Workshop MMA and KemI
Brasilia October 2018

Decision-making in the EU – including examples

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Decision making in the EU

Workshop on Risk reduction
Brasilia 18-19 October 2018

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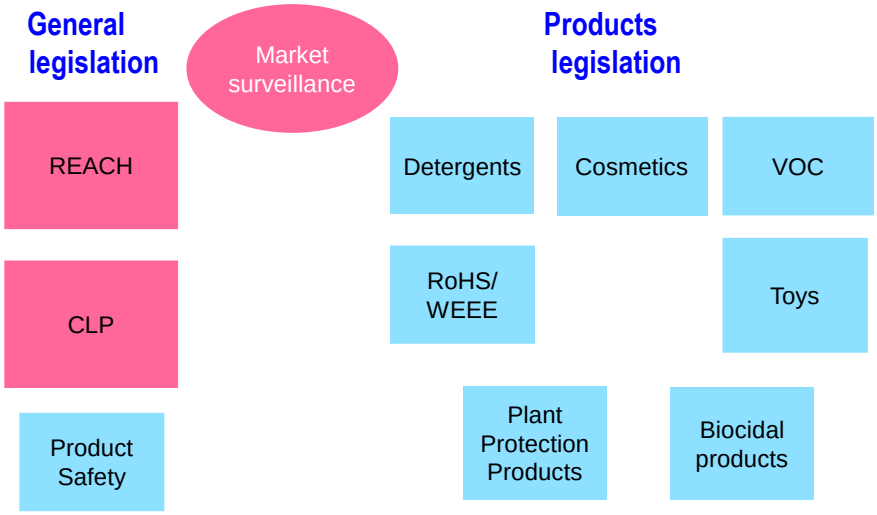
EU Chemicals legislation



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REACH

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

Entered into force 1 June 2007 and was fully applicable 1 June 2008

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Before REACH

4 EU legislative instruments:

- Directive 67/548: notification of new chemicals, classification & labelling of dangerous chemicals
- Directive 76/769: Restrictions of marketing & use of certain dangerous substances & preparations
- Directive 88/379: classification and labelling of dangerous preparations (mixtures)
- Regulation 793/93: evaluation and control of risks of existing substances

REACH: Why?

Limited knowledge about possible negative effects for humans and the environment of the vast majority of chemicals

Shortcomings of previous chemicals legislation:

- **No obligation for risk assessment** for existing chemicals unless prioritised
- **Data gaps**: 86% of HPVs less than base data set
- **Slow and resources intensive** processes
- **Burden of proof** on public authorities
- **Downstream Users** stayed out of the picture, actual uses of chemicals unknown
- **Administrative and regulatory burden** prevented innovation
- **Over 40 single legal acts** prior to REACH - simplification needed under one piece of legislation

Solution:

A New EU Chemicals Policy

Registration, Evaluation
and
Authorisation of Chemicals

REACH

REACH – aim

Main objectives:

to ensure a high level of protection of the human health and the environment […] while enhancing competitiveness and innovation…

Five principles:

- shift of responsibilities from public authorities towards industry (shift of burden of proof)
- "duty of care"
- "no data, no market"
- a strong European CHemicals Agency (ECHA)
- special attention to SMEs

REACH: Main features

A Single Coherent System for new (non phase-in) and existing (phase-in, in EINECS) substances

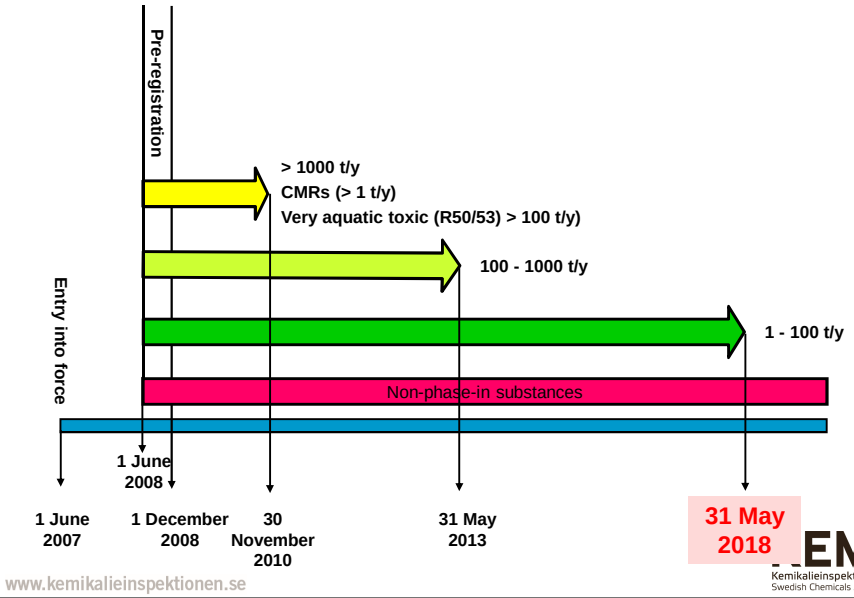
- New registration requirements for old substances.
- Data sharing as a general principle.
- Industry to generate information about substances and adopt risk management measures.
- Increased obligations to transmit information down the supply chain.
- New authorisation procedure

❖**Focus on priorities:**
- ❖ High volume chemicals (greatest likely exposure) register first
- ❖ Greatest concern chemicals (CMR and R50/53) register first

REACH: Key elements

- **R**egistration of chemicals
- **E**valuation of some registered chemicals
- **A**uthorisation of (some) **Ch**emicals
- Restriction of (some) **Ch**emicals

Registration
WHEN?



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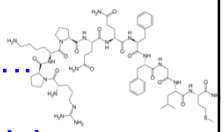
What Must Be Registered?

- Registration only concerns substances…..



- .....on their own, in preparations or in articles
- Mixtures and articles themselves are not registered

- Only substances manufactured/imported over 1 ton/year

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Information requirements (inherent properties)

- Physical-chemical properties (e.g. solubility, vapour pressure)
- Toxicity properties (e.g. acute toxicity, irritation, mutagenicity, carcinogenicity)
- Fate properties (e.g. (bio)degradation, partition coefficients)
- Ecotoxicity properties (e.g. toxicity to aquatic or terrestrial organisms)

REACH and other EU-legislation and authorities' risk management instruments in REACH

Examples of EU legislation with provisions on chemicals

Focus on individual substances:

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

Focus on specific product groups

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

Focus on the use phase:

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

What is REACH?

- Regulation (EC) no 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Is together with the CLP-regulation the basis of the EU chemicals legislation
- In principle, REACH applies to all chemical substances; not only those used in industrial processes
  - Not food or feed
- The EU Classification, Labelling and Packaging (CLP) Regulation is based on the United Nations' Globally Harmonised System (GHS)

Key elements of REACH

- Protection of human health and promotion of non-toxic environment
- Maintenance and enhancement of the EU chemical industry
- Prevent fragmentation of the internal market
- Increasing transparency
- Integration with international aspects
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO – trade barriers

Key elements of REACH (cont.)

- Protection of human health and promotion of non-toxic environment
  - Setting deadlines
  - Making industry responsible for safety
  - Extending the responisbility along the manufacturing chain
  - Authorsiation of Substances of Very High Concern
- Maintenance and enhancement of the EU chemical industry
- Prevent fragmentation of the internal market
- Increasing transparency
- Integration with international aspects
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO – trade barriers

Key elements of REACH (cont.)

- Protection of human health and promotion of non-toxic environment
- Maintenance and enhancement of the EU chemical industry
  - Stimulating innovation
  - Realistic timetable for submission of data
- Prevent fragmentation of the internal market
- Increasing transparency
  - Providing full information to the public
  - A more transparent regulatory system
- Integration with international aspects
- Promotion of non-animal testing
- Conformity with EU international obligations under the WTO – trade barriers

Key elements of REACH (cont.)

- Protection of human health and promotion of non-toxic environment
- Maintenance and enhancement of the EU chemical industry
- Prevent fragmentation of the internal market
- Increasing transparency
- Integration with international aspects
  - Contributing to safe use of chemicals at a global level
  - Testing in a global market
  - Recognising non-EU test results
  - Complying with OSPAR (protection of North East Atlantic)
  - Persistent Organic Pollutants
  - Developing countries
- Promotion of non-animal testing
  - Maximising the use of non-animal test methods
  - Encouraging development of new non-animal test methods
  - Minimising test programmes
- Conformity with EU international obligations under the WTO – trade barriers

Key parts of REACH

Generate data, assess risk
- Registration – ”no data, no market”
- Evaluation

Inform in the supply chain
- Safety data sheets (SDS)
- Article 33 for articles

REACH

Substance specific risk management
- Restrictions
- Authorisation

Organisation
- European Chemicals Agency ECHA

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REACH scope

- Equal standards for the manufacturing, supply and safe use of chemicals apply across the entire European Economic Area (EEA),
  - apply to companies regardless of their position in the supply chain and the products they manufacture, import, export, supply or use
- Covers all sectors manufacturing, importing, distributing or using chemicals as raw material of finished products
- Applies regardless of company size
- Obligations depend on the type of products placed on the market/used:
  - Substances on their own (including metals),
  - mixtures, or
  - articles

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REACH and other regulatory acts

CLP is completely aligned with REACH

Substances covered by other legislation

- Completely – excluded from REACH
  - Radioactive substances
  - Waste (as long as it is waste)
- Partly – excluded from major parts of REACH
  - Medicinal human and veterinary
  - Cosmetics
  - Medical device (certain)
  - Food/feedingstuffs
- Under other authorisation regime
  - Plant protection products – active substances and co-formulants considered registered, excluded from authorisation
  - Biocidal products – active substances considered registered, excluded from authorisation

REACH and other regulatory acts (cont.)

- Product safety legislation – RoHS, Toy Safety Directive and more – all legal acts in force if product is in scope
  - Example: Teddy bear with sound (electrical)
    - Toy safety directive restrictions on chemical substances apply
    - RoHS restriction on hazardous substances apply (to whole toy)
    - Relevant REACH restrictions apply
      - For example certain phthalates, Cadmium in plastic
- Worker protection legislation
  - REACH informs – classification and labelling, SDS, exposure scenarios etc.
  - But for example an occupational exposure limit (OEL) is not seen as 'adequate control of risk' in authorisation

REACH registration principles

- 'This Regulation is based on the principle that it is for *manufacturers, importers and downstream users* to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment.'
  - (REACH article 1(3))

- 'No data, no market'
  - (REACH article 5)
- Registration provisions require manufacturers and importers to:
  - generate data on the substances they manufacture or import
  - use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures

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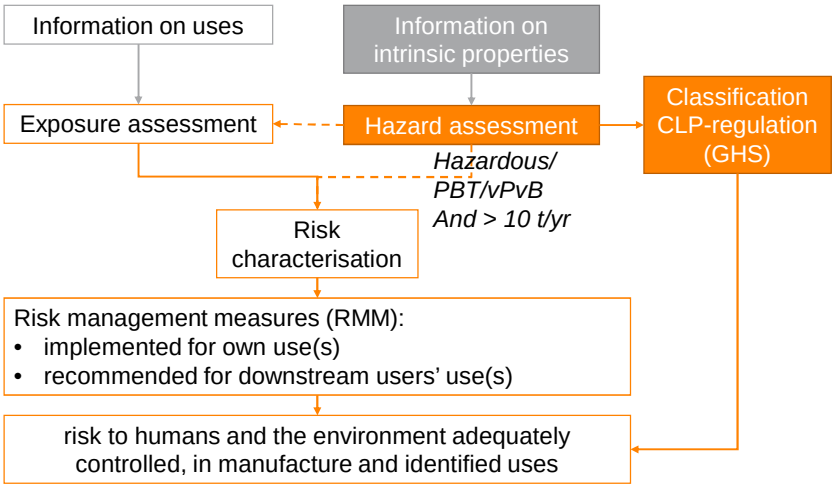
Assessing substances in REACH registration



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Regulatory tools – REACH and CLP

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

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

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

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Regulatory Management Option Analysis (RMOA)

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

Information for RMOA

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

Evaluation and measures for safe use

Manufacturers/importers

- Registration
  - ≈ 21 500 substances

Authorities

- Substance evaluation
  - Concluded ≈ 80 substances
  - On-going ≈ 180 substances
  - Planned ≈ 90 substances
    - Start 2020 or earlier
- Candidate list SVHC
  - ≈ 200 substances
- Authorisation Annex XIV
  - ≈ 40 substances
- Restrictions
  - 13 adopted 2011 – 2016

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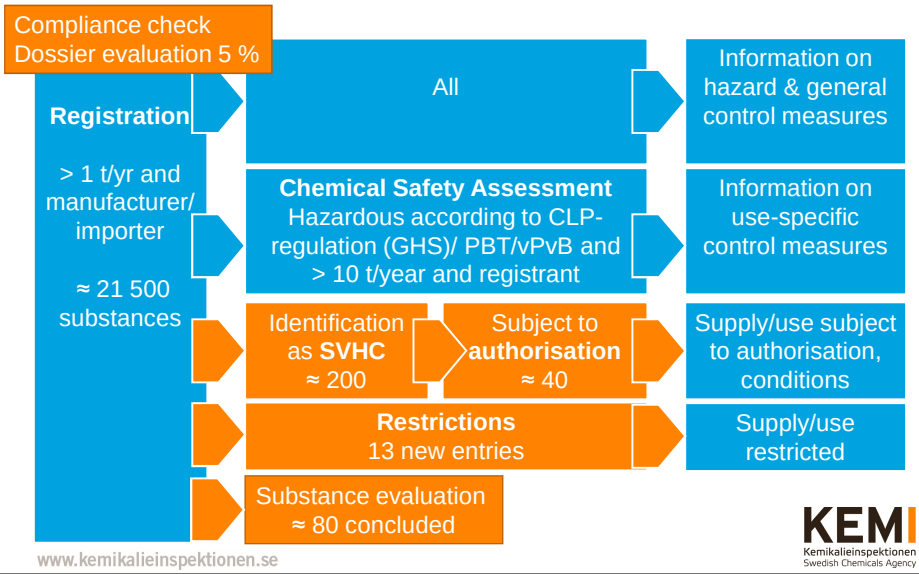
REACH risk management



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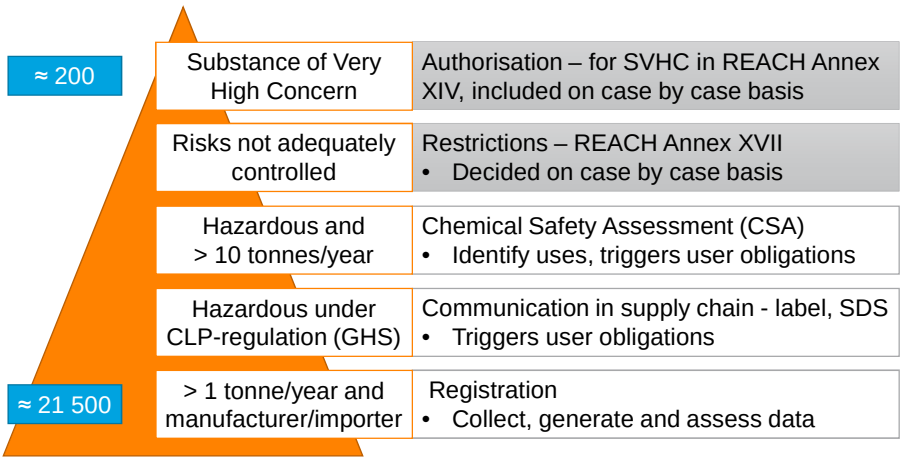
Risk management in REACH



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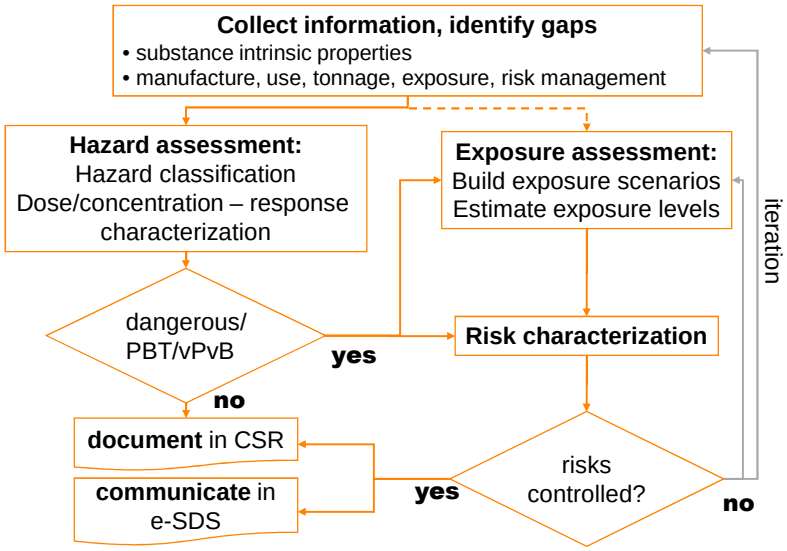
Chemical Safety Assessment – the process



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Safety data sheet – who is responsible and what does it contain

- Obligations on supplier
  - Supply to downstream users/distributors
    - Industrial or professional activities – not consumers
  - Free of charge on paper or electronically no later than the date on which the substance or mixture is first supplied
  - Specified format – 16 headings
  - Official language(s) of member state where it is placed on the market, clear and concise (REACH)
  - Up to date

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Safety data sheet – exposure scenarios (ES) in REACH

- Contains
  - Operational conditions and risk management measures, describe how the substance is used
  - One ES may cover one specific process or use or several processes or uses
- Part of registration in some cases
  - Basis for exposure assessment
- Also part of communication (in some cases)
  - Recommendation how to control exposures
  - Communicated in e-SDS (extended SDS)

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Responsibilities in supply chain – substances/mixtures

Substance	Manufacturer/importer supply chain obligations	User obligations
More than 1 tonne/year and manufacturer/ importer	Registration • Generate and assess data	• General considerations for chemicals e.g. in occupational safety • Workers right to information
Hazardous according to CLP-regulation (GHS)	Communicate in supply chain • Safety Data Sheet (SDS) • Label If > 10 tonnes/year • Chemical Safety Assessment (CSA) – Exposure scenario (ES)	• Identify and apply appropriate measures to adequately control risks • If not identified use – do CSA • Workers right to information
Substance of Very High Concern (SVHC) in Annex XIV	Apply for authorisation for specific uses	Only use if valid authorsiation for that use – comply with conditions in authorisation
Subject to Restrictions	Comply with requirements in relevant restriction	Comply with requirements in relevant restriction

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What information can be requested in substance evaluation?

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

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Decisions in substance evaluation

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

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From report on operation of REACH (2018)

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

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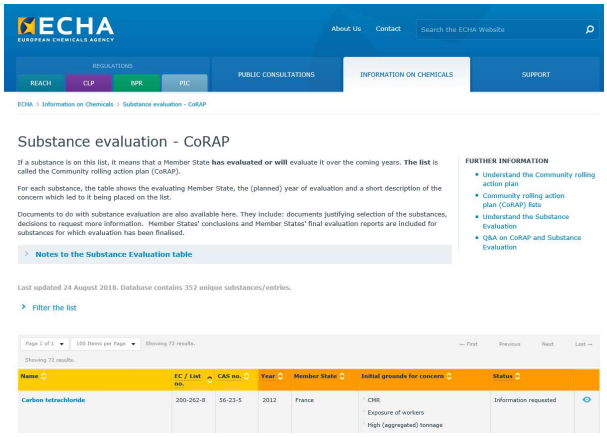
Substance evaluation – decisions

ECHA > Information on Chemicals > Substance evaluation > CoRAP



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What happens after a substance evaluation

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

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Evaluation of the substance evaluation process

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

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

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Regulatory risk management tools in REACH and CLP

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

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Harmonised classification and labelling

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

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The classification under CLP can trigger legal obligations

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

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Example – Swedish worker protection legislation

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

Example – EU Toy Safety Directive

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

Example – Permits for very hazardous chemical products in Sweden

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

- Acute toxicity in hazard categories 1, 2 and/or 3
  - Hazard pictogram GHS06: Skull and crossbones. Signal word: "Danger“

- Carcinogenicity in hazard category 1A or 1B, Germ cell mutagenicity in hazard category 1A or 1B, or Reproductive toxicity in hazard category 1A or 1B
  - Hazard pictogram GHS08: Health hazard. Signal word: "Danger".

- Specific organ toxicity - single exposure, hazard category 1
  - Hazard pictogram GHS08: Health hazard. Signal word: "Danger“

- Skin corrosion in hazard category 1A
  - Hazard pictogram GHS05: Corrosive. Signal word: "Danger".

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Authorisation, approval, licensing

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

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

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

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

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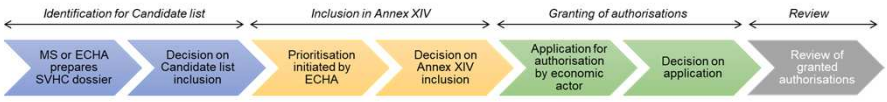
Authorisation process



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Authorisation process

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

Candidate list

- Member state or ECHA propose SVHC for inclusion
- Regulatory decision on whether to include the substance

Annex XIV

- Regulatory decision to include substance from candidate list
- Substance requires authorisation
- Sunset date

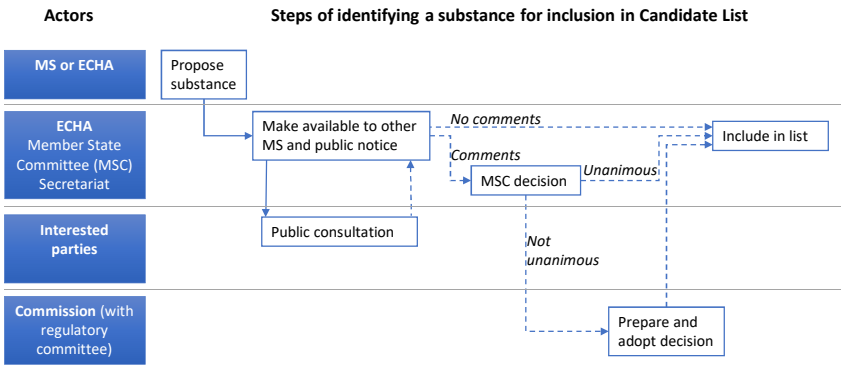
Authorisation

- Companies can apply
- Regulatory decision
- Time-limited
- Only if risks adequately controlled or no alternatives and benefits > risk

Candidate list for authorisation under REACH

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

Identifying substance for inclusion in REACH Candidate List



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Other uses of lists – example candidate list

- Inclusion in Candidate list triggers information requirements – SVHC in articles (article 33)
- Several companies use Candidate list in their purchase requirements – their own Restricted substances lists – going beyond legislative requirements
  - Easier to establish and maintain than own list
  - More known to suppliers, test-houses…
  - Official list, readily available for all

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List of substances subject to authorisation REACH Annex XIV

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

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Prioritisation for including substances in Annex XIV

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

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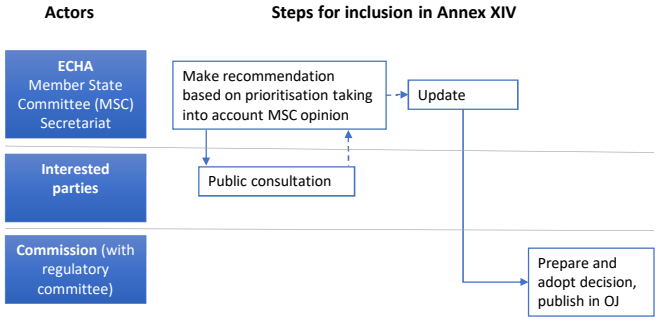
Inclusion in Annex XIV – Substances subject to authorisation



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Granting an authorisation

- Specific for
  - person,
  - substance and
  - use(s)
- Conditions
- Time-limited review period
- Can have monitoring arrangement
- **Applicant** shall justify why authorization shall be granted

Granting an authorisation

- shall be granted if the risk to human health or the environment are adequately controlled – only if threshold for effect can be established
- may be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance **and** if there are no suitable alternative substances or technologies

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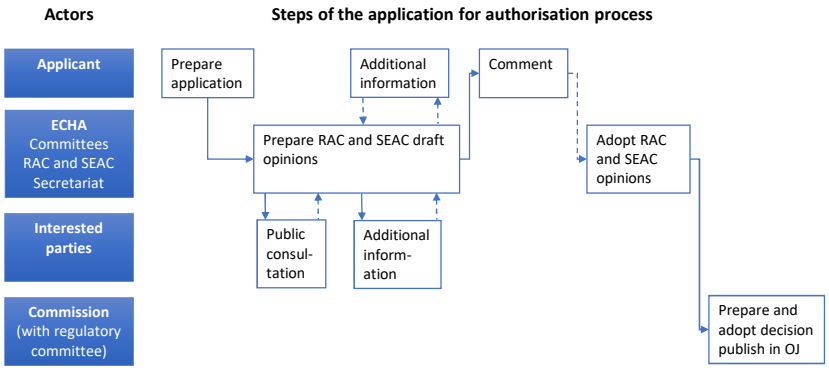
Granting an authorisation



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

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

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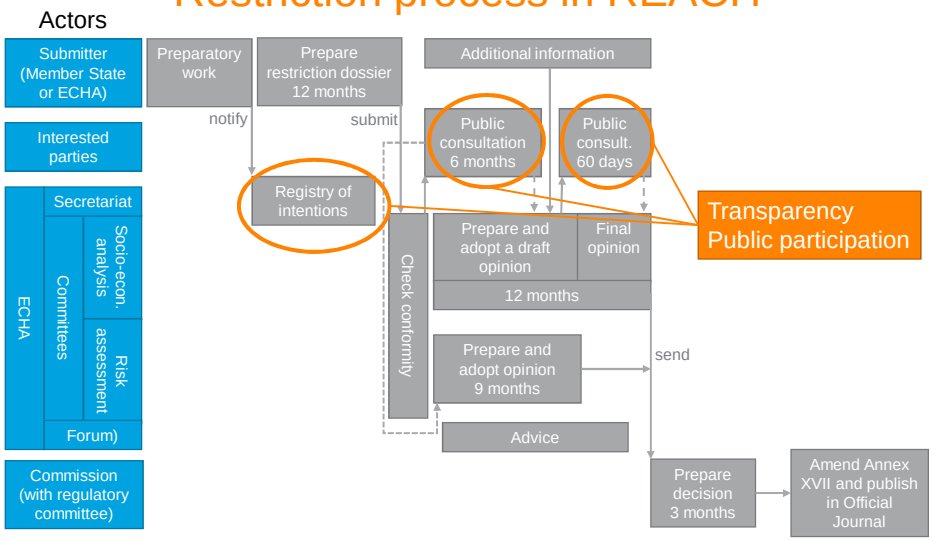
Restriction process in REACH



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Justifying a restriction

- Identified concern
  - *'…there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis…'* (REACH article 68(1))
- Justification for a restriction on Community-wide basis:
  - Effective in managing the identified concern
  - Proportional – benefits versus costs for society
  - Practical – the restriction can be implemented, enforced and managed
  - Possible to monitor the effect of the restriction over time

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Restrictions in REACH – examples 1

Asbestos fibres (defined by CAS-no)

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

SVHC: Authorisation route – no authorisations would be granted!

Toluene

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

Probably not SVHC
Authorisation route would mean many applications for authorisation!

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Restrictions in REACH – examples 2

Three phthalates DINP, DIDP, DNOP

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

Probably not SVHC
Authorisation route would mean many applications for authorisation!
Imported articles would not be in scope

CMR-substances (listed in appendix)

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

SVHC but Authorisation route would mean many applications for authorisation!

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Example restriction – Nonylphenol ethoxylates

- Nonylphenol ethoxylates (NPE)
  - Substance of very high concern (SVHC)
    - Persistent, bioaccumulating and toxic, PBT
  - toxic to aquatic life with long lasting effects
  - causes serious eye irritation
  - causes skin irritation

- Nonylphenol (degradation product) – Priority hazardous substance in the EU Water framework directive (WFD)
  - One purpose of the WFD: cessation or phasing-out of discharges, emissions and losses of the priority hazardous substances

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Example restriction – Nonylphenol ethoxylates (cont.)

First restriction (2005)

- Not to be used on its own or in mixtures, some exemptions

REACH Annex XVII, entry 46

⇩

Continued use outside EU in the manufacturing of textile articles

⇩

Release from washing textiles in EU 320 tonnes NPE/year
+ releases outside EU

Extended restriction

'Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01 % by weight of that textile article or of each part of the textile article.'

[…]

REACH Annex XVII, entry 46a

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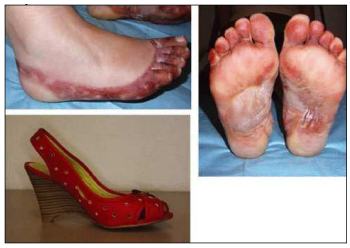
Example restriction – Dimethyl fumarate

- Dimethyl fumarate (DMFu)
  - harmful in contact with skin
  - causes serious eye irritation
  - causes skin irritation
  - may cause an allergic skin reaction
- Acute and severe effects
- Found in imported articles (shoes, furniture etc.) – fungicide
  - not used in EU, would be biocide
- Restriction only option
  - not possible to control the manufacture or use of the substance as such



From: Background document to RAC and SEAC opinions on Dimethylfumarate (DMFu)

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Comparison Restriction – Authorisation under REACH

Restrictions in REACH	Authorisation in REACH
Justified by risk	Justified by intrinsic hazardous properties – Substance of Very High Concern
Ban or conditions for manufacture, placing on the market or use	Ban unless economic actor has relevant authorisation
Can be on all, some or only minor part of uses	Applies to all uses unless specifcally exempted (few and minor excluded)
Substance as such, in mixture or in article	Substance as such
Regulatory decision – Applies to all when in force	1. Regulatory decision to make a substance subject to authorisation 2. Economic actor apply for authorisation 3. Regulatory decision on granting authorisation – time-limited, conditions

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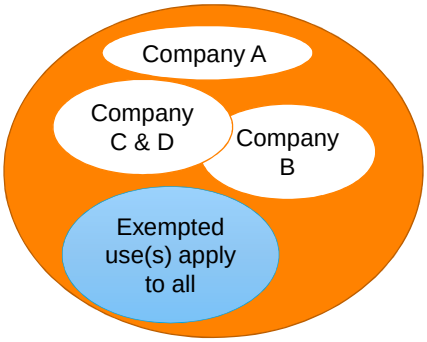
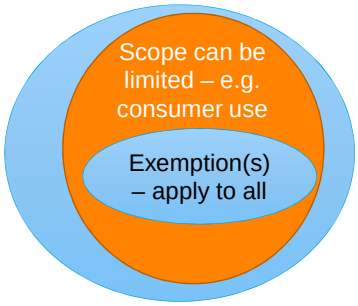
Comparison Restriction – Authorisation under REACH (cont.)

Authorisation



Restriction



Both are based on substances (groups of substances)

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Exclusion of substance specific uses from restrictions or authorisation requirement

Authorisation under REACH

- Uses may be exempted from the authorisation requirement only if other EU legislation controls the risk to human health and the environment
- Done in decision on inclusion of substance in Annex XIV – substances subject to authorization

Scientific research excluded in restrictions and authorisation

Restrictions

Restrictions in REACH

- Scope of uses to be included is determined in developing the restriction
- Change is same process as new restriction

Restrictions in RoHS

- Exempted applications (uses) in annex
- Time-limited, review process
- Anyone can apply for new exemption
- Apply for all if accepted

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Restriction versus Authorisation – criteria for choosing

Restrictions	Authorisation

• Developing a restriction is demanding in resources
  • 0,5 – 1,5 MEUR
• Member State/ECHA must identify scope, need for exemptions
  • E.g. for safety reasons, not proportional
• Push for substitution only if use is in scope
  • Compulsory if in scope
	• A system must be in place and maintained to handle authorisations
	• Economic actors has costs to apply for authorisation
	• Does not address risks from imported articles
	• Push for substitution even if authorisation for use granted
	  • Authorisation time-limited

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Developments in EU chemicals legislation

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Situation in EU

- Framework legislations in force and operational
  - REACH-regulation
  - CLP-regulation
  - Plant Protection Product Regulation
  - Biocidal Product Regulation
- Include processes for developing the regulation
  - REACH – request more information on hazard and risk
  - REACH – new restrictions
  - REACH – identify more substances as SVHC, include in Candidate list
  - REACH – make more substances subject to authorisation requirement, include in Annex XIV
  - CLP – harmonised classification and labelling

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REACH review – 10 years after entry into force

- Fully operational and delivering results towards achieving its objectives!
- Costs justified by results
- Manufacturers/importers have delivered registrations – no major disruptions in market
- Continued increase in information in supply-chain
- ECHA has been instrumental in the implementation of REACH

Shortcomings – actions

- Registration dossiers – address non-compliance
- Authorisation process – needs simplification
- Not level playing field non-EU companies – restrictions, enforcement
- Clarify interface REACH – other EU-legislation

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Authorisation under REACH

- SVHC roadmap developed
  - Identify all SVHC by 2020
- First substances identified CMRs, PBT/vPvB – well-defined
- Later also 'Equivalent level of concern' – less well-defined
- First authorisation applications mainly specific, well-described uses, few sites
- Now also wider uses
- Roadmap progressing beyond expectations
- Progressive substitution of SVHCs
  - Applications for 21 of 31 substances
- Improved risk management and seek substitutes if substitution not possible
- Room to improve authorisation application process
  - Cost ~ 120 000 EUR per substance, use and applicant

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Restriction under REACH

- 13 new restrictions adopted 2011 to 2016
- Fast track for introduction of restrictions on CMRs in consumer articles
  - Avoid moving production outside EU to bypass authorisation
- Slower pace of proposals than expected
  - Demanding in member state resources, 0,5 – 1 million EUR
  - Lack of information to identify needed restrictions
  - High demands by ECHA committees
- Room for improvement in restrictions process

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

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

Information on substances in articles – to authorities REACH article 7

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

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

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

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

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

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Information on substances in articles – follow up

- Divergence in interpretation of ’0,1 % of article’ now decided by European Court
  - ’once an article always an article’
- Information flow in supply chain is improving but slower than foreseen
- Fewer than expected notifications to ECHA
  - Lack of awareness
  - Difficulties to get information needed
  - Descriptions of uses in registration to broad => means exemption to broad
  - Cost of communication
  - Lack of methods for risk assessment and measurement of content

Directive 2011/65/EU Restriction of hazardous substances in electrical and electronic equipment – RoHS

- Restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.
- CE-marking directive
- Also obligations on manufacturers, importers and distributors, examples:
  - Manufacturer’s to have technical documentation, traceability of product etc.
  - All to handle any non-compliances

Restriction on hazardous substances

Maximum concentration limit in **homogenous material**

- Lead (0,1 %)
- Mercury (0,1 %)
- Cadmium (0,01 %)
- Hexavalent chromium (0,1 %)
- Polybrominated biphenyls (PBB) (0,1 %)
- Polybrominated diphenyl ethers (PBDE) (0,1 %)

The restriction of DEHP, BBP, DBP and DIBP shall apply

- From 22 July 2019, except:
- medical devices, including *in vitro* medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.
- Bis(2-ethylhexyl) phthalate (DEHP) (0,1 %)
- Butyl benzyl phthalate (BBP) (0,1 %)
- Dibutyl phthalate (DBP) (0,1 %)
- Diisobutyl phthalate (DIBP) (0,1 %)

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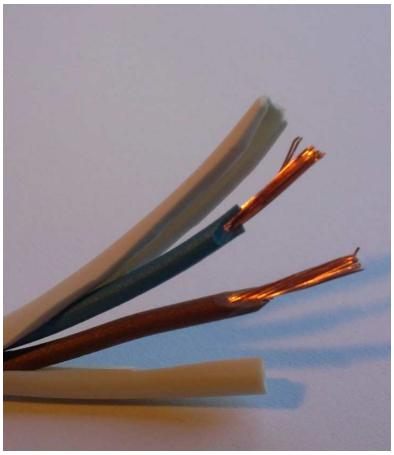
Homogenous material – example

At least:

1) White plastic
2) Blue plastic
3) Brown plastic
4) Cupper



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Exemptions from restrictions

- Exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution
- Apply for specific use – not for specific economic actor
- Time limited – maximum validity period 5 years (7 years for some categories)
- Can be renewed
- Listed in annex III and IV
- Examples of exemptions

Number	Exemption
6(b)	Lead as an alloying element in aluminium containing up to 0,4 % lead by weight
7(b)	Lead in solders for servers, storage and storage array systems, network infrastructure equipment for switching, signalling, transmission, and network management for telecommunications

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RoHS developments

- November 2017, the rules were amended to further strengthen circular economy – repair as produced
- More substances:
  - The use of four phthalates will be restricted (from July 2019)
  - Proposal to add Medium-Chained Chlorinated Paraffins
- Continuous review of exempted applications
  - Directive has been revised to give longer time for decision on applications for exemptions
- Evaluation and Fitness Check Roadmap – proposal in public consultation (till 2020)
  - RoHS restrict certain harmful substances in EEE, to:
    - protect human health and the environment
    - maximise the recovery of such substances after use.
  - The evaluation will assess how effective, efficient, relevant and consistent the rules are, and whether they usefully supplement national efforts.

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Toy Safety Directive 2009/48/EC

- *Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain*
- CE-marking directive
- Stricter requirements for chemical substances than previous directive:
  - CMR substances (1A, 1B, or 2) not allowed in the accessible parts of toys
  - 19 'heavy elements' (migration limits) not allowed in toy parts accessible to children
  - 55 allergenic fragrances have been banned, 11 substances must be specified on the label
  - Nitrosamines and N-nitrosatable substances are prohibited in toys for children under 36 months intended to be put in the mouth
- Safety assessments, traceability, documentation
- Detailed provisions in harmonised standards EN 71

Toy Safety Directive 2009/48/EC - developments

- Evaluation 2015
  - Effective in enhancing the level of safety of toys, facilitating the internal market
  - Consumer associations and some Member States sceptical about limit values for some hazardous chemicals
  - Compliance costs high, especially for SMEs
  - The added value confirmed by all stakeholders, good legislative practice, with clear and focused provisions covering all major needs and ensuring common requirements across the EU

Requirements and obligations

The product

Is it a toy under the TSD?

- Definition and exclusions
- Extensive guidance

If it is a toy – identify the requirements

The economic actor

Identify role under TSD?

- Manufacturer
- Importer
- Distributor
- Authorised representative

Identify obligations

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In scope of TSD or not – major impact on obligations and requirements

Basketball/football  Sports equipment – not a toy		X	The official and training balls are used in the sporting event
Basketball/football  Toy	X		Major changes in physical/material properties to adjust the product to children's play movements

Example from European Commission Guidance document no. 14 On the application of the directive on the safety of toys – Sports equipment versus toys

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Control of provisions in TSD

- Official controls – inspections
  - Visual inspection of toy and documentation – CE-marking, identification number, name and address, safety instructions…
  - Chemical testing
  - Inspection of documentation and procedures
- Controls in the supply chain
  - Importer and distributor can do visual controls – low cost
  - Importer (and distributor) can do chemical testing – costly
  - Importer can review documentation and procedures – costly

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End-of life vehicles (ELV) – Directive 2000/53/EC

- Every year ELVs generate between 7 and 8 million tonnes of waste
- The ELV-directive
  - aims at making dismantling and recycling of ELVs more environmentally friendly
  - sets clear quantified targets for reuse, recycling and recovery of the ELVs and their components
  - Restricts use of hazardous substances (in particular lead, mercury, cadmium and hexavalent chromium), thus promoting the reuse, recyclability and recovery of waste vehicles
- The Commission is currently carrying out an evaluation of the ELV Directive to identify good and bad practices in its implementation and assess whether it has met its objectives using the criteria of: (i) effectiveness, (ii) efficiency, (iii) coherence, (iv) relevance and (v) EU added value. Feedback in end 2018

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Substances of concern and circular economy

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