

Principles of REACH

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Why is Ecology here?

- **Wish to provide WA business whatever TA is needed to ensure successful global trade**
- **See opportunity to integrate regulatory chemicals guidance with business needs**
- **Ecology, Department of Health and local governments wish to prevent confusion and duplicity**
- **Need to hear what WA businesses exporting or supplying to exporting businesses need to meet international chemicals policy seamlessly**
- **Fill in where federal government has not been able to help**



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Presentation

- REACH in a Page
- REACH by Element
 - **Scope**
 - **Registration**
 - **Evaluation**
 - **Restrictions**
 - **Authorisation**
 - **Information**
- Interim Strategy

Key Elements

- **Better information**
- **Joined, seamless supply chain**
- **Industry responsibility for safe management**

REACH by Element

- Scope
- Pre-registration
- Registration
- Information Through the Supply Chain
- Evaluation
- Restrictions
- Authorisation
- Confidentiality

Scope

- **General exemptions:**
 - Waste and food fully exempted
 - Non-isolated intermediates
- **Worker and environmental legislation applies “without prejudice” to REACH**
- **Exemptions from Registration include:**
 - Uses covered by sectoral legislation (e.g. medicinal uses, food additives)
 - Identified individual substances (Annex IV)
 - E.g. some organics, cellulose pulp
 - Categories of substance (Annex V). For example:
 - Ores, ore concentrates, minerals exempted unless chemically modified
 - Cement clinker, LPG, crude oil, coke, coal unless chemically modified.

REACH in a Page

REACH = Registration, Evaluation and Authorisation of Chemicals

High level of health and environmental protection with the goal of achieving sustainable development.

- Single coherent system for new (non phase-in) and existing (phase-in) chemicals
- Elements:
 - **Registration** of substances ≥ 1 tonne/yr (**1.1 US Tons**) (staggered deadlines)
 - More **information and** better **communication** through the supply chain
 - **Evaluation** of some substances by European Chemicals Agency (MS support for substance evaluation)
 - **Authorisation** only for 'Substances of Very High Concern' (SVHC)
 - **Restrictions** - the safety net
 - **Agency** to manage system
- Focus on priorities:
 - high volumes (early deadline)
 - greatest concern (CMRs and high volume R50/53 early)

A Tiered Approach

REACH enforced June 1 2007

- Enterprises which manufacture or import more than one ton of a chemical substance per year
- **Pre-register** substances 6-01-2008 to 12-01-08
- Required to register in a central database administered by **E**uropean **C**hemicals **A**gency
- **ECHA** provides [IT tools](#) and [guidance](#)
- Member States offer [helpdesk](#) assistance to the impacted companies.

Pre-registration

- **Pre-registration Deadlines**
 - **June 1 2007** manufacturers/importers
 - **December 1 2008**
 - Downstream User (DU) if substance not pre-registered by Manufacturer /Importer (M/I))
- **What?**
 - Substance name, potential registrant details (or 3rd party representative), deadline for registration, similar substances (for read-across)
- **Agency publishes list of information on website**

REACH Training

- “R” in REACH Workshop
 - Who has to fulfill what and when
 - Held 21 June 2007 in Bohn, Germany
 - Provided to businesses and governments alike

REACH Registration & Database

- Use IUCLID 5, the IT tool used to:
 - Obtain data submission requirements of REACH and other programs (like RoHS)
 - Industry stakeholders, EU Member States, the European Chemicals Agency (ECHA) , and any other interested party can install IUCLID from this web site <http://ecbwbiu5.jrc.it/>
 - Use the local IUCLIDs to capture & store, submit, and exchange data on chemical substances stored according the format of the OECD “[Harmonized Templates](#)” to enter test results like reactivity

Harmonized Templates

- A standard format for reporting a summary of the results of a test on a chemical to determine its properties or effects on human health and the environment
 - (e.g., hydrolysis, skin irritation, repeat dose toxicity, etc.). These templates can be used for reporting summary results for testing on any type of a chemical (e.g., pesticides, biocides, industrial chemicals).
- Templates aimed at developers of database systems to prescribe the formats for information to be entered in maintained in database.
- Governments and industry able to electronically exchange test study summary information.
- Harmonized Templates can generate data files that can be imported
 - to other database systems
 - each template has a corresponding “XML schema” (i.e., a common electronic data export/import format).
- The harmonized templates are merely guides to structure data entry/database management systems; they are not data entry screens.
- Further information on templates can be found under [“Frequently asked Questions”](#).

REACH-IT

- REACH-IT = Central IT system supporting REACH
- European Chemical Agency
- Submit registrations and share information on chemicals online
 - Companies will register substances
 - ECHA and Member States evaluate product dossiers
 - Helps public in accessing information on chemicals
 - Available starting June 2008

Registration: general

Registrant collects information, assesses and implement/recommend relevant control measures

- **Scope**
 - substances produced/imported ≥ 1 tonne/year
 - Isolated intermediates: reduced requirements.
 - Exemptions e.g. Product or Process Orientated Research and Development, polymers, non-isolated intermediates
- **Tasks of the registrant (manufacturer/importer (only rep.):**
 - obtain adequate information (Qualitative) Structure Activity Relationship and existing data)
 - perform Chemical Safety Assessment (CSA) for substances > 10 metric tonnes/year (demonstrate “adequate control” per use)
 - send information to Agency by deadline (and to clients)
- **One Substance One Registration (OSOR) (Pre-registration – 18 months)**

No formal acceptance - industry retain responsibility

Registration: Timing

Volume of substance produced or marketed (per manufacturer or importer)	Registration period for existing substances (Deadlines in Bold) 2007 start
≥ 1,000 tons p.a. or CMR or PBTs/vPvBs (R50/53)>100t p.a.	2007 - 2010
100 – 1,000 tons p.a.	2010 - 2013
10 – 100 tons p.a.	2013 - 2018
1 tons p.a.	2013 - 2018

High data



Chemical Safety Reports (CSRs)



'Screening'

Intelligent Testing Strategies

Registration: One Substance One Registration (OSOR)

- Pre-registration
 - June 1 2007-December 2008
- Data sharing
 - Animal data always shared
 - Non animal data shared on request
- Joint data submission: mandatory with opt outs:
 - Disproportionate cost
 - Commercial secrets
 - Disagreement on selecting data

Information Requirements

TECHNICAL DOSSIER

- Common information for all registrations
 - Annex VI
- Depending on tonnage threshold
 - > 1 t/yr ⇒ Annex VII
 - > 10 t/yr ⇒ As above + Annex VIII
 - > 100 t/yr ⇒ As above + proposals for Annex IX
 - > 1000 t/yr ⇒ As above + proposals for Annex X

Chemical Safety Report (CSR) if > 10 t/yr

Generation of Information

- (Q)SARs (Quantitative Structure Activity Relationships i.e. computer modelling)
- Use of category approaches
- Analogs, read across
- Available data (non-EU, to Good Laboratory Practice (GLP), non-GLP)
- Historical human data
- Data sharing (existing and new)
- Testing (*in vitro*, *in vivo*) as a last resort

See Annex XI = FLEXIBILITY !

- **Information requirements may also be waived**
 - because testing can't be done on a substance
 - for some tests (mainly in Annexes VII and VIII) because of no/limited exposure (exposure based waiving)

Registration: 1 – 10t

- 1-10 tonnes
 - All: physicochemical properties of Annex VII (+ available information).
 - New substances: full Annex VII
 - Screening by registrant:
 - likely CMR, PBT or vPvB, or
 - Dangerous for health and environment plus widespread exposure?
- => full Annex VII

Registration: Substances in articles (SIA) (1)

- Registration of substances intentionally released (Art. 6.1)
 - applies to all SIA (i.e. no requirement to meet criteria for classification as dangerous)
 - deadlines as other substances

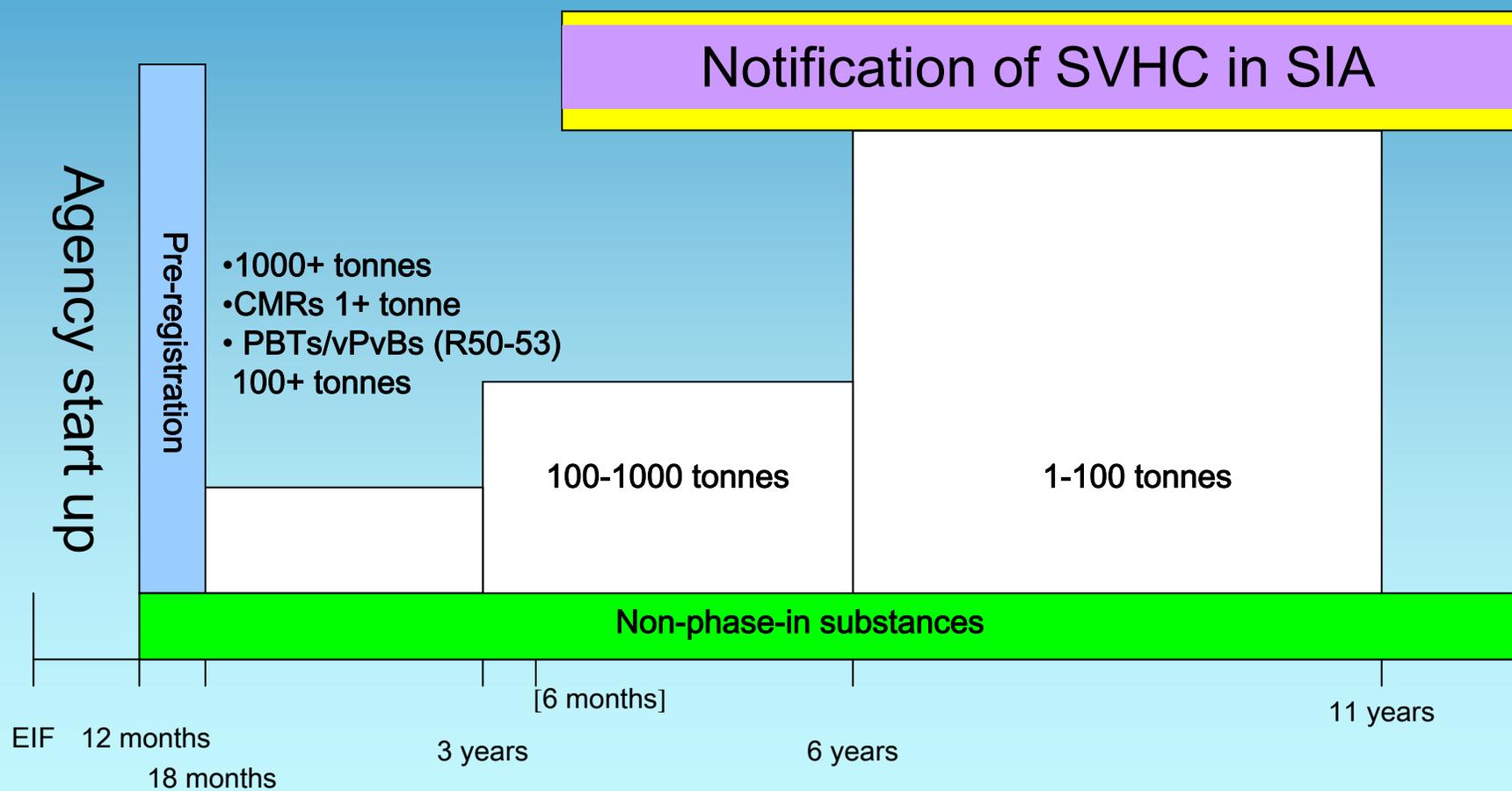
Registration: Substances in articles (SIA) (2)

- **Notification of substances of very high concern (Art. 6.2) if:**
 - present above a concentration limit of 0,1%,
 - exposure of the public or the environment during the full life cycle cannot be excluded,
 - it is present above 1 tonne
- **applies 6 months after substance listed on authorisation candidate list – i.e. only commences 3 years and 6 months after entry into force**

Registration: Substances in articles (SIA) (3)

- Agency can request registration of any notified substance contained in articles, when:
 - Substance is present over 1t; AND
 - Suspects that the substance is released and that release presents a risk to human health or the environment; AND
 - Substance is not subject to Art. 6.1

Registration: Overview



Real Life Example 1

“I produce an article that contains a working fluid. The working fluid is a mixture that contains registered substances. The registration covers my use as a working fluid. The fluid must be replaced at regular intervals. I also distribute the working fluid through my service and repair operations. The annual market for the fluid is greater than 1 metric ton.

Since the fluid is intended to be released, the article and the replacement fluid would both be subject to registration. However, since my supplier has filed a registration that covers my use, I am covered under that registration & would not be required to register. If my supplier either chose to exclude my use, or was from outside the EU, I then become the importer responsible for registration.”

Real Life Example 1

“I produce an article that contains a working fluid. [Who is meant by “I”? I assume a US based manufacturer. There are no duties placed on US companies, only on EU based ones e.g. manufacturers, importers, downstream users.]

The working fluid is a mixture that contains registered substances. The registration covers my use as a working fluid. The fluid must be replaced at regular intervals. I also distribute the working fluid through my service and repair operations.

The annual market [EU or US? Only relevant for REACH purposes if for the EU. N.B. metric tonnes] for the fluid is greater than 1Mt.

Real Life Example 1

Since the fluid is intended to be released, the article and the replacement fluid would both be subject to registration. [only substances are subject to registration; on their own, in mixtures, or in articles if intended to be released] However, since my supplier has filed a registration that covers my use, I am covered under that registration & would not be required to register [true; as long as your supplier and you are based in the EU and if you are within the scope of the exposure scenario developed (if one was required in the first place)]. If my supplier either chose to exclude my use, or was from outside the EU, I then become the importer responsible for registration. [only EU companies have duties. If based in the EU, what are you? An importer of articles? A downstream user?]"

Conclusion: I need more information to fully answer this query.

Information through the supply chain

Aim: Improve Risk Management

- **What:**
 - Expanded (Material) Safety data Sheets (SDS) with information from Chemical Safety Reports - exposure scenarios (ES)
 - Information on risk management, authorisations, restrictions, registration number etc.
 - Information up the supply chain on new hazards
- **Result?**
 - more information on risks
 - downstream users benefit
 - dialogue up/down the supply chain-encouraged/stimulated

Exposure Scenarios

An exposure scenario (ES) is a set of information and/or assumptions that describe how the substance is manufactured or used during its life-cycle, including the waste stage. It also sets out how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.

Information could include:

- relevant characteristics of the substance; e.g. physical state (powder, liquid, gas) and vapour pressure (ability to evaporate),
- technical description of use and control,
- process description,
- tasks of the operator (description, duration, frequency of exposure),
- risk management measures (process control, storing/handling and personal protective equipment)

Exposure Scenario	Paint for indoor use
Composition	Concentration of chemical PTK.(AF)ERF < 10% No organic solvents
Use characteristics	Spray application
Duration & frequency	4 hours/day, 150 days/year
Cleaning	Equipment can be cleaned by hot water and detergent
Risk management measures	<p>Provide ventilation of rooms with a replacement rate of 1 per hour. Wear mask to x standard and x gloves during use.</p> <p>Containers and other waste must be treated as hazardous waste, i.e. delivered to collection system.</p> <p>Liquid waste incl. cleaning water may be disposed via sewage system if connected to a sewage treatment plant (unless other constituents require differently); otherwise it must be treated as hazardous waste.</p>

Downstream Users (DU)

- **Manufacturer/importer CSR to cover all uses identified by downstream users.**
- **DU benefit from choice of:**
 - supplier carrying out assessment, or
 - for confidentiality reasons doing own assessment.
- **If using suppliers CSR just have to:**
 - implement supplier's RRM for identified uses
- **If carrying own CSR (>1t) will have to:**
 - perform assessments only for 'unidentified uses' (using supplier hazard information)
 - inform Agency of 'unidentified uses'

Testing Guidelines

- **The OECD Guidelines for the Testing of Chemicals are to assess the safety of chemical products.**
 - a collection of the most relevant internationally agreed testing methods
 - Currently used by government, industry and independent laboratories
 - [SECTION 5: Other Test Guidelines](#)
- **02-Feb-2007 Encompasses all Test Guidelines not within**
 - Section 1: Physical-Chemical Properties (series 100);
 - Section 2: Effects on Biotic Systems (series 200);
 - Section 3: Degradation and Accumulation (series 300);
 - Section 4: Health Effects (series 400).
 - [Peer Review Packages Available](#)
- **04-Oct-2006 for Test Guideline 407, the Hershberger Assay and the Stably Transfected**
- **Transcriptional Activation Assay are now available**
 - [Endocrine Disruptors Testing and Assessment \(EDTA\) Task Force](#)
 - **26-Jan-2006** The Endocrine Disruptors Testing and Assessment (EDTA) validation and reporting activities for test methods in environmental species during 2006-2007.
 - Includes test methods already on the work plan of the Test Guidelines Program for **fish**, **amphibians** (thyroid disruption) and **invertebrates** for assessment of ED on development and reproduction.

REACH: Help Desk

- What is the REACH helpdesk?
- The REACH helpdesk is the national information centre for producers, importers and users of chemical substances. It provides information and guidance in connection with the implementation of REACH and support with the registration, assessment and authorization of chemical substances.

The helpdesk comprises experts from the federal authorities who are ready to provide specific information and expert knowledge.

- Federal Environmental Agency (UBA),
- Federal Institute for Risk Assessment (BfR),
- Federal Institute for Occupational Safety and Health (BAuA) and the
- Federal Institute for Materials Research and Testing (BAM)
-

[The Internet pages relating to the REACH helpdesk as the national information centre](#) are only available in the German language.

REACH Oversight

European **C**hemicals **A**gency
(**ECHA**)

Responsibility

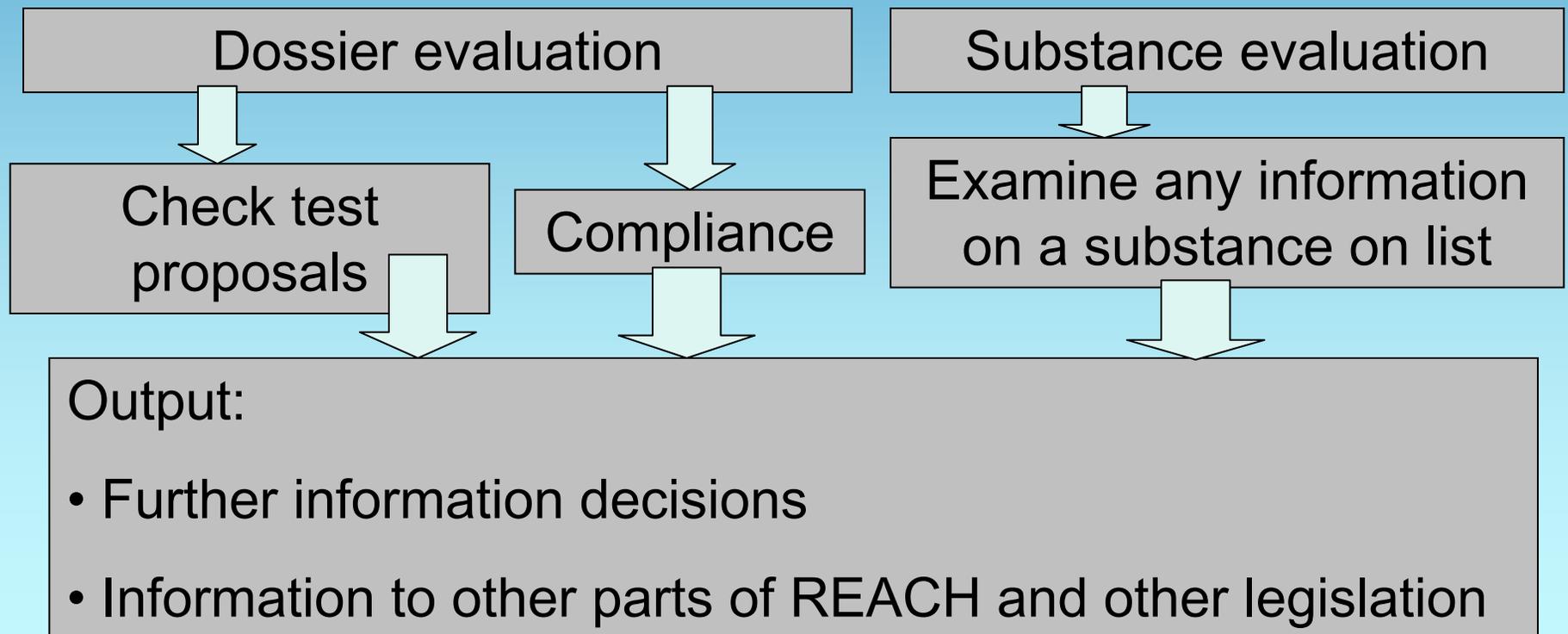
How ECHA Works

- Environmental **CH**emicals **A**gency will evaluate only products and substances that fall within their tier 1 definition
- http://ec.europa.eu/echa/reach_en.html

- **About REACH**
- This section provides you with an overview of the Regulation. It lets you get started with REACH processes, chemicals covered, methods and tools used and parties involved (Actors under REACH).
- [More](#)
- **Navigator**
- The Navigator is an interactive tool that lets companies answer questions on their substance and quickly find out what they need to do under REACH.
- [More](#)
- **Guidance**
- REACH guidance documents provide supplementary information to the legal text. They cover all technical aspects of REACH. These documents have been produced with the assistance and endorsement of the Member States authorities, the European Commission and industry. Therefore companies should use the guidance documents as the primary source of information when they need advice on how to fulfill their REACH duties.
- [More](#)
- **Software tools for REACH**
- To assist with chemical data management and registration submission under REACH, two software tools will be available: REACH-IT and IUCLID5.
- [More](#)
- **Frequently Asked Questions (FAQs)**
- If you have a question the quickest way for you to get an answer may be the database of Frequently Asked Questions.
- [More](#)
- **Helpdesks**
- The Agency helpdesk assists companies with questions relating to their registrations of chemical substances. Each Member State provides REACH helpdesk services to all interested parties in their country. These helpdesks are operating in a network that will harmonize the answers to ensure consistent support to companies across Europe. IUCLID helpdesk assists registered users of the software.

Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing



Evaluation (2)

- ECHA is responsible for:
 - dossier evaluation
 - test proposals and
 - 5 % + conformity checks
 - establishing draft list (Community Rolling Plan (CRP)) for substance evaluation
 - substance evaluations (but will rely on Member State (MS) Competent Authority (CA) expertise)

Restrictions

Safety net

- Community wide concern
- Member State or EU Commission initiated (Annex XV dossier)
- Agency Committees examine:
 - the risk, and
 - the socio-economic aspects involved
 - 3rd party comments
- Consumer use CMR substances - fast track possible.
- Commission - final decision through consensus
- Carry-over of existing restrictions, like RoHS

Authorization

Ensure risks from substances of very high concern are properly controlled and eventually substituted

- **Applies to:**
 - Carcinogens, Mutagens, and Reproductive Toxicants (CMRs), Persistent Bioaccumulative Toxics (PBTs), and Very Persistent Very Bioaccumulative substances (vPvBs)
 - ‘equivalent concern substances with scientific evidence of probable serious effects’ e.g. Endocrine Disrupting Substances (EDS)
- **Prioritised (progressively authorised as resources allow)**
- **Commission grants authorisations**
- **DU can use suppliers authorisation or apply for their own**

Authorization (2)

- Criteria for granting authorizations:
 - Authorisation granted if adequate control
 - Not available for PBT, vPvBs or CMRs/substances of equivalent concern if not possible to determine a threshold.
 - Still possible to grant authorization if socio-economic benefits outweigh the costs
 - Analysis of substitutes in all cases.
- Public list of substances to be authorized (eventually):
 - Published by Agency
 - Candidate list: substances meeting criteria
 - Annex XIV (substances prioritised and picked for authorisation within set timeframe)

Confidential Business Information

- Published information (art 116)
 - Published on web, free of charge:
 - Information on substance identity,
 - classification,
 - physicochemical data,
 - results of toxicological and ecotoxicological studies,
 - Derived No Effect Level, Predicted No Effect Concentration,
 - guidance on safe use,
 - analytical methods.
 - Published on web, free of charge, unless companies justify otherwise:
 - Information on tonnage bands,
 - impurities,
 - information in the SDS (unless above)
 - study summaries/robust study summaries.

Application for confidential treatment of the chemical identity of a substance

- APPLICATIONS FOR CONFIDENTIAL TREATMENT OF THE CHEMICAL IDENTITY OF A SUBSTANCE IN A PREPARATION ACCORDING TO ARTICLE 15 OF DIRECTIVE 1999/45/EC CONCERNING THE APPROXIMATION OF THE LAWS, REGULATIONS AND ADMINISTRATIVE PROVISIONS OF THE MEMBER STATES RELATING TO THE CLASSIFICATION, PACKAGING AND LABELING OF DANGEROUS PREPARATIONS (PREPARATIONS DIRECTIVE)
 - IF CERTAIN PRECONDITIONS ARE MET IT IS POSSIBLE TO USE A GENERIC NAME TO DISGUISE THE ACTUAL CHEMICAL IDENTITY OF THE CONSTITUENTS OF PREPARATIONS. FOR THIS PURPOSE, PRODUCERS OF PREPARATIONS CAN SUBMIT AN APPLICATION TO THE NOTIFICATION UNIT OF THE FEDERAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH.
 - DOWNLOADS
 - [FORM FOR THE "APPLICATION FOR CONFIDENTIAL TREATMENT OF THE CHEMICAL IDENTITY OF A SUBSTANCE IN A PREPARATION ACCORDING TO ARTICLE 15 OF DIRECTIVE 1999/45/EC" \(PREPARATIONS DIRECTIVE\)](#) (PDF FILE, 15 KB), [WORD-DOCUMENT](#) (WORD FILE, 24 KB)
(GERMAN VERSION ONLY)
- [PLEASE ALSO READ IN THIS REGARD THE SHORT GUIDANCE DOCUMENT RELATING TO THE APPLICATION.](#) (PDF FILE, 14 KB)
(GERMAN VERSION ONLY)

A Word About RoHS

- **R**estriction **o**f **H**azardous **S**ubstances
- Restricts concentrations in products at 1,000 ppm:
 - Lead
 - Mercury
 - Cadmium
 - Hexavalent Chromium
 - Polybrominated biphenyls (PBB)
 - Polybrominated biphenyl Ether (PBDE)

EU RoHS

- **The 1,000 ppm limit applies to**
 - single substance that can be (theoretically) separated mechanically
 - examples: sheath on cable, tinning, pen ink
- **Applies to all manufacturers**
 - within the EU
 - Exporting from EU
 - Importing to the EU

The Other RoHS

- **Not all RoHS are alike**
 - Canada's contains more potential chemicals
 - Korea, Brazil and others consider Canada's
 - U.S. state by state, one chemical, under PBTs
 - China's does not restrict exportation from their manufacturers
 - China currently accepts only test results conducted by Chinese labs
 - (United Labs is negotiating a contract with China to test outside of China)

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