

3E Company HazMat Management Web Seminar Series

**Are You Ready For REACH?
Implications of the Proposed New
European Chemicals Policy**

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Are You Ready For REACH?
Implications of the Proposed New European
Chemicals Policy

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February 17, 2005

Topics

- The new European chemicals policy reform
- The REACH system and its implications
- Roles and responsibilities under REACH
- Export/import of chemicals from outside Europe – 4 examples
- How to prepare for REACH
- Links
- Questions?

Registration (all substances above > 1 t)

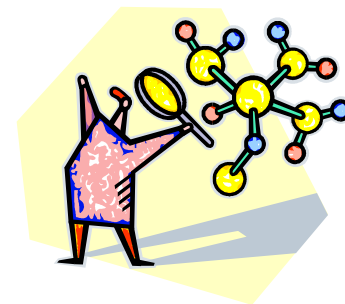
- Notification (dangerous substances < 1 t)

Evaluation (all substances above > 100 t as well as substances of high concern)

Authorization (for substances of high concern)

Chemical Substances

(and the missing R \Rightarrow **Restriction**)



- Current system is inadequate
 - lack of data on substance properties (physical-chemical, health, environment)
 - lack of knowledge about the uses of substances, especially downstream uses
 - authorities do not have sufficient data and resources for hazard and risk assessment
 - too few substances have been through risk assessment

Provide a single, coherent system for new and existing chemicals with focus on high volumes and substances of greatest concern.

- ❑ Manufacturers and importers of chemical substances will be responsible for documenting that the chemical substances are safe through their lifecycle
- ❑ Downstream users can
 - Inform suppliers about the use of the substance, or
 - Take over the responsibility for documenting chemical safety for the particular use

- Manufacturers of chemical substances and articles
- Importers of chemical substances, preparations and articles
- Distributors
- Downstream users of chemical substances
- Authorities: The Chemical Agency, Member States, the Commission

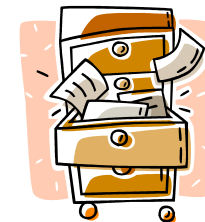
(Exporters of substances and preparations to EU must provide the EU based importer with information necessary to comply with REACH)

- The objectives of REACH:
 - Protection of human health and the environment
 - Maintenance and enhancement of the competitiveness of the EU chemical industry
 - Prevention of fragmentation of the internal market
 - Increased transparency
 - Promotion of non-vertebrate animal testing
 - Conformity with EU international obligations under the WTO

No data – No marketing

- Radioactive substances
- Substances under customs supervision
- Non-isolated intermediates

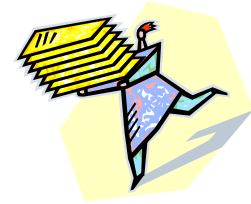
- Registration is for substances only
- Registration is required for substances produced or imported in quantities of 1 tonne or more per manufacturer/importer per year
- Substances are registered for particular uses
- Registration requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely
- The amount of information to be submitted with the registration to the new Chemicals Agency depends on the produced or imported volume of the substance
- Substances registered under the current system are considered registered under REACH
- Duty to pre-register phase-in substances



- Substances imported (alone or in preparations) or manufactured in volumes < 1 t
- Substances included in Annex II (exempt from the present legislation (Reg.793/93), e.g. fatty acids and veg. oils)
- Substances fulfilling criteria listed in Annex III (e.g. certain substances resulting from incidental chemical reaction, hydrates, substances occurring in nature unless dangerous)
- Substances used in medicinal products, food additives, flavourings in foodstuffs, additives in feeding stuffs, substances in animal nutrition
- Active substances manufactured or imported for use in plant protection products and biocides only and registered for that use

- Substances on their own or in preparations, registered before export from the Community and reimported by an actor in the same supply chain
- Substances in articles if they are not intended to be released under normal and foreseeable conditions of use or if they are not considered dangerous
- Polymers
- Non-registered substances < 2% in polymers
- Substances for Product and Process Oriented R&D (PPORD)(temporary)

- A technical dossier (content depend on the quantity of the substance manufactured or imported per year)
 - Identity of the manufacturer(s) / importer(s)
 - Identity of the substance(s)
 - Information on manufacture and use(s)
 - Classification and labeling
 - Guidance on safe use
 - Summaries of information from tests
 - Robust study summaries
 - A statement as to whether information is generated by testing on vertebrate animals
 - Proposal for testing where required
 - A declaration regarding agreement to share tests not involving vertebrate animals against payment



A chemical safety report (≥ 10 tonnes):

- Summary of risk management measures
- Declarations regarding risk management measures
- Identification of substance and physical and chemical properties
- C&L
- Environmental fate
- Human health hazard assessment
- Environmental hazard assessment
- PBT and vPvB assessment
- Exposure assessment
- Risk characterization



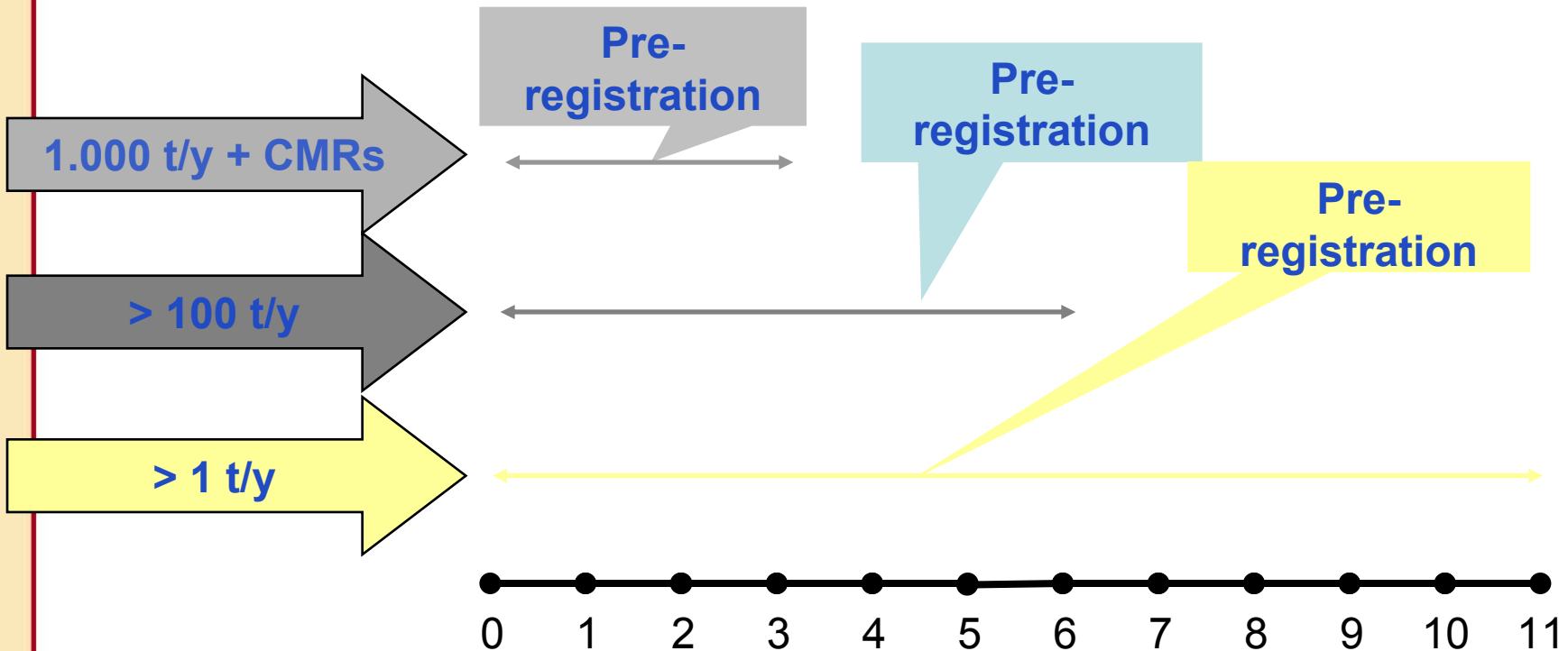
Safety data sheet (down the supply chain independent of volume)

- EU manufactures
- Importers
- EU-based representatives of a non-EU manufacturer (only representative)



- **Registration**

- Phase in substance (ELINCS/ELINCS or NLP)?



Two types of evaluation:



- Dossier evaluation
 - Authorities examine proposals for testing to avoid unnecessary animal testing and costs
 - Authorities examine proposals to check compliance of registration dossier
- Substance evaluation
 - Performed by authorities when there is reason to expect that the substance presents a risk to human health or the environment
 - All registration dossiers are examined together

Authorities may require registrants and DSU's to provide further information

- Authorization is required for use and placing on the market of substances of high concern
 - to ensure that risks are adequately controlled or justified by socio-economic grounds,
 - or
 - that the substances are replaced by safer alternatives
- The procedure to include substances into the authorization system consists of three steps:
 - Identification of the properties of the substances
 - Prioritization of the substances
 - Inclusion in Annex XIII (List of substances subject to authorization)

Substances identified as being of high concern include:

- Cancer-causing chemicals (carcinogens, cat 1 & 2)
- Chemicals that cause mutations (mutagens , cat 1 & 2)
- Those that harm reproduction (reprotoxins , cat 1 & 2)
- Persistent, bioaccumulative and toxic substances (PBT)
- Very persistent, very bioaccumulative substances (vPvB)
- Substances which cause serious and irreversible effects to humans or the environment of equivalent concern to those mentioned above. This class may include substances found to have endocrine disrupting properties. This class will be assessed on a case-by-case basis.



- Safety net for substances posing an unacceptable risk to human health or environment
- Initiated by Member States or the Commission
- Pertains to all types of substances not covered by other legislation
- Substances on Annex XVI and XVII may not be manufactured, placed on the market or used unless specific conditions are met



Existing regulation:

- Directives: 67/548/EEC, 1999/45/EC, 76/769/EEC – placing on the market
- Regulation : 93/793 - placing on the market
- Existing vs. new substances
- Duties:
 - **Industry:** to classify, label and provide of SDS; notify new substances (draft RA), provide of information
 - **Authorities:** RA of existing substances, harmonization of classifications (Annex 1), marketing and use restrictions

New REACH regulation:

- All chemicals – manufactured and used on site, placed on the market, imported
- Different requirements for phase-in substances (based on existing and new substance status)
- Duties:
 - **Industry:** to register, provide data, RA, propose risk management measures, co-operate, classify, label, provide SDS and CSR
 - **Authorities:** to evaluate and decide on restrictions, authorizations, animal testing

Existing regulation

- Gaps of knowledge about properties of existing substances
- Burden of proof
 - Authorities to prove unsafe before restricting
- Notification of new substances > 10 kg
- RA – responsibility of authorities, data from industry
- Harmonized Annex 1 – rigid but useful
- Bureaucracy

REACH

- Collect existing data
- Close cooperation between industries to ensure safe use chemicals
- Registration of all substances produced in quantities >1 tonne
- Use and share existing data, limitation of animal testing, use of QSAR modelling
- Industry list , harmonized Annex 1 – CMRS
- Industry prepares CSR - RA

- Switch from 10 kg to 1 ton
- Transparency in decision making process
 - Board , Committees, Forum – public knowledge
 - Board of appeal
 - Ombudsman
- Regulation contra directive
 - enforcement
- Long transition period for phase-in substances
- Definition of grey zones
 - Articles
 - Confidential information
 - New knowledge

Brief history:

- Feb. 2001: White Paper published
- May 2003: Internet consultation (6000+ comments received)
- Aug/Sep 2003: Proposed strategy substantially amended as a result of comments
- 29 Oct. 2003: Draft REACH regulation adopted by the Commission

Current status:

- Jan - 2005: Discussed by the European Council of Ministers and the European Parliament.
- Sep/Oct 2005: European Council common position expected and European Parliament 1st reading
- 2008: Estimated entry into force

- Introduces notification regime of C&L (C&L inventory)
 - Introduces registration regime for all substances (EINECS and new) produced or imported in quantities over 1 ton/yr to be registered = approx. 30 000 substances
 - Requires separate registration for each producer and importer
 - Data sharing
 - Substance information exchange forum
 - Only representative
- (Proposal for One Substance One Registration)

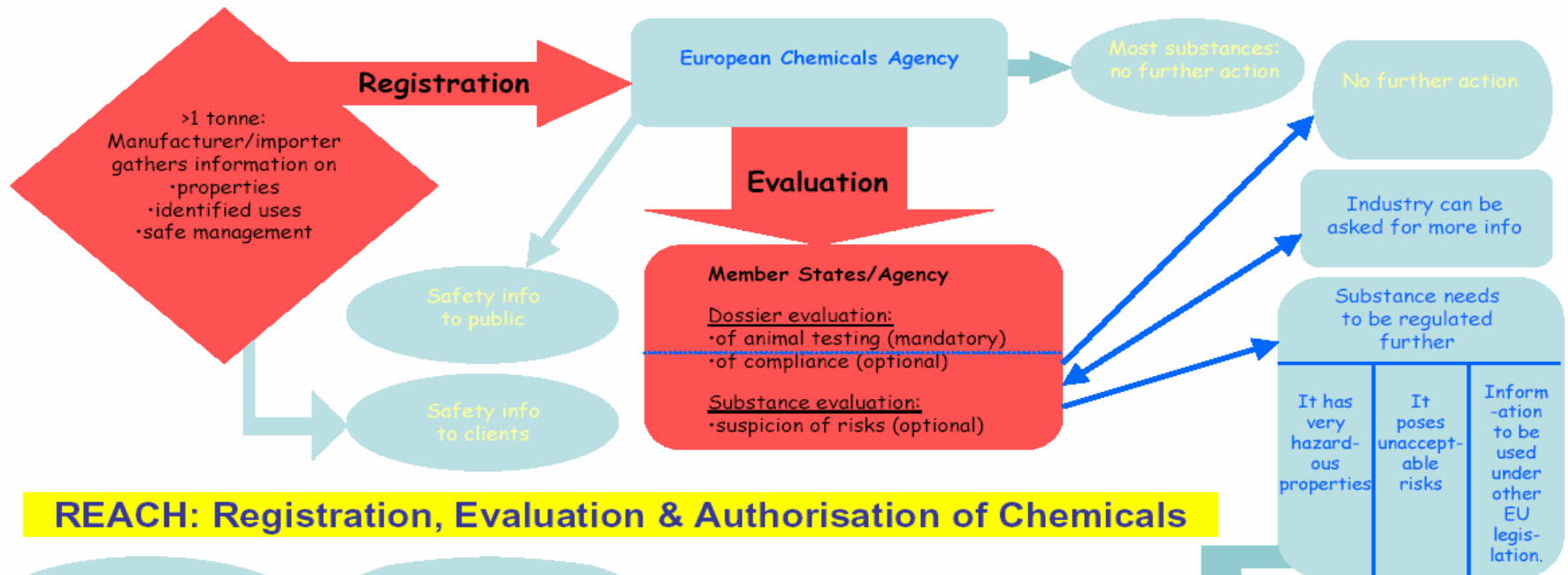
- Calls for communication and dialogue in the supply chain between producers, importers and down-stream users (DSU) (confidentiality)
- Consolidates current EU inventories (EINECS and ELINCS) and creates new industry list with product registration number
- Reverses the “Burden of Proof” – from CA onto industry (demonstration of safe use)
- Advocates “substitution” and “minimal animal testing” - resulting in the need for data sharing

Classification and labeling notification

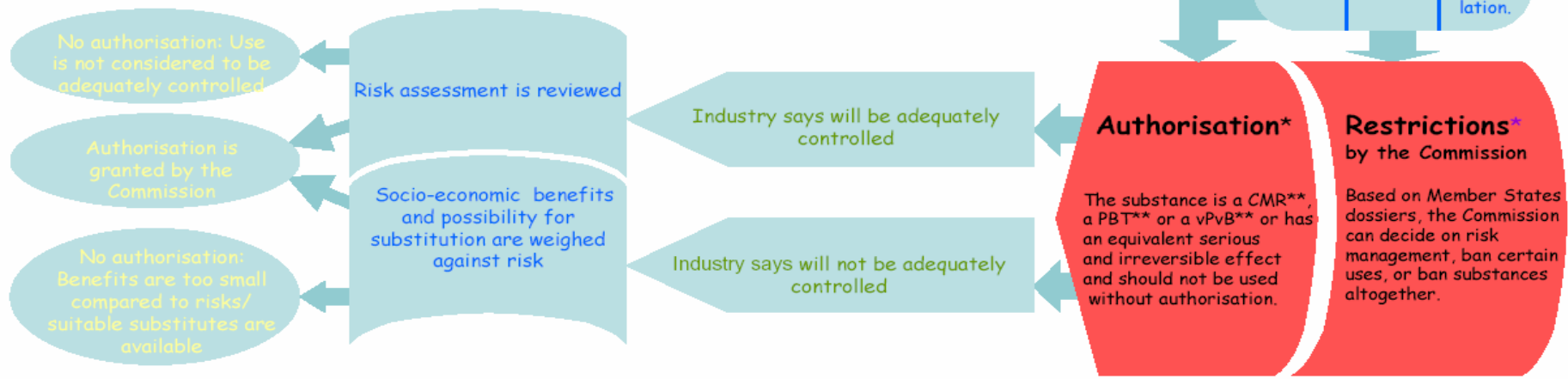
- The classification and labeling inventory will be based on the classification and labeling notified by importers or manufacturers to the Agency (industry list)
- EU harmonized classifications will only be required for:
 - category 1, 2 and 3 carcinogens
 - category 1, 2 and 3 mutagens
 - category 1, 2 and 3 substances toxic to reproduction
 - Respiratory sensitizers
- EU harmonized classification will be added to Annex I to 67/548/EEC
- It is not yet decided how the current Annex I to will be "carried over" into REACH
- The classification and labeling inventory will be maintained by the Agency

- Notification of classification and labeling (responsibility of chemical producers and importers)
 - All substances meeting criteria for classification
 - In preparations - Concentration above limits specified in Preparation Directive
- Registration (responsibility of chemical producers and importers)
 - All EINECS substances (>1 ton) must be registered by producer and by use
 - Registration includes information on properties and uses of chemicals
 - Data may be obtained through computer modeling, epidemiological studies or animal testing. Proposals for animal testing must be submitted and approved, and data sharing will be required.
 - Registration of substances produced in quantities > 10 tons/yr must include both a new SDS and a Chemical Safety Report (CSR). CSR require data from DSUs.

- Evaluation (instigated by Competent Authority)
 - Two types of evaluation:
 - Dossier evaluation prior to animal testing
 - Substance evaluation with regards to risk
 - Reasons for evaluation = substance may present a risk to human health or the environment
- Authorization/Restriction (instigated by Competent Authority)
 - Restricts the application and/or use of the substance
 - Substances likely to be subject to authorization:
 - Cat. 1 and 2 carcinogens, mutagens or reproductive toxins
 - Persistent, bio-accumulative & toxic substances (PBT and vBvPs)
 - Endocrine disrupter and similar (i.e. flame retardants)



REACH: Registration, Evaluation & Authorisation of Chemicals



* Substances do not have to be registered or evaluated to be placed under authorisation or restriction. They can be identified in other ways.
 ** Can cause cancer or mutations, or is toxic to reproduction; or is persistent, bio-accumulative and toxic, or very persistent and very bio-accumulative.

- **Notification:**
 - **Submits and updates information**
- **Registration:**
 - Collects and submits data
 - Assesses risks and identifies risk management measures
 - SDS, CLP, CSR
 - Keeps registrations updated, proposes testing schemes
- Evaluation:
 - Provides further information if required
- Authorization/Restriction
 - Submits application dossier
 - May provide information for socio-economic assessments

- Registration:
 - Reports uses to manufacturers/importers
 - Reports uses not covered by manufacturers/importers safety assessment to the Agency
 - Reports alternative risk management measures to the Agency
- Evaluation:
 - Contributes with further information if required
- Authorization:
 - Informs the Agency about any authorized use, complies with authorization
- Restriction:
 - Complies with restrictions, should they be imposed

- SDS - Primary information carrier in the supply chain
- Chemical Safety Reports (CSR)
 - Required for substances produced or imported in quantities over 10 tons/yr
 - Includes information on:
 - Chemical safety assessment (including exposure scenarios, risk characterization, and possible animal testing)
 - All identified uses
 - Proposed classification/packaging/labeling
 - Guidance on safe use
 - Input to the SDS (safety data sheet)
- Down-stream users (DSUs)
 - Have the right to make a use known to the manufacturer/importer or supplier
 - Must provide sufficient information for exposure scenarios
 - Prepares a CSR if the use is outside the conditions referred to in SDS

- Transparency
 - substance information exchange forum (SIEF)
- Data sharing
 - avoidance of unnecessary animal testing (vertebrates)
- Cost sharing
 - Carrot and stick (voluntary or forced)
- Penalties
 - Determined at national level



- The authorities can only oblige registrants to share results of vertebrate animal tests
- Other data may be shared
- The proposal ensures proportionate sharing of costs – registrants only pay for data they are required to have, i.e. a low volume producer will not share costs for tests required for a higher tonnage level



Transparency

Hazard communication

- The right to information

Article 73 Agency Tasks

Article 105 Stakeholders

Article 106 Rules on transparency

Article 120 Communication to the public



Confidentiality

Intellectual property

- The right to protect investment

Article 115 Access to information

Article 116 Confidentiality

- Non-confidential information
 - Trade name
 - IUPAC name (if dangerous)
 - EINECS name
 - Physico-chemical data
 - Results from tox/ecotox tests
 - Derived no-effect level
 - Derived no-effect concentration
 - Degree of purity/identity of impurities
 - Guidance on safe use
 - Information in SDS
 - Analytical methods (if requested)
 - Testing on vertebrate animals
- Confidential information
 - Details of the full composition of a preparation
 - The precise use, function or application of a substance
 - The precise tonnage of the substance or preparation manufactured or placed on the market
 - Links between a manufacturer or importer and his downstream users



- Technical Guidance Documents and tools for industry
 - TDG on preparing the Technical dossier
 - TDG on preparing CSR
 - Guidance on information requirements
 - Guidance on pre-registration
 - Guidance on DSU requirements
 - Guidance on fulfilling requirements for articles
- Technical Guidance documents and tools for authorities
 - Priority setting for evaluation
 - Dossier and substance evaluation

- GHS = Global Harmonized System of Classification and Labeling of Chemicals
- GHS was not formally adopted by UN at the time of adopting the REACH proposal – and is therefore not included in the current REACH proposal
- The Commission is preparing legislation in order to implement GHS at the same time as REACH
- It is not yet decided if and how GHS will be integrated in REACH

1. Export of < 1 tonnes per year of a substance to EU – either on its own or as part of a preparation
2. Export/import of cosmetics to EU
3. Export/import of articles to EU
4. Export/import of plastic to EU



Export of a substance – either on its own or as part of a preparation

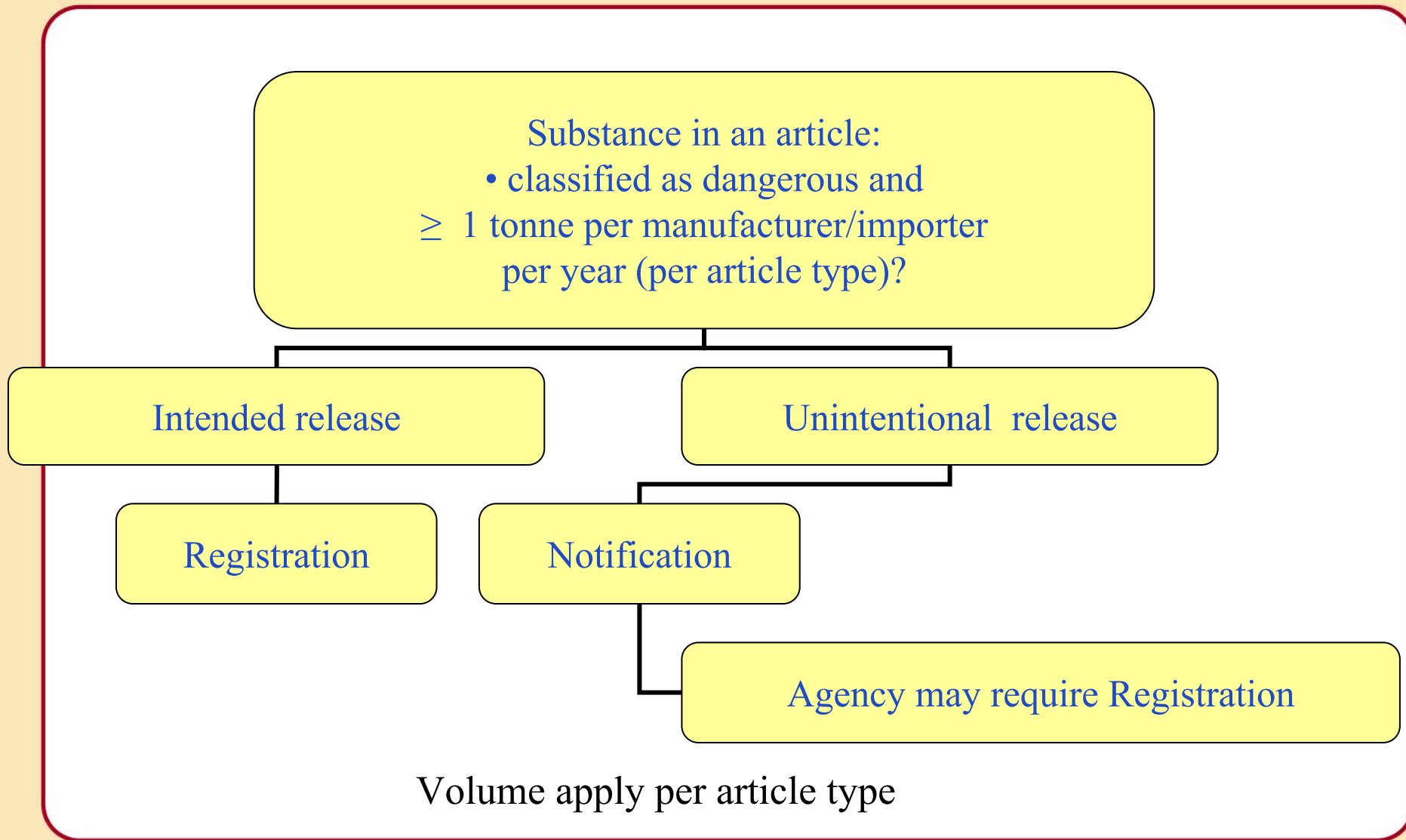
- Check if any restrictions or bans applies (annex XVI and XVII)
- Apply for authorization for intended use if the substance is listed in Annex XIII
- Hazardous: the classification must be notified to the Chemical Agency
- Prepare and supply a Safety Data Sheet to downstream users
- Prepare information on non dangerous substances for downstream users
- Carry out national product registrations

Export/import of an ingredient for cosmetics:

- Registration required if ≥ 1 tonne
- CSR (if ≥ 10 tonnes) need not consider risks to human health
- Restrictions/authorization only based on environmental effects

Export/import of a finished cosmetic product:

- Registration of ingredients required if ≥ 1 tonne
- CSR for ingredients above classification limit and ≥ 10 tonne need not consider risks to human health
- Restrictions/authorization only based on environmental effects



Plastic: polymer plus additives (technically a preparation)

Additives added during polymerisation \Rightarrow "end polymer"

Additives added after polymerisation \Rightarrow preparation

"End polymer" \Rightarrow "substance" under current legislation

"End polymer" \Rightarrow not expected to be considered a preparation under REACH



"End polymer" \Rightarrow substance or polymer? Does not meet the definition of either a substance or a polymer

"End polymer" \Rightarrow expected to be considered a polymer under REACH

Consequence of definition of polymer:

- Polymers do not need registration (initially)
- The importer will not need to register the "end polymer"
- The importer must however classify the polymer (data from the manufacturer)
- The importer must comply with any relevant restrictions
- The importer must comply with any other national downstream regulation, e.g. product registration

Chemical importers/exporters:

- Create a company inventory of all substances imported into the EU (including raw materials, intermediates, additives, and final product chemical compounds);
- Determine which substances on this inventory will require immediate registration or pre-registration
- Check for possible restrictions or authorizations- consider substitutions
- Determine what information is proprietary and protect your IP
- Make a list of competitors (including importers to the EU)
- Form consortia where possible
- Review existing data (phys/chem data, tox/eco-tox data), in order to identify possible data gaps
- Collect info on use and exposure to your products
- Check whether all raw material from EU remain available
- Strategic timing of registrations (current system/REACH)

- Exporters of chemicals to EU must be ready to provide the importer with information enabling the importer to meet the obligations under REACH
- Importers of chemicals from EU should check the continued supply of the imported chemicals

- <http://ecb.jrc.it/REACH/>
- <http://europa.eu.int/comm/enterprise/reach/index.htm>
- <http://europa.eu.int/comm/environment/chemicals/index.htm>
- <http://glossary.eea.eu.int/EEAGlossary/>



Questions?