA envisions to:

- Take on **further legislation**
- Develop **capacity building** in the EU and beyond
- Strive to become the EU's **chemical knowledge centre**

➡ **2018 European Commission review of chemicals legislation provides valuable steer**

Questions?



2018 deadline: what happened?

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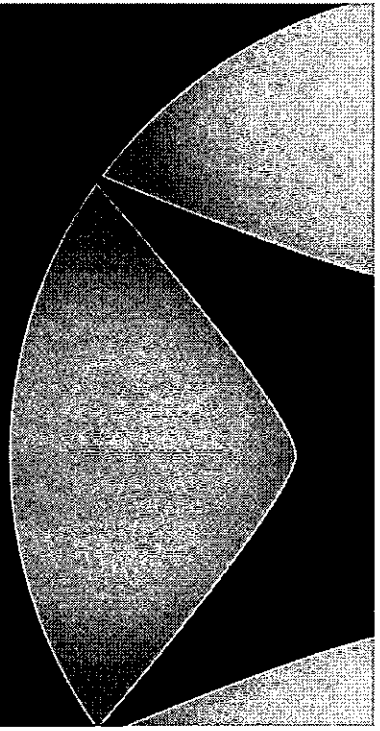
REACH 2018 deadline and future challenges

Visit of Taiwanese delegation

04 September 2018

Tiago Pedrosa
Dossier submission and PIC unit
Registration directorate



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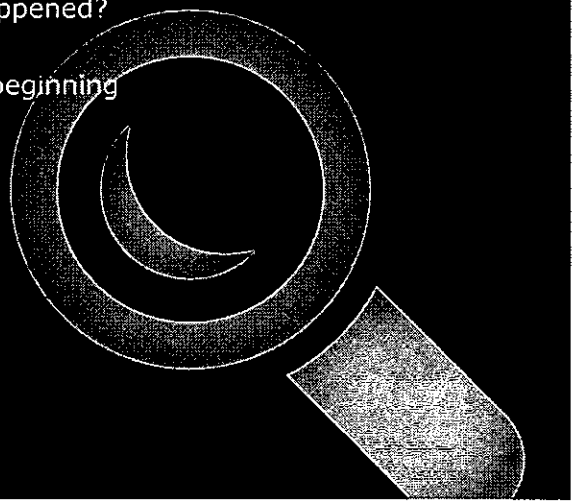
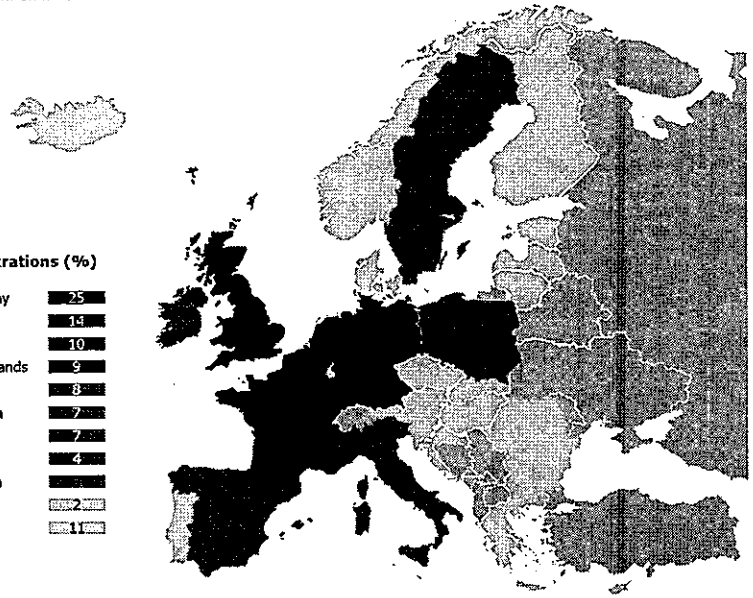
Registration: at the core of REACH

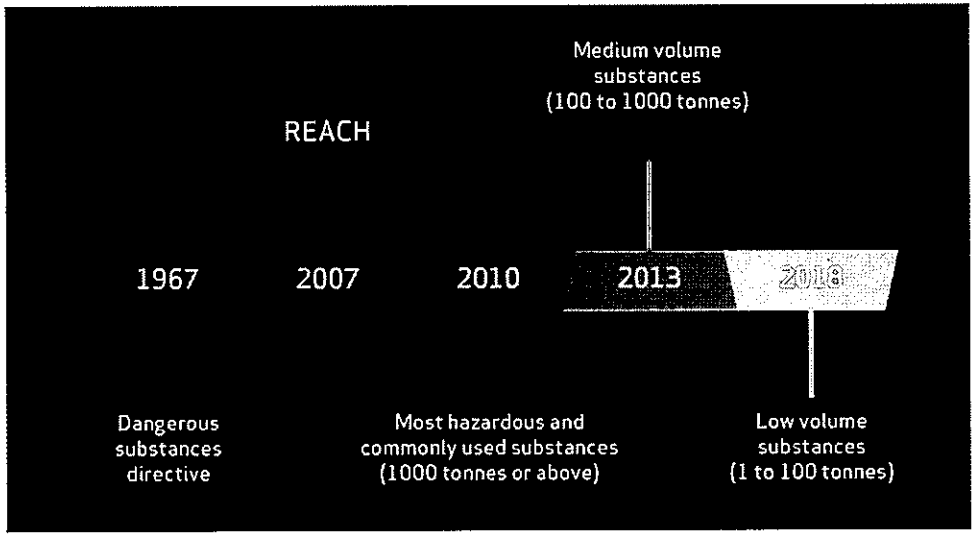
- Registration process is vital
- Dossiers show that industry knows the substance and can demonstrate safe use
- Basis for all other processes:
  - Informed decisions by authorities
  - Safety instructions in the supply chain
  - Information available to the general public



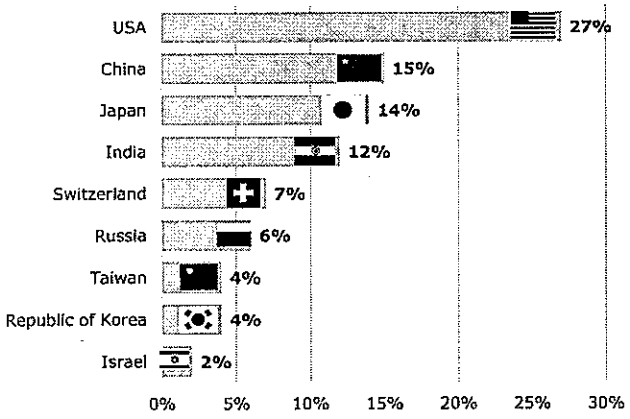
EU/EEA countries (all)



The journey



Top 10 non-EU countries



Main outcome

	All	DL 2018
Registrations	88 319	33 363
Substances	21 551	11 114

- All registrations processed by ECHA
- 18% of registrations from SMEs
- Registrations from outside of EU: 43% from importers and 29% from OR

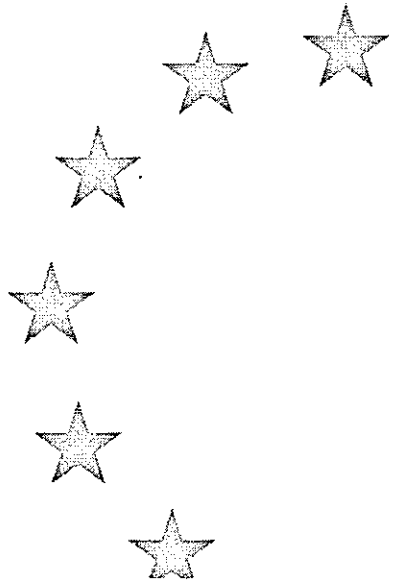
Summary

- 21 550 chemicals registered - we know more than ever about the chemicals used in the EU
- Companies have done their part - information flows in the supply chain improving workers' safety and resulting in safer products
- EU has established clear and harmonised rules for all companies
- Registration is only the start

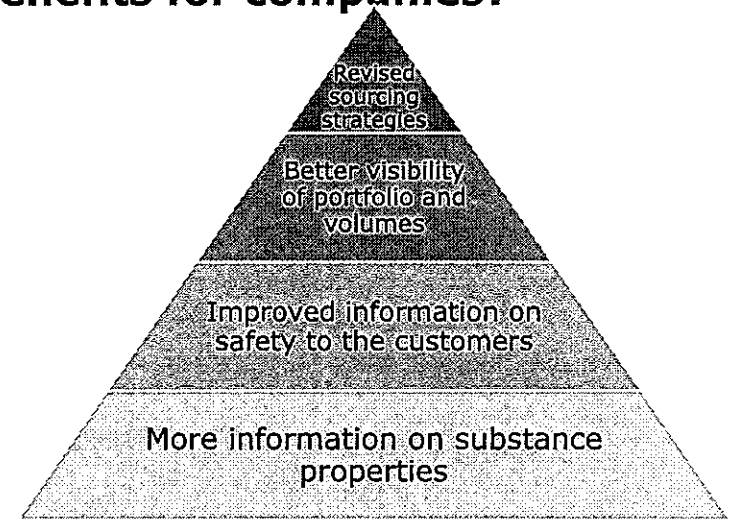
Was the outcome as expected?

- **Fewer** registrations and substances than forecasted for the 2018 deadline
- Overall, **closer** to the forecast for all tonnages
- Registrations **still** coming in
- **Number of substances similar** to the US market

Life after the deadline



Benefits for companies?



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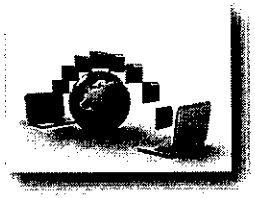
Retrospective checks



Old dossiers may be checked retrospectively for completeness and fulfilling OSOR

- Enhanced completeness check introduced in 2016
- Dossiers not updated are targeted for retrospective checks to ensure level playing field
- First campaigns showed that registrants were able to fulfil information requirements, e.g. provide a missing study
- Some registration decisions were revoked

- One substance, one registration (OSOR): Implementing Regulation from 2016 tasked ECHA to ensure joint submission

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Current situation* (1/2)

- All dossiers submitted by the deadline have been processed
- 32 515 registration numbers granted out of the 33 363 dossiers submitted by the deadline.
- Update pending for 848 dossiers (out of 2 039 for which more information has been requested).
  - 557 registrations benefitted from DCG solutions for exceptional circumstances with an extended deadline to submit the information (mostly because of late availability of laboratory results)

- ECHA expects to conclude all pending cases by May 2019.

* *As of end of August 2018*

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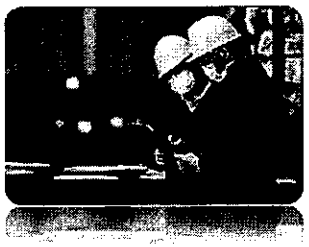
Enforcement by national authorities

- Project in **2019** (reporting in 2020)
- All EU countries foreseen to participate
- Scope:
  - Registration obligations in cooperation with customs authorities
  - This includes verification of strictly controlled conditions applicable to substances registered as intermediates



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Current situation* (2/2)

- 194 dossiers also pending due to ongoing data-sharing disputes
- 99.7% of all completed registrations already published on ECHA's website.

- Additional **1 649** deadline-relevant registrations by 30 August

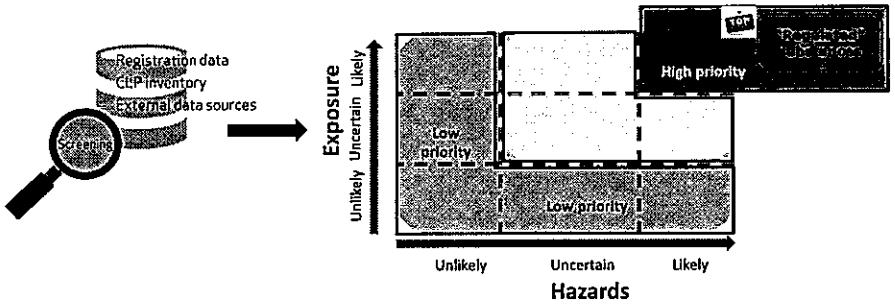
Other activities following on deadline submissions

- Verification of company size for all dossiers submitted by SMEs
- Legal entity changes
- Assessment of confidentiality claims (may lead to request for information)

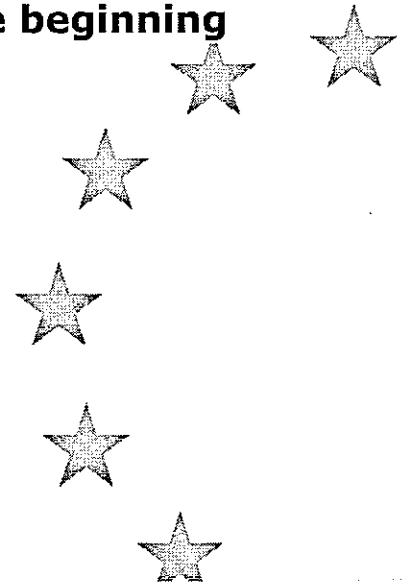
* *As of end of August 2018*

Screening and prioritisation

- All dossiers screened and prioritised for further assessment by authorities: evaluation or risk management



Registration is just the beginning



Authorities work progress can be followed at PACT

- Public activities coordination tool: echa.europa.eu/pact
- Find out: nature of our concern (CMR, PBT…), on-going activities, authority in charge and outcome

Name	EC/List No.	CAS Number	Authority	Activity	Latest update	Scope	Outcome	
1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]	244-617-5	21850-44-2	Germany	Hazard assessment	05/01/2018	PBT	Substance evaluation under development	Details
Disodium octaborate	234-541-0	12008-41-2 12280-03-4	Sweden	RMOA	05/01/2018	CMR	Appropriate to initiate regulatory risk management action	Details
Hexahydrophthalic anhydride	247-094-1	85-42-7	Finland	Hazard assessment	09/11/2017	PBT	According to authority's assessment NOT PBT/vPvB	Details

Registration is the beginning of a journey

- The registration dossier is proof of safe use
  - Companies know the properties of the substance
  - clients are informed about how to use them safely
- Authorities look at the registration

Convinced by the information provided and your assessment?	Dossier evaluation (compliance check) by ECHA
Further information to clarify a concern?	Substance evaluation by EU Member States
Further risk management at EU level?	Candidate list of SVHCs, harmonised classifications and restrictions

Obligation to keep the dossier up-to-date

- Updating is a legal obligation (article 22)
- On own initiative, without undue delay, after changes in:
  - company status
  - composition of the substance
  - tonnage band
  - new identified uses
  - new risks of the substance to human health and/or the environment
  - classification and labelling of the substance
  - ...
- When the Agency requests an update of the registration after a dossier or substance evaluation decision
- After an authorisation or a restriction for the substance

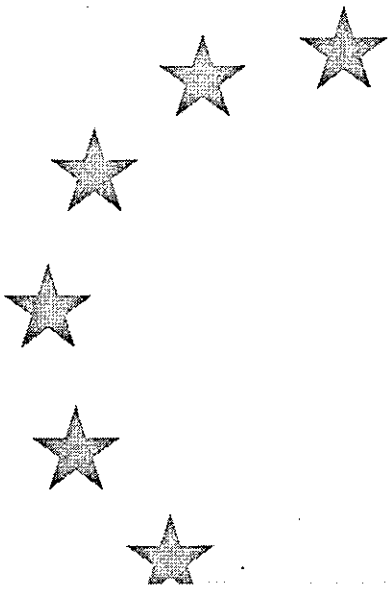
Compliance check

- The dossier may be prioritised if ECHA is not convinced by the information provided
- All registrants relying on the non-compliant information are responsible to satisfy the request for additional information following a dossier compliance check
- Recommendations for dossier improvements in annual Evaluation reports: http://echa.europa.eu/evaluation

Obligation to keep the dossier up-to-date

- The reality:
  - 67% of all dossiers have never been updated (excluding DL-2018 dossiers)
  - 47% of lead registrant dossiers have never been updated
  - Feedback from registrants survey: 85% of the companies are familiar with the update obligation, but only 55% have already discussed how to handle future updates
  - Most updates follow a request by ECHA (dossier or substance evaluation) or letter campaign; few spontaneous updates
- Need to ensure that companies and the authorities assess safe use based on up-to-date and reliable data

Dossier update



Action 1 in the REACH review

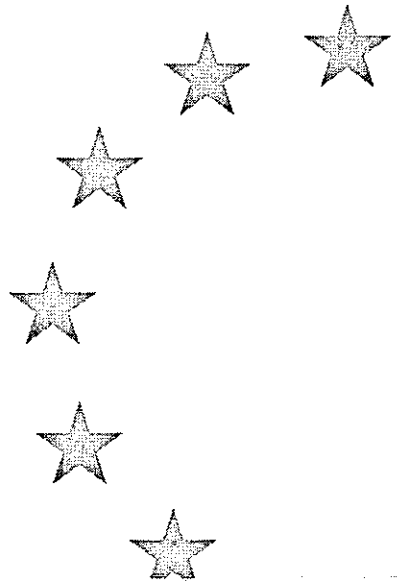
- Commission:
  - preparation of a possible Implementing Regulation on dossier updates, clarifying e.g. "without undue delay", …
- ECHA:
  - possible simplifications for updating (e.g. tonnages), …
- Member States:
  - REF-7: Check if companies have systems in place to ensure updates in case of change of tonnage or uses (awareness raising)
  - Future enforcement of registration: National Enforcement Authorities (NEAs) are invited to always check if duty of update is complied with when checking registration and include it in future enforcement projects that cover registration
  - …

Reasons why dossiers are not updated

- From a study* into the drivers, barriers, costs and benefits for updating REACH registration (2017):
  - Industry has no incentive to update because registration is seen as the end of the process, payments and access to market are one-off.
  - Lack of clarity on what needs to be done, by whom and when in order to update.
  - REACH fatigue in companies with limited resources allocated to REACH compliance once registration is done.
  - Limited use of the data generated for registration. Therefore there is no external pressure to improve the dossier although downstream users would need better information.

*https://echa.europa.eu/documents/10162/22931011/study_drivers_and_obstacles_reach_clp_updates_en.pdf

What else will change



Action 1 in the REACH review

Proposed actions

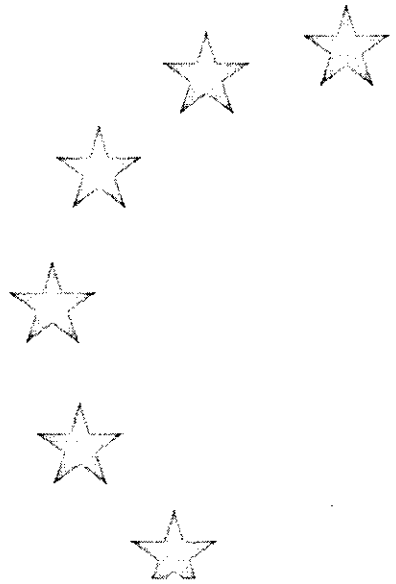
ACTION 1: encourage updating registration dossier. *Why?*

1) Improve compliance and rectify important data gaps and data quality issues

2) Updates by companies considered insufficient

Actors involved : COM, ECHA, Member States and industry delivering proposals by first quarter 2019.

conclusion



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Changes in regulatory requirements (1/2)

Nanoforms:

- Clarification of requirements voted in April
  - Changes in Annexes I, III,VI, VII-X, XI, and XII
- Changes not expected to enter into application until January 2020
- Guidance and support under preparation

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Summary

- 21 550 chemicals registered - we know more than ever about the chemicals used in the EU
- Numbers lower than forecasted, but no major concerns observed so far
- Registration is not over with the last deadline
- Registration is only the start for other evaluation and risk management activities
- The information must be kept up to date - this is the law, and also the proof that companies take safe use of chemicals seriously
- Legislation will keep evolving

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Changes in regulatory requirements (2/2)

1-10 tonnes and polymers:

- Part of REACH Review
- Chemical safety report requested for CMR & increasing information requirements for 1-10?
- Registering polymers of concern?

Other changes in REACH annexes or CLP annexes because of adaptation to technical progress

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Thank you

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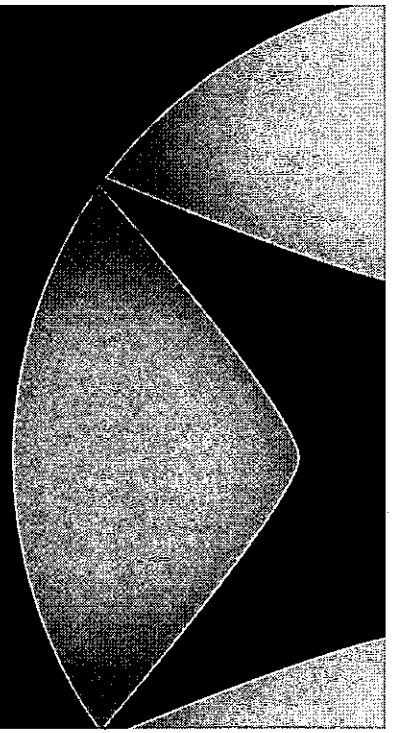

RMOA – a tool for discussion & info sharing

- Analyses a need for further regulatory risk management activities – Y/N – the instrument
- Part of the SVHC Roadmap – voluntary
- From scientific study to a basic assessment - based on facts, emphasis may differ by MS
- May conclude a need for e.g. candidate Listing, restriction or "no need for regulatory action"
- Activity and the final *conclusions* published in PACT (Public Activities Coordination Tool)
  https://echa.europa.eu/fi/pact

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REACH evaluation and regulatory risk management - restriction and authorisation processes

Visit of Taiwanese delegation
4 September 2018

Jukka Peltola
Socio-Economic Analysis
Risk Management Implementation Unit
European Chemicals Agency

RMOA - mechanism

- MS/ECHA prepares - responsibility with the author – "may change in the light of new information or further assessment"
- A guideline and a template available - no timing
- Discussion – other MSs comment the draft, may cooperate – finalised – published
- Another MS may produce another RMOA e.g. with different concern e.g. sensitiser (restriction), CMR (on hold)
- Currently in PACT
  - 15 MS worked on RMOAs since 2013
  - 98 RMOA conclusions available - 94 "active"
  - Most on CMRs, EDs, PBTs increasing

Risk management option analysis - RMOAs

- RMOA – what it is
- RMOA - mechanism
- Examples
- Description of Restrictions and Authorisations

Restrictions under Reach

- ❑ Restriction as a regulatory tool
  - ✓ Characteristics – purpose
- ❑ Information needs for a restriction case
- ❑ Opinion forming process
- ❑ Examples

RMOA - conclusion

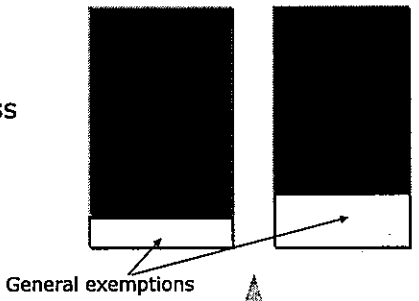
- ❑ Voluntary mechanism
- ❑ Depends on the interest of an MS – different emphasis i.e. specific environmental / human health concern
- ❑ Capacity constraints within an MS
- ❑ Inclusion in PACT – transparency and predictability

Restriction as a tool – characteristics and purpose

- ❑ To tackle use(s)/manuf./placing on the market posing unacceptable risks
  - ✓ Continues the work done under Directive 76/769/EEC
  - ✓ A safety net where other REACH processes or other Community actions are not more approriate
- ❑ Community-wide action: the same requirements apply
- ❑ Proposal from a Member State or ECHA (initiated by Commission, or by ECHA on substances on the Authorisation list that are in articles)

REACH Risk management instruments for authorities

- ❑ Restriction
  - ✓ (any) condition on the specified uses, manufacture, placing on the market
  - ✓ can be a full ban of a substance
- ❑ Authorisation
  - ✓ after a given date uses of a substance are banned unless specifically authorised



SEA under Restriction procedure

- ❑ Is restriction beneficial for the society
  - ✓ Impose a restriction (compared to using other or no additional risk management options)
- ❑ Baseline vs. restriction in place:
  - ✓ What if the restriction on use is introduced (alternatives, relocation etc.)
  - ✓ Identify positive and negative impacts
- ❑ Refining the scope/conditions of a restriction (e.g. timing)
- ❑ An integral part of an Annex XV restriction report

Information needs - basis for decision

The decision to restrict a substance or use shall take into account:

- ❑ Whether there is an unacceptable risk to human health or the environment – not adequately controlled?
- ❑ Appropriateness of the proposal to reduce the risk – risk reduction?
- ❑ The socio-economic impact of the proposed restriction – costs/benefits?

Risk assessment and socio-economic analysis is needed. REACH establishes two scientific committees, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC)

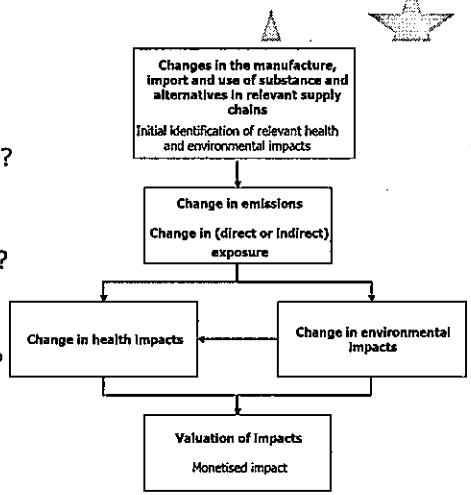
Assessment of a proposal – main steps

- ❑ Registry of Intentions (RoI), submission and the conformity check
- ❑ Consultations of interested parties
- ❑ Opinion forming of RAC and SEAC
- ❑ Commission decision

From hazard to risk to impact to value

- ❑ Four basic steps:

1. Hazard assessment: is there a potential for an adverse health and or environmental outcome?
2. Risk assessment: who/what would be negatively affected from the use of this substance?
3. Impact assessment: what are the expected impacts on health, environment & society?
4. Valuation: what values does society attach to the different impacts?



Methanol in windshield washing – opinion??

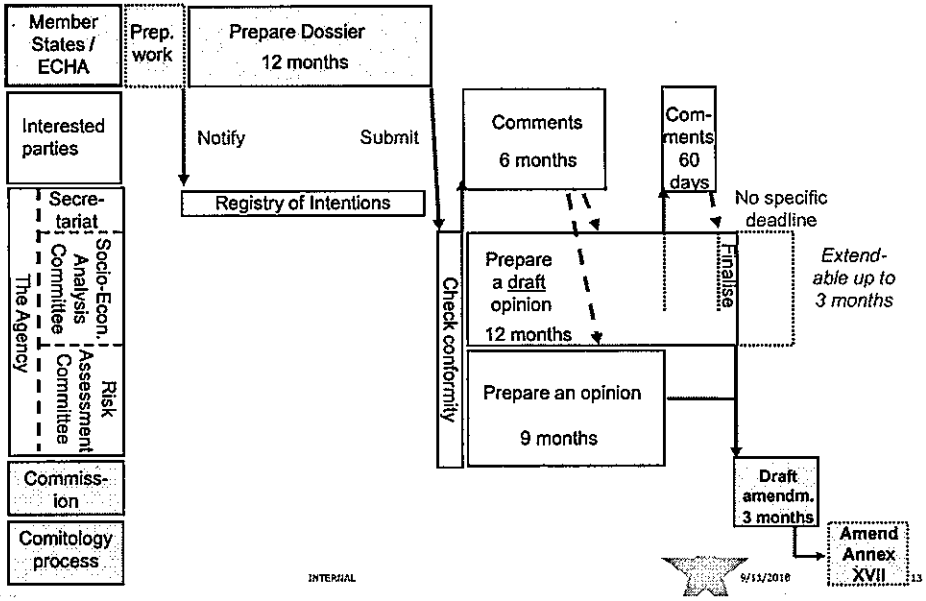
- Poland (with help from Finland)

Shall not be placed on the market for supply to the general public: as a constituent of windshield washing fluids (including windshield defrosters) in concentration equal to, or greater than 0.6% by weight.

Costs: the substitution cost is estimated to be €40.4 million. Translate into 10 fatalities/year (VSL). Break-even, would require the same size benefits (as avoided deaths/other)

Benefits: SEAC estimates 82 deaths/y may be avoided EU-wide. The monetized value €209-323 million (VSL). Also other benefits (vision impairment, medical care, productivity loss).

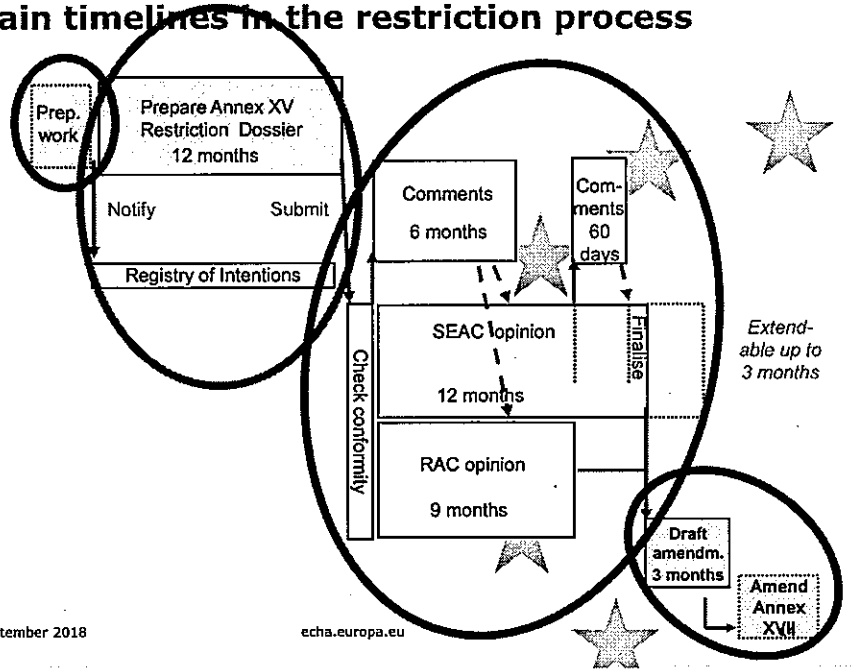
Actors Main timelines in the restriction process



Restriction on tattoo inks – opinion ??

- ECHA w/ NO, IT, DK (DE) – started in Dec-17 (PC)
- 12% Europeans tattooed (24% of 18-35 y), up to 20% PMUs
- 68% of tattooed reported skin problems, 6.6% systemic reac.
- Colourants contain impurities (carcinog., mutag, reprotoxic properties) - inks distribute in the body (lymph nodes & liver)
- aims to:
  - *restrict the intentional use of or to impose concentration limits for selected substances (placing & using)*
  - *Some colourants exempted (no alternatives or information)*
- Costs: (substit, analytics) <M5€, 1(4)€ per tattoo (PMU)
- Benefits: 320–1050 avoided tattoo removals cost the ~same
- The scope: Commission request – national regulations – risk analysis – practical, impact analysis

Main timelines in the restriction process



Authorisations under Reach

- Authorisation as a regulatory tool
  - ✓ Characteristics – purpose
- The application process and information needs for an authorisation case
- Assessment of an authorisation application
- Examples

State of play – mature restriction process

- First ones submitted in April 2010
  - RAC and SEAC opinions 2011
- Altogether by end of 2017:
  - 16 adopted decisions by Commission
- Committees have adopted opinions on 21 restrictions in the past years
- Intentions 31
- Dossiers submitted / MS 18, ECHA 9
- The guidelines, structure of the dossier & opinion in continuous development

Authorisation – the main principles

Ultimate goal: substitution by safer alternatives

Focus on most hazardous substances = Substances of Very High Concern (SVHC) for which uses may lead to significant exposure

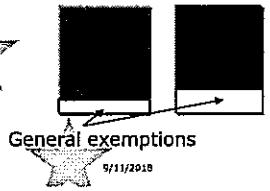
Principle:

after a certain date ("*sunset date*") the use of an Annex XIV substance is forbidden unless specifically authorised/exempted(annex)

Ensure that risks from SVHC are properly controlled

Progressive replacement of SVHC where economically and technically viable

Authorisation – with a review period !!



General conclusions - restrictions

- Provide a safety-net - supplement other REACH procedures & other Community measures
- Soon 40 years history in the EU - REACH brings new features to the procedure
  - Stringent timelines
  - Guidance available
- More information: http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/restriction

Authorisations – largely the same issues apply as to restrictions

Decision to restrict/authorise the use of substances shall consider:

- ✓Whether risk to human health and/or environment is adequately controlled
- ✓Appropriateness of the proposal to reduce/control the risk
- ✓Socio-economic impact of the applied authorisation and availability of substitutes
- ✓Authorisation - a driver for substitution of SVHC

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The authorisation procedure & actors: a two-step approach

- Step 1: subjecting substances to the authorisation requirement

  Step 1.1: Identification of SVHCs → ***"candidate list"***

  Step 1.2: Prioritisation of substance ("recommendation") and Inclusion in Annex XIV → ***"authorisation list"***

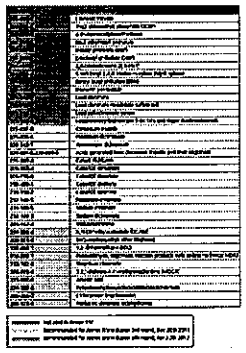
Public authorities (mainly)

- Step 2: authorisation applications and decisions

Industry

Specific to authorisation cases

- ❑ Industry has clearly burden of proof
  - ✓Direct costs of non-use generally known
  - ✓Indirect costs to society (unemployment, price increases,...) much less known
  - ✓Costs of alternative(s) sometimes known
- ❑ Difficult cases:
  - ✓benefits of authorisation outweigh the monetised health impacts,
  - ✓but also involve large health risks
- ❑ Might lead to:
  - ✓additional risk management measures and monitoring requirements
  - ✓authorisation with a short review period
- ❑ Review report can be submitted



What is REACH Authorisation

An 'Authorisation' can be granted for a **'specific use'** on the basis of an application made to ECHA

Users should consider if they [or society] really need to use a substance

Evaluated by ECHA's committees for Risk Assessment (RAC) and Socio-economic analysis (SEAC)

An authorisation is valid until amended or withdrawn but subject to time-limited 'review'

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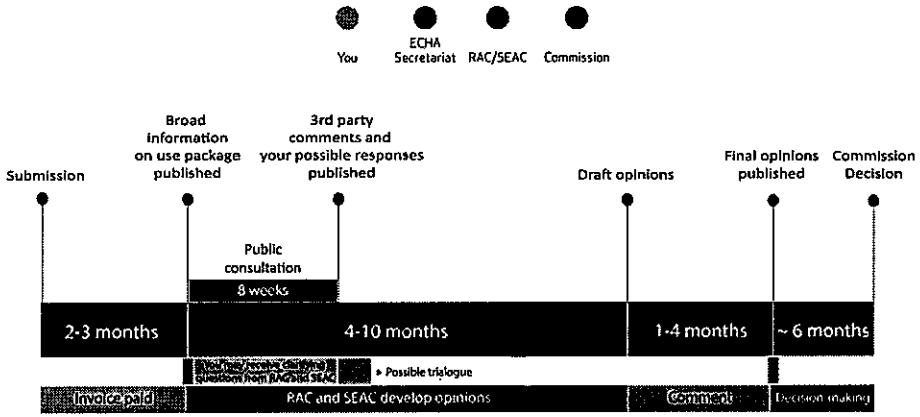
Application timeline: About 2 year cycle



Application – a starting point

Adequate control route

Threshold substances,

Risk Characterisation Ratio's <1

Socio-economic route

Non-threshold substances (mostly genotoxic carcinogens)

Threshold substance for which adequate control is not supported

Company position - upstream/downstream

Scope - how to define it

When can an authorisation be granted?

An authorisation may be granted if:

1. Adequate control

   Exposure below a PNEC or DNEL

   Where alternatives are 'suitable' an application must include a 'substitution plan'

2. Benefits outweigh risks & no suitable alternatives

   a) 'non-threshold' substances

   b) Threshold substances where a threshold has not been demonstrated

   c) uses of substances with a threshold, without adequate control

Components / parts in the application

Chemical Safety Report	**RAC**
Assessment of Alternatives	**SEAC (RAC - risks)**
Socio-Economic Analysis*	**SEAC**

The CSR:

- the industrial process
- the operational conditions (OC),
- the risk management measures (RMM) in place
- the exposure and risk to workers and the environment

The AoA & SEAC:

- The existence of alternatives, R&D undertaken
- Cost and benefits of authorisation

** May be submitted*

Review periods (RP)

RAC and SEAC opinions recommend the length of the RP - case-by-case basis

RAC and SEAC's note on "setting the RP" describes information taken into account (opinion trees)
https://echa.europa.eu/documents/10162/13637/opinion_trees_non_treshold_subs_en.pdf/d66547fb-f3df-4081-bc8a-c66fc4e1b671

- Short (e.g. four years); normal (7 years); long (12 years)

Applicants should present clear justifications to support their requested RP

- When could alternatives be suitable (e.g. certification/qualification)
- Remaining risks of continued use

Committee roles: RAC

RAC formulates its recommendations on the basis of:

- The risks posed by the use (and the alternatives), including the hazard(s) and exposures
- Appropriateness and effectiveness of risk management measures (RMM) in place
- Adequate control or minimisation of risks(non-threshold)

RAC may recommend:

- Additional conditions and monitoring arrangements
  - Related to continued use of the substance e.g. The appropriateness of OCs and RMMs
  - Related to monitoring

RAC communicates: its concerns regarding the uncertainties and control of risk to SEAC and the European Commission

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Applications received and opinions adopted (17 June 2017)

Substance	Number of Applications received	Number of Uses
Phthalates	8	17
Lead chromate pigments	1	12
HBCDD	1	2
Diarsenic trioxide	4	5
Trichloroethylene	13	19
Lead chromate	1	1
EDC	15	15 + 3
Chromium VI substances	61	96 + 4
Diglyme	8	9
Arsenic acid	1	1
Technical MDA	1	2
MOCA	1	1
Total:	**115 from 199 applicants**	**180 + 7 more in opinion development**

(24 May 2018: 124 applications by 211 applicants, and 199 opinions done)

Committee roles: SEAC

SEAC evaluates and formulates its recommendation on the basis of:

- Whether the applicant's assessment of risk/benefit is plausible (if risks not adequately controlled)
- The feasibility and availability of alternatives (info from the PC)
- Quantitative or qualitative descriptions of benefits and risks
- The evidence presented for the length of the time-limited review period

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Thank You

Authorisation cases:

- Dometic
  - Level of risks
  - Outsourcing
- Federal Mogul
  - Outsourcing
  - Fuel economy
  - Long contracts
- Microbeads
  - Level of risks in Europe
  - Important use in US
- Special cases
  - Spare parts
  - Airspace, military

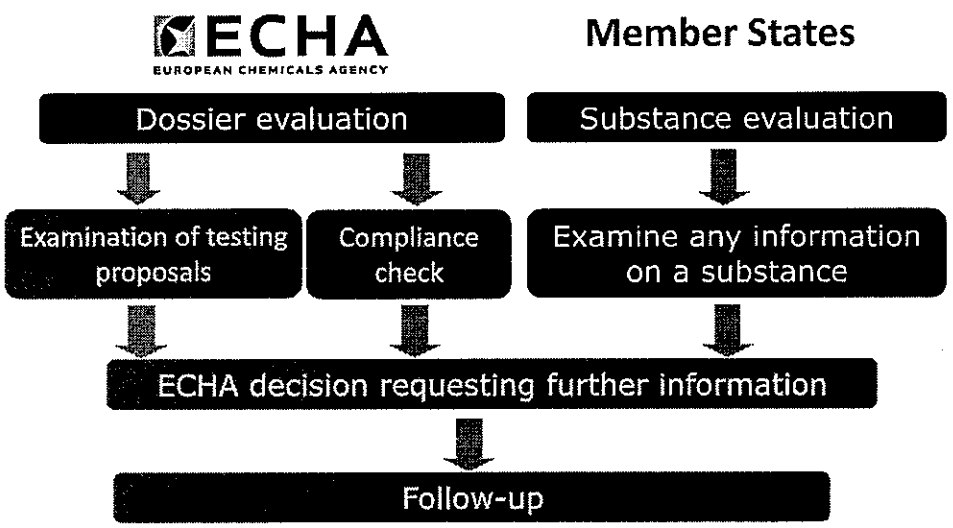
General Conclusions - authorisations

- ❑ Promotes substitution
- ❑ Industry has a burden of proof - usually has relevant information about costs and feasibility of alternatives
- ❑ Asymmetric information: SEAC and RAC often need to rely on industry information
- ❑ Benefits hard to quantify due to externalities and goods (EDCs - time lags, valuation)
- ❑ (Risks of) alternatives are less well-known

BUT

- ❑ Seems to be working:
  - ❑ Many not applying but substituting away
  - ❑ Review reports "missing"

REACH Evaluation processes



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Topical issues in the dossier compliance check process -

Addressing groups of substances and ECHA screening of compliance check candidates

Visit of Taiwanese delegation

04 September 2018

Hannu Braunschweiler
Evaluation Unit II
Evaluation Directorate
ECHA

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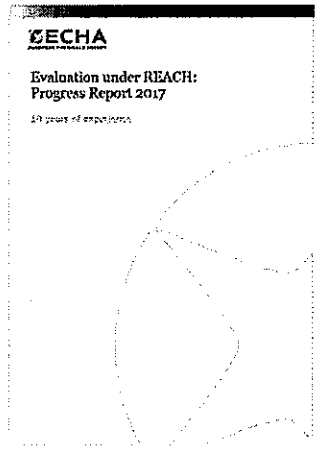
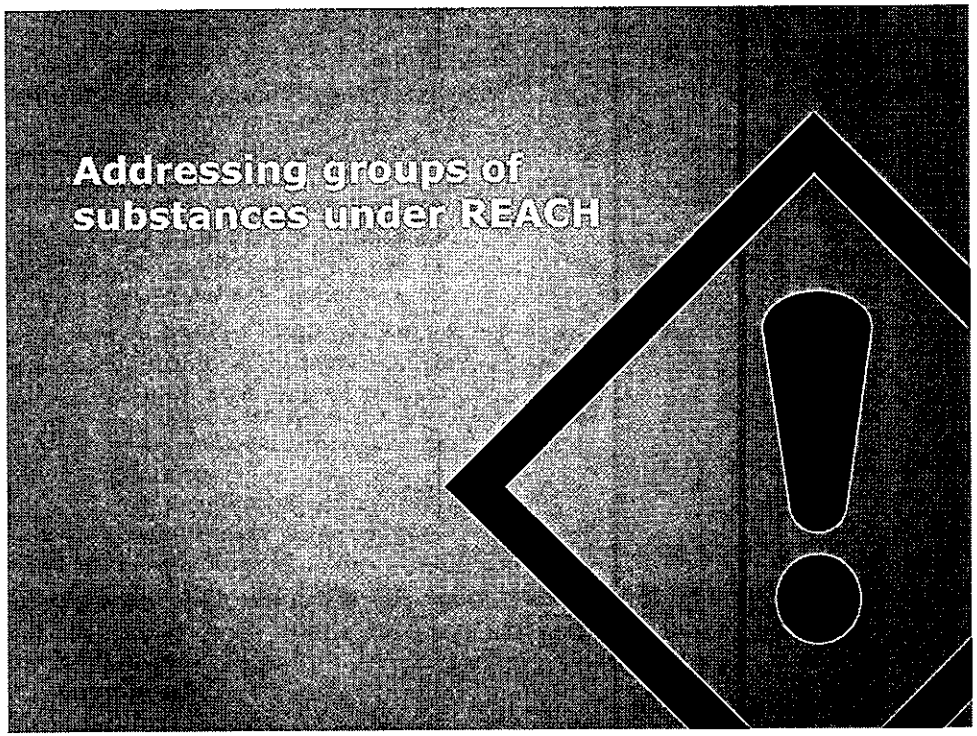
Over 10 years of dossier evaluation*)

- 1780 dossiers checked, to various degrees, for compliance
  - In the majority of the cases, non-compliance in one or more endpoints established
- 4170 requests made in ECHA dossier evaluation decisions
- 1442 dossier evaluations concluded, of which 1235 with compliant information
  - High rate of compliance with ECHA decisions!
  - 73 substances flagged for harmonised classification, 11 for substance evaluation



*)https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf/24c24728-2543-640c-204e-c61c36401048

Contents



Requests made in substance evaluation decisions in 2017 1(2)

Suspected Concern	Types of hazard information requested to clarify the concern	Total requests
PBT/vPvB	Simulation biodegradation test	16
	Daphnia magna reproduction test	6
	Physico-chemical tests	5
	Aqueous exposure bioaccumulation fish test	5
	Ready biodegradability test	4
	Fish, early-life stage (FELS) toxicity test	3
	Sediment-water *Chironomid* toxicity test	2
	Toxicity of sediment-associated contaminants with freshwater invertebrates	1
	Aquatic toxicity test with bivalves	1
	Freshwater algae and cyanobacteria, growth inhibition test	1
	Sediment-water *Lumbriculus* toxicity test	1
Reproductive toxicity	Extended one-generation reproductive toxicity study	3
	Combined repeated dose toxicity study with reproduction/developmental toxicity screening test	1
Mutagenicity	*In vivo* mammalian alkaline comet assay	3
	Combined mammalian erythrocyte micronucleus test and mammalian alkaline comet assay	3
	Transgenic rodent somatic and germ cell gene mutation assay	3
	In vitro mammalian cell micronucleus test	2
Endocrine disruption	Fish sexual development test	3
	Larval amphibian growth and development assay	1
	H295R steroidogenesis assay	1
Sensitisation	Skin sensitisation local lymph node assay	2
	Information on composition	7
Other hazard-based concerns	Sediment-water *Lumbriculus* toxicity test	1
	Daphnia magna reproduction test	1
	Sediment-water *Chironomid* toxicity test	1
	Sub-chronic 90-day toxicity study	1
	Total	79

5

Grouping under regulatory processes

- Grouping of substances: not a new concept
- Substances have been grouped together and addressed under different regulatory processes based on e.g.:
  - Structural similarity
  - Same use profile
- Examples of grouping approach are available:
  - REACH/CLP risk management processes: from Harmonised Classification and Labelling, SVHC identification, Annex XIV inclusion to Restriction
  - REACH processes to generate further information: Substance Evaluation and Compliance check
  - Steps supporting the REACH/CLP processes: e.g. screening

Requests made in substance evaluation decisions in 2017 2(2)

- Examples of exposure related information requests (in total in 14 decisions):
  - Clarification and detailed justification for environmental exposure scenarios;
  - Further information and justification on input parameters used for exposure assessment;
  - Improved characterisation of the tasks and processes covered in exposure scenarios.

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Benefits of working with groups -2

- Enhance coherence of authorities' work through all steps
  - from screening,
  - via further information generation (compliance check, substance evaluation, other means including direct contacts with industry)
  - to regulatory risk management (harmonised classification, SVHC identification and authorisation, restriction, but possibly also actions under other legislation)
- Maximise the use of available resources by avoiding overlaps/gaps of activities while providing transparency towards industry
- Support industry to avoid regrettable substitution

Working and thinking in terms of groups does not necessarily mean regulating (the same) groups!

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Why shifting towards groups?

- Looking at substances in isolation is not the optimal approach and grouping is essentially unavoidable
- To speed up the processes
- To coordinate with many on-going processes on related substances; for most identified substances, action is ongoing on it or a relative
- To avoid regrettable substitution

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Registrants' vs Regulatory Strategy's grouping approach

- Regulatory Strategy's *grouping approach* should not to be confused with the *grouping and read-across approach* as described in Annex XI, 1.5.

- The scope of the grouping approach in our Regulatory Strategy is to cluster potentially related registered and non-registered substances

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Benefits of working with groups -1

- By pooling together all hazard information for related substances it may be possible to conclude on the need for regulatory risk management despite data gaps for individual substances
- By looking at the whole group, including substances for which information generation is being considered or on going, it may be easier to fine tune our regulatory actions
  - Target the right substance at the right time
- Consistency in how related substances are treated
- Fairness to industry and better informed substitutions

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Grouping by read-across/categories

- Grouping is made by collecting analogues from *one-to-one read-across* or *category* statements proposed by either registrants or regulatory authorities
- The following sources of analogues have been used by ECHA
  - one-to-one read-across in endpoint study records
  - categories in IUCLID dossiers
  - categories from other international programs (US EPA, IMAP, OECD)
- The list of external sources can be extended further in the future

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Grouping similar substances: how?

1. structural information

- substance identity information in IUCLID
- external sources to convert names and numerical identifiers into structures

2. read across & category information

- test material identifiers in endpoint study records (read-across information)
- category objects in registration dossiers
- external sources with category information

➢ *Future developments: uses, structural alerts, Mode of Action, metabolism prediction…*

➢ Finding related substances at the initial stage of screening is not the same as fulfilling the criteria of Annex XI, 1.5 of REACH (grouping and read-across)

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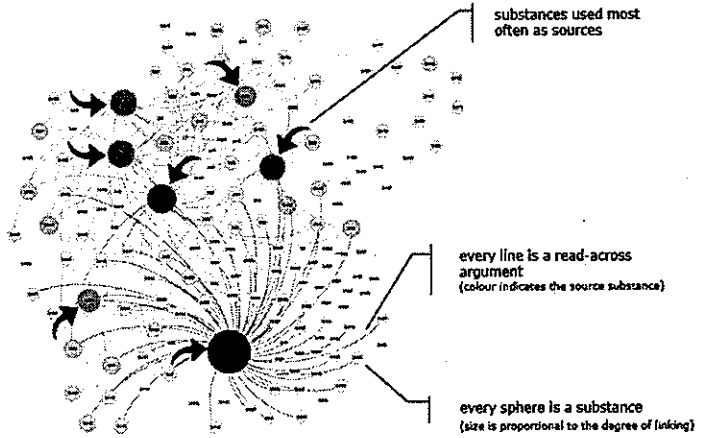
Visualising substance groups by read-across/categories



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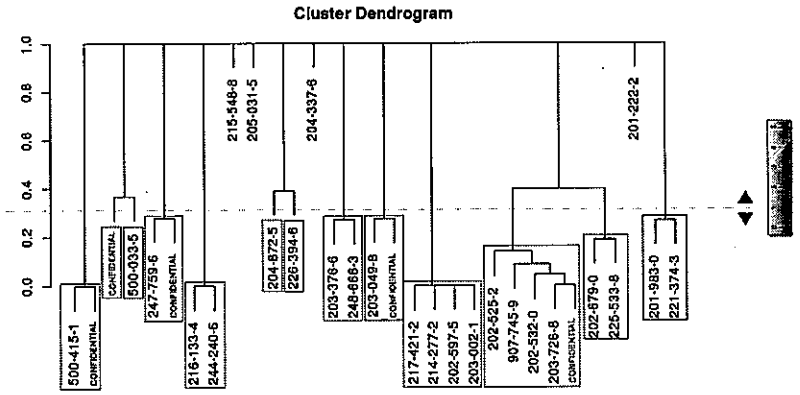
Grouping by structural similarity – dendrogram



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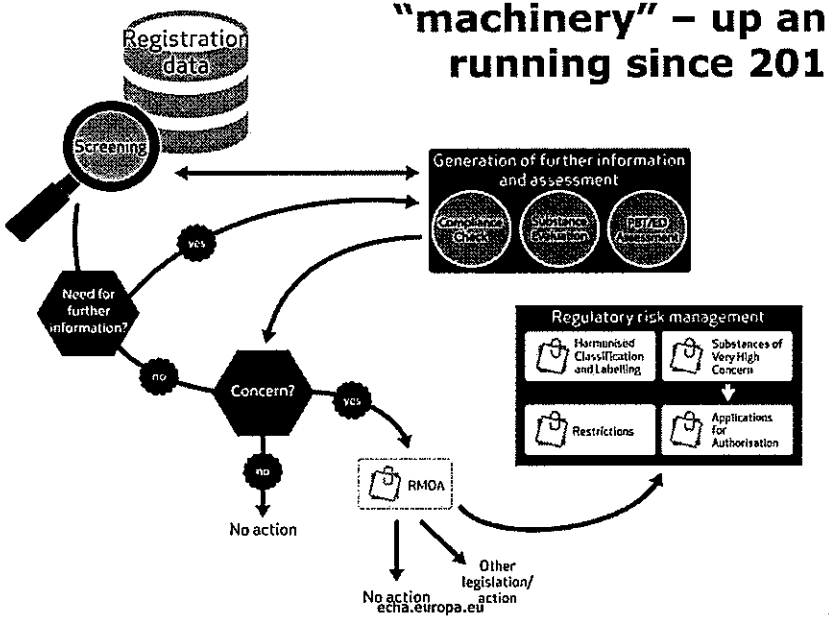
Integrated regulatory "machinery" – up and running since 2016



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Challenges in working with groups and related on-going activities

Challenges

- Developing a 'grouping' strategy together with Member States and Registrants
  - legal challenges
  - timelines when addressing multiple substances
- Have a more integrated strategy on grouping starting from screening to regulatory risk management

Some recent or ongoing related activities:

- Piloting early interaction with registrants for categories under compliance check
- Manual screening of groups of related substances (ECHA and Member States)
- 5 pilot projects run on early collaboration between ECHA, evaluating Member states and registrants, final report published in June 2018
- Sectoral approach

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Common screening approach applied also for compliance checks

Identification and **prioritisation** of substances for further information generation and/or further regulatory action based on:

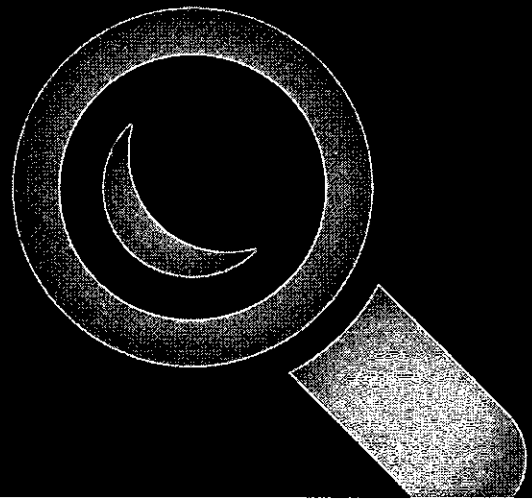
- ✓ Hazard information
- ✓ Tonnage
- ✓ Use and exposure information

⇒ ***Substances that matter!***

⇒ 8 super endpoints (endpoints are linked to clarification of CMR and PBT concern)

⇒ high potential for exposure of humans or environment

ECHA screening of compliance check candidates



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Key tasks of ECHA screening of compliance check candidates

- Aim
  - ECHA screening of compliance check candidates contributes to consistent implementation of the integrated regulatory strategy in selection of new CCH cases.
- Tasks
  - Identification of proper substance groups for compliance check and proper testing proposal cases or direct to other REACH/CLP processes or deprioritise
  - Support the optimal allocation of the groups/case to evaluating teams
    - Including review of boundaries of a substance group
  - Indicate major issues found during screening
    - Including initial view how to best process the substance group

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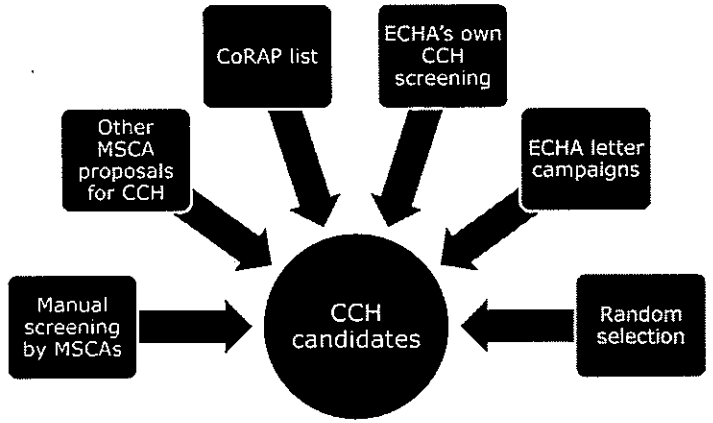
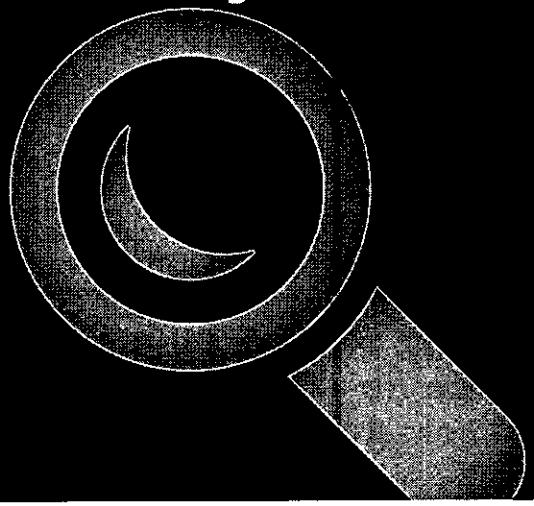
Multiple sources of compliance check (CCH) candidates



Sequential testing in dossier evaluation decision making



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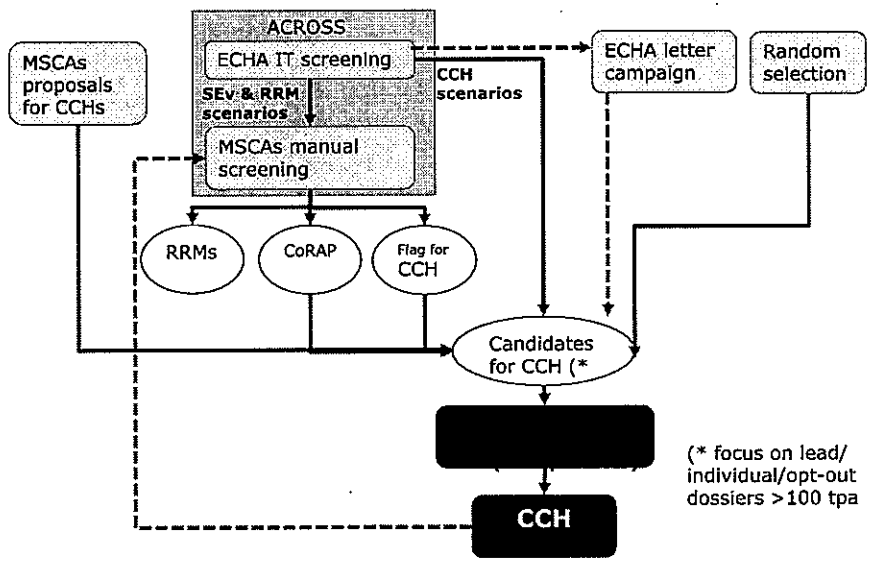
Screening of dossiers for CCH



(* focus on lead/ individual/opt-out dossiers >100 tpa

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Thank you

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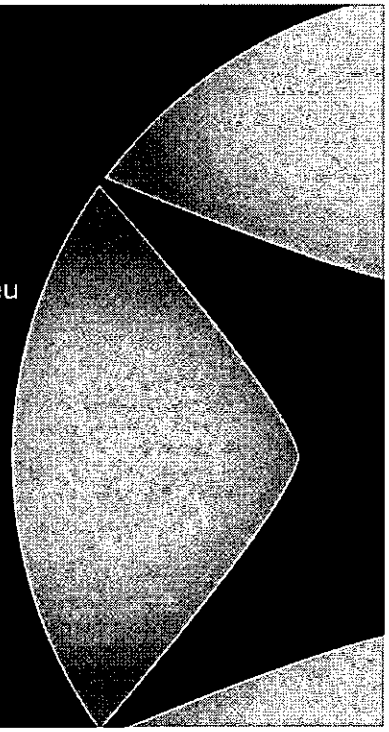

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Facilitating sequential testing in dossier evaluation decisions -1

- Facilitating sequential testing in ECHA dossier evaluation decisions supports integrated testing strategies and increases process efficiency
- Example: New approach to facilitate this for 90-day repeated dose and extended 1-generation reproduction toxicity (EOGRTS) sequential testing
  - If a dossier has data gaps or testing proposal for sub-chronic toxicity study (90-day) as well as for EOGRTS, ECHA issues two decisions, one at a time
  - By this approach, the results of the 90-day study can be taken into account for EOGRTS evaluation without the need to evaluate and discuss the EOGRTS request twice

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Facilitating sequential testing in dossier evaluation decisions -2

- 90-d RDT & EOGRTS sequential testing example:
  - The first decision will request the 90-day study results to be submitted by a shorter 12-month deadline; it does not contain a request for EOGRTS. However, in the same decision the registrant is informed that EOGRTS information requirement will be addressed in a subsequent decision after the results of the requested 90-day study have been submitted. The registrant is also reminded that he can submit a testing proposal for EOGRTS including his justification for an appropriate design together with the 90-day study results.
  - The second, targeted decision requests the EOGRTS with appropriate design taking into account the results of the newly submitted 90-day study results

The Swedish Chemicals Agency

- Supervisory authority under the Ministry of the Environment and Energy, founded in 1986
- Works in Sweden, within the EU and internationally to reduce risks from chemicals to human health and the environment
- Focus on preventive chemicals control, placing chemicals on the market.
- Located in Stockholm. Staff: about 280 (chemists, toxicologists, ecotoxocologists, lawyers, economists etc.)

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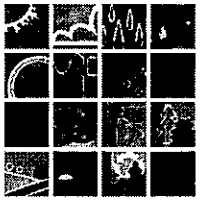
Swedish Chemicals Agency

The Swedish Chemicals Agency



The driving force in efforts to attain a non-toxic environment

Anna Fransson
International Unit, Swedish Chemicals Agency

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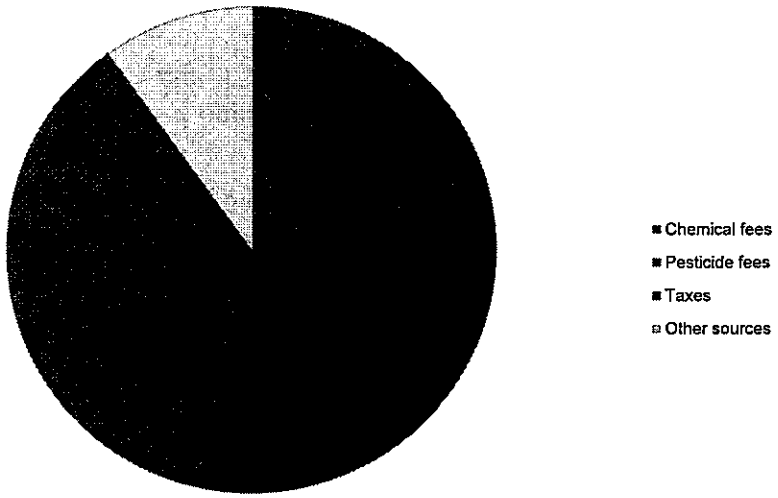
Swedish Chemicals Agency

Financing of Keml

(some years old)



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History – Swedish Chemicals Control

- 1663-1906 first regulations on poisons
- 1953 Plant Protection Ordinance
- 1962 Poison Board and new legislation
- 1971 restrictions on PCB
- 1973 Act on Products Hazardous to Health and the Environment
- 1973 Product Control Board
- 1986 Act on Chemical Products
- **1986 Swedish Chemical Agency**
- 1995 Sweden becomes an EU member state
- 1998 Environmental Code
- 1999 Environmental Quality Objectives
- 2000- A number of EU legislations and international conventions and agreements

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Swedish Chemicals Agency

KemI reduces chemical risks in Sweden

Through managing applications for approval of pesticides and biocides:

- Pesticides and biocides must be assessed and approved before they can be sold and used in Sweden
- KemI decide on conditions for use and restrictions (crops, dose, number of applications etc.). Approvals are time limited.

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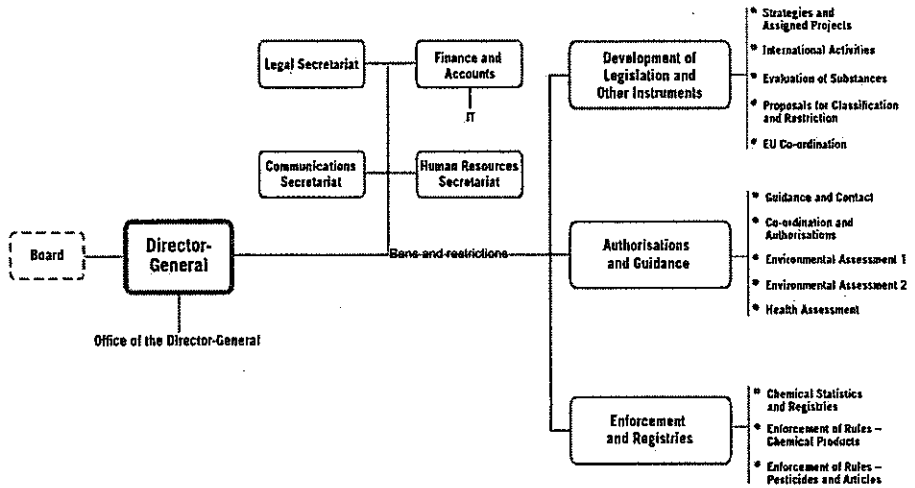
Organisation



KemI reduces chemical risks in Sweden

Through applying:

- REACH (**R**egistration, **E**valuation, **A**uthorisation and restriction of **CH**emicals)
- GHS (**G**lobally **H**armonised **S**ystem for classification and labelling). Implemented through the regulation on Classification Labelling and Packaging (CLP regulation)

- ➢ Take part in expert committees
- ➢ Prepare reports with assessment of chemicals, classification of substances, nomination of Substances of Very High Concern (SVHC) and restrictions

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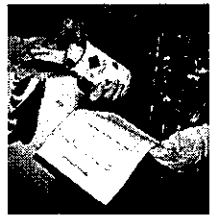
KemI reduces chemical risks in Sweden

Through inspections and guidance:

- Monitor companies' compliance with legislation and regulations (manufacturers/importers)
- Provide guidance to regional and local inspectors



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Work within the European Union

- Prepare and present documentation for development of EU legislation on chemicals (chemicals legislation is harmonised within EU)
- Take part in various expert groups and meetings, pushing for Swedish opinions
- Ensure that regulations and directives are implemented and complied with in Sweden

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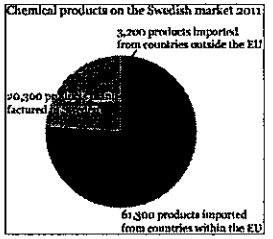
Keml reduces chemical risks in Sweden

Through development and use of statistics and flow analyses

- Keml keeps a product register.
- The register contains information on about 150,000 chemical products and biotechnical organisms from about 2,500 companies (producers, importers, volumes, use areas)



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International work

Support the Swedish government in work related to international chemicals conventions and agreements:

- Stockholm Convention (on Pesistent Organic Pollutants, POPs)
- Rotterdam Convention (on Prior Informed Consent, PIC)
- Minamata Convention (on mercury)
- SAICM (**S**trategic **A**pproach to **I**nternational **C**hemicals **M**anagement)
- The Globally Harmonized System for Classification and Labelling (GHS)

STOCKHOLM CONVENTION

Rotterdam Convention

MINAMATA CONVENTION UNEP ON MERCURY

saicm

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THE SWEDISH PARLIAMENT HAS ADOPTED 16 ENVIRONMENTAL QUALITY OBJECTIVES

- Reduced Climate Impact
- Clean Air
- Natural Acidification Only
- **A Non-Toxic Environment**
- A Protective Ozone Layer
- A Safe Radiation Environment
- Zero Eutrophication
- Flourishing Lakes and Streams
- Good-Quality Groundwater
- A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos
- Thriving Wetlands
- Sustainable Forests
- A Varied Agricultural Landscape
- A Magnificent Mountain Landscape
- A Good Built Environment
- A Rich Diversity of Plant and Animal Life

Development Cooperation

Projects/programmes funded by Swedish International Development Cooperation Agency, Sida

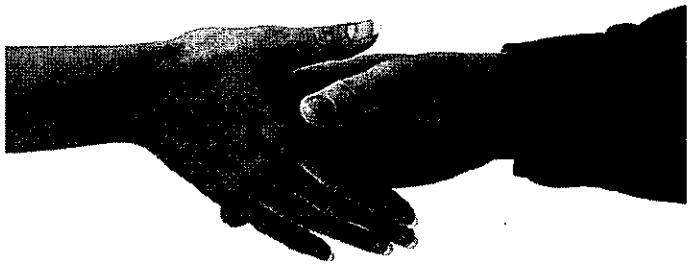
- Global programme
- Regional Programme in South-East Asia
- Bilateral collaboration – Serbia
- International Training Programme (ITP) on chemicals management

Bilateral cooperation with strategic countries (funding from MoEE)

- China
- Brazil
- Uruguay
- South Africa
- Vietnam
- Indonesia

Thanks for your attention!

Developing guidance and contact services



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Communication and help desk facilities

Mr. Jonas Falck

Adviser – Chemicals legislation

Guidance and Contact Unit

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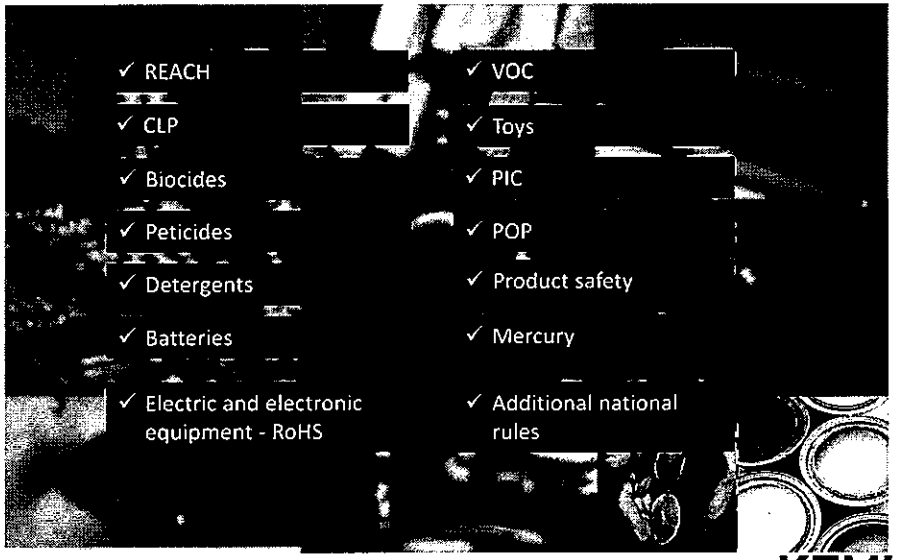
There are many rules on chemiclas…



…to mention several but not all.

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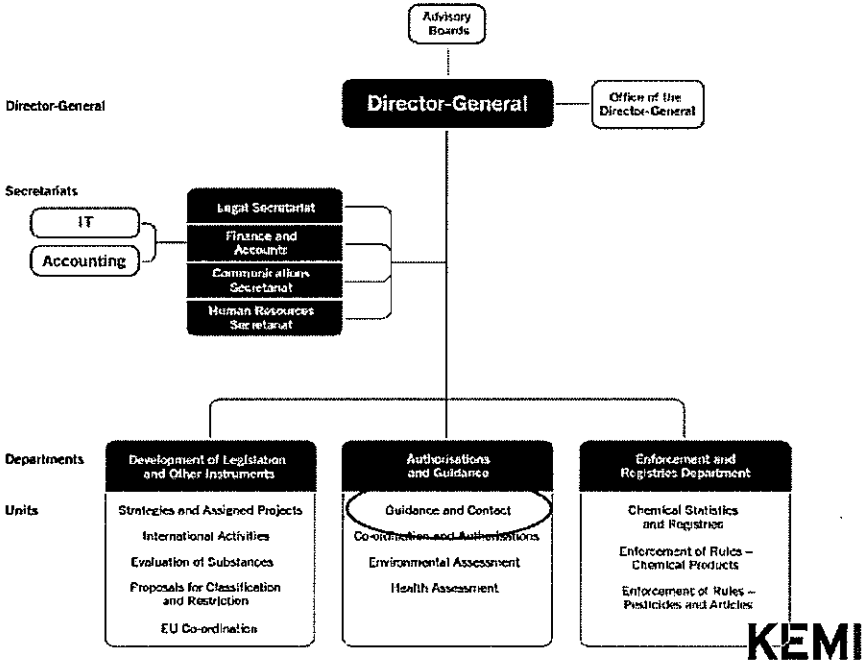

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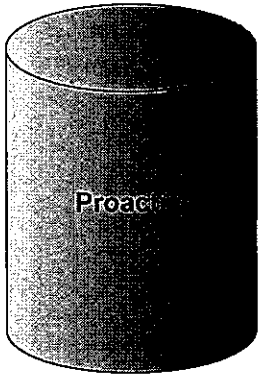
In order to reach out we need to be both proactive and reactive



- Web pages based on users, areas and topics
  - Legal documents
  - Explanation pages, guidance and FAQs
  - Guidance documents
  - Fact sheets
  - Brochures, leaflets
  - Posters
  - Kemi newsletter subscription (also reactive)
- Targeted letters (also reactive)
- Information and links at other authorities sites
- Fairs 2-4 / year
- Seminars >10 /year

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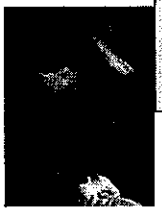
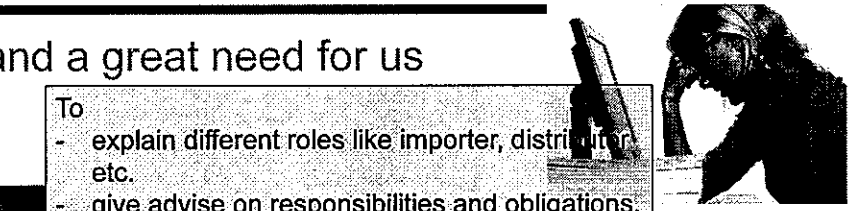
...and a great need for us





To
- explain different roles like importer, distributor etc.
- give advise on responsibilities and obligations, and
- explain guidance

To
- Inform about customers right to know, and
- what the information means

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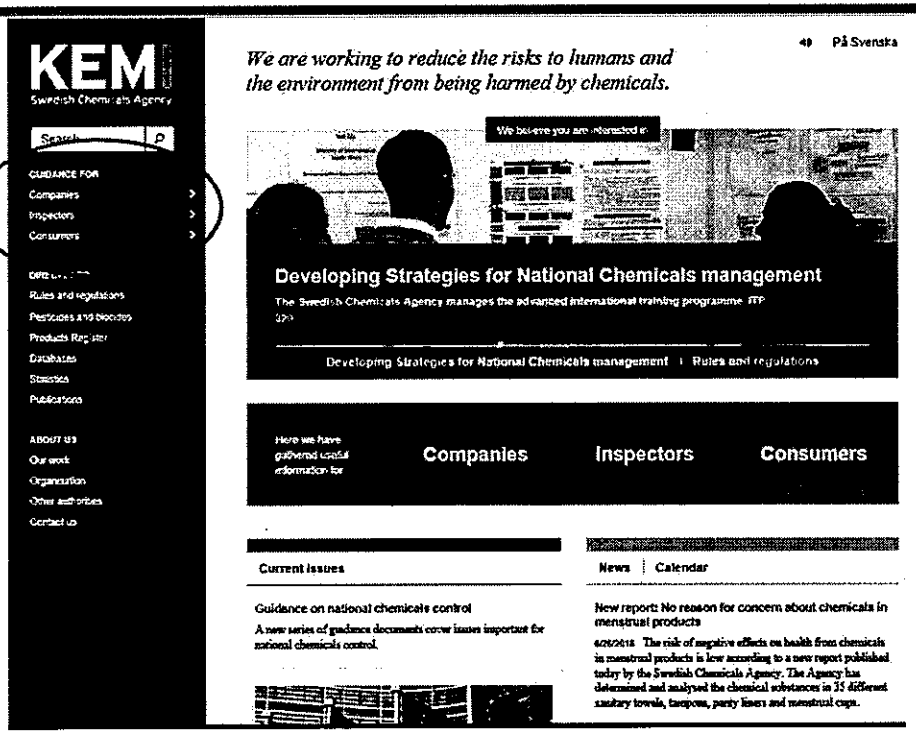
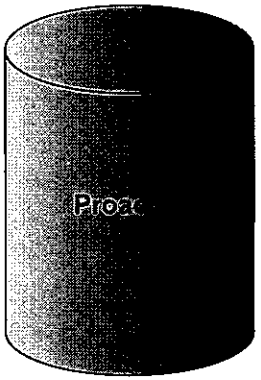
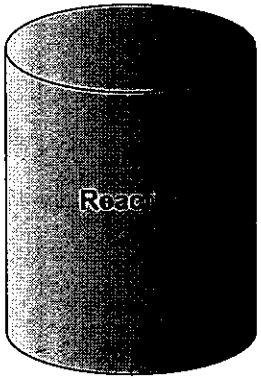


In order to reach out we need to be both proactive and reactive





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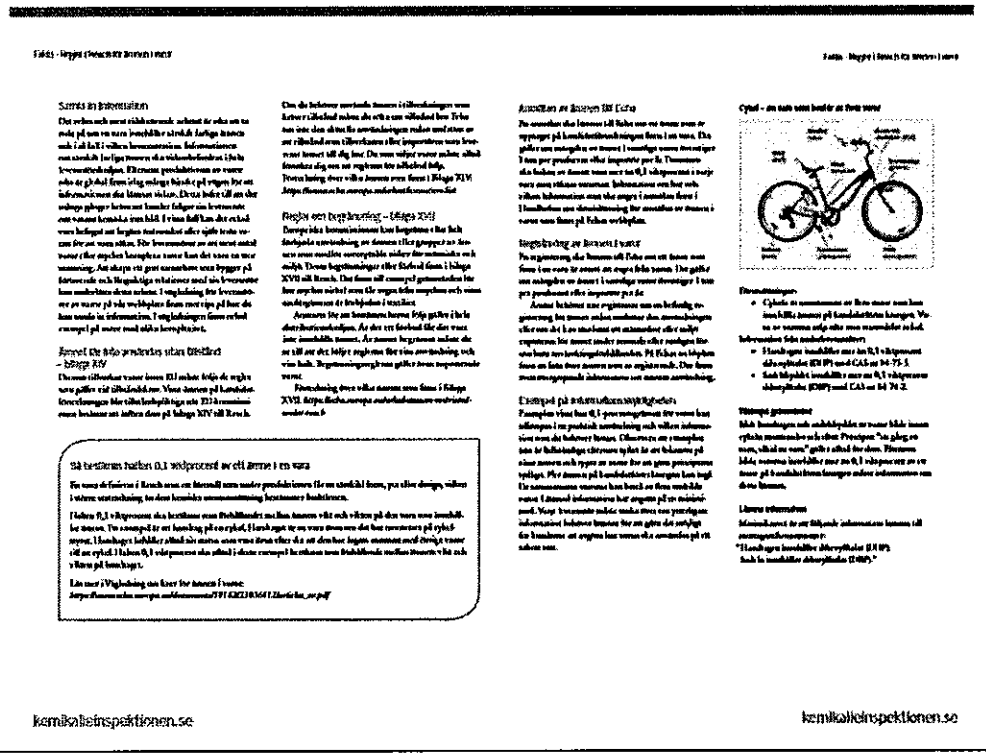

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Sök

- Lagar och regler
  - Reach-förordningen
    - Kort om Reach
    - Guide till Reach-registrering
    - Företagens roller i Reach
    - Tillstånd
    - Kandidatförteckningen
    - Begränsning
    - Säkerhetsdatablad
    - Reach och varor
    - Frågor och svar om Reach
  - CLP - Klassificering och märkning
  - Regler för biocidprodukter
  - Regler för växtskyddsmedel
  - RoHS – Elektrisk och elektronisk utrustning
  - Ytterligare EU-regler
  - Regler som endast gäller i Sverige
  - Miljöbalken, lagar och förordningar
  - KIFS – Kemikalieinspektionens föreskrifter

Guide till Reach-registrering

Om du ska tillverka eller importera att ton eller mer av ett ämne per år måste du registrera ämnet hos den europeiska kemikaliemyndigheten Echa. Det innebär att du måste lämna uppgifter om ämnets egenskaper och information om hur ämnet kan användas på ett säkert sätt. Företag som ska registrera samma ämne måste samarbeta och lämna in vissa uppgifter gemensamt.

Om du inte registrerar ämnet är det olagligt att tillverka det och/eller släppa ut det inom EES-området (EU-länderna samt Norge, Island och Lichtenstein).

Läs mer i Echas vägledning om registrering.

Läs mer om att komma igång med din registrering.

- Vad ska registreras?
- Finns det ämnen som är undantagna?
- Vem ska registrera ämnen?
- När ska ämnen registreras?
- Vilken information ska finnas i registreringen?

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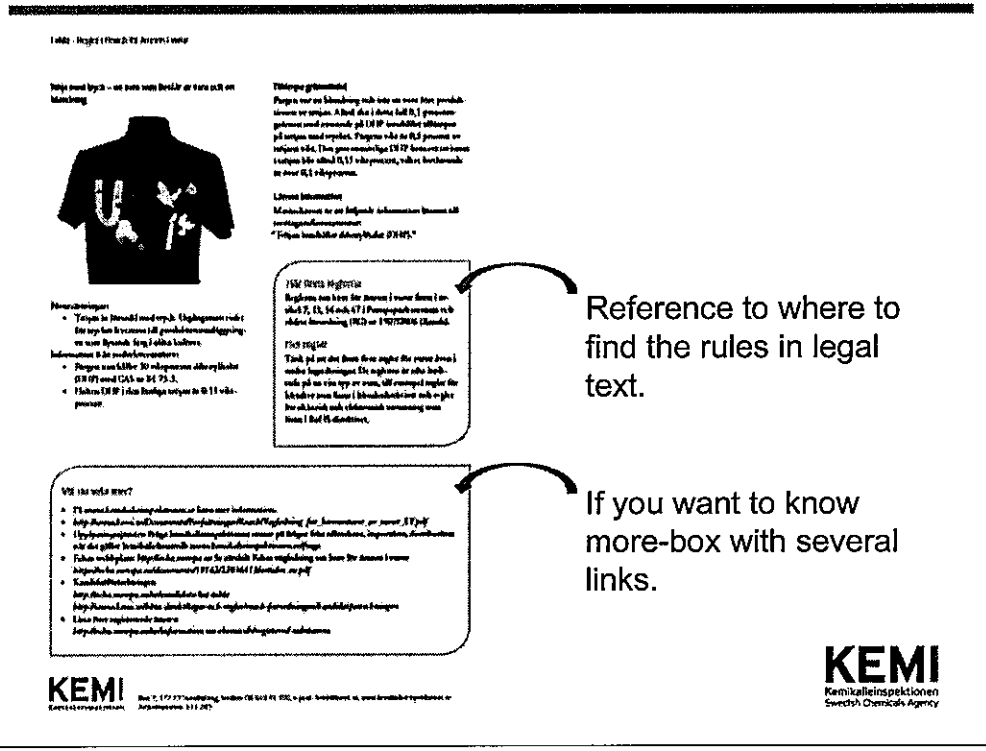

Reference to where to find the rules in legal text.

If you want to know more-box with several links.

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Fact sheets

For example →
Rules in REACH for substances in articles.

This is the front page of a four page fact sheet.

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FAKTA

April 2018

Regler i Reach för ämnen i varor

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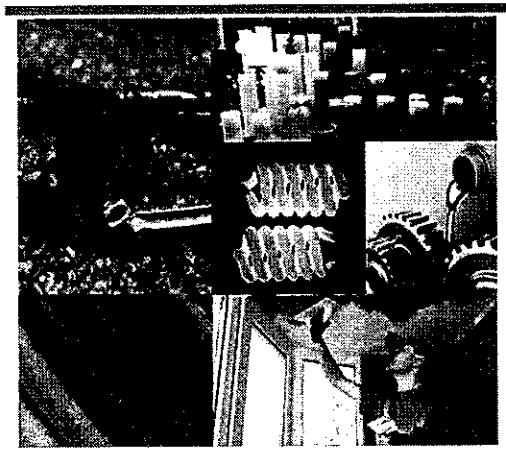
kemikalieinspektionen.se



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+46 8 519 41 100

Visitors' and delivery address
Esplanaden 3A, Sundbyberg

kemi@kemi.se
www.kemikalieinspektionen.se

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

Article number: 511 277.

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Brochures, leaflets

For example →

- An easy leaflet just to wake new and unaware companies up.
- They are affected by rules on chemicals in articles and chemical products.
- Where they can find out more.

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All products are covered by chemicals legislation – do you know how this affects your company?

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Brochures, leaflets

Another example →

- A 24 page brochure with more comprehensive information on labelling and responsibilities regarding chemical product in your store.

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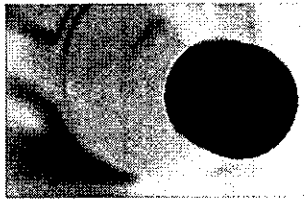
Kemiska produkter i butiker
Märkning och ansvar



There are chemicals in everything. And as a business operator you are responsible.

As a business operator, you are responsible for ensuring that the products you import, manufacture or sell comply with the laws and regulations for chemicals. This may seem far-fetched if you deal with everyday items such as electronics, shoes and toys. But these products are also covered by chemical regulations, just like glue, paint and lubricants.

What you need to know

Rules regarding chemicals are governed by a number of different laws, regulations and directives, depending on criteria such as product, substance and volume. Some substances are banned in certain products, others require you to have a permit. But for most products you must comply with the regulations, which have implications including the following:

- that you know that your products do not contain banned substances
- that you can be obliged to inform your customers if the products contain certain substances
- that the product is clearly labelled in Swedish, for example how it must be handled in order to ensure safe use
- that you may need to report products to the Products Register

Your responsibility – and others

The regulations differ, depending on whether your company is a manufacturer, importer, distributor or end user. The important point is that every link in the supply chain bears its own responsibility. Therefore, you cannot refer to the fact that you bought something from a supplier who has to comply with the regulations. Your company must take your own responsibility regardless of where you source raw materials, materials or finished products. Ask and make demands of your supplier!

Did you know that

- most products are covered by several different sets of rules
- Allyer by sportswear, for example, is considered a pesticide (biocide) as it is there to kill bacteria
- even small columns, as in a little tube of glue, are covered by chemical regulations
- CE marking is not a guarantee that all regulations have been met
- products made of natural materials such as wood or leather are also covered by rules about chemicals

If you make a mistake

We conduct checks and inspections to make sure that companies are complying with the rules. Inspections are also conducted by municipalities, county administrative boards and other authorities. Companies that fail to comply with the rules about chemicals must rectify any deficiencies. You may have a sales ban imposed or be forced to recall the product from your customers. More serious infringements may lead to a report of a suspected environmental offence. The company can also be forced to pay an environmental sanction charge.

Find out more

At the Swedish Chemicals Agency, we want to make it easy for you as a business operator to do the right thing. There is information at kemikalieinspektionen.se/en about what the rules are for different kinds of businesses, products and substances. You can also find Q&As there and ask your own questions. Why not visit our website today to find out how your business is affected and what you need to know to take your responsibility?

Find out about the rules and how your company is affected – visit

www.kemikalieinspektionen.se/en

Swedish Chemicals Agency

Fairs 2-4/year

www.kemikalieinspektionen.se

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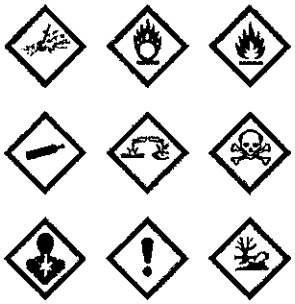
Märkning enligt CLP-förordningen

Enligt bestämmelserna i CLP-förordningen ska kemiska produkter, som är farliga antingen som fysikaliska faror (brand, explosion) eller farliga för människors hälsa eller för miljön, vara märkta med

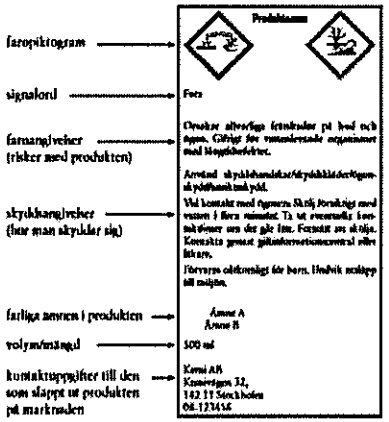
- faropiktogram
- signalord
- faroangivelser – talar om på vilket sätt produkten är farlig
- skyddsangivelser – talar om hur man skyddar hälsa och miljö.

Faropiktogrammen nedan finns i CLP-förordningen och används för olika typer av faror. Vilken farlig egenskap som det handlar om framgår av ett faropiktogram i kombination med en faroangivelse.

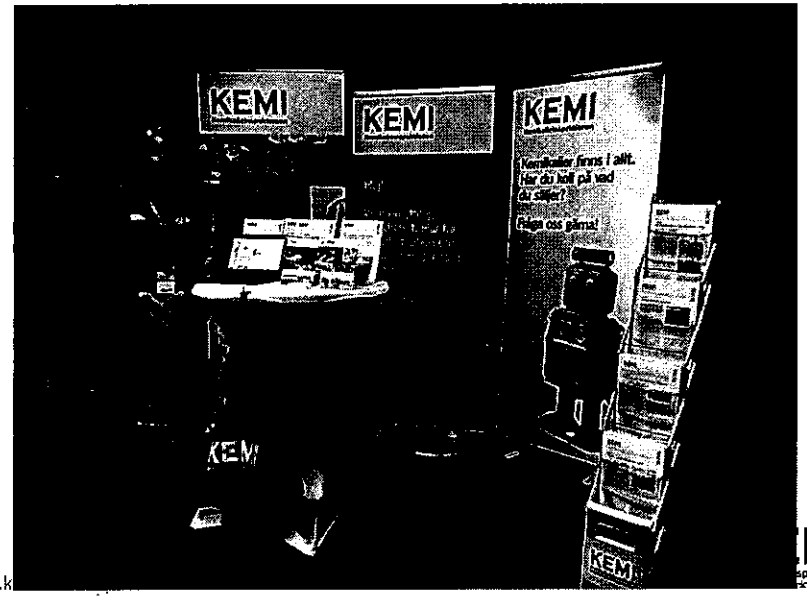


Så här kan märkningen se ut

Farliga kemiska produkter ska vara märkta på svenska och märkningen måste ha ett bestämt innehåll enligt exemplet nedan.



Fairs 2-4/year



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CLP - poster

Klassificering och märkning enligt CLP

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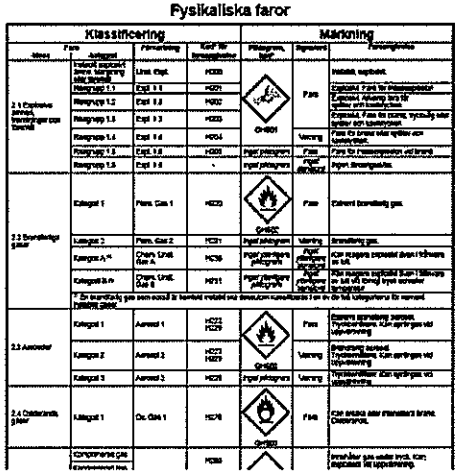
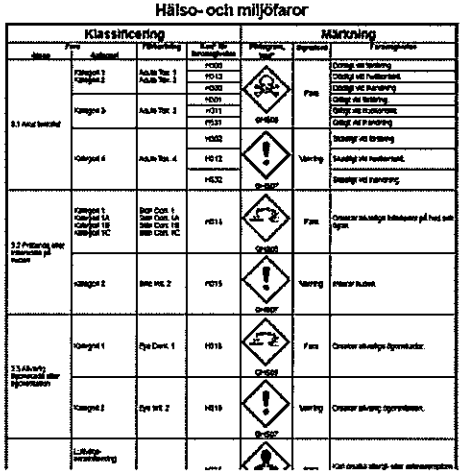
Förordning (EG) nr 1272/2008 (till och med tionde tekniska anpassningen, ATP10)

Fysikaliska faror



Hälso- och miljöfaror



Verksamt.se
Coordinated services from public authorities

Search...

Considering | Starting | **Running** | Developing | Closing down | Services

Product responsibility for chemicals

Chemicals are found in all products, and no matter how small or large your enterprise is, your products must comply with the requirements in legislation and rules for chemicals.

There are many rules restricting chemicals in for example:

- Electronics
- Construction products
- Clothing and footwear
- Jewellery
- Toys
- Furniture and home furnishings
- Packaging
- Laundry and dishwashing detergents
- Adhesives
- Paint
- Lubricating oils.

What you need to monitor?

What happens if you don't comply?

Hygiene product, cosmetics and foodstuff?

Read more about your responsibility on the Swedish Chemicals Agency website

Read more about safe food on the Swedish National Food Agency website (in Swedish)

Read more about chemicals in hygiene products and cosmetics on the Swedish Medical Products Agency website (in Swedish)

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www.kemikalieinspektionen.se

Information and links at other authorities sites

Bolagsverket
Swedish Companies Registration Office

Verksamt.se
Coordinated services from public authorities

www.bolagsverket.se

www.verksamt.se

www.kemikalieinspektionen.se

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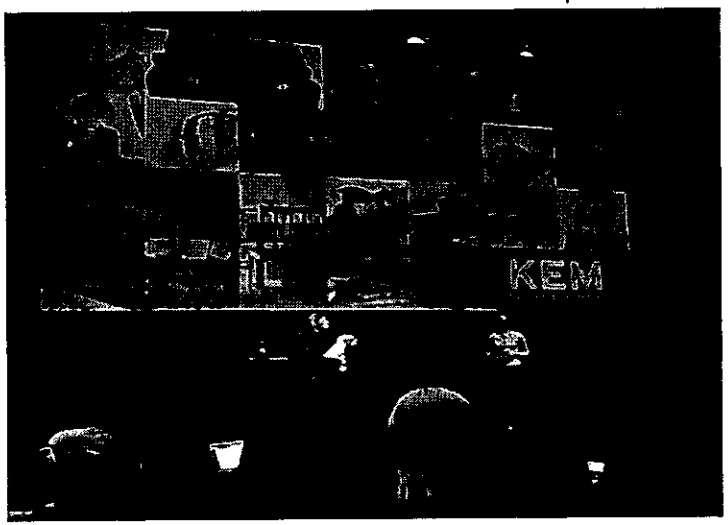
Seminars - both ours and invited as speakers...



...collaboration with authorities as well as industry organisations.

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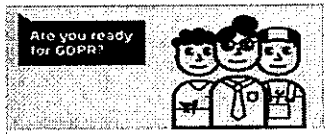
Tips and advice

Do you need to apply for a permit?

Here we have gathered information about permits you may need to apply for before you start your business. For example, if you want to run a food establishment or want to sell alcohol.

Read more about permits >



Are you ready for GDPR?

The GDPR guide at verksamt.se provides you with some of the most important basic information in the new data protection regulation for your business. Answer a few quick questions and receive tips on how to prepare yourself.

Go to the GDPR guide >

Read more about GDPR >

Find advisors

Do you need help with setting up your business? Here you will find information about support available for you.

Entrepreneur stories

Here we have gathered examples of how other business owners have done when starting or developing their businesses.

Click here to see all entrepreneur

Work in Sweden

Do you have professional qualifications from another EU/EEA country? Get them officially recognised to start working in Sweden.

www.kemikal

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Swedish National Helpdesk

- Written queries
- Telephone service (open 2 hours/day)

} 500 / month

Employees working part of their time to:
- cover different legislation following a schedule,

- reply on written queries within 7 days.

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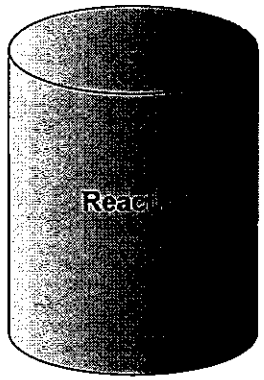
In order to reach out we need to be both proactive and reactive

- Written questions
- Telephone service

- Press
  - Interview for articles
  - Press releases

- Targeted letters and Kemi newsletter (also proactive)



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Cooperation

HelpNet

National Helpdesk Network, also with observers from Industry and some non MS.

HelpEx

HelpNet Exchange forum.

} ECHA EUROPEAN CHEMICALS AGENCY

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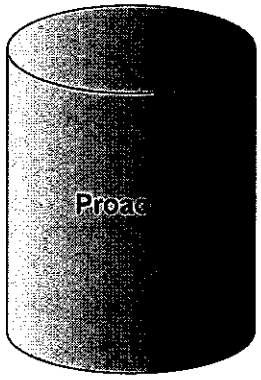
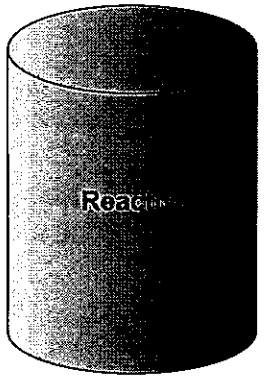
... and also flexible





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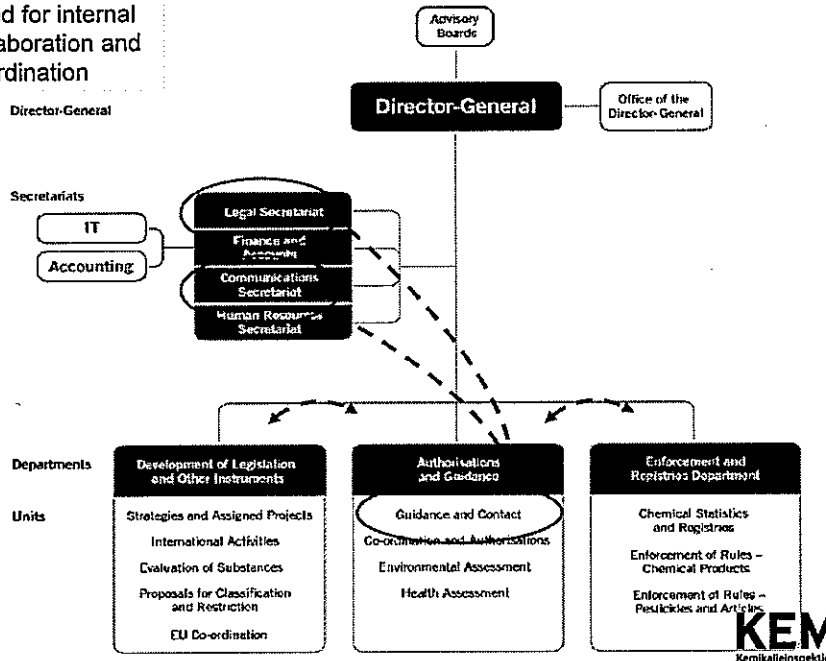
Need for internal collaboration and coordination



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Sometimes also targeted letters

For example:

- New restrictions - - - - - - - - lead in certain products sold to the general public.
- Low compliance - - - - - - - - e-commerce.

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And also - Materials for preschool and school children (in collaboration with other authorities)

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Swedish Chemicals Agency

Taiwan study visit to Sweden 6-7 September 2018

REACH processes – restrictions and authorisation of chemicals

Mats Forkman
mats.forkman@kemi.se

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Proposed topics for the afternoon

- Introduction
- REACH principles and overview
- Regulatory actions
  - Substance evaluation
  - Selecting a regulatory risk management option – RMOA
  - Harmonised classification and labelling
  - Authorisation
  - Restrictions
- Information on substances in articles

Please feel free to ask questions!

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Introduction

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In Real Life – Complexity

- Substance-based
  - Many substances
  - Not always easy to define
  - …
- Hazardous properties
  - Many end-points
  - Thresholds?
  - Dose response
  - …
- Supply chain and uses
  - Many actors
  - Global
  - Used in mixtures, mixtures of mixtures, articles…
  - Commercially sensitive information
  - Individuals use – variance
  - …
  - Changing over time!

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In Real Life – Complexity (cont)

- Information
  - Generate
  - Collect
  - Evaluate
  - Communicate to those that need the information in way that can be comprehended
  - …
- Regulatory landscape
  - EU – 28 member states
  - Many legal acts
  - Historical legacy
  - Conflicting interests
  - …
- Impacts from intervention
  - Intended
  - Unintended
  - …

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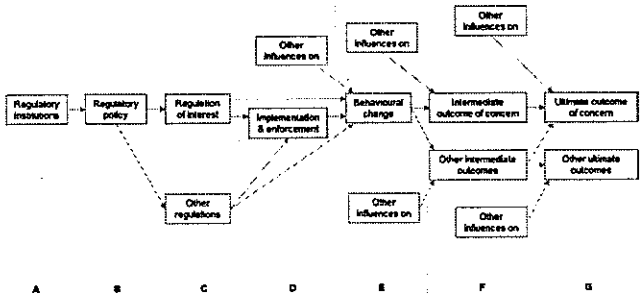
A causal map of regulation and its effects



Adapted from Coglianese, 2012. *Measuring Regulatory Performance - Evaluating the impact of regulation and regulatory policy*, OECD.

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Examples of EU legislation with provisions on chemicals

Focus on individual substances:

- REACH, CLP, POP regulation (Stockholm convention) – Apply to (almost) all non-food/non-feed

Focus on specific product groups

- Biocidal product regulation and Plant protection product regulation
- Toy safety directive
- Restriction of hazardous substances in Electrical and Electronic equipment – RoHS directive
- Food Contact Materials (FCMs) – several regulations
- Cosmetics directive
- Medicinal products for human or veterinary use

Focus on the use phase:

- Environmental legislation – Water framework directive
- Worker protection legislation – Chemical agents at work directive

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Control of general industrial chemicals before REACH – framework

- Distinguished between
  - "existing substances"
    - all chemicals declared to be on the market in September 1981, and
  - "new substances"
    - those placed on the market since that date
- Testing and assessing risks to human health and the environment
  - Existing substances – 140 priority substances out of > 100 000 subject to comprehensive risk assessment carried out by Member State authorities
  - New substances – Testing and assessing risk required by manufacturer/ importer
- Information on downstream uses generally scarce
- Decisions on further testing taken via a lengthy committee procedure and could only be requested from industry after authorities have proven that a substance may present a serious risk
- Restriction of marketing and use required the European Commission to carry out risk assessments and adequate analyses of the costs and the benefits

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Control of general industrial chemicals before REACH – consequences

- A general lack of knowledge about the properties and the uses of existing substances
- A slow and resource-intensive risk assessment process did not allow the system to work efficiently and effectively
- The allocation of responsibilities was inappropriate because authorities were responsible for the assessment instead of enterprises which produce, import or use the substances
- More requirements on new substances – did not stimulate innovation

Development and adoption of new legislation – REACH

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REACH overview and principles

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Aim and scope of REACH

Purpose

- high level of protection of human health and the environment,
- promotion of alternative methods for assessment of hazards of substances
- free circulation of substances on the internal market
- enhancing competitiveness and innovation.

Principles

- it is for **manufacturers, importers and downstream users** to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment
- provisions are underpinned by the precautionary principle.

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Environmental principles in the EU treaties

General

- Proportionality
  - the action of the EU must be limited to what is necessary to achieve the objectives of the Treaties
- Subsidiarity
  - the EU does not take action unless it is more effective than action taken at national, regional or local level

Environment

Article 191(2) TFEU defines environmental principles :

- take into account the diversity of situations in the various regions
- based on the precautionary principle
- preventive action
- damage should be rectified at source
- polluter should pay

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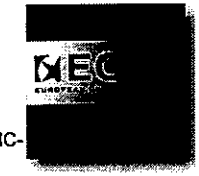
Legal and organisational context

- REACH
  - Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- CLP
  - Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
  - Implements GHS in the EU
- ECHA
  - European Chemicals Agency
  - Located in Helsinki, Finland
  - Established under REACH
  - REACH, CLP, Biocidal Products Regulation, PIC-regulation



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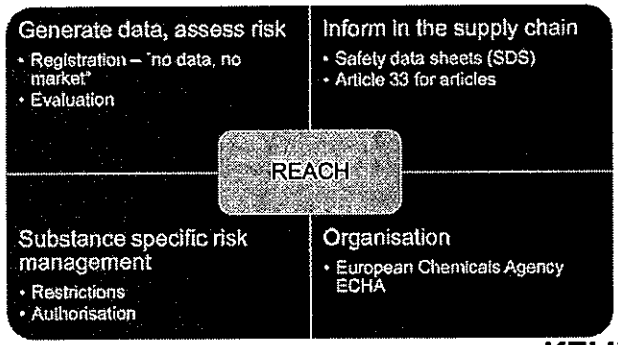
Key parts of REACH



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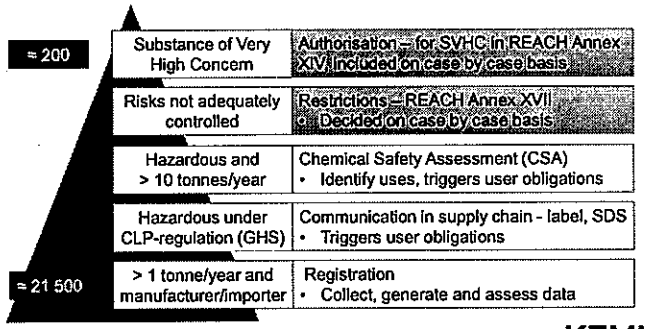
Risk management in REACH



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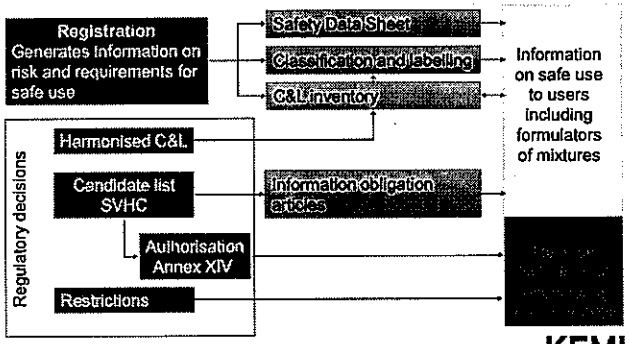
Framework of registries/inventories/lists



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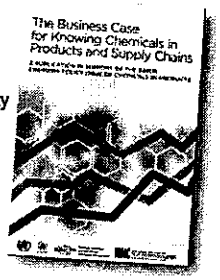
Market pressure

- Business to Consumer
  - Brand reputation
- Business to Business
  - Employer's obligations occupational safety and health
  - Environmental permits
  - Sustainability commitments
  - Brand reputation
  - Need to redesign
  - Costly actions in future (asbestos in buildings…)
  - Buyer's product becomes non-compliant
  - …



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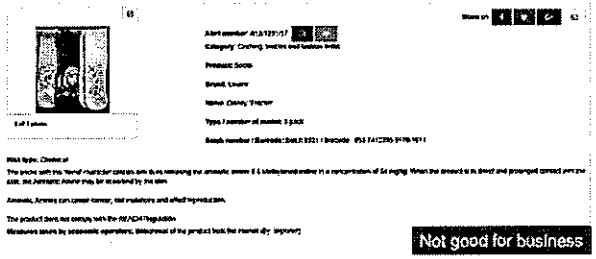
Rapid Alert System for dangerous non-food products – Rapex

Publicly available information on non-safe products in Rapex – example



https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

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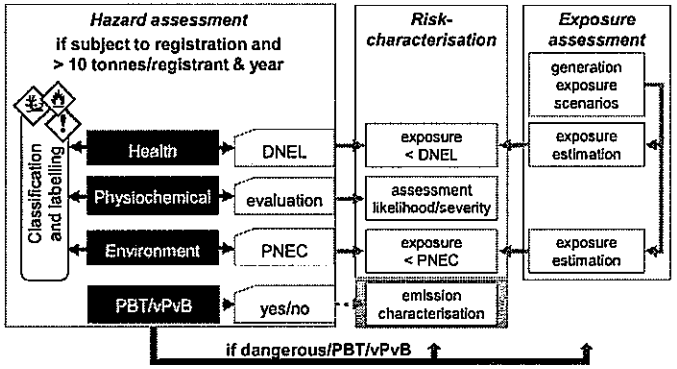
Chemical Safety Assessment in REACH registration



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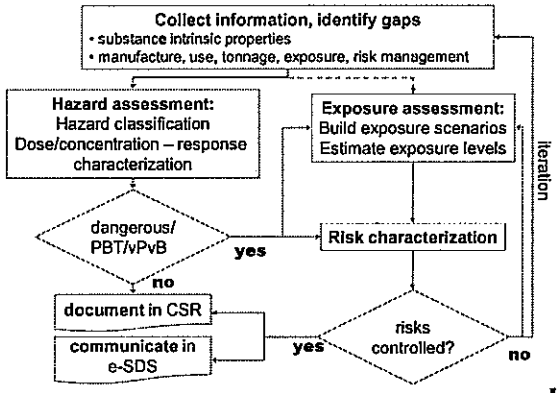
Chemical Safety Assessment – the process



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Regulatory tools – substance evaluation

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Regulatory tools – REACH and CLP

- Ensure compliance
  - Enforcement
  - Registration dossier evaluation
- Generate new information
  - Substance evaluation
- New provisions
  - Harmonised Classification and Labelling
  - Authorisation requirements
  - Restrictions on manufacturing, placing on the market and use

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What information can be requested in substance evaluation?

- Any information if justified
  - *'If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission.'*
    - Reach article 46(1)
- Registrants submit information
- Examples
  - Toxicity testing
  - Eco-toxicity (including fate) testing
  - Exposure information
    - Use information
    - Exposure assessment...

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Decisions in substance evaluation

- Regulatory decision requesting information – legally binding for registrant
- Member State Committee
  - If unanimous – decision taken
  - If not unanimous – decision moved to next level, EU Commission supported by regulatory committee
- Registrant can appeal

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From report on operation of REACH (2018)

- Fewer substance evaluations have taken place than predicted, with 82 decisions by ECHA on substance evaluation adopted so far.
- The administrative processes associated to dossier and substance evaluation and the time needed to generate information is taking a lot of time.

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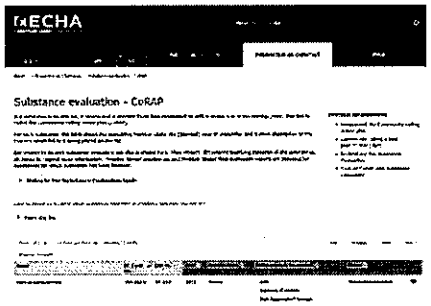
Substance evaluation – decisions

ECHA > Information on Chemicals > Substance evaluation > CoRAP



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What happens after a substance evaluation

- No further action
- A proposal for harmonised classification and labelling for carcinogenic, mutagenic or toxic to reproductions, respiratory sensitisers or other effects.
- A proposal to identify the substance as a substance of very high concern (SVHC).
- A proposal to restrict the substance.
- Actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions.

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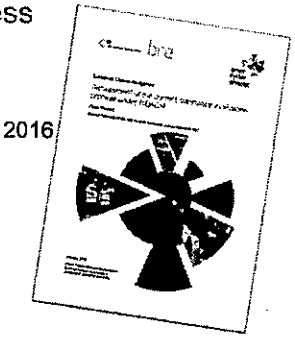
Evaluation of the substance evaluation process

An assessment of the current substance evaluation process under REACH was published in 2016



- https://echa.europa.eu/documents/10162/13628/sev_survey_2015_en.pdf/b1532056-a551-4d25-aa6e-d29998713685

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Regulatory risk management tools and how to prioritise

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Regulatory risk management tools in REACH and CLP

	Harmonised classification	Authorisation	Restriction
Scope substances	With specified hazardous properties	With specified hazardous properties	Any leading to unacceptable risk
Provision	Binding classification	Place on market and use requires authorisation	Restriction on manufacture, place on market, use Case by case
Scope of provision	Substance	Substance	Substance, mixture, article

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How prioritise regulatory action - Regulatory Management Option Analysis (RMOA)

- Purpose
  - help decide whether further regulatory risk management activities are required for a substance
  - identify the most appropriate instrument to address a concern
  - case-by-case analysis.
- Voluntary – not part of the processes as defined in the legislation
- Documenting the RMOA allows information to be shared
- Communication
  - Economic actors can be proactive
  - Contribute information
  - Legitimacy of subsequent regulatory processes

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Regulatory Management Option Analysis (RMOA)

- No action at present time
- Restriction
  - information on hazards and risks
  - alternatives
  - justification for restrictions at Community level
  - socio-economic assessment
- Identification of substance for Candidate list
  - Justification inherent properties versus criteria
    - Information on exposures, alternative substances and risks
    - The available use and exposure information and information on alternative substances and techniques shall be provided
- Harmonisation of classification and labelling of substances normally for:
  - respiratory sensitisation, category 1
  - germ cell mutagenicity, category 1A, 1B or 2
  - carcinogenicity, category 1A, 1B or 2
  - reproductive toxicity, category 1A, 1B or 2
  - active substance PPP, biocide
  - case-by-case basis
- Other regulatory regimes

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Information for RMOA

- Data from registration
- Environmental monitoring
- Biological monitoring
- Consultations
  - Industry
  - Academia
- Open sources
- Swedish Product Register
- ...

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The Swedish Products Register

- National database on chemicals
- 90 000 chemical products
- 15 000 substances
- 2 500 companies
- Each year: 9 000 new products in the register, 7 000 products go out of market → net growth: 2 000 products

- Only registration – no approval of chemicals/pesticides
- Excluded: pharmaceuticals, food stuffs, cosmetics

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Products subject to registration

- Manufactured in or imported to Sweden
- Renamed or repackaged products
- Production of mixtures / preparations
- Manufacture or transfer of chemical pesticides

- Customs Tariff Number (list of about 1 000 numbers)
- Quantity of at least 100 kg per year

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What data is submitted?

- Product name
- Origin (Manufacture, import, transfer, name change)
- Quantity / Year
- Consumer available?
- Statistical Custom Tariff Number
- VOC (Volatile Org. Compounds – for paints and lacquers)
- Product category (function)
- Sector of use (NACE - Statistical Classification of Economic Activities in the European Community)
- Estimated distribution
- For further sale or own use?
- Export
- Classification (GHS, DSD, DPD)
- Product composition (exact composition details)

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Harmonised classification and labelling

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Harmonised classification and labelling

- Manufacturers, importers or downstream users have to (self)classify and label hazardous substances and mixtures
- For hazards of highest concern (CMR and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management
- This is done through harmonised classification and labelling (CLH)
- Harmonised classifications are listed in Annex VI to the CLP Regulation and should be applied by all

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The classification under CLP can trigger legal obligations

- In the EU:
  - The classification of a substance under the CLP-regulation can trigger:
    - Obligations on child-resistant packaging and tactile marking in CLP
    - Obligations and requirements in other legislation
- Worker protection legislation requires employers to do risk assessment
  - Information in SDS and from classification and labelling shall be taken into acount
- Effective – other legislation does not have to include lists of substances (that have to be updated)

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Example – Swedish worker protection legislation

- If risk for exposure in a workplace to substances classified as
  - H317: May cause an allergic skin reaction
  - H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
- Then regulatory requirements on the employer to:
  - Ensure that only people possessing special theoretical and practical training and knowledge of the risks and protective measures may work with these substances
  - People in a supervisory position must also undergo training
- Signs where there is risk for exposure
- And more...

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Example – EU Toy Safety Directive

- ...substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys

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Example – Permits for very hazardous chemical products in Sweden

You will need a permit either if you as a professional are placing very hazardous chemical products (> one of classifications below)on the market or if you are a private user

- Acute toxicity in hazard categories 1, 2 and/or 3
  - Hazard pictogram GHS06: Skull and crossbones. Signal word: "Danger"
- Carcinogenicity in hazard category 1A or 1B, Germ cell mutagenicity in hazard category 1A or 1B, or Reproductive toxicity in hazard category 1A or 1B
  - Hazard pictogram GHS08: Health hazard. Signal word: "Danger".
- Specific organ toxicity - single exposure, hazard category 1
  - Hazard pictogram GHS08: Health hazard. Signal word: "Danger"
- Skin corrosion in hazard category 1A
  - Hazard pictogram GHS05: Corrosive. Signal word: "Danger".




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Authorisation

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Authorisation, approval, licensing

- Typically
  - Specified substances/mixtures/products in scope
  - Economic actor must have authorisation (with conditions) to place on the market/use
  - Authority/agency grant authorization after application
- Example of authorisation systems in the EU
  - Plant Protection Products
  - Biocidal Products
  - Authorisation under REACH – Substances of Very High Concern
- Registration under REACH not authorisation
  - Registration is accepted if required information is supplied and of sufficient quality
  - Requirement: "No data – no market", but no decision on whether substance or use is "OK"

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Aim of authorisation and considerations for substitution (REACH article 55)

'The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.'

- Functioning market
- Risks controlled
- SVHC progressively replaced
- Manufacturers/importers/downstream users obligations

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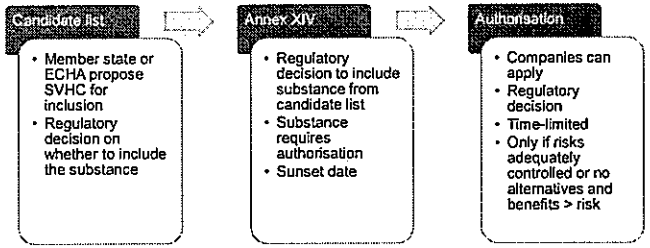
Authorisation process

The authorisation process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less dangerous substances or technologies where technically and economically feasible alternatives are available.



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Other uses of lists – example candidate list

- Several companies use Candidate list in their purchase requirements – their own Restricted substances lists – going beyond legislative requirements
  - Easier to establish and maintain than own list
  - More known to suppliers, test-houses...
  - Official list, readily available for all

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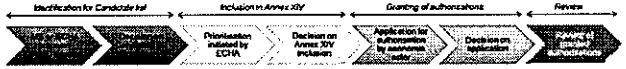
Authorisation process



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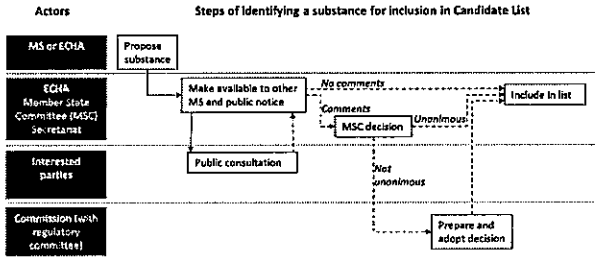
Identifying substance for inclusion in REACH Candidate List



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Candidate list for authorisation under REACH

- Substances with the following hazard properties may be identified as SVHCs:
  - carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with CLP
  - persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII
  - case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances
- Currently > 170 substances
- New substances added twice per year

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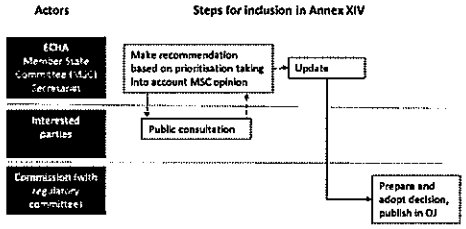
Inclusion in Annex XIV – Substances subject to authorisation



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Prioritisation for including substances in Annex XIV

- Done by ECHA at least every other year
- Priority shall normally be given to substances with:
  - PBT or vPvB properties; or
  - wide dispersive use; or
  - high volumes.
- The number of substances included in Annex XIV and the dates shall also take account of the Agency's capacity to handle applications in the time provided for.
- Scoring system
  - Each criteria given score of 0 to 15
  - Sum of scores for a substance gives prioritisation
- Also other considerations , for example
  - Other regulatory action
  - Drop in substitute for other substance in Annex XIV

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List of substances subject to authorisation REACH Annex XIV

- Substances in Annex XIV may only be placed on the market or used with authorisation
  - Some exemptions, for example where covered by other legislations
  - After transitional period for the specific substance
- Substances included from candidate list
  - But not all substances on the Candidate list will be included in Annex XIV – the Authorisation process is resource demanding
- Companies apply for authorisation to ECHA – regulatory decision on whether to grant authorisation
- > 40 substances

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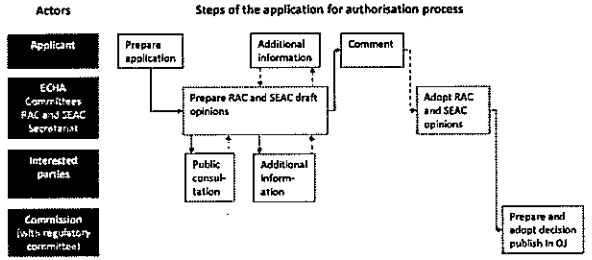
Granting an authorisation



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Restrictions

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Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles – REACH annex XVII

- List of provisions on specific substances/groups of substances
- Approximately 70 entries
- Examples
  - Asbestos – ban
  - Limit on migration of nickel in articles in skin contact
- Based on risk – not inherent properties of substance
- Lengthy procedure to add new restrictions – years
- Requires extensive information to develop – demanding in resources
- Once adopted – no built in possibility for getting exemptions, legal text needs to e changed

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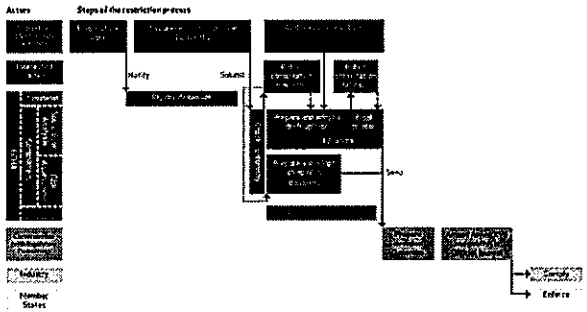
Involving stakeholders – example restriction process in REACH



From echa.europa.eu

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Restrictions in REACH – examples 1

Asbestos fibres (defined by CAS-no)

- The manufacture, placing on the market and use of these fibres and of articles and mixtures containing these fibres added intentionally is prohibited. [...]
- The use of articles containing asbestos fibres referred to in paragraph 1 which were already installed and/or in service before 1 January 2005 shall continue to be permitted until they are disposed of or reach the end of their service life. [...]

Toluene

- Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.

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Restrictions in REACH – examples 2

Three phthalates DINP, DIDP, DNOP

- Shall not be used as substances or in mixtures, in concentrations greater than 0,1 % by weight of the plasticised material, in toys and childcare articles which can be placed in the mouth by children.
- Such toys and childcare articles containing these phthalates in a concentration greater than 0,1 % by weight of the plasticised material shall not be placed on the market.
- For the purpose of this entry 'childcare article' ...

CMR-substances (listed in appendix)

- Shall not be placed on the market, or used, — as substances, as constituents of other substances, or, in mixtures, for supply to the general public when the individual concentration in the substance or mixture is equal to...
- Shall be marked with 'Restricted to professional users'.
- Some exemptions

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Comparison

Restriction

- Can target low hazardous substance with specific use with high exposure/ vulnerable group
  - More efficient than broad ban
- May have to exclude uses where substitution not possible – can be difficult to identify
- Apply to all economic actors

Authorisation

- Requires a system in place
- Economic actors identify uses where substitution is not possible
- Granted to individual economic actors
- Requires system for application/assessment

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Information on substances in articles

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Information on substances in articles – in supply chain REACH article 33

- Who
  - Supplier's duty to communicate information on substances in articles to recipient
- In what case
  - If a Substance of Very High Concern (SVHC) that are included in the Candidate list (190+ substances) is present > 0,1 % in the article
- What
  - Minimum name of substance, sufficient information, available to the supplier, to allow safe use of the article
- When
  - Directly to industrial/ professional
  - On request by a consumer, free of charge, answer within 45 days of receipt of the request

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Information on substances in articles – to authorities REACH article 7

- Substance intended to be released
  - Registration requirement if > 1 tonne per producer/importer and year
- Notify (not full registration) to ECHA if SVHC in article and
  - the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
  - the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).
- Exemptions
  - producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.
  - Substances that have already been registered for that use by any registrant

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Information on substances in articles – to authorities REACH article 7 (cont.)

- The information to be notified shall include the following:
  (a) the identity and contact details of the producer or importer
  (b) the registration number(s), if available;
  (c) the identity of the substance
  (d) the classification of the substance(s)
  (e) a brief description of the use(s) of the substance(s) in the article
  (f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.
- ECHA may take decisions requiring producers or importers of articles to submit a registration if certain conditions are met

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Information on substances in articles – to authorities REACH article 7 (cont.)

- DEHP examples of notified uses from 125 notifications:
  - Wide range of consumer products containing soft plastic, rubber or fabric parts
  - PVC hairdryers (looks like a shower cap and has an extension to be connected to the hairdryer machine)
  - Electrical equipment
  - Motorcycles
  - Training device for CPR (cardiopulmonary resuscitation) training

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Substances of concern and circular economy

- A non-toxic material cycle is one of the main prerequisites for a circular economy
- Information on substances (of concern) in products and articles
  - Systems for communicating information needed
    - Buyers making informed choices
    - Reuse
    - Recycling
- Restrictions on the use of substances of concern

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Guidance

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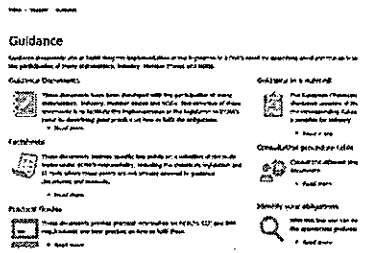
Guidance on REACH, CLP and more

- Echa.europa.eu
- ECHA > Support > Guidance
-



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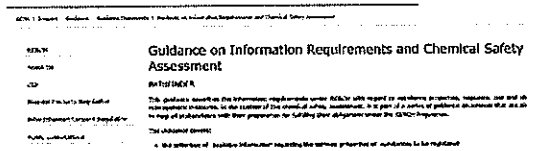
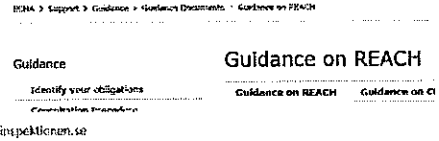
Some examples

- Detailed guidance on risk assessment including exposure



- Guidance on restrictions, authorisation, doing socio-economic analysis...



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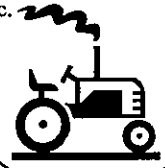
Pesticides are either

Agro-pesticides →
(in EU = Plant protection products, PPP)
such as
* Herbicides, insecticides, fungicides
* Growth regulators
etc.



or

Non-agro-pesticides →
(in EU = Biocidal products)
such as
* Antifouling products
* Mosquito repellent products
* Wood preservatives
* Rodenticides etc.

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Taiwan study visit to Sweden 6-7 September 2018

Risk assessment and risk management of pesticides

Helena Casabona

www.kemikalieinspektionen.se

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Main pesticide regulations in EU

- **Plant Protection products (PPP):**
  Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and Directive 2009/128/EC to achieve the sustainable use of pesticides

- **Biocides (BP):**
  Regulation (EU) No 528/2012 concerning the making available and use of biocidal products

  Biocides are classified into 22 biocidal product-types, grouped in four main areas → partly based on differences in exposure to health and the environment

- **Sustainable use of pesticides**

Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides

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Content of presentation

- EU legislation
- Risk assessment – human health
- Risk assessment – environment
- Risk management
- Questions

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Reg. 1107/2009

High level of protection

- **Strict criteria for approval** of active substances
- **Human and environmental criteria**
- High risk substances: **candidates for substitution**
- **EU Approval** also for **safeners and synergists**
- **Prohibition** of unacceptable co-formulants

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EU reulations

Dual system

Active substances

Plant protection products

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EU regulations

Competitiveness of agriculture

- **More predictable and quicker** approval and authorisation process
- **Derogation** to certain approval criteria
- Simplified rules for **low risk and basic substances**

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EU regulations

Objectives

- **High level of protection** of human and animal health and of the environment
- Safeguard **competitiveness of EU agriculture**
- Increase **free movement** and **availability** of plant protection and biocidal products

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EU regulations

Criteria for approval

Exclude from the market substances of high concern for human health

- ✓ **Carcinogens (cat 1,2)**
- ✓ **Mutagens (cat 1,2)**
- ✓ **Toxic for reproduction (cat 1,2)**
- ✓ **Endocrine disrupters**

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Reg. 1107/2009

Free movement & availability of plant protection products

- **Obligatory mutual recognition**
- Simplification for **minor crops**
- Rules for **parallel trade**
- **Free movement of seeds**

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EU regulations

Criteria for approval

- **Exclude from the market substances of high concern for the environment**

- ✓ **POP (persisten,organic pollutant)**
- ✓ **PBT (persistent, bioaccumulative and toxic)**
- ✓ **vPvB (very persistent and very bioaccumulative)**

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Mutual recognition system

Reg. 1107/2009

North

Center

South

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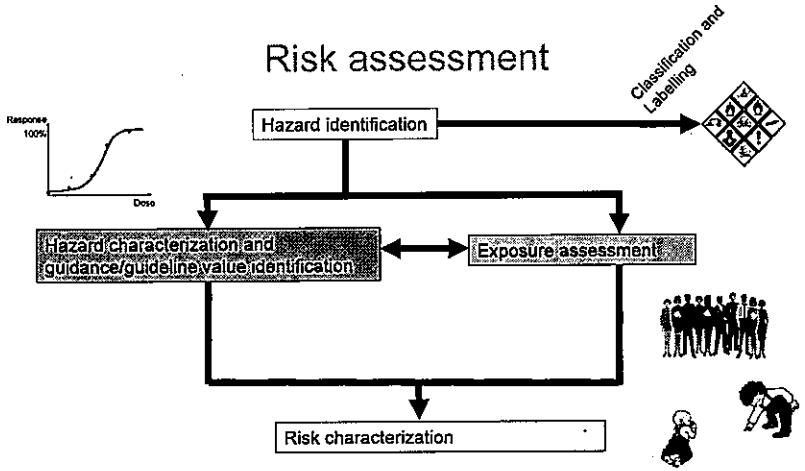
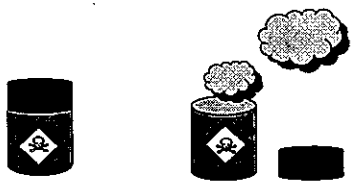
Risk assessment



From: WHO Human Health Risk Assessment Toolkit

Hazard versus risk

- Hazard = ability to cause damage or harm (intrinsic hazardous properties)
- Risk = probability for damage or harm to occur under defined circumstances

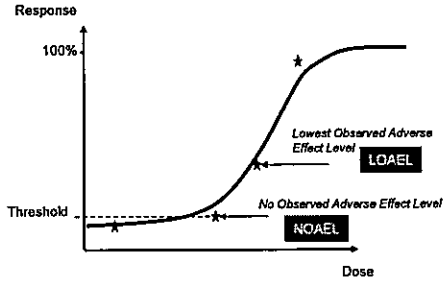


Risk = Hazard x Exposure

Hazard identification

- Is the identity of the chemical known?
- Is the chemical potentially hazardous to humans?

- Studies on absorption, distribution, metabolism and excretion in mammals
- Acute toxicity (oral, dermal, inhalation, skin and eye irritation, skin sensitization)
- Short term toxicity (28 and 90 days)
- Genotoxicity (in vitro, in vivo)
- Long term toxicity and carcinogenicity
- Reproductive toxicity (generational studies, developmental toxicity studies)
- Neurotoxicity studies
- Delayed polyneuropathy studies
- Other toxicological studies (toxicity of metabolites, endocrine disrupting properties)
- Medical data



Risk assessment for human health

Risk characterization

How does the estimated exposure compare with guidance/guideline values for the chemical?

Hazard characterization
Effect data + dose response data ⇨ NOAEL

Acceptable Operator Exposure Level (AOEL):
NOAEL* (oral abs.)/100

Exposure assessment (modelling)
using input data on:
- the type of product (solution, powder etc.),
- concentration of active substance in product and in spraying solution.
- % skin absorption of product/solution

Risk characterization

Compare simulated exposure in with AOEL

When the exposure is below the AOEL the risk is considered acceptable

In case exposure needs to be decreased, personal protection equipment may be needed, applied in a step-wise approach

In case exposure is still exceeding AOEL, a refinement of the assessment may be needed (replacement of default value with real data etc.)

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Hazard characterization

- What properties of the chemical have the potential to cause adverse health effects?
- Do guidance or guideline values from international organizations exist for the chemical?
- What assumptions about exposure and dose are incorporated into guidance/guideline values for the chemical?
- Do those assumptions reflect conditions specific to the local population?

Assessment Factors
To address the differences between the experimental data and the human situation, taking into account the uncertainties in the extrapolation procedure and in the available data set.
Often 10 x 10 = 100
for intra-species and interspecies variation

Example guidance value:

Acceptable Operator Exposure Level (AOEL):

AOEL= NOAEL*(oral abs.) /100 (mg/kg bw/day)

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Environmental Risk Assessment



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Exposure assessment

- First tier: Exposure models:
  - Non dietary
  - Dietary
  - Environment
  - Etc.
- Higher tiers: Field studies




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Risk characterization

Compare environmental concentrations with the concentration below which effects are not expected

Test organisms for hazard identification :

- Birds and other terrestrial vertebrates
- Aquatic organisms
- Bees and other pollinators
- Non-target arthropods other than bees
- Non-target soil meso- and macrofauna
- Soil nitrogen transformation
- Effects on terrestrial non-target higher plants
- Earthworms

Decision criteria

Models for predicting environmental concentration:

- Soil
- Groundwater
- Surface water
- Sediment

If a substance is persistent, bioaccumulative or toxic (PBT), very persistent/very bioaccumulative (vPvB) or a persistent organic pollutant (POP) it cannot be approved

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Why do environmental risk assessment

To help taking decisions on risk management actions.

Chemicals reach the environment, examples (routes):

- outlets from industry (chimney, sewage)
- when applying pesticides (surface water runoff, spraydrift)
- chemicals used in households (sewage water, washing car)
- use of products (emitting, wear and waste disposal)

Are the chemicals toxic to the environment at the concentrations they appear in the environment?

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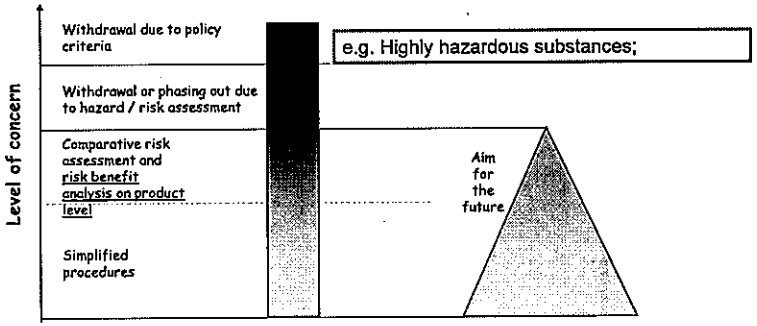
Use of comparative assessment and decision-making criteria



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Risk Assessment

Tools for decision making based on predicted environmental effects

- o Hazard assessment – based on basic properties only (e.g. classification)
- o Estimation of environmental exposure

→ Possibility to do a risk assessment and to make some sort of decision (rejection, request for more data, approval, restrictions, etc.)

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Pesticides
(Plant Protection Products and Biocides)

- DG Health and Food safety (Plant Protection Products) http://ec.europa.eu/food/plant/index_en.htm
- European Food Safety Authority, EFSA (Plant Protection Products) http://www.efsa.europa.eu/en/panels/pesticides.htm
- DG Health and Food safety (Biocides) http://ec.europa.eu/health/biocides/policy/index_en.htm
- ECHA (Biocidal active substances) http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances

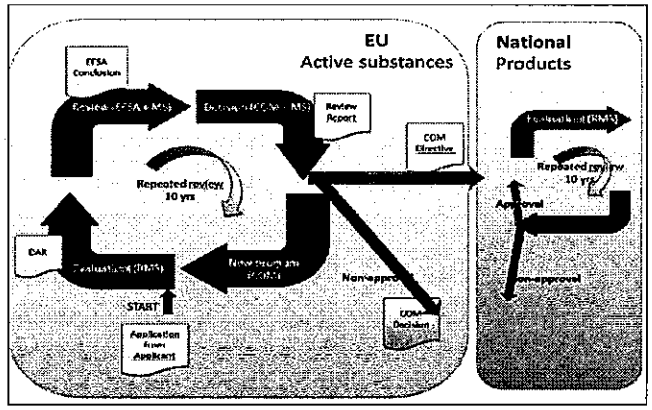
European Food Safety Authority (EFSA)

- Pesticide Risk Assessment Peer Review http://www.efsa.europa.eu/en/panels/praper.htm

European Chemicals Agency (ECHA)

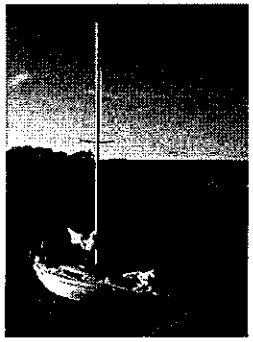
- Assessment report for biocidal active substances

http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances



Thank you for your attention!

Questions?



Sustainable use

Reduce risks and impacts on humans and the environment

1. **Training**
2. **Sales**
3. **Awareness raising**
4. **Equipment**
5. **Aerial applications**
6. **Aquatic environment**
7. **Protected areas**
8. **Handling, storage, disposal**
9. **Integrated pest management**

NATIONAL ACTION PLANS

ENVIRONMENTAL OBJECTIVES - A SYSTEM WITH SEVERAL GOALS

Adopted by Swedish parliament 1999

- Generational goal
- Environmental quality objectives
- Milestone targets

"The overall goal of Swedish environmental policy is to hand over to the next generation a society in which the major environmental problems in Sweden have been solved, without increasing environmental and health problems outside Sweden's borders."

GENERATIONAL GOAL

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Swedish environmental objectives

Emma Westerholm
Swedish Chemicals Agency

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Environmental quality objectives

- Adopted by the Swedish parliament
  - To be achieved by 2020
- Describing the overall quality and state of the environment
- A generational goal and 16 environmental quality objectives
- Cover different environmental areas, e.g air and waters, biodiversity and eco systems
- The Swedish EPA coordinates the work

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Our main objective: Sound chemicals management

- Development of legislation and other instruments.
- Authorisations (pesticides) and guidance.
- Enforcement (producers and importers, chemical products and articles) and registries.
- **Focus Environmental quality objective: A Non-Toxic Environment.**

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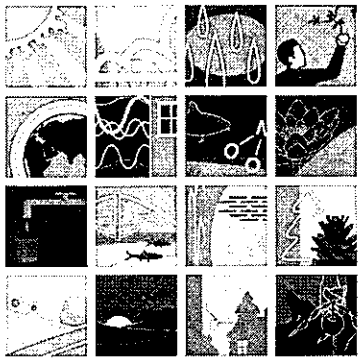
Environmental quality objectives



1. Reduced Climate Impact
2. Clean Air
3. Natural Acidification Only
4. A Non-Toxic Environment
5. A Protective Ozone Layer
6. A Safe Radiation Environment

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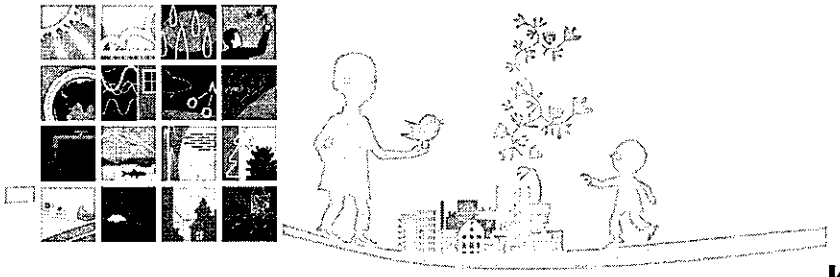
ENVIRONMENTAL OBJECTIVES - A SYSTEM WITH SEVERAL GOALS

Adopted by Swedish parliament 1999

- Generational goal
- Environmental quality objectives
- Milestone targets

"The overall goal of Swedish environmental policy is to hand over to the next generation a society in which the major environmental problems in Sweden have been solved, without increasing environmental and health problems outside Sweden's borders."

GENERATIONAL GOAL



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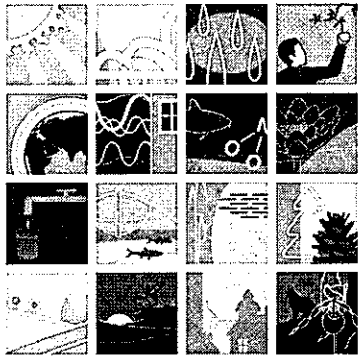
Environmental quality objectives



7. Zero Eutrophication
8. Flourishing Lakes and Streams
9. Good-Quality Groundwater
10. A Balanced Marine Environment, Flourishing Coastal Areas and Archipelagos
11. Thriving Wetlands

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What the generational goal means in practice

- Ecosystems have recovered, or are on the way to recovery, and their long-term capacity to generate ecosystem services is assured.
- Biodiversity and the natural and cultural environment are conserved, promoted and used sustainably.
- Human health is subject to a minimum of adverse impacts from factors in the environment, at the same time as the positive impact of the environment on human health is promoted.
- Materials cycles are resource-efficient and as far as possible free from hazardous substances.
- Natural resources are managed sustainably.
- The share of renewable energy increases and use of energy is efficient, with minimal impact on the environment.
- Patterns of consumption of goods and services cause the least possible problems for the environment and human health.

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A non-toxic environment

- Exposure to chemical substaces is not harmful
- Use of SVHC should be phased out
- Knowledge about chemical properties is available
- Information about hazardous chemical substaces in materials, products and articles is available
- Occurance of unintentionally formed substances with hazardous properties
- Remediation of contaminated sites

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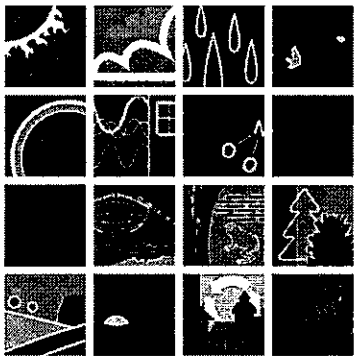
Environmental quality objectives



12. Sustainable Forests
13. A Varied Agricultural Landscape
14. A Magnificent Mountin Landscape
15. A Good Built Environment
16. A Rich Diversity of Plant and Animal Life

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Milestone targets – Hazardous substances

- Substances of very high concern (SVHC)
- Knowledge about chemical properties, health and environment
- Information about hazardous chemical substaces in articles
- Development and application of EU legislation
- Efficient market surveillance within EU
- Non-toxic and resource efficient material cykles
- Reduce children's exposure to hazardous substances
- Include environmental consideration to a greater extent in pharmaceutical legislation and internationally

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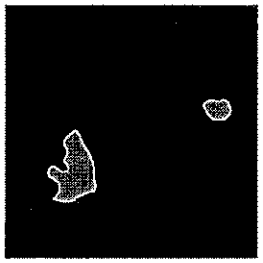
A non-toxic environment



The occurrence of man-made or extracted substances in the environment must not represent a threat to human health or biological diversity.

Non-natural substances close to zero, impacts on human health and on ecosystems negligible.

Natural substances close to background levels.

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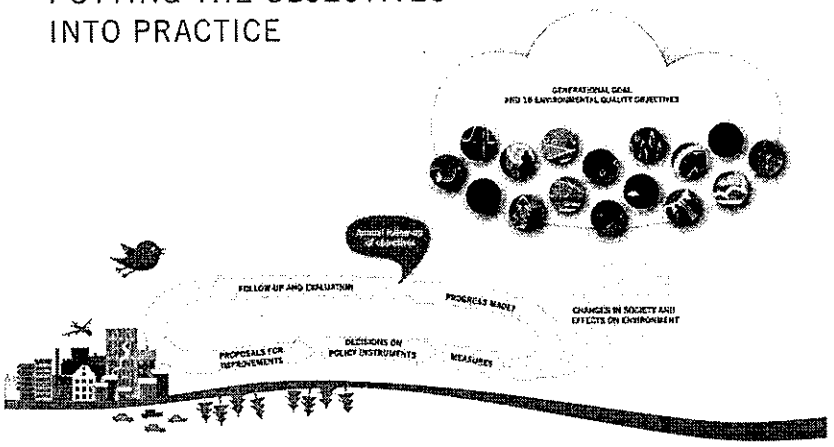
PUTTING THE OBJECTIVES INTO PRACTICE



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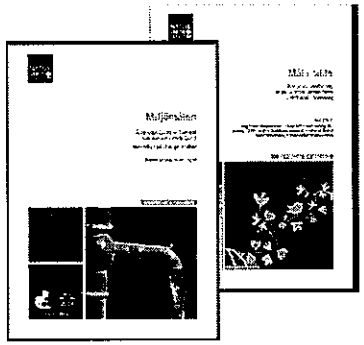
Follow-up and evaluation

- Are necessary conditions in place?
- Need of additional action or measures?
- Annual follow-up
  - Report result
  - Budget proposal
- Extended evaluation
  - State of the environment and the development
- Indicators as follow-up



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Additional benefits of the system with environmental quality objectives

- Firm ground and long-term orientation for Swedish positions, both within EU and in the international work
- Basis for development of legislation and other instruments in order to achieve the goals
- Strong national direction for the environmental work – actors at different levels
- Basis for plans and strategies at regional and local level in Sweden

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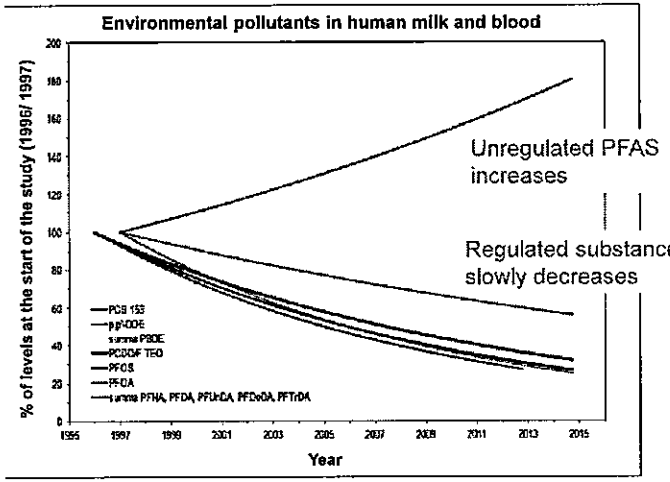
Environmental pollutants in human milk and blood



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Cooperation and Information

Anna Lindberg
2018-09-07

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Agenda 2030 for a sustainable development

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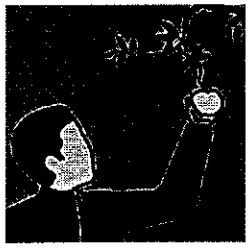
Non-toxic environment & Toxic-free every day life

Environmental objective & Generation goal



Action plan 2011-2020

- A step towards the non-toxic environment
- To reduce the risks faced by people in their everyday lives of being exposed to hazardous chemicals
- Focus on children and adolescents

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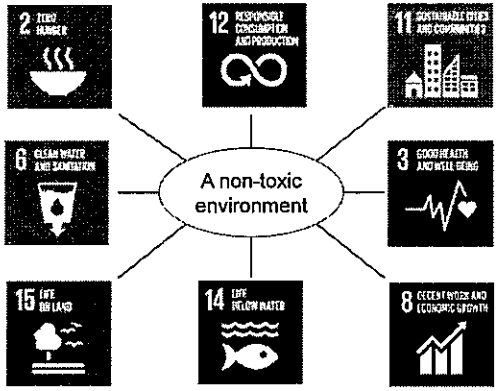
A non-toxic environment contributes to the UN SDGs and Agenda 2030



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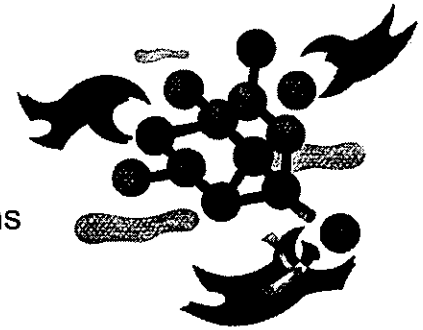
Actors

- National agencies
- Industry
- Academia
- Non-governmental organisations
  - environmental
  - consumers



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Action plan for a toxic-free everyday environment

- Hazardous substances in articles is a growing problem
- Our food and drinking water must be better protected
- Children and adolescents are particularly sensitive to the effects of chemicals

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Multisectoral cooperation

Example:

Industry dialogues with pro-active companies

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Measures to be undertaken, examples

- Strengthen EU legislation
- Increase knowledge about health risks of chemicals
- Improve information on hazardous substances in articles
- Promote and support companies in the process of substitution
- Increase the monitoring of hazardous substances in consumer products
- Analyse how economic instruments can be used to bring about substitution
- Criteria for public procurement of products in preschools
- Information to consumers

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Measurable goals

Choice of substances
the companies limit and replace hazardous substances

Information activities
targeted to companies, professional users or to consumers

Knowledge sharing
between companies and government agencies.

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Industry Dialogues
Promote and support companies

- Hazardous substances may be found in articles/products and need to be phased-out
- Knowledge and resources are needed
- Which are the obstacles – how can they be removed?
- Which are the possibilities – how can they be strengthened?
- Keml initiated dialogues with three industry sectors; Toys / Textiles / Cosmetics
- Initiate and support substitution made on a voluntary basis

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Examples

Choice of substances
- Construct a model for companies in order to prioritize and reduce unwanted substances (e.g. CMR) in the products

Information activities
- An information campaign addressed to hairdressers concerning hair colours, risks for allergy and the age limit of 16 years

Knowledge sharing
- Contribution in the Keml assignment to develop / propose …coherent EU regulation on hazardous substances in textiles

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	There is Specific Legislation	Keml is the Competent Authority	The Supply Chain is long
Toys	Yes ✓	Yes ✓	Yes ✓
Cosmetics	Yes ✓	No ✓	No ✓
Textiles	No ✓	Yes ✓	Yes ✓

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Collaboration with the foundation "Keep Sweden Tidy"

- Keep Sweden Tidy works with the concept of "Green Flag"
- Schools and kindergartens certifies to become Green Flag-tagged
- Network with 2,200 schools and pre-schools
- Different themes
  - Lifestyle and health
  - Local environment
  - Water
  - Climate and energy
  - Consumption
  - Recycling
  - Chemicals New

Eco-Schools

KEEP SWEDEN TIDY

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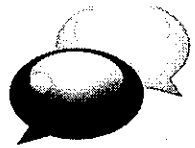
Conclusions – Industry Dialogue



- The industry dialogues means that agencies and companies together works with chemicals issues to reduce the children's exposure to hazardous substances.
- Measurable goals concerning substitution / reduction of hazardous substances have been set by the participating companies in each dialogue. The Agencies supports and facilitates the companies.
- An evaluation shows that the actors find this approach of great value. The industries themselves have now taken them further.

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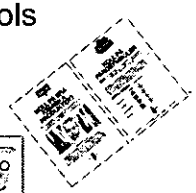
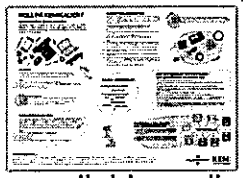
Information and involvement

KEEP SWEDEN TIDY

- Inform and involve children and young people, as well as the teachers
- Educational material towards preschools and schools
  - *Activitity cards for preschool – fun and simple!*
  - *Lessons for school – from age 6 up to 19*
  - *Tips and Posters*
  - *Short films*





- The material can be used free and is available on-line

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Consumer information

Example

Cooperation with Eco-Schools/ "Keep Sweden Tidy"

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ABOUT US
OUR PROJECTS
OUR NETWORK
TOOLS & RESOURCES
NEWS
CONTACT
Engaging the youth of today to protect the planet of tomorrow

Study design

- Used the published inventory lists (no confidential substances)
- Only substanes with CAS numbers included

Comparing inventories around the world – differences and similarities

Stellan Fischer
Swedish Chemicals Agency

The aim with the study

- Estimate the degree of overlaps between diffierent national chemical inventory lists.
- Identify number of unique substances in different inventory lists.
- Showing the need of a world wide strategy to manage risks from chemicals imported in articles.

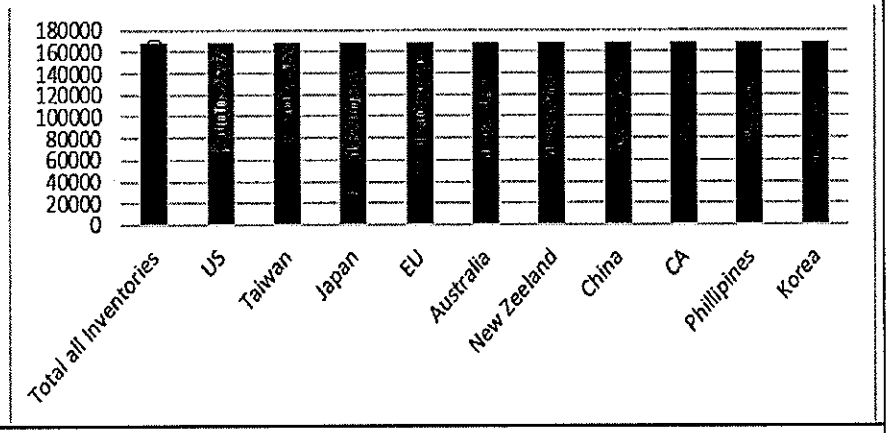
Inventories included "existing chemicals"

+ Taiwan**

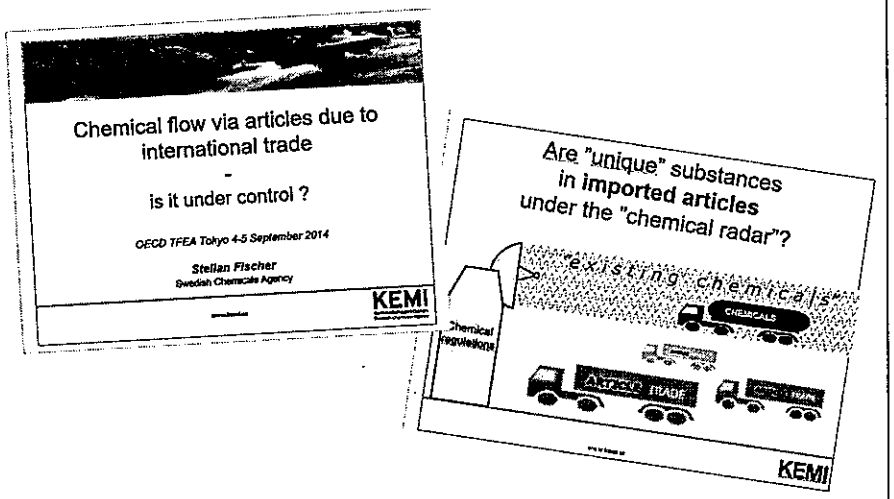
Country
US
Japan
EU
Australia*
New Zeeland
China
The Philippines
Korea

* Part of; ** TCSI

Missing number of world market substances in different national inventories

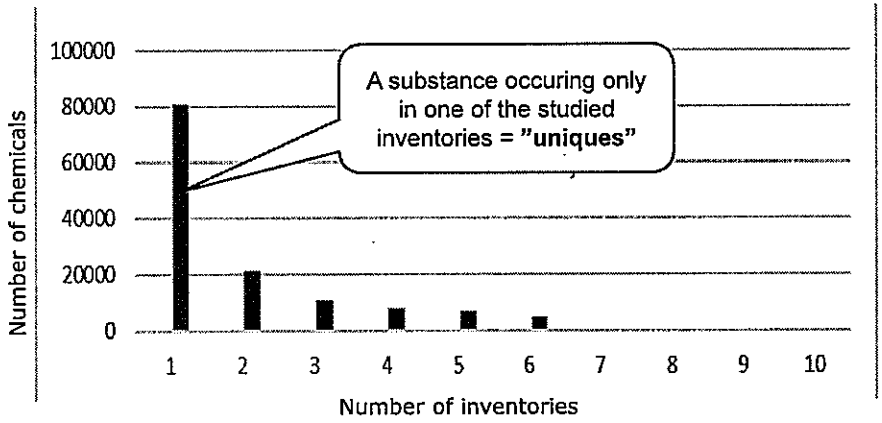


The result presented on a OECD meeting in Japan 2014

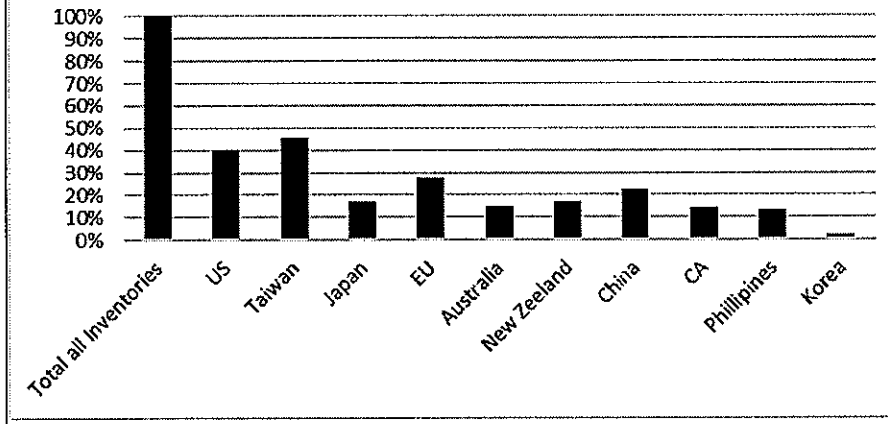


Frequency of registered chemicals in different inventories

(without the Taiwan list)



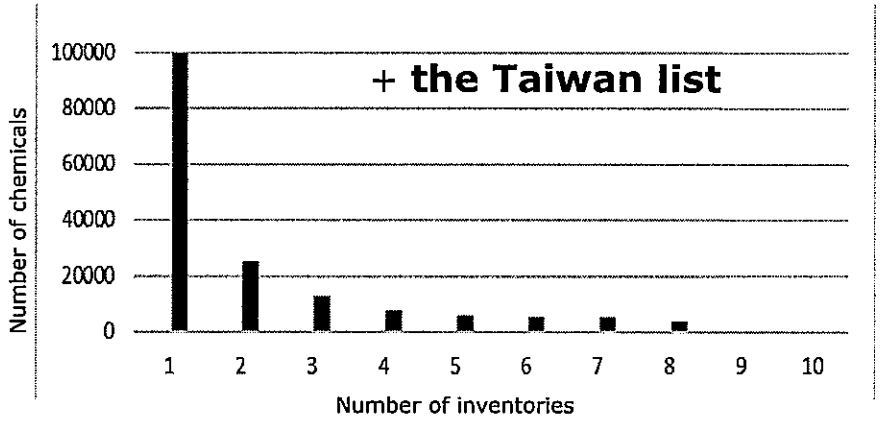
Coverage of world market substances in different national inventories



Characteristics of the "unique" Taiwan chemicals

- 29 124 (38%) of the chemicals on the inventory list are not found in other inventory lists.
  - 98% are organic substances
  - 54% are singel component substances
  - 20% are polymers
  - 2% are mixtures
- At least 8 900 (30%) of these have the same, or similar structures to substances in other inventories
  → High potential for "read across" inherent properties (e.g. hazard & fate).

Frequency of registered chemicals in different inventories



CMR* classified substances similar to unique substances in the Taiwan Inventory List

In the Taiwan inventiry list		The same or similar substance in other invenory lists	
Name	CAS No	Name	CASno
1(3H)-Isobenzofuranone, 3,3-bis(4-hydroxyphenyl)-	5768-87-6	1(3H)-Isobenzofuranone, 3,3-bis(4-hydroxyphenyl)-	77-09-8
1,4-Dioxane	54841-74-6	1,4-Dioxane	123-91-1
8-Quinolinol, sulfate, hydrate (2:1:1)	207386-91-2	8-Quinolinol	148-24-3
Benzene, 1,1'-methylenebis[4-isocyanato-	97568-33-7	Benzene, 1,1'-methylenebis[4-isocyanato-	101-68-8
Borax (B4Na2O7.10H2O)	1344-90-7	Borax (B4Na2O7.10H2O)	1303-96-4
Borax (B4Na2O7.10H2O)	71377-02-1	Borax (B4Na2O7.10H2O)	1303-96-4
Boric acid, magnesium salt	12619-64-6	Boric acid, disodium salt, pentahydrate	12179-04-3
Boron sodium oxide (B4Na2O7)	1332-28-1	Boron sodium oxide (B4Na2O7)	1330-43-4
Guanidine, N,N'-diphenyl-, sulfate (2:1)	32514-47-9	Guanidine, N,N'-diphenyl-	102-06-7
Hexanoic acid, 2-ethyl-, sodium salt (1:1)	1337-21-9	Hexanoic acid, 2-ethyl-	149-57-5
Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride, hydrate (1:1:9)	60662-33-1	Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride (1:1)	548-62-9
Petrolatum	8063-27-2	Petrolatum	8009-03-8
Piperazine	81546-15-8	Piperazine	110-85-0
Piperazine, sulfate (1:1)	4554-26-1	Piperazine	110-85-0
Sulfuric acid, cobalt(2+) salt (1:1)	139939-65-4	Sulfuric acid, cobalt(2+) salt (1:1)	10124-43-3

* *Cancer or Mutagen or Reprotoxic (according to the CLP classification)*

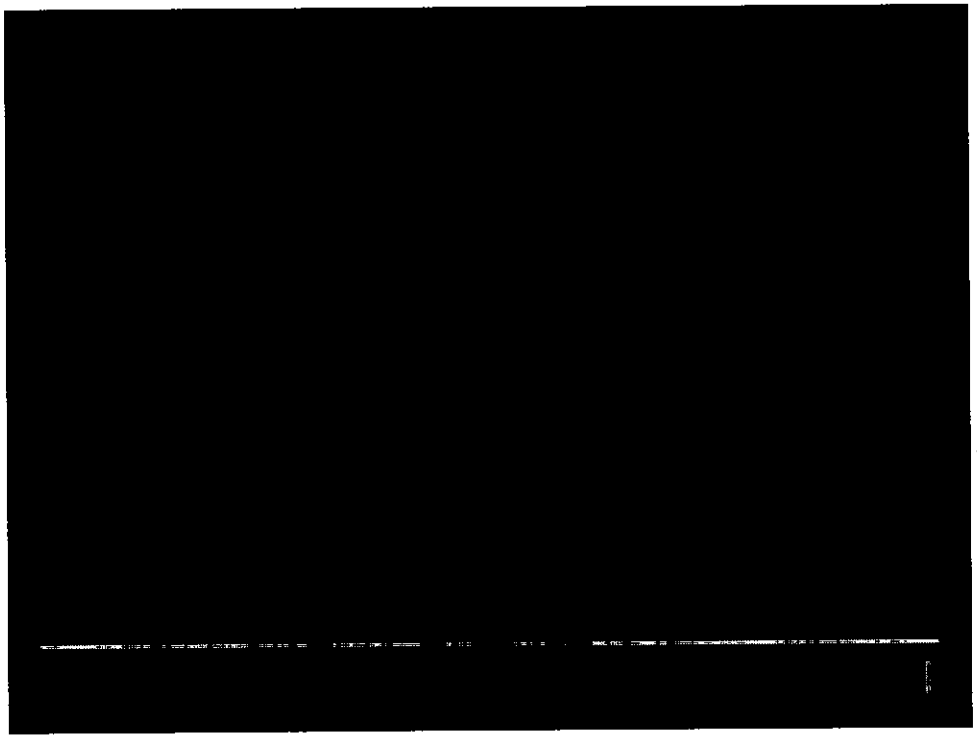
Conclusions

- A majority of the market substances do not en up in national inventories.
- A considerable number of substances are only traded nationally → many "unique" substances.
- Such "unique" substances are unknown for authorities in other markets.
- The number of "uniques" shows a large regionally variation.

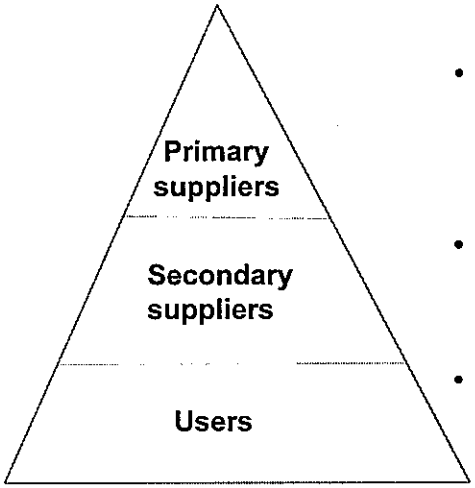
* *That is unique among the countries included in the study*

InchIKey (extrainfo. not shown on the presentation)

- A new international chemical identifier
- Complement to the indentifier "CAS No."
- Users: Analytical laboratories around the world
- Molecule specific (The CAS No. is not molecule specific)
- Developer: IUPAC (NGO)
- Example of a InchIKey: "BQJCRHHNABKAKU-KBQPJGBKSA-N"
- More information:
  https://en.wikipedia.org/wiki/International_Chemical_Identifier



Different business roles



- Relatively few. Often very good knowledge about the chemicals.
- Larger amount. Less knowledge.
- Product information should be written and given by primary and secondary suppliers.

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Enforcement strategies

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Karin Rumar, Senior Technical Officer
Enforcement

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Keml´s enforcement

Chemical products
- 14 inspectors
- ~ 2 500 companies (1 level)
- No of inspections per year: : ~ 400 (15%)

Pesticides
- 5 inspectors
- ~ 500 företag companies (1 level)
- No of inspections per year: ~ 100 (22%)

Articles (chemical <u>in</u> products)
- 9 inspectors
- ~ 60 000?? (all levels)
- No of inspections per year: ~ 250 (0,4%)

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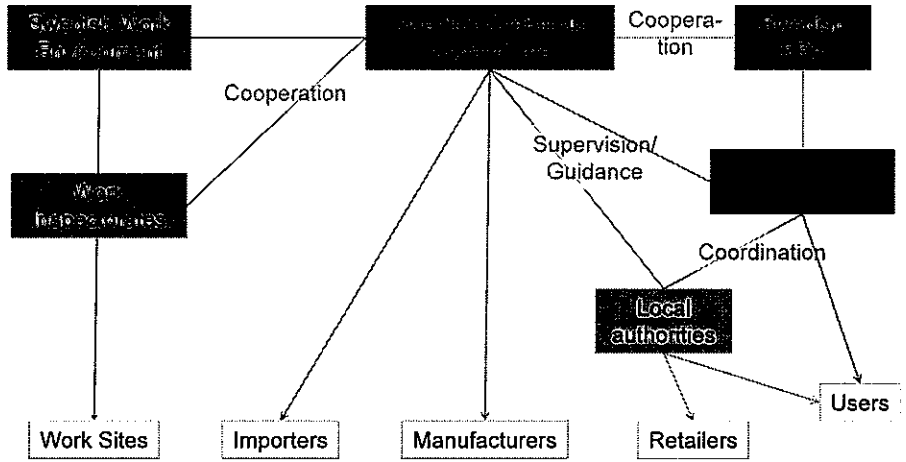
Inspection levels and cooperation



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Inspection method - articles

Analyses of restricted substances

- XRF for screening
- Sent to an external accredited laboratory

Documentation (toys and electronic products)

- DoC – EU Declaration of Conformity
- CE-label and company information label
- Sometimes technical documentation

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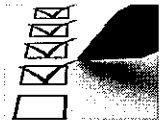
Enforcement strategy - criteria



All groups:

- Governmental instructions
- International projects (EU networks)
- Experience – earlier projects, other authorities, poison centre
- Outside: investigations, media, research,

- Hazardous substances
- Use pattern; exposure etc
- Vulnerably groups such as children
- Number of products, large volumes, widely spread
- New legislation

Articles

- Low price, low quality consumer products
- Material – soft plastic material, textile etc

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Inspections methods – chemical products

On site

- Product investigation
- Tactile warning
- Child resistant fastening
- Permits
- Classification
- Products register
- SDS and labelling
- Distribution system
- Product substitution

By mail

- Classification
- Products register
- SDS and labelling
- Product substitution

Checklist
Protocol

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Focus areas - articles

EEE

Toys

Sport and leasure

Construction articles, Interior design products

Clothes, shoes, accessories

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Most common fails - articles

- Lead in solders in electronic
- Short chained paraffins (SCCP) in soft plastic
- Cadmium, lead and nickel in jewellery
- Phtalates in soft plastic (PVC)
- Information on CL substances not given
- Labelling missing on biocide treated artcles

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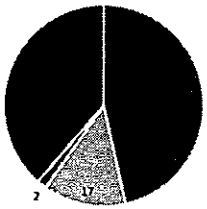
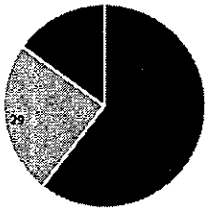
Result of enforcement of articles 2014-2015

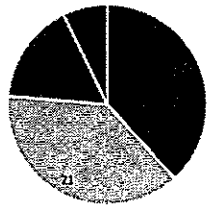
Electric equipment



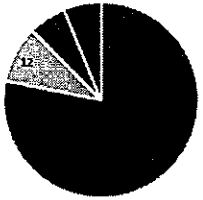
Toys and other childcare articles



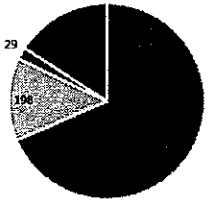
Sports, recreation



Construction articles, interior design articles



Clothes, shoes and accessories



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Common non-compliances chemical products/pesticides

- Report to Product register missing
- Selling illegal pesticides without approval
- Permit for dangerous products missing
- Deficiences in labels and SDS:
  - Incorrect classification
  - Incorrect labelling
  - SDS not provided to buyer
  - Inconsistent information within SDS
  - SDS and label doesn't match

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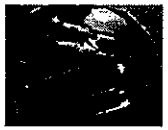
Examples - articles

Findings

- Soft plastic material: Phtalates
  SCCP
- Electronic products: Pb in solders
  SCCP
- Textiles: azodyes
  NP/NPEO
- Others: Pb and Cd in jewerly
  Cd i PVC package material



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Non-complaince – Measures

Non-compliance (depending on severity):

1. The company has to stop selling the product
2. The company has to update label and SDS
3. The company has to pay for the analytical costs
4. Report to the prosecutors office
5. Environmental sanction fee
6. Rapex registration