"Training programme for consultants located in the Baltic States on the New European Chemicals Policy (REACH)".

1 Introduction to the training manual

1.1 Background to the manual

This manual has been developed in the frame of the project "Training programme for consultants located in the Baltic States on the New European Chemicals Policy (REACH)". The project started in February 2004 and ended in Mail 2005 and was funded by the German Environment Foundation as well as the in-kind contributions of the project team and trainees. The project was carried out by Oekopol, institute for environmental strategies Ltd, Contract KG and the Baltic Environmental Forum (BEF).

One part of the project work consisted of the preparation and conduction of 5 training sessions. The content of the seminars was divided between training of factual knowledge on REACH and practicing consulting and training situations using concrete examples. The seminar titles were:

1) General introduction to REACH

2) Hazard assessment and general consulting capacity, first contacts to clients

3) Exposure assessment and moderating business talks

4) Preparing a training on REACH

5) Overall summary of content and consulting capacity trained

The second part of the project work was conducted by the trainees and consisted of a visit and business impact assessment in one company, the contribution to this manual by writing parts of chapters and the development and conduction of "test trainings" with different target groups.

1.2 Target group and aim of the manual

The main target group of this manual are the trainees of the project. Content and structure have been agreed in the training group and fulfil the needs of the future trainers. Nevertheless, it may be helpful also to other actors working and wanting to train companies and autorities on REACH.

The aim of the manual is to assist the trainees of the project to conduct basic trainings on REACH in their countries for different groups of actors. It therefore contains "ready to use" presentations and exercises as well as links to further information. The manual does not explain in detail and plain text the mechanisms of REACH, as they are assumed to be understood through the training programme.

1.3 Structure of the manual and how to use it

The training manual consists of 14 chapters. Of these the majority contains materials for training preparation grouped in different topics. Some chapters are overarching and containing supporting materials. These are: Chapter 2 containing definitions of relevant terms under REACH, Chapter 11 giving examples of training designs tested in the project, Chapter 12 listing different questions and answers to "test" knowledge of the trainees, Chapter 13 giving a comprehensive list of different information sources in the internet and Chapter 14 listing and explaining frequently used abbreviations.

Each of the content chapters follows the same structure:

- x.1.1 - Content of the chapter: overview of the chapter content, some important issues are described in flow-text
- x.1.2 - Reference to the REACH proposal: information where to find the specific issues in the draft proposal (version of October 2003)
- x.1.3 – Further background information on content: information on what the trainer could study in order to better prepare himself for a training or where to find more details on the topic
- x.1.4 – Important terms: those definitions, which are especially relevant for the chapter, are given. This repeats the overview of definitions in Chapter 2
- x.1.5 – Actors for which the chapter is relevant: in form of a table, hints are given why the topic is important for which types of actors, and what are the specific interests. Also some information on expected difficulties or resistance from the actors are indicated
- x.2 - Presentations: examples of presentations are given. Most of the times a general introductory presentation is shown, which can be used for all actors and one more detailed presentation addressing specific items or giving more information on methodology are included. The slides of the presentation are provided in digital form on CD ROM. In the right column, comments give additional information to the slides, draw the attention to possible discussion issues, etc.
- x.3 – Exercises: exercises for practicing the knowledge trained in presentations are given. It is indicated for which target group the exercise is appropriate, how the setting could be arranged etc. All materials for carrying out the exercise are provided on CD ROM for direct use.
- x.4 – Discussions in plenum: here some ideas are given, which issues could be discussed in the plenum or with different target groups
- x.5 – Further work for preparation for REACH: some ideas on how the different economic actors could prepare for REACH with regard to the topic of the chapter are given.

1.4 Updating

The manual was finalised in May 2005 and bases on the REACH text as published by the EU Commission in October 2003. The decision making process on REACH may involve changes in the details of the proposed regulation, whereas the main principles will probably remain unchanged. It is expected that REACH will be finally adopted in spring 2006. At the same time the REACH implementation projects will provide important guidance on how to interpret and fulfil the requirements of REACH. Most relevant with regard to this manual are the projects with the numbers 3.1-3.10. The first results of these projects are expects to be published starting in August 2006.

As changes are still possible, the manual has to be used with care and it is very likely that the presentations and exercises will have to be updated in the future. The entire project team (trainers and trainees of the Baltic States) are attempting to use the established consultant network to efficiently take account of the future developments.

1.5 The editorial team

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2 Definitions

Term	Legal definition (if existing)	Simple explanation
(Q)SARs		Qualitative structure-activity relationship models – model to predict properties based on molecular structure
Actors in the supply chain	All manufacturers and/or importers and/or downstream users	Manufacturers, importers, professional and industrial users, distributors of substances, preparations
Acute toxicity		Intrinsic property of a substance to be injurious to an organism in a short-term exposure to that substance.
Article	An object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does	Manufactured product that has a final shape that is related to its use (example: car, computer but not paint).
Authorisation		Use-specific permission to use substances of very high concern
Chemical safety assessment		Structured assessment of hazards and exposures related to the manufacture, formulation, use and disposal of a substance resulting in a characterisation of risks
Chemical safety report		Documentation of the chemical safety assessment, to be included in the registration dossier
Chronic Toxicity		Potential or actual properties of a substance to cause adverse effects to aquatic organisms during exposures which are determined in relation to the life-cycle of the organism
Classification		Assessment of a substance regarding its dangerous properties on the basis of European-wide harmonised criteria and standardised test methods. Depending on the dangerous properties the substance is assigned, one or more risk phrases (R-phrases).
Communicate down the supply chain	Each actor in the supply chain communicates to the client whom he supplies with a substance or preparation	
Communicate up the supply chain	A downstream user communicates to the actor in the supply chain who has supplied him with a substance or preparation	

Term	Legal definition (if existing)	Simple explanation
Competent authority	The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation	
Completeness check		Checking whether all fields in the registration dossier are filled with data.
Costs & benefits analysis	A form of economic analysis in which costs and benefits are converted into money values for comparison over time (OECD guidance)	
De-selection		Disappearing/withdrawal of substance or functionality from the market
Direct costs		Costs arising due to compliance with the direct duties originating from the legislation, e.g. substance registration, which means testing, costs of CSA/CSR, exposure analysis, communication and cooperation, administration etc.
Distributor	Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties	Company trading chemicals within the EU territory, no import!
Downstream user	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 4(2)(c) shall be regarded as a downstream user	Companies that use substances professionally or industrially (on their own, in preparations). Example: a manufacturer who mixes different chemicals to make ink, or uses the ink to print leaflets.
EC_{50}	Effective concentration – concentration of a substance at which 50% of the test organisms exhibit the examined effect	
Economic analysis	Aimed at evaluating all of the effects of a policy or project and valuing them in national resource terms. This takes place in a “with” and “without” framework (OECD guidance)	Assessment of positive and negative, direct and indirect impacts of the proposal with a situation if nothing changes
Evaluation		Qualitative assessment of registration dossiers and/or registered substances
Existing substance		Chemicals that were reported to be on the market in 1981, when the requirement to notify new chemicals entered into force. There are about 100,000 existing chemicals.

Term	Legal definition (if existing)	Simple explanation
Exposure		The fact that humans or the environment are in direct contact with a substance
Exposure assessment	Estimation of the concentration/dose to which human populations (e.g., workers, consumers and man exposed indirectly through the environment) or environmental compartments (e.g., aquatic environment, terrestrial environment, atmosphere) are or may be exposed. This estimation entails the determination of the sources, emission routes and degradation pathways of the chemical	Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration
Exposure level		Dose or concentration of a substance to which humans or the environment are exposed to
Exposure scenario	A set of conditions or assumptions about sources, exposure pathways, amount or concentrations of agent(s)involved, and exposed organism, system or (sub) population (i.e. numbers, characteristics, habits) used to aid in the evaluation and quantification of exposure(s) in a given situation	A set of information or assumptions about the type of use, processing and products of a substance including the conditions of use (duration, frequency, amounts) and the applied risk reduction measures
External abatement measures		Emission treatment done off-site, e.g. a community sewage treatment plant
External(-ized) costs	Costs incurred as a result of individual decisions, but which are borne by an individual other than the person making the decision. (For example, a private landfill operator which allows the site to contaminate groundwater may impose costs on neighbouring residents or businesses, in terms of health damage, the costs of water purification, or the costs of obtaining alternative uncontaminated sources) (OECD guidance)	Costs caused by industrial processes but paid by the society. Usually they are related to environmental impacts (e.g. costs due to chemicals related health impacts (ozone depletion causing skin cancer), costs for decontamination/purification (soil and water pollution), disturbed ecosystem, loss of biodiversity).
Ex-vivo test		Pertaining to a biological process or reaction taking place outside of a living cell or organism
Hazard	An inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.	Dangerous properties of a substance
Hazard Assessment	A process designed to determine the possible adverse effects of an agent or	Evaluation of test data of a substance to derive the classification, labelling and the

Term	Legal definition (if existing)	Simple explanation
	situation to which an organism, system or (sub) population could be exposed	no-effect levels for human health and the environment.
Hazard Characterization	The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties	
Hazard Identification	The identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population	Process of finding out which hazardous properties a substance has got.
Identified use	A use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user and that is covered in the safety data sheet communicated to the downstream user concerned	Any use which is known to the registrant, for which he registers the substance and indicates the use in the safety data sheet
Import	The physical introduction into the customs territory of the Community	Bringing a chemical into the territory of the EU from non-EU countries
Importer	Any natural or legal person established within the Community who is responsible for import	
Indirect costs		Costs arising due to the market response to the changes (e.g. product availability, substitution possibilities) caused by the direct impacts. It could be increase of price, price for reformulation of preparation, change process etc.
Intermediate	A substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called *synthesis*): (a) *non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well	Chemicals that are used in the process of making other chemicals (synthesis). The following differences are important: a) the intermediate only exists for a short time in the production vessel and then reacts further (low potential of exposure) b) it is taken out of the production vessel and put into another on the same production premises in order to further react (medium potential of exposure) c) it is taken out of the production vessel and transported somewhere else for further reaction (highest potential of exposure)

Term	Legal definition (if existing)	Simple explanation
	as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture; (b) *on-site isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities; (c) *transported isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites	
Intrinsic properties		Properties which chemical bears in its nature, e.g. explosivity
In-vitro tests		A study conducted with tissues, cells or substances in solution in a controlled model system and not a living animal or organisms
In-vivo tests		A study conducted using living animals
Labelling		Labelling of substances or preparations as dangerous with respective symbols and R-phrases and S-phrases. Not all dangerous properties of a substance automatically lead to labelling.
LC_{50}	Lethal concentration – concentration of the substance which is lethal for 50% of the test organisms	
Life-cycle		The different steps of use of a substance, starting from generation of raw materials, manufacture, marketing, use and disposal of a product
Manufacturer	Any natural or legal person established within the Community who manufactures a substance within the Community	
Manufacturing	Production and extraction of substances in the natural state	Production of substances through a chemical reaction (synthesis) or extraction and purification (e.g. refinement of crude oil, extraction of metal ores, but also extraction of natural substances from plants)
Margin of Safety	The margin between the reference dose and the actual exposure dose or concentration	

Term	Legal definition (if existing)	Simple explanation
New substance		Substances that have been placed on the market after 1981. These have to be notified to the Competent Authorities under the current EU chemicals legislation. There are around 3,400 'new' substances on the market.
NOEC	No observed effect concentration – highest concentration of a substance which does not cause an observable effect in long-term tests.	
Non-phase in substance		All substances introduced after REACH will come into force; existing substances which are not produced/used within last 15 years or which are not pre-registered
Notified substance	A substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC	New substances for which a notification dossier has been prepared and submitted according 67/548/EEC
On-site abatement		Emission treatment measures like a waste water treatment plant or an air scrubber, which lead to a reduced release of the substance by destruction, transformation or controlled disposal
PEC	Predicted environmental concentration. Environmental concentrations for certain areas of the environment are calculated on the basis of production and market volumes, use patterns and physical-chemical properties of substances. This is done with the aid of mathematical models which simulate the substance transport and emissions.	
Per year	Per calendar year unless stated otherwise	
Phase-in substance	A substance which, over the 15 years preceding the entry into force of this Regulation, meets at least one of the following criteria: (a) it was manufactured in or imported into the Community, or the countries acceding to the European Union on 1 May 2004, by a manufacturer or importer and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS); (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer;	Existing substance for which it can be proved that it was produced, imported or used in EU-25 within last 15 years

Term	Legal definition (if existing)	Simple explanation
	(c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC29, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC30; provided the manufacturer or importer has documentary evidence of this.	
Placing on the market	Supplying or making available, whether in return for payment or free of charge, to a third party. Import into the customs territory of the Community shall be deemed to be placing on the market	Selling or giving away for free a substance to someone within the European market
PNEC		Predicted no effect concentration – on a basis of acute or chronic effect concentrations established in laboratory tests, concentrations are calculated using safety margins, for which no effects are expected to occur in the environment.
Polymer	A substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following: (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; (b) less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a	Large molecules consisting of repeated chemical units (monomers) joined together. Examples of polymers: plastic materials, rubber.

Term	Legal definition (if existing)	Simple explanation
	'monomer unit' means the reacted form of a monomer substance in a polymer	
Positive effects		Any benefits originating from the legislation, e.g. to the society (e.g. reduced externalized costs), business (e.g. better image, less scandals), workers (decreased potential for occupational diseases), consumers (e.g. reduction of diseases related to hazardous chemicals in articles), environment (e.g. prevention of damage to environment from products and processes) due to better info on properties and systematic assessment of risks
Preparation	A mixture or solution composed of two or more substances	Mixtures, combinations and solutions consisting of two or more substances. Including polymer-containing preparations such as "masterbatches" or "compounds".
Process and product integrated measures		Measures in production (e.g. recovery of materials) or in products (e.g. barrier to evaporation) leading to reduced emissions
Product and process orientated research and development	Any scientific development related to product development, the further development of a substance in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance	Research which is not aimed at inventing new substances but at developing new or better uses of exisiting substances
Rationalisation		Decreasing number or diversity of substances used in the process/product while maintaining their performance
REACH mechanisms		Duties and procedures originating from the draft legislation for the different actors in a supply chain
Read- across		Assuming a linear relationship in substance groups the structure of which follow a regular pattern, e.g. decreasing volatility with increasing chain lengths of alkanes
Registrant	The manufacturer or the importer submitting a registration	Producers of substances and importers of substances and preparations if the

Term	Legal definition (if existing)	Simple explanation
		total amount exceeds 1 t/a
Registrant's own use	An industrial or professional use by the registrant	Use of substance for own needs
Registration		Action of submitting a dossier to the chemicals agency with information on substance properties and for dangerous substances also on uses and exposures.
Registration dossier		Information on a substance compiled in a dossier in order to register the substance (according Articles 9 and Annex IV)
Response	Change developed in the state or dynamics of an organism, system or (sub) population in reaction to exposure to an agent	
Restriction	Any condition for or prohibition of the manufacture, use or placing on the market.	
Reversed burden to proof		In case of REACH: shifting the authorities' responsibility of proving that a substance poses a risk to industry having to prove that a substance is safe.
Risk	The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent	
Risk Analysis	A process for controlling situations where an organism, system or (sub) population could be exposed to a hazard.	
Risk Assessment	A process intended to calculate or estimate the risk to a given target organism, system or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.	The Risk Assessment process includes four steps: hazard identification, hazard characterisation (related term: dose-response assessment), exposure assessment, and risk characterization
Risk communication	Interactive exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups and the general public	Information exchange on chemicals related risks. In case of REACH: along the supply chain
Risk management	Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and	Assessing risks, evaluating options to reduce existing risks and implementing measures

Term	Legal definition (if existing)	Simple explanation
	non-regulatory options and to select and implement appropriate regulatory response to that hazard. Risk management comprises three elements: risk evaluation; emission and exposure control; risk monitoring.	
Risk reduction measure		Any measure reducing either the hazardousness of product or process components (substitution) or the releases and exposures of humans and the environment
Robust study summary	A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimizing the need to consult the full study report	
Scientific research and development	Any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 ton per year	
SIEF		Part of internet based information system organised and maintained by the European Chemicals Agency, where all pre-registrants of one specific substance are member of. It aims at facilitating data sharing and the formation of consortia in general.
Site	A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared	Grounds where a company has got its production facilities
Socio-economic impacts	Any impacts upon society/the economy as a result of a policy or project, such as price changes, welfare changes, employment, reduction in health impacts, and so on (OECD guidance)	
Substance	A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition	Chemical elements and their compounds as they occur in the natural state or as produced by industry. If e.g a solvent is derived by purification (refinery) it is regarded a substance, although it may contain many different components. This is for example the case with “Solvent Naphta”
Substitution		Avoiding use of a hazardous substance by replacing it with another substance (a

Term	Legal definition (if existing)	Simple explanation
		substitute) or by changing production methods.
Toxicity		Property of chemical causing adverse effects on humans, animals or plants (e.g. causes cancer or death)
Undesirable use	A use which the registrant advises against	
Use	Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.	The use comprises the entire life-cycle of a substance, so far there are no rules how to describe it. Examples for a description of a use could be “additive in plastic”, “lubricant” or “application in spray paints”
Use advised against		If the chemical safety assessment shows that a use of a substance results in a risk, he should explicitly communicate this as a use advised against
Waiving		Refraining from testing requirements based on strong argumentation that exposure is very unlikely. If e.g. contact of humans with a substance can be excluded throughout the entire life-cycle, reprotoxicity tests may be omitted. This has to be decided by the authorities based on the information in a CSR[1].

[1] Waiving is possible only for substances produced / imported in amounts > 10t/a (starting in Annex VI)

3 Introduction to REACH – general overview

3.1 Introduction

3.1.1 Content of the chapter

The proposed REACH Regulation is a fundamental reform in chemicals regulation. REACH covers all[2] chemical substances. It requires every manufacturer and importer of substances in amounts > 1t/a to register it prior to its marketing. The data requirements for registration depend on the imported/produced tonnage and the types of exposures expected during its life-cycle.

REACH establishes a system of registration, evaluation and authorisation of chemical substances and creates a European Chemicals Agency. The elements:

- **Registration** requires industry to obtain relevant information on their substances and their uses and deliver it in form of a registration dossier to the Chemicals Agency prior to marketing.
- **Evaluation** is the task of the competent authorities to check compliance of registration dossiers (random) or testing proposals (obligatory) and provides confidence that industry is meeting its obligations and prevents unnecessary testing. In addition, single substances can be prioritised for in-depth evaluation by the Member States.
- **Authorisation** is a safety net mechanism for substances of very high concern. If these are listed on Annex XIII, use is only permitted for holders of an authorisation. This can be applied for and granted if the reviewed shows that the substance in the use of the applicant is adequately controlled, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies.
- The **Restrictions** procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system.

"The **Agency** will manage the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that the REACH system functions well and has credibility with all stakeholders."[3]

[2] with the exception of polymers and a few specifically listed substances

[3] Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), COM(2003) 644 final, VOLUME I, p.12, Brussels, 29.10.2003

3.1.2 Background information on content

- Text of the proposal (http://europa.eu.int/comm/environment/chemicals/reach.htm)
- REACH - New Chemicals Legislation, Background documents and Links (http://europa.eu.int/comm/press_room/presspacks/reach/pp_reach_en.htm)
- Flowcharts on the new EU chemicals legislation REACH, Commission of the European Communities, 04/04/2004 (http://europa.eu.int/comm/environment/chemicals/reach.htm)[4]
- REACH in brief: Why do we need REACH? How will REACH work? What are the costs and benefits? What is the state of play? 15.09.2004 (http://europa.eu.int/comm/enterprise/reach/overview.htm)
- The REACH Proposal Process description - result of the Reach Implementation Project 1 (RIP 1). Document describes the main processes and procedures set out in the REACH Proposal, June 2004 (http://europa.eu.int/comm/enterprise/reach/overview.htm)

3.1.3 Important terms related to the topic

General terms: substance, preparation, existing substance, new substance, phase-in substance, non-phase in substance, manufacturer, importer, downstream user, competent authority.

3.1.4 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?
Manufacturers / Importers	Yes	All tasks connected to the registration of substances manufactured / imported in quantities > 1 t/a
Formulators	Yes	Needs to comply with the exposure scenarios obtained with the SDS, needs to get feeling about availability of raw materials
Down-stream users	Yes	Needs to comply with the exposure scenarios obtained with the SDS, will get more information on his chemicals
Traders (no import)	Yes	Are involved in supply chain communication
Ministries / state officials	Yes	Enforcement of regulation, evaluation of testing proposals and dossier/substance evaluation, communication Agency etc.
Inspectors	Yes	Supervision of implementation of requirements by industry actors
NGOS	Yes	Principle of REACH is to protect human heath and environment
Journalists	Yes	Will remain important topic for economy and environmental journalists

[4] This document is also provided on the CD ROM

3.2 Presentations

3.2.1 Short and easy introduction of REACH

Goal

The presentation gives an overall overview on REACH. It suits for a general introduction for all actors. Trainees shall understand:

- History how REACH was developed and main deficits of current system
- The goals of REACH
- The main elements and principles
- Impacts of REACH in general

Key messages

25 years chemicals debate has shown shortcomings[5] in chemicals control system and REACH was initiated due to these deficits.

The Commission proposal for a regulation on REACH came out in October 2003. REACH is a profound reform of the European chemicals policy.

The new proposal introduces: a single system for existing and new substances; a Duty of Care for all handlers of chemicals; the shift of responsibility for the assessment of chemicals risks from authorities to industry; a mechanism to divide responsibility for chemicals safety among the actors of a supply chain; an authorisation system for substances of very high concern.

[5] E.g. within the present system of chemicals control during 30 years, for approximately only 7.000 substances a harmonised classification and labelling was agreed. During the last 20 years approximately 3.700 substances were notified under the Directive on the Notification of New Substances. Under the Existing Substances Regulation; within 10 years only 80 Risk Assessments were completed. The ICCA HPV program covered 150 substances since 1999. This shows, that the generation of knowledge and the agreement on management of chemicals takes a very long time under the existing chemicals regime.

Presentation and explanation

Slide of presentation

Comments, key messages

REACH
General
Introduction

The Current System:
Milestones in chemicals control

- **1967:** Classification, Packaging and Labelling of Dangerous Substances (67/548/EEC)
- **1976:** Restriction on the Marketing and Use of Certain Dangerous Substances and Preparations (76/769/EEC)
- **1976:** Dangerous substances in water (76/464/EEC)
- **1981:** New Substance Regulation (6th and 7th amendment of 67/548/EEC)
- **1988:** Classification, Packaging and Labelling of Dangerous Preparations (revised Directive 1999/45/EC)
- **1993:** Evaluation and Control of the Risks of Existing Substances (793/93/EEC)
- **1994:** priciples of risk assessment -> TGD

Important for all: names relevant legislative acts at the moment and shortly what these regulate

Explains terms: 'existing substances', 'new substances'

Present achievements

- **Classification and Labelling (approx. 2600 harmonised, 4000 self-classified)**
- **New Substances Notification (approx. 3700 in 20 years)**
- **Existing Substances Reg. (approx. 80 Risk Assessments in 10 years)**
- **ICCA HPV (150 since 1999)**

Stress that only 80 risk assessment are done during 10 years to existing substances, but there are 30 000 of them

Reasons: 1) industry is not obliged to provide data and 2) Member States cannot agree

Deficits of the current system

- Insufficient information for adequate risk assessment of all substance uses in EU (no obligation for industry to provide data).
- Absence of classification does not mean absence of dangerous properties (Dir 67/548/EEC, no duty to produce data!).
- But system is based on proven intrinsic properties (regulation bases on the classification of substances).
- Patchwork of environmental legislation is intransparent, partly inconsistent and difficult to execute at downstream level.

Explain what are intrinsic properties
Take time to explain what the deficits are, so everyone can follow even if the current legal background is not clear

Deficits of the current system

- Different requirements and responsibilities for risk assessment of New Substances and Existing Substances.
- Process for assessment, decision and restriction of Existing Substances is time- and manpower-consuming and does not involve down-stream users (Assessment process and agreements at EU level).
- Responsibilities in the supply chain are not assigned.
- Supply chain communication works only down-stream (SDS is obtained but seldom any feedback).

Chemicals policy review

- **Commission Proposal for a Regulation on**
  - **REACH**

COM(2003) 644 (29 October 2003)

- **Registration**
- **Evaluation**
- **Authorisation of**
- **CHemicals**

Mention already here that this is State of Play, revision is ongoing and a new proposal will be published after the first reading of parliament.

Goals of REACH according to White Paper

- Protection of human health and the environment
- Maintaining and improving competitiveness of industry in the EU
- Prevention of fragmentation of the internal market
- Raising of transparency
- Integration of work in international “projects”
- Promotion of test methods without animals
- Compliance with WTO agreements

Note: so far everyone has confirmed that he/she agrees with the goals!

Main Features of REACH

- A single system for existing and new substances
- Shift of responsibility for substance risk assessment from authorities to industry
- Divided responsibility along the supply chain for the safe handling and use of substances
- Authorisation system for substances of very high concern

Main Steps in REACH

A single system for non-phase-in (new) and phase-in (existing) substances

- **Pre-Registration: data sharing and avoidance of unnecessary testing**
- **Registration of substances of 1 ton or more per M/I/year**
- **Information in the supply chain; downstream users**
- **Evaluation of dossiers by Member States**
- **Authorisation for substances of very high concern**
- **Restrictions – the safety net**

The Agency to manage the system

Explain: what means pre-registration
Explain terms: manufacture, importer and downstream user

Registration

- **Substances >1 ton/producer/year**
- **Exemption from the scope**
  - Substances for uses covered by other legislation, e.g. medical products, additives in food- and feeding stuff
  - Substances in Annex II, III
  - Polymers (preliminary)
  - Intermediates – reduced requirements
  - PPORD exempted from registration for 5 (+5) years
- **Deemed to be registered**
  - Plant protection products, biocides
  - Notified substances (67/548/EEC)

Stress: substances in plant protection and biocidal products are deemed registered only in as far as they are used for biocides and plant protection products
Note: intermediates have limited registration requirements (look article 15 and 16)

Evaluation – Title VI

Substances will be evaluated by the Member States CAs

- **Dossier evaluation**
  - **Examination of testing proposal: prevent unnecessary animal testing**
  - **Compliance check**
- **Substance evaluation**
  - **Clarify the suspicion of risks to human health or the environments of a substance.**

Note: completeness check of dossier is done by Agency and compliance check is done by MS CA
Substance evaluation is not done for only one dossier but EU level, taking account of all dossiers submitted for the one substance.
Explain term: competent authority

Authorisation - Title VII

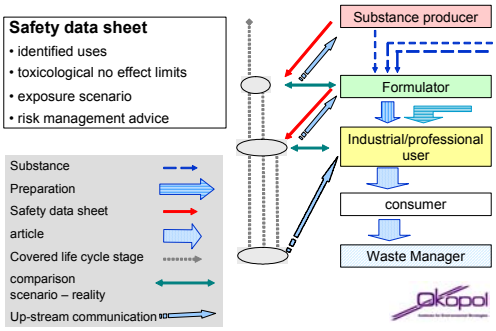
Certain substances may need to be authorised before placing them in the market

- **CMRs Cat. 1&2, PBTs & vPvBs**
- **Other substances which can cause irreversible effects in humans or environment – No scientific criteria given**
- **authorisation is not an automatical process!**
  - **Identification of properties (by registrant)**
  - **Proposal for listing (MS) → adoption of proposal (MSs)**
  - **Publication of listing (Annex XIII)**

In total there will not be so many substances subject to authorisation (PBTs around 150 under discussion).

Last bullets are important to mention, this is often not understood!

Information flow under REACH



Main elements

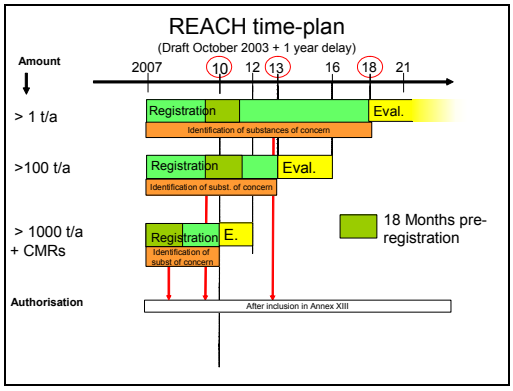
- **Manufacturer/importer responsible to get and provide information on chemicals and assess their risks**
- **Dangerous substances for which safe use is not ensured may not be used**
- **System will start with high volume substances and very dangerous substances, others follow later (phase-in scheme)**

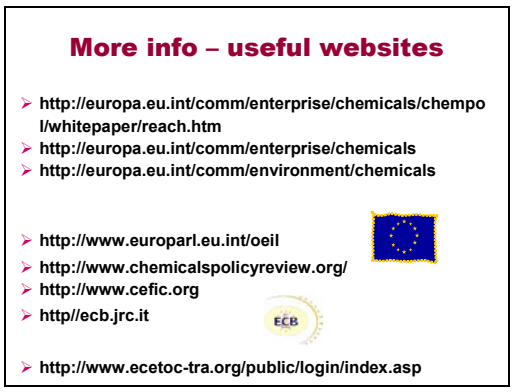
Important impacts of REACH

- **Information share and availability in supply chain**
- **Direct costs - chemical producers and importers**
- **Substance and chemicals availability**
- **Research, development, innovation, risk assessment**

Note: direct costs are for producers and importers. Indirect costs result from the need to substitute substances, reformulate preparations, loss of innovative capacity.

Some substances can be deselected because of too high registration costs compared to the profit earned by the substance.





3.2.2 More detailed introduction to REACH

Goal

Trainees (manufacturers, importers, downstream users) shall understand:

- what means REACH and its main features
- what mean registration, evaluation, authorisation and restrictions
- information flow under REACH

Key messages

REACH is a profound reform of the European chemicals policy → new approaches for improved chemicals control. All actors will face new tasks and challenges

New approach is to shift and (re-)define responsibilities from authorities to industry (incl. safety assessment, definition of risk management in the market).

The registration of substances is the key mechanism under REACH to collect data and assess the uses and connected risks (chemical safety report) of chemicals. Producers and importers are responsible for the soundness of the knowledge base for the entire supply chain.

All substances are “treated” equally (a single system for existing and new substances). A phase-in period is foreseen the registration of most chemicals.

Presentation and explanation

Slide of presentation	Comments, key messages
REACH **In-depth Introduction**	
Chemicals policy review • Commission Proposal for a Regulation on • REACH COM(2003) 644 (29 October 2003) • Registration • Evaluation • Authorisation of • CHemicals	On October 29, 2003 European Commission came out with Proposal for a Regulation on Registration, Evaluation, Authorisation of Chemicals It has evolved in a long and participatory process between Commission, Member States and different stakeholders.
Main Features of REACH • A single system for existing and new substances • Shift of responsibility for substance risk assessment from authorities to industry • Divided responsibility along the supply chain for the safe handling and use of substances • Authorisation system for substances of very high concern	All chemicals are covered by REACH, but the scope of the registration covers only those produced/imported in amounts > 1t/a. REACH requires for all substance that they are handled with care. The general term "Duty of Care" which was originally part of the proposal has been taken out, because the Member States did not see it enforceable.

Main Steps in REACH

A single system for non-phase-in (new) and phase-in (existing) substances

- **Pre-Registration: data sharing and avoidance of unnecessary testing**
- **Registration of substances of 1 ton or more per M/I/year**
- **Information in the supply chain; downstream users**
- **Evaluation of dossiers by Member States**
- **Authorisation for substances of very high concern**
- **Restrictions – the safety net**

The Agency to manage the system

REACH Proposal - Format

Section	# pages	Content
Volume I	149	Regulation including Explanatory Memorandum Amended Directive 67/548
VolumeII Annexes I-IX	84	Annexes covering Chemical Safety Report (CSR) format, exemptions and information requirements for Registration
Volume III Annex X Part A	173	Test methods for physico-chemical properties
Volume IV Annex X Part B	293	Test methods for toxicity & other effects
Volume V Annex X Part C	343	Test methods for eco-toxicity
Volume VI Annexes XI- XVIII Legislative Financial Statement	273	CSR for downstreamers; Criteria for PBT and vPvB; List of substances subject to authorisation; Dossiers Socio-economic analysis; Restrictions on manufacture, placing on market of dangerous substances, preparations and articles; Persistent Organic Polultants;

Total 1315 pages

General issues - Title I (1)

- **Scope**
- **REACH covers:**
  - Manufacture, import, placing on the market and use of substances
  - Substances "on their own", in preparations or in articles
- **General exemption from scope: radioactive substances, substances to custom supervision, non-isolated intermediates**
- **Specific exemptions from parts of REACH set out in those Titles (Annex II)**

30,000 substances

General issues - Title I (2)

- **Definitions**
  - Polymer - = 3 monomer units bound to one other monomer unit
  - Downstream user – distributor is not a downstream user
  - Intermediates
    - **Non-isolated**
    - **Isolated, same site**
    - **Isolated, transported**
  - Phase in and non Phase-in substances
  - Product and Process Oriented R&D (PPORD) – includes to test the fields of application at the downstream user

Explain: what means pre-registration → data sharing and avoidance of unnecessary animal testing is explained after some slides

Explain main terms under REACH: manufacturer, importer, DU

Establishment of a separate Agency is essential for the effective implementation of the proposed REACH system. The Agency will manage the technical, scientific and administrative aspects of the REACH system at Community level.

REACH proposal (October 2003) includes 15 titles, 137 articles, and 14 Annexes

Registration – Title II (1)

Subject of Registration

- Substances >1 ton/producer/year
- Non-registered monomer substances if present at >2% in a polymer
- Substances in Articles if present > 1 ton, dangerous (67.548/EEC) and intended for release
- PPORD exempted from registration for 5 (+ 5) years
- Polymers – exempted from registration – but EC is committed to consider how polymers can be addressed in the future
- Intermediates - reduced requirements
- Exemption – Annex II & III

Manufacturer/importer of a substance in quantities of 1 ton or more per year shall submit a registration to the Agency

Manufacturer/importer of a polymer: registration of the non-registered monomer substance(s) if polymer consists of 2% (w/w) or more and the total quantity makes up > 1 ton/a

Producer/importer of articles registration for dangerous substances in articles, if present in quantities >1 ton per producer or importer per year and is intended to be released

Registration - Title II (2)

- **Exemption from the scope**
  - Substances for uses covered by other legislation, e.g. medical products, additives in food- and feeding stuff
  - Substances in Annex II, e.g. Ar, N_2, CO_2, H_2O, , specific natural substances
  - Substances in Annex III, e.g. by-products, hydrates – kind of block exemptions
  - Substances for product and process oriented research and development (PPORD) exempted under specific conditions, 5 (+5) years, medical products 15 years
  - Polymers, but EC is committed to consider how polymers can be addressed in the future
- **Deemed to be registered**
  - Plant protection products, biocides
  - Notified substances (67/548/EEC)

Stress: substances in plant protection and biocidal products are deemed registered only in as afar as they are used for biocides and plant protection products

Registration – Annexes

- **Information required for the Technical Dossier**
  - **Identity of manufacturer or importer, identity of substance**
  - **Information about manufacturing process and produced quantity incl. all identified use(s)**
  - **Proposal for classification and labelling**
  - **Recommendations for safe handling (storage, disposal, first aid measures)**
  - **Summary and "robust study summaries" of test data (Annex V-IX)**
  - **Statement, whether information has been generated by testing on vertebrates**
  - **Proposal for additional tests**
  - **Declaration regarding agreement of sharing non vertebrate animal tests**

Annex IV - information requirements referred to be submitted for general registration purposes

Stress: Importers are to report imported amounts

Registration – Title II (3)

- **Registration Annexes**
- **Annex V**
  - Physicochemical properties
  - Basic human health data (4 end-points)
  - Short term aquatic toxicity
- **Annex VI**
  - Human health data (including *in vivo*)
  - Ecotoxicological data
- **Annex VII and Annex VIII**
  - Long term, repeat dose, chronic, fate etc
- **Annex IX**
  - Adaptations of the testing regimes
- **Exemptions built into Annexes V to VIII**

Registration – Title II (4)

Chemical Safety Assessment/Report

- Shall consider all stages of the life-cycle of a substance as defined by the identified uses and will contain the following information:
  - 1. Human health hazard assessment
  - 2. Human health hazard assessment of phys-chemical properties
  - 3. Environmental hazard assessment
  - 4. PBT and vPvB assessment
  - - - - if dangerous or a PBT or vPvB - - - -
  - 5. Exposure assessment
  - 6. Risk characterization
- CSR – Rules defined in Annex I / Point 7

CSA shall be carried out by manufacturers/importers → if substance produced > 10 t/a and dangerous; DUs → when their application of a chemical substance is not covered in Safety Data Sheet and they don't want to make it known. Its documentation is called Chemicals Safety Report (CSR) and is part of the registration dossier.

The purpose of the chemical safety assessment is to identify the safe conditions of all identified uses for a substance (no risks occur, exposure remains under the safe levels).

Data sharing and avoidance of unnecessary testing - Title III

Potential registrants are to share vertebrate animal studies, access to information via SIEF

- First step of the process
  - Send a enquiry to the Agency with specific information (non phase-in)
  - Duty to Pre-register – send specific information to the Agency to join a SIEF (phase-in)
  - Summaries submitted more > 10 years freely available

For phase-in substances, a system (SIEF) is established to help registrants to find other registrants with whom they can share data

Registrants not having manufactured or placed a substance on the market must obtain data from previous registrants of that substance (vertebrates). The subsequent registrant is expected to pay an equal share of the costs incurred.

SIEF - substance information exchange forum: composed of all who have pre-registered the same substance.

Downstream Users – Title IV & V

Duty to communicate information in the supply chain

- Through Safety data Sheet for classified substances
- Specific information when no SDS is required
- Downstream Users have also duties!
- Check that the use and conditions of use comply with the info given in the SDS
- Make known any unidentified uses, if not possible – confidentiality (uses out of the scope must be assessed by the DU (Downstream user CSA))

If substance or preparation meets criteria for classification as dangerous the person responsible for placing that substance on the market, shall supply the recipient with a SDS compiled in accordance with Annex Ia.

If SDS is not required then the information down the supply chain should be forwarded according article 30

Stress: information should be forwarded up the supply chain according article 31.

DUs duties are explained in Article 34-36

Authorisation - Title VII

Certain substances may need to be authorised before placing them in the market

- CMRs Cat. 1&2, PBTs & vPvBs
- Other substances which can cause irreversible effects in humans or environment – No scientific criteria given
- authorisation is not an automatical process!
  - Identification of properties (by registrant)
  - Proposal for listing (MS) → adoption of proposal (MSs)
  - Publication of listing (Annex XIII)

Note: evaluation of testing proposals aims to prevent unnecessary animal testing. Evaluation of compliance aims at enforcement of REACH

Substance evaluation (EU-level): substances where risks are suspected that producers can systematically not see (e.g. a lot of small amounts are used) are assessed. Information from all registration dossiers of that substance are used!

Evaluation may lead authorities to the conclusion that action should be taken under the restrictions or authorisation procedures.

Authorisation - Title VII

Certain substances need to be authorised before placing them in the market

- CMRs cat. 1&2
- PBTs & vPvBs (according to Annex XII)
- Other substances which can cause irreversible effects in humans or environment – No scientific criteria given

How to apply for an authorisation

- Send an application including
- Identity of the substance and applicant
- Request for authorisation
- CSA if not registered
- Optional information: Socio-economic analysis & Analysis of alternatives

Substances with hazardous properties may be proposed for authorisation. The aim is to have checked that they are used under adequate control (← means no risk occurs)

Requirements for applications for authorization are explained in Article 59

Restrictions – Title VIII

- The system's safety net
- Community wide concern
- Agency Committees examine
  - The risk and
  - The socio-economic aspects involved
- By-passing of risk assessment, socio-economic analysis for CMR cat. 1&2 for consumers
- Commission takes final decision through comitology
- Carry-over of existing restrictions under Directive 76/769/EEC

Restrictions are a safety net because any substance on its own, in a preparation or in an article may be subject to wide restrictions if a risk needs to be addressed.

Proposals for restrictions shall be prepared by Member States or the Commission in form of a structured Dossier. This Dossier is required to demonstrate that there is a risk to human health or the environment that needs to be addressed to explore the options for managing that risk.

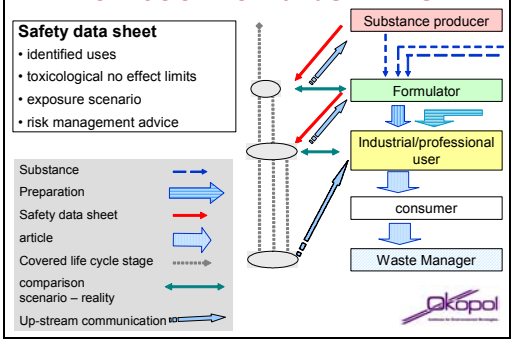
REACH - challenges

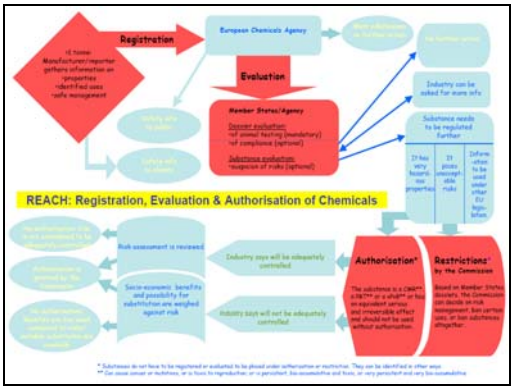
The challenge for chemical industry

- assess (including data generation)
- document (Chemical Safety Report)
- register (together with other producers and downstream users)
- communicate (via Safety Data Sheet)

30.000 substances in 11 years

Information flow under REACH





Mechanisms under REACH (1)

- Prioritisation and risk reduction measures are based on intrinsic properties **and** exposure.
- Equal requirements for New Substances and Existing (phase-in) Substances.
- More options for read-across without (animal) testing
- Long term: Adoption of the GHS.
- Provision for long term effects in the environment.

Mechanisms under REACH (2)

- Every actor in the supply chain receives necessary information on a) safe use and b) safe supply of substances to next actor.
  - Clearly assigned responsibilities in the supply chain (defined, where responsibility ends):
    - The placer on the market accounts for assessment and downstream information transfer.
    - The user has to check/complete information and accounts for safe use of the chemical and downstream information transfer
  - Improved risk management in the supply chain

Market Mechanisms under REACH (3)

- defined data requirements
- transparent goals for risk reduction
- clear responsibilities
- clear rules for risk information transfer

The REACH market mechanism supports responsible companies. Finally the actors in the supply chain will be interested in avoiding negative publicity caused by insufficient information/assessment or careless use of chemicals.

Information on intrinsic properties of substances may be generated by tests, through the use of qualitative or quantitative structure-activity relationship models (QSAR) or from information from structurally related substances (conditions in Annex IX).

Explain read-across testing, QSAR

Key points of REACH

- REACH was initiated due to several short-comings in the current system → council working group, Commission analysis, whitepaper
- It has evolved in a long and participatory process between Commission, Member States and different stakeholders
- The proposal → regulation will be subject to further adaptation and complementation by guidance documents after its adoption

Key points of REACH

- REACH is a profound reform of the European chemicals policy
  - shifting and (re-)defining responsibilities (safety assessment, definition of risk management in the market)
  - establishing standards for knowledge management and risk communication
  - "treating" all substances equally

REACH: More info – useful websites

- **http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm**
- **http://europa.eu.int/comm/enterprise/chemicals**
- **http://europa.eu.int/comm/environment/chemicals**
- **http://www.europarl.eu.int/oeil**
- **http://www.chemicalspolicyreview.org/**
- **http://www.cefic.org**
- **http//ecb.jrc.it**
- **http://www.ecetoc-tra.org/public/login/index.asp**

3.3 Discussions in plenary

Check and discuss whether it is understood what means registration, evaluation and authorisation! It can be made in question style: e.g

- *Question:* Estonian company imports HCl from France 10 t/a. Does he need to register substance? *Answers:* Yes/ no/ don't know
- *Question:* Latvian company imports CMR substance from Ukraine 0.9 t/a. Does he need to register substance? *Answers:* Yes/ no/ don't know
- *Question:* Latvian company produces CMR substance 10 t/a? What it means for him? *Answers:* Registration of substance in first phase-in period/ registration and authorisation of substance/ don't know

Discussion about timeline of REACH, what are different timings for pre-registration, registration and evaluation, why was the phase-in scheme proposed (work load and predictability of the system)

Discussion of scope of REACH and scope of registration (all chemicals may be subject to registration / authorisation, all dangerous substances need SDS regardless of produced amount etc.)

3.4 Further work for preparation for REACH

This is only an introduction to the policy framework. The further work is therefore only at general level. More preparatory work is listed in the chapter 10 on business impacts.

- Get in contact with the association to get to know more about REACH and find out what information is provided there.
- Update oneself about the further REACH process (Commission website → DG environment → chemicals → REACh or DG http://europa.eu.int/comm/enterprise/reach/index.htm)
- All actors: get better idea of the own role, tasks etc.
- Read brief introduction to REACH published by the Commission (CD ROM)
- NGOs: identify own role in policy development of REACH, get an overview on positions of other stakeholders and define own position

4 Main Changes in chemicals legislation with REACH

4.1 Introduction

4.1.1 Content of the chapter

Discussion about the necessity of changes in the current system started already in 1989. Some Member States requested that the Commission would review the European chemicals legislation.

The main deficits of the current legislation and possible solutions under REACH are:

1) Authorities have to prove that the use of a substance is risky, whereas industry does not have the duty to prove that their products are safe → under REACH: reversed burden of proof, industry assesses the safety of its products

2) Classification of substances and preparations is based on available data, but there is no duty to generate data. "No classification" does not necessarily mean no hazard → under REACH: a minimum data (Annex V) set is to be provided in the registration dossier, more data is required according to volume and exposure. This data is the basis for classification (not all endpoints for low tonnages!)

3) The risk assessment and risk management process is very slow, as there are no sanctions in case industry does not provide information. Additionally, all Member States have to agree on the risk assessment result → under REACH: industry assesses the risk, Member States and the Chemicals Agency can focus on priority issues (substance evaluation). There are strict timelines set for this process

4) New substances are discriminated against existing substances → all substances will be treated equal under REACH. For new substance development, registration can be postponed upon request for research purposes.

5) Very little information is available on the uses of chemicals, there is no duty to collect such information → under REACH: in the frame of the chemical safety assessment and the DU notification, a lot of information on the uses of chemicals is provided and directly used for the safety assessment.

6) Supply chain communication works only down-stream → under REACH: also DUs have duties to communicate upstream, suppliers have a need to get information from down-stream.

4.1.2 References to REACH regulation

- Background to the proposal → Explanatory memorandum to REACH
- Obligations to register substances → Article 5
- Information to be submitted with registration → Article 9, Annexes V, VI, VII, VIII
- Requirements for generation of information on intrinsic properties → Article 12
- Sharing of existing data between registrants → Articles 25, 28
- Duty to communicate information down and up the supply chain → Articles 29, 30, 31
- Authorisation requirements → Articles 54
- PPORD exemptions → Article 7

4.1.3 Further background information on content

Deficits of the current system and key elements of REACH to overcome them:

- White paper – Strategy for a future Chemicals Policy http://europa.eu.int/comm/enterprise/reach/whitepaper/intro.htm
- REACH in brief: http://ecb.jrc.it/reach/
- What we need from REACH – A compilation of views by companies and other organizations www.chemsec.org

See also Chapter 13 Information sources on:

- Current EU and national chemicals legislation
- Main institutions currently dealing with chemicals on EU level and information provided in their websites
- Databases on intrinsic properties of chemicals

4.1.4 Important terms related to the topic and links to other chapters

General terms: existing substances, new substances, classification, labelling, ELICS, EINECS, intrinsic properties, intended use, communication down and up the supply chain, manufacturer, importer, downstream user → see *Chapter 2 Definitions*

Term	Simple explanation
Reversed burden to proof	In the case of REACH: shifting the responsibility of authorities of proving that a substance poses a risk to industry having to prove that a substance is safe. Currently authorities are assessing risks posed by existing substances under Regulation 793/93/EC and for new substances under the New Substances Directive
Seveso	On 10.7.1976 the extremely toxic dioxin TCDD was released from a reactor of the company ICMESA near the city of Seveso (Italy). Due to the accident many animals died. Many persons suffered from health damages (especially dermal effects), houses had to be destroyed and soil decontaminated and landfilled.
Bhopal	Known as worst chemical catastrophe in history: On 03.12.1984 the pesticide methyl isocyanate was emitted from a factory in Bhopal (India) Methyl isocyanate is corrosive and severe damages to internal organs resulted from the exposure of victims of the accident. The responsible company (now Dow Chemicals) paid 690 m dollars compensation
Sandoz	After a fire in the chemical works of Sandoz in Basel on 01.11.1986 1000 t of water for fire fighting were discharged to the river Rhine. This killed masses of fish and polluted the drinking water of the region.
Placer on the market	Person or institution who sells or gives away for free a substance to someone else within the European market.

Links to other chapters:

Introduction to REACH - general overview → chapter 3

Roles and responsibilities under REACH → chapter 5

Information collection strategy on hazards → chapter 6

4.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufactu_rers / Importers	Yes	Shifted responsibilities to prove safety of chemicals All substances >1 t/year to be registered, safety to be assessed What is really new, what will change and what will remain	Frustration due to seeing only costs and no benefits, (esp. importers → many substances and uses) REACH will only work when it is also enforced! Fear that others don't comply
Formulators	Yes	What will improve, what will be more complicated, what is really new? New responsibility – communication upstream on uses	More losses than benefits, confidentiality of information
Down-stream users	Yes	What will REACH improve? What is really new? New responsibility – to communicate up to supply chain	Communication with suppliers on uses
Traders (no import)	Yes	Intermediate chain between producer/importer and user → may be involved in communication	Communication up-down chain
Ministries / state officials	Yes	Shifting burden of proof Single integrated system of chemicals control REACH is a regulation	Understanding the own role and importance of having targeted strategic enforcement
Inspectors	Yes	Which inspectorate will be responsible? What expertise is needed?	System bases on responsibility of all actors but still a lot of mistrust in companies
NGOS	Yes	Finding own role in future system. Industry responsibility and animal testing, which data will be available?	Low expertise and understanding of chemicals issue
Other	Yes	Safer consumer products & environment	Increased price, little understanding of chemicals issues

4.2 Presentations

4.2.1 Review of the current system of chemicals legislation

Goal

Participants have an overview and understand:

- mechanisms of the current chemical control system (all)
- what are shortcoming/ gaps in the current system (all)
- why the current legislation is not sufficient to protect human health and the environment (all)

- how shortcoming of the current legislation reflects in the every day life of company (especially industry)

Key messages

- Preventing/minimising risks from chemicals is extremely difficult (many substances, many uses). The current EU chemical legislation is a patchwork, which started with the substance classification and has developed and improved over time. As it has always been amended but never restructured, it is doubling requirements but also "leaves gaps". Thus it is not ensuring adequate management of chemical risks.
- The chemicals risk management under the current chemical legislation system is based on the availability of information on chemicals hazards, what means “no information = no risk”!
- The current system does not stimulate generation of information on chemicals (properties and uses/exposures) and searching for less hazardous alternatives.
- The state authorities have the burden to proof that a chemical product poses a risk. Industry tends “to defend” their substances.

Presentation and explanation

Slide of presentation	Comments, key messages
Deficits of current EU chemicals legislation	
Content • Chemicals debate and development of EU chemicals control legislation • Mechanisms of the current system • Deficits of the current system • Consequences at company level	Overview on content of the presentation. Stress already here that the information is produced in order to explain the main reasons for new chemicals policy

History: chemicals debate

- "Started" by following catastrophic accidents (Seveso, Bophal, Sandoz)
- Discovery of long lived chemicals in the environment and their effects, e.g. DDT (egg-shell thinnin) and PCBs (diseases and reproductive disorders of seals) → Book: Silent spring
- Long range transport of persistent chemicals (CFC, PCB) → POPs end up in places where they have never been used
- Endocrine Disruption → more and more knowledge on modes of action of chemicals which interfere with the hormone system → reprotoxic effects, effects on immune system e.g. tributyltin in antifouling paints causes feminisation of snails
- Asbestos → first indications of cancerogenicity in 1889 → regulated for use at workplaces 100 years later!!!

Some important milestones in chemicals debate.

They have showed what risks chemicals can pose to human health and the environment and thus caused large debates.

Discussion about issues / accidents in "former" times?

Milestones in chemicals control

1967: Classification, Packaging and Labelling of Dangerous Substances (67/548/EEC)

1976: Restriction on the Marketing and Use of Certain Dangerous Substances and Preparations (76/769/EEC)

1976: Dangerous substances in water (76/464/EEC)

1981: New Substance Regulation (6^{th} and 7^{th} amendment of 67/548/EEC)

1988: Classification, Packaging and Labelling of Dangerous Preparations (revised Directive 1999/45/EC)

1993: Evaluation and Control of the Risks of Existing Substances (793/93/EEC)

1994: Principles of risk assessment → TGD

Overview on main directives and regulations of EU chemicals legislation.

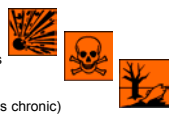
67/548/EEC: first environmental EU-directive, defines methods for classification, labelling and packing of substances = chemicals language.

Regulation 793/93/EEC complements existing rule governed by Council Directive 67/548/EEC for "new chemical substances".

Classification and Labelling (C&L) (1)

Harmonised C&L of dangerous substances and preparations in Europe

Based on available data on



- Dangerous physical or chemical properties
- Toxic properties (acute and chronic)
- Ecotoxic properties (acute and more or less chronic)

For every substance all available (test) data needs to be assessed for each end-point

Every dangerous substance has to be classified (with R-phrases) and labeled (with related hazard symbol)

Directive 67/548/EEC provides tools to classify: test methods, classification criteria, harmonised R- and S-phrases, symbols…

Objective of C&L is the identification of PC and (eco-)toxic properties as a requirement for safe handling by all actors.

Duty to C&L: each placer on the EU market of substances

Mechanisms to be explained more detailed to those who are not well acquainted with chemicals legislation. For state authorities it could be short.

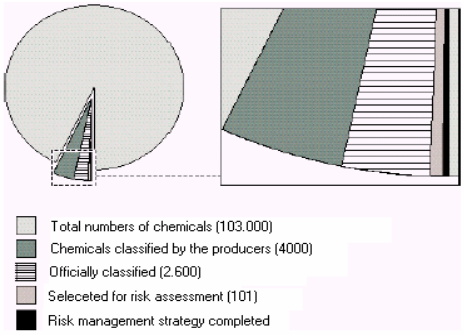
Classification and Labelling (C&L) (2)

- "DANGEROUS" means 1 of the criteria of directive 67/548/EEC is fulfilled
- Classification occurs if available (test)data show related effects
- No classification occurs if available (test)data show no related effects
- From SDS it is seldom visible, what is the basis for "non-classification"

No classification occurs if no data is available

No data → no classification → **no risk!**

Availability of information



Total: ca. 100 000 “existing” substances (EINECS) + 3000 “new” substances (ELINCS)

“Existing” substances: 30 000 really used

legally **harmonized** classification only of 2600 (Annex 1)

Since 1993, only for 126[6] substances risk assessments were drafted, finalised are 70 (ecb newsletter, December 2004)

Briefing: Classification

Classification = assigning categories of danger and R-phrases = comparing test results to classification criteria

- 10 categories of danger
  - Physical chemical hazards
  - Health hazards
  - Environmental hazards
- Standard risk phrases (R-phrases) specifying the nature of property and exposure pathway (human health → ingestion, inhalation, skin contact)

- Labelling: show on the label, some special rules

Explain shortly what classification means, e.g. for NGOs!

Use an example, e.g. Asbestos

Category of danger: Carcinogen Category 1; Toxic (i.e. health hazard), R45 May cause cancer; Toxic: danger of serious damage to health by prolonged exposure through inhalation

Concept of classification - substances

Legal/harmonised classification (Annex I, 2,600 substances)
Agreed at EU level, 67/548/EEC amended by ATPs (current 29th)

Category of danger	Unit	Criteria	Test
Acute toxictiy	LD_{50} LC_{50}	< 25 mg/kg 25 < x < 200 200 < x < 2000	result 75 mg/kg
67/548/EEC main text		Annex VI CL-guide	Annex V test methods

Classification is based on comparison of test data with a set of criteria.

Briefing: classification of preparations

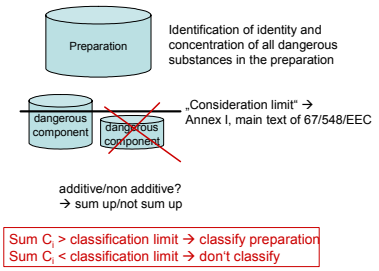
- Same categories of danger and R-phrases as for substances
- Classification based on the classification of ingredients
  - Generic and specific (Annex I) concentration limits for substances triggering classification of a preparation
  - physico-chemical → testing of preparation
  - health and environment → conventional method
    - summing up components with the same toxic effects
    - compare sum to classification criteria

Basically same principle, if substance is contained in very low concentrations, it is neglected.

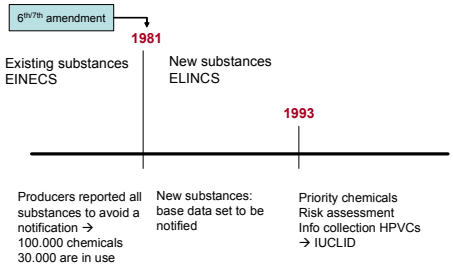
The composition of preparation should be well known in order to properly classify it!

[6] Slide is a bit outdated, there were some more substances selected and started for risk assessment in the meantime

Briefing: classification of preparations



Existing and New Substances



"Existing" substances (before 1981) are contained in EINECS. "New" substances (after 1981) are listed in ELINCS, currently 3000. For new substances a notification is needed prior to marketing → data on substance ID, properties, amounts and intended uses to be submitted to Competent authority.

Council Reg. No. 793/93 → risk evaluation for prioritized substances

Existing Substances Regulation 793/93

- Reporting of available data by producers/importers of substances in amounts exceeding10t/a
- Establishes priority lists → priority setting based on expert judgment and ranking of substances according to level of risk (modeling) by EU → 141 substances
- In-depth risk assessment of prioritised substances by Member States according to agreed method (TGD)
  - result of an assessment: #
    - concern → ...
    - no concern
    - more data needed
- Risk reduction measures based on the output of RA

Users are not involved in reporting → no known use patterns

Lack of info on downstream uses is one of main deficits of the current system.

Data submission by producers: 14% of EU HPVs only have base-set data, for 65%: less than that and for 21% no data exist at all (infosource: ECB, JRC --> HPVC)

Existing Substances Regulation 793/93 (2)

EU-wide risk management

- Substance assessed as 'of concern'
  - for human health (worker / consumers)
  - for environment
- Elaboration of a risk reduction strategy = proposal of measures how to deal with the substance
- If the risks due to exposure of human health or the environment is not acceptable (e.g. CMRs, PBTs, POPs), further restriction measures are applied → one option is to impose 'marketing and use restrictions' under the directive 76/769

This is the "safety assessment" of authorities!

Marketing and use restriction is also an element of REACH (safety net)

Existing Substances

- **30 000** "existing substances" in use
- Volume (tonnage): **99%** "existing substances"
- Data reporting → **users are not involved**
- **No need for data submission on properties** until 1993

↓

- Priority setting: 2620 HPVCs → 4 lists with **141** substances
- In-depth **risk assessment by Member States** → "Burden of proof" is on authorities, industry is "defending" their substances

↓

- ca. **126** risk assessments started, **70** completed (Dec. 2004)

↓

- **57** substances requires **risk reduction measures**→ ca. **12 recommendations** for risk reduction → **4** substances **restricted** by 76/769/EEC

Process is very slow ← no consequences if industry does not provide data, long discussions among authorities

New Substances

- Notification of New Substances (placed on the market after 1981)
- Minimum data depending on predicted market volume
- Risk assessment by authorities of Member States

↓

- Around **3 000** "New" substances notified in ELINCS since 1981
- Data submission from 10 kg onwards
- **Only 0,6% of notified substances are marketed in amounts > 1 000 tonnes per anno**

Notification: quite a lot of data before marketing needed, already at low amounts → lack of incentives for innovation (not clear if substance will succeed on the market and investment will pay off.

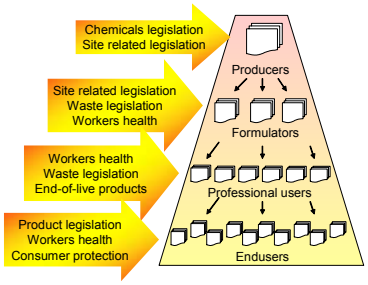
Other relevant legislation

- 91/155: format of SDS, no provisions on the control of content → remains under REACH
- 91/414 (Plant protection products) and 98/8 (Biocides): active substances approved at EU level, products to be approved at national level
- Import export notification, Ozone depleting substances
- many more on specific substances (e.g. PCBs), environmental media (e.g. WFD), risk management (e.g. CAD).....

Stress that all the above will change, due to REACH coming into force (REACH, GHS, Pops will be in REACH).

Other legislation on environment or workers health will all remain!!!

Current (horizontal) chemicals related regulation → doubling and gaps



Responsibilities & information flow

- Placer on the market (substances)
  - classifies based on accessible data
  - forwards info on label and in safety data sheets
- Placer on the market (preparations)
  - classifies based on information up the supply chain and accessible data
  - forwards info on label and in safety data sheets
- Users of chemicals
  - use information from up the supply chain to comply with legislation

Only downstream communication.

User may get different information on the same substance or type of preparation.

The ability of user to comply with legislation much depends on the availability of information from up the supply chain

Communication along the supply chain

Based on classification, the placer on the market has to provide information for downstream users:

- intended uses of the substance/preparation
- dangerous properties of substance/preparation (classification and labelling)
- risk management recommendations (e.g. limits for work places, personal protection…)
- transport labelling
- waste management information

SDS is an instrument for risk communication

The current system does not ensure adequate communication of risk relevant information: no feedback to producer of SDS, no common language, no specific information on RMM

SDS for risk communication

Analysis of 929 SDS from 395 companies by German Competent Authorities (2000)

- 619 SDS graduated as „bad", 141 SDS graduated as „excellent", 169 SDS graduated as „good"

„bad" SDS contain inadequate information on

- Classification
- Chemical composition and concentrations
- Measures for safe handling and storage
- Fire fighting measures
- Physical properties…

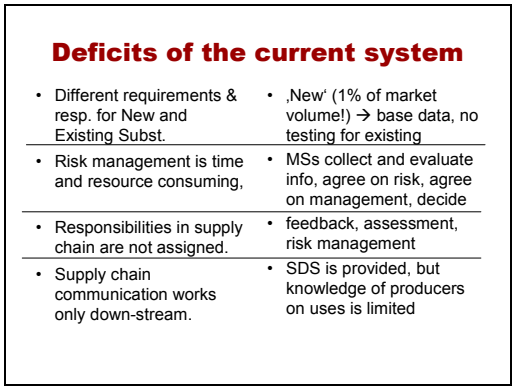
The safety data sheet is designed for professional users. It must enable them to ensure safe use of chemicals substances.

Current quality of SDS is low also in EU 15. REACH does not have a new mechanism to prevent bad SDSs

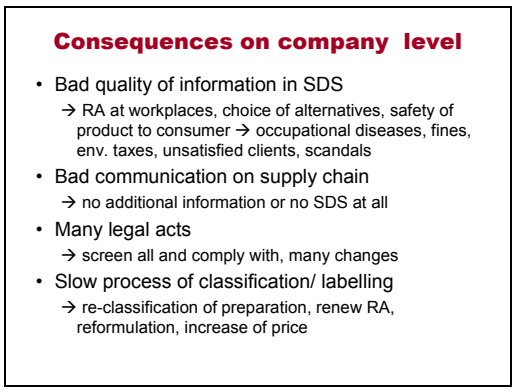
Deficits of the current system

• Insufficient info for adequate RAs of all substance uses in EU	• No duty to carry out tests, no info on uses collected (risk = hazard * exposure)
• System based on proven intrinsic properties	• Substances with unknown properties are missed
• Absence of classification does not mean absence of dangerous properties	• No duty to test for all end-points, no need to show basis of classification (data or no data)
• Patchwork of env. leg. is intransparent, partly inconsistent and difficult to execute at down-stream level	• Improvement of system over time, different regulatory approaches over time, end of supply chain untrained in chemicals

Summary of deficits of the current system and explanation of the deficits-related problems



More than 40% of citizens in EU are "very concerned" about chemical pollution and that only 1% of the public trust companies on environmental issues (Results of *Eurobarometer opinion poll*).



For industry trainings (especially DU): Illustrate what consequences those deficits may impose to their company. It can be discussed here whether they have faced them in real life.

4.2.2 What will change under REACH

Goal

Trainees understand:

- Which are the main mechanisms of REACH to overcome deficits of the current system (all)
- REACH is based on similar principles as the current system. Main differences regard changes in responsibilities and the equal treatment of new and existing substances (all)

Key messages

The main aim of REACH is to protect human health and the environment while safeguarding the competitiveness of enterprises and improving the potential for product innovation.

REACH is not being proposed in a regulatory vacuum but it is intended for elimination of uncertainties and weaknesses in the current European legislative framework.

The improvements are mainly driven through the clear setting of tasks and responsibilities for the early identification of risks of chemical substances and the proposal of procedures including deadlines and methods.

Presentation and explanation

Slide of presentation	Comments, key messages
What will change under REACH ?	
Content • Development of new approach in chemicals control • Goals of REACH • Basic principles of REACH to overcome deficits of the current system	
New approaches for improved chemicals control **Worldwide** • **1992:** Rio Conference on Environment and Development → Globally Harmonised System of Classification (GHS) • **2002:** Johannesburg (Rio plus 10) • **2004:** POP-Convention (Stockholm-Convention) **Europe** • **2001:** White paper • **2003:** REACH-Proposal • **2004-2006:** REACH implementation projects (RIPs) • **2007-2018:** Implementation of REACH and GHS tiered for phase-in substances	Milestones in the development of new approaches in chemicals control system in Europe and worldwide.
The main aim of REACH is to create a sustainable chemicals policy that can... ➢ Ensure sufficient information about chemicals and their risks to human health and the environment ➢ Ensure a high level of protection as result of using the information in safe handling ➢ Maintain and enhance the competitiveness of the EU chemicals industry	The new chemicals policy will initiate a significant change in the chemicals management and raises hopes of a significant improvement in the handling of chemicals in the EU, and thereby significant progress towards an improved level of protection

Basic principles of the REACH

- Reversed burden of proof
- "No registration no market"
  (Lack of data leads to a ban on sales)
- Very hazardous substances should be substituted or need authorization
- Safety assessment = knowledge management along the supply chain = compiling and assessing information from producers and users
- Increased transparency about chemicals on the market (availability of data, publishing in data bases…)
- 1 single integrated system

Note: there is no duty to substitute under REACH nowhere!!!!

Consumers and NGOs will have access to lots more substance data on properties. How and if the data on uses will be published is not yet clear.

Reversed burden of proof

Current system	REACH
If state authorities want to manage chemicals risks, they have to prove that they pose a risk	Manufacturers and importers are required to prove that the substances they place on the market are safe for all the uses and the entire life-cycle. They have to „recommend" risk reduction measures for safe handling of the substance for the down stream users

Under REACH, the burden of proof of a chemical's safety is on manufacturers and importers. Industry bears responsibility that only safe chemicals (for their intended use) are produced and sold.

All handlers are responsible for implementing the recommended risk management measures and safe handling.

No registration no market

Current system

New chemicals have to be tested and notified before marketing starting from volumes as low as 10 kg per year.

REACH (phase-in)

Registration 3 years after REACH is in force: CMRs produced / imported in amounts > 1t/year per M/I and substances produced / imported in amounts > 1000 t / year per M/I

Registration 6 years after REACH is in force: substances produced / imported in amounts > 100-1000 t/year per M/I

Substances produced in quantities of 1-100 t/year per M/I– 11 years after adoption of the regulation

No registration = No marketing

The aim is within 11 years to have satisfactory information about all chemicals used in volumes of more than 1 ton/year/M or I.

If a company is unable to provide the information within this deadline, the substance may no longer be sold.

All non-phase in substances have to be registered when REACH comes into force directly!

Current system – notification **REACH - registration**

Exceptions

EINECS-listed substances	Substances notified under 67/548 or reviewed under Regulation 93/793 are considered as registered and be automatically transferred in REACH
R&D and PPORD substances	
Polymers made of EINECS-listed substances	All polymers made of registered substances
Substances marketed below 10 kg/year/placer on the market	Substances marketed below 1 t/year/ manufacturer or importer

Only for trainees with deeper knowledge

Where EU risk assessments are currently done, substance are exempted (no doubling).

Polymers (only postponed! too much work at the moment for little risk expected)

R&D of new substances under current legislation: 1) for scientific R&D – until 100 kg/year/manuf./importer; 2) for technological R&D – not longer than 1 year, no volume restrictions.

Current system – notification **REACH - registration**

Exceptions

The following "regulated" substances:	The following uses of regulated substances:
- Additives and substances for exclusive use in animal feedingstuffs.	- Additives and substances for animal feedingstuffs.
-Substances used exclusively as additives and flavourings in foodstuffs.	- Additives and flavourings in foodstuffs.
- Active ingredients used exclusively in medicinal products.	- Active ingredients medicinal products.
	- Fertilizers
- Substances for exclusive use in other sectors with equivalent data submission requirements:	- Food-Contact substances
- Active ingredients of biocidal products	
- Active ingredients of pesticides	

Only for trainees with deeper knowledge and producers / importers

Notification includes	Registration includes
Physico-chemical data	Physico-chemical data
Toxicological data	Toxicological data
Ecotoxicological data	Ecotoxicological data
Proposed classification and labeling	Proposed classification and labeling
	Preliminary risk assessment covering the intended uses and proposed risk management measures
10 kg → one animal test is needed. 1 ton → further animal tests are needed.	As far as possible, animal testing to be minimised.

Only for trainees with deeper knowledge

REACH: M/I have to gather information on substance properties and perform risk assessment for all identified uses in order to manage chemicals safely through all their life-cycle.

REACH: in-vitro methods shall increasingly replace in-vivo methods (decreasing of animal testing).

Authorisation

Current system	REACH
If risk assessment under 793/93 concludes on risk → risk reduction strategy is elaborated (which measures are the most cost effective?) Under Directive 76/769 a ban or use restriction may be decided	Authorisation: substances which are CMR (Cat 1 or 2), PBT/vPvB or "similar" may be put on authorisation list → substance may not be used anymore except one is owner of an authorisation (has to be applied for; M, I or DU may)
Under workers protection legislation, the substitution of dangerous chemicals at workplaces (especially CM) is first choice of measures if possible	Restriction: if at EU level it becomes clear that a substance poses a risk which shall be addressed at Community level, the restrictions procedure under 76/769/EC can be applied
CMRs (Cat 1+2) may not be used in consumer preparations	
POPs are restricted / banned	

A CMR does not automatically need to be authorised!!!!

There is no requirement to substitute!

Authorisation is granted only if the applicant can prove adequate control or a societal benefit that outweighs the risk.

"Knowledge management" under REACH

Current system	REACH
Manufacturers / importers provide information about substances •existing subst. risk assessments •notifying a new substances •Via safety data sheets.	M/I provide information in registration dossier and SDS Downstream users provide information about uses and conditions of use.
	Non-confidential data concerning properties, use and safety of chemicals will be available to the public and to the downstream users.
	All actors in a supply chain have duty to communicate.

Non-confidential data will be published in an open database by EU Agency

Communication up the supply chain by chemicals users is not obligatory under the REACH, but helpful for all and may be necessary to avoid having to make an own CSA

Single integrated system

Current system	REACH
"40" different regulations and directives	One regulation
Dual system for "existing" and "new" substances	The same requirements for all chemicals
Mixture of horizontal and vertical legislation	Vertical regulation from top ← excludes many cases for regulation downstream

REACH will replace current legislation[7] and apply directly. (No transposition required) It will not replace all chemicals-related legislation, e.g. biocides, cosmetics will remain.

Note: what is really new is that by assessing risks along the life-cycle, horizontal downstream legislation (also environment and workers health) should be covered.

4.3 Exercises

4.3.1 Exercise 1

Note: Recommended to be performed after introduction to REACH

Goal of the exercise: to bring up the concrete problems actors face at the moment and raise discussion whether these problems will be solved by REACH

Target group: all actors

Setting: actors-specific working groups of 4-5 persons

Questions to be discussed:

What problems you face today regarding chemicals management, list some 5.

Whether REACH will contribute to solving those problems and how?

Tools: Table with headlines (marked in **bold**) prepared on flipcharts/ handouts in advance and filled in during discussions by facilitator or participants. Each actor specific group discusses only their own experiences.

Actors	Problems	Will REACH help and how?
Manu-factu-rers	Difficult to C& L – no data	Yes: under REACH they will generate more data (also a burden!) BUT: Responsibly operating companies have already generated these data.
	Difficult to prepare SDS	
	Difficult to reply when asked for additional info	Yes/No: more data but all intended uses to be assessed
	High investments for new substances	Yes, more data available
	Many legal acts to comply with	Registration from 1 t/a, 5+5 years exception for PPORD
		Yes, 1 regulation
Impor-	Get bad quality SDS/ wrong C& L	Yes/No: more data but still quality of SDS

[7] Note: do not stress this too much, as it is a bit "shallow argument". These 40 pieces of legislation include e.g. also just amendments to directives etc.

Actors	Problems	Will REACH help and how?
ters		depends on expertise
	Don't get additional information from producer when asking	Yes, info made available
	Many legal acts to comply with	Yes: 1 regulation
Down-stream users	Missing info in SDS → difficult to assess, plan and apply risk management measures	Yes: more info available, assessment for their use made
	Info is not reliable, no info on priority haz. substances in preparation	Yes/No: more info but quality much depends on expertise of producer/ importer
	Difficult to comply with other legislation, which require info on used chemicals	Yes: more info for IPPC, WFD etc.
	Suppliers don't provide additional info	Yes: more info available
	Contradicting classification	Yes/No: REACH wants M/ I to agree on one entry in data base, no full harmonisation required!
	Many legal acts to comply with	Yes/No: REACH replaces legislation but still env., H&S etc. left
	Not big/ difficult choice of alternatives	Yes/No: more data – easier to compare; but requires expertise
State autho-rities	Too many directives → transposition	Yes: 1 legal act + regulation, but further implementing legislation is necessary! BUT: subordinated legislation must be developed and national procedures for control must be established.
	RA of existing substances	
	Lack of expertise on RA	
	Implementation+ enforcement	Yes: REACH shifts to industry
		No: still expertise will be needed for evaluation
		Yes/No: enforcement measures improved in REACH but still REACH is very complex
NGOs/ public	Not classified/ labelled chemical products	Yes, more info available on substances → help C&L of products
	Consumers complains about allergies etc. from products	Yes: better known properties; authorisation
	Public concerned about chemicals in the human, animals	Yes: better known properties; authorisation
	Small choice of env. friendly, ecologic products on the market	Yes: REACH enhances substitution principle
	Don't know how to dispose "end-of-life products" environmentally friendly.	Yes: REACH forces risk management for whole life-cycle
	Decrease of life quality due to loss of biodiversity, contaminated food etc.	Yes/No: more info available, better risk management, but many "historical" chemicals can not be taken out anymore

Reporting to plenum: flipcharts are hanged on the walls, each group has 3 min to report their findings/conclusions; common discussions

Timing: discussions in WG – 20 min; reporting to plenary and discussions – 20 min

Supporting material: presentations

4.4 Discussions in plenary

Check how much trainees know about current overall legislative framework on chemicals control.

Discussion with any group: What deficits of the current system they specifically face in their current everyday work? Which of them will be improved by REACH and which not? Why?

Discussion with manufacturers / importers: What could they gain from REACH - what is their experience with development of new substances/safer alternatives?

Discussion with formulators: How much do they know about uses of their preparations? What is considered as confidential information?

Discussion with DUs: Where do they need information on chemicals for compliance with other legislation? Whether they ask for information from supplies and whether they get it?

Discussion with NGOs: Does REACH really require less testing?

4.5 Further work for preparation for REACH

All: get more acquainted with REACH as a whole system and its specific mechanisms

Market actors: check availability of information on their chemicals, start communication along the supply chain

Authorities: help in raising awareness of industry on REACH and its explanation; provide updates on the REACH development process and proposals for changes

5 Roles and responsibilities under REACH

5.1 Introduction

5.1.1 Content of the chapter

REACH concerns all actors of the chemicals supply chain.

Manufacturers/importers of substances produced/imported above 1t/a are responsible to provide and communicate all information necessary to ensure safe handling of a substance:

- properties, classification and safe exposure levels (PNEC, DNEL);
- uses, potential exposures and risk management measures for substances produced or imported in amounts > 10 t/a;
- SDS (with exposure scenarios);
- recommend risk management measures in SDS.

Down-stream users (DU) of substances have to:

- compare information and advice given by the supplier with uses, processes and risk management measures in the own company;
- implement RRM as described in the SDS and ensure safe handling of the sustance → no risk occurs
- communicate relevant information upstream the supply chain.

Producers and Importer of articles have to register or notify dangerous substances in articles when they are intentionally or unintentionally release from the article (tonnage trigger > 1 t/a/importer/article type).

The Agency manages the REACH system. Among the tasks are

- ensuring a harmonized approach in evaluation
- resolving disputes about requests for information on substances in evaluation
- providing expert opinion and recommendations to the Commission in the authorisation and restriction procedures
- handling requests for exemptions from the registration requirement for PPORD
- facilitation of sharing of animal test data at the pre-registration stage (establishing SIEF)

The Commission

- oversees the work of the Chemicals Agency
- decides on proposals following substance evaluation if Member States fail to reach an agreement
- decides on authorizations and restrictions of substances.

The competent authorities in the Member States are responsible

- for checking and evaluating of registration dossiers
- for enforcing the new system within their territory

Member States provide expertise for the operating of Agency.

5.1.2 References to REACH regulation:

Roles and duties of stakeholders related to:

- Registration → Articles 5 -19
- Evaluation → Articles 38 - 46
- Restrictions → Articles 64 - 70
- Authorisation → Articles 52 - 63
- Information flow on the supply chain → Articles 29 - 33
- Data sharing → Articles 23 – 25
- Downstream users → Articles 34 - 36
- Agency → Articles 72 - 108
- Classification and labelling → Articles 110 - 112
- MS Competent authorities → Articles 118 - 121
- Enforcement → Articles 122 - 124

5.1.3 Further background information on content

Short overview on the main stakeholder roles and duties:

- The REACH Proposal Process description (prepared under RIP1), pages 13-18 http://ecb.jrc.it/reach/
- Guidance on roles and tasks for supply chain actors will be developed in the REACH implementation projects

5.1.4 Important terms related to the topic and links to other chapters

General terms: actors on the supply chain, registration, competent authority, communication down and up the supply chain, registration dossier, CSA/CSR, risk management, risk communication

Term	Simple explanation
REACH mechanisms	Duties and procedures originating from the draft legislation for the different actors in a supply chain
Completeness check	Checking whether all fields in the registration format are filled in with data.

Links to other chapters:

- Introduction to REACH – general overview → chapter 3
- Main changes: current/previous legislation to REACH → chapter 4
- Chemical safety assessment/ chemical safety report → chapter 7

5.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufacturers / Importers	Yes	What are the new responsibilities under REACH? How are responsibilities shared among actors? With which autority to communicate?	Responsibility for safe handling seen on DUs
Formulators	Yes	What will change under REACH? Which information may be kept confidential? What to communicate and when up and down the supply chain?	Confidentiality of information, communicating upstream
Industrial/ professional users	Yes	What are the new responsibilities under REACH What to communication and when up the supply chain? Is manufacture/importer obliged to consider their use?	Expertise to deal with received information
Traders (no import)	Yes	Do not have any obligations under REACH but will be involved in supply chain communication	May not see any responsibility
Ministries / state officials	Yes	Duties at EU and at country level Specific role in each REACH procedure How to organise shift in responsibilities, how to strengthen self-responsibility in industry	
Inspectors	Yes	Enforcement of all REACH mechanisms – need to know well who does what Develop clever and integrated inspection	Expertise
NGOS	Yes	They have no duties but got rights/possibilities under REACH	Expertise in order to contribute

5.2 Presentations

5.2.1 Roles and responsibilities of industry

Goal

Trainees should learn:

- what new tasks/duties REACH imposes on industry and why they are necessary in order to improve chemicals management;
- what duties and procedures originate from the draft legislation for the different actors on the supply chain.
- logics of self – responsibility of industry and REACH-integrated “enforcement” mechanisms in the market and by inspections

Key messages

Under REACH, a shift and (re-)definition of responsibilities for the safe handling of chemicals is established.

Industry has to ensure that their products are handled safely. The system provides for incentives and mechanisms how market actors control each other.

Authorities have to enhance the system by checking quality of registration dossiers and implementing enforcement measures at company level.

REACH provides standards for knowledge management and risk communication.

Implementation of REACH mechanisms requires cooperation and communication among all actors on the supply chain, both down-stream and up-stream.

The REACH market mechanisms only function when companies take their responsibilities. It bases on the actors' motivation to avoid business risks, negative publicity and unnecessary costs.

Presentation and explanation

Slide of presentation	Comments, key messages
REACH **Roles and Responsibilities of Industry**	
Safe handling of chemicals… • requires: – communication of information on: • potential risks (properties, safe levels and exposures) • ways to avoid them (risk management) – means to understand the information and to implement the respecitive measures	General introduction on why clear roles and responsibilities facilitate the safe handling of chemicals! You may also repeat the goals of REACH

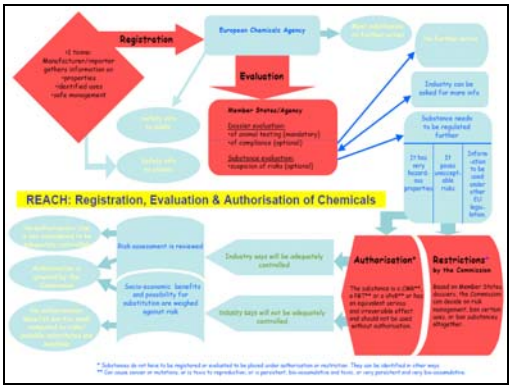
Division of responsibility

- manufacturers and importers:
  - generate / collect information (tests, uses...)
  - process them to be understandable (SDS and Annex to it)
  - communicate them downstream
- users of chemicals:
  - implement recommended measures
  - communicate deviations and additional information upstream (and to the agency)

Advantages of the system

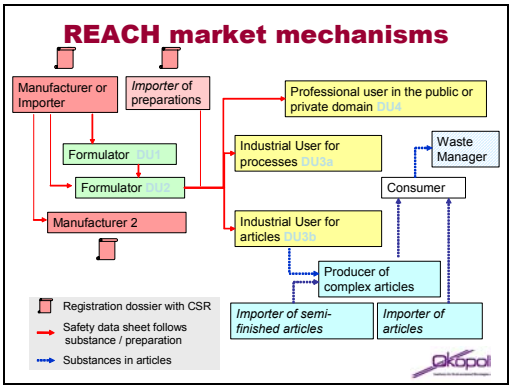
- A few manufacturers work for many downstream users
- Information gaps are filled for all actors
- Liability and business risks are reduced
  - clear tracing of „who is guilty“
  - knowledge to take „better“ decision is provided
  - cooperation is facilitated, common language developed

Advantages for the single actor. This slide could be also discussed in plenum after the presentation and filled with examples and details!



Start from obligation to register substances in amounts >1 t/a.

Presentation focuses on new tasks but doesn't give details (see other chapters for that)



"REACH mechanisms": duties and procedures for different supply chain actors

DUs under REACH: formulator, professional, industrial users

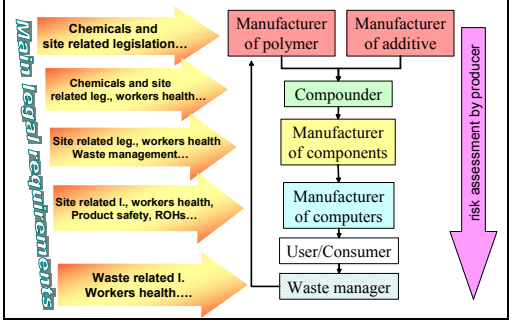
Here the roles of the participants in the supply chain can be questioned and discussed.

REACH focus

– Substances on their own, in preparations, in articles
– Intrinsic properties **and** exposure
– Supply chain/ life-cycle approach
– Shared responsibilities among the actors on the supply chain
– Communication on the supply chain

Aspects/elements of REACH, which cause new tasks/duties to industry/trade

REACH: Supply chain approach example: plastic additive in computer components

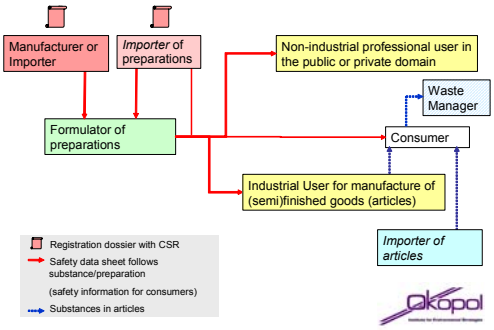


Manufacturer assesses risks for the entire life-cycle (ensure safe use)! Covers different actors, crosscutting different legislation

Example plastic additive in computer components → legal integration to be worked on in the future!!!

ROHs – regulation on hazardous substances in electric appliances

Information flow under REACH



Stress that division of responsibility is defined by forwarding SDS with information on safe use! Supplier "guarantees" if use accords to Annex of SDS and RRM recommended, he is responsible. If DU does differently, he takes responsibility for that.

Information flow under REACH (1)

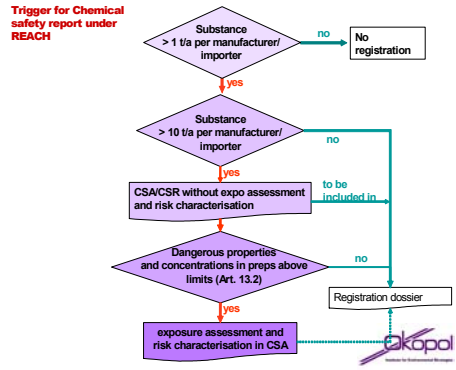
Tasks of producers/importers of substances

Preparation of Registration Dossier, incl. information on:

- members of consortia
- identified uses
- quantities and composition of waste resulting from production and identified uses (where known)
- uses advised against
- statement as to whether or not information has been generate by testing vertebrate animals
- proposals for testing where necessary
- declaration whether information is shared with subsequent registrants
- when required: chemicals safety report (CSR)

Slide focuses on "new type of information" on substance required by REACH.

Full list of information to be provided with technical dossier see Article 9 and Annex IV



Trigger is valid for manufacturers and importers!
Exposure scenario is added as Annex to SDS.
Safety assessment is check whether the product is safe for a use!

Information flow under REACH (2)

Tasks of producers/importers of substances

Preparation of chemical safety report: Generation and collection of information on and assessment of

- Substance properties
- Substances uses
- Exposure scenarios (workers, human beings and the environment)
- Adequate risk management

Communication of relevant information to down-stream users ***via safety data sheet***:

- Identified uses of the substance
- Uses advised against
- Classification and labelling
- Exposure scenarios (from CSR)
- Guidance on safe use, toxicological no effect levels, risk management advice based on CSR

What is really new?

1) derivation of PNEC and DNEL (former: authorities derived e.g. environmental quality standards or occupational exposure limit values)

2) PBT assessment

3) assessment of uses and exposures

Stress what is “new” in SDS

Information flow under REACH (3)

Tasks of importers of preparations:

– Identification of ingredients of preparation

– Registration dossier for ingredients > 1 t (per importer)

– Combination of information on contained dangerous substances

Importer of preparation needs to seek information on substances in preparations!

Information flow under REACH (4)

Tasks of DU of dangerous substances/preparations

- Compare information and advice of supplier with uses, processes and risk management measures in the own company.
- If compliance is given (“identified use” and risk management), DU may use the substance
- If compliance is not given (“non identified use” or less risk management), DU has different options:
  - adapt own processes and uses to comply with advices,
  - contact supplier to request for assessing and adding the different process in the exposure assessment,
  - notification of deviance (if amount > 1tpa) and preparation of own chemical safety report,
  - look for another supplier, who offers the same product and whose advice compatible.

Discuss:

Why would a DU not inform a supplier?

Why may a supplier not take up a use in his assessment? What are the consequences for the supplier and the DU?

Information flow under REACH (5)

Tasks of manufacturer of preparations

- Combine information on substances (from substance SDSs or own CSR)
- Advice on uses of preparation
- Communicate information on preparation via SDS for further DU

Same duties as all other DUs. In addition: combine information from SDSs of suppliers and communicate down the supply chain.

Mechanism for articles

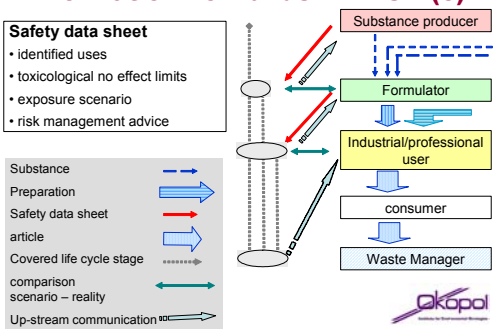
Tasks for manufacturers and importers of articles:

- Collect information on the content of dangerous substances (kind of substances, amount per type of article)
- Estimate release of dangerous substances (intended or not intended, during processing, use and disposal)
- Assess risk of released substances for humans and the environment

REACH covers also substances in articles, which may be released intentionally or not! This applies to manufacturers and importers!

Discuss what benefit this has got regarding the safe use of chemicals and the entire REACH system (safety net if producer uses only EU-chemicals, not registered uses would be detected!)

Information flow under REACH (6)



Summary on info flow under REACH

Roles and responsibilities of industry (1)

- Management of risk information in the market
  - Generation of basic information on properties
    - to classify, label and assess hazards
    - to identify PBT/vPvB
    - to ensure basic and general risk management
  - Collection of information on uses
    - determine potential types and levels of exposure
    - define safe conditions of use including the necessary risk management measures
- Risk management triggers the type of information to be sought! No data which isn't used

REACH aims at well informed risk management. Good information on hazards and uses of substances is a prerequisite for that.

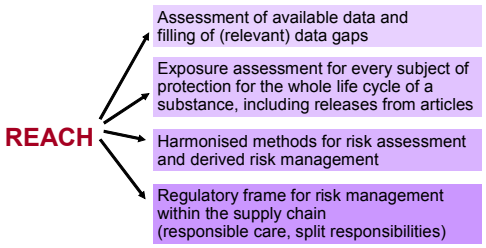
Roles and responsibilities of industry (2)

- Chemicals risk management in the market
  - documented chemicals safety assessment
    - for all identified uses and all subjects of protection
    - along the life-cycle of a substance
    - considering risk reduction measures and including a characterisation of potential risks
  - risk communication
    - down-stream: "translation" to understandable information for SDS, exposure scenario defines border of responsibility
    - up-stream: uses, unidentified uses, information on exposure, information request to be able to take over responsibility

Roles and responsibilities of industry (3)

- Chemicals risk management in the market (cont.)
  - Risk reduction
    - unsafe uses are not to be "identified"
    - unsafe conditions of use are to be excluded by definition of the exposure scenario
    - all actors profit from better information basis when targeting their risk reduction measures
- New roles and tasks for all actors in the supply chain require more cooperation and communication

Summary – Market Mechanisms under REACH



5.2.2 Roles and responsibilities of authorities

Goal of presentation

Trainees should understand:

The involvement and roles of different authorities under the main procedures of REACH, e.g. registration, evaluation, authorisation, restriction as well as in a whole REACH system.

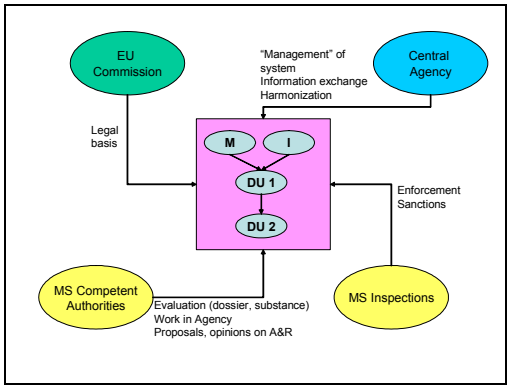
Key messages

- Four main authorities are involved: European Commission, European Chemicals Agency and competent authorities in the Member States, inspections in the Member States.
- The Agency will manage the technical, scientific and administrative aspects of the REACH system. An important task is to harmonise approaches in the MS. The Commission will oversee the implementation of REACH by all actors and especially the Chemicals Agency. It will be involved in evaluation, authorisations and restrictions of uses.
- Inspections are necessary to enforce REACH. What to inspect and how as well as sanctions are tasks of the MS.
- State authorities will need expertise which may not be existing yet. The MS CA is the main responsible for checking and evaluating of the dossiers and substances and needs to provide much of the expertise to Agency.
- While authorities get a number of new duties under REACH, they retain traditional roles, such as ensuring a level of playing field, enforcement, support and advice.

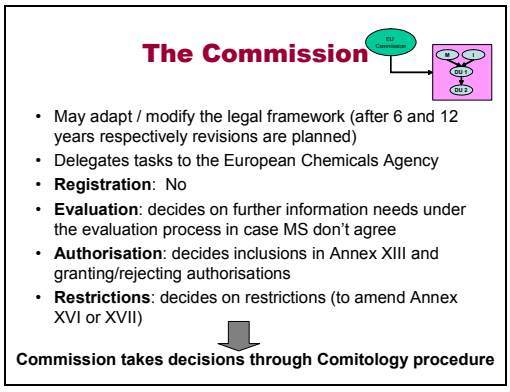
Presentation and explanation

Slide of presentation

Comments, key messages



Introduce “types” of state authorities involved into REACH and identify on very general level what is the very main general duty of them



Overview on general Commission’s tasks and mechanism-specific.

Comitology procedure: Commission takes decision after so-called “comitology” committee, composed of representatives of MS has given its opinion on the Commission proposal.

(The majority of measures with legal consequences in the EC are not adopted by the principal legislative authorities (Council and Parliament), but by the Commission after the Council and/or Parliament have conferred implementation powers on it)

y

It is worth to mention that in the registration process, no formal acceptance of data is foreseen, only completeness check (computerised process!). Industry retains responsibility for quality of data

European Chemicals Agency

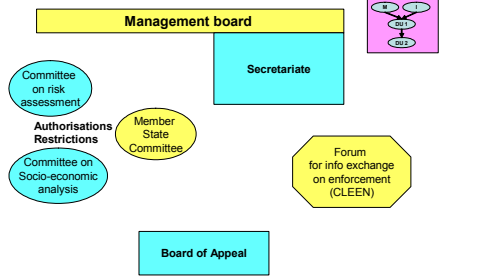
Other roles:

- Performs pre-registration
- Facilitates contacts and operates rules for data - sharing
- Advises (opinions, recommendations)
- Provides guidance, formats, tools
- Develops prioritisation criteria
- Receives and checks PPORD exemptions
- Manages transperancy, database - publishes data bases and runs info web-sites
- Deals with appeals – registration, R&D, evaluation, confidentiality

Agency will be in Helsinki, financing via fees of industry

Communication of industry with national authorities → language

European Chemicals Agency



Management Board: 6 nominated by Council, 6 by Commission, 3 non-voting stakeholders

Committees: 1) MS: substance evaluation, C&L, identification of SVHC. MS may nominate 1 expert member not representing a MS; 2) RA: opinions on risk assessments; 3) SEA: opinions on socio-economic analyses (authorisation applications and restrictions procedure)

Technical and scientific Secretariat: registration, C&L, Agency decisiosn, management of Committees

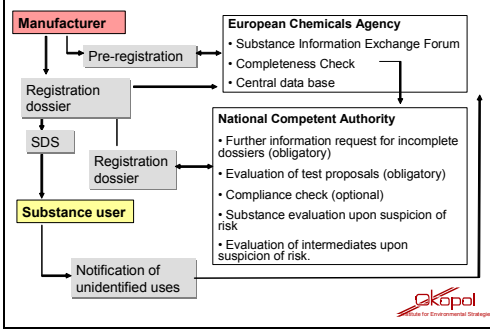
Foreseen staff ~200 persons

MS Competent Authorities

- Checking / evaluating dossiers / substances
- Contribution to work at EU level (e.g. Committees)
- Proposals for restrictions/substance evaluations
- Ensuring enforcement and establishing sanctions (Member State governments, inspections)
- Report about implementation and enforcement to the Commission

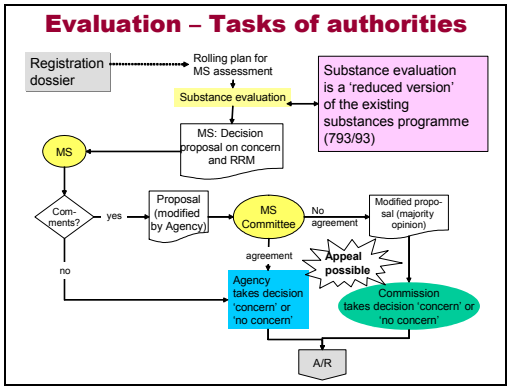
MS CA has biggest responsibility in evaluation (dossiers and testing proposals).

Registration – Tasks of authorities



Explain flow of documents

Commission is not involved in registration. The main responsible for registration – Agency. MS are mainly dealing with enforcement regarding registration.



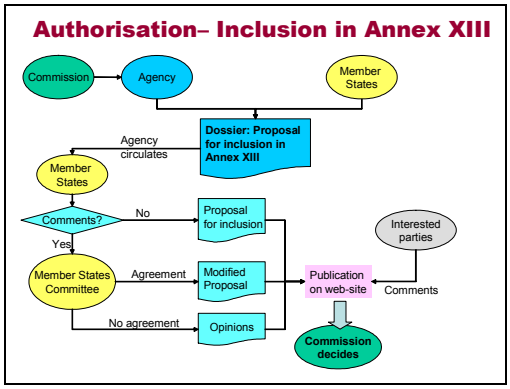
Explain differences of evaluation of dossier's and substances

The Authorisation procedure

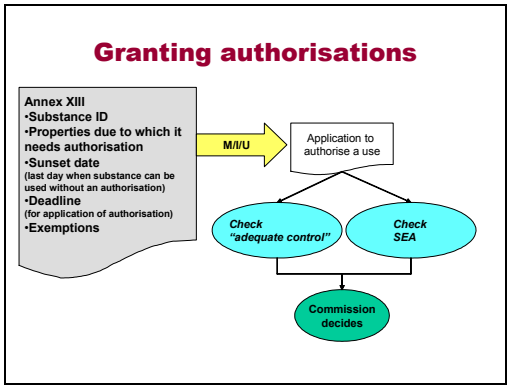
- Candidates for authorisation, criteria:
  - CMR 1+2 (existing list + newly detected)
  - PBT, vPvB (list in progress)
  - hazardous properties of similar concern (unclear)
- The Commission will propose the first substances for Annex XIII
  - industry gains security on which substances will be affected
  - more substances included subsequently

Important! Authorisation does not mean "No registration".

Annex XIII will be empty when REACH will come into force.



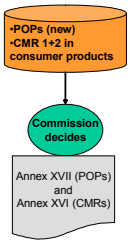
CMRs, PBTs and SVHC will not be "automatically" subject to authorisation!



When a substance is included into Annex XIII, the application and sunset date (18 months later) are set.

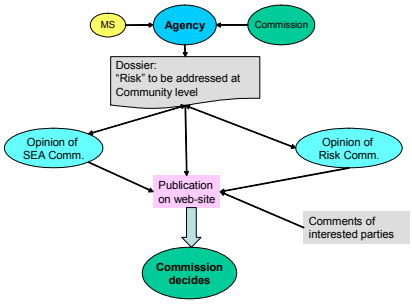
In the application for authorisation, safe use must be proven for that use by applicant. Anyone can apply!

Restriction procedure (1)



For POPs and CMR fast track will be applied.
Annex XVII contains only POPs, Annex XVI all other restrictions including a consolidation of restrictions contained in 76/769/EC.

Restriction procedure (2)



Safety net, applies for risks at community level (not local!)

Inspections

- Will control at DU level
  - use and exposure scenarios apply
  - no risk results from use
- Expertise and responsibilities will have to be discussed, as inspection strategies will have to be reconsidered!!!!

Inspections will have to be reorganised!
Important to enforce the implementation of safe handling at DUs
Important incentive to comply with the REACH requirements!

Summary – Roles and responsibility of authorities (1)

- The traditional role of authorities:
  - Ensure a level playing field
    - standardised procedures and equal requirements in the EU
    - promote "European standard" in international trade
  - Ensure compliance
    - control that requirements are complied with
    - prevent free riders
  - Support and advice
    - practical assistance in technical questions
    - help desk to provide guidance and answers to questions
    - knowledge transfer?

Summary – Roles and responsibility of authorities (2)

- Authorities' role in the EU context
  - Risk assessment
    - quality checking of registration dossiers (+ testing proposal)
    - substance evaluation → cumulative risk at EU / global level which is invisible to single actors
  - Risk reduction at EU level: initiative and / or contribution to restrictions or authorisation procedure
  - Contribution to various committees
- Management role of authorities
  - facilitation of industry cooperation (identification of partners, (SIEF), data sharing)
  - flow of documents (registration dossiers, CSAs, notifications…)

Summary: Authorities - Who does what?

	Agency	Member States authorities	European Commission
Registration	Receives registration dossiers. Checks them for completeness. Maintains the database and provides information to the public.	Enforcement.	-
Evaluation	Co-ordinates the work of the Member State authorities, develops evaluation criteria, takes decisions on requesting more information from industry if all Member States agree.	Review individual dossiers. Prepare rolling plans for substance evaluations and carry them out. Prepare draft decisions on further information requirements.	Takes decision on requesting more information from industry if Member States don't all agree
Authorisation	Publishes applications on its website. Recommends priorities. Committees draft opinions. Supports Commission in decision-making.	Submit proposals for substances that are considered to pose serious and irreversible effects equivalent to CMRs, PBTs and vPvBs.	Takes decisions on priority setting (step 1) and on granting authorisations (step 2)
Restriction	Provides opinions and comments. Publishes the Member State restriction proposals and its Committee's draft opinions on the Internet.	Submit proposals	Takes decisions on restrictions of production, marketing and use.

This slide could be applied when there is a time pressure and only general idea is needed, e.g. in NGOs training

Other stakeholders: industry groups/ associations, NGOs, public

Possibilities:

- Access to non-confidential information via Agency's web-site
- Request access to information
- Authorisation:
  - Provide comments on substances which Agency proposed to be prioritised and on uses which are to be exempted from the authorisation requirements
  - Provide information on possible alternatives
- Restrictions:
  - Provide comments on restriction poposals
  - Provide socio-economic analysis fro suggested restrictions or information to contribute to one
  - Provide comments on draft opinions from RA and SEA Committees of Agency

This slide does not fall under any topic but important to show and explain when NGOs/ associations are trained. It is related to their rights.

5.3 Exercises

5.3.1 Exercise 1 - Characterisation of supply chain actors and their current and future tasks

Note: Exercise for industry.

Goal of exercise: to deepen participants' understanding on:

the place of the own company in the supply chain

current chemicals-related tasks under the legislation/ future tasks under REACH associated with the role of the company on the supply chain

Target group: different actors on the supply chain: manufacturers, formulators and industrial/prof. users

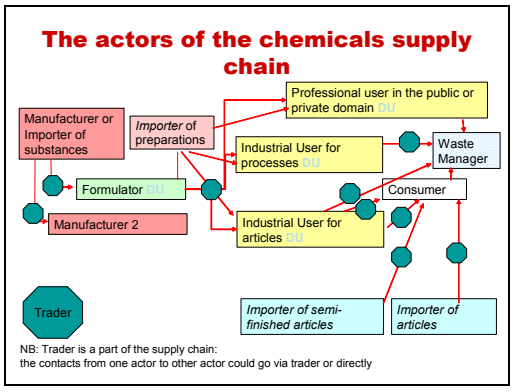
Setting: actors-specific groups of 6-8 participants

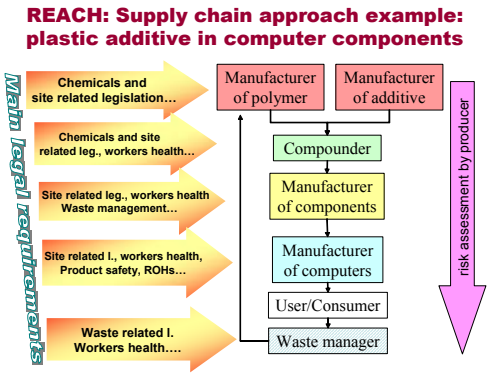
Questions to be discussed:

What is my company's main role in the supply chain? (in case of DU: which type of DU?) Which other roles my company has?

What are the current tasks under chemicals legislation/ future tasks under REACH associated with the role of the company on the supply chain?

Tools: Both schemes – actors and supply chain approach - to be once more introduced in plenary before the working group.





Participants split into groups. Trainers go around and help with the identification of roles. It is recommended to facilitate the work on current/ future tasks by trainers.

Table with the answers for discussion on current/future tasks:

Role in the supply chain	**Current tasks under chemicals legislation**	**Tasks under REACH**
Manufacturer of substances	Collect information on properties of substance (no testing) for classification Perform testing - for new substances Classify & label Prepare SDS Prepare registration dossier – for new substances (*also biocides, pesticides, pharmaceuticals**) Assess chemicals risk – only active substances in biocides and ppps and specific ones* Propose risk reduction measures (SDS) Communicate info on substances downstream (SDS, label) Follow bans and restrictions	Collect information on properties of substance (no testing) Perform testing if info is not available Classify & label Prepare SDS (also with exposure scenarios) Prepare registration dossier for all substances in amount of >1t/a CSA/CSR for substances in amounts >10t/a Collect info on uses of substance Exposure scenarios for dangerous substance in >10t/a Propose risk reduction measures Communicate info on substances downstream (SDS, label) Follow bans and restrictions Aim to agree with others on harmonised classification Share information on vertebrate tests
Importer of substances	Same as for manufacturer	Same as for manufacturer
Importer of preparations	Collect information on properties of substances (no testing) for classification Classify & label Prepare SDS Propose risk reduction measures (SDS) Communicate info on substances downstream (SDS, label) follow bans and restrictions	Identify ingredients of more >1t/a Collect information on properties of all (!) substances in preparations (including testing if info not available) Classify & label Prepare SDS (also with exposure scenarios) Communicate info on substances downstream (SDS, label) Prepare registration dossier for all ingredients in amount of >1t/a → the same further info as for importer/manufacturer of substance to combine info on dangerous substances in case of dangerous preparations
Producers and importers of articles	follow bans and restrictions	collect info on the content of dangerous substances in articles estimate release of dangerous substances during all life cycle assess risk of released substance to human health and environment

Formulator	Collect information on properties of substances (no testing) for classification of preparation Classify & label Prepare SDS Propose risk reduction measures (SDS) Communicate info on substances downstream (SDS, label) follow bans and restrictions	communicate uses upstream compare information and advice of supplier with own conditions if not in compliance, communicate with supplier or notify deviance and prepare CSR Classify & label to combine info on dangerous substances in case of dangerous preparations Prepare SDS Communicate info on substances downstream (SDS, label)
Industrial/professional user	follow bans and restrictions	communicate uses upstream compare information and advice of supplier with own conditions if not in compliance, communicate with supplier or notify deviance and prepare CSR

* these have specific requirements, further on called specific substances

Note: each group works only on their own tasks and duties under legislation!

Reporting to plenary: groups present their results, other groups comment. Common discussion on whether the tasks of actors change with REACH a lot.

Timing: introduction to WG & schemes – 5 -10 min, discussions in WG: on roles – max. 15 min, on tasks – 30-40 min; reporting to plenary and discussions – 20 min

Supporting material: scheme of the supply chain, presentations

5.3.2 Duties and involvement of stakeholders under REACH

Note: Exercise recommended for authorities and stakeholders groups other than industry

Goal of exercise: to deepen knowledge on the duties and involvement of different stakeholders under REACH

Target group: authorities, NGOs

Setting: groups of 5-7 persons

Questions to be discussed:

What are the main duties of industry under different REACH procedures?

How the authorities of different levels will be involved under different REACH procedures?

Tools: Table with headlines (marked in **bold**) prepared on flipcharts/ handouts in advance and filled in during discussions by facilitator or participants.

	Industry	Agency	Member States authorities	European Commission
Registration	Collects and submits data. Assesses risks and identifies risk management measures. Keeps registrations updated. Proposes testing schemes.	Receives registration dossiers. Checks them for completeness. Maintains the database and provides information to the public.	Enforcement.	---
Evaluation	Provides further information if required.	Co-ordinates the work of the Member State authorities, develops evaluation criteria, takes decisions on requesting more information from industry if all Member States agree.	Review individual dossiers. Prepare rolling plans for substance evaluations and carry them out. Prepare draft decisions on further information requirements.	Takes decision on requesting more information from industry if Member States don't all agree
Authorisation	Submits application dossier	Publishes applications on its website. Recommends priorities. Committees draft opinions. Supports Commission in decision-making.	Submit proposals for substances that are considered to pose serious and irreversible effects equivalent to CMRs, PBTs and vPvBs.	Takes decisions on priority setting (step 1) and on granting authorisations (step 2)
Restriction	Provides socio-economic assessments.	Provides opinions and comments. Publishes the Member State restriction proposals and its Committee's draft opinions on the Internet.	Submit proposals	Takes decisions on restrictions of production, marketing and use.

Reporting to plenary: 1 group reports, others add up/ comment. Discussion on misunderstandings, open questions.

Timing: discussions in WG – 30 min; reporting to plenary and discussions – 20 min

Supporting material: presentations

5.4 Discussions in plenary

Check if everybody from industry understood where they stand in the supply chain and whether they have several roles.

Discussion with all: Why consumers and waste companies appear on the chemicals supply chain and what is their role under REACH?

Discussion with market actors: Their current experiences regarding communication up/down the supply chain. Experience with collection of information on chemicals.

Discussion with DUs: What is the quality of SDS currently? For what they are using SDS info at the company?

Discussion with manufacturers / importers: How much they know about uses of their substances?

Discussion with importers: Do they have own chemical experts in the companies? Who is making SDS, classifying/labelling substances/preparations?

Discussion with authorities: What are major problems in enforcement of current legislation? What are current main incompliances with legislation?

5.5 Further work for preparation for REACH

DUs: Clarificy roles in the supply chain

Market actors: check availability of information on own substances, start communication along the supply chain on uses, determine own wish to keep substance and conditions of use confidential, get an overview on markets and uses of substances

Authorities: enhance enforcement of current legislation, take part in RA work on existing substances at EU level, twinning with experienced MS in testing projects.

6 Information collection on hazards

6.1 Introduction

6.1.1 Content of the chapter and reference to the REACH proposal

Data needs on substance properties are triggered by the market volume (Annexes V-VIII). Information on substance properties, which is not available, is to be generated by the registrant. Exposure data is to be collected only for the safety assessment[8].

Registrants may used available data, read-across approaches or QSARs to substitute testing. Vertebrate test data must be shared[9] other test data may be shared. Vertebrate data older than 10 years can be made available by the Agency for free. For vertebrate studies younger than 10 years the Agency may forced data sharing, even if the owner does not want that. Here the costs are to be shared. Available data must be submitted with the registration. If the data is not available, only the testing proposal is to be submitted in the registration. In registration dossiers of consortia all property data may be submitted jointly. For higher volume chemicals, exposure driven waiving of data needs is possible. For substances produced / imported in amounts > 100 t/a, tests are to be proposed in the registration dossier and may be carried out only after approval by the authorities. On request of authorities (dossier evaluation, substance evaluation), further data on a substance than required in the Annexes may have to be provided.

6.1.2 References to REACH

REACH contains the following articles related to information collection on hazards:

- information to be submitted depending on tonnage → Article 11, Annexes IV-IX;
- general requirements for the generation of information on intrinsic properties of substances → Article 12, Annex X;
- data sharing and avoidance of unnecessary testing → Articles 23-28;
- cost sharing for tests involving vertebrate animals → Article 50;
- description of testing methods (Volume III to V)

[8] This will not be discussed in this chapter. See chemicals safety assessment and exposure assessment chapter on that.

[9] Vertebrate data older than 10 years can be made available by the Agency for free. For vertebrate studies younger than 10 years the Agency may forced data sharing, even if the owner does not want that. Here the costs are to be shared. Available data must be submitted with the registration. If the data is not available, only the testing proposal is to be submitted in the registration.

6.1.3 Further background information on content

Instructions where to start information collection on a substance by using available Internet resources:

→ ESIS – European chemical Substances Information System (European Chemicals Bureau)

Search by CAS No or substance name in ESIS - EINECS and ELINCS database. Information on risk assessments of existing substances (Council Regulation 793/93). High and Low Production Volume chemicals – list of EU producers / importers, classification and labelling information if classified in the Annex I of Directive 67/548/EEC, IUCLID chemical data sheet and European Risk Assessment information (if available). IUCLID chemical data sheet contains overview of available test data with references. http://ecb.jrc.it/esis

→ Riskline

Riskline contains over 7,000 bibliographical references to peer-reviewed information on 3,000 chemical substances. Contains information on both environmental effects/ecotoxicology and health effects. Search by CAS no.

http://www.kemi.se/riskline/index.htm

→ TOXNET

TOXNET is a cluster of databases on toxicology, hazardous chemicals, and related areas http://toxnet.nlm.nih.gov/

6.1.4 Important terms related to the topic and links to other chapters

General terms: manufacturer, importer, downstream user, PPORD, notified substance, phase-in substance.

Term	Simple explanation
In-vivo tests	a study conducted using a living animals
In-vitro tests	a study conducted with tissues, cells or substances in solution in a controlled model system and not a living animal or organisms
Ex-vivo test	pertaining to a biological process or reaction taking place outside of a living cell or organism
(Q)SARs	qualitative structure-activity relationship models – model to predict properties based on molecular structure
Read-across	Grouping of substances of which it is assumed that their properties change regularly depening on their structure, e.g. decreasing volatility with increasing chain lengths of alkanes
Waiving	Refraining from testing requirements based on strong argumentation that exposure is very unlikely. If e.g. contact of humans with a substance can be excluded throughout the entire life-cycle, reprotoxicity tests may be omitted. This has to be decided by the authorities based on the information in a CSR[10].
Omission of PC-data	Information requirements on physico-chemical properties may be omitted in the registration, if other data show that they are not necessary. E.g. if a solid substance is proven to be explosive, flammability information does not have to be tested.
SIEF	Part of internet based information system organised and maintained by the European Chemicals Agency, where all pre-registrants of one specific substances are member of. It aims at facilitating data sharing and the formation of consortia in general.

Links to other chapters:

Chemical safety assessment → chapter 7

Hazard assessment → chapter 8

Information sources → chapter 14

6.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufacturers / Importers	Yes	How to find out what is needed? (practical assistance) Strategies to obtain data in the most efficient way.	Frustration because of "many tests needed"
Formulators	Hardly, only specific cases	May carry out tests or propose testing in the frame of a DU CSA	

[10] Waiving is possible only for substances produced / imported in amounts > 10t/a (starting in Annex VI)

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Down-stream users	Hardly, only specific cases	May carry out tests or propose testing in the frame of a DU CSA	Lack of experience and human resources
Traders (no import)	No	Don't have to collect information on hazards	
Ministries / state officials	No	Don’t have to collect information on hazards	Lack of expertise
Inspectors	No	Don't have to collect information on hazards	
NGOS	Only partly	Principles of data generation and collection Accessibility of information on substance properties	Low expertise and understanding of chemicals issue
Scientific institutions	Only partly	May provide information, interested in a broader data base on substances	Trust in existing data (validity)

6.2 Presentation

6.2.1 Information collection

Goal

Trainees shall understand:

- where information collection is regulated and needed under REACH (all)
- which options exist to avoid testing and how to organise an efficient data collection (all)
- practical steps how to collect information (manufacturer/importer)
- one opportunity is to form a consortia (manufacturer/importer) or share data (all)

Key messages

The purpose of registration is to ensure that the minimum information necessary for safe handling of a substance is compiled and communicated prior to its marketing. This information includes data on substance properties.

Testing is very last choice of data collection on substance properties.

Information collection is an iterative process. It starts from the identification of a substance’s production/import volume, listing data requirements (see relevant Annexes) and then starting to search all available information.

All possible available existing data and alternative data (QSAR, read-across etc.) can be used in certain conditions for identifying substance hazards.

Presentation and explanation

Slide of presentation	Comments, key messages
Information collection on substance properties under REACH	
Content • Requirements for information collection on substance properties under REACH • Practical steps how to start information collection • Sharing information • Conclusions and further steps	
Requirements for information collection • Data collection based on risk – volume triggers data needs on properties – based on exposure information, requirements can be waived • Information needs base on risk management needs – low volumes: data suffices for accident response and workers protection – higher volumes: long-term exposure likely → chronic testing for human health and environment	Volumes indicate (!) a potential risk. Some substances may nevertheless not be emitted at all. Be prepared to argue on this with industry!

Registration – exemption from the scope

- Substances covered by other legislation, e.g. medical products, additives in food- and feeding stuff
- Substances listed in Annex II (known to not be harmful)
- Substances in Annex III (results of unintended chemical reactions, not marketed by-products...)
- PPORD, 5 +5 years upon justification
- Polymers (may be addressed in the future)
- Deemed to be registered
  - Pesticides, biocides (for that use!)
  - Notified substances (67/548/EEC)

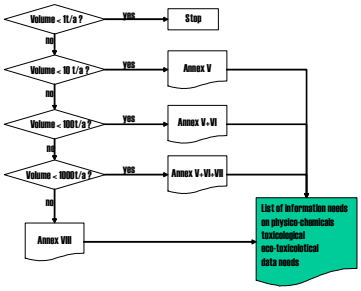
Criteria for substances in Annex II are unclear, List may be expanded.

Annex III: not that by-products have to be registered if they are marketed!

PPORD does not have to be conducted at the manufacturer's site, but also in a DU installation.

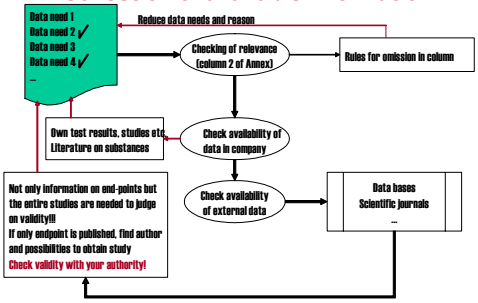
If biocides or pesticide active substances are applied for another use than biocide or pesticide, this respective use has to be registered.

Overview identification of info needs



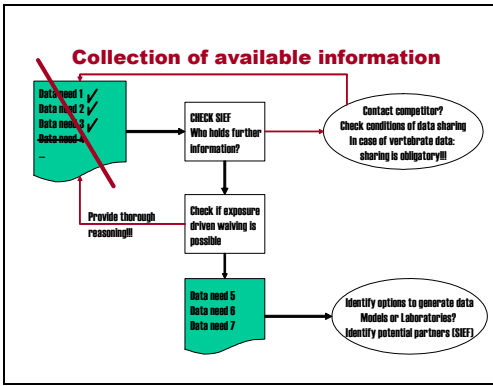
If information is available it must be always submitted, also if it is not required! It must be used e.g. to determine the classification and labelling.

Collection of available information



Details on the single steps are given later, this is only the overview!

Collection of available information



Rules for omission

- In column 2 of the Annexes V-VIII rules for omission are given for each end-point, e.g.
- Basis is subsidiarity/obvious non-sense
  - boiling point for gases
  - self-ignition temperature of explosives
  - aquatic toxicity of insoluable substances
- Basis risk management options, e.g.
  - no skin irritation if substance is corrosive

This sort of rules does not have anything to do with exposure driven waiving but just common sense!

Checking own data

- Tests may have been conducted earlier
  - documentation must be available and complete, e.g. methods, results...
  - should be conducted according to standard methods
- Literature may be available in the company
  - it is not enough to just provide the result, but the test conditions must be transparent (see above)

When using available data it should be checked if the studies are valid. Validity criteria will be developed by the EC. It may be useful to check with the competent authority.

External information sources

- Data banks on substance properties (examples)
  - **IUCLID** http://ecb.jrc.it/esis →Data sets show which company has conducted which test
  - **Riskline** http://www.kemi.se/riskline/index.htm
  - **TOXNET** http://toxnet.nlm.nih.gov/
- Literature research
  - scientific journals (environment, medical data banks)
  - thesis works of students...
- Identification of authors and „purchasing“ of study may be necessary !

There are many more data bases on the internet, but many do not identify authors of studies!

It has shown that additional literature research is very laboursome and shows little results, most data is on the internet!

SIEF

- The aim of substance information fora is to facilitate cooperation and data sharing of registrants
  - check who registered and holds with information
  - decide whether or not and with whom you would share data, decide what you can offer (data, money)
  - get in contact and negotiate
  - Note that vertebrate data must be shared

The SIEF is made to exchange data! Data sharing is not a consortia but a bilateral agreement between companies!

The agency can make vertebrate studies available for free if it has been conducted more than 10 years ago. When sharing other studies, the cost for that shall be borne by all registrants wishing to use it.

Use of existing data – Annex IX

- Existing data need not have been conducted under GLP:
  - physical-chemical properties
  - animal experiments
  - Historical human data – epidemiological studies
- Rules on validity leave room for interpretation, guidance will be developed
- If unsure → discuss with Competent Authority

It is not yet clear, what criteria will be applied for the validity of tests. In general authorities state that they are rather willing to accept existing data…

You may read the Annex with the group when discussing this and the following slides

Weight of evidence – Annex IX

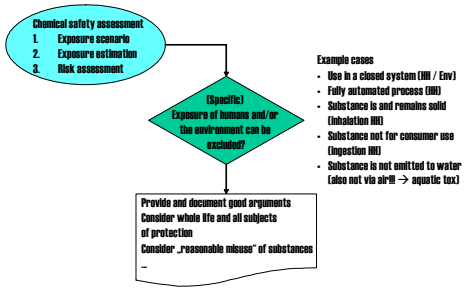
There may be sufficient weight of evidence from several independent sources of information leading to the conclusion that a substance has or has not a particular dangerous property

while the information from each single source alone is regarded insufficient to support this notion

In all cases adequate and reliable documentation shall be provided

This exists also currently for classification and labelling. It requires expertise!

Exposure driven waiving



Options to generate data

- If no data can be made available, it must be generated
- Testing or alternative data can be provided
- Laboratories / experts should be consulted
  - Applicability of different methods
  - Costs and time
- Contact other registrants (SIEF) which may also have to conduct the test if you want to share costs!

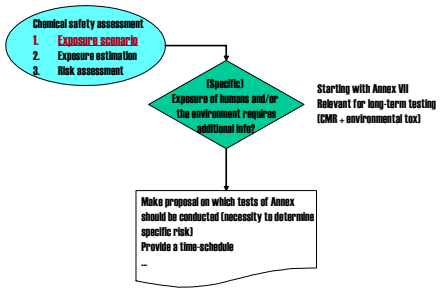
Alternative data – Annex IX

- (Q)SARs - qualitative structure-activity relationship → consult experts if models can be applied
- „Extrapolation" of properties → requires special expertise
  - Grouping of substances with similar structures or structures following a regular pattern
  - Read-across: interpolation of data within the group, 1 reference substance, others are derived avoids the need to test every substance for every endpoint
  - Example: volatility of alkanes decreases with increasing chain lengths

QSARs are available only for a few end-points. Extensive research is ongoing to reduce testing costs.

Both QSARs and Read-across require expertise and may well be outsourced to experts.

Exposure driven testing proposals



Guidance on how to determine the need for additional substance property information will be provided in the frame of the RIP process (preparation of registration dossier)

Consortia I

- One producer prepares (part of the) registration dossier representing all the others Sharing of information on
  - identity of registrant... → not possible
  - substance properties → encouraged
  - uses and exposures → up to companies to decide (confidentiality!)
- No rules for consortia under REACH, except for fees

Consortia are voluntary!

OSOR proposal → obligatory consortia! Not clear if the modification will be accepted or not

Consortia II

- Advantages
  - sharing of data (reduces costs) and evaluation
  - less efforts for authorities
  - SMEs have better chances to register substances
  - ...
- Disadvantages
  - risk of foul play and exclusion of competitors from consortia
  - administrative efforts are high
  - who is responsible at the end?
  - ...

Discuss more advantages or disadvantages

Summary

- Identify data needs for the substance
- Start with easily available information, iterate further data needs also accounting of potential exposures
- Assess all possible sources before conducting tests
- Consider whether forming / joining a consortia is benefitial or not

6.3 Exercises

6.3.1 Exercise 1

Goal of exercise: to raise understanding of the participants about their tasks related to information collection, how to start and how to proceed to get needed data for registration.

Target group: manufacturers and importers of substances

Setting: Preferably actors-specific working groups of 3-4 persons

Tools: scenarios for 2 substances are prepared. Scenario includes info about one substance produced by one example company:

1) name of substance and produced / imported amount
2) list of available information
3) list of competitors and their information in SIEF

Equipment needed – flipchart, flipchart pens and blue tag.

Materials needed: - list of testing costs, copy of relevant Annexes

Facilitation depends on the level of knowledge of the participants

Task for trainees:

Each group gets a scenario

The following questions are discussed:

1. Which information is required? (Make a list!)
2. Which information is available? Which of the available information can really be used? Which information is missing?
3. Discuss pro's and con's of sharing data with competitors (SIEF)
4. Calculate what are possible testing costs taking account of existing and potentially shared data

Reporting to plenary: one group presents results; discussion on additions, different opinions, making strategy/procedure list how to collect information on hazards

Timing: discussions in WG – 40 min; reporting to plenary and discussions – each 10 min

6.3.2 Exercise 2

Goal of exercise: to give practical guidance for search for available data (e.g. on the Internet)

Setting: Internet session with 2-4 persons

Task for trainees:

Explore different data sources in the internet and describe

- what type of information can be found on substances (give 10 example substances)
- how to evaluate the quality of information
- if it is useful for the registration of a substance, if not what is missing and how could it be obtained
- find laboratories which conduct a short term test on Daphnia, an Ames test and a test for skin sensitisation according to GLP

Tools: Internet

Supporting material: List of links to different databases (ESIS, TOXNET, Chemfinder, KEMI (N-Class), Google)

Reporting to plenum: each group presents results according to the above listed bullets

Timing: work in WG – 30 min; reporting to plenary and discussions – 15 min each

6.4 Discussions in plenary

Check and discuss whether it is understood who needs to collect information on hazards and on what basis

Check understanding that REACH does not mean testing + testing + testing ... but as much as possible existing data must be used. Discuss on availability of existing data.

Check and discuss whether it is understood that pre-registration is necessary for phase–in substances to enable registrants to co-operate with each other to avoid excessive testing and related costs.

Discuss how substance information exchange forum (SIEF) could work in practice - How easy / complicated is work in SIEF?

6.5 Further work for preparation for REACH

- Study REACH proposal Annex IV - guidance in getting information for technical dossier.
- Get an overview on existing information on hazards for your substances.
- Develop skills in getting information for technical dossier, search Internet databases.
- Get overview of GLP principles (e.g. .OECD homepage: www.oecd.org/env/glp
- Follow up REACH developments – Agency in cooperation with Member States should develop guideline on use of alternative test methods.

7 Chemical safety assessment

7.1 Introduction

7.1.1 Content of the chapter and reference to the REACH proposal

REACH requires a "Chemical Safety Report" (CSR) as part of the registration dossier for all substances manufactured or imported in amounts > 10t/a. It is the documentation of the “mental exercise” of a Chemicals Safety Assessment (CSA) and is part of the registration dossier.

In the CSA the hazardousness of a substance according to the criteria of Directive 67/548/EEC is to be assessed. If the substance is dangerous, the CSA must also contain an exposure assessment and risk characterisation. The CSA needs to address all identified uses of the substance.

The exposure assessment (for details see chapter 9 on exposure assessment) comprises the entire life-cycle of a substance and consists of:

- a description of exposure scenarios including risk management measures
- an estimation of the exposure levels for workers, consumers and the environment.

Exposure scenarios are to be communicated along the supply chain as Annex to the SDS.

In the risk characterisation, the levels of exposure are compared to the DNELs and PNECs resulting in a statement on the risk. If a risk is determined, the risk assessor can:

- collect further information and refine the assessment conditions (e.g. stricter risk management measures) or
- refrain from registering that particular use

CSA/CSR shall be carried out by:

- manufacturers and importers of substances → if the substance is produced > 10 t/a;
- downstream users → when their application of a chemical substance is not covered in Safety Data Sheet and the DU wishes not to identifiy it to the supplier or the supplier does not want to include that use.
- Manufacturers and importers of dangerous substances in articles if they are intended to be released and the total amount in one article type exceeds 1 t/a

CSR is not required in the case of: i) < 10 t/a, ii) on-site isolated intermediates, iii) transported isolated intermediates < 1000 t/a

7.1.2 References to REACH regulation:

Requirements on obligation to make CSA/CSR and its content:

- manufacturer and importers → Article 13, Annex I;
- down stream users → Article 34, Annex XI.
- Manufacturers and importers of substances in articles → Article 6

7.1.3 Further background information on content

Methodologies, tools and technical guidance for REACH implementation are developed in the REACH Implementation Projects (**RIPs**):

→ **RIP 3.2: Technical Guidance Document on preparing the Chemical Safety Report**.

Guidance for manufacturers, importers and down-stream users of chemicals on performing and documenting a chemical safety assessment; description and simplifications regarding exposure scenarios and appropriate risk management measures will be included as well as communication of information through SDS.

→ **RIP 3.5:** Guidance Document on Downstream-User Requirements

Guidance for downstream users (DUs) on their obligations under REACH. Guidance on when to do a chemical safety assessment will be included.

More information: http://ecb.jrc.it/RIP/

→ **RIP 3.8:** Guidance Document on requirements for manufacturers and importers of articles

Projects on REACH testing (Strategic Partnership):

→ **S**trategic **P**artnership **o**n **R**EACH **T**esting (**SPORT**), initiated by CEFIC.

Test of different REACH mechanisms with 9 (categories of) substances or categories of substances. The final report should be ready for publication on 1 July 2005.

More information: http://www.cefic.be

→ **P**iloting **R**EACH **O**n **D**ownstream **U**se and **C**ommunication in **E**urope (**PRODUCE**).

PRODUCE: test of entire REACH process.

7.1.4 Important terms related to the topic and links to other chapters

General terms: manufacturer, importer, downstream user, identified use, hazard assessment, exposure assessment, DNEL, PNEC

Term	Legal definition	Simple explanation
Use	„means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;"	The use comprises the entire life-cycle of a substance, so far there are no rules how to describe it. Examples for a description of a use could be "additive in plastic", "lubricant" or "application in spray paints"
Identified use	means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user and that is covered in the safety data sheet communicated to the downstream user concerned;	Any use which is known to the registrant, for which he would like to register the substance
Use adviced against		If the chemical safety assessment shows that a use of a substance results in a risk, the manufacturer/importer should explicitly communicate this as a use adviced against
Chemical safety assessment	risk assessment in which the registrant takes account of the risk management measures that he either implements himself for his own uses or proposes to downstream users for their uses	structured assessment of hazards and exposures related to the manufacture, formulation, use and disposal of a substance resulting in a characterisation of risks
Chemical safety report	documents the choice of risk management measures and information on the substance in technical dossier required for registration. The chemical safety report (CSR) details a chemical safety assessment (CSA).	documentation of the chemical safety assessment, to be included in the registration dossier
Life-cycle		The different steps of use of a substance, starting from production to formulation, use in preparations or articles until disposal.

Links to other chapters:

- Hazard assessment → chapter 8
- Exposure assessment → chapter 9

- Information collection on hazards/testing requirements → chapter 6

7.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufacturers / Importers	Yes	Main responsible for making CSA/CSR Interlinkage registration dossier- CSR/CSA- SDS How and what to communicate to whom How does it work, what instruments and assistance can be expected	Frustration because of "so many uses"
Formulators	Yes	"What do I get?" → Annex to SDS "What do I need to do?" → Comparison of exposure scenarios with own practice CSA/CSR for preparations? Action in case of unidentified use	Complexity of getting many CSRs to be combined in a preparation
Down-stream users	Yes	"What do I get?" → Annex to SDS "What do I need to do?" → Comparison of exposure scenarios with own practice Actions in case of unidentified use Understanding of need and use of information communicated down and up to the supply chain Different requirements for CSA (Annex XI)	Communication with suppliers on uses Ignorance regarding risk assessment (→ examples from workers health)
Traders (no import)	No	Don't work with CSA	
Ministries / state officials	Yes	Testing proposals and waiving will be based on exposure part of CSA/CSR, compliance checking of reg. Dossiers	Lack of expertise
Inspectors	No	Don't work with CSA/CSR	
NGOs	Yes	Principle of how safety assessment works, how liability is connected to risk characterisation and exposure scenarios	Low expertise and understanding of chemicals issue
Other	Yes		

7.2 Presentations

7.2.1 CSA overview

Goal

Trainees shall understand:

- CSA/CSR is a tool to structured information collection and evaluation on potential risks related to the use of a substance
- the concept of an "identified use" (all)
- when a CSA/CSR is necessary for the registration (manufacturer)
- when a CSA/CSR is necessary by other actors (all)

- what is contained in a CSA/CSR (all)

Key messages

The purpose of the chemical safety assessment is to identify safe conditions for all identified uses of a substance (no risks occur, exposure remains under the safe levels).

The assessment starts with available information and default assumptions. If the result is that a risk may occur, further data is to be collected and assumptions need to be refined. Only that data is collected which is really needed.

If a downstream user deviates from the identified use or conditions of use (exposure scenario) he is responsible for all consequences.

Presentation and explanation

Slide of presentation	Comments, key messages
Overview of chemical safety assessment under REACH	
Content • What is a chemical safety assessment • What is required under REACH? • Main content in the assessment • Chemical safety report • Challenges in the assessment • Communication of safety assessment in the supply chain	Stress that information is compiled and evluated in order to improve the overall risk management Mention that the CSR is an instrument to bring together existing knowledge on substances in one document

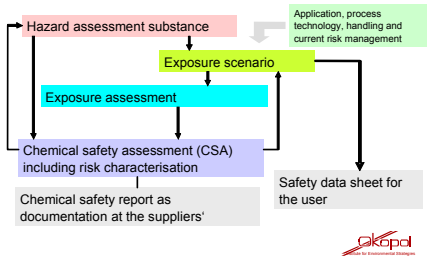
Chemical safety assessment

- Structured way to assess the risks related to the use of chemical substances in specific applications
- Divided into hazard assessment (intrinsic dangerous properties of the substance) and exposure assessment (likelihood and extent of exposure)
- To be done for human health and environment
- Result: Statement on RISK
- CSR documents the CSA and is contained in the registration dossier

CSA for a specific substance and defined use!

Explain what is an "identified use" and a "use advised against"

Development of the scenario



CSA is an iterative process. Starts with easily available info. In case the result is unclear or a risk is identified, the assessment is to be refined.

For manufacturers and authorities: the integration of the risk management measures into the assessment is new! for all risk assessors.

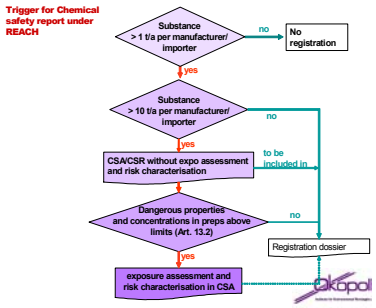
Aim of the CSA

- Identification of safe conditions of use
- For all non-dangerous substances, safe use in any application is assumed
- For dangerous substances the risk needs to be characterised
  - exposure levels remain under safe level (DNEL/PNEC) → safe conditions
  - exposure levels exceed safe level → refinement of the assumptions in the exposure assessment is necessary

Stress aim of CSA!

Safe levels (DNEL/PNEC) are to be determined by the manufacturer / importer of a substance → compare chapter on hazard assesment.

The exposure assessment is an interative process, where the resulting exposure level is compared to the safe level.



For manufacturers: Necessity of preparing a CSA/CSR.

Stress difference between CSR and exposure / risk assessment

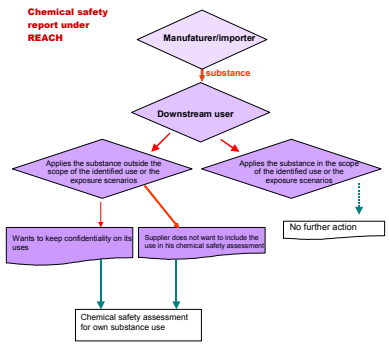
If the substance is contained in preparations below the limits given in Article 13.2 the exposure assessment of the CSA does not have to be done.

When CSA needs to be carried out by registrant?

- When the substance is produced or imported > 10 t/a

Look at previous flow chart for CSA necessity

Note that CSA is performed also for not dangerous substances, but exposure assessment under CSA is made only when a substance is dangerous according to the criteria of classification in Directive 67/548/EEC or 1999/45/EC or PBT or vPvB



Necessity for DU CSA[11]

DU CSA is necessary if supplier has the duty to prepare it

Notification to Agency necessary if total amount exceeds 1 t/a

Identified use: application of a substance which is known to the safety assessor and which is taken into account in exposure scenarios. An unknown use can become an identified use when it is communicated to the safety assessor

Information of the chemical safety assessment (1)

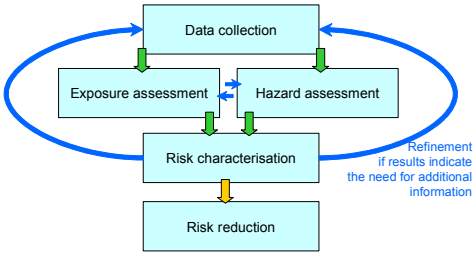
- Information of the CSA shall be consistent with that of the registration dossier
- CSA in accordance with Annex I, including the following steps:
  - Human health hazard assessment
  - Human health hazard assessment of physiochemical properties
  - Environmental hazard assessment
  - PBT and vPvB assessment
- If substance is identified as dangerous then also the following steps are necessary:
  - Exposure assessment
  - Risk characterisation

Exposure assessment is part of the safety assessment!

Note: if CSA is done by DU, then information can only be derived from SDS and public databases, as the registration dossier is not known.

[11] In general, a DU may not apply a “use advice against”. If he can prove by an own CSA that the use is safe he can disregard the suppliers recommendation but has to take full responsibility.

Safety assessment process



Iterative process!

Start with easily available info and assumptions on use conditions. Refine assumptions if assessment results in risk.

Hazard assessment - overview

- Summarises and structures info on hazardous properties to be manageable for 'non-experts'
  - classification and labelling information → basic information for substance handlers
  - derivation of safe levels (DNELs, PNECs) → to be used in risk characterisation
- REACH Annex I 0.5:
  1. Human health hazard assessment
  2. Human health hazard assessment of physicochemical properties
  3. Environmental hazard assessment
  4. PBT and vPvB assessment

Toxicological info is translated to standard language (C&L) and safe levels / concentrations where no effect is expected

Also interesting to NGOs

Hazard assessment – overview (2)

- Steps in the hazard assessment (Annex I, sections 1,2, 3, 4):
  - Evaluation of data
    - availability, validity of data,
    - test proposal depending on relevant exposures
  - Classification and Labelling
    - Translation of hazard information in into a standard language
  - Derivation of safe exposure levels (DNEL and PNEC)
    - for all relevant subjects of protection and all exposure pathways (e.g. inhalation, ingestion, dermal contact)
    - to be used in risk characterisation → orientation for safe conditions and application of risk reduction measures

Existing property data: validity refers to testing methodology and statistical relevance of results (ISO methods, GLP)

Derivation of safe levels new exercise, requires expertise!!!

Also interesting to NGOs

Exposure assessment

- Exposure assessment aims at determining the likelihood and the extent of potential exposure
- It is a systematic analysis of
  - types of exposures occurring during the life-cycle of a substance
  - doses/concentrations for each type of exposure of humans/environment
- Exposure assessment is described in Annex I, section 5
- Steps of assessment:
  - Step 1 – definition of the "use"
  - Step 2 – description of exposure scenarios along the life-cycle and for all subjects of protection
  - Step 3 – assessment of the exposures (quantification)

Risk characterisation

Exposure scenario is summarised in annex of SDS!

Risk characterisation

comparison of exposure with safe levels and statement on nature and extent of risk

- Risk characterisation should be carried out for each exposure scenario
- Risk characterisation consists of:
  - Comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL
  - Comparison of the predicted environmental concentrations in each environmental sphere with the PNEC
  - Assessment of the likelihood and severity of an event occurring due to the physiochemical properties of the substance
  - Combined exposures if relevant
- Risk characterisation is described in Annex I, section 6

Risk characterisation must result in “no risk”
Also interesting to NGOs

Information of the chemical safety assessment (2)

- Downstream users must prepare CSA according to Annex XI:
  - Development of exposure scenarios
  - If necessary generating / providing new data on substance properties
  - Risk characterisation
- If M/I considers that CSA carried out for one substance is sufficient to assess the risks arising from other substance or substance group then he can use same CSA, justification need to be provided

Important for downstream user - need to consider Annex XI for his CSA/CSR

Main challenges in the assessment

- Data on substance properties are not available → new information must be generated
- Existing data on substance properties must be evaluated regarding validity and summarised (robust study summary)
- New communication routines up and down supply chain to identify uses, conditions of use and applied risk reduction measures of DUs to assess safety
- Specific education/expertise is needed

For manufacturers: data is not available, communication with DU on receiving data is new and could be difficult at the beginning.

For DUs: M/I do not want to include the use of substance in CSA, communication up supply chain is new, too high costs to keep use confidential

Summary

- CSA to be done for substances produced/imported in amounts > 10t/a, if dangerous → exposure assessment is needed
- Aim of CSA is to identify safe uses and conditions of use of a substance
- Information on uses is to be communicated up (Dus to risk assessor) and down (supplier via SDS if dangerous) the supply chain
- Exposure assessment of dangerous substances is an interative process

7.2.2 CSR – overview on the documentation requirements

Goal

Trainees shall understand:

- what is contained in a CSR (all)
- what CSR structure and overall principles (all)
- who evaluates CSR (all)

Key messages

CSR is a part of the registration dossier. The CSR is the documentation of the chemical safety assessment and is not forwarded in the supply chain but to the authorities.

Content of a CSR is described in Annex 1 of REACH.

Part of the hazard assessment is the derivation of safe exposure levels (DNELs for human health and PNEC for the environment)

Main element of the exposure assessment is the description of exposure scenarios for the identified uses.

The CSR aims at deriving safe conditions of use.

Presentation and explanation

Slide of presentation	Comments, key messages
Chemical Safety Report under REACH Details on the documentation	

Content

- What is chemical safety report?
- Main content of the report
- Explanation of Part A
- Principles of Part B and C
- Evaluation procedures

Overview on content of the presentation,
Stress already here that the CSR is part of the registration dossier (not for DU CSR!!!)

What is a chemical safety report?

- Documentation of chemical safety assessment
- CSA = structured approach to compile, assess and evaluate information on
  - substance hazards
  - exposures for different uses
  - risk management options to reduce exposures and
  - potential risks resulting from a use

Chemical safety report

- CSR is part of the registration dossier or separate document if done by DU!
- CSR consists of 3 parts:
  - PART A: declaration that the risk management measures are implemented by the manufacturer or importer and that exposure scenarios are communicated further down the supply chain
  - PART B: includes identification of the substance, physical and chemical properties, classification & labelling and environmental fate properties
  - PART C: summary of all relevant information used in addressing CSA including exposure assessment and risk characterisation for dangerous substances

Overview on the content of CSR

Part A in CSR

- Part A of chemicals safety report includes:
  - Summary of risk management measures (← exposure scenarios)
  - Declaration that risk management measures are implemented
  - Declaration that risk management measures are communicated to DUs

risk management measures are determined and described in the exposure scenarios. These are communicated as Annex to the SDS

- If the DU does not comply with the prescribed safe conditions of use in the exposure scenario, he is responsible for all consequences (demarkation of responsibility for safe use)

Stress Part A demarks responsibilities for safe handling along the supply chain. If exposure scenarios and RRM are communicated down the chain

Part B and Part C of the CSR

- Part B:
  - Identification of the substance
  - Classification and labelling
  - Environmental fate properties, i.e degradation, environmental distribution and bioaccumulation
- Part C
  - Hazard assessment
  - Exposure assessment
  - Risk characterisation

Information on hazards, exposures arising from any life-cycle step and identified use. Risk charakterisation shows if safe handling for a specific substance in a specific use is ensured

Benefit - liability

- Definition of uses and exposure scenarios are a condition for the use and not only a recommendation
  - Responsibility shared along the chain
  - Liability on case of mistakes in the risk characterisation
  - Unclear what happens with e. g. reaction products of substances
- Definition of use and scenarios may draw attention to unsafe uses and phase them out

If risk characterisation is wrong and damage occurs the supplier is liable. If RRM are not implemented according to SDS, DU is liable.

Subordinated legislation necessary to enforce liability! (MS responsibility)

CSR for downstream users

- Dus consider info in SDS for their CSR
- CSR should follow CSA (Annex I, Part C)
- Part A of CSR shall include declaration that
  - risk management measures in exposure scenario are implemented for own uses
  - risk management measures outlined in exposure scenarios for identified uses are communicated down the supply chain
- CSA/CSR for downstream user is described in Annex XI

For DUs: take account of information received in the Safety Data Sheet from the supplier of the chemical

Chemical safety report – further procedures

- CSR is submitted with registration dossier to Chemical Agency (DU-CSR remains at DU site)
- CSRs are evaluated:
  - Chemical Agency as part of the completeness check
  - MS competent authorities in the frame of
    - a compliance check of a registration dossier
    - the evaluation of testing proposals
    - in the frame of a substanc evaluation

Explanation about evaluation of CSR

Communication of the safety assessment in the supply chain

- Exposure scenarios developed by M/I is annexed to SDS (requirements in Article 29)
- CSR is submitted to the chemicals agency together with the registration dossier
- DUs should communicate other uses and conditions of use up the supply chain
- Confidentiality may be an issue regarding
  - the identity of substances (impurities tell about production know-how)
  - uses of substances (innovative uses, innovative risk reduction as part of process know-how, concentrations in preparations → recipe)

How the Annex to the SDS will look like will be developed during the RIP process

Confidentiality is important issue in the communication of uses

Safety Data Sheet under REACH

- Adapted with information of CSA
  - identified use → section 1
  - hazards → hazard identification (section 2), properties (section 9 and 10) toxicological info (section 11), ecological info (section 12)
  - safe handling (risk management measures) → handling and storage (section 7), exposure control (section 8), disoposal considerations (section 13)
  - Annex to SDS → exposure scenario

Important for DUs: shows how SDSs may improve under REACH due to new information

Conclusions

- CSR is a part of registration dossier, consists of 3 parts
- CSR is documentation of assessment, forwarded to authorities
- The CSR developed in accordance with Annex I, and in particular the exposure scenarios, should be used to complete the safety data sheet
- More information for manufacturers and importers on CSR is described in Annex I and for downstream users in Annex XI
- Expected challenges:
  - missing/not available data on substances
  - communication up and down supply chain
  - lack of resources/expertise

7.3 Exercises

7.3.1 Exercise 1

Goal of exercise: to raise understanding of the participants about their tasks related to CSA, needs to communicate information along supply chain and to authorities and differences comparing to current system.

Target group: different industries and importers, also authorities may be interested

Setting: Preferably actors-specific working groups of 4-5 persons

Questions to be discussed:

5. When do you need to prepare CSA?

6. When and what you need to communicate up/down supply chain and to authorities?
7. What are potential difficulties to comply with the requirements regarding CSA?

Tools: Table with headlines (marked in **bold**) prepared on flipcharts/ handouts in advance and filled in during discussions by facilitator or participants

Actors	**Need to prepare CSA**	**Need to communicate in the supply chain and with state authorities: when and what issues?**	**Potential difficulties**
(M/I)	If substance is imported/ manufactured in >10t/a If it is dangerous the CSR needs to include an exposure assessment also	get information on uses (from DU) if dangerous: add exposure scenarios to SDS as Annex to communicate it to DU to provide CSR/CSA with registration dossier to authorities	Data on substance not available from data bases Communication with DU on receiving data is new and it could be difficult at the beginning of process, confidentiality issues Specific expertise needed
DUs	if application is not described in SDS if DU wish to keep use of substance confidential and if M/I does not take up use in own CSA/CSR	Receiving SDS of supplier communicate to M/I on use of substance (proactive → now) communicate to M/I on use which is not but wished to be included to CSA Own CSA communicate with further DU on uses add exposure scenarios to SDS as Annex to communicate it to DU notify authority on unidentified use	Receiving SDS of supplier M/I do not want to include the use of substance in CSA Own CSA Communication with DU on receiving data is new and it could be difficult at the beginning of process Specific expertise needed

Reporting to plenary: one group presents results; discussion on additions, different opinions

Timing: discussions in WG – 30 min; reporting to plenary and discussions – 20 min

Supporting material: presentations on CSA/ CSR, REACH Regulation.

7.4 Discussions in plenary

Check and discuss thoroughly whether it is understood who needs to make a chemical assessment!

Discussion with DUs: what are the options when the own use is not covered by the exposure scenario? What are advantages and disadvantages of the different options?

Discussion with formulators: how can the substance information be merged for the preparations? When is a chemical safety assessment necessary? Discussion of chemicals safety assessment for a preparation (Annex 1b) → be careful, this is a delicated and complex topic!

Discussion with manufacturers / importers: How much is known about the applications and conditions of use of a substance? How can applications / uses be grouped?

Discussion on understanding of potential problems at the beginning of REACH Regulation implementation of the CSA and CSR, e.g. formulators will get Annexes to SDSs with exposure scenarios at different times since substances will be registered according produced/imported volumes.

Check if the participants understand what exactly contains CSA (exposure assessment only if dangerous, hazard assessment always)

7.5 Further work for preparation for REACH

- Market actors: start communication along the supply chain on uses, determination of own wish to keep substance and conditions of use confidential
- Market actors: learn principles of exposure assessment from labour protection (risk assessment at workplace)
- Get an overview on markets and uses of substances
- Follow the development of guidance for the chemical safety assessment - RIP 3.2
- Follow the results/ conclusions regarding CSA practice in projects under Strategic Partnership
- Authorities: take part in RA work on existing substances at EU level, twinning with experienced MS in testing projects

8 Hazard assessment

8.1 Introduction

8.1.1 Content of the chapter

Basic approach to risk assessment: Risk = Hazard x Exposure

Hazard assessment is a part of the chemical safety assessment performed by a manufacturer or an importer of a substance and includes:

1. Human health hazard assessment
2. Human health hazard assessment of physicochemical properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

A summary of all relevant information used in addressing these points, shall be presented in the CSR. Parts of the information of the hazard assessment are to be summarized in the Safety Data Sheet (e.g. under headings 2, 8, 9, 11, 12).

For determining the potential of a substance to cause adverse effects, registrants can use information from numerous existing sources: databases with studies (e.g. epidemiological, animal, cell culture studies etc.) or mathematical models as QSAR. QSARs could be used to supplement experimental data and/ or to replace testing (refer to Annex IX).

In case of substances produced or imported in amounts < 100 t/year the required data set is not sufficient to perform a PBT and vPvB assessment, therefore the registrant shall consider whether further information needs to be generated to fulfill the objective of the PBT and vPvB assessment.

8.1.2 References to REACH regulation

Requirements to perform a Chemical Safety Assessment → Article 9 and 13

Hazard assessment for substances → Annex I 0.5; 1.0.3; 3.0.4

Hazard assessment for preparations → Annex Ib 2

Criteria for PBT and vPvB → Annex XII

8.1.3 Further background information on content

Technical Guidance Document on Risk Assessment: http://ecb.jrc.it/

Hazard assessments as a part of the risk assessment report undertaken under the regulation 793/93/EC. The reports can be downloaded from the website of ECB: http://ecb.jrc.it/existing_chemicals/

OECD website: http://www.oecd.org/

Note: info related to chemicals safety
http://www.oecd.org/topic/0,2686,en_2649_34365_1_1_1_1_37465,00.html

- Database on Chemical Risk Assessment Models
- OECD Environment, Health and Safety Publications; Series on Testing and Assessment:
- Description of selected key generic terms used in chemical hazard/ risk assessment

8.1.4 Important terms related to the topic and links to other chapters

General terms: CSA, PBT, vPvB, C&L

Term	Explanation
Hazard	An inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.
Hazard Assessment	The intellectual exercise of determining possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed
Hazard Identification	The identification of the type and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population.
Hazard Characterization	The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties.
Effect	Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent
Adverse effect	Any biochemical, physiological, anatomical, pathological, and/or behavioural change that results in functional impairment that may affect the performance of the whole organism or reduce the ability of the organism to respond to an additional challenge
Effect Assessment	Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose-effect relationship associated with that agent in a specific target organism, system or (sub-)population
Dose-Response Relationship	Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub-)population and the change developed in that organism, system or (sub-)population in reaction to the agent
NOEC	No observed effect concentration – highest concentration of a substance which does not cause an observable effect in long-term tests.
PNEC	Predicted no effect concentration – on a basis of acute or chronic effect concentrations established in laboratory tests, concentrations are calculated using safety margins, for which no effects are expected to occur in the environment.
Response	Change developed in the state or dynamics of an organism, system or (sub-) population in reaction to exposure to an agent
Risk	The probability of an adverse effect in an organism, system or (sub) population caused under specified circumstances by exposure to an agent
EC50	Effective concentration – concentration of a substance at which 50% of the test organisms exhibit the examined effect
LC50	Lethal concentration – concentration of the substance which is lethal for 50% of the test organisms

Links to other chapters:

- Information collection strategy on hazards → chapter 6
- Chemicals safety assessment/ Chemicals safety report → chapter 7
- Exposure assessment → chapter 9

8.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufac-turer / Importer	Yes	Main responsible for registration and CSA/CSR Interlinkage registration dossier – CSA/CSR – SDS → what info to include where and communicate to whom? How to derive the different parameters, derivation of PNEC/DNEL is a new task	Little experience in generation of new data Not sufficient (eco-)toxicological expertise to derive DNELs/PNECs
Formulator	Yes	Being able to make plausibility checks on supplier information Compilation of SDS for preparation	Believe that quality of information from upstream won't change under REACH
Down-stream users	Partly	Improved information in SDS How to check, question and efficiently use communicated information on hazards	Need good expertise for interpretation of info in SDS
Traders (no import)	No	Only forward information	
Ministries / state officials	Yes	Should have knowledge for checking dossiers	
Inspectors	Yes	Check completeness/ quality of SDS	Need good expertise for interpretation of info in SDS
NGOs	Yes	Background knowledge on chemicals effects Principles of hazard assessment PBT/vPvB assessment	Good knowledge on chemicals issues needed
Science	Yes	Carry out researches – source of data	Go for never ending data collection/testing

8.2 Presentations

8.2.1 Introduction to hazard assessment under REACH

Goal

Trainees shall understand:

- the goals and principles of hazard assessment
- the parameters determining the effects of substance to human health and environment.

Key messages

- The outcome of the hazard assessment (classification of substance and safe levels of exposure to substance) is a basis for the risk characterisation and gives orientation for potential risk reduction measures.
- CSA including hazard assessment should be performed for substances > 10t/a, but there is no tonnage threshold for the classification of substances!
- PBT assessment is to be performed for all substances independent of their volume. REACH sets specific criteria for PBT assessment (Annex XII).

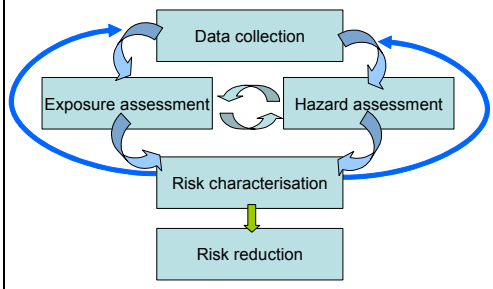
Presentation and explanation

Slide of presentation	Comments, key messages
Introduction to hazard assessment under REACH	
Content • Assessment of health hazards – Human health effects – Save exposure levels, according to exposure route: DNEL • Assessment of environmental hazards – Ecotoxicological effects – Save exposure level for different compartments: PNECs • PBT/vPvB assessment – PBT and vPvB criteria (according to REACH)	Industry is responsible to ensure safe handling of chemicals (no adverse effects to human health and environment) → need to determine dangerous properties and to identify safe exposure levels

Risk = exposure x hazard

Risk is determined by hazard **and** exposure. If substance is not hazardous → no risk, if hazardous but there is no exposure, e.g. fully closed system → no risk

Risk management process



Risk / Safety assessment is an iterative process starting with readily available data.

The need to determine further hazard information may be triggered from the exposure situation, e.g. if it is known that repeated contact of humans to a substance is likely (chronic exposure), information on chronic toxicity is needed.

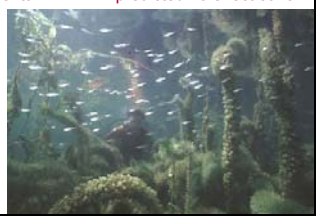
Example: protection of aquatic ecosystems

What is the concentration of a substance in the water

Exposure assessment
-> predicted environmental concentration

What is a safe exposure level which protects the ecosystem if not exceeded?

Hazard assessment
-> predicted no effect conc.



Is there a risk or not? (risk characterisation)

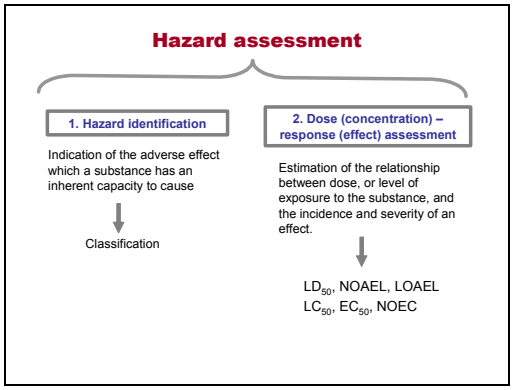
Hazard assessment

- Summarises and structures info on hazardous properties to be manageable for "non-experts"
  - C&L of substance (PC, (eco-)toxicological properties)
  - Safe levels of exposure to the substance: DNEL, PNEC → used for risk characterisation
- Note that all available data needs to be used, not only that which is required under REACH!!!!!

C&L important for safe handling (basic information, also triggering legal requirements in other legislation)

Mention that it is possible that the DNEL differs from an existing Occupational Exposure Limit Value. DNELs for the same substance derived from different manufacturers may differ too!

Stress the goals of hazard assessment



Hazard assessment consist of 2 steps.

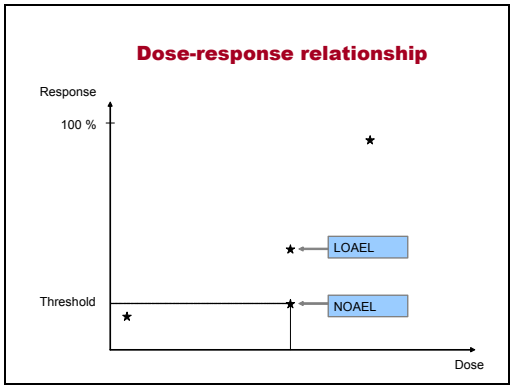
LD_{50}, NOAEL, LOAEL → human health

LC_{50}, EC_{50}, NOEC → environment

NOEL / NOAEL and LOEL/LOAEL can be used.

NOEL = highest dose of a substance which causes **no changes** distinguishable from those observed in normal animals. NOAEL = highest dose of a substance at which **no toxic** (*i.e.* adverse) **effects** are observed.

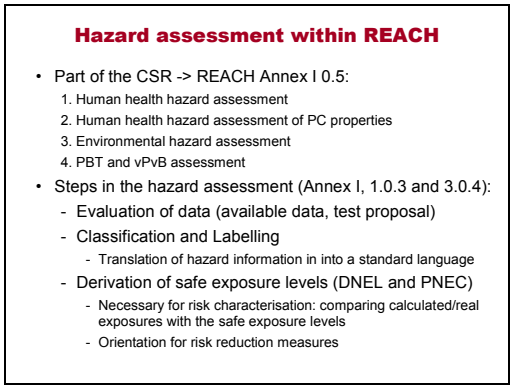
LOEL and LOAEL accordingly indicate the lowest dose of a substance to cause **changes** or **adverse effects** in animals.



Simplified example of test result: different concentrations are tested, % of test organisms showing effect are shown in graph.

NOEL/NOAEL and LOEL/LOAEL are determined by reading measurement points and scientific judgement

"Threshold" means the level of a stimulus that comes just within the limits of perception and below which **no** recognisable response is noticed

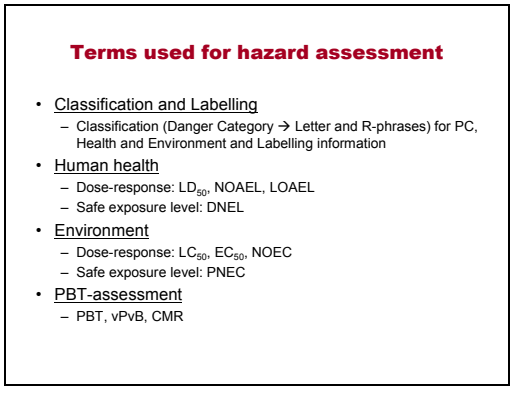


Hazard assessment is a part of CSA and should be documented in CSR.

Risk characterisation is a separate step, in which the results of the hazard assessment are used.

Safe level – concentration where no effect is expected.

Derivation of safe levels is a new task under REACH! Expertise is necessary.



Human health hazard assessment

- Potential effects:
  - Acute effects (acute toxicity, irritation, corrosivity)
  - Sensitisation
  - Repeated dose toxicity
  - CMR
- Mechanisms how the body may "deal" with a substance
  - toxicokinetics → which effects occur over time
  - metabolism → how is the substance "digested" by the body (e.g. detoxification in the liver)
  - and distribution in the body → different concentrations

Human health effects assessment to be conducted for all endpoints (if no data is available and needs not be generated → indication that endpoint cannot be assessed) For each endpoint a NOAEL should be determined. If a NOAEL cannot be determined, then a LOAEL should be identified. If this again is not possible, then it should be determined if the substance has an inherent capacity to cause such an effect.

Health hazards

- Acute effects:
  - short term exposure, one-time
  - Route of exposure: oral, dermal, inhalative
  - LD_{50} (lethal dose for 50% of tested animals: oral, dermal, inhalative)
- Chronic effects
  - Long term exposure, continued
  - Route of exposure: oral, dermal, inhalative
  - NOAEL: no observed adverse effect level for a certain endpoint
  - LOAEL: lowest observable adverse effect level for a certain endpoint

NOAEL, LOAEL serve to calculate the DNEL

Health hazards

- Safe exposure level:
  - DNEL: Derived no effect level [mg/kg bw/d]

$$\frac{Tox_{exposure\ route,duration,frequency}}{safety\ factor_{subgroup}} = DNEL_{subgroup/exposure}$$

Workers
Consumers
Humans via environment
Children
Pregnant women

+

Oral
Dermal
Inhalation

Safety factors (SF) are not necessarily rigidly applied:

SF of 10 applies when appropriate human data are available;

SF ensures additional protection for special risk groups (*e.g.* infants, pregnant);

SF raises where the toxicological data is of poor quality or incomplete or the nature of the potential hazards indicates the need for additional caution etc.

SF may range from 10 till 1000 (e.g. CMR)

Health hazards - questions

- *Why do we need a safety factor?*
- *Why is it necessary to consider the route of exposure, the duration and the frequency for the derivation of the DNEL?*
- *What are the different subgroups of population?*
- *Why is it necessary to derive different DNELs for different subgroups?*
- *How to consider different endpoints for derivation of DNEL?*
- *How would you define the DNEL for exposure via food?*
- *How would you define the DNEL for exposure due to the use of hairspray?*
- *Do you know endpoints, for which a NOAEL/ LOAEL cannot be defined?*

DNEL derives from NOAEL/LOAEL

DNEL - food: $DNEL_{oral/chron/kids}$

DNEL - hairspray: $DNEL_{dermal/chron}$; $DNEL_{inhal/chron}$

No DNEL for sensitization – very subjective!

Environmental hazards

Annex I 3.0.2.:
potential effects on five environmental spheres:

- aquatic environment (including sediment)
- terrestrial compartments
- atmospheric compartments
- food chain accumulation
- microbiological activity

Question:
Do the data requirements of REACH enable you to assess potential effects for every environmental sphere?

REACH requirements for environmental hazards

Environmental hazards

- Acute effects
  - Short term exposure
  - LC_{50}: lethal concentration: 50% of tested the organisms die in the test period [mg/l]
  - EC_{50}: effect concentration: in 50% of the tested organisms an effect is observed (e.g. growth inhibition, immobilisation)
  - Relevant for short term exposure
- Chronic effects
  - NOEC: no observed effect concentration [mg/l]
  - Relevant for continued exposure

LC50, EC50, NOEC are determined via tests

Environmental hazards

- Save exposure level:
  - PNEC: predicted no effect level [µg/l]
  - PNECs for water, sediment, soil, microorganisms

$$PNEC_{water} = \frac{\text{Long term tox}_{\text{most sens species}}}{AF}$$

AF = Assessment factor (safety factor)

Question: why do we need a PNEC for microorganisms?

PNEC for microorganisms → sewage treatment plants

An assessment factor expresses the difference between effect values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere

New approach: PBT and vPvB assessment

Concerns:

- Accumulation of persistent substances in the environment, effects hardly predictable in the long-term
- Emissions are irreversible

→ **No "safe" concentration!**

↳ identification of inherent properties

↳ emission characterisation

Discussion on what are PBTs/vPvB, why they are very hazardous, why they are subject for authorisation

REACH requires to identify PBT/vPvB properties and characterise emissions with a goal to reduce/stop releases

PBT and vPvB assessment - criteria Annex XII

PBTs
- Persistence: half life in simulation tests
  - marine water > 60d or
  - fresh- / estuarian > 40d or
  - marine sed. > 180d or
  - fresh- / est. sediment or soil > 120d
- Bioaccumulation
  - BCF > 2000
- Toxicity
  - NOEC < 0.01 mg/l or
  - CM 1+2 or R 1-3
  - evidence of chronic tox (e.g. R48)

vPvBs
- Persistence: half life in
  - marine, fresh or estuarian waters > 60d or
  - marine, fresh or estuarian sediments > 180d or
  - soil > 180d
- Bioaccumulation
  - BCF > 5000

Half-life: 50% of substance degraded

BCF - bio-concentration factor: the relation between the substance concentration in an organism and surrounding waters, e.g.

BCF (fish)= C (fish)/C (water)

BCF used for assessment of secondary poisoning

Reprotoxic effect: may have important influence on the stability of an eco-system through affecting a species ability to reproduce

Summary: hazard assessment

- Human health
  - Dose-response: LD50, NOAEL, LOAEL
  - Safe exposure level: DNEL
- Environment
  - Dose-response: LC50, EC50, NOEC
  - Save exposure level: PNEC
- Assessment (safety) factors are used for derivation of safe exposure levels to account for uncertainties in measurement and extrapolation to reality
- Exposure routes, duration and frequency have to be considered to protect a certain organism or system

Question: What about hazards that cannot be expressed in standard phrases (special observations, epidemiological studies on systemic effects where no R-phrases exist)? How could they be considered?

Yes, through SF/AF

Summary: hazard assessment

- Summarises and structures existing info on hazardous properties
  - Point out the relevant test data (as little ambiguity in information as possible, elimination of invalid tests, demand for additional well-defined tests)
  - Chemical hazards are described with standard language → understandable for everyone who handles the chemical (e.g. classification, summary of info in safety data sheet)
- Identifies types of effects & doses/concentrations at which they occur

Improved SDS:
hazard identification → section 2
properties → sections 9, 10
tox. Info → section 11
ecotox. Info → section 12

Summary: hazard assessment

- Derivation of safe exposure levels for
  - Risk characterisation: comparing calculated/real exposures with the safe exposure level
  - Orientation for risk reduction measures:
    - Measures to reduce the release of a substance in a way that the safe exposure level is no more exceeded (e.g. waste water treatment, improved ventilation, containment)
    - Measures to protect if release is not avoidable (personal protection)
    - Criteria for substitution: Selection of substances with same purpose, but higher safe level (while exposure is similar or reduced)

Haz. assessment is essential step in overall risk management system

8.2.2 Environmental hazard assessment (detailed)

Goal of presentation

- Trainees shall understand the principles how to derive a PNEC and determine PBT properties as well as try it out practically.

Key messages

- Fairly "easy" and well described methodology exists for PNEC derivation (TGD)
- In the derivation the most sensitive species are to be considered
- Lack of certain data is accounted for by the value of an assessment (safety) factor
- In a case of substances in amounts < 100 t/a the data requested for registration dossier is not sufficient for full classification (e.g. not possible for CMR, PBT, also env. toxicity[12] in case of <10t/a)
- For PBT and vPvB substance the “safe” concentration in the environment cannot be established.

[12] According to current discussions it is likely that the base data set will be changed in the further legislative process

Presentation and explanation

Slide of presentation

Comments, key messages

Environmental hazard assessment (detailed)

PNEC

- EFFECTS ASSESSMENT
  Ecotox. studies → LC50, EC50, NOEC
- Extrapolation
  Assessment factors
- Derivation of PNEC
  Predicted no effect concentration

Steps to derive a PNEC

PNECs for different compartments

Target	Medium of exposure (PEClocal / PECregional)		PNEC
Aquatic organisms	Surface water		$PNEC_{water}$
Benthic organisms	Sediment		$PNEC_{sed}$
Terrestrial Organisms	Agricultural soil		$PNEC_{soil}$
Fish-eating Predators	Fish		PNECoral from $NOAEL_{avian/mammalian}$
Worm-eating Predators	Earthworms		PNECoral from $NOAEL_{avian/mammalian}$
Microorganisms	STP aeration tank		$PNEC_{microorganisms}$

As risks are to be characterised for different compartments, different PNECs are needed.

Different PNECs base on different ecotoxicological study results with different species

PNEC

Ensures overall protection of the environment if not exceeded

Assume:

Sensitivity of an ecosystems depends on the most sensitive species in each environmental compartment

$$PNEC_{water} = \frac{\text{Long term tox}_{\text{most sens species}}}{AF}$$

AF = Assessment factor (safety factor)

Question: why is an assessment factor used and what may influence the value of the AF?

It is assumed that:

- ecosystem sensitivity depends on the most sensitive species, and;
- protecting the ecosystem structure also protects the ecological function.

In most cases only short-term toxicity data are available → then AF=1000

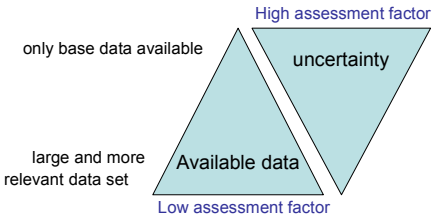
PNEC

Available data and uncertainties

- Variation of species (what is the most sensitive species, how many have to be tested)?
- Measurement errors
- Sampling errors
- Variation of laboratory testing
- short term to long term toxicity extrapolation (long term toxicity data often not available)
- laboratory data to field impact extrapolation (field data are generally not available with a few exemptions)

Reasons for applying AFs, could be discussed in the group!

PNEC



$$PNEC_{water} = \frac{tox_{aqua}}{AF}$$

The relation between value of AF and data availability.

PNEC: assessment factors TGD

Table 16 Assessment factors to derive a $PNEC_{aquatic}$

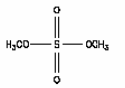
Available data	Assessment factor
At least one short-term L(E)C50 from each of three trophic levels of the base-set (fish, Daphnia and algae)	1000 a)
One long-term NOEC (either fish or Daphnia)	100 b)
Two long-term NOECs from species representing two trophic levels (fish and/or Daphnia and/or algae)	50 c)
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10 d)
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case) e)
Field data or model ecosystems	Reviewed on a case by case basis f)

Question: Why are all three trophic levels assessed (fish, daphnia, algae)?

Strict rules are developed for the use of AFs

PNEC

Example:



DMS (dimethyl sulphate):

Leuciscus idus melanotus:	96-hour LC50	14 mg/l
Menidia beryllina:	96-hour LC50	15 mg/l
Daphnia magna:	48-hour EC50	17 mg/l
Scenedesmus subspicatus:	72-hour EC50	46.9 mg/l (for growth rate)

AF: 1000

$PNEC_{water}$ = 14mg/l / 1000 = 14 µg/l

Note: first provide slide without answers!
Questions:
which is most sensitive species?
is a 96 h study a long or short term test?
A single dose of the substance with 14 days observation is still considered as acute toxicity study.

PNEC

MCCP (medium chained chlorinated paraffins, **ALKANES, C14-17, CHLORO**):

Species	Result
Oncorhynchus mykiss (rainbow trout)	No adverse effects at 4.5 mg/l over 60 days
Alburnus alburnus (bleak)	96h-LC_{50} >5,000 mg/l
Water flea (*Daphnia magna*)	48h-EC_0 = 140 µg/l (measured) 48h-EC_{25} = 339-423 µg/l (measured)
	21-day NOEC = 10 µg/l (measured) 21-day LOEC = 18 µg/l (measured)
	21d-NOEC = 12.6-15.6 µg/l (measured) 21d-LOEC = 25.3-31.3 µg/l (measured)
Crustacean (*Gammarus pulex*)	96h-LC_{50} > 1.0 mg/l
Mussel (*Mytilus edulis*)	60-day NOEC = 0.22 mg/l (measured concentration)
Alga (*Selenastrum capricornutum*)	96h-EC_{50}(biomass) = >3.2 mg/l 72h-EC_{50}(growth rate) = >3.2 mg/l (nominal concentrations)

AF: 50

$PNEC_{water}$ = 0.2 µg/l

Note: first provide slide without answers!

PBT assessment

- Data collection:

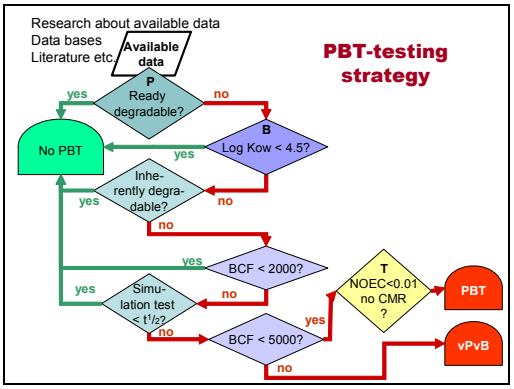
Question: Is the required data set of Annex VI sufficient for PBT assessment?

Question: How would you classify a known PBT or vPvB according to 67/548/EEC?

- Comparison of substance properties with criteria of Annex XII
  - P: ready biodegradability:
    if ready biodegradable -> P-criterion not fulfilled
    if not -> further data necessary
  - B: log Kow:
    if log Kow <= 4.5 -> B-criterion not fulfilled
    if log Kow > 4.5 further data necessary
  - T: short term toxicity
    long term NOEC is necessary

Conclusion: With the available data set a PBT assessment is not possible!

Only for advanced group!
For PBT substances a “safe” concentration in the environment cannot be established
Ready biodegradability – if degrades > 70% of substance within 28 days
Octanol/water partition coefficient (Kow) can be estimated using QSAR models.
If P and B criteria are fulfilled, lonf term toxicity test should be performed.



8.3 Exercises

Materials and task descriptions for the following two exercises can be found as separate files on the CD ROM.

8.3.1 Exercise 1 – PNECs and PBT assessment

Note: for more detailed, in-depth training, e.g. preparation of CSA

Goal of exercise: practical exercise to check data needed for specific volume of substance to register, to calculate PNEC and assess PBT properties of the substance

Target group: manufacturers/ importers going to perform CSA; also state authorities may be interested

Setting: groups of 3 - 4 persons

Questions to be discussed:

Exercise – PNEC and PBT assessment

Material: comments on data set with environmental test data

- Check: is the provided data set sufficient for registration of 64 t/a (related to environmental hazards)?
  - If not, which data are missing?
- Check: is the provided data set sufficient to derive a $PNEC_{water}$
  - If not, which data are missing
  - If yes, which assessment factor is appropriate and what is the value of the derived PNEC — AF = PNEC =
- Assess and justify:

PBT-assessment	fullfilled	Not fullfilled	Additional data needed:
P-criterion			
B-criterion			
T-criterion			

Tools: The information on substance – pentachloro benzenethiol is provided.

The answers:

1) missing data (from Annex VI): activated sludge respiration inhibition testing; hydrolysis as a function of pH
2) $PNEC_{water}$= Tox_{water}/AF → no long-term test → AF =1000 → most sensitive – algae → $PNEC_{water}$=0.042mg/l /1000= 0.42 μg/l

PBT assessment	Fulfilled	Not fulfilled	Additional data needed
P-criterion	Yes → vP (0%)		
B-criterion	Yes → vB (LogKow, BCF)		
T-criterion	?	?	NOEC? CMR?

Reporting to plenary: one group reports on question 1 and 2, another on PBT assessment; other groups comment, add

Timing: discussions in WG – 30 min; discussions in plenary – 20 min

Supporting material: information on substance – pentachloro benzenethiol; REACH regulation - Annexes VI, XII; presentations

8.3.2 Exercise 2 – Data needs for registration & classification

Note: for more detailed, in-depth training, e.g. on preparation registration dossier

Goal of exercise: to practice with estimation of data needs for registration of the specific substance

Target group: manufacturers/ importers going to submit registration dossier; also state authorities may be interested

Setting: groups of 3-4 persons

Questions to be discussed:

Exercise – Task description

- Assume you register a substance (64 t/a)
  - Which test data do you need to submit in the registration dossier according to which Annex? Differentiate between Annex V and VI
  - For which endpoints (R-phrases) could you classify the substance provided that the test data is available?
    - physical chemical properties
    - health
    - environment

Tools: participants are provided with empty table below (only with heading in **bold**) and need to fill it in.

Which data needs to be submitted (64 t/a)?

	Annex 5	Annex 6	R-phrases	Required test data
Explosivity	Explosivity		2,3	Explosivity testing
Oxidising	Oxidising		7,8,9	Oxidising testing
Flammability	Flash point Flammability		10,11,12,15, 17	Flashpoint Flammability
Acute tox, oral		Oral (animal)	28,25,22, 68	LD50 oral, rat
Acute tox, skin		Dermal (animal, rat)	27,24,21, 68	LD50 dermal, rat or rabbit
Acute tox, inhal.		Inhalation (animal / rat)	26,23,20, 68 (67)	LC50 inhalation, rat
repeated dose tox.		28d in vivo, most appropriate route	48 (33)	subchronic or chronic toxicity tests (28 or 90 d)
Corrosion, Skin	In vitro if validated		34,35,(66)	In vivo test skin corrosion, pH Validated in vitro (human skin model, rat skin transcutaneous)
Irritation, Skin	In vitro	In vivo	38	Rabbit: cutaneous irritation (in vivo) human data
Irritation, Eye	In vitro	In vivo	36,41	In vivo testing
Irritation, Respiration	no test in REACH		37	Human data, animal testing (not specified)
Sensitisation, Inhalation	no test in REACH		42	Human experience, immunological tests (even in vitro), isocyanates
Sensitisation, Skin	In vitro		43	Human experience, animal tests (eg guinea pig maximisation test)
Carc. (1)			45,49	Human evidence
Carc. (2)			45,49	a) tests with two animal species b) one species + supporting ev. (genotoxicity metabolism, QSAR or epidemiological evidence)
Carc. (3)			40 (subcat. of (2))	
Muta (1)	In vitro bacteria	In vitro cytogenicity and gene mutation mamallian cells	46	Human evicence
Muta (2)			46	Only in vivo tests
Muta (3)			68	Only in vivo tests (in exceptional cases with supported evidence classification may be based on in vitro results)
Repro (1) fer.			60	Human evidence
Repro (2) fert.			60	Animal studies
Repro (3) fert.			62	Animal studies

	Annex 5	Annex 6	R-phrases	Required test data
Repro (1) dev.			61,64,(33)	Human evidence
Repro (2) dev.		1 generation	61,(33)	Animal studies
Repro (3) dev.		1 generation	63,(33)	Animal studies
Toxicokinetics		toxicokinetic behaviour	64,33	animal studies
Acute aquatic toxicity	Daphnia	algae, fish, degradation	50, 50/53, 51/53, 52/53, 53, (33)	Acute toxicity (daphnia, algae or fish) + water solubility + log Kow + ready biodegradability
	Log Kow			
degradability		ready biodegradability Hydrolysis as function of pH		
Toxic to flora, fauna, soil organisms, bees, long term			R54 – R58	Available evidence
Dangerous for the ozone layer			R59	Available evidence, list of Montreal Protocol

Note:

- Annex 5-6 of REACH; R-phrases, required test data according 67/548/EC
- RED cells – not enough data for classification; GREEN – sufficient info for classification, Yellow cells – not clear, if information suffices for classification or not.

Reporting to plenary: 1 group presents + common discussion

Stress some conclusions from exercise:

- According to Annex V (substances < 10 t/a) no environmental and no general acute toxicity classification is possible
- According to Annex VI data, reprotoxic effects (development) can be classified. Other long-term effects are still lacking appropriate data
- For substances produced in amounts < 100 t/a, it is not possible to identify substances of high concern for the authorisation procedure (CMR + PBT)
- Nevertheless, existing data needs to be taken account of, even if it is not required in the Annex!!!!!

Timing: discussions in WG – 45 min; reporting to plenary and discussions – 30 min

Supporting material: REACH regulation – Annex V-VI, Annex VI on classification of Dir. 67/548/EEC

8.4 Discussions in plenary

Check whether it is understood who and when should perform hazard assessment and what are the outcome of it.

Discussion with manufacturers / importers: difficulties to perform hazard assessment; why to consider such a number of different parameters; whether all data should derive from testing; whether data collected for registration dossier is sufficient for PBT assessment and classification; some more questions inserted in slides.

Discussion with formulators: what should be done regarding haz. assessment of preparations

Discussion with DUs: how to interpret the parameters from haz. assessment and efficiently use improved information in SDS.

8.5 Further work for preparation for REACH

- Market actors:
  - follow REACh developments, especially guidance materials for hazard assessment
  - learn about GLP principles, classification principles and methodologies for hazard assessment
  - start getting familiar with the GHS
  - look at TGD and existing risk assessment reports to further study the methodology of hazard assessment
- Authorities: learn from old MS work on RA of existing substances, read TGD and existing risk assessment reports

9 Exposure assessment

9.1 Introduction

"It is recommended to closely follow the RIP 3.2 project, as it is expected that examples for exposure scenarios will be published. Use these to illustrate the concept to the trainees".

9.1.1 Content of the chapter

Explanation of exposure assessment under REACH and current legislation

Main principles of exposure assessment: as all life cycle stages are covered, the whole supply chain is relevant regarding emissions. Exposure scenarios are descriptions of standard situations where the substance is used. They can contain assumptions (default setting). In the emission estimation it is calculated which amount of the substance is emitted if handled under the conditions of the respective exposure scenario. Risk management measures are part of the scenarios and become “binding prescriptions” of safe handling when communicated via an Annex to the SDS. The environmental behaviour and fate are modelled in order to obtain the exposure of the environment. This is not relevant for human exposure except the substance accumulates along the food chain.

Available tools, RIP process

Supply chain communication

9.1.2 Reference to the REACH proposal

- Article 9 and 13: requirement for producers / importers to register and carry out an exposure assessment as part of the chemical safety assessment.
- Article 6: requirement for producers and importers to register or notify dangerous substances in articles may include a CSA and exposure assessment
- Article 29: Exposure scenarios are to be communicated as Annex to the Safety Data Sheet
- Article 34: Downstream user safety assessment
- Annex 1 Headline 5: Description of exposure assessment method for substances
- Annex 1b Headline 4: Description of exposure assessment for preparations

9.1.3 Further background information on content

- http://ecb.jrc.it/existing chemicals/: Exposure assessments are part of the risk assessment reports undertaken under Regulation 793/93 EC. Reports can be downloaded from the web-page of the ECB

- http://ecb.jrc.it/ : Emission scenario documents exist for various industrial sectors, describing processes, products, emissions sources and modelling exposures. They are part of the Technical Guidance Document, which describes the agreed method for risk assessment in the EU. In the biocides section also some biocide-specific emission scenario documents are available.
- www.oecd.org/: The OECD has also published emission scenario documents for various industrial sectors and processes.
- Chemrisk: is a model to derive consumer exposures from chemicals contained in articles.
- http://ecb.jrc.it/REACH: the RIP process is documented on these pages. RIP 3.2 develops a common methodolgy for the assessment of exposures for human health and the environment under REACH.
- EUSES: software to assess exposures according to TGD methodology (download possible) http://eusesconsortium.org/
- ECETOC: exposure assessment tool developed by ECETOC, a group of scientists employed by industry http://www.ecetoc.org/Content/Default.asp
- German EPA: exposure estimation tool for textile processing (report, access based software not yet available) http://www.umweltbundesamt.de/index-e.htm

9.1.4 Important terms related to the topic and links to other chapters

Term	Easy and understandable words
Exposure	The fact that humans or the environment are in direct contact with a substance
Exposure level	Dose or concentration of a substance to which humans or the environment are exposed to
Risk reduction measure	Any measure reducing either the hazardousness of product or process components (substitution) or the releases and exposures of humans and the environment
On-site abatement	Emission treatment measures like a waste water treatment plant or an air scrubber, which lead to a reduced release of the substance by destruction, transformation or controlled disposal
Process and product integrated measures	Measures in production (e.g. recovery of materials) or in products (e.g. barrier to evaporation) leading to reduced emissions
External abatement measures	Emission treatment done off-site, e.g. a community sewage treatment plant
Exposure scenario	A set of information or assumptions about the type of use, processing and products of a substance including the conditions of use (duration, frequency, amounts) and the applied risk reduction measures
PEC	Predicted environmental concentration

The chapter is related to the chapters: introduction (chapter 3), main changes (chapter 4), chemical safety assessment (chapter 8).

9.1.5 Actors for which the chapter is relevant

Actors	Relevant (yes/no)	What is of special interest?	Possible critical issues
Manufacturers / Importers	Yes	How to carry out the assessment, how to obtain the information, what tools are available	Very new assignement, difficulties in understanding why it is wanted
Formulators	Partly	What information needs to be checked at the own production site, which information needs to be forwarded	How to handle safety assessment for preparations[13]
Down-stream users	Partly	What information is obtained in the SDS, what needs to be done with it?	
Traders (no import)	No	Information is simply forwarded	
Ministries / state officials / competent authorities	Yes	General understanding, competent authorities expert knowledge for checking dossiers	Competent authorities doing evaluations may have too scientific approach
Inspectors	Yes	What in the SDS needs to be compared to the situation at the downstream user?	
NGOs	Yes	Exposure assessment basis for responsibility of actors	May think that companies only “cheat” on authorities and the public
Science	Yes	How to simplify a complex task of assessing exposures to a workable procedure	Simplification may be seen as unscientific, discussion on details

9.2 Presentations

9.2.1 Overview on exposure assessment under REACH

Goal of presentation

1. participants have an overview over the principles and what needs to be taken into account in an exposure assessment under REACH
2. participants have understood by which parameters exposure is determined in general

Key messages

- Exposure is as important as the hazardousness of a substance regarding the risk
- Exposure assessment requires knowledge about the uses of a substance, both in industrial processing and during service life

[13] Unfortunately there are few good ideas on this issue. It is difficult and complex and should not be dealt with in detail

- Exposure assessment is not easy but manageable and will be supported by tools and guidance from the Commission and Member States

9.2.2 Introduction to exposure assessment under REACH

Presentation and explanation

Slide of presentation	Comments, key messages
Introduction to exposure assessment under REACH 1	
Content • Why is an exposure assessment required under REACH? • What is an exposure assessment in general? • Who needs to do an exposure assessment? • What does an exposure assessment need to contain according to REACH? • What of the exposure assessment is communicated down the supply chain? • Summary 2	
Why is an exposure assessment required? • REACH aims at regulating substances based on risks – Volume trigger for hazard data (Annexes V and VI) – Concrete exposure trigger for hazard data (Annexes VII and VIII) • Chemical risks are determined by – Hazard (substance physico-chemical and (eco-)toxicological properties and – Exposure (contact of humans or the environment with the substance) • Exposure assessment allows for targeted data collection → iterative process of safety assessment 3	The responsibility to determine and ensure that adverse effects are unlikely to occur lies on industry Be prepared to have arguments against you when you say REACH is risk based!!! Industry has a different opinion on that.

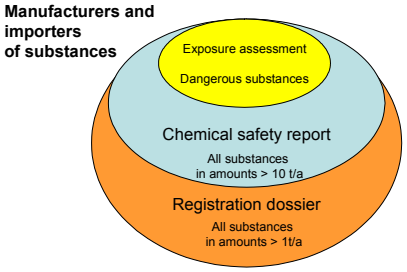
Why is an exposure assessment required? (2)

- Exposure assessment also a means to assign responsility for safe handling
  - producer responsible that if substances are handled as recommended, no risks occur
  - user responsible for any risks ocurring when he uses the substance in other ways than recommended
- Exposure assessment will deliver knowledge about substance uses relevant for policy makers and the general public

4

Conditions of use are not really recommendations! If they are in the Annex of the SDS, then they demark the responsibility of the producer from that of the DU

Who needs to do an exposure assessment? (1)



5

A chemical safety report may also be complete without an exposure assessment in case the substance is not dangerous!

What is an exposure assessment ?

- Risks only realise if the subject of protection is exposed to the dangerous substance
- Exposure assessment aims at determining the likelihood and the extent of exposure
- It is a systematic analysis of
  - types of exposures occurring during the life-cycle of a substance
  - doses/concentrations for each type of exposure

6

RISK = HAZARD X EXPOSURE

Who / what can be exposed to chemicals?

- humans
  - workers: during processes where the chemical is used
  - consumers:
    - when using chemical preparations (e.g. paints)
    - or when using articles containing substances released during use (e.g. printer cartridge → intended release or textile dyes → unintended release)
  - workers and consumers:
    - via the environment (air, water, soil)
    - via uptake with food (if chemicals accumulate in the food chain)

7

You may discuss some examples here.

If one person is in contact with a substances during work, in his “private” life and via his food, in order to determine the risk all exposures would have to be summed up.

Who / what can be exposed to chemicals?

- environment
  - releases during production, formulation and processing of substances
  - releases during transport and storage
  - releases from products during service life and disposal
- Exposures add up!

8

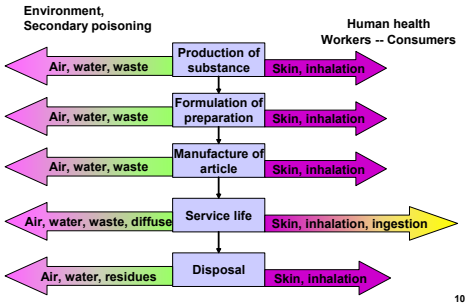
Concentrations in the environment usually are rather low (high dilution).

Exposure pathways

- The ways on which a substance is emitted and taken up by the subject of protection
- Environment
  - emissions to air, soil, water or waste
  - substances may partition (e.g. air → deposition to soil and water)
- Humans
  - uptake via inhalation, ingestion, dermal exposure

9

Expo assessment – life-cycle approach



10

Who needs to do an exposure assessment? (2)

- Downstream users of dangerous substances where the use is not covered by the supplier's CSA/Annex to SDS and shall not be communicated for confidentiality reasons
- Producers and importers of articles containing dangerous substances
  - where the total amount contained in one article type exceeds 1t/a
  - the release is intended and
  - the use has not been registered upstream

11

DUs: option to make the use known to the supplier !!!

Articles → it is not yet clear how the registration and notification process will be structured (RIP 3.8)

Exposure assessment under REACH

- Guidance on "how" in Annex I
- Step 1: Definition of the "use"
- Step 2: description of exposure scenarios along the life-cycle and for all subjects of protection
- Step 3: assessment of the exposures (quantification)

- Risk characterisation: comparison with safe levels and statement on nature and extent of risk

12

Risk characterisation is not (!) part of the exposure assessment but a separate step.

Exposure assessment under REACH (2)

- Definition of the "use"
  - the use defines the life-cycle of a substance
    - e.g. lubricant → use in processes only
    - e.g. additive for plastic → use in articles (e.g. computer)
  - the use needs to be defined in a way that:
    - the amount of uses per substance are small (work load)
    - the condistions of use are still similar (homogenous group of cases)
  - there are no rules how to define a use yet

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You may discuss ways of describing a use or ask, how the use is currently described (already now required in the SDS but in a different meaning)

Exposure assessment under REACH (3)

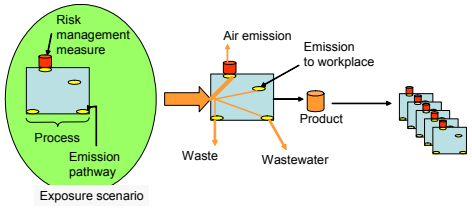
- An exposure scenario is a description of
  - the substances „life" following it from the production to final disposal
  - the processes it undergoes and the risk management measures taken (emission reduction) by each handler of the substance at each life-cycle stage
  - how exposure of humans and the environment could happen
- The description can contain assumptions and make prescriptions how to handle a substance! (Generic scenario)

14

Explain it as the "average situation" of use.

Exposure assessment under REACH (4)

- Emission estimation and quantification of exposure by modelling emissions and fate



15

There may be one scenario for production and one for formulation but e.g. 3 for the downstreamuse and e.g. 7 for the service life.

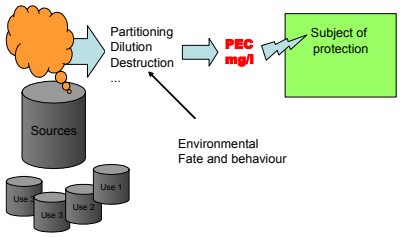
Exposure assessment under REACH (4)

- Emission estimation and quantification of exposure by modelling emissions and fate
  - the emitted amount in a given scenario depend on
    - amount used
    - mobility of the substance (water solubility, vapour pressure, dustiness etc.)
  - the exposure level depends on the further behaviour of the substance e.g.
    - behaviour related to environment (e.g. adsorption to particles, partitioning in different media)
    - dilution in air (e.g. at workplaces) or in water (environment)
    - accumulation in the foodchain

16

Emission estimation requires knowledge on the substance properties. Discuss which properties may be relevant, but do not go into detail

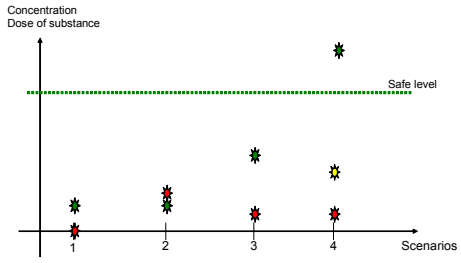
"simple" calculation → PEC (predicted environmental concentration)



17

Basic logics, this is very simplified!

Assessment of safety



18

Green = environment, red = worker, yellow = consumer. Graph shows possible result of modelling exposure in 4 scenarios. Safe level = PNEC or DNEL → chapter hazard assessment

What is communicated in the supply chain ?

- Communication via the safety data sheet
- Identified use (section 1) which is relevant for the downstream user
- Information on safe handling (sections 7, **8**, 9, 12, 13,)
- Exposure scenarios in the Annex
  - only relevant scenarios
  - human health and environment

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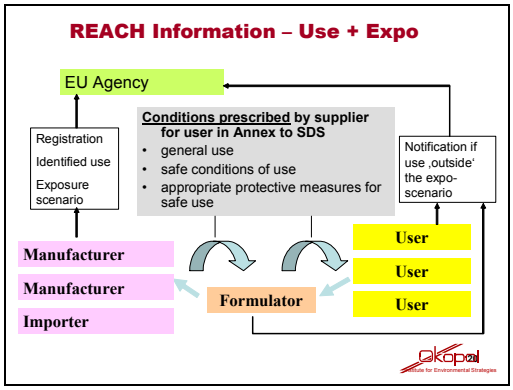
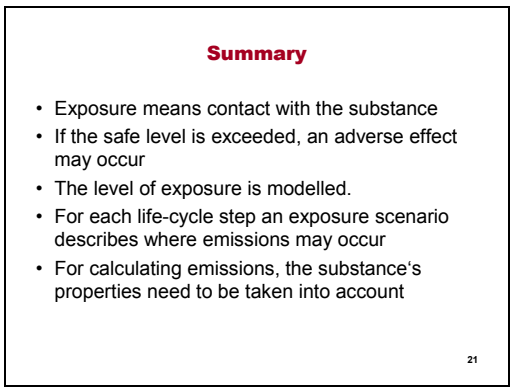


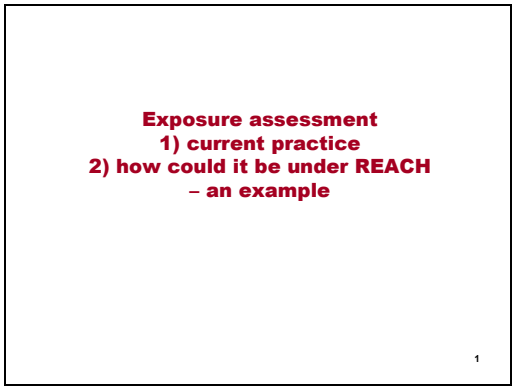
Information up and downstream but also to the authorities. Important is the grey box



9.2.3 Exposure assessment, current practice and an example how the future may look like

Slide of presentation

Comments, key messages



Content

- More details on the assessment of exposures according to current practice
  - human health
  - environment
- Example how it could work under REACH
- Outlook on EU-Process and tools

2

Introduction to TGD

- Currently: MS assess in the frame of Regulation 793/93 according to method described in the „Technical guidance document" = TGD = Risk assessment for:
  - new notified substances (Commission Directive 93/67/EEC)
  - existing substances (Commission Regulation No. 1488/94)
  - biocidal active substances (Directive 98/8/EC)
- Principles of method will be applied under REACH

European Commission, Joint Research Centre 2003
Available at
http://ecb.jrc.it/php-bin/reframer.php?A=ECB&B=/DOCUMENTS/TECHNICAL_GUIDANCE_DOCUMENT/

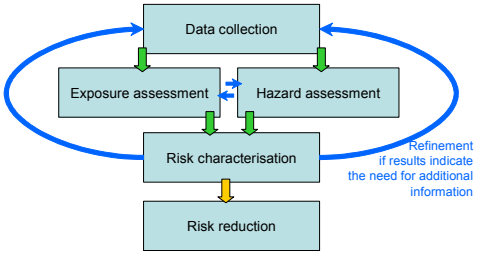
3

TGD structure

- Part I
  - Chapter 1 General Introduction
  - Chapter 2 Risk assessment for Human Health
- Part II
  - Chapter 3 Environmental Risk Assessment
- Part III
  - Chapter 4 Use of (Quantitative) Structure Activity Relationships ((Q)SARs)
  - Chapter 5 Use Categories
  - Chapter 6 Risk Assessment report Format
- Part IV
  - Chapter 7 Emission Scenario Documents

4

Safety assessment process



5

Interative process starting with available information and rough assumptions. Refinement and data collection if result is risk!

No unnecessary data collection

General principles of safety assessment

- For human health and the environment
- Hazard assessment
  - Dose (concentration) – response (effect) assessment (-> derivation of safe levels)
- Exposure assessment
- Risk characterisation
- To be addressed:
  - all toxic effects (endpoints)
  - different human populations (workers, consumers, vulnerable groups = children, elderly...)
  - different environmental media

6

Principles and procedures in current practice by MS are the same as for industry actors under REACH. The procedure is the same for environment and human health.

Safety assessment procedure

- Screening (qualitative): likelihood of exposure → „identification of relevant scenarios " → Under REACH: description of exposure scenarios
- Quantitative exposure assessment → determination of the level of exposure using measured / modelled data → Under REACH: exposure estimation
  - emissions
  - risk management measures / dilution
  - fate and behaviour (only environement)
- Risk assessment → comparison of (combined) exposures with safe levels (PNEC, env.) or derivation of margin of safety (MOS, humans) → Under REACH: risk characterisation

7

Risk assessment (793/93) - results

- Conclusions are expressed in standard phrases (existing substances)
  - (i) need for further information and/or testing
  - (ii) at present no need for further information and/or testing and no further risk reduction measures
  - (iii) need for additional risk reduction measures
- Under REACH → only safe uses are allowed, therefore result will be
  - „no risk"
  - „use adviced against"
  - further refinement of assessment

8

Human health – exposure assessment

To be considered:

Exposure routes
- Inhalation
- Dermal exposure
- Ingestion

Extent of exposure (emissions)
- Dose/amount/concentration (in air, water, food, skin contact)
- Frequency and duration

Quantitative determination of exposure (with preferential hierarchy)
- Measured data
- Appropriate analogous data
- Modelled estimates

9

You may take additional slides from the hazard assessment presentation to explain the terms

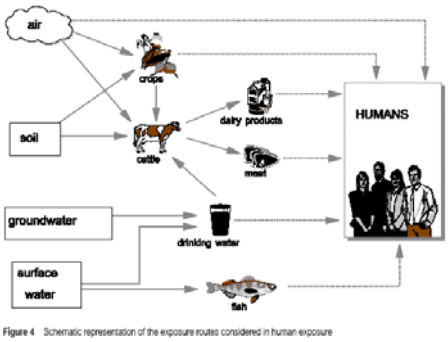


Figure 4 Schematic representation of the exposure routes considered in human exposure

Human health – exposure assessment

Measured exposure data, e.g.

- measurement data of companies (workplace)
- tests / studies for consumer exposure
- measurements in foodstuff, air monitoring (environment)

- Several models (computer tools) exist to model/calculate exposure if no measured data exist. Example:
  - EASE (Estimation and Assessment of Substance Exposure) → demo version on http://ecb.jrc.it
    - inhalation and dermal exposure
    - Also relevant for many types of consumer exposure

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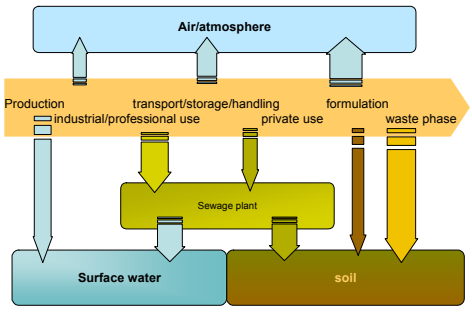
Exposure assessment environment

- Environmental media:
  - Aquatic ecosystems,
  - Terrestrial ecosystems,
  - Top predators -> secondary poisoning
  - Microorganisms in sewage treatment systems
  - atmosphere
  - marine ecosystems (including sediment)
  - marine top predators -> secondary poisoning

12

Emissions to the environment during the life-cycle of a substance



Environment – exposure assessment

- Usually concentrations are modelled, monitoring data are only a check-up whether calculations fit to reality!
- Three scales are distinguished
  - local scale: $PEC_{local,}$
    - only point sources (installations, STP) at specific locations
    - only dilution
  - regional scale: $PEC_{regional}$
    - point and diffuse sources (emissions from products, many small installations or households...)
    - distribution and fate are considered
  - continental scale:
    - „background" concentration in the environment for local and regional scale
- PEC_{local} and $PEC_{regional}$ are relevant for risk characterisation

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Modelling because measurements are "accidental" → dilution and heterogeneous distribution in environment.

To be detected at scales:

Local: "acute" risk, specific location and time

Regional: "chronic" risk, low concentrations but long times

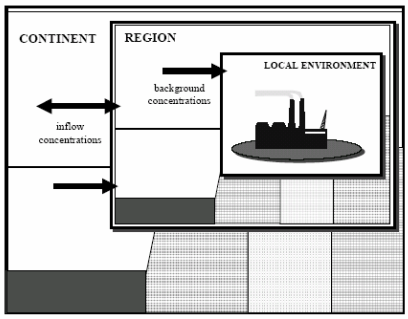

Figure 1 The relationship between the continental, regional, and local scale exposure assessments

15

Continental scale: will probably not play a role under REACH.

Currently: "background concentrations" to which the local / regional concentrations are added

Environment – exposure assessment

Data for exposure models, release estimations are based on:

- Physico-chemical properties (mobility), e.g.
  - Molecular weight
  - Log P_{ow}
  - Water solubility
- Amounts and use pattern of the substance
  - Production volume
  - Used volumes
- In the TGD, uses are grouped in categories connected to emission scenarios
  - Main category
  - Industrial category
  - Use Category (use pattern)

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Categories: important to understand → system to group similar emission situations, can be compared to exposure scenario at rough level, but no risk reduction measures included ← new under REACH!

Examples of industrial categories

IC2 Chemical industry: basic chemicals
IC4 Electrical/electronic
IC5 Personal/domestic
IC8 Metal Extraction, refining and processing
IC11 Polymers industry
IC14 Paints, lacquers and varnishes industry

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Emission estimation

- Emission scenario documents or simple tables in TGD or by OECD for main, industrial and use categories
  - description of processes and products
  - lists of emission factors (default values) depending on substance properties
  - „realistic worst case“ is assumed
- Emissions are calculated (simplified) for all life cycle stages
  - amount of substance X factor

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This is a bit more complicated, but only the principle should be understood.

Exposure assessment

- Fate and behaviour of substance in the environment is modelled, e.g.
  - partitioning, dilution, adsorption
  - degradation, abiotic destruction...
- Concentration in the environment is derived
- Usually: assessment of concentration in water soil, waste and air, other media are derived from these

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In human health assessment, no fate and behaviour exist! You can discuss here why.

→ Exposure occurs in short term after release, long-term exposure due to frequent / constant releases, substances only dilute but don't react

Model for environmental exposure assessment

EUSES: European Union System for the Evaluation of Substances

- Developed in The Netherlands by the National Institute of Public Health and Environmental Protection (RIVM)
- Integrated modelling system
- Decision support instrument
- Contains the EASE-Tool for workplace exposure

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Demo version on ECB website

Environment – exposure assessment

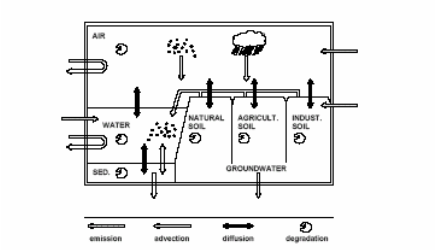

Figure 13 The relevant emission and distribution routes

Consequences risk assessment (currently)

- if further testing necessary → industry is asked to provide data, risk assessment process continues
- if no need for tests or risk reduction → report published and no further action
- if need for risk reduction → preparation of risk reduction strategies by MS and usually decision on marketing and use restrictions (Dir. 76/769)

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Under REACH, the current method will be further applied by MS for the substance evaluation procedure. Restrictions may be decided on as it is done to date

Exposure assessment under REACH

- The same principles will be applied, the assessment steps shall be
  - Simplified
  - Standardised
  - Digitalised (IT-Tools) if possible
- Frame described in Annex 1
- Details under development in RIP process
- The assessment for all steps is normally done by the producer

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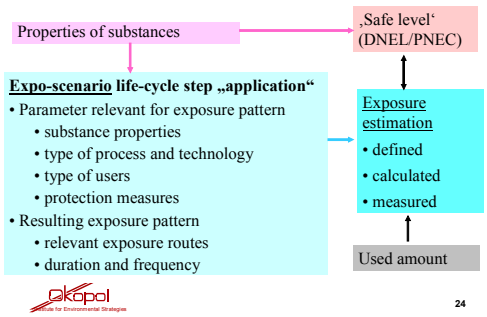
RIP 3.2. → development of format and methods for chemical safety assessment

REACH exposure assessment

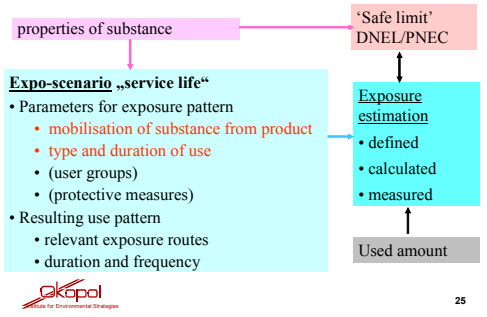


24

Scheme explains how primary information on properties and uses (expo scenario, amount) are combined in the safety assessmet

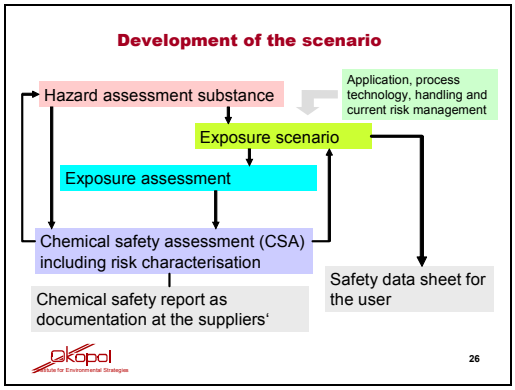
Here: use in industrial process

Reach exposure assessment

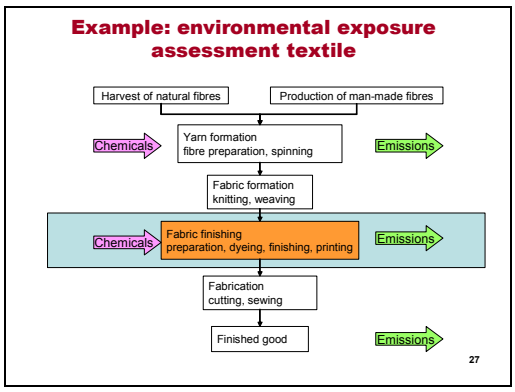


25

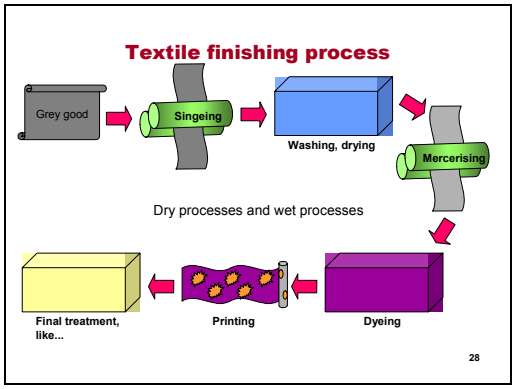
Mobilisation from product and type of product determine expo in service life



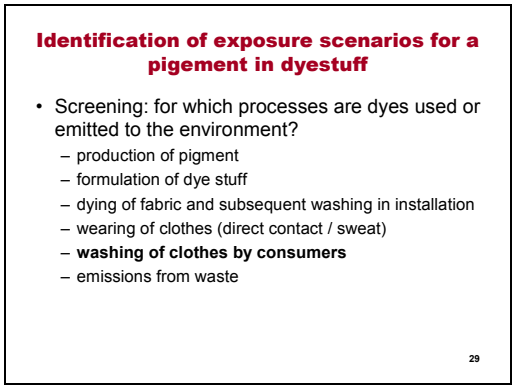
Shows workflow for CSA and resulting documents



Whole life-cycle



Processing steps, need not be explained in detail, discuss which emissions could occur for substances which are volatile or well soluble in water



Example in practice

Example washing by consumer

- Description of scenario (assumptions)
  - clothes are washed in washing machine
  - water temperature 40°C
  - clothes are dried inside
  - washing happens once every month
  - washing machine uses 50 l per washing
  - clothes are discarded after 1 year
  - water is discharged to local sewage system and treated in sewage treatment plant
  - no special risk reduction measures

30

Information necessary for describing the exposure scenario

Example washing by consumer (simplified) (2)

- Information for emission estimation
  - from substance producer/formulator: during each washing at 40°C, 1% of the dye is released from textile refinisher: clothe contains 10 g of pigment
  - 12 washings X 10 g X 0.01 = 1.2 g/a, concentration per washing = 10g X 0.01 in 50 l = 0.002 g/l
- Exposure assessment
  - dilution in sewage (1000 m^2) → 0.000002 mg/l
  - removal by sewage 50% → 0.000001 mg/l
  - dilution in surface water (20000) → very small conc.

31

Very rough calculation, in reality more complicated. Principle is important!

Exposure assessment in practice

- Manufacture starts with all information available to him (mainly substance properties)
- Unknown parameters are either
  - estimated / assumed (default values)
  - asked from down-stream
- Comparison of PEC/PNEC and risk characterisation
- If comparison = or > 1 → refinement of assessment

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Exposure assessment - summary

- Manufacturers / importers have complex task
- Detailed information on uses, processes, products etc. are necessary
- All life-cycle steps are to be covered
- Usually exposures will be modelled and not measured
- Exposure levels are concentrations or doses, comparison with safe level → risk
- More details → TGD or current RIP process

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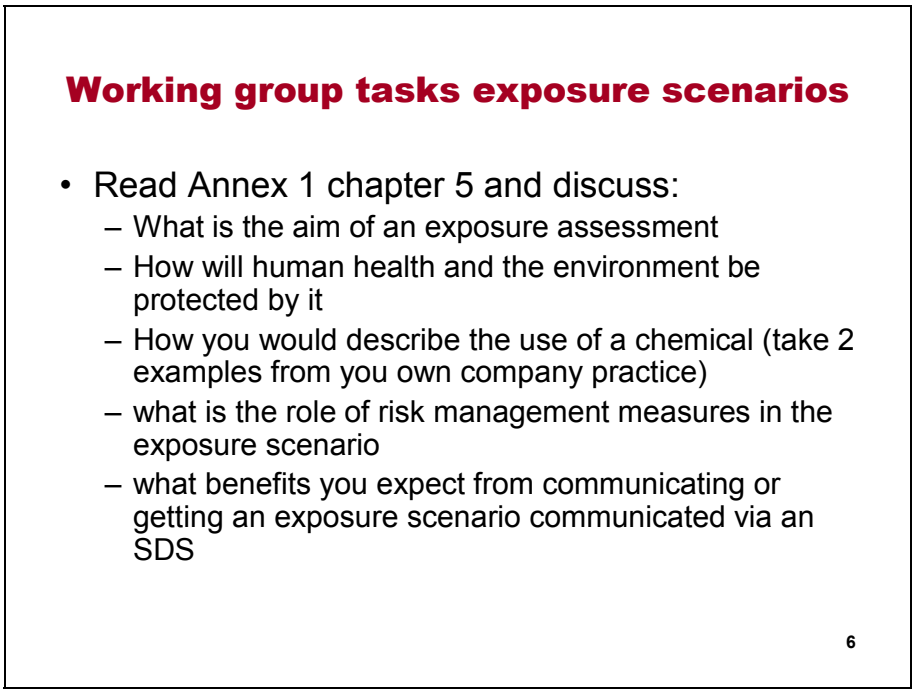
9.3 Exercises

The slides of the excercises are contained as separate file on the CD ROM

9.3.1 Working group on content of exposure assessment (general level)

Duration: introduction 10 minutes, working groups 45 minutes, reporting to plenary 10 minutes each group.

Materials: Flip charts, sheets with task description, copy of Annex 1



9.3.2 Working groups on collecting data for exposure assessment (elevated level, for all actors)

Duration: 10 minutes explanation of task, 30 minutes working groups, 5 minutes reporting to plenary

Material: flipcharts and sheets with working group tasks, copy of Annex 1

Working group tasks should be described shortly in plenary. The discussion will be more fruitful if the participants really pick one concrete example and don't discuss in general. You may prepare simple cases beforehand

1) manufacturer of a plastic additive or a pigment
2) formulator of a paint for construction material
3) formulator of a paint for car refinishing
4) producer of a plastic toy

Working group tasks communicating exposure information (producers / importers)

- Discuss for which types of chemicals you would have to do an exposure assessment
- Select one „case" of one participant and characterise
  - what substance is under question
  - which potential uses would have to be assessed
  - how you would obtain the information necessary to do an exposure assessment
- Use Annex 1 for help

2

Working group tasks communicating exposure information (formulators 1)

- Discuss for which types of chemicals you would have to do an exposure assessment
- Select one „case" of one participant and characterise
  - what substances are under question
  - which potential uses would have to be assessed
  - how you would obtain the information necessary to do an exposure assessment
- Use Annex 1 for help

3

Working group tasks communicating exposure information (formulators 2)

- Discuss under which circumstances you would have to communicate information on exposures up the supply chain
- Select one „case" of one participant and characterise
  - what substances are under question
  - which potential uses would have to be assessed
  - which information would have to be communicated upstream and how it could be obtained
- Use Annex 1 for help

4

Working group tasks communicating exposure information (manufacturers of articles)

- Discuss what you can do already now in order to make sure that you don't have to do an exposure assessment
- Select one „case" of one participant and characterise
  - what substances are under question
  - what you would communicate upstream
  - what you would not like to communicate and why
- Use Annex 1 for help

5

You may further ask the participants to describe one use and the related exposure pathways and identify missing information.

9.4 Discussions in plenary

9.4.1 Voting on exposures qualitative

Use the following slides to make people "voting" on information on exposures

Likelihood and extent

- How would you characterise the likelihood of contact of a substance with consumers in
  - use in braking fluids
  - use in children's toys
- How would you characterise the likelihood of contact of a substance with workers
  - varnishing of cars

low
medium
high

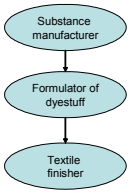
7

Likelihood and extent II

- Which parameters determine the extent of contact with humans in a consumer product?
- **amount of substance in the product and time it is used**
- **ability of the substance to "move out of the product"**
- **both**

8

Textile supply chain



Which type of environmental exposure scenario do you expect to be necessary for a dye stuff?

Air
Air and water
Water

9

Emissions of dye stuff in processing

- biological degradation
- log Pow
  - **most important parameter to find out if the substance is emitted to water**
  - **determines if the risk is in water phase or WWT/sediment**
  - **both**
- log Koc
- water solubility
- vapour pressure
- fixation rate

10

Who has got which information?

- biological degradation
- maximum amount used per day
- log Pow
- concentration in preparation
- ionic properties
- water solubility
- dilution in waste water
- vapour pressure
- fixation rate
- molecular weight

- **Manufacturer of substance**
- **Formulator of preparation**
- **User of preparation**

11

9.4.2 Discussion on exposure scenarios

1) manufacturers and importers of substances: discuss what could be the difficulties in making an exposure assessment
2) formulators: discuss what would be the task of a formulator when receiving an exposure scenario via the SDS
3) formulators: discuss advantages and disadvantages on making a use known to the supplier
4) other downstream users: discuss what would be the consequences of a definition of an exposure scenario based on a broad definition of a use and a narrow definition of a use

9.5 Further work for preparation for REACH

Manufactures and importers: start collecting information on uses of the chemicals by communicating with users

Users (formulators and others) start communicating uses upstream to make sure it will be covered in the suppliers assessment

All: contact associations and discuss with them what would be the branch specific issues in exposure assessemnt

All: watch the RIP 3.2 results for guidance on exposure assessment and the results from the pilot trials for potential difficulties and learnings

10 Business impact assessment

10.1 Introduction

10.1.1 Content of the chapter

Regulatory Impact assessment (RIA) is obligatory for every upcoming legislation according to EC Communication on Impact assessment – COM (2002) 276 final. IA at company level is performed as proactive preparation for upcming legislation and upon own decision.

Three types of business impacts are expected due to REACH:

- Direct costs resulting from administration for the preparation of a registration and the data collection, testing and fees necessary for that. These costs are mainly born by importers and manufacturers
- Indirect costs resulting from price increases (forwarding of registration costs by M/I) and from the need to reformulate preparations or change products and processes due to deselection of substances from the market. These costs mainly occur at DU-level.
- Innovation effects (positive and negative) due to less stringent requirements for the registration of currently “new” substances and better knowledge on substances and uses as well as (feared) losses of business know-how. These effects regard all actors in the supply chain.

Downstream users may also bear the costs for registration when their application of a chemical substance is not covered in exposure scenario communicated via SDS.

Further effects in availability of substances are expected due to the authorisation procedure of substances of very high concern (CMRs, PBT, vPvB and ED) is required.

REACH provides the mechanisms to minimise the registration costs:

- QSAR, use of category approach, available data, historical human data, read-across, registration of groups of substances → Annex IX;
- waiving of testing requirements → Annex VI-VIII;
- obligatory sharing the data (e.g. vertebrate animals testing);
- consortia building etc.

10.1.2 Reference to the REACH proposal

- Requirements for registration – Articles 5, 6
- Requirements for data to be submitted – Annexes V – VIII
- Cost-saving mechanisms: waiving of testing requirements – Annex VI-VIII, read-across, QSARs, registration of groups of substances, GLP – Annex IX

10.1.3 Further background information on content

The European Commission has carried out many studies on the impact of the New Chemicals Policy in different areas, e.g. economic, social and environmental impacts, occupational health, implications for animal testing etc. Also studies regarding the potential deselection of substances and its effects on innovation as well as business benefits in the specific supply chains were performed:
http://europa.eu.int/comm/environment/chemicals/whitepaper.htm;
http://europa.eu.int/comm/enterprise/reach/index.htm

Information on REACH impacts from **industry perspective**:

- **CEFIC** (www.cefic.org): Horizon 2015: Perspectives for the European Chemicals Industry (http://www.cefic.org/files/Publications/Scenarios2.pdf); Summary of business impact assessments of New Chemicals Policy
- **MERCER** Management Consulting Study of the impact of the future chemicals policy http://www.uic.fr/an/5_actualite/Final%20Mercerstudy%20%208%204%202004.pdf
- Impact Assessment Study of the Chemical Strategy on **Retailers and Wholesalers** www.eurocommerce.be/upload/6/95756414194096896023489139321432242601568921269f2995v1.pdf

Other studies to illustrate different impacts of REACH:

→ **Nordic Council of Ministers**: http://www.norden.org/pub/tryckt/sk/rapporter.asp

- "The True Costs of REACH" - study by economy professor F. Ackerman in Boston
- Cost of Late Action – the Case of PCB - costs for remediation of Polychlorinated biphenyls

→ **International Chemicals Secretariat**: http://www.chemsec.org

- Cry Wolf - predicted costs by industry in the face of new regulations
- REACH - a leap forward for industry
- REACH - What does it cost?
- New chemicals policy in the EU - Good or bad for companies?

→ **WWF – UK:** http://www.wwf.org.uk/chemicals/

- Innovation in the chemicals sector and the new European Chemicals Regulation
- Social cost of Chemicals
- Contamination: the next generation

→ **WWF – The Conservation Organisation**: http://www.panda.org

- Chemical Check Up - An analysis of chemicals in the blood of Members of the European Parliament
- Compromising our children: chemical impacts on children's intelligence and behaviour

→ **ETUC – European Trade Unions Confederation** http://www.etuc.org

- The potential benefits of REACH to occupational health with the focus on skin and respiratory diseases (ongoing study)

Some **methodologies how to perform IA** at national level can be found on the website of the **OECD** (http://www.oecd.org/, under "Chemicals safety" → "Chemicals risk management" → "Publications and documents"):

- Framework for Integrating Socio-Economic Analysis in Chemical Risk Management Decision Making
- Guidance for Conducting Retrospective Studies on Socio-economic Analysis
- Technical Guidance Document on the Use of Socio-Economic Analysis in Chemical Risk Management Decision Making etc.

10.1.4 Important terms related to the topic and links to other chapters

General terms: No specific. See Chapter 2 Definitions

Term	Legal definition	Easy and understandable words
Economic analysis	Aimed at evaluating all of the effects of a policy or project and valuing them in national resource terms. This takes place in a "with" and "without" framework (OECD guidance)	Assessment of positive and negative, direct and indirect impacts of the proposal compared with a situation where nothing changes
Costs & benefits analysis	A form of economic analysis in which costs and benefits are converted into money values for comparison over time (OECD guidance)	
Socio-economic impacts	Any impacts upon society/the economy as a result of a policy or project, such as price changes, welfare changes, employment, reduction in health impacts, and so on (OECD guidance)	
Direct costs		Costs arising due to compliance with the direct duties originating from the legislation, e.g. substance registration
Indirect costs		Costs arising due to the market response to changes (e.g. product availability, substitution, price increases) caused by the direct impacts.
Positive effects		Any benefits originating from the legislation for society (e.g. reduced externalized costs), business (e.g. better image, less scandals), workers (decreased potential for occupational diseases), consumers (e.g. reduction of diseases related to hazardous chemicals in articles), environment (e.g. prevention of damage to environment

Term	Legal definition	Easy and understandable words
		from products and processes).
External(-ized) costs	Costs incurred as a result of individual decisions, but which are borne by an individual other than the person making the decision. (For example, a private landfill operator which allows the site to contaminate groundwater may impose costs on neighbouring residents or businesses, in terms of health damage, the costs of water purification, or the costs of obtaining alternative uncontaminated sources) (OECD guidance)	Costs caused by industrial processes but paid by society. Usually they are related to environmental impacts (e.g. costs due to chemicals related health impacts (ozone depletion causing skin cancer), costs for decontamination/purification (soil and water pollution), disturbed ecosystem, loss of biodiversity).
Rationalisation		Decreasing number or diversity of substances used in the process/product.
De-selection		Disappearing/withdrawal of substance or functionality from the market

Links to other chapters:

- Roles and responsibilities under REACH → chapter 5
- Information collection strategy on hazards → chapter 6
- Chemicals safety assessment/ Chemicals safety report → chapter 7
- Exposure assessment → chapter 9

10.1.5 Actors for which the chapter is relevant

Actors	Relevan (yes/no)	What is of special interest?	Possible critical issues
Manufacturers / Importers	Yes	Direct registration costs per substance How to estimate overall REACH costs for company? How to minimize REACH costs? Are there any benefits for producers/ importers?	Don't' see any benefits Difficult to estimate costs, no possibility to get exact figures
Formulators	Yes	What are direct costs for them? In which cases? What are indirect impacts? How to estimate indirect impacts? Ways to minimise impact Benefits of REACH for them	Costs due to indirect impacts could be as big as the direct ones Difficult to foresee indirect impacts
Industrial/ professional users	Yes	Benefits of REACH and how to "explore" them in practice Do they experience any direct costs? What may be indirect costs for company?	
Traders (no import)	Yes	Will they have any extra costs due to REACH?	

Actors	Relevan (yes/no)	What is of special interest?	Possible critical issues
Ministries / state officials	Yes	Balance between costs and positive impacts Impact to a country's economy, ways to assist industry to reduce costs	Difficult to express positive impacts in quantities Attacked from two sides: industry and society
Inspectors	No		
NGOS	Yes	Positive impacts of REACH	Difficult to express positive impacts in quantities

10.2 Presentations

10.2.1 REACH impact to business (direct & indirect costs)

Goal

The trainees should understand:

- what are the benefits of making IA for any new legislation;
- what are the direct costs of REACH, how they influence the costs for downstream users and how they can be reduced;

Key messages

Many BIAs have been prepared with different outcomes, also depending on who paid the study. The aims of these are not (!) to determine the absolute costs, but to research the mechanisms increasing or decreasing costs and thus to optimise the legal framework.

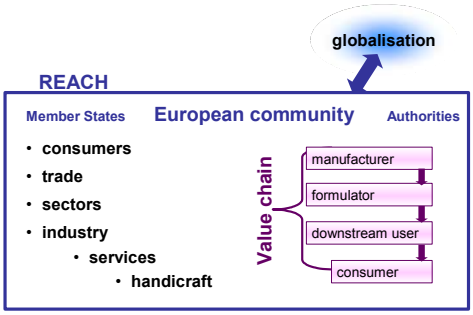
REACH causes direct costs for M/I for the substance registration.

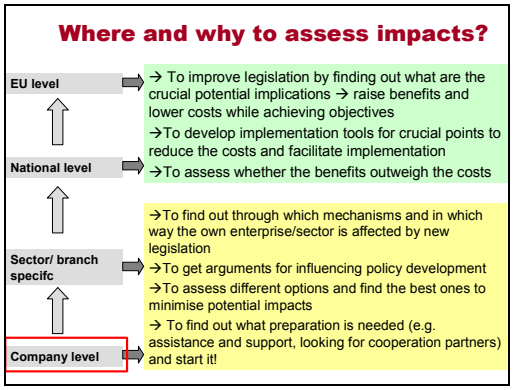
Indirect effects / costs result from the way the market actors react to the direct costs. M/Is can forward costs via prices or not to register a substance at all. Price increases can be split further in the supply chain or result in substition by DUs. If substances are deselected from the market, substitution is unavoidable. The structure of the chemical industry may change due to this (concentration of production, dangers for SMEs and especially importers)

Higher availability of information on substance properties and their uses may also enhance innovation, as well as the PPORD provisions.

The impact assessment at company level is performed by the company itself. It is recommended as first and important step in preparing for the implementation of new legislation! It helps to understand the requirements of proposal, to identify the most vulnerable issues for the company and to start developing a strategy for minimizing negative effects.

Presentation and explanation

Slide of presentation	Comments, key messages
Potential business impacts of REACH **Introduction**	
Impacts of REACH • Reasons for IA • Direct costs • Indirect impacts • Costs drivers and ways to reduce costs • Benefits	Overview on content of session on impacts
REACH – affected parties 	REACH concerns many actors at various levels
Impacts of REACH **36 IA studies by October 2004!** • Direct costs for chemicals industry: 2,3bil EUR over 11 years • Adaptation costs for downstream users related to substitution or withdrawn of substances (1-2%): 2,8 – 5,2 bil EUR over 15 years • Potential benefits for human health over 30 years: about 50 billion • Potential impacts on innovation and competitiveness (no quantification) • Potential benefits for environment (no quantification) Source: EC, EIA, 2003	Some more figures/ estimates: Health benefits: 5-284 billion EUR depending on the method (WWF) Extent of withdrawal of substances – 20-40% (VCI) → COM disagrees Loss of GDP 1.7-3.2%/year after 10 years; job losses – 360000-670000 (Mercer study) → industry financed Benefits only for occupational skin and respiratory diseases – 1.425 billion EUR (ETUC) NOTE: The findings of new EC studies to be added when available



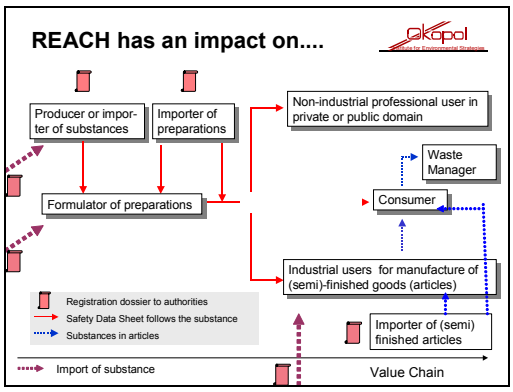
Higher level IA should consider impacts on company level

Focus of presentations – IA for industry

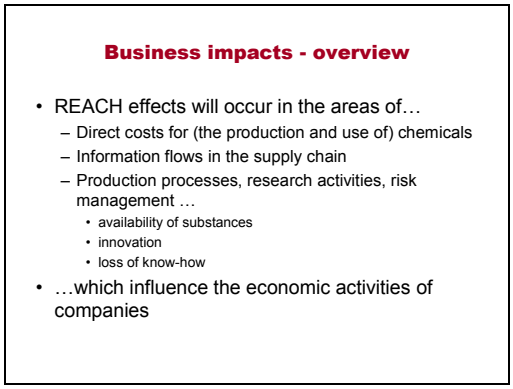
Short term perspective – focus only on immediate costs, but in longer term they may turn to positive outcome, e.g. increased competitiveness.

Narrow perspective – focus only on negative impacts to industry

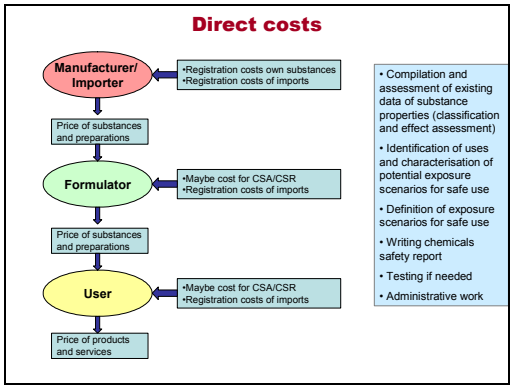
Wide perspective – looking on both negative and positive impacts, including downstream users, society in general, consumers etc.



Important to repeat info flow, exposure analysis and communication upstream – they are drivers for costs



Stress that impacts for every company will be different depending on its role in the supply chain and concrete activities.



Any supply chain actor might be influenced by direct costs in a twofold way: directly and indirectly

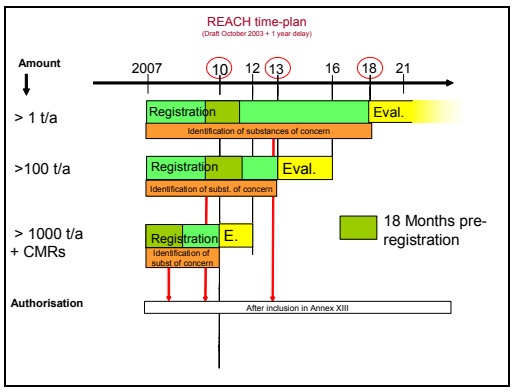
Easiest model of direct costs – everyone forwards costs down via increased price

Current cost estimates (unit costs)

t/a costs per substance	1 -10 t/a	10-100 t/a	100 – 1000 t/a	>1000 t/a
Hazard Assessment Robust Study Summary	-	1.500	8.700 500*	8.700 1.000*
Exposure Assessment Liaison with User	-	2.700* 3.500*	7.200* 12.000*	19.500* 15.000*
Risk characterisation Report (CSR)	-	800* 1.000	3.500* 2.000	3.500* 2.000
Administration	5.000	5.000	10.000	10.000
Testing*	5.800	73.100	163.000	208.000

* average substance → some tests available, very expensive testing not likely data from various sources (BIA RPA, BIA JRC, own data, German VCI)

Explanation of unit costs. Here is average cost per unit calculated from different figures.



It is important to know the timeline, i.e. how urgent is an action!

Here is a chart showing the phase-in scheme.

Options of the manufacturer/importer to avoid / recover the registration costs

- Increase the price of the substance
- Try to cross-finance non-profitable substances or accept smaller profit margin
- Increase the production of the substance
- Phase-out of production of the substance

Demand for good quality

Goods necessary for every day life

Competitors on the market

Alternatives available on the market

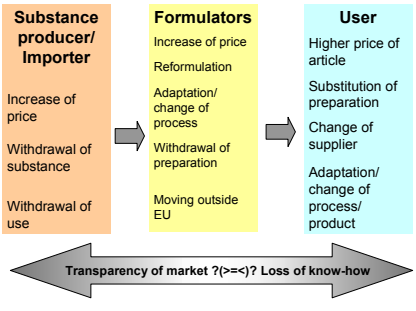
Ask the group for a brainstorm if the listed options are correct, then bring in the full text of the slide.

Critical for DU – higher price or withdrawal; if low volume/low value substances are really needed, higher prices might be accepted. Therefore early discussion about it with clients would be good.

Highest impact on companies producing many substances in low volumes (specialty substances) or importing high numbers

Discussion on potential factors influencing decision of action.

Indirect impacts = response to direct costs



For all actors

Explanation of market reaction to direct costs. Ask group for more options of potential reaction.

Bring in Consumer – how much more is he ready to pay for a good quality product?

Indirect impacts

- Deselection of substances
- Overburdening innovation capacity
- Loss of know-how
- Loss of competitiveness
- Reduced functionality of substance
- Increase of market prices (substances, preparations, articles)
- Reduced availability of imported preparations

Deselection of substances

10-40 % of substances disappear from the market (industry estimate)

- When might formulators be affected by deselection?
  - Import or use of low value/ low volume substances
- What could be impacts?
  - reduction of substance portfolio
  - investments to reformulate preparation or change/ modify processes
  - decreased competitiveness
- Deselection problems may be faced several times for the same product due to the phase-in scheme

10-40% withdrawl are strongly doubted by the Commission based on their impact studies! This is a CEFIC figure!

Innovation -- definition

- New economically successful chemical products
  - new substances
  - new combination of new substances and/or existing substances
  - new uses of „existing“ substances
- New process technology, process organisation
- Better ways to organise risk management of chemicals in the EU

Innovation I

- Rationalisation of substances on the market
  - negative: less possibilities to explore ‚new uses‘ of existing substances
  - positive: incentive to develop new and safer substances and products
- Data requirements for first marketing of non-phase-in substances
  - requirements for registration for 1-10 t lowered
  - substance is extremely successful
  - marketing of > 10t/a only after data are provided

Explain more detailed what “rationalisation” means and what consequences arise from that. Ask the group if they agree.

Non-phase-in substances could be e.g. new substances. Explain the “scenario” how usually new substances are introduced to the market.

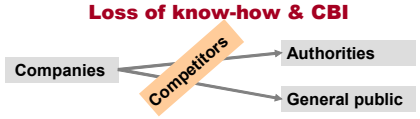
Innovation II

Further positive mechanisms

- Provisions for R&D are good → PPORD
  - use of a substance at the downstream user for R&D purposes
  - prolongation → 10 years in total
- Better contact between supplier and client expected → tailor-made solutions and efficiency gains by enhanced communication
- More knowledge on substances

Everyone in the supply chain gains from innovation.

Loss of know-how & CBI



1) Specific uses of substances
2) Non dangerous substances in preparations (article 30)

→ more transparency on the flow of chemicals on the market is experienced as a thread to CBI by many market actors but

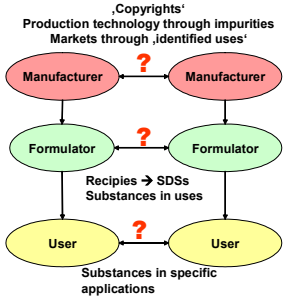
→ more transparency is essential for risk management

Article 116 → list of types of information which shall always be regarded confidential and which not

Information is made available via the internet, consortia (M/I), identified uses (M/I), parts of recipes (formulators, use of substance in specific application (users)

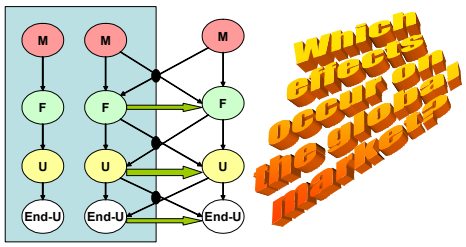
Explain that in general REACH gives some possibility to keep the information confidential (must be requested with good reasons or costs additional money for company in case of seperated registrations.

Loss of confidential business information



Show the supply chain and ask the group where they see the risk to loose information and what kind of information could be lost.

Competitiveness



Discuss with the group:

- Advantages of EU products compared to non-EU: quality of product, service
- disadvantages for EU companies regarding competition with other EU and non-EU companies: substances in products, process auxiliaries, import of articles

Potential effects on the global market: competition/ prices, moving of company, “outsourcing” of parts of processes, reimporting

What could be good strategies to overcome “unfair” competition?

Drivers of costs – options to reduce

- Testing costs
  - Existing data (→ to be acknowledged by authorities)
  - Annex IX (read across, QSARs, registration of groups of substances, GLP)
  - Annex VI - VIII (waiving of testing requirements)
- Exposure analysis
  - Width of exposure scenarios
  - Depth of analysis
- Communication and cooperation (consortia)
  - Existing stakeholder networks, associations…
  - Communication and documentation standards (RIPs, branch initiatives…)

REACH brings in itself the possibilities to minimise costs!

REACH is not aiming to phase out substances of high costs but of high risk, i.e high risk = high costs

Large-scale data collection ≠ large scale testing

Other reasons for change in availability of substances

- Authorisation
  - CMRs
  - PBTs / vPvBs
  - other properties of equal concern
- Restrictions
  - "no" change from current situation

There also other reasons for "de-selection" and they are similar as under current system

Conclusions for enterprises

- Effects on the market are difficult to predict due to complex interlinkage of actors and products
- Current knowledge on low-volume/low value substances is an assumption
- Early communication on potential strategies is necessary as well as indicating needs and willingness to develop solutions in the supply chain!
- Potential benefits are long-term, costs are short term!

Important issues to consider for companies when evaluating impact studies and carrying out IA themselves

10.2.2 Potential benefits of REACH

Goal

Industry: to learn where they can benefit from REACH and plan a long-term strategy accordingly.

All: to understand what could be **potential** benefits and that it is not easy to express positive impacts in monetary value.

Key messages

There is are few and little accepted methods to express environmental and health benefits in terms of money. Therefore a qualitative assessment is most often used to estimate and describe benefits.

Positive effects are most often occuring only in the long-term. Therefore the link between them and the cause for them usually are not obvious.

No regulation can be equally beneficial for everybody: for some companies the economic impacts might be purely positive e.g. enhanced competitiveness, better risk management. Others may bear mainly the burdens.

It is also difficult to predict which costs or damages REACH will really prevent.

The main positive impacts are believed to occur outside the company - environment, society, public health.

Presentation and explanation

Slide of presentation

Comments, key messages

Potential benefits of REACH

Benefits

- Benefits for business
- Costs of occupational diseases
- Benefits for society (environment & health)
  - What are externalised/ societal costs
  - Methods to derive external costs

EU economy without REACH

- Global competition is increasing
- Brands and enterprises are sensitive
  - Losses at stock markets due to toxic issues
  - Loss of reputation for brands → loss of money for the company
  - Liability claims
- Costs to compensate insufficient risk management:
  - Human health: injuries, loss of ability to work, allergies…
  - Real estate: accidents, damaged buildings due to acid rain
  - Environment: end-of-pipe solutions, cleaning of rivers…
- Some values can be partly compensated (e.g. crop loss to farmers or related to occupational diseases), some other values **cannot be compensated** and their **loss is irreversible**! (e.g. loss of biodiversity)

REACH can be an instrument for companies to prevent it

When assessing impacts of new legislation, the situation without changes is always to be considered!

The fact that existing requirements are not fully implemented is frequently not taken account of!

REACH – potential business benefits

General expectations on what may REACH improve

- More chemicals related information, more reliable, more transparent
- Increased practicability and harmonisation of risk assessment and risk management
- Prevention of business risks
- Better public image for companies
- Legislation is more transparent and simple
- First movers benefits
- Innovation will be supported (very contrary discussed)
- Less occupational diseases

Question – what is the background of those benefits (answer – availability of information)

Ask from which REACH mechanisms these benefits result

Availability of information

- Benefits due to better info on properties & systematic assessment of risks
  - national level: externalised costs reduced/internalised
  - company level: better risk management possible, better product design, info requests from downstream can be satisfied, scandals & claims from clients/workers can be avoided
  - consumer level: reduction of diseases related to hazardous chemicals are expected to decrease
  - environment: prevention of damage to environment from products and processes

Benefits on different scales due to better information and information flow

REACH – potential business benefits

Use of **New Substances**

- Development and application without registration costs up to 1t/a.
- For registration of new substances up to 10 t/a costs for required testing are 10-20% lower compared to the current system.

➢ Reduced costs for **manufacturers/ importers** for registration of new substances.

➢ **manufacturers/ importers** of substances have to deal with relevant registration costs at a point when they are able to predict the market success.

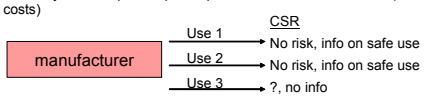
REACH – potential business benefits

Responsibility shared along the chain

➢ REACH provides a mechanism to define responsibility for product safety within the supply chain

➢ For **manufacturer/importer** liability is limited to that type of use and exposure which has really been assessed

➢ This may be an important pre-requisite for insurance contracts (reduce costs)



➢ If the use/exposure is covered by the SDS of the supplier, **downstream users** may get all necessary information to ensure safe use in an understandable form

➢ Efforts to ensure legal compliance may be reduced when REACH is implemented

Initiates further benefits - to general society

REACH – potential business benefits

Use of **Existing substances**

- A minimum data set is obligatory for all registered substances >1t/a. Hazard assessment is obligatory for medium and high volume substances. Thus, REACH may reduce the occurrence of un-assessed components

➢ For **downstream users** the risk of unexpected hazardous substances in products or processes may gradually decrease
➢ unexpected problems within recycling operations may also decrease
➢ Saves costs in risk management at **downstream users** (waste disposal, waste water treatment, workers protection)

REACH – potential business benefits

Information provided with registration

- Characterisation of substances
  - by a basic set of data (including QSAR predictions) and
  - harmonised safety assessment methodology

➢ New system supports **producers and formulators** doing good documentation and careful assessment, while the current system (no data = no classification) provides an incentive not to communicate all available information.
➢ Changes in the classification of a single component may gradually decrease. **Formulators and their clients** may have less trouble with changing classifications and resulting reformulations.

REACH – potential business benefits

REACH may create a level playing field

- Same requirements and same chances for every business player with regard to
  - Risk assessment
  - Risk management (gradually)

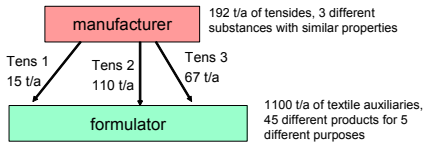
➢ Long term: more predictable business rules for the whole supply chain
Replacement of ad-hoc regulatory decisions (current system) by an agreed set of criteria and assessment methodology (REACH).

REACH – potential business benefits

Rationalisation (this is very contrary discussed)

- REACH may create awareness at company level on the number or diversity of chemicals handled and whether rationalisation may be possible while maintaining product or process performance.

➢ Identification of options for **manufactures and formulators** to increase efficiency and competitiveness



Discussion – if it is really „rational“?
Potential losses on consumer side

REACH – potential business benefits

Summary

- Many potential benefits could be identified that may improve competitiveness of companies and branches in the global context.
- Potential benefits may differ, depending on the role and position of a company in the supply chain
- Some of the described benefits may be realised within a short term after implementation of REACH
- Some of the described benefits may be seen as a long term perspective for improvement and global competitiveness
- Realisation of the benefits will often depend on the ability of the related supply chain to develop suitable chain management and communication strategies to deal with the REACH requirements.

Thus, starting communication on REACH now is not too early!

Communication requires a lot of time and efforts → it should be started as soon as possible, no need to wait for the very final regulation

Occupational health benefits & REACH

- Information on health effects from chemicals will lead to reduction of exposure and prevention of illness
- Some of chemicals-related occupational diseases are linked to unknown effects from those chemicals

	Skin diseases	Respiratory d.
Recognised cases/ year (LFS, Eurostat 1999, EU-15)	18 000	17 000
Not recognized (ETUC study)	x 11 times	x 35 times
Chemicals-related	**88 %**	**36 %**

Only some occupational diseases are recognised! Many cases e.g. shorter allergic reaction are not considered at all

Skin and respiratory diseases taken as examples because they are most often underestimated and the damage appears shortly after exposure, so it is easy to see the link between exposure of chemical and damage

Costs of occupational diseases

Costs per case include:

- Costs for medical treatment
- The value of lost output
- Human costs (for cancer = value of a statistical life)
- Compensation payment

Example - Germany

•ca. 1500 new cases of skin diseases/ year acknowledged → ca. 140 Mil. Euro (2002) + Costs due to absence of ill workers is estimated to be in the same range

→extrapolated to Europe (280 Mil. Euro for approx. 43 Mil. insured workers in Germany) → EU: approx. 215 Mil. workers → **1.4 bil. EURO**

•Sum of all chemicals related occupational diseases could be calculated as **3 bil. EURO** in Europe (including e.g. asthma)

Still…

•Less than 10 % of the applied cases get acknowledged

•Diseases of non industrial workers and consumers are not included

Issues to consider when expressing occupational diseases in monetary value

Figures are extrapolated from 1 country to EU level

Substance	Costs [Mill. Euro]
Aromatic amines	15.1
Halogenated hydrocarbons	7.5
Chromium(VI)	4.7
Isocyanates	4.9
Organic solvents	0.8

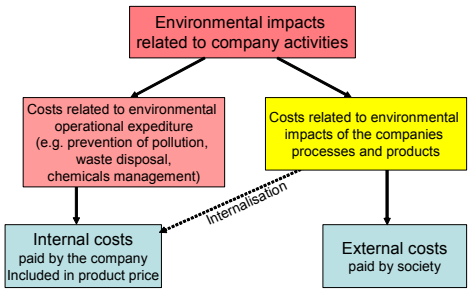
Examples for chemicals related skin diseases

Explanation of the link between public health and exposure of society to industrial chemicals

Society & health

- **Public health** → influence through environment (soil, air, water)
- **Consumer health** → direct exposure of consumers through skin contact, eating/drinking and indoor exposure

Externalised costs



Society is partly paying for environmental impacts caused by industry! Mainly because it is impossible to prove whose fault it is.

What are externalised costs?

Examples for externalised costs

- Costs due to chemicals related health impacts (e.g. by contaminated food)
- Costs for decontamination (soil or water pollution)
- Disturbed ecosystems
- Ozone depletion → skin cancer
- Loss of biodiversity

Examples for internalisation strategies

- Taxes (e.g. eco-tax on fuel, phthalate tax)
- Rate for contaminated waste water
- Appropriate disposal or incineration costs
- Duty to take back end-of-life products (ELV and WEEE)
- Liability claim/Insurance costs

Examples of externalised costs and ways how to internalise it

Internatisation – making costs accounted for by the industry actor responsible for the damage.

Methods to calculate external costs

Direct methods:

- Willingness to pay:
  - What are you willing to pay for less polluted drinking water?
  - What is a company willing to pay to be allowed to contaminate your drinking water?
- Willingness to sell
  - What would you demand as compensation for a more polluted drinking water?

Indirect methods:

- Costs for reparation/decontamination
- Costs for prevention (of pollution, e.g. costs for communal waste water treatment)
- Costs for alternative or adapted measures (to deal with a damaged environment, e.g. transport of drinking water from remote sources or higher efforts to get adequate groundwater)

There are only unprecise methods to monetarise external costs. The method is subjective and it is imortant that the persons understand the issue to give a reflected answer. Asking unknowledgable persons for their willingness to pay for phthalate free toys does not lead to reliable answers.

Indirect methods are good to illustrate the potential range of costs for damage but the results will not show whether REACH will really prevent these.

Examples for externalised costs

PCB-decontamination of schools in Bremen (Germany)

- Cost for rebuilding: 143 mil. Euro (1960 – 1975), about 10% estimated to be directly related to PCB-decontamination: 14.37 Mil. Euro
- Measurements: > 200,000 Euro
- Costs for organisation and administration (not included)

Sum: 14.6 Mil. Euro for 661,000 inhabitants

= 22 Euro per inhabitant.

Costs for PCB remediation 1971 – 2018 based on Swedish study for EU 25: 15 –75 Bil. Euro

Would these costs have been prevented if PCBs had had to be registered under REACH?

Only 1 example to be presented depending which one is more relevant or better known by the group.

Examples for externalised costs

Drinking water treatment in the Netherlands (1991-2000):

- Additional costs for pesticide removal from drinking water:
  240 Mil. Euro over 10 years NL (15 Mil. Inhabitants)

= 2.4 Euro per inhabitant per year

Communal waste water treatment: costs for additional equipment to remove 4 oestrogenic substances in sewage effluent to achieve "good water status" (UK, 2005 – 2012)

- Costs for investment and operation (over 20 years) (UK: 59 Mil. Inhabitants)
  = 1.5 Bil. Euro -> 2 Euro per inhabitant per year

Summary

- Monetarisation of unpriced values difficult… but
  - damage is obvious and should be prevented
  - externalised costs should be prevented
- Not very clear to which extent REACH can prevent external costs…
- Relation between factors causing damage - properties vs behaviour

Nevertheless…

- REACH may prevent exposure, as substances will be assessed
- REACH will change behaviour and enhance risk management measures and better risk communication

Ideal IA, which we all want, considers...

- Direct impacts on businesses, regulators and other stakeholders
- Impacts on human health and the environment
- Indirect and wider economic effects (e.g. DU)
- Competition, employment and trade issues
- Impacts on small ad medium sized enterprises

How to get all that expressed in figure?

The wish to get a figure on exact impacts is unrealistic.

It is impossible to include everything in one study. The clear focus/target of the study should be set from the very beginning. Nevertheless, it is important to remember that in IA's long term and broad perspectives are necessary.

10.2.3 How to get started: BIA at company level

Goal

Industry/importers should learn:

- what information is essential to get an idea on impacts at company and why;
- how to collect and assess that information;
- how the preparation for REACH implementation can start.

Key messages

Data screening/collecting is a time and resource consuming task but necessary for evaluating potential impacts on the company. Good electronic databases on products, raw

materials and substances is the best tool for screening, especially for importers, formulators, users, where many substances are handled.

Good knowledge on REACH is required for the interpretation of collected data.

There are many unpredictable factors, such as reactions of other market actors, which might change the estimates in real life.

Companies may need longer time periods to adapt to changes imposed by REACH (e.g. substitution of chemicals, processes, reformulation, changing profile etc.), therefore it is not too early to start already now!

Presentation and explanation

Slide of presentation

Comments, key messages

This presentation gives practical hints for both – assessment of impacts and preparation for REACH

How to get started?

Which effects can be assessed?

Manufacturers / Importers

- Registration costs → number of substances to be registered, amounts and properties
- Potential effects on prices of own products → registration costs per kg/substance

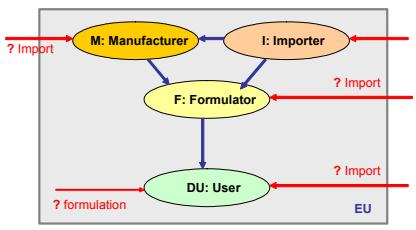
Downstream users

- Availability of substances → market volumes of substances used, dangerous properties
- Dependency on substances → which substances are essential for processes (specialties)

Overview, why which data collection at company level is important.

What is your role in the supply chain?

Type of actor/ role of company



First all roles should be clarified. This already gives hints for the areas of potential risks/impacts of company

Business impacts manufacturers

Collect data and fill the table for the entire portfolio for assessing the cost for registering all substances.

Tonnage band	1-10	10-100	100-1000	> 1000
Dangerous				
Not dangerous				
Average reg. costs Euro not dangerous dangerous	10800	79600 84100	181700 197200	226700 245200
Registration deadline				

Manufacturers (also importers) can use the below table to assess the overall impacts. It is also important to understand for DUs

Compilation of registration dossier

1. Check what data are needed → Annexes V-VIII
2. Collect available data → own + other sources, tests, non-test data
3. Identify gaps and check:
   - Which data is not scientifically necessary
   - Where grouping/ read-across is applicable
   - Where the use of QSARs possible
4. For remaining gaps → check whether exposure driven waiving is possible
5. Only for rest → testing according to GLP (NB! vertebrate tests first should be proposed to the competent authority and approved)

Assessment in detail: finding out which tests are really needed and what they may cost.

Manufacturers – profitability of registration – exposure part

- Exposure assessment is difficult to estimate
  - diversity of uses
  - methodology and instruments for exposure assessment still under development
  - average of one month of work can be estimated
- Communication with users may help in finding out, if price increases may be tolerated

Manufacturers – profitability registration

- Calculate the total costs for registration (testing, hazard and exposure assessment, administration etc.)
- Calculate profit from marketing of substance
- Assess whether registration costs can be
  - forwarded via prices
  - absorbed by the margin
  - are justified due to strategic reasons of the company

This is normal company business!

Screening information on chemicals in the company - 1

Main information of interest (M/I/DU):

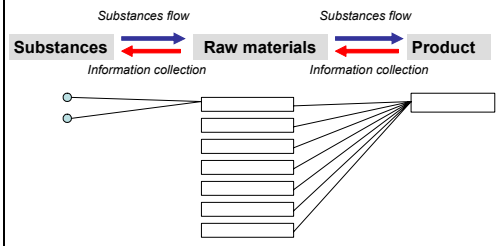
- Number and volumes of substances
- Dangerous substances (number + type)
- CMRs/ PBT/ vPvB/ ED/ respiratory sensitizers
- Number of new substances
- Typical market price
- Main uses

List of information to be well known at company level in order to assess the situation

New substances are regarded registered → no registration costs

Main uses / special uses → shows vulnerability of the company, how much does it rely on a substance

Screening information on chemicals in the company -2

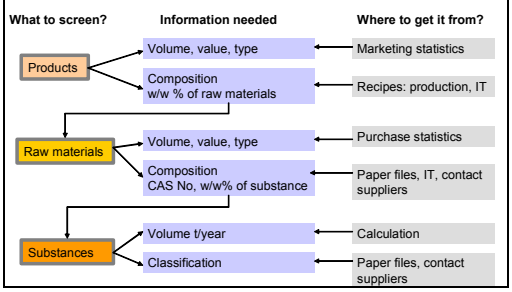


REACH is about substances!

Stress that REACH is on substances and information on chemicals needs to reach "substance level".

The way of collecting information is opposite to the substance flow

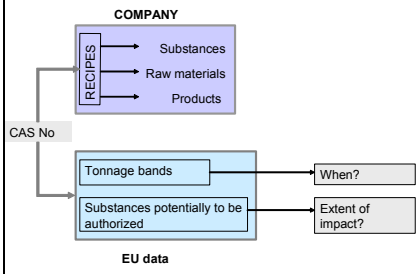
Screening information on chemicals in the company - 3
Number and amount of substances



Easy to follow scheme what to look for where and how to get needed information

The final goal of data collection on substances: CAS No, amounts t/a, classification

Screening available data in EU - 1



Company data could be compared with data available at EU level to make the estimation more realistic

Screening data available in EU - 2

Properties of substances:

- **CMR cat. 1-2** → **R45, R46, R49, R60, R61** → screen Annex I of 67/548/EEC (incl. 29th ATP)
- **PBT/vPvB** → criteria in Annex XII, no final list available
- **Endocrine disrupters** → COM (2001)262 – Annex 15. http://europa.eu.int/comm/environment/docum/01262_en.htm#bkh
- **Respiratory Sensitisers** → **R42** → screen Annex I of 67/548/EEC (incl. 29th ATP)

Volume of substance:

- **HPVC/LPVC →ECB** http://ecb.jrc.it/existing-chemicals/

New substances: ELINCS, ECB http://ecb.jrc.it/new-chemicals/

Sources where to find information in EU databases.

Market volume: ESIS database contains information on amount of producers (names!) and market volumes (in IUCLID files)

Evaluation of data – 1 Amounts

< 1t/a	1-10 t/a	10-100 t/a	100-1000 t/a	> 1000 t/a
No actions required				
Registration	within 11 years	within 11 years	within 6 years	within 3 years
Data	Basic data - Annex V	Annex V+ Annex VI	Annex V + Annex VI +Annex VII	Annex V + Annex VI +Annex VII + Annex VIII
CSA/CSR	No	Yes	Yes	Yes
Other		Risk of de-selection		

Requirements of REACH related to volume bands

Evaluation of data – 2

Properties:

- **Dangerous substances >10t/a** → exposure scenarios + extended SDS
- **CMR cat. 1-2** → registration within 3 years + authorisation
- **PBT/vPvB/ED/sensitizers** → authorisation

Other:

- **HPVC** → registration within 3 years
- **LPVC** → registration within 6 -11 years
- **New substances** → dossier prepared/ under preparation → no further registrtion under REACH

Predict when substances will be registered and/or if they may have to be authorised.

New subsatnces will not have to be registered again! If tonnage bands are exceeded, respective tests data has to be provided nevertheless.

Evaluation of data – 3

- **Price of substance/ product** → low value/low volume substances/products may be de-selected
- **Type of use**:
  - wide-spread use → high potential to be registered
  - very specific use → manufacturer may refuse to register
  - active substance in biocide → does not fall under REACH

What conclusions can derive from the price of substances/ products or type of use

What else to consider?

- **Vulnerability of processes** → how dependent is the company on a certain substance (special performance)
- **Cooperation in the supply chain and with competitors** → shared registrations, consortia
- **Clients** → balance of power between demand and supply
- **Own innovative capacity** → how easily can processes or chemicals be changed?
- **Strategic decisions** → where are investments likely in order to maintain good market positions?

Some more factors influencing potential impact of REACH to the company

What's next?

- Improve / set up electronic inventory based on products, raw materials, substances
- Start communication along the supply chain: substances, uses, relevance of substance to client/supplier
- Check availability of information on substance
- PBT/vPvB/CMR/ED/sensitizers → look for substitutes
- Get overview on the market
  - for the same products/substances → potential for sharing costs,
  - for available substitutes with the same functionality → request of clients for your specific product and readiness to pay
- Build up expertise
- Try to compile 1 registration dossier

Ideas how to start preparation for REACH based on the findings from data screening/collection

10.3 Exercises

10.3.1 Exercise 1

Goal of exercise: to help participants to structure and "fix" the knowledge obtained during presentation on potential costs of REACH discussing concrete example of a company

Target group: different industry - manufacturer, formulator and industrial user, importer

Setting: Everyone works alone and checks for one substance / preparation he uses. Working groups are also possible.

Questions to be discussed:

1. What is the role of the company in the supply chain, which general impacts are expected due to that role

Each participant select one substance or preparation which is produced / used by the company. For that a checklist is made:

2. What can be the possible impacts for that substance / preparation? Which information would have to be collected to find out more specifically what would happen under REACH? Is all information available? What information is missing?
3. List main possible impacts for the concrete company
4. List main possible benefits for the concrete company

Answers

Manufacturer	Formulator	User	Importer
1.	1.	1.	1.
2.	2.	2.	2.
3.	3.	3.	3.
4.	4.	4.	4.

Reporting to plenary: each participant prepares a flipchart on findings and shortly presents; discussions (grouping is possible).

Timing: self-reflection or discussions in WG – 30 min; reporting to plenary and discussions – 30 min

10.3.2 Exercise 2

Goal of exercise: to stimulate thinking about possible impacts of REACH for the own companies and what steps could be taken in order to better prepare for REACH

Target group: manufacturers, formulators, industrial users, importers

Setting: Actors-specific groups of 3-5 persons

Questions to be discussed:

1. What would be the 5 most important issues to look at in my company to evaluate the possible impact of REACH? (i.e. making check list).
2. How to find out whether those issues are really important for your company?
3. Develop strategy how to get missing information for 1 of the listed important points.

Tools: No specific tools are required (Note: companies could be asked in advance to bring general information on chemicals they handle). Groups note down the results of discussions on flipcharts.

Table below gives ideas on potential answers:

Actors group	Potentially important issues	To do in company
Manufacturer/ Importer	amounts of substances produced/imported (>1t, >10t, >100t, >1000t per year) properties of substances imported (PBT, vPvB, CMR, sensitizers…) data availability and quality expertise/competence within the company (communicate risk down, designate use/risk assessment…) knowledge on use price/ market share for substances of 10 -100 t/a R& D activities	Screen company statistics: production, marketing, supply, personnel Screen chemicals inventory Check what data is needed according REACH (depends on volume) → check whether such data available in company → check other sources Discuss with product development unit how much they know about uses of products Discuss with products development unit what is the information to be kept confidential → check whether it does not fall under "open" information under REACH
Formulator	amounts of substances used for formulation (assumption on production volumes >1t, >10t, >100t, >1000t per year) combination: big share of substances of 10-100 t/a in preparation of low value properties of substances imported (PBT, vPvB, CMR, sensitizers...) confidentiality of information knowledge on use share of direct import of chemicals	
User	Use of CMR Number of substances/preparation classified as dangerous Availability of SDS for dangerous substances/preparations Share of direct import of chemicals Chemical expertise/ personnel	

Examples of strategies:

1. **Data on amounts & properties of chemicals handled**: try to compile data on amounts and properties of handled substances with existing tools in the company → if not possible technically, improve current system/ set up new chemicals inventory → if not possible due to availability of information (no full composition, no hazards indicated) communicate to suppliers on properties/ composition/ concentration ranges
2. **Availability and quality of information on chemicals**: check what data is needed according REACH (depends on volume) → check whether such data is available in the company (tests, non-tests, GLP…) → check other sources/ databases → identify gaps in information → check whether they can be estimated/modelled → check whether they can be waived according REACH

Reporting to plenum: each group presents the results in plenum, other groups add/ comment; joint discussion/clarifications.

Timing: discussions in WG – 30-40 min; reporting to plenary and discussions – max. 20 min

Supporting material: presentations (especially "How to get started"), information about companies if available

10.3.3 Exercise 3

Goal of exercise: to discuss potential positive impacts from implementation of REACH for specific actors/company and to identify indicators to estimate that

Target group: all actors groups

Setting: Actors-specific working groups of 4-5 persons

Questions to be discussed:

If you look at the processes in your company and your position in the supply chain, what do you expect to be the most relevant business benefits related to the implementation of REACH (max. 5)

What could be potential indicators to check whether it really worked out?

Tools: No specific tools, only flipcharts, pens.
Table below give some examples of answers (but not necessary that groups would come to the same)

Actors group	Benefits	Indicators
Manufacturer	Innovation	Increased number of new substances/ uses More personnel involved into R&D
	Increased competitiveness due to quality of products	Increased market for products outside EU (foreign trade)
	Better risk management in the company	No accidents related to unknown properties of chemicals
	Better image due to sharing responsibilities	decreased number of claims/ scandals due to incorrect use
Importer	Better image, closer relation too client	Stable client relationships
DU	Better quality of SDS	Less requests for additional information from clients If still information requested, less efforts to answer No “not available” in SDS
	Improved product development, design	Less “reformulations” needed More “environment friendly” products developed
	Better RA at working places	less workers on sick leave related to work conditions, accidents, exposure
	Saved costs in risk management	less investment to abetement technologies less costs for discharges of haz. substances to WWTP less haz. waste less investments to PPE with the better efficiency of protection
	Better risk management in the company	No accidents related to unknown properties of chemicals
	Easier compliance with other legislation, especially environmental	No difficulties to collect needed information on chemicals (e.g. for IPPC, WFD)
	Improved image of company	No unexpected scandals due to chemicals in products/processes
	Increased competitiveness due to quality of products	Increased market for products outside EU (foreign trade)

Actors group	Benefits	Indicators
NGOs (for consumers/society/ environment side)	safer products	reduced number of poisoning related to chemicals in products reduced number of diseases (especially allergies) related to chemicals in products
	better environment	decreased load of chemicals to environment less losses of biodiversity due to chemicals occurrence
	increased animal welfare	less animal testing less chemicals related animal diseases/ extinction / mutations

Reporting to plenum: each group prepares flipchart on results of discussions and shortly presents their **main findings/conclusions**; joint discussions what could be potential timing when the benefits will become visible.

Timing: discussions in WG – 30 min; reporting to plenary – 5 min/group, common discussions – 10 min

Supporting material: presentations

10.3.4 Exercise 4

Goal of exercise: to try to interpret the data

Target group: all actors groups

Setting: actor-specific or mixed working groups of 4-5 persons

Questions to be discussed:

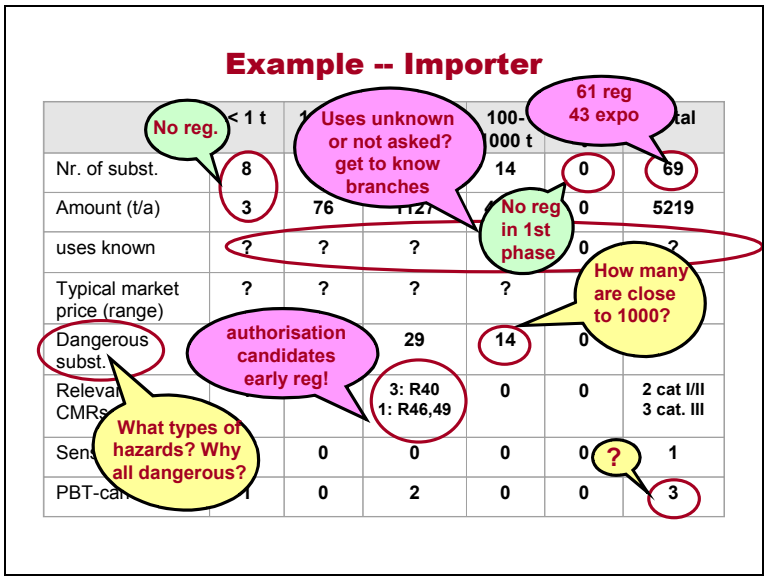
1. Which chemicals are “critical” and why?
2. What info is missing to conclude on impact?

Example -- Importer

	< 1 t	1-10 t	10-100 t	100-1000 t	>1000 t	Total
Nr. of subst.	8	17	30	14	0	69
Amount (t/a)	3	76	1127	4012	0	5219
uses known	?	?	?		0	?
Typical market price (range)	?	?	?	?	0	?
Dangerous subst.	7?	17	29	14	0	66
Relevance CMRs	1	0	3: R40 1: R46,49	0	0	2 cat I/II 3 cat. III
Sensitisers	1	0	0	0	0	1
PBT-candidates	1	0	2	0	0	3

Tools: Example table with summary data on chemicals used in the company to be given to groups.

The answers for trainer:



Reporting to plenum: answers from the place, one group after another + direct discussions

Timing: discussions in WG – 20 min; common presenting/discussions in plenary – 20-30 min

Supporting material: presentations on BIA, example tables

10.4 Discussions in plenum

Discussions for any group: Whether all costs are due to REACH or some are “myth” and are related to improper implementation of current legislation? What are the risks of inaction, i.e. waiting for final REACH regulation? Does REACH give any “advantages” for SMEs?

Discussion with manufacturers / importers: What are their potential reactions to additional costs due to REACH requirements (e.g. increase price of chemicals, move outside EU…)? What ways to reduce the costs they see as realistic? What are the potential areas of serious concern and what should be done to clarify whether they are such in reality? What information they consider as really sensitive for their business?

Discussion with DUs: Are they aware of their potential multiple role on supply chain? Whether they understood that also can face direct costs? What potential indirect impacts they see most critical for their own companies and what could be their reaction to that? What information they consider as really sensitive for their business? What is their current experience regarding communication and cooperation downstream and upstream – what works well and what not?

Discussion with NGOs: What positive impacts they see most important? Where is the margin between still acceptable costs and benefits?

10.5 Further work for preparation for REACH

DUs: Clarification of all roles in the supply chain

Market actors:

Rough assessment of potential impact of REACH to company (according questionnaires developed for homework, they can be provided to companies).

Develop the strategy how to prepare for REACH

Get overview on the market for the same products, substances (to know potential for sharing costs)

Start communication on the supply chain.

NGOs: Raising awareness on positive impacts of REACH

11 Training concepts

11.1 Training on principles of the chemicals safety assessment

General target group: manufacturers/importers of substances (and preparations) > 10t/a

Target group regarding specific company representatives: technical personnel responsible for dossier

Type of training:

Option 1: 1 day introductory training or

Option 2: training of 3 parts: 1 day + homework + 0,5 day follow up

Goal: to learn what resources (experts, time, money) and information is needed (type of data, downstream uses)

Preliminary programme

Content	Timing
1) Presentation: General content of CSR key words headlines in Annex I of REACH proposal (basis = CSR format)	1 h
2) Presentation: Hazard assessment (overview) human hazards, including physical-chemical DNEL's environmental hazards, including effects, fate, PNEC classification & labelling Note: 1-2 little exercises how to determine/ calculate AF, PNEC, PBT	1,5 h
3) Presentation: Exposure assessment development of scenarios (info on downstream uses!) exposure estimation Note: do little exercises how to calculate PEC	1,5h
4) Presentation and discussion: Risk characterisation comparison of DNEL's, PNEC's with estimated doses and concentrations assessment of likelihood and severity of effects	1 h
5) Presentation: Specific guidance available Results of RIP's (not yet available!)	0,75 h
6) Exercise/practice: Go through 1 example (to be prepared in advance)	1,5 - 2 h

11.2 Training on CSA/CSR (modification of above)

1st part: Training as described above

Homework: to prepare CSR for 1 substance (1-1,5 months)

2nd part: exchange of experience, open questions (0,5 day)

11.3 Impact assessment at company level, first steps to prepare for REACH

General target group: Manufacturers/ Importers /DU (proposal to choose one actors group for training)

Target group regarding specific company representatives: Top managers, specialists responsible for chemical issues

Type of training: 3 parts training: 1 day introductory training + homework + 0.5 day follow-up meeting

Goals: to learn how to identify potential impacts of REACH on the company activities and how to start preparing.

Outcomes:

knowledge on general requirements of REACH;
role of the company under REACH;
possible impacts for company;
action plan for preparation

Preliminary programme

Content	Timing
Part I – 1 day	
Opening	0,25 h
1) Presentation: Introduction to REACH basic principles roles & responsibilities (focus of specific target group) changes in current system timelines & developments Note: many clarification questions to be expected	1,25 h
2) Presentation: Impacts of REACH overall impacts (short) actors-specific impacts Note: be specific and focus on target group, good to prepare examples	1 h
3) Working group I - Potential impacts for my company (0,5 h) and discussion of results in plenum (0,25 h)	0,75 h
4) Presentation: Costs drivers & Potential ways to minimise impacts	0,75 h
5) Short presentation and discussion: Practical steps how to start work on impact assessment and preparation for REACH	0,75 h
6) Open questions/ Summary/ Introduction to homework Giving homework task (based on the presentation 5): 1) Screen information on chemicals in the company 2) Evaluation and drawing conclusions on potential issues of concerns/ impacts 3) Development of the actions programme	1 h
Part II – 0.5 day	
Feedback, questions on homework General discussions in plenary Individual work and reflection of results	 1.5 h 2-3 h

11.4 Training on REACH for Downstream users (DU)

General target group: downstream users (separately for formulators and professional/industrial users)

Target group regarding specific company representatives: Top managers, responsible for chemical issues

Type of training: 1 day introductory training

Goals:

to inform DU about their roles in the system, tasks, responsibilities, possible benefits; present case studies;
introduce cooperation possibilities

Preliminary programme

Content	Timing
1) Welcome & introduction	0,25 h
2) Presentation: Deficits of the current system and potentials of REACH to contribute to its solving Note: start with open discussion about chemicals-related problems in the own company, only then present overview of deficits → very basic principles of REACH → which deficits REACH will solve and with not.	0,5 h
3) Presentation: Introduction to REACH basic principles roles & responsibilities (focus on DUs) timelines & developments Open discussion on the role of the participating enterprises in the supply chain	1 h
4) Working groups – Exercise on roles and responsibilities - to identify own position in the supply chain - to determine the chemicals-related tasks in the own company: current and under REACH	1 h
5) Impacts (costs and benefits) of REACH for DUs Note: focus on concrete changes/impacts for DUs	0,75 h
6) Presentation and discussion: Costs drivers & Potential ways to minimise impacts	0,5 h
7) Presentation and discussion: Practical steps how to start work on impact assessment and preparation for REACH in the company	0,75 h
8) Example case from projects: Impacts for DUs Note: if there is time	1 h
9) Q&A, feedback, possible continuation	0.5 h

11.5 Training on REACH for NGOs

General target group: environmental and consumer protection organisations (central and regional)

Type of training: 2 parts training, 1 and 0.5 day

Goals:

to get overview on REACH requirements, background/ reasons for REACH, deficits of the current system;
to learn about the role of NGOs in policy development in general and regarding REACH;
to get an overview on positions of other stakeholders and define own position;
to reach agreement on further communication and dissemination of information

Preliminary programme

Content	Timing
Part I	
1) Introduction round Note: include some words on how policy development works in general	0,25 h
2) Presentation: Deficits of the current system – where do the deficits become evident? (e.g. accidents, scandals on chemicals in products (e.g. children's toys, phthalates in T-shirts etc.) Note: first discussion then systematised presentation	0,5 h
3) Presentation: Introduction to REACH elements and basic principles	1 h
4) Presentation: Roles and responsibilities, actors under REACH	0,5 h
5) Working groups 1: Benefits and drawbacks of REACH Note: environmental and consumer NGOs should be in separate working groups	0,75 h
6) Presentation: state of the REACH proposal, ongoing discussions and elaboration of the proposal, position of different stakeholders (main highlights)	0,75 h
7) Presentation or discussion: EU process: developments, where to find updates	0,5 h
8) Working group 2: What are the interests of NGOs to participate in REACH policy development	0,5 h
9) Summary & agreements (leadership, procedures for drafting position etc.)	0.5 h
Part II	
1) Review & Introduction	0.2 h
2) "Quiz show" on REACH	1 h
3) Discussion: Work on REACH in the country (national working group, position etc.) Note: presentation by state authority would be helpful	0.75 h
4) Working groups: Positions of other stakeholders (industry, NGOs, trade unions) identify 5 most important points raised (benefits or problems) prepare 3 min speech for national parliamentarians (to be performed in plenary)	0.75 h
5) Discussion on positions of NGOs (with stickers)	0.2 h
6) Discussion/agreement on next steps	0.5 h

12 Questions & answers

12.1 Content

12.2 Introduction

The following questions can be used to "test" whether the participants have understood the content of presentations and exercises.

Note that the questions are answered according to the current interpretation of REACH. This may change still and especially the RIP process will clarify some issues. Be careful about questions on waste! These are very complicated and difficult to understand.

Questions	Answers
1.Scope of REACH	
Which substances are not (fully) under the scope of REACH (list min. 5 cases)? 3 Minutes	radioactive substances within the scope of Council Directive 96/29/Euratom substances (on their own/in a preparation or article) subject to customs supervision (provided that they do not undergo any treatment or processing, and substances in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit; non-isolated intermediates. pesticides, biocides, medicines, pharmaceuticals and cosmetics, and natural products will generally be outside the scope of REACH where they are covered by other legislation (mainly regards the use of the substance).
Under which circumstances and in which role could a waste managing company be regulated / have explicit duties under REACH? 5 minutes	If a waste management company produces a new substance from waste (not identical to those contained in waste) and he places it on the market yes. He is however not covered by REACH in his function as waste manager. Note: COM will work further on the exact scope of REACH regarding waste!
Is there an obligation to register distilled waste solvents? Give a	Yes, because the identity of the solvent is changed. Exemption: the manufacturer of a solvent also distils the waste and has

Questions	Answers
reason for you answer 3 minutes	included that in his exposure assessment.
Is there an obligation to register substances in imported scrap metal? Give a reason. 3 minutes	No preparation or article! No registration is necessary, unless the waste is used to manufacture a new substance in waste recovery operations
Is there an obligation to register metals? 3 minutes	Yes, according REACH they are substances (also under current EU legislation they are considered as chemical substance)
2.Definitions	
What is a phase-in substance? 2 minutes	A phase-in substance is a substance which has been produced or used in the EU or the accession countries of May 2004 until 15 years before the coming into force of REACH
When phase-in substance is it treated as a non-phase-in substance? 2 minutes	It can become a non-phase in substance, when a manufacturer "forgets" to pre-register the substance within the given time
What is an intermediate? 4 minutes	An intermediate is a substance that is solely manufactured for and consumed in chemical processing in order to be transformed into another substance.
Which types of intermediates are differentiated between under REACH and why? 4 minutes	Non-isolated intermediate (no intentional removal, sampling for product control is allowed) On site isolated intermediate (not a non-isolated intermediate and transformation takes place at another location than where the intermediate is produced) Transported isolated intermediate (isolated intermediate transported between different sites). These substances need to be under contractual control. Differentiation, because different exposures are expected
What does the abbreviation PPORD stand for? 3 minutes	Product and process oriented research – substances may be used for research purposes by the manufacturer and / or a limited number of clients. The PPORD must be notified to the Agency and some information must be submitted. Upon positive decision, the actual registration requirement does not apply, neither for the Manufacturer / Importer, nor the down-stream user for 5 years. The time period for researching can be extended for another 5 years on request.
What is a QSAR? Explain in less than 21 words. 3 minutes	A way to model substance properties from their molecular structure
3.Roles and responsibilities	
Which actors need to compile a registration dossier for which chemicals? 2 minutes	Manufacturers and importers of substances under the scope of REACH who are placing substances on the market in amounts exceeding 1 t/a.

Questions	Answers
For which types of chemicals is a safety data sheet to be prepared? 3 minutes	SDS needs to be provided for all dangerous substances and all dangerous preparations. Upon request comparable information needs to be provided for non dangerous preparations, where dangerous substances are contained which could pose a problem.
Who makes completeness checks of registration dossiers? 1 minute	Chemicals agency
Who makes compliance checks of registration dossiers? 1 minute	Member State competent authorities (of the registrant country)
Who checks correctness of SDSs 2 minutes	There is no legal obligation to have SDSs checked. Chemicals inspectors may in special campaigns check and the users of chemicals 'check' the information
Which are the main tasks of the competent authorities under REACH? List at least 3 5 minutes	Evaluation of testing proposals (obligatory) Compliance check, substance evaluation (optional) Ensure enforcement (obligatory) Contribute to Chemicals Agency and work at EU level
4.Registration	
Is it possible for a non-EU enterprise to register jointly with an EU enterprise? 5 minutes	No, only EU-based enterprises can register, also in consortia.
Think of 2 cases, in which a substance manufacturer could refuse to register a particular use communicated to him by a user? 5 minutes	Manufacturer decides not to sell to the user anymore Use proves to be too risky
How long it will take to register all substances under REACH? 1 minute	11 years
Why are the registration requirements for a substance based on the production / import volumes (2 reasons) 5 minutes	Information on volume is easily available Proxy for exposure, enforceable
How many substances have to be registered (approx.)? 2 minutes	30 000 – it is believed that so many substances are in use at the moment
How should a manufacture/ importer register a preparation or article containing many substances? 2 minutes	No preparations or article to be registered under REACH. The substances in preparations and articles are potentially subject for registration
5.Evaluation and authorisation	
What are 2 types of evaluation?	Substance and dossier evaluation

Questions	Answers
2 minutes	
Which properties make a substance to candidate for the authorisation procedure? 1 minute	CMR Cat 1 and 2, PBTs, vPvBs and substances of similar concern
How will the first list of substances to be included in Annex XIII be compiled? 5 minutes	Authorisation: establishing the first list to be decided for inclusion in Annex XIII Candidates based on criteria defined in REACH Com or MS check whether criteria are fulfilled Candidate list Prioritisation by Commission based on criteria in REACH inclusion Annex XIII by comitology procedure and setting of sunset date Further proposals are phased-in later as result of a) new classification of substances or b) substance evaluations by Member States. Proposal for inclusion in Annex XIII
What is the sunset date? 2 minutes	Last day on which a substance subject to authorisations can be used without an authorisation
Under which conditions is an authorisation granted? 3 minutes	The manufacturer or user needs to prove in the application that the substance is either used under 'Adequate control' → no emission = no risk. Or he may prove by a SEA that no alternative is available and the benefits outweigh the risk
Who grants the authorisation? 2 minutes	Commission
6.Restrictions	
When would a substance be proposed for the restrictions procedure and not the authorisation procedure? 3 minutes	The risk is to be addressed at Community level. One reason for doing so would be that the single manufacturer or importer cannot take note of the risks from his perspective (cumulative risks) or have rather practical reasons of data availability on uses.
Which substances will be introduced into the restrictions without the involvement of Member States? 2 minutes	POPs and CMR cat 1 and 2 in consumer preparations
Starting from which volume threshold may substances be subject to restriction authorisation classification and labelling 3 minutes	There is no volume threshold for these procedures
7.Cost drivers	
Where does REACH define which types of test need to be performed	Annexes V + VI + VII

Questions	Answers
for the registration of a substance produced in 430 t/a? 2 minutes	
What is allowed by „waiving“ and under which types of conditions (name 2)? 4 minutes	Waiving means that some requirements can be omitted in case that defined conditions are met. Waiving based on property information: in Annexes some tests need not to be done if other tests have been performed (e.g. no testing of skin irritation if a substance is known to be corrosive). Waiving based on exclusion of exposure: Annex VI states that some testing requirements don't need to be performed in case human exposure can be excluded (e.g. short term repeated dose toxicity). Annex IX states, that the studies in for substances produced in amounts > 100 t/a can be waived due to exclusion of exposure. Waiving has its justification in the fact, that the substance information is needed for risk management decisions and not for producing scientific knowledge.
When does the substance need to be pre-registered and registered? –production volume 215 t/a, very toxic and R53 2 minutes	Pre – registration until 06.2010, registration until 12.2012
List at least 3 mechanisms foreseen in REACH to minimise the costs for registration 2 minutes	consortia waiving – Annex VI flexibility – Annex IX mandatory sharing data on animal testing
8.Business impacts	
What is meant with “deselection of substances” under REACH? 3 minutes	Deselection means the total disappearance substances from the market due to high registration costs
Name 4 options, how a down-stream user can react, if the price of a substance he uses is tripled due to REACH 5 minutes	Forward higher prices to clients Substitute substance Change process Cessation of production Moving production site outside the EU
Name three ways how companies could benefit from REACH 3 minutes	Less complicated chemicals legislation Better information for risk management → better workers protection, better environmental compliance, better products could be produced Less liability risks due to clearer responsibilities Harmonisation of risk management and risk assessment, common language
Name two ways how the benefits of REACH are researched / calculated 2 minutes	Calculation of costs prevented Assessment of willingness to pay Assessment of willingness to sell

Questions	Answers
What are externalised costs? 2 minutes	Costs which are resulting from the own/company activities, but which are paid by society via taxes etc.
Name three examples of externalised costs (which can be expressed in terms of money / prices) of companies 3 minutes	Drinking water purification, restoration of public buildings, wastewater treatment…
9.Safety assessment	
Name the three conditions triggering that a registrant has to carry out a chemical safety assessment ? 5 minutes	When the substance is produced > 10 t/a and is dangerous and is supplied in concentrations exceeding the lowest of the limits defined in legislation referenced by REACH
Under which circumstances would a down-stream user carry out a chemicals safety assessment? 5 minutes	The down-stream users applies a substance outside the scope of the identified use or outside the exposure scenario and he does not want to make it known to his supplier
What is the difference between a chemical safety assessment and a chemical safety report? 1 minute	Report is documentation, assessment is the intellectual procedure
For which subjects of protection does an exposure assessment need to be done? 1 minute	Workers health, consumers health and the environment
What does DNEL and PNEC stand for? 3 minutes	DNEL = Derived no effect level PNEC = Predicted no effect concentration
What is the tonnage trigger for a DU to do a chemical safety assessment for a non-identified use 2 minutes	No tonnage trigger, however identified use > 1t/a makes notification to the agency necessary Note: the DU only needs to do a CSA if his supplier would have to do it (DU needs to find out if the substance is produced/imported in amounts exceeding 10 t/a)
How is „adequate control“ defined under REACH? 3 minutes	Adequately controlled is defined in Annex 1 point 6: “exposure of humans and the environment are considered to be adequately controlled if the DNELS and PNECs are not exceeded”
10.Hazard assessment	
What are the three main steps in hazard assessment according to REACH? 2 minutes	Data evaluation (and effects assessment) Classification and labelling Derivation of safe exposure levels
Name three reasons why a safety factor is used in the derivation of the PNEC	Variation of species, (what is most sensitive, how many tested, measurement errors, sampling errors, variation of laboratory testing, short term / long term toxicity extrapolation, laboratory

Questions	Answers
3 minutes	data to field impact extrapolation
What are the exact criteria for a PBT (one criterion per letter) 2 minutes	Persistence: half life in simulation tests marine water > 60d or fresh- / estuarian > 40d or marine sed. > 180d or fresh- / est. sediment or soil > 120d Bioaccumulation BCF > 2000 Toxicity NOEC < 0.01 mg/l or CM 1+2 or R 1-3 evidence of chronic tox (e.g. R48)
Does a complete hazard assessment need to be done for substances produced in amounts < 10t/a? 2 minutes	No, only classification and labelling is required, no in-depth assessment of data, no derivation of safe levels
11.Exposure assessment	
Name three parameters determining the level of consumer exposure to additives in floor coverings 3 minutes	Amount of substance in floor covering, duration of stay of persons in the rooms, degree of contact (children inhalation and skin, grown-ups only inhalation), temperature in the room, mobility of the substance, adsorption to dust…
Which processes in the environment influence the PEC of a substance? (name 3) 3 minutes	Fate and behaviour in the environment: Biological degradation, hydrolysis, photodegradation, oxidation, Dilution, partitioning between media, Absorption, lipophilic properties
What are „EASE“ and „CONSEXPO“? 3 minutes	Models to calculate exposure of humans
At which 3 scales can an environmental PEC be developed and which one of these is not relevant for the risk characterisation according to the TGD? 5 minutes	Local, regional and continental scale. Continental scale is not relevant.
12.REACH development	
The actual REACH draft proposal is dated from…3 Minutes	The actual draft proposal is dated 29.10.03
According to the new (!) expected time plan, the registration period for phase-in substances > 100 t/a ends in the year ... 2 Minutes	2013
What does the abbreviation RIP mean in the context of REACH?	REACH Implementation Projects, responsible is the European Commission

Questions	Answers
Who is the inventor of it? 2 Minutes	
Name at least 4 EU “institutions” (WGs and (Sub)Committees) who are discussing REACH 2 Minutes	EU Parliament Parliament Committee on Environment and Health Parliament Committee on industry Parliament Committee on internal market EU Commission EU Commission working group on impact assessment EU Council (environment, industry)

13 Information sources

13.1.1.1.1.1 ⌧REACH proposal and process

- REACH proposal: http://europa.eu.int/comm/environment/chemicals/reach.htm
- White paper – Strategy for a future Chemicals Policy http://europa.eu.int/comm/enterprise/reach/whitepaper/intro.htm
- The REACH Proposal Process description: http://europa.eu.int/comm/enterprise/reach/overview.htm
- REACH in brief: http://ecb.jrc.it/reach/
- Flowcharts on the new EU chemicals legislation REACH: http://europa.eu.int/comm/environment/chemicals/reach.htm
- REACH - New Chemicals Legislation, Background documents and Links: http://europa.eu.int/comm/press_room/presspacks/reach/pp_reach_en.htm
- Methodologies, tools and technical guidance for REACH implementation are developed in the REACH Implementation Projects (**RIPs**): http://ecb.jrc.it/RIP/
- Press releases, agenda, reports of environmental council meetings: http://www.eu2005.lu/en/calendrier/2005/03/10environnement/index.html

⌧ Main EU institutions/ organizations dealing with REACH

European Commission:

- DG Environment: http://europa.eu.int/comm/environment/
- DG Enterprise: http://europa.eu.int/comm/enterprise/
- European Chemicals Bureau → Joint Research Center: http://ecb.jrc.it/

European Chemicals Agency: http://www.hel.fi/eca/eca.html

Other organizations:

Organisation for Economic Co-operation and Development – OECD: http://www.oecd.org/

European Chemical Industry Council - CEFIC: www.cefic.be

Downstream Users of Chemicals Co-ordination (DUCC) Group: www.duccplatform.org

European Centre for Ecotoxicology and Toxicology of Chemicals: www.ecetoc.org

European Environmental Bureau: www.eeb.org

WWF – World wide fund for Nature: www.panda.org

Greenpeace: www.greenpeace.org

International Chemicals Secretariat: www.chemsec.org

European Consumers' Organisation: www.beuc.org

European Trade Unions Confederation: www.etuc.org

⌦ Current EU and national chemicals-related legislation

The portal to European Union Law → Eur-Lex

Find EU legislation (in force and in preparation), treaties and issues of the last two months of the official journals (newest legislation, information and notices) are provided. Documents are available in .html or .pdf format. Html documents usually do not contain tables and annexes, while .pdfs are full official print versions. Some documents are presented as consolidated version (amendments are inserted in original legislation). These do not have an official status.

- search with key words or document number: *http://europa.eu.int/eur-lex/en/search/index.html*
- surfing according to the topic: *http://europa.eu.int/eur-lex/en/lif/index.html*
- consolidated legislation: *http://europa.eu.int/eur-lex/en/consleg/index1.html*
- official journal: *http://europa.eu.int/eur-lex/en/oj*

Overview on EU legislation related to chemicals

13.1.1.2 Overview of some important directives relating to community level risk reduction of chemicals. gives short introductions to the content of ca. forty directives. Risk reduction measures concerning workers and consumer health and the environment are described in general:
http://www.norden.org/miljoe/sk/January02version.pdf

Direct links to some EU directives

- Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances:
  http://www.europa.eu.int/comm/environment/dansub/main67_548/index_en.htm
- Directive 1999/45/EC concerning the classification, packaging and labelling of dangerous preparations
  http://europa.eu.int/eur-lex/pri/en/oj/dat/1999/l_200/l_20019990730en00010068.pdf
- Directive 76/769/EEC on restrictions on marketing and use of certain dangerous substances & products: *http://europa.eu.int/eur-lex/en/consleg/pdf/1976/en_1976L0769_do_001.pdf*
- Water Framework Directive 2000/60/EEC
  http://europa.eu.int/eur-lex/en/consleg/pdf/2000/en_2000L0060_do_001.pdf

National links to EU legislation

EU legislation in English and Estonian: *http://www.legaltext.ee*

EU legislation in Latvian: *http://www.varam.gov.lv/en/direktivas/ltulkdir.htm*

EU legislation in Lithuanian: *http://www3.lrs.lt/n/eu/DPaieskaeu.html*

National legislation

Estonia:

- Laws, orders and resolutions starting from the year 1996: http://www.riigiteataja.ee
- Overall database of Estonian legislation. Access is possible through internet, however it is not free of charge: http://lex.andmevara.ee/estlex/index.jsp
- Databases on area-specific legal acts . not free of charge: http://seadus.ibs.ee

Latvia:

- Legislative acts starting from 1990 (Amendments listed as separate files): http://www.likumi.lv
- NAIS (legislation information system) offers a complete set of legal acts (laws, bills, regulations, decrees, etc.) and international conventions and agreements in the most current versions. The database is not free of charge: http://www.nais.dati.lv
- Environment related legislation on the website of the Ministry of Environment: http://www.varam.gov.lv/varam/Llikumd.htm

Lithuania

- Laws, orders and resolutions beginning from year 1994: http://www3.lrs.lt/DPaieska.html
- Draft legislation: http://www3.lrs.lt/pls/inter/ta_projektai_nauji
- Database of legal acts, not free of charge: http://www.infolex.lt/portal/start_litlex.asp?act=llinter

⌦ Databases on substance properties

EINECS - European Inventory of Existing Commercial Substances

This online Information System provides information on 100196 substances included in the EINECS (inventory of existing substances). CAS number, EINECS number, substance name and chemical formula can be looked up. http://ecb.jrc.it/existing-chemicals/

ECB Classlab database

Database on harmonised classification and labelling for substances or groups of substances included in Annex I of Directive 67/548/EEC. Search is possible using EC, CAS number or substance name. The working database contains information on classifications and labelling for one or more toxicological endpoints of substances or groups of substances.
Classifications are not legally binding but recommended by the Commission Working Group. Substances proposed for inclusion in the Annex I can be sorted out.
http://ecb.jrc.it/classification-labelling/

ESIS – European chemical Substances Information System (European Chemicals Bureau)

Several modules, which can be assessed by editing CAS No or substance name in ESIS - EINECS and ELINCS database, European Priority Lists Information (Council Regulation 793/93), High and Low Production Volume Information – list of EU producers / importers, classification and labelling information if classified in the Annex I of Directive 67/548/EEC, IUCLID chemical data sheet and European Risk Assessment information (if available). IUCLID chemical data sheet contains overview of available test data with references. http://ecb.jrc.it/esis

N-CLASS Database on Environmental Hazard Classification

The database contains classification and additional information on approximately 7400 dangerous substances. It also contains information on substances which classifications are under consideration and substances that have not been classified but data have been produced. *http://www.kemi.se/nclass/default.asp*

Risk assessments of existing substances

The Online EURATS (European Risk Assessment Tracking System) provides information at which stage the EU risk assessment of a substance is and gives an overview of conclusions, statistics and testing requirements. *http://ecb.jrc.it/existing-chemicals/*

TOXNET - Toxicology Data Network

The Toxnet is an integrated system of toxicology and environmental health databases that are available free of charge on the web. *http://toxnet.nlm.nih.gov/*
Some databases, which are available for searching via TOXNET:

HSDB (Hazardous Substances Data Bank) is a comprehensive, scientifically reviewed, factual database containing records for over 4500 toxic or potentially toxic chemicals. It contains extensive information in such areas as toxicity, environmental fate, human exposure, chemical safety, waste disposal, emergency handling, and regulatory requirements.

IRIS (Integrated Risk Information System) is an online database on carcinogenic and non-carcinogenic health risk assessment and regulatory information on over 500 chemicals.

Haz-Map is an occupational toxicology database seeking information about the health effects of exposure to chemicals at work. It links jobs and hazardous tasks with occupational diseases and their symptoms. The approximately 1,000 chemicals and biological agents in the database are related to industrial processes and other activities.

CCRIS (Chemical Carcinogenesis Research Information System) is a factual data bank, which contains evaluated data and information on over 8,000 chemicals carcinogens, mutagens, tumor promoters, cocarcinogens, metabolites and inhibitors of carcinogens).

PBT Profiler - Persistent, Bioaccumulative and Toxic Profiles for Organic Chemicals

Online screening tool for checking if substances may have PBT-properties. Conclusions are not sufficient for definite PBT determination, but chemicals that need further evaluation for PBT characteristics are identified. Analysis is based on modelling and estimates but not on experimental data. *http://www.pbtprofiler.net/default.asp*

ECOTOX Database

The database provides toxicity information for aquatic and terrestrial life. It is useful for examining impacts of chemicals on the environment. Information on species, substances, test methods and results are entered into the database. *http://www.epa.gov/ecotox/*

RISKLINE Database

Riskline contains information on both environment and health related substance properties. Search is possible with CAS No., substance name or key word.
http://www.kemi.se/riskline/index.htm

SPIN: Substances in preparations in Nordic Countries

SPIN provides data on the use patterns of substances in Nordic countries. It is available on the Internet and as program and database on CD. Data on uses of chemical compounds in different industries and different purposes (products) can be obtained.
http://www.spin2000.net

Online databases/estimation software of SRC (Syracuse Research Corporation)

Different databases can be accessed via *http://esc.syrres.com/interkow/onlinedb.htm*

- **EFDB (Environmental Fate Database)**: bibliographic and experimental data files on environmental fate and physical/chemical properties
- **On-line Log P** (octanol/water partition coefficient) database, including experimental data: Reliable, evaluated log P values - 13,058 records
- **Physical Properties Database (PHYSPROP):** the PHYSPROP database contains chemical structures, names and physical properties for over 25,000 compounds

Estimation Program Interface (EPI) Suite

The EPI SuiteTM is a suite of physical/chemical property and environmental fate estimation models. It includes estimation programs for log KOW, KOC, Atmospheric Oxidation Potential, Henry.s Law Constant, Water Solubility, Melting Point, Boiling Point, Vapour Pressure, Biodegradation, Bioconcentration Factor, Hydrolysis, Sewage Treatment Plant Removal, Fugacity

Modelling and Multimedia Modelling. The programme can be downloaded for free from the Internet: *http://www.epa.gov/oppt/exposure/docs/episuite.htm*

14 Abbreviations

ATP	Adaptation to Technical Progress
BIA	Business impact assessment
C&L	Classification and Labelling
CA	Competent authority
CAD	Chemical Agents Directive
CAS No	Chemical Abstracts Service number
CFC	Chlorofluorocarbons
CMR	Carcinogenic, mutagenic, toxic to reproduction
CSA	Chemical safety assessment
CSR	Chemical safety report
DDT	Dichlorodiphenyltrichloroethane
DG	Directorate General
DNEL	Derived no effect level
DU	Downstream user
EC	Effective concentration
ECB	European Chemicals Bureau
ED	Endocrine disrupters
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ELV	End-of-life vehicle
EPA	Environmental Protection Agency
ESIS	European chemical Substances Information System
ETUC	European Trade Unions Confederation
EU	European Union
EUSES	European Union system for the evaluation of substances
GHS	Globally Harmonised System for classification and labelling of chemicals
GLP	Good laboratory practice
H&S	Health and Safety
HPVC	High production volume chemicals
IA	Impact assessment
IC	Industrial category

ICCA	International Council of Chemical Association
IFCS	Intergovernmental Forum on Chemicals Safety
IPPC	Integrated Pollution Prevention and Control
ISO	International Organisation for Stardardization
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
LC	Lethal concentration
LD	Lethal dose
LOEL	Lowest Observed Effects Level
LPVC	Low production volume chemicals
M/I	Manufacturer/ Importer
MS	Member state
MTD	Maximum Tolerated Dose
NGO	Non governmental organisation
NOAEL	No observed adverse effect level
NOEC	No Observed Effects Concentration
OECD	Organisation for Economic Co-operation and Development
OSOR	One substance one registration
PBTs	Persistent, bio-accumulative, toxic
PC	Physico-chemical
PCB	Polychlorinated biphenyls
PEC	Predicted environmental concentration
PIC	Prior Informed Consent
PNEC	Predicted no effect concentration
POPs	Persistent organic pollutants
PPORD	Product and process orientated research and development
QSAR	qualitative structure-activity relationship
R & D	Research and development
RA	Risk Assessment
REACH	Registration, evaluation, authorisation of chemicals
RIA	Regulatory impact assessment
RIP	REACH implementation project
RMM	Risk management measures
ROHs	Regulation on hazardous substances in electric appliances
RRM	Risk reduction measures

SDS	Safety data sheet
SEA	Socio-economic analyses
SIEF	Substance information exchange forum
SMEs	Small and medium sized enterprises
SPORT	Strategic Partnership on REACH Testing
SVHC	Small volume high concern
TGD	Technical guidance document
UNEP	United Nations Environment Programme
vPvB	very persistent, very bio-accumulative
WEEE	Waste Electrical and Electronic Equipment
WFD	Water Framework Directive
WTO	World Trade Organisation