REACH and CLP

GREEN CHEMISTRY
CHANGE MANAGER

The EU's chemicals legislation

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- Main pillars
  - REACH-regulation
  - CLP-regulation
- Special restrictions, e.g.
  - persistent organic pollutants (POPs)
  - mercury and compounds
  - RoHS-directive
- Special uses and their rules, e.g.
  - f-gases
  - fertilisers
  - biocidal products
  - plant protection products
  - cosmetics
  - detergents
- Export rules
- SCIP-system

How many chemicals are there in the EU?

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- Depends on what we are looking at:
  - substances
  - mixtures
  - quantities
  - …
- What is usually looked at, are “substances”
- BUT a “substance” is not necessarily a pure entity, so lets have a look at a legal definition:

Article 3 of the REACH-regulation

1. Substance:

„means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition“

- Determining substance identity in a legal context is not (always) trivial:
  - Guidance on Identification and Naming of Substances
  - SIP: Substance Identification Profile

Definition: substance

- Different groups of substances:
  - well-defined substances:
    - » mono-constituent substances
    - » multi-constituent substances
  - UVCBs: Substances of Unknown or Variable composition, Complex reaction products or Biological materials
    - » chemical composition: not (clearly) defined or variable
    - » identity based on: source (e.g. plant- or animal species), manufacturing-process (e.g. extraction), others (e.g. enzyme index)
    - » name can be based on manufacturing-process: e.g. “extraction product of…”, “reaction product of…”
    - » variable concentration or/and concentration range of components

How many substances are there in the EU?

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- Substances notified to the Classification and Labelling Inventory
  approx. 250.000

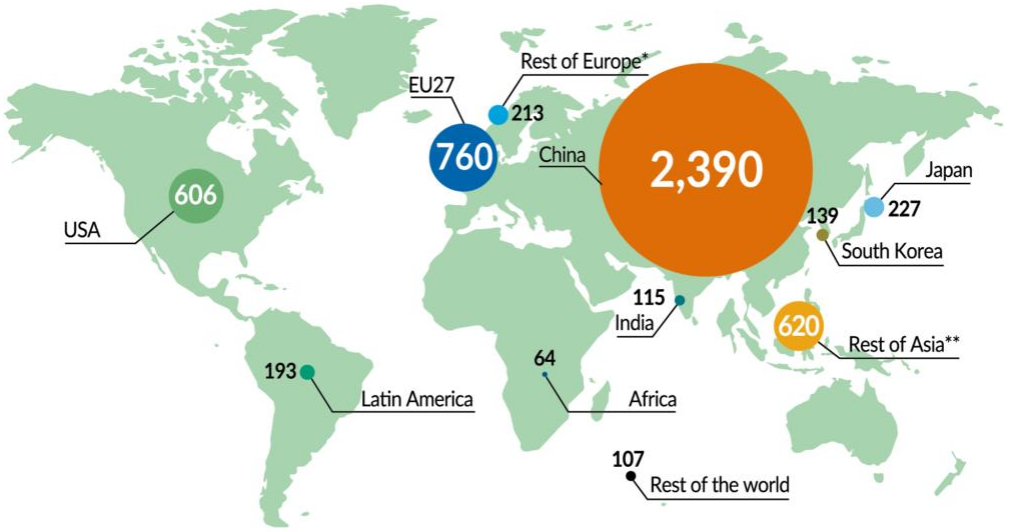
- REACH-registered substances
  approx. 30.000

- 99% of the quantities are high-volume substances, means manufactured or imported in a quantity of > 1.000 t/a
  approx. 4.000

→ **Compare: CAS-registry contains tenths of millions substances**

Economic relevance of chemicals

- Sales of chemicals in 2022:
  - € 5.434 bio. globally
  - € 760 bio. by the EU



Source: Cefic Chemdata International
*Rest of Europe covers UK, Switzerland, Norway, Turkey, Russia and Ukraine
**Asia excluding China, India, Japan and South Korea

- 1.2 mio. direct jobs
- Today the EU is the 2nd largest actor in chemicals, while its share will decreas until 2030
- Chemical manufacturing is the EU‘s 4th largest industry sector approx. 30 000 companies; 95 % SME

REACH regulation

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- Registration
  - Notification to the European Chemicals Agency (ECHA) by manufacturer or importer of all substances from 1 t/a and considering relevant uses
  - Data about hazardous properties and risk-assessment dependent on quantities
- Evaluation
  - Assessment of notified data by member states/agency
  - Further data can be requested
- Authorisation and restriction
  - Authorisation and/or substitution of substances of very high concern
- Chemicals

REACH briefly explained

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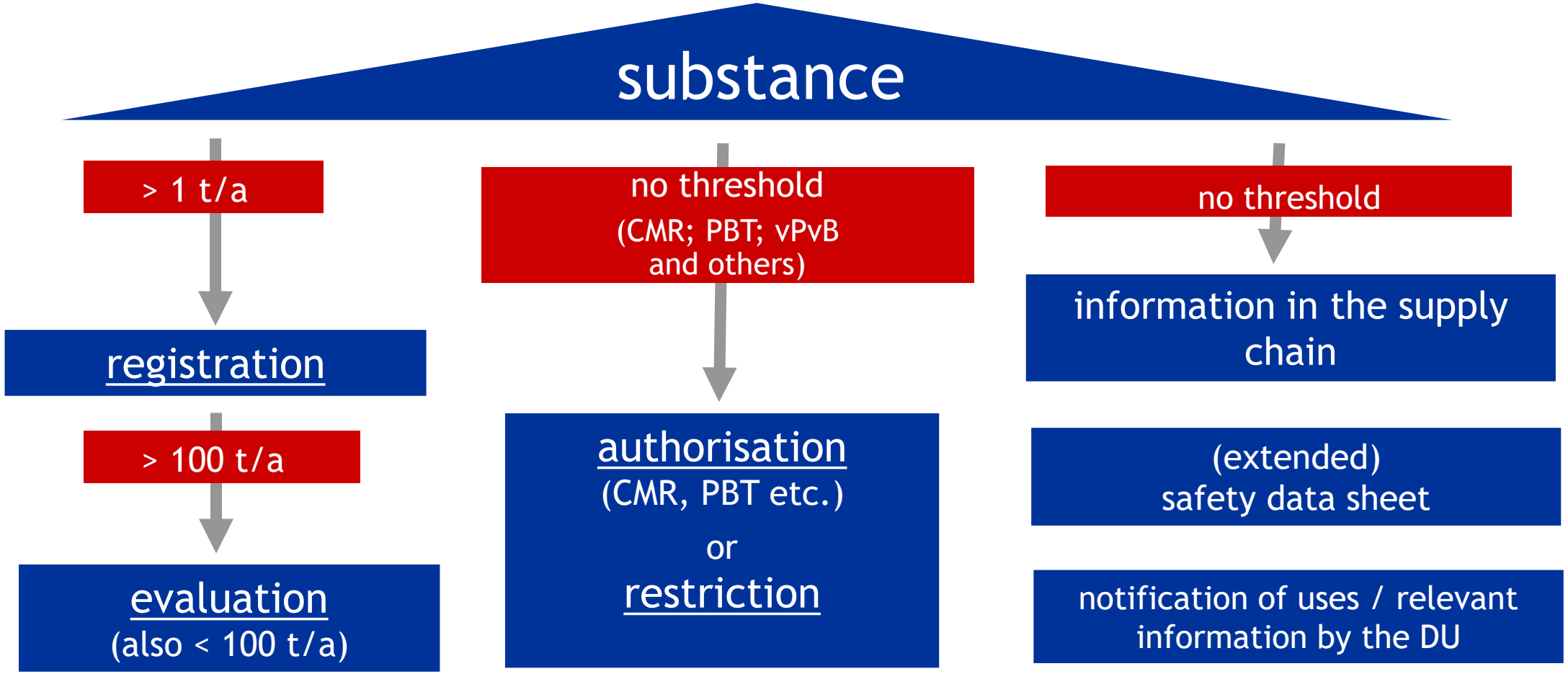
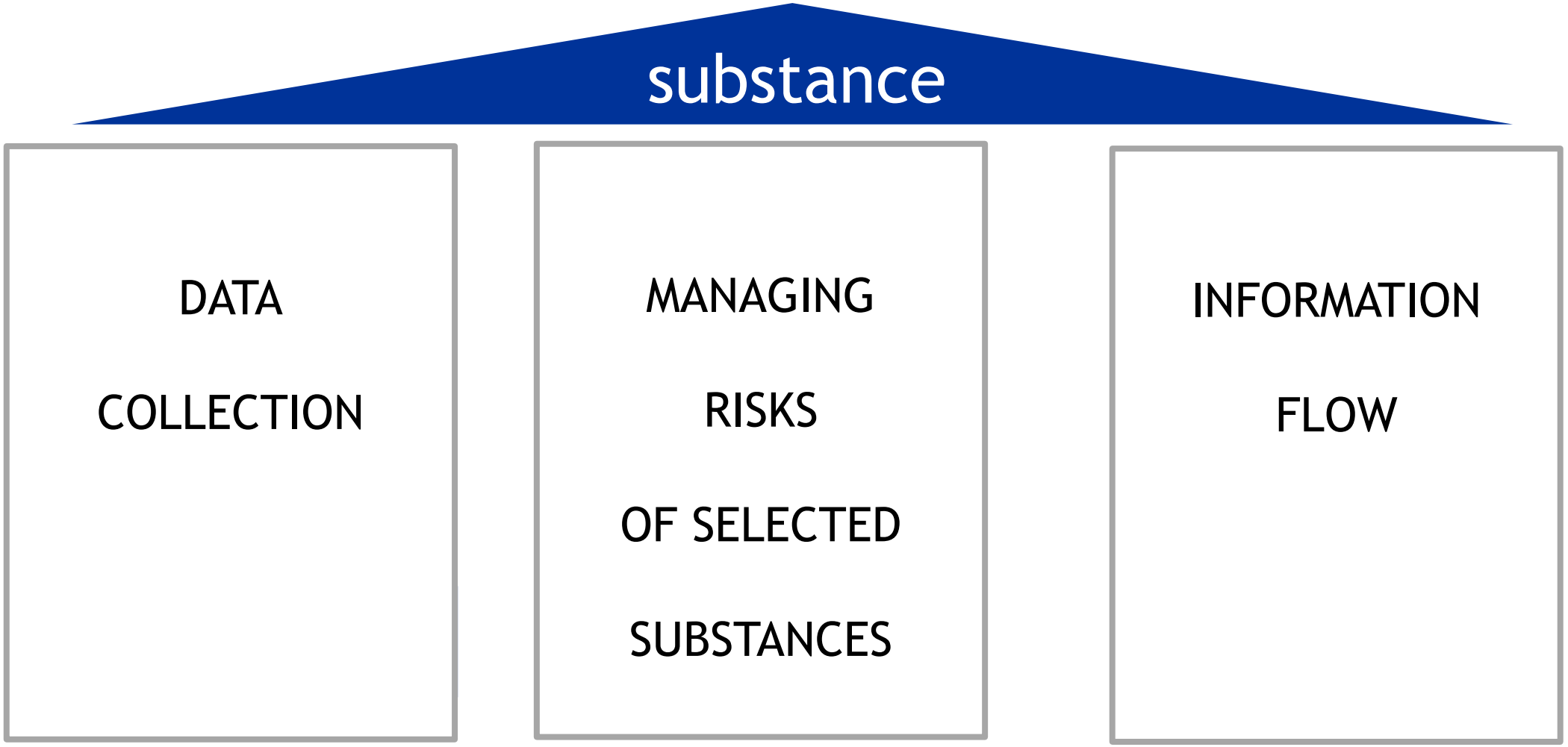


REACH briefly explained

GREEN CHEMISTRY CHANGE MANAGER



Where does REACH apply?

- In all 27 Member States of the EU
  - Croatia had some special rules according to its Accession Treaty, but the last expired in 2015
- Norway, Iceland, Lichtenstein (EEA) based on the EEA-treaty
- Micro-states like Andorra, Monaco, San Marino are part of the „REACH-world“ due to bilateral contracts with EU-MS
- Switzerland has implemented some elements, but is not part of the „REACH-world“
- Brexit complicated everything (a bit) and UK is out of the “REACH-world”
- Don‘t ask about the Vatican …

REACH: Aim & Scope

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*" (1) The purpose of this Regulation is to ensure a **high level of protection of human health and the environment**, including the promotion of alternative methods for assessment of hazards of substances, as well as the **free circulation of substances on the internal market** while enhancing **competitiveness and innovation**.*

*(2) This Regulation lays down provisions on **substances** and **mixtures** within the meaning of Article 3. These provisions shall apply to the **manufacture, placing on the market** or **use** of such **substances on their own, in mixtures or in articles** and to the placing on the market of mixtures." -*

REACH Art. 1

Scope is in principle open

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- But many exemptions, which are full or partial:
  - REACH not applicable
    (e.g. waste, transported substances)
  - National exemptions in the interest of defence possible
  - Exempted from registration
    (e.g. food, meds)
  - Special rules for the registration
    (e.g. polymers, intermediates)
  - regarded as being registered
    (actives of biocidal products and pesticides)
  - Exempted from the information in the supply chain
    (e.g. food, cosmetics)
  - Exempted from the authorisation
    (e.g. biocides, fuels)
  - Exempted from the restriction
    (only cosmetics for HH)

Relevant definitions

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2. Mixture (preparation):

„means a mixture or solution composed of two or more substances“

3. Article:

„means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”

Relevant definitions

15. Intermediate:

„means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

a) *non-isolated intermediate*

b) *on-site isolated intermediate*

c) *transported isolated intermediate*

Relevant definitions

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5. Polymer:

„means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

(b) less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer"

6. Monomer:

„means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process"

Relevant definitions

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7. Registrant:
“means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance”

8. Manufacturing:
„means production or extraction of substances in the natural state”

9. Manufacturer:
„means any natural or legal person established within the Community who manufactures a substance within the Community“

11. Importer:
„means any natural or legal person established within the Community who is responsible for import“

Relevant definitions

GREEN CHEMISTRY CHANGE MANAGER

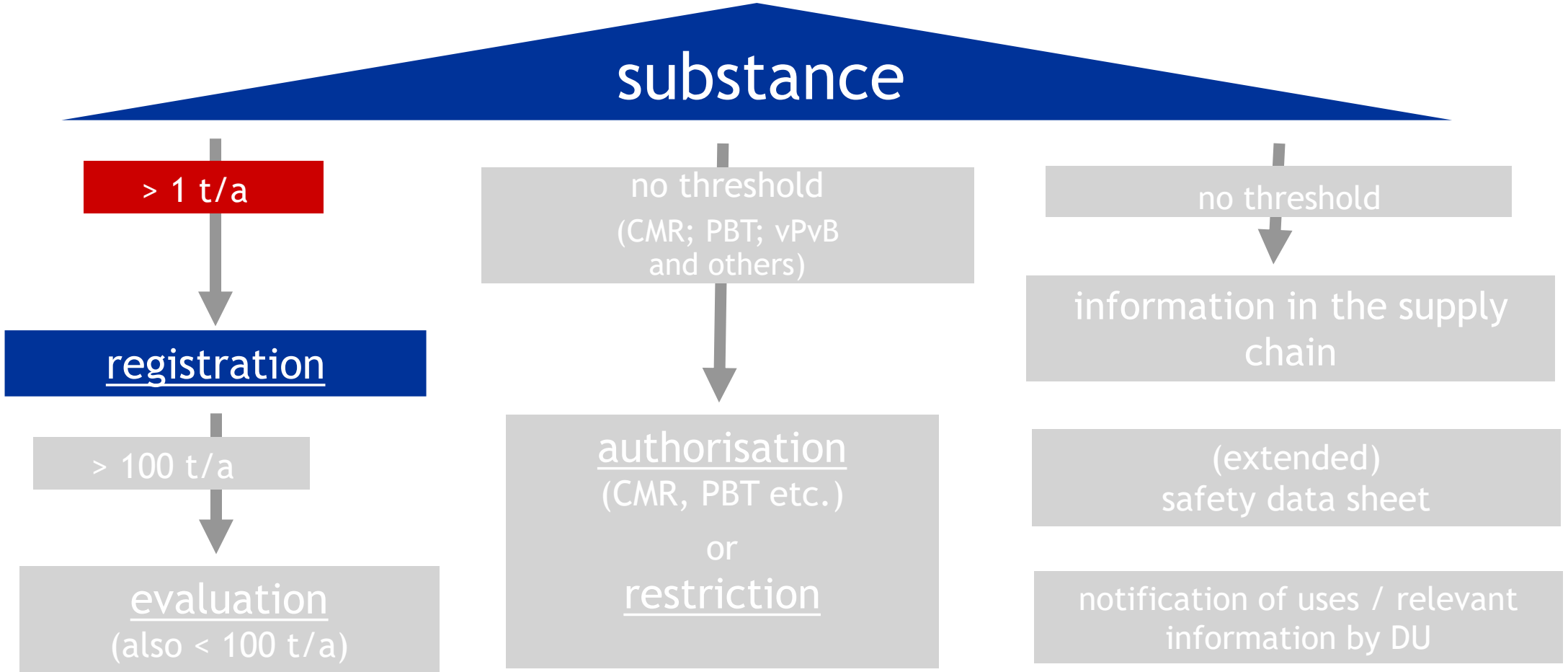
10. Import:
„means the physical introduction into the customs territory of the Community“

12. Placing on the market:
„means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market“

13. Downstream User:
„means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user […]“

14. Distributor:
„means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties“

Registration



General registration obligations

- No data – no market

> „*Subject to Articles 6, 7, 21 and 23, substances on their own, in mixtures or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.*”

(Art. 5)

The REACH-registration is practically a huge data-collection mechanism for substances.

General registration obligations

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- Registration obligation (Art. 6) for
  - substances → manufacturer or importer
  - substances in mixtures → importer (otherwise: down stream user)
  - special cases (substances in article, PPORD, intermediates, polymers)
- considering the use of the substance
- independent of the properties of the substance (hazardous, non-hazardous)
- independent of the concentration in a mixture
- within the scope of the registration obligations

Who can register?

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- Manufacturer of a substances
- Importer of a substances
  - as such
  - in a mixture
  - (eventually) in an article
- Only Representative (OR), who is representing a non-EU-manufacturer of substances, mixtures and/or articles

- Third representative – to keep identity of the actual registrant confidential
- A downstream user is not allowed to register

What was the pre-registration?

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- Phase-in substances could be preregistered (in 2008)
- Prerequisite for transitional periods until 2018
- Relatively simple procedure, lots of „trash“
- Purpose:
  - market-overview,
  - data-sharing,
  - joint submission.

- **Important today:**
  - became irrelevant on 1st June 2018
  - however, a certain abuse of pre-registration numbers

Registration-timeline – overview

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- since 1st June 2008
  - Non-phase-in substances
  - Not preregistered phase-in substances

- since 1st December 2010
  - Phase-in substances from 1000 t/a
  - Phase-in substances from 100 t/a & R50/53
  - Phase-in substances from 1 t/a & CMR, Cat. 1A/B

- since 1st June 2013
  - Phase-in substances from 100 t/a

- since 1st June 2018
  - Phase-in substances from 1 t/a

Some numbers on REACH

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- Numbers phase-in
  - 2010: ~3.400 substances
  - 2013: ~3.000 substances
  - 2018: ~10.500 substances
- and all together
  - total: ~22.500 substances (inkl. non-phase-in)
  - CLI: 250.000+ entries

These are 95+ % of the quantities

- Estimations were much higher, e.g. only for 2018: ~25.000 substances
- Dossiers: ~106.000 / Registrants: ~17.500
- However, only limited disappearance of substances
- Today there are still non-registered substances on the market
  - for some this is ok (e.g. exemptions),
  - some should be registered, but are not.

Registration-procedure today

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Every manufactured and imported substances over 1 t/a needs to be registered upfront:

- 1st step: Inquiry
  - → Is my substance already registered?
  - → Can I share data?
- 2nd step: Dossier preparation
- 3rd step: Submission
- 4th step: Assignment of registration number
  - → 01-1234567890-12-1234

Dossier: Information requirements

- requirements
  - general requirements, e.g. substance name, registrant & uses
- Tiered approach regarding quantities
  - information requirements (annexes VII-X)
  - technical dossier always
  - chemical safety assessment / report (CSA/CSR) from 10 t/a onwards
- Joint preparation / submission of data obligatory

Registration information (Art. 12)

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Substances ≥ 1 t/a	Substances ≥ 10 t/a	Substances ≥ 100 t/a	Substances ≥ 1000 t/a
Technical Dossier	Technical Dossier	Technical Dossier	Technical Dossier
Annex VII *	Annex VII, VIII	Annex VII, VIII	Annex VII, VIII
		Annex IX (testing proposal)	Annex IX, X (testing proposal)
	Chemical safety report	Chemical safety report	Chemical safety report

* Only pyhsicochemical information necessary, if criteria of Annex III are not met

Tiered approach: Why it matters

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No	Toxicological information	~ T€
8.1.1	Skin irritation (rabbit)	**0,7**
8.2.1	Eye irritation (rabbit)	**0,8**
8.3	Skin sensitisation (mouse); LLNA	**2,5**
8.4.1	Gene mutation in bacteria (Ames-Test)	**2,6**
8.4.2	Cytogenicity in mammalian cells (in vitro)	**≤ 20**
8.4.3	Gene mutation in mammalian cells (in vitro)	**10 - 15**
8.4	Mutagenicity (in vivo)	**15**
8.5.1	Acute toxicity (by oral route)	**0,8 – 2**
8.5.2	Acute toxicity (by inhalation)	**15 - 20**

Tiered approach: Why it matters

GREEN CHEMISTRY CHANGE MANAGER

No	Toxicological information	~ T€
8.5.3	Acute toxicity (by dermal route)	**2**
8.6.1	Short-term repeated dose toxicity test (28 days)	**40 - 120**
8.6.2	Sub-chronic toxicity (90 days)	**75 - 170**
8.6.3	Long-term repeated dose toxicity (≥ 12 months)	**320**
8.7.1	Screening for reproductive/developmental toxicity	**70 – 100**
8.7.2	Pre-natal developmental toxicity	**90**
8.7.3	Extended One-Generation Reproductive Toxicity Study	**350 - 400**
8.9.1	Carcinogenicity	**600 - 700**

Tiered approach: Why it matters

No	Ecotoxicological information	~ T€
9.1.1	Short term aquatic toxicity on invertebrates (Daphnia)	**4**
9.1.2	Growth inhibition aquatic plants (algae)	**5**
9.1.3	Short-term aquatic toxicity to fish	**4**
9.1.4	Activated sludge respiration inhibition test	**2**
9.1.5	Long-term aquatic toxicity on invertebrates (Daphnia)	**10 - 12**
9.1.6	Long-term aquatic toxicity on fish	**12 - 15**
9.2.1.1	Ready biodegradability	**2 – 3**
9.2.2.1	Hydrolysis as a function of pH	**4 – 5**

Tiered approach: Why it matters

GREEN CHEMISTRY CHANGE MANAGER

No	Ecotoxicological information	~ T€
9.3.1	Adsorption/desorption screening	**≥ 3**
9.3.2	Bioaccumulation in fish	**20 - 50**
9.4.1	Short-term terrestrial toxicity to invertebrates (earthworm)	**6 - 7**
9.4.2	Effects on soil micro-organisms	**5**
9.4.3	Short-term terrestrial toxicity to plants	**15 - 20**
9.4.4	Long-term terrestrial toxicity to invertebrates	**10 - 12**

→ **These costs are estimates!**

Tiered approach: Costs in practice

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- We see, testing costs highly depend on the tonnage

- Per substance costs are approx. :
  - 1-10 t/a: € 30-50.000,-
  - 1-100 t/a: € 300-500.000,-
  - 100+ t/a: ?
    - max. I saw € 2mio,- for > 1000 t/a
    - average € 250-750.000,-
    - BUT: for ann. IX and X first only proposals are necessary

Test Methods Regulation

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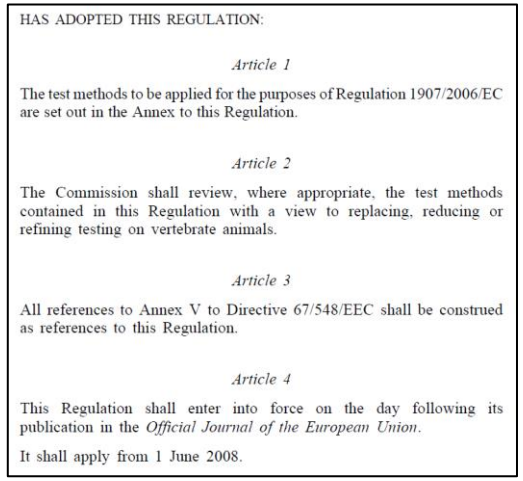
- Commission regulation (EC) No 440/2008 laying down test methods pursuant to REACH
  - 2 pages body text (including recitals and 4 articles)
  - Annexes
    - » Part A: Methods for pysico-chemical properties (better to use: UN manual of tests and criteria)
    - » Part B: Methods for the determination of toxicity and other health effects
    - » Part C: Methods for the determination of ecotoxicity



HAS ADOPTED THIS REGULATION:

Article 1

The test methods to be applied for the purposes of Regulation 1907/2006/EC are set out in the Annex to this Regulation.

Article 2

The Commission shall review, where appropriate, the test methods contained in this Regulation with a view to replacing, reducing or refining testing on vertebrate animals.

Article 3

All references to Annex V to Directive 67/548/EEC shall be construed as references to this Regulation.

Article 4

This Regulation shall enter into force on the day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 June 2008.

- Regular ATPs

Test Methods Regulation

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▼B

ANNEX

PART A: METHODS FOR THE DETERMINATION OF PHYSICO-CHEMICAL PROPERTIES

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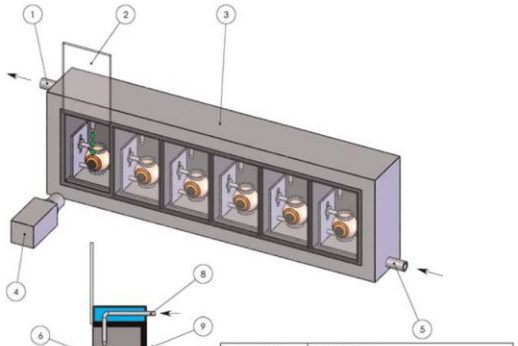
▼M2

Appendix 3

Diagrams of the ICE superfusion apparatus and eye clamps

(See Burton et al. (17) for additional generic descriptions of the superfusion apparatus and eye clamp)



ITEM NO.	DESCRIPTION
1	OUTLET WARM WATER
2	SLIDING DOOR
3	SUPERFUSION APPARATUS
4	OPTICAL MEASURING INSTRUMENT
5	INLET WARM WATER
6	SALINE SOLUTION
7	WARM WATER
8	INLET SALINE SOLUTION
9	COMPARTMENT
10	EYE HOLDER
11	CHICKEN EYE
12	OUTLET SALINE SOLUTION
13	SETSCREW
14	ADJUSTABLE UPPER ARM
15	FIXED LOWER ARM

The global influence

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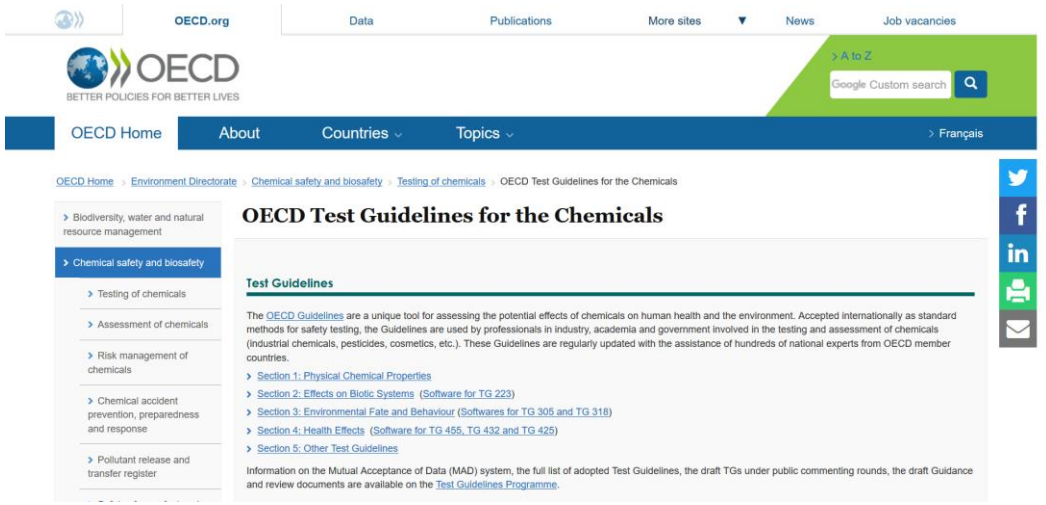
- **OECD Chemicals Testing Guidelines**
- Basis for EU-test-methods
- Accepted test-methods also for REACH-purposes
  - Section 1: Physical Chemical Properties
  - Section 2: Effects on Biotic Systems
  - Section 3: Degradation and Accumulation
  - Section 4: Health Effects
  - Section 5: Other



Chemical safety report (CSR, Art. 14)

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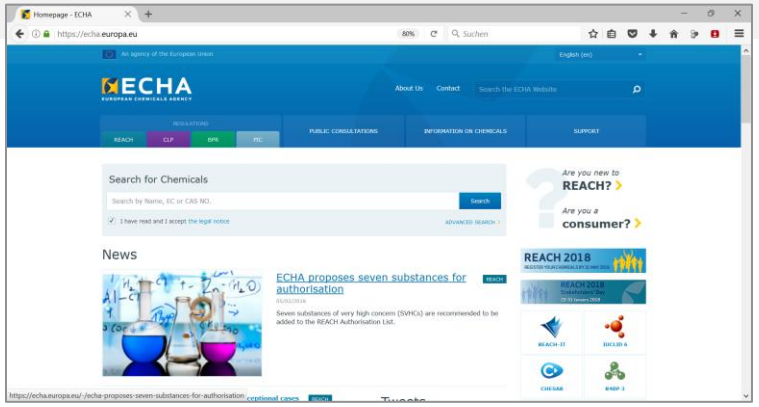
- For all registrations ≥ 10 tonnes/year:
  - (a) human health hazard assessment;
  - (b) physicochemical hazard assessment;
  - (c) environmental hazard assessment;
  - (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment
- if „hazardous“* or PBT/vPvB
  - exposure assessment (including the generation of exposure scenario and exposure estimations) taking all uses into account
  - risk characterisation (eventually refinement of risk management measures necessary)

* Reference to 67/548/EWG in the original REACH text, thus some CLP hazard classes/categories omitted through CLP adaptation

Registration - Where?



- ECHA – European Chemicals Agency
  - in Helsinki, Finland
  - managment board
  - 3 committees
    - » RAC – Committee for Risk Assessment
    - » SEAC – Committee for Socio-economic Analysis
    - » MSC – Member State Committee
  - Forum for Exchange of Information on Enforcement
  - Board of Appeal
  - National Helpdesks
  - http://echa.europa.eu

Registration – How?

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- IT-tools:
  - REACH-IT (online communication platfrom)
  - IUCLID 6 (local database)
  - IUCLID Cloude (online database)
  - Chesar (supports CSR)
  - Validation tools

- Each registrant pays individual fee
- and gets (semi-)individual registration number:
  - 01-1234567890-12-0000
  - 01-1234567890-12-0001
  - …
  - 01-1234567890-12-0700

Registration fees

Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to (incl. amendments)

- General structure:
  - tonnage band – 4 groups (1-10 / 10-100 / 1000-1000 / >1000)
  - company size (large / medium / small / micro) – COM-recommendation for the definition
  - individual or joint submission
- Kind of registration
  - “standard” substance (annex I)
  - intermediate (annex II)
- Fees also for updates, confidentiality claims, etc.

Fees - examples

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- General registration fee (annex I): € 65 - 33.699
- Intermediate (annex II): € 65 - 1.739
- Update registration (annex III):
  - tonnage band € 110 - 31.960
  - other updates € 61 - 4.892
- Confidentiality requests (Annex IV) : € 61 - 4.892
- PPORD Notifikation (Anhang V): € 27 - 1.087

Let’s go back to the costs and tests

Tiered approach: Costs in practice

- We see, testing costs highly depend on the ton
- Per substance costs are approx. :
  - 1-10 t/a: € 30-50.000,-
  - 1-100 t/a: € 300-500.000,-
  - 100+ t/a: ?
    - max. I saw € 2mio,- for > 1000 t/a
    - average € 250-750.000,-
    - BUT: for ann. IX and X first only proposals are ne

Consider the following:

- Costs are per substance; some on animals.
- For example, ethanol, is registered by 700+ entities.

→Are we now testing Ethanol 700+ times for the same endpoints in the EU?

Data-/cost-sharing is the solution

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- SIEF (substance information exchange forum:
  - *"Each SIEF shall be operational until 1 June 2018."*, but in practice: longer operational period necessary
- Today "inquiry" facilitates data-sharing
- Animal welfare is strong driver
- Reduces burden on SME
- Data-protection of 12 years after submission

SIEF rules and recommendations

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- Different possibilities of access to data and cooperation:
  - Full access to the complete study report (partial ownership)
  - Letter of access for “general purposes”
  - Letter of access only for REACH purposes
  - Cooperation contracts
  - Formalised consortia
- Cost sharing in a fair, transparent and non discriminatory way (see also: Implementing Regulation (EU) 2016/9)
- Assignment of a lead registrant
- Duty to answer to request from other co-registrants
- (EU)-Competition law needs to be respected

Joint submission (registration)

- Joint submission of some data by multiple registrants mandatory
- Information requirements always based on the tonnage band for the registration
- “Opt-out“ (for non-animal tests) possible, if
  - Disproportionate costs to submit the information jointly
  - Disclosure of commercially sensitive information
  - Disagreement on the selection of the information

→ One Substance, One registration (OSOR)

Simplified registration

- on-site / transported isolated intermediates

→ much less data / cheaper / limited use

- PPORD – Product and process oriented R&D

→ quick process / cheap / limited use and users / timely limited

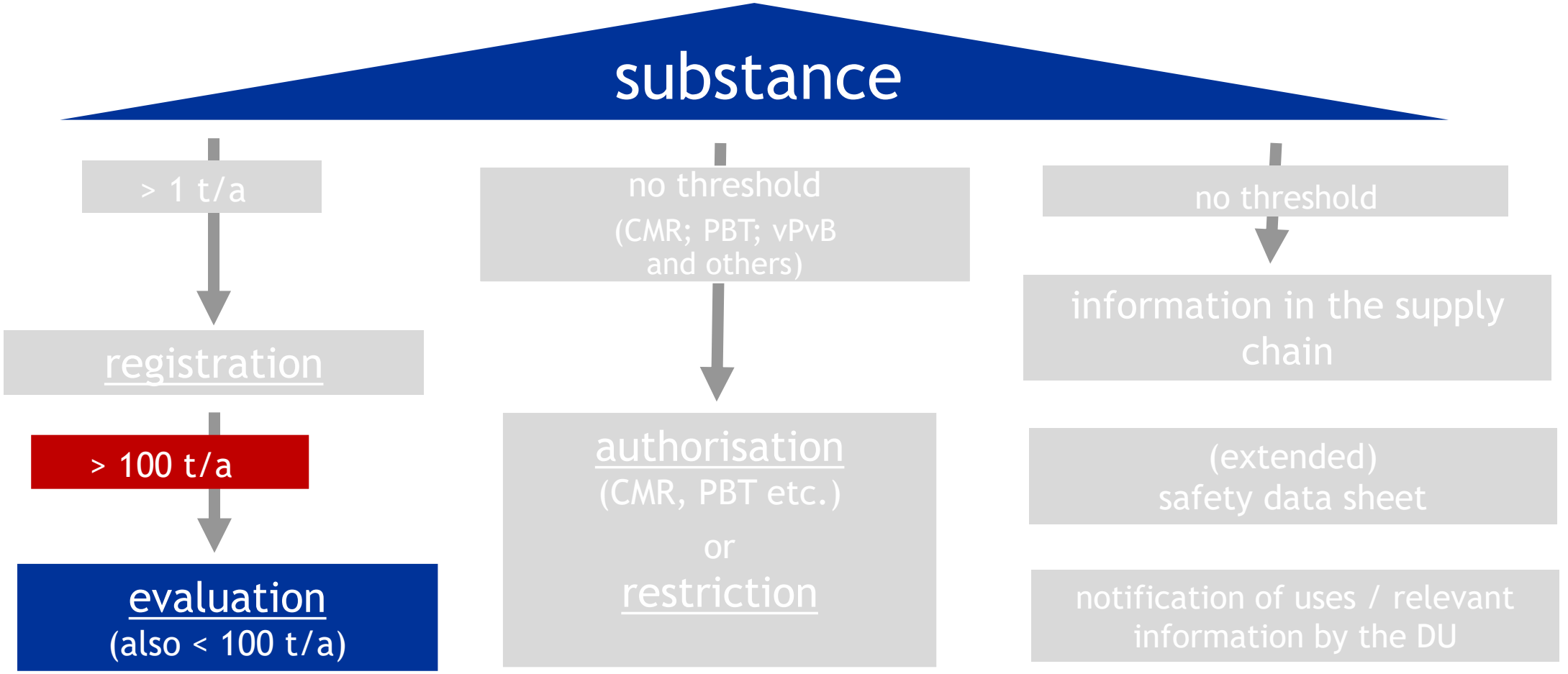
- Polymers

→ scientifically strange / easier / political compromise

- Recovered substances

→ flexible exemption if already registered

Evaluation


substance
> 1 t/a
registration
> 100 t/a
evaluation
(also < 100 t/a)
no threshold
(CMR; PBT; vPvB
and others)
authorisation
(CMR, PBT etc.)
or
restriction
no threshold
information in the supply chain
(extended)
safety data sheet
notification of uses / relevant information by the DU

Evaluation – Why?

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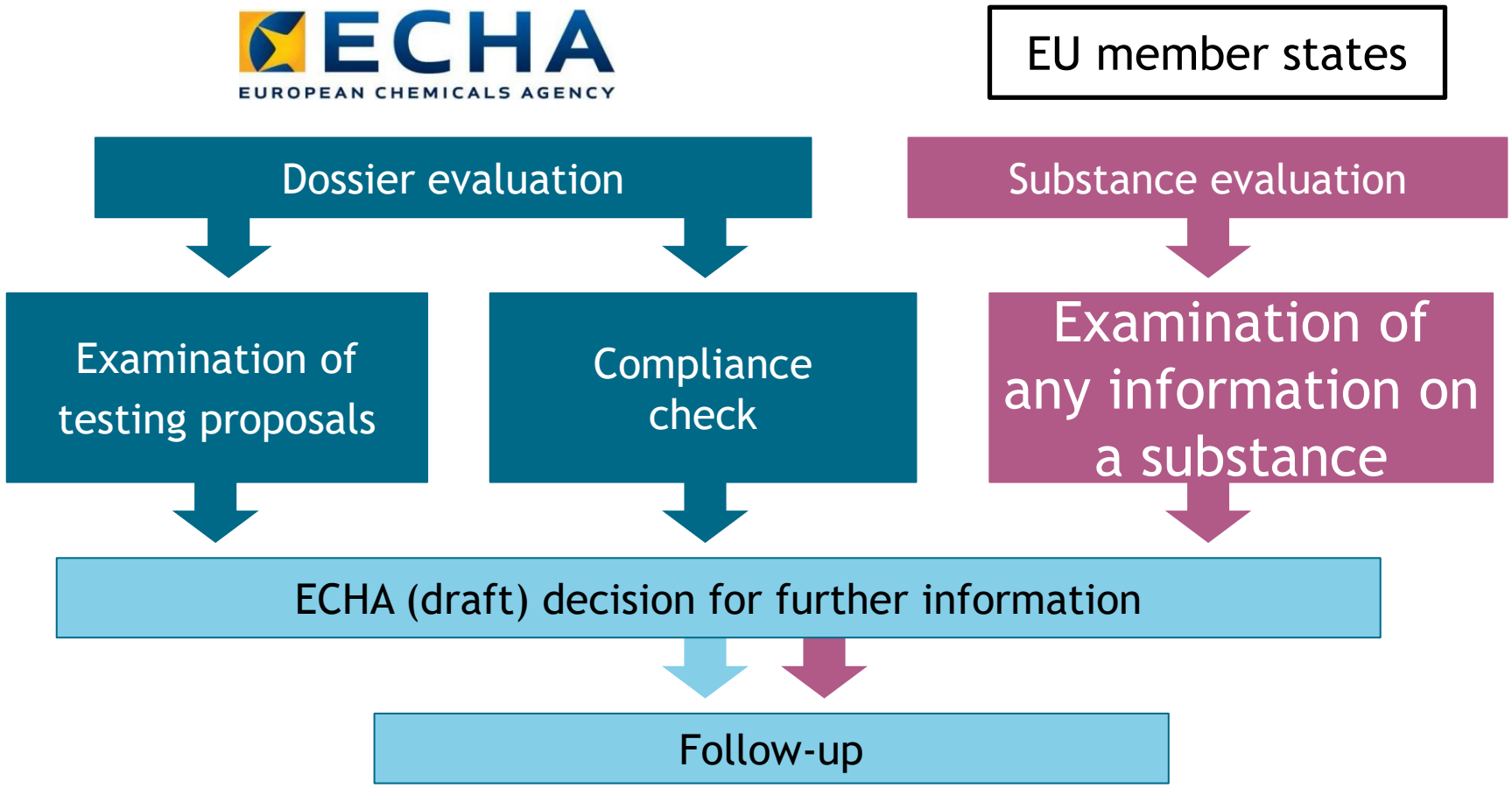
*"The evaluation provisions should provide for **follow-up to registration**, by allowing for **checks** on whether **registrations are in compliance** with the requirements of this Regulation and if necessary by allowing for **generation of more information** on the properties of substances. If the Agency in cooperation with the Member States considers that there are **grounds for considering** that a substance **constitutes a risk** to human health or the environment, the Agency should, after having included the substance in the **Community rolling action plan** for **substance evaluation**, relying on the competent authorities of Member States, ensure that this substance is evaluated."*

– REACH Recital (20)

Evaluation - 3 types



Evaluation – some numbers

- Overall progress in 2009 - 2022

Evaluation progress, 2009-2022

Evaluation process	Adopted decisions	Information requests	Information requests by area				
			Annex I (incl. CSR, RSS, PBT)*	Annex VI (incl. SID, C&L)*	Physico-chemical	Environment	Human Health
Compliance check	2 130	8 669	431	579	292	3 629	3 738
Testing proposal examination	1 472	2 834	N/A	N/A	164	885	1 785
Substance evaluation **	194	699	261	22	45	161	210
TOTAL	**3 796**	12 202	692	601	501	4 675	5 733

* Annex I: General provisions for assessing substances and preparing chemical safety reports (CSR); Annex VI: Information requirements referred to in Article 10 (information to be submitted for general registration purposes); CSR: chemical safety report; RSS: robust study summary; PBT: persistent, bioaccumulative and toxic; SID: substance identification; C&L: classification and labelling.
** The substance evaluation process started in 2012.

Testing proposal

- Examination of testing proposals (to avoid animal testing)

  - decisions to
    - perform proposed test, or
    - perform modified test, or
    - perform one or more additional tests (to fulfill the information requirements), or
    - reject the testing proposal

  - all testing proposals need to be checked

Compliance check

GREEN CHEMISTRY CHANGE MANAGER

- Compliance check of registrations in order to verify
  - compliance with information requirements
  - focus on opting-out of the joint submission
- Targeted Compliance Check
  - Computer assisted selection of dossiers (focus areas)
  - preparation for substance evaluation
- Originally check-rate was 5%
  - extension and factual rate ~20%

Substance evaluation

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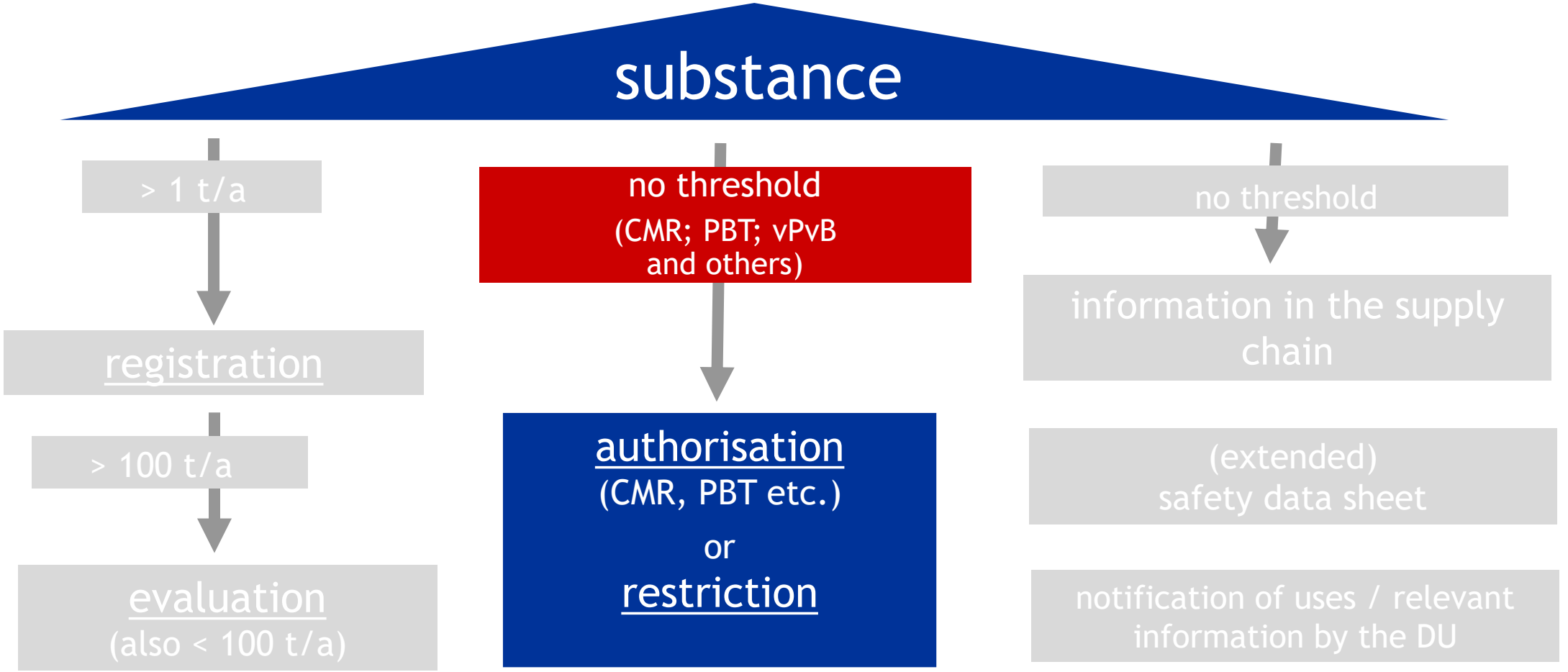
- Priority criteria, which are risk based but dynamic
- Compilation of a Community Rolling Action Plan (CoRAP), always for 3 years, e.g.: 10 substances proposed for evaluation in 2024

- Outcome (2013 – 2022):
  - No further action for 97 substances
    - » 85: not hazardous and/or no risk based on the exposure information
    - » 12: actions by the registrants to ensure safety
  - Regulatory follow-up for 112 substances:
    - » 74: harmonised classification and labelling
    - » 18: SVHC-identification
    - » 12: restriction
    - » 21: another EU-wide risk management measures (e.g. OEL)

Restriction / Authorisation



Restriction process (art. 68)

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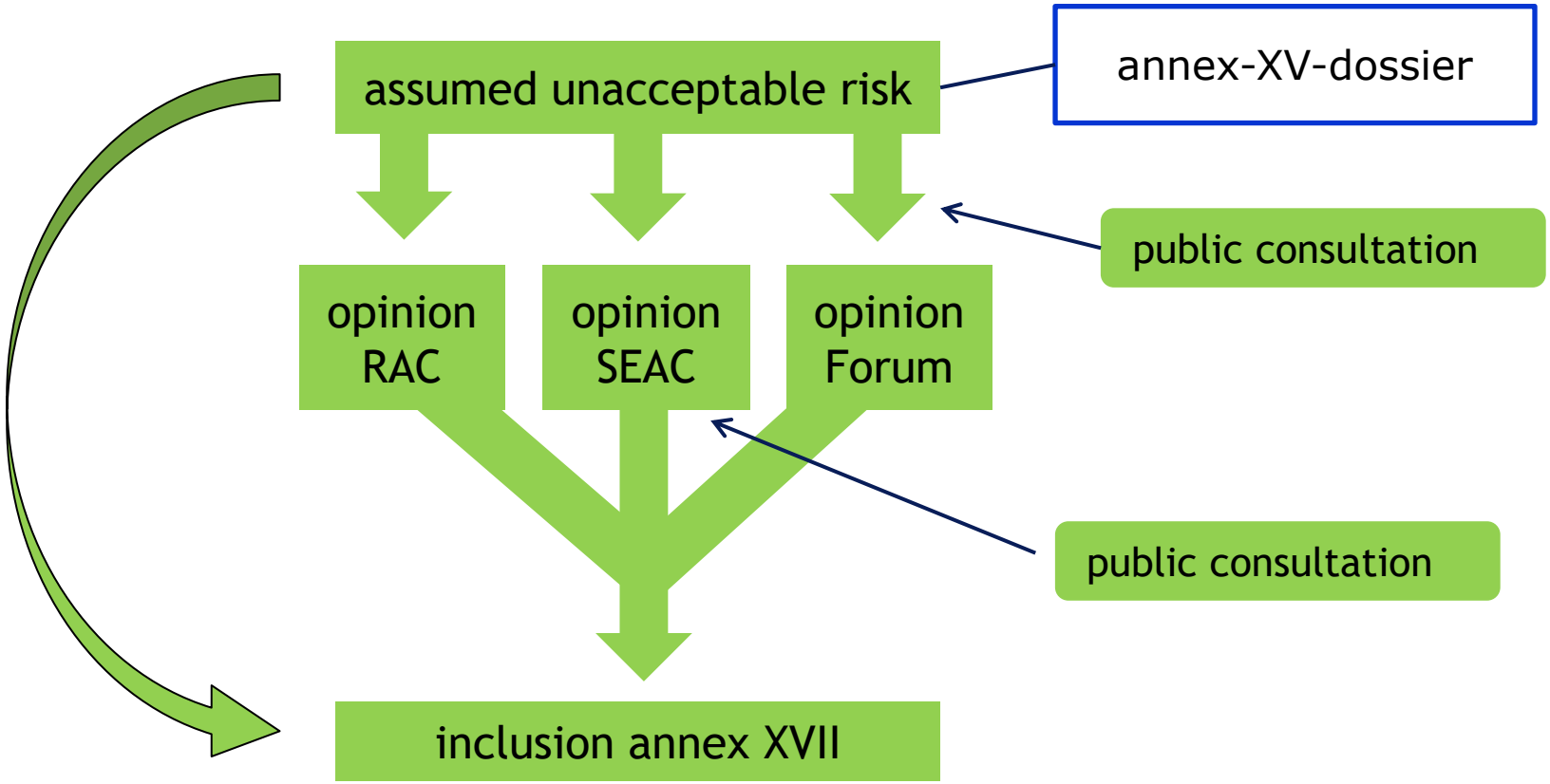
Introducing new and amending current restrictions

When 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, Annex XVII shall be amended […] by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles […] Any such decision shall take into account the socio- economic impact of the restriction, including the availability of alternatives.

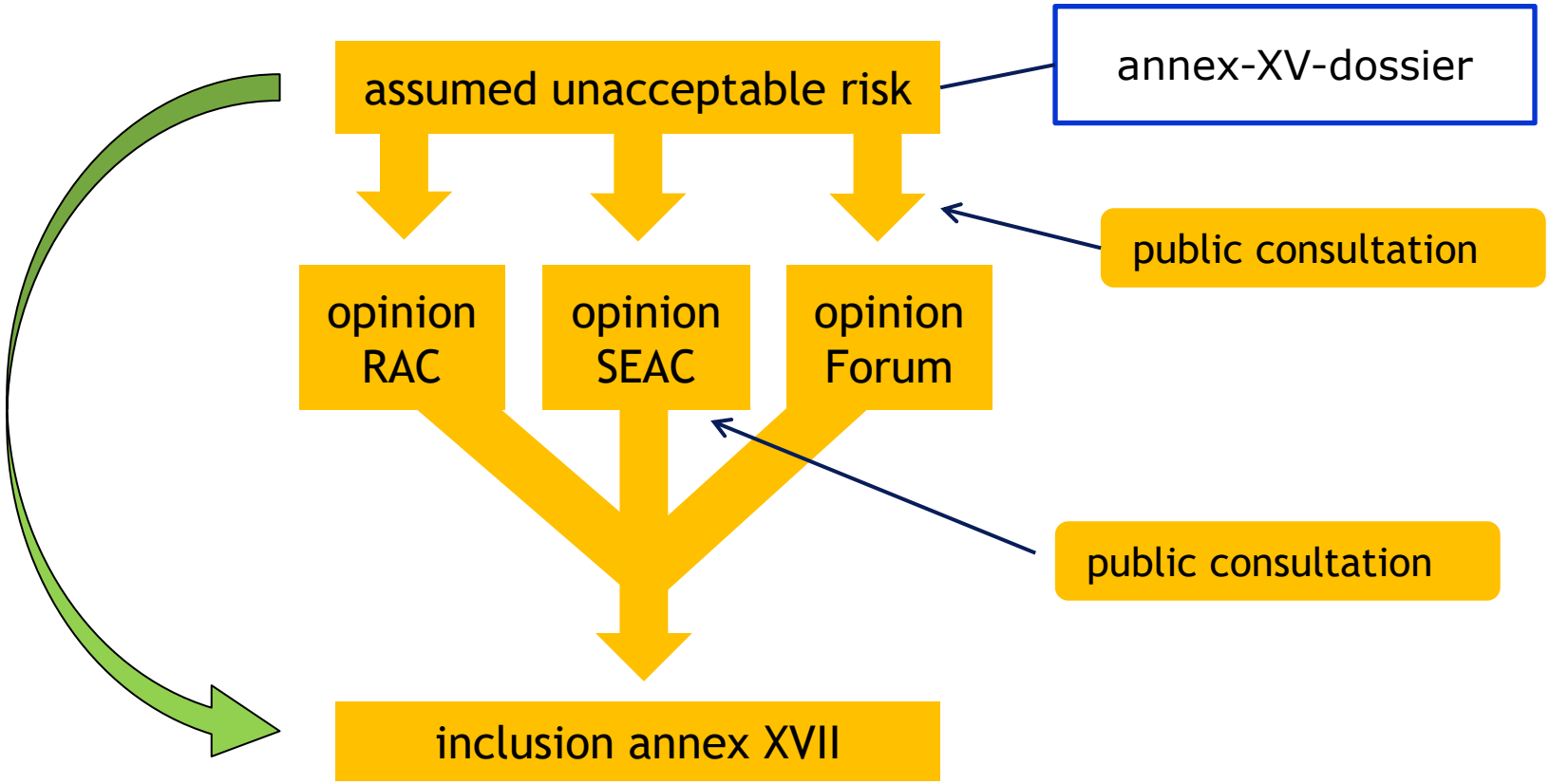
→ There must be an unacceptable risk for human health or the environment

- Authorities have to prove the risk
- Valid for substances on their own, in mixtures and in articles
- All substances within the REACH-scope can be restricted (except cosmetics for HH-risks)

Restriction - 2 pathways



Restriction - 2 pathways



Committee-procedure

- a member state or ECHA (COM) prepares proposal
  - defines the substance identity
  - addresses the risk
  - suggests a restriction
- public consultation of the dossier (6 months)
- assessment in ECHA‘s committees
- COM proposal to amend annex XVII
- decisionmaking via comitology (pre-Lisbon → PRAC)

Involved committees

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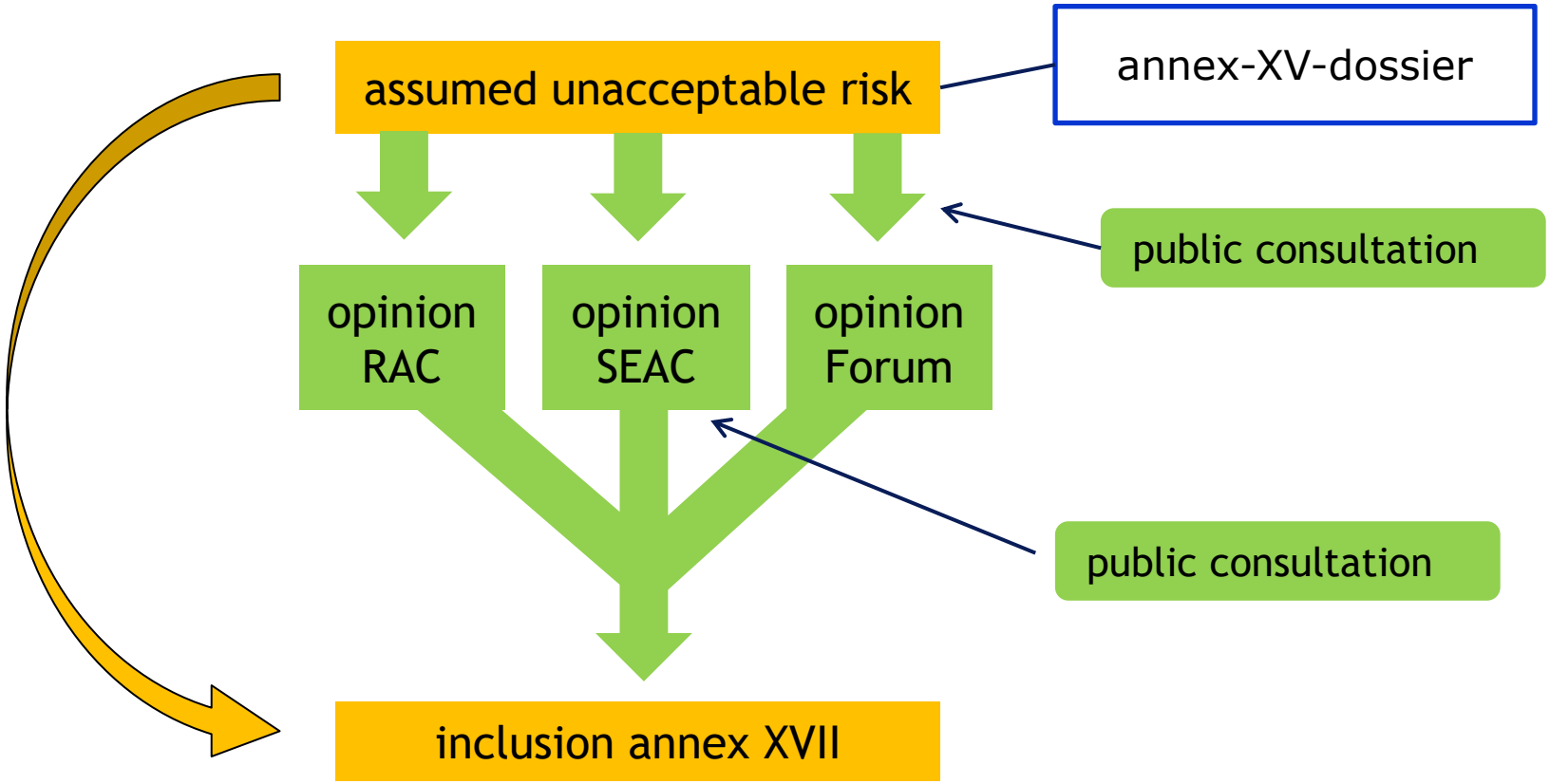
- RAC = Committee for Risk Assessment
  - assess risk related aspects of the proposed restriction
- SEAC = Committee for Socio-economic Analysis
  - assess socio-economic aspects of the proposed restriction
  - cost-efficiency
  - alternatives for the restricted substances/use
- Forum (on the harmonisation of enforcement)
  - on the practical enforceability of the restriction

Restriction - 2 pathways



Fast-track-procedure

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- CMR-substances cat. 1A/B on their own, in mixture or in articles
- For (possible) consumer uses
- Proposed by COM
- No involvement of the Committees
- But informal consultations usual

- COM proposal to amend annex XVII

- decisionmaking via comitology (pre-Lisbon → PRAC)

Example: PAHs

- Annex XVII, entry 50 - Polycyclic aromatic hydrocarbons

50. Polycyclic-aromatic hydrocarbons (PAH) (a) Benzo[a]pyrene (BaP) CAS No 50-32-8 (b) Benzo[e]pyrene (BeP) CAS No 192-97-2 (c) Benzo[a]anthracene (BaA) CAS No 56-55-3 (d) Chrysen (CHR) CAS No 218-01-9 (e) Benzo[b]fluoranthene (BbFA) CAS No 205-99-2 (f) Benzo[j]fluoranthene (BjFA) CAS No 205-82-3	1. From 1 January 2010, extender oils shall not be placed on the market, or used for the production of tyres or parts of tyres if they contain: — more than 1 mg/kg (0,0001 % by weight) BaP, or, — more than 10 mg/kg (0,001 % by weight) of the sum of all listed PAHs. ►M30 The standard EN 16143:2013 (Petroleum products — Determination of content of Benzo(a)pyrene (BaP) and selected polycyclic aromatic hydrocarbons (PAH) in extender oils — Procedure using double LC cleaning and GC/MS analysis) method for demonstrating co referred to in the first subpara

►M24 5. Articles shall not be placed on the market for supply to the general public, if any of their rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use, contain more than 1 mg/kg (0,0001 % by weight of this component) of any of the listed PAHs.

Such articles include amongst others:

Restrictions are evolving

GREEN CHEMISTRY CHANGE MANAGER

- Some recent examples:
  - ~300 substances in textiles and construction-products
  - ~4.000 substances in tattoo and permanent make-up
  - training requirements for diisocyanates
  - Microplastics, not really substance-specific (synthetic polymeric microparticles)
  - In the pipeline, e.g.:
    - » PFAS: ~10.000 individual substances, almost all uses
    - » skin sensitisers in consumer mixtures

Authorisation (article 55)

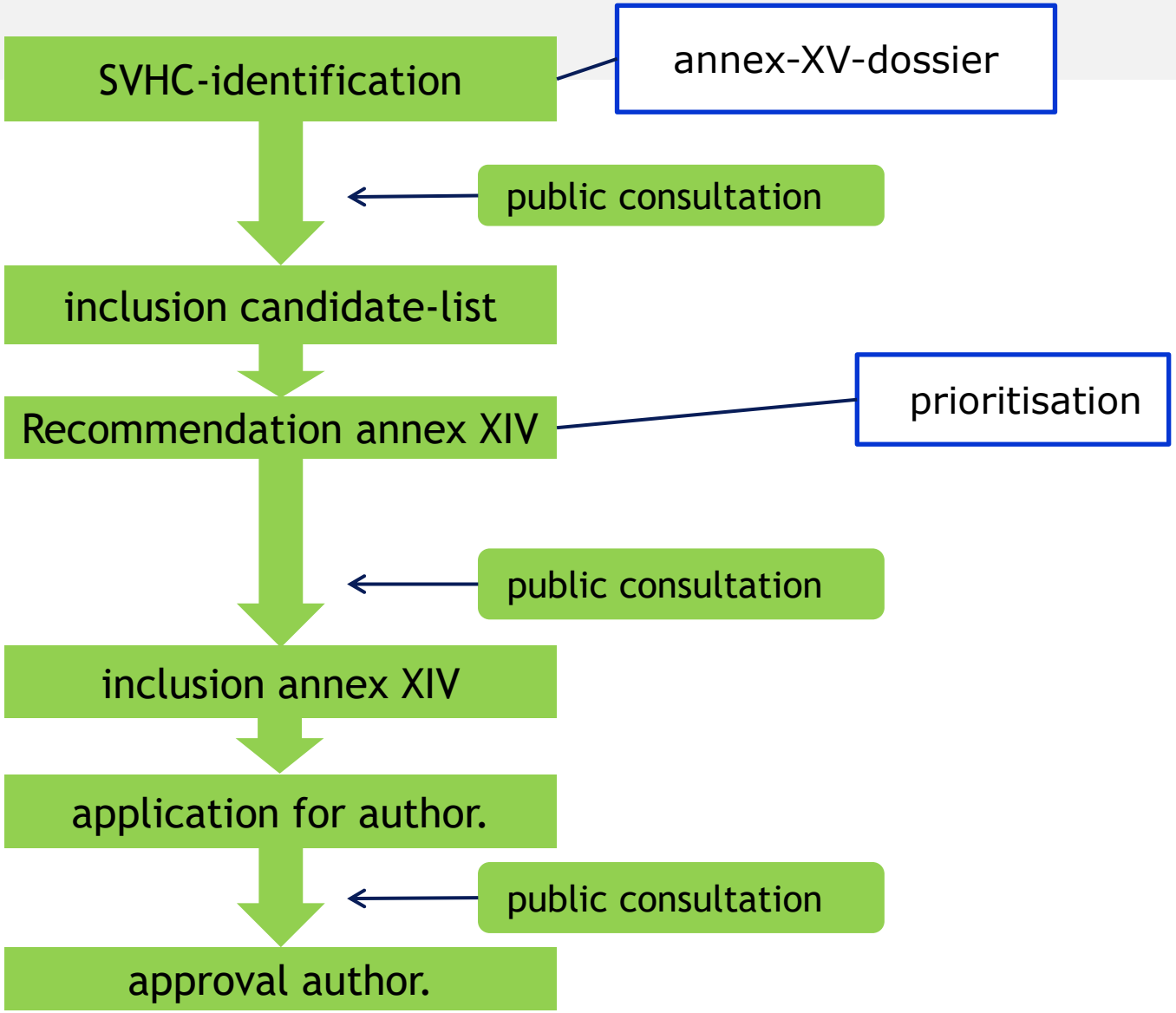
GREEN CHEMISTRY CHANGE MANAGER

Aim of authorisation and considerations for substitution

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.

- Hazardbased instrument
- Substitution at the end
- Focus on SVHC (Substances of Very High Concern)

The authorisation - a multiple-step approach



SVHC - Substance of Very High Concern

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- CMR (cat. 1A and 1B) – carcinogen, mutagen, reprotoxic
- PBT – persistent, bioaccumulative, toxic
- vPvB – very persistent, very bioaccumulative
- equivalent level of concern (e.g. endocrine disruptor, PMT)

- SVHC-identification, no automatism
  - → inclusion to the candidate list
  - → so far 241 substances
  - → twice annually

- Market pressure observed

Inclusion to authorisation

GREEN CHEMISTRY CHANGE MANAGER

- Priorisation of candidate substances
- Based on criteria and a score-system

- Recommendation by ECHA for inclusion to COM
  - 116 substances prioritised in 12 recommendations
  - no 13 in preparation

- COM proposal to amend annex XIV, includes always transitional arrangments (sunset-date, latest-application date)

- decisionmaking via comitology (pre-Lisbon → PRAC)
  - 59 substances included in annex XIV
    → full ban, application for authorisation (afa) necessary

Scoring for priorisation

GREEN CHEMISTRY CHANGE MANAGER

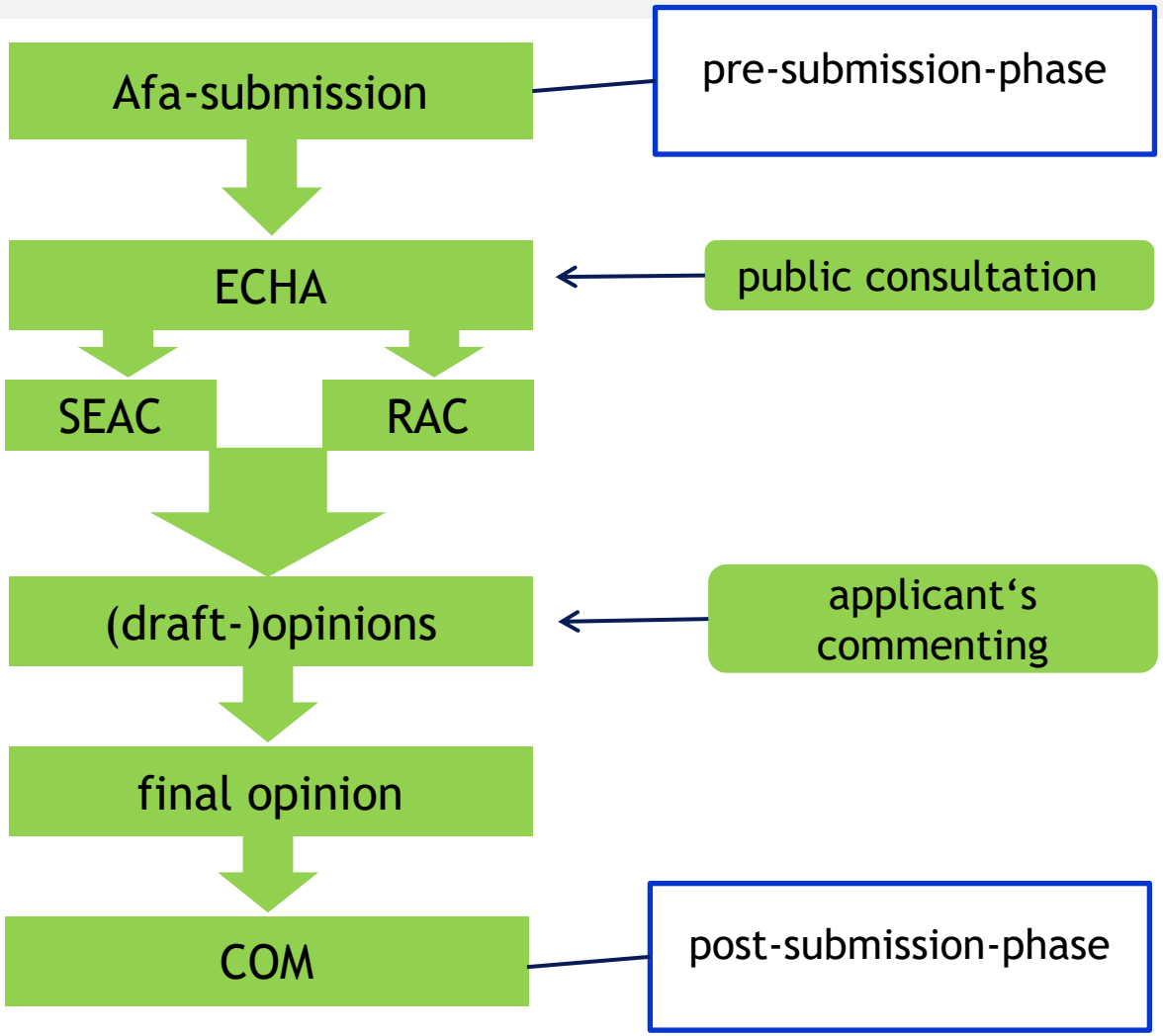
	Conclusion on				Final conclusion, taking regulatory effectiveness considerations into account
Substance	**Inherent properties**	**Volumes**	**Wide dispersiveness of uses**	**Priority**	
Chromium trioxide *(VAA)*	Art. 57 (a) & (b); Carcinogen 1A, Mutagen 1B	According to registration information the amount of chromium trioxide used in the EU is in the range 1,000 – 10,000 t/y. The largest part of the registered amount is allocated to uses in the scope of authorisation (this is a volume above 1000 t/y).	The uses identified in the registration dossier in the scope of authorisation are: formulation of mixtures containing chromium trioxide, which are mainly used for metal finishing or, in much smaller amounts, as catalysts containing chromium trioxide. In addition, the substance is used outside the scope of authorisation, e.g. as intermediate in the synthesis of other chromium compounds and in low volumes by professionals as a laboratory agent. As regards the main uses, exposure of workers cannot be excluded and its extent depends on the operational conditions and risk management measures in place. Recent exposure information reported in the Annex XV dossier prepared by Germany shows that workers are exposed to significant concentrations of chromium VI compounds, particularly in the following sectors (of relevance for chromium trioxide): formulation of metal treatment products, use in electrolytic metal treatment, decorative plating and hard chrome plating. According to the registration information the formulation of the metal treatment mixtures is performed at a small number of sites. It can	Chromium trioxide is used in high volumes. The uses falling under authorisation are expected to take place at a high number of sites and significant exposure of workers may occur in a number of uses with releases to the workplace. Some of the uses could therefore be wide-dispersive. Based on the criteria, chromium trioxide has high priority.	On the basis of the prioritisation criteria chromium trioxide gets high priority for inclusion in Annex XIV. **Therefore, it is proposed to recommend chromium trioxide for inclusion in Annex XIV.** There are other chromium VI compounds on the Candidate List with (partially) the same uses, or which could be used to replace chromium trioxide in (some of) its uses (and vice versa). Therefore, these substances should as well be considered for inclusion in Annex XIV in order to avoid evasion of the authorisation requirement and substitution of SVHCs with other SVHCs.
			be expected however that the surface treatment itself is performed at a high but unknown number of sites in the EU.		
Chromium trioxide *(SCA)*	Score : 1	High volume allocated to uses in the scope of authorisation. Score: 7	Substance used at a high number of sites. Score: 3. Releases and exposure to workers might be controlled in most instances, however some of the uses appear to have a potential for significant worker exposure. Score 3 Overall score: 9	**Total score: 17**	**The same considerations apply as brought forward under the verbal-argumentative approach.**

Annex-XIV-entries

GREEN CHEMISTRY CHANGE MANAGER

Entry Nr	Substance	Intrinsic property(ies) referred to in Article 57	Transitional arrangements		Exempted (categories of) uses	Review periods
			Latest application date (1)	Sunset date (2)		
5.	Benzyl butyl phthalate (**BBP**) EC No: 201-622-7 CAS No: 85-68-7	Toxic for repro-duction (category 1B)	21 August 2013	21 February 2015	Uses in the immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC.	
16.	Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	Carci-nogenic (category 1A) Mutagenic (category 1B)	21 March 2016	21 September 2017	—	—

Granting of an authorisation



Afa - Overview

- Applicants:
  - manufacturer,
  - importer,
  - downstream user,
  - only representative
- in the scope are:
  - uses of substances on its own
  - uses of substances in mixtures
  - the incorporation of substances into an article (=use)
- no quanity-threshold
- for one/more substance(s) and one/more use(s)
- individual or joint application possible
- data-sharing not obligatory
- competition law relevant
- a number of exemptions

Content of afa

GREEN CHEMISTRY CHANGE MANAGER

- Standard info (substance, applicant)
- Relevant use(s)
- Chemical safety report (CSR)
- Analysis of alternatives (AoA)
- R&D-activities (if relevant)
- Substitution-plan (if relevant)
- Reasoning for grouping (if relevant)
- Socio-economic analysis (optional)
- Justification for not considering risks (optional)

The 2 Afa-routes

GREEN CHEMISTRY CHANGE MANAGER

- Adequate control route:
  - substances has a threshold for the relevant property/effect
  - related risk is adequately controlled
- Socio-economic route:
  - adequate risk-control cannot be demonstrated
  - no adequate alternative substances/technologies
  - socio-economic benefit outweighs the existing risk

Way to a final decision

GREEN CHEMISTRY CHANGE MANAGER

- RAC / SEAC evaluate afa (9/12 months)
- ECHA finale opinion within 3-4 months; submitts to COM
- COM prepares within 3 months a decision
- Decisionmaking via comitology
- Content:
  - standard info (authorisation-holder, substance, covered use(s))
  - any conditions and/or monitoring-arrangements
  - time-limited review-period
  - authorisation-number (eg REACH/24/1/0)
- Review periods: usually 4 (short), 7 (medium) or 12 (long) years

Costs

GREEN CHEMISTRY CHANGE MANAGER

- Afa-process takes 2 years and more
- Dossier development costed so far in average € 250.000,-
- Fees for Afa / review of an authorisation (Annexes VI & VII of the fee-regulation):
  - basic fee € 5.410 - 54.100
  - additional fee per use € 4.869 - 48.690
  - additional fee per substance € 1.082 - 10.820
  - additional fee per applicant dropped in 2018

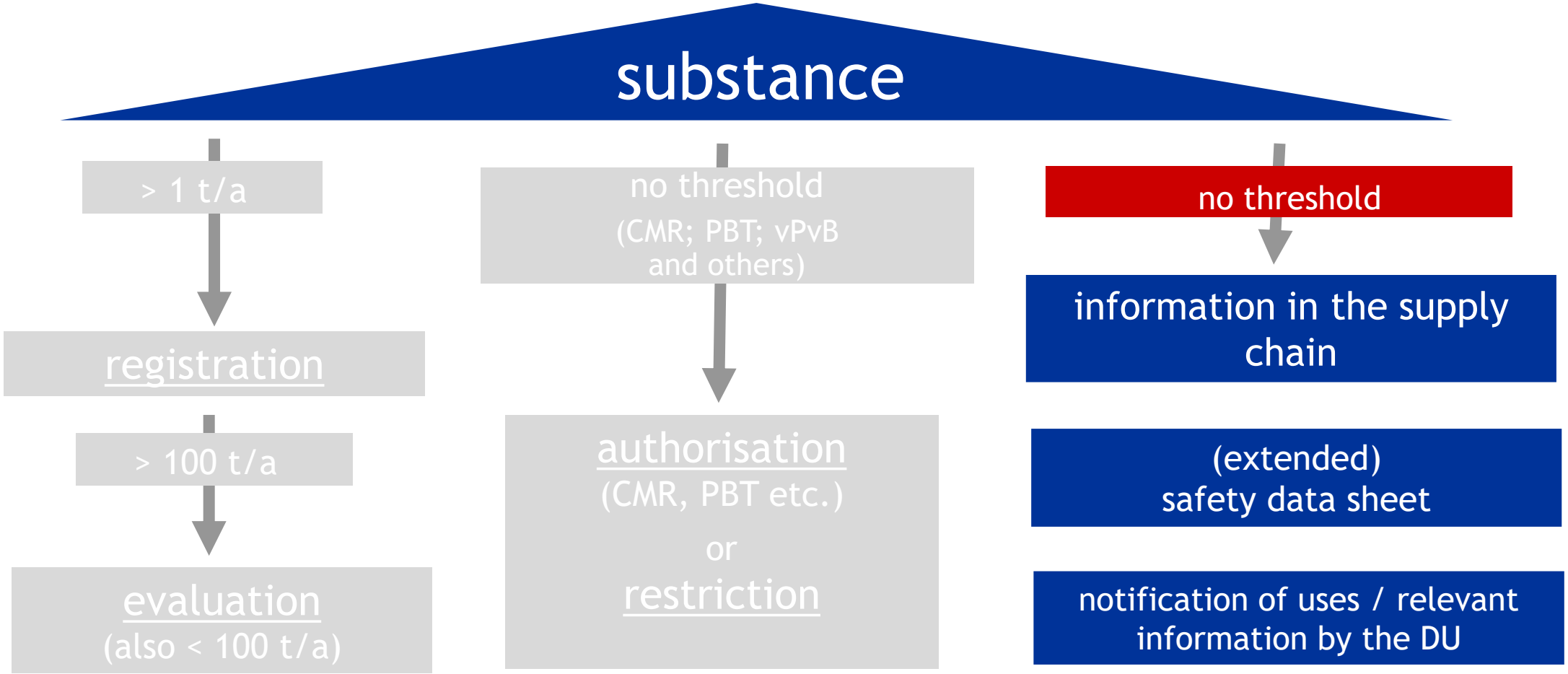
Some statistics

GREEN CHEMISTRY CHANGE MANAGER

- Some statistics from end 2022:
  - For 30 of 59 substances no authorisation submitted
  - The other 29 substances:
    - » 285 Afas submitted
    - » for 438 uses
    - » 248 authorisations granted

- During 2023 first Afas got negative decisions
- Pressure on the decision making is growing (court cases)
- Application process is highly overloaded
- Good half of all Afas are for surface plating - Cr(VI)

Information flow



Excursion: Downstream user

"downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professsional activities. A distributor or a consumer is not a downstream user."

- Definitely the largest group of actors under REACH, e.g.:
  - formulators (manufacturers of mixtures),
  - assemblers,
  - carpenters,
  - or simply a bank clerk using a pencil

Excursion: Downstream user

- DUs can play a very important role in supply-/communication-chains, e.g. info on uses, safety…
- Can have diverse obligations, e.g. implement risk management measures, respect restrictions…

- One central obligation is to use chemicals safely

  → Safety Data Sheet (SDS)

Safety Data Sheet - SDS

GREEN CHEMISTRY CHANGE MANAGER

- Why are safety data sheets necessary?

  „The safety data sheet shall enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment. The writer of the safety data sheet shall take into account that a safety data sheet must inform its audience of the hazards of a substance or a mixture and provide information on the safe storage, handling and disposal of the substance or the mixture. (REACH – Annex II)

- How should it, thus, be compiled?

  „The information in the safety data sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs and knowledge of the user audience, as far as they are known. “
  (REACH – Annex II)

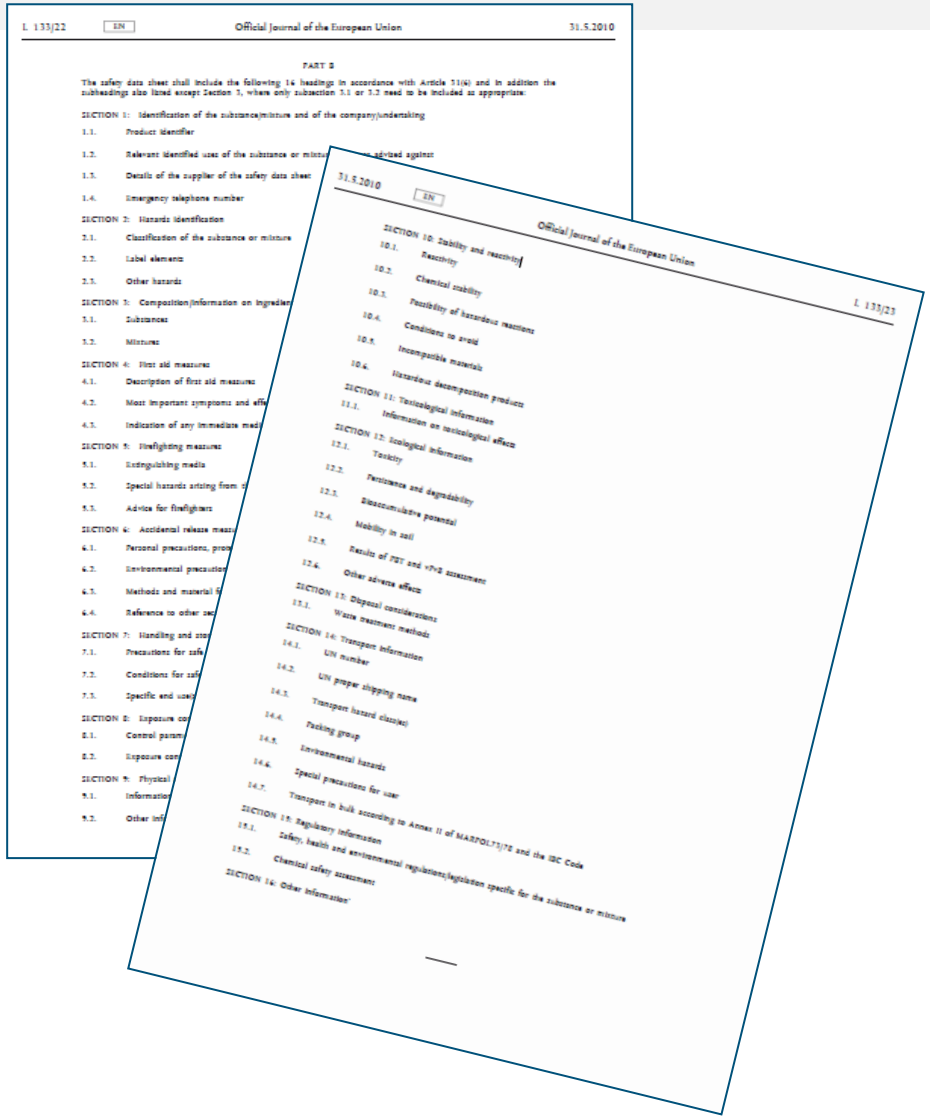
Safety Data Sheet

GREEN CHEMISTRY CHANGE MANAGER

- SDS required mainly for
  - hazardous substances & mixtures
  - PBT and vPvB substances
  - other SVHC substances

- In practice also for non-hazardous substances & mixtures common
- 16 chapters, e.g. composition, use, storage, waste…
- Extended Safety Data Sheet
- basically an instruction how to safely use a substance/mixture

Safety Data Sheet



- for the customer:
  - on paper or electronically
  - free of charge
  - in national language(s)

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Developing a data-base on chemical properties, risks, uses etc.
- Phasing out / substitution of problematic substances
- Animal protection
- PPORD exemption
- Cooperation and communication in the supply chains improved
- Regulation is becoming speedier, pressure to develop clean(er) chemicals is growing

CLP - Classification, Labelling & Packaging

GREEN CHEMISTRY CHANGE MANAGER

- UN-GHS – Globally Harmonised System for the C&L of Chemicals
  - „Building block approach“ gives flexibility
  - non-binding international recommendation
  - WTO – point of view (1999): UN GHS international standard for trade
  - No country specific criteria of GHS possible
  - Non-compliance of GHS: possible technical barrier for trade
  - Technical adaptations every 2 years (Revision)

- Provisions in the EU’s chemicals law transposed with:
  - REACH for the safety data sheet
  - CLP Regulation (EU) No. 1272/2008 for the rest
  - and the adaptation

CLP - Regulation: Implementation of UN-GHS in Europe

GREEN CHEMISTRY CHANGE MANAGER

2002 2004 2006 2008 2010 2012 2014 2016 2018 2020 2022

UN GHS | GHS Rev. 1 | GHS Rev. 2 | GHS Rev. 3 | GHS Rev. 4 | GHS Rev. 5 | GHS Rev. 6 | GHS Rev. 7 | GHS Rev. 8 | GHS Rev. 9

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures … - CLP Reg.

Regulation (EU) No 487/2013 amending, … (4th ATP)

Regulation (EU) No 2016/981 amending, … (8th ATP)

Regulation (EU) No 2019/521 amending, … (12th ATP)

In preparation

Building block approach

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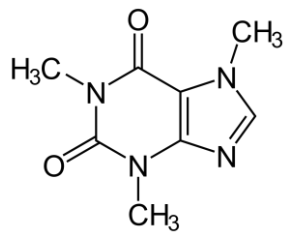
- Not all hazard classes or hazard categories need to be implemented
- Other options for detailed implementation (e.g. concentration limits)
- BUT, you need to stay within the given framework
- Examples of different levels of harmonisation:



Caffeine: Globally classified
- from acute tox 3
- to no classification

	Supply & use	Transport
Hazard classes		
Physical Hazards	☑	☑
Environmental Hazards	☑	☑
Health Hazards	☑	partially
Acute toxicity	☑	☑
Sensitizers	☑	☒
CMR - STOT	☑	☒

EU: CLP and transport
- different blocks
- but same criteria

Acute Toxicity					
Supply & use	1	2	3	4	5
Transport	1	2	3	4	5

EU: CLP and transport
- different categories
- but same criteria

GHS: International implementation

Argentina - Armenia - Australia – Austria - Belarus - Belgium - Bolivia - Brazil – Bulgaria - Cambodia - Canada - Chile - China - Colombia - Costa Rica - Côte d'Ivoire - Croatia - Cyprus - Czech Republic - Democratic Republic of Congo – Denmark - Ecuador – Estonia - Finland – France - Gambia - Germany - Ghana - Greece - Guatemala – Guinea - Honduras – Hungary - Iceland - Indonesia - Ireland - Israel – Italy - Japan - Kazakhstan – Kyrgyzstan - Lao People's Democratic Republic - Latvia - Liechtenstein - Lithuania – Luxembourg - Madagascar - Malaysia - Malta - Mauritius - Mexico - Montenegro – Myanmar - Netherlands - New Zealand - Nigeria – Norway - Paraguay - Peru - Philippines - Poland – Portugal - Republic of Korea - Romania - Russian Federation - Senegal - Serbia - Singapore - Slovakia - Slovenia - South Africa - Spain - Sweden – Switzerland - Thailand - Tunisia – Turkey - Ukraine - United Kingdom - United States of America – Uruguay - Viet Nam – Zambia

→ >100 individual countries have implemented GHS in one or more of their national legislations

→ **BUT, national deviation are happening, e.g. EU did some as well**

CLP: Basics

GREEN CHEMISTRY CHANGE MANAGER

- All chemical substances and mixtures covered (including consumer chemicals, pesticides, biocides, detergents)
- Becomes relevant, when these are placed on the market
- Exemptions (Substances & mixtures covered by equivalent EU legislation)
- Different roles, but in general classification from upstream can be taken over
- Rules for advertising

GREEN CHEMISTRY CHANGE MANAGER

A simple view on how CLP works

1.step: supplier classifies → “self-classification”

2.step: based on classification, supplier labels and packages

→ There are very detailed rules on that, especially in annex I of CLP

CLP-regulation

GREEN CHEMISTRY CHANGE MANAGER

- All chemical substances and mixtures covered (including consumer chemicals, pesticides, biocides, detergents)
- Some exemptions for substances & mixtures covered by equivalent EU legislation
- Classification according:
  - physical hazards
  - health hazards
  - environmental hazards

CLP: Physical hazards - overview

GREEN CHEMISTRY CHANGE MANAGER

- Explosives(2.1)
- Flammable (incl. unstable & pyroph.) gases (2.2)
- (Flammable) Aerosols (2.3)
- Oxidising gases (2.4)
- Gases under pressure (2.5)
  - Compressed gas
  - Liquified Gas
  - Refrigerated liquefied gas
  - Dissolved gas
- Flammable liquids (2.6)
- Flammable solids(2.7)
- Self-reactive substances & mixtures (2.8)
- Pyrophoric liquids (2.9)
- Pyrophoric solids (2.10)
- Self-heating substances & mixtures (2.11)
- S./m. in contact with water → flam. gases (2.12)
- Oxidising liquids (2.13)
- Oxidising solids (2.14)
- Organic peroxides (2.15)
- Corrosive to metals (2.16)
- Desensitized explosives (2.17)

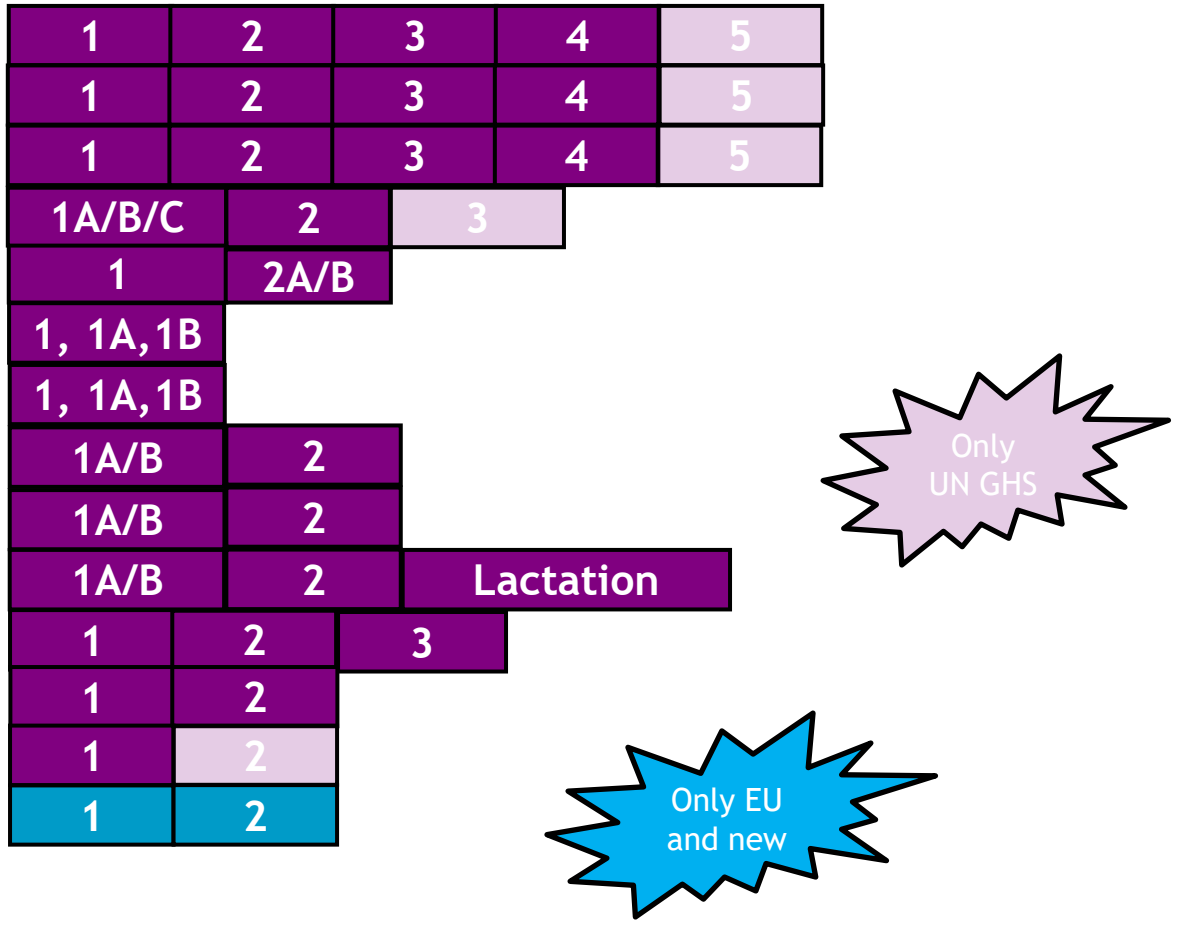
Unstable Explosives	Div1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
1	2	Pyr.	A	B		
1	2	3				
1						

1						
1						
1						
1						
1	2	3	4			
1	2					
Type A	Type B	Type C	Type D	Type E	Type F	Type G
1						
1						
1	2					
1	2	3				
1	2	3				
1	2	3				
Type A	Type B	Type C	Type D	Type E	Type F	Type G
1						
1	2	3	4			

CLP: Health Hazards

GREEN CHEMISTRY CHANGE MANAGER

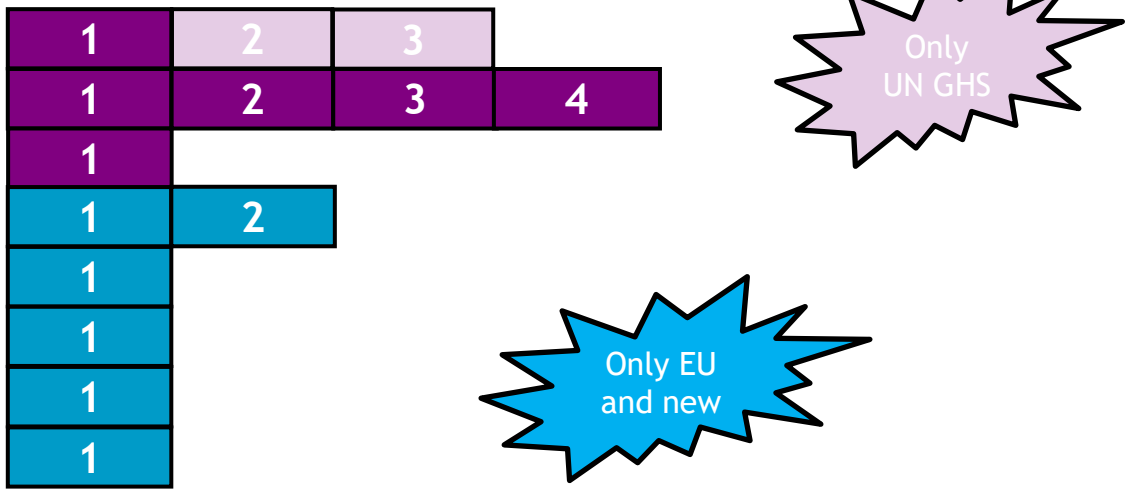
- Acute toxicity, oral (3.1)
- Acute toxicity, dermal (3.1)
- Acute toxicity, inhalation (3.1)
- Skin corrosion/irritation (3.2)
- Serious eye damage/eye irritation (3.3)
- Respiratory sensitisation(3.4)
- Skin sensitisation(3.4)
- Germ cell mutagenicity (3.5)
- Carcinogenicity (3.6)
- Reproductive toxicity (3.7)
- STOT (single exposure) (3.8)
- STOT (repeated exposure) (3.9)
- Aspiration toxicity (3.10)
- Endocrine disruption for human health (3.11)



CLP: Environmental Hazards

GREEN CHEMISTRY CHANGE MANAGER

Acute aquatic hazard (4.1)
Chronic (long term) aquatic hazard (4.1)
Hazardous to the ozone layer (5.1)
Endocrine disruption for the environment (4.2)
Persistent, bioaccumulative and toxic – PBT (4.3)
Very persistent, very bioaccumulative – vPvB (4.3)
Persistent, mobile and toxic – PBT (4.4)
Very persistent, very mobile – vPvB (4.4)

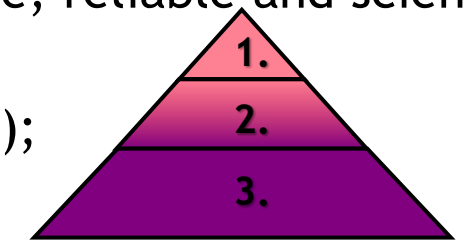


General obligations

- General obligations to classify, label and package
  - Manufacturers, importers and downstream users shall classify substances or mixtures before placing them on the market (self classification)
  - Classification in accordance with harmonized entry in Annex VI for hazard classes mentioned (harmonized classification)
  - Labelling and packaging according to CLP before placing on the market
  - Special responsibilities for distributors and down stream users

CLP: Classification

- Identification and examination of available information
  - on substances
    - » Available data; epidemiological data and experience on the effects on humans; any other information; any new scientific information (adequate, reliable and scientifically valid)
  - on mixtures
    1. Available information on the mixture itself (see above); exemptions: CMR-properties, biodegradation
    2. Similar (tested) mixtures → bridging pinciples
    3. Information on ingredients



- Testing:
  - for physical hazards: information mandatory - quality assurance by standards (e.g. GLP, ISO 17 025, other recognized standards)
  - only as last resort for health and environm. hazards following Test Method Reg. (REACH) or other scientific principles (internationally recognized)

CLP: Harmonised Classification

"To ensure a harmonised level of protection for the general public, and, in particular, for persons who come into contact with certain substances, and the proper functioning of other Community legislation relying on classification and labelling, an inventory should record the classification in accordance with this Regulation agreed, if possible, by manufacturers and importers of the same substance, as well as decisions taken at Community level to harmonise the classification and labelling of some substances"

- Harmonised classification in Annex VI
  - CMR substances, respiratory sensitizers
  - active ingredients for plant protection products and biocides
  - others (on a case by case basis)
  - Delegated act

- Annex VI NOT fully harmonized
  - only the hazard classes mentioned in Annex VI are harmonised

602-006-00-4	chloroform; trichloromethane	200-663-8	67-66-3	Carc. 2 Repr. 2 Acute Tox. 3 Acute Tox. 4 STOT RE 1 Eye Irrit. 2 Skin Irrit. 2	H351 H361d H331 H302 H372 H319 H315	GHS06 GHS08 Dgr	H351 H361d H331 H302 H372 H319 H315

Narcotic effect (STOT SE 3, H336) not considered in CLH dossier

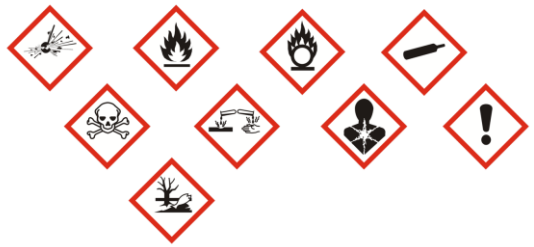
Labelling

Table 3.2.5

Label elements for skin corrosion/irritation

Classification	Sub-Categories 1A/1B/ 1C and Category 1	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H314: Causes severe skin burns and eye damage	H315: Causes skin irritation
Precautionary Statement Prevention	P260 P264 P280	P264 P280
Precautionary Statement Response	P301 + P330 + P331 P303 + P361 + P353 P363 P304 + P340 P310 P321 P305 + P351 + P338	P302 + P352 P321 P332 + P313 P362 + P364
Precautionary Statement Storage	P405	
Precautionary Statement Disposal	P501	

There are 4 main labelling elements:



- pictogram
- signal word
  - Two: Danger & Warning
- hazard statement (H-statement)
  - Long list + EUH-statements
- precautionary statement (P-statement)
  - Long list

Labelling, Examples

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Product identifier (including BPR requirements)

Supplemental information

Hazard pictograms

Signal word

Hazard statements

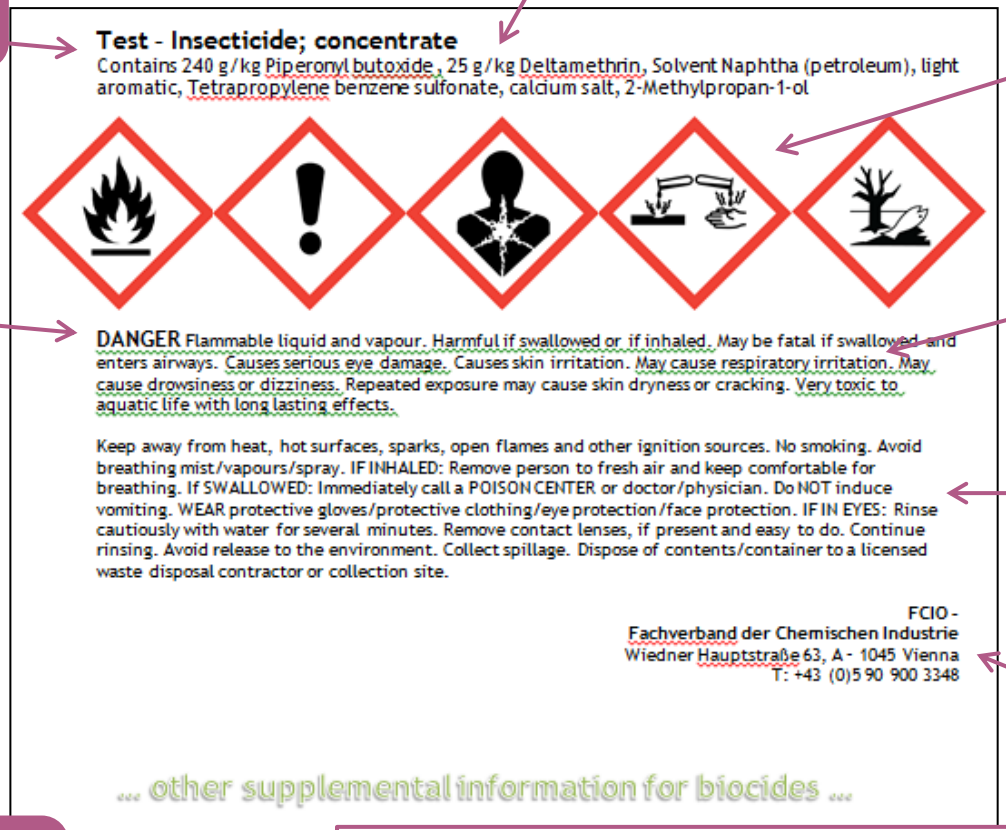
Additional information for general public: nominal quantity; P-statements; …

Precautionary statements

Supplier information

Supplemental information

Other regulatory regimes (e.g. REACH, BPR, PPPR, Paints Directive) require additional labelling



Test - Insecticide; concentrate

Contains 240 g/kg Piperonyl butoxide, 25 g/kg Deltamethrin, Solvent Naphtha (petroleum), light aromatic, Tetrapropylene benzene sulfonate, calcium salt, 2-Methylpropan-1-ol

DANGER Flammable liquid and vapour. Harmful if swallowed or if inhaled. May be fatal if swallowed and enters airways. Causes serious eye damage. Causes skin irritation. May cause respiratory irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking. Very toxic to aquatic life with long lasting effects.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid breathing mist/vapours/spray. IF INHALED: Remove person to fresh air and keep comfortable for breathing. If SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Do NOT induce vomiting. WEAR protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Avoid release to the environment. Collect spillage. Dispose of contents/container to a licensed waste disposal contractor or collection site.

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… other supplemental information for biocides …

Notification obligations

- Notification to the CLI (Classification and Labelling Inventory) for substances that are placed on the market
  - no threshold

- Notification of data about mixtures to poison centers (PCN)
  - no threshold

→ pretty holistic collection of data about chemicals in the EU

→ relative good tracability

Putting in perspective to Green Chemistry

- Classification plays a crucial role in defining what is problematic and what not
- CLP as such is not supporting nor hampering Green Chemistry, it is simply a tool to assess properties of chemicals
- UN-GHS is raising global standards of chemicals management

Conclusions

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- There is no concrete legal framework for green/sustainable in the EU
- Legislation is not pushing explicitly in this direction
- Many regulatory elements are, however, relevant and contributing
- Trend is clearly green/sustainable
- Problems will be in the future (in my view):
  - competetivness
  - enforcement
  - customers paying (or not)

Now I am looking forward…

GREEN CHEMISTRY CHANGE MANAGER

… for your questions and opinions!

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Co-funded by the European Union