The broader chemicals legislations in the EU

GREEN CHEMISTRY
CHANGE MANAGER

The EU's chemicals legislation

GREEN CHEMISTRY CHANGE MANAGER

- 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

persistent organic pollutants (POPs)

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- What is a POP?
  - an organic chemical;
  - not easily degradable, i.e. is persistent or stable in environmental media;
  - accumulates in the environment (soil, water);
  - can be bioaccumulating and accumulate in plants or animal tissue;
  - can be transported over long distances and for longer periods of time, e.g. by wind or thermals;
  - harmful to the environment and health.

→ Not only inherent properties are relevant.

→ Not necessarily equivalent to PBTs or vPvBs as defined in the EU

persistent organic pollutants (POPs)

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- So, how is a POP identified?
  - by an international evaluation process
  - expert body
  - case-by-case decisions

- Everything happens within the framework of

  the Stockholm Convention

Stockholm Convention

GREEN CHEMISTRY CHANGE MANAGER

- international agreement
  → sort of global chemicals legislation
- secretariat at the UN in Geneve
  http://chm.pops.int/
- legal framework for regulating POPs globally and in the EU
- POPs are listed in annex I and II to the convention

Implementation in the EU

- Implementation in the EU:
  - Regulation (EU) No 2019/1021
  - in force since 15. Juli 2019
  - replaced the old regulation from 2004

- Objectives are:
  - End the manufacturing, import, export and use of all POPs asap.
  - Reduction or stop of the release, including non-intentionally produced POPs.
  - Absolutely necessary uses only under strict conditions.
  - Damageless disposal of existing stocks.
  - Rules for treatment, monitoring and destruction.
  - Plant-related strategies to avoid creation and emission of POPs.

Annex I (and II) - Bans and restrictions

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- Included substances / substance-groups:
  - different bromo-phenyl ether
  - Perfluorooctane sulfonic acid and its derivatives (PFOS)
  - different pesticides, e.g. DDT, Dieldrin, Endrin, Endosulfan
  - chloro-benzene / -phenyls
  - Hexabromocyclododecane
  - Pentachlorophenol and its salts and esters
  - Polychlorinated naphthalenes
  - Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)

- Substance-specific conditions described in individual restriction-entries

Annex I - example

GREEN CHEMISTRY CHANGE MANAGER

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
1 Hexabromocyclododecane 'Hexabromocyclododecane' means: hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha-hexabromocyclododecane; beta-hexabromocyclododecane; and gamma-hexabromocyclododecane	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	247-148-4, 221-695-9	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of hexabromocyclododecane equal to or below 100 mg/kg (0,01 % by weight) where it is present in substances, mixtures, articles or as constituents of the flame-retarded articles, subject to review by the Commission by 22 March 2019. 2. Expanded polystyrene articles containing hexabromocyclododecane already in use in buildings before 21 February 2018 in accordance with Commission Regulation (EU) 2016/293 (5) and Commission Implementing Decision No 2016/C 12/06 (6), and extruded polystyrene articles containing hexabromocyclododecane already in use in buildings before 23 June 2016 may continue to be used. Article 4(2), third and fourth subparagraphs shall apply to such articles. 3. Without prejudice to the application of other Union provisions on the classification, packaging and labelling of substances and mixtures, expanded polystyrene placed on the market after 23 March 2016 in which hexabromocyclododecane was used shall be identifiable by labelling or other means throughout its life cycle.

Annex III, IV and V

GREEN CHEMISTRY CHANGE MANAGER

- List of substances subject to release reductions provisions
  - 7 substances included
  - primarily relevant for Member States
- List of substances subject to waste management provisions
  - more or less the same as annex I
  - concentrations for waste-contamination
- List related to waste-management:
  - treatment methods for disposal and recovery
  - waste from different operations

Annex IV & V - examples

GREEN CHEMISTRY CHANGE MANAGER

Substance	
Endosulfan	11 95 33
Hexachlorobutadiene	87-
Polychlorinated naphthalenes (1)	
Alkanes C_{10}-C_{13}, chloro (short-chain chlorinated paraffins) (SCCPs)	85

Wastes as classified in Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV (1)	Operation
10	WASTES FROM THERMAL PROCESSES	Alkanes C_{10}-C_{13}, chloro (short-chain chlorinated paraffins) (SCCPs): 10 000 mg/kg; Aldrin: 5 000 mg/kg; Chlordane: 5 000 mg/kg; Chlordecone: 5 000 mg/kg; DDT (1,1,1-trichloro-2,2-bis (4-chlorophenyl) ethane): 5 000 mg/kg; Dieldrin: 5 000 mg/kg; Endosulfan: 5 000 mg/kg; Endrin: 5 000 mg/kg; Heptachlor: 5 000 mg/kg; Hexabromobiphenyl: 5 000 mg/kg; Hexabromocyclododecane (3): 1 000 mg/kg; Hexachlorobenzene: 5 000 mg/kg; Hexachlorobutadiene: 1 000 mg/kg; Hexachlorocyclohexanes, including lindane: 5 000 mg/kg; Mirex: 5 000 mg/kg;	Permanent storage shall be allowed only when all the following conditions are met: (1) The storage takes place in one of the following locations: — safe, deep, underground, hard rock formations, — salt mines, — a landfill site for hazardous waste, provided that the waste is solidified or partly stabilised where technically feasible as required for classification of the waste in subchapter 19 03 of Decision 2000/532/EC. (2) The provisions of Council Directive 1999/31/EC (4) and Council Decision 2003/33/EC (5) were respected. (3) It has been demonstrated that the selected operation is environmentally preferable.
10 01	Wastes from power stations and other combustion plants (except 19)		
10 01 14 * (2)	Bottom ash, slag and boiler dust from co-incineration containing hazardous substances		
10 01 16 *	Fly ash from co-incineration containing hazardous substances		
10 02	Wastes from the iron and steel industry		
10 02 07 *	Solid wastes from gas treatment containing hazardous substances		
10 03	Wastes from aluminium thermal metallurgy		

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- POPs are completely in the scope of REACH, this can for example mean:
  - registration necessary,
  - safety data sheet necessary,
  - authorisation may be relevant, but can´t repeal an existing POP-restriction,
  - art. 33 information requirements (incl. SCIP) may be relevant
  - coordination between authorisation and restriction in the past,
- A POP-restriction is independent of REACH
  - it can complement a REACH-restriction
  - it should not double-regulate or contradict a REACH-restriction
  - some POP-conditions could be relevant for a REACH-registration (waste-stage, safety-requirements…)
- A POP is a substance for phase-out
  - a registration may be economically not rational,
  - same goes for an authorisation.

Interface CLP

- POPs are completely in the scope of CLP, this can for example mean:
  - classification and labelling is relevant
  - notification to the CLI may be relevant
  - PC-notification may be relevant

  → provided that a specific POP can still be placed on the market

- Take care in relation to biocidal products and plant protection products → many POPs are active substances

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Don´t use POPs…

  … full stop

- It could be seen as first global and careful steps to a greener chemistry.

mercury and mercury compounds

GREEN CHEMISTRY CHANGE MANAGER

- Minamata Convention
  - international agreement
    → sort of global chemicals legislation as well

- Under the auspices of UNEP in Geneve
  http://www.mercuryconvention.org/

- Objective is to prevent (chronic) poisoning with Hg and its compounds, and the pollution of the environment with them

- covers the whole life cycle (incl. waste) as well

Implementation in the EU

- Implementation in the EU:
  - Regulation (EU) No 2017/852
  - in force since 1st January 2018
  - replaced the old regulation from 2008

- Objective is the precautionary protection of human health and the environment

- Regulated are
  - Hg and Hg-compounds
  - Mixtures containing Hg
  - products containing Hg
  - Hg-waste

Implementation in the EU

- The instruments of the EU-regulation to achieve the objectives:
  - Rules for export, import and manufacture of a range of Hg-containing products (Articles 3 to 6)
  - bans and restrictions (Articles 7 & 8)
  - Substitution of Hg and compounds (Article 8)
  - Special rules for sectors with a particularly large usage of Hg (e.g. gold-mining, dental amalgam (Articles 9 & 10)
  - Rules on the waste status (e.g. shipment, storage, monitoring, record-keeping) (Articles 11 to 15).

- Important technical and substance/product-specific aspects in the annexes

Annex I

GREEN CHEMISTRY CHANGE MANAGER

- restriction/ban for import, export and use of
  - Hg compounds
  - mixtures of Hg
- list of different relevant Hg-compounds and deadlines (all already in force)

Mercury compounds prohibited for export from 1 January 2018:

— Mercury (I) chloride (Hg_2Cl_2, CAS RN 10112-91-1)

— Mercury (II) oxide (HgO, CAS RN 21908-53-2)

— Cinnabar ore

— Mercury sulfide (HgS, CAS RN 1344-48-5)

Mercury compounds prohibited for export from 1 January 2020:

— Mercury (II) sulphate ($HgSO_4$, CAS RN 7783-35-9)

— Mercury (II) nitrate ($Hg(NO_3)_2$, CAS RN 10045-94-0)

Mixtures of mercury prohibited for export and import from 1 January 2018:

— Mixtures of mercury with other substances, including alloys of mercury, with a mercury concentration of at least 95 % by weight.

Annex II

GREEN CHEMISTRY CHANGE MANAGER

- restriction/ban for import, export and use of of mercury-added products
- For example:

Mercury-added products	Date from which the export, import and manufacturing of the mercury-added products are prohibited
1. Batteries or accumulators that contain more than 0,0005 % of mercury by weight.	31.12.2020
2. Switches and relays, except very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge, switch or relay.	31.12.2020
3. Compact fluorescent lamps (CFLs) for general lighting purposes: (a) CFL.i ≤ 30 watts with a mercury content exceeding 2,5 mg per lamp burner; (b) CFL.ni ≤ 30 watts with a mercury content exceeding 3,5 mg per lamp burner.	31.12.2018

Annex III & IV

GREEN CHEMISTRY CHANGE MANAGER

- Annex III is a list of requirements applicable to manufacturing processes
  - bans, e.g. as electrode, catalyst…
  - restriction for production of sodium or potassium methylate or ethylate

- Annex IV is mainly relevant for authorities
  - Content of the national plan on artisanal and small-scale gold mining

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- Hg and compounds are completely in the scope of REACH, this can for example mean:
  - registration necessary,
  - safety data sheet necessary,
  - authorisation may be relevant,
  - art. 33 information requirements (incl. SCIP) may be relevant

- A Hg-restriction is independent of REACH
  - it can complement a REACH-restriction (e.g. Hg-thermometers), but usually, it will be stricter anyway
  - it should not double-regulate or contradict a REACH-restriction
  - some Hg-conditions could be relevant for a REACH-registration (waste-stage, safety-requirements…)

- A Hg-compound is a substance for phase-out
  - a registration may be economically not rational,
  - same goes for an authorisation (so far no Hg-compounds in the scope).

Interface CLP

- Hg-compounds are completely in the scope of CLP, this can for example mean:
  - classification and labelling is relevant
  - notification to the CLI may be relevant
  - poison-center notification may be relevant

→ provided that a specific Hg-compound can still be placed on the market

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Don´t use Hg and Hg-compounds…

… full stop

- It could be seen as further global and careful steps to a greener chemistry.

Excursion to global chemicals management

GREEN CHEMISTRY CHANGE MANAGER

- Chemicals legislation is a relatively globalized policy field.
- Important actors are:
  - UN
  - OECD

- diverse activities:
  - high level policy
  - technical frameworks
  - guidelines
  - …

United Nations

- Specialized agencies and subsidiary organs, e.g. FAO, UNEP, UNIDO, WHO
- Multilateral Environmental Agreements (Basel, Rotterdam, Minamata and Stockholm Conventions, Montreal Protocol)
- Strategic Approach to International Chemicals Management (SAICM) as Policy Framework
- Global Framwork on Chemicals (in the future)
- Funding mechanism, e.g. Global Environment Facility GEF, Multilateral Fund MLF

United Nations – diverse initiatives/guidance

GREEN CHEMISTRY CHANGE MANAGER

- Green and sustainable chemistry (UNEP 2020) https://www.unep.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/green-and-sustainable-chemistry
- Global Chemical Outlook II (UNEP 2019) https://www.unep.org/resources/report/global-chemicals-outlook-ii-legacies-innovative-solutions
- Assessments on impact of certain issues, e.g. cadmium, mercury
- Green chemistry and other toolkits (IOMC toolkit project):
  - https://greenchemistry-toolkit.org/
  - https://chemicalleasing-toolkit.org/
  - https://iamc-toolkit.org/

OECD

GREEN CHEMISTRY CHANGE MANAGER

- GLP (Good Laboratory Practice)
- Approximately 160 Test Guidelines
  - Physical-chemical properties
  - Bio-degradation and accumulation
  - Ecotoxicity
  - Mammalian toxicity
  - Efficacy, Pesticide residue testin
- MAD (Mutual Acceptance of Data)
- Strong focus on non-animal tests

OECD

GREEN CHEMISTRY CHANGE MANAGER

- Discussion of New Approach Methods (NAMs)
  - Chemical grouping
  - Integrated Approaches to Testing and Assessment (IATAs) Case Studies Project
  - Various topic-specific guidance documents
    - » Report on survey of Occupational Exposure Limits approaches
  - QSAR Toolbox
    - » QSAR Assessment Framework project
  - Omics approaches
- diverse guidelines, e.g.
  - Substitution of harmful chemicals
  - designing sustainable plastics

RoHS-directive

GREEN CHEMISTRY CHANGE MANAGER

- Directive 2011/65/EU on the **R**estriction of the use **o**f certain **H**azardous **S**ubstances in electrical and electronic equipment

- Key aspects:
  - an EU-directive
  - very focused restriction-instrument
  - regulates a very limited number of substances
  - homogenous materials are in the focus
  - very specific sector → EEE (electrical & electronic equipment)

RoHS-directive

- Being a directive:
  - needs transposition into national laws
  - deadline was by 2nd January 2013
  - harmonisation in the EU is not complete
  - consider national legislation for details

- It´s objective:
  - sound waste-management
  - reduction/removing of problematic substances

- It´s main legal instruments:
  - restrictions
  - assessment/declaration of conformity
  - CE-marking

Scope

- electrical and electronic equipment is in the focus
- it is divided in numerous categories (annex I), e.g.
  - Large & small household appliances.
  - Consumer equipment.
  - Lighting equipment.
  - Electrical and electronic tools.
  - Toys, leisure and sports equipment.
- lots of relevant exemptions
- “Everyone” can apply for an exemption or for changing it

Relevant substances

GREEN CHEMISTRY CHANGE MANAGER

- Restricted substances are listed in annex II:
  - Lead
  - Mercury
  - Cadmium
  - Hexavalent chromium
  - Polybrominated biphenyls
  - Polybrominated diphenyl ether
  - Bis(2-ethylhexyl) phthalate
  - Butyl benzyl phthalate
  - Dibutyl phthalate
  - Diisobutyl phthalate
- List can be extended, but does not happen too often
- Consider also relevant concentration values from annex II

Annex III, IV & V

GREEN CHEMISTRY CHANGE MANAGER

- Annex III is a long list of general substance- and product-specific exemptions

- Annex IV are exemptions as well, but focused on:
  - medical devices
  - monitoring instruments
  - control instruments

ANNEX III

Applications exempted from the restriction in Article 4(1)

	Exemption	Scope and dates of applicability
1	Mercury in single capped (compact) fluorescent lamps not exceeding (per burner):	
1(a)	For general lighting purposes < 30 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011 until 31 December 2012; 2,5 mg shall be used per burner after 31 December 2012
1(b)	For general lighting purposes ≥ 30 W and < 50 W: 5 mg	Expires on 31 December 2011; 3,5 mg may be used per burner after 31 December 2011
1(c)	For general lighting purposes ≥ 50 W and < 150 W: 5 mg	
1(d)	For general lighting purposes ≥ 150 W: 15 mg	
1(e)	For general lighting purposes with circular or square structural shape and tube diameter ≤ 17 mm	No limitation of use until 31 December 2011; 7 mg may be used per burner after 31 December 2011
1(f)	For special purposes: 5 mg	
2(a)	Mercury in double-capped linear fluorescent lamps for general lighting purposes not exceeding (per lamp):	
2(a)(1)	Tri-band phosphor with normal lifetime and a tube diameter < 9 mm (e.g. T2): 5 mg	Expires on 31 December 2011; 4 mg may be used per lamp after 31 December 2011
2(a)(2)	Tri-band phosphor with normal lifetime and a tube diameter ≥ 9 mm and ≤ 17 mm (e.g. T5): 5 mg	Expires on 31 December 2011; 3 mg may be used per lamp after 31 December 2011
2(a)(3)	Tri-band phosphor with normal lifetime and a tube diameter > 17 mm and ≤ 28 mm (e.g. T8): 5 mg	Expires on 31 December 2011; 3,5 mg may be used per lamp after 31 December 2011

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- All RoHS-substances as such are in the scope of REACH, but they are incorporated in EEEs
  - registration necessary only up the supply chain,
  - safety data sheet only up the supply chain, not for the EEE,
  - REACH-authorisation may matter up the supply chain, some RoHS-substances are listed in REACH-annex-XIV
- A RoHS-restriction is independent of REACH
  - it is more specific, so are also the exemptions,
  - but in principle a RoHS-restriction is very similar to many REACH-restrictions
- EEEs are articles / complex objects
  - Most RoHS-substances are listed on the REACH-candidate-list
  - art. 33 information requirements (incl. SCIP)

Interface CLP

GREEN CHEMISTRY CHANGE MANAGER

- RoHS-substances are in the scope of CLP…
- … but this should be more of a topic upstream.
- EEEs as articles /complex objects are not in the scope of CLP.

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- RoHS gives clear signals, what needs to be substituted.
- It makes the supply chain more transparent in relation to the content of certain chemicals.
- Still it does not actively support green solutions.
- BUT it became a blueprint for many other regions globally.

fluorinated gases (f-gases)

GREEN CHEMISTRY CHANGE MANAGER

- Montreal Protocol
  - international agreement
    → sort of global chemicals legislation as well
- Under the auspices of UNEP in Montreal and Nairobi https://www.unep.org/ozonaction/who-we-are/about-montreal-protocol
- legal framework for regulating f-gases and ozone-depleters (ODS) globally and in the EU
- Objective is to reduce and/or stop the use of f-gases & ODS

Implementation in the EU

- Implementation in the EU:
  - Regulation (EU) 2024/573
  - in force since 1st January 2024
  - replaced the old regulation from 2014

- Regulatory instruments:
  - bans and restrictions
  - quota-system – phase down
  - qualifications requirements and certification
  - monitoring of leakages
  - reporting and documenting obligations
  - labelling of equipment / articles

f-gases - annex I

- What are f-gases?
  - greenhouse gases
  - fluorinated carbohydrates
  - have a high global warming potential, measured by the GWP
  - defined at the global level and included in annex I

ANNEX I

FLUORINATED GREENHOUSE GASES REFERRED TO IN POINT 1 OF ARTICLE 2

Substance			GWP (1)
Industrial designation	Chemical name (Common name)	Chemical formula	
Section 1: Hydrofluorocarbons (HFCs)			
HFC-23	trifluoromethane (fluoroform)	CHF_3	14 800
HFC-32	difluoromethane	CH_2F_2	675
HFC-41	fluoromethane (methyl fluoride)	CH_3F	92
HFC-125	pentafluoroethane	CHF_2CF_3	3 500
HFC-134	1,1,2,2-tetrafluoroethane	CHF_2CHF_2	1 100
HFC-134a	1,1,1,2-tetrafluoroethane	CH_2FCF_3	1 430
HFC-143	1,1,2-trifluoroethane	CH_2FCHF_2	353
HFC-143a	1,1,1-trifluoroethane	CH_3CF_3	4 470
HFC-152	1,2-difluoroethane	CH_2FCH_2F	53
HFC-152a	1,1-difluoroethane	CH_3CHF_2	124

f-gases

GREEN CHEMISTRY CHANGE MANAGER

- What is the GWP?
  - GWP = 1 for the effect of 1 kg CO2 over 100 years
  - some f-gases have GWPs of over 10.000
  - high GWP means high climate-impact

- Mixtures are covered as well
  - annex IV sets down a calculation method to define the GWP

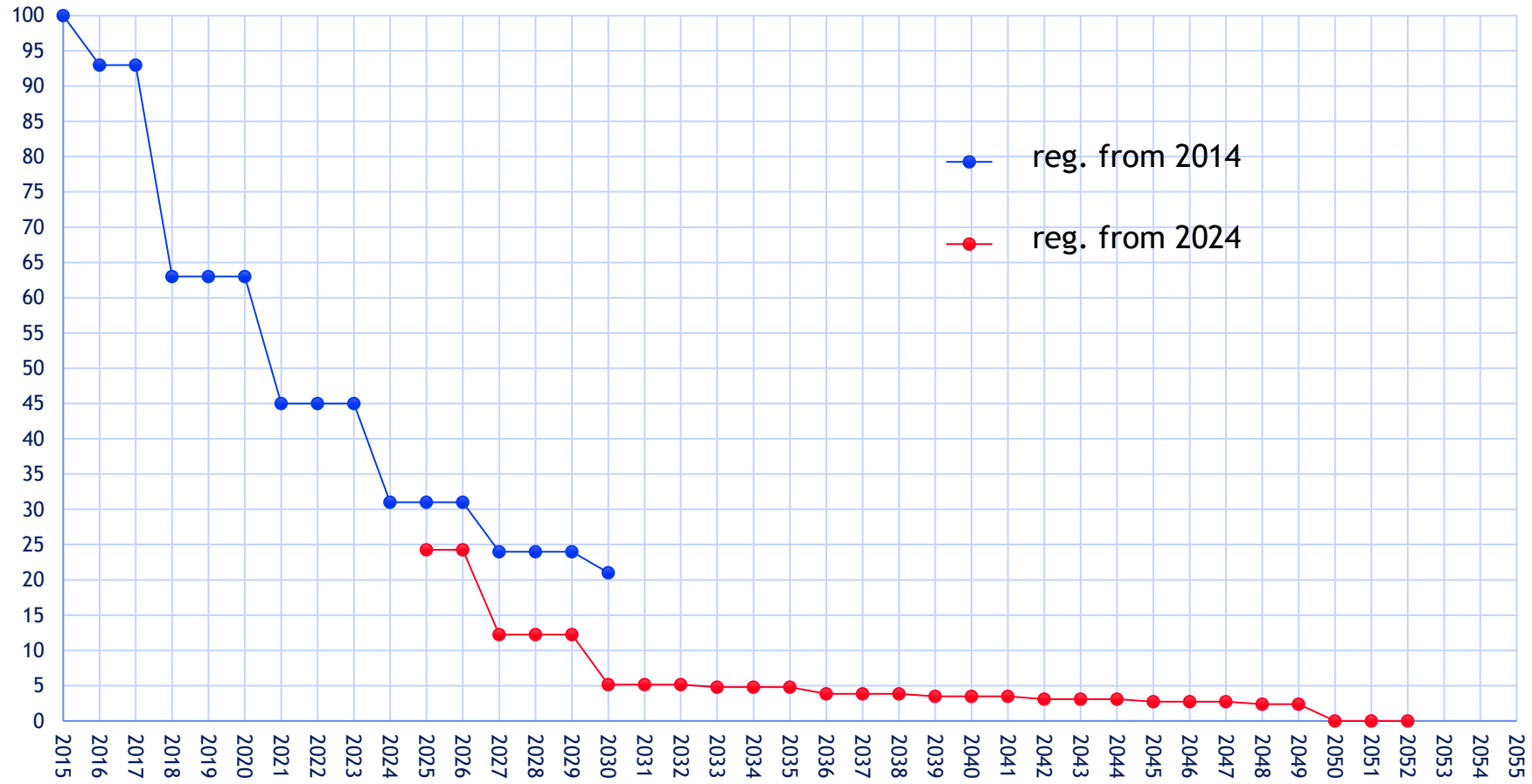
quota-system – phase-down

- a limited number of quotas (kind of CO2-certificates) are available
- manufacturer and importer of f-gases can apply
- annual attribution of quotas
- step-wise reduction until 2050 (phase-down)
- management of quotas via the “F-Gas-Portal”

→ **no quota, no market**

Source: Umweltbundesamt

quota-system – phase-down



bans and restrictions

- Restrictions of the placing on the market of certain products and equipment (Annex III)

	Products and equipment	Date of prohibition
(1)	Non-refillable containers for fluorinated greenhouse gases listed in Annex I, empty, partially or fully filled, used to service, maintain or fill refrigeration, air-conditioning or heat pump equipment, fire protection systems or electrical switchgear, or for use as solvents.	4 July 2007
	STATIONARY REFRIGERATION	
(2)	Domestic refrigerators and freezers:	(a) that contain HFCs with GWP of 150 or more; — 1 January 2015
		(b) that contain fluorinated greenhouse gases, except if required to meet safety requirements at the site of operation. — 1 January 2026
(3)	Refrigerators and freezers for commercial use (self-contained equipment):	(a) that contain HFCs with GWP of 2 500 or more; — 1 January 2020
		(b) that contain HFCs with GWP of 150 or more; — 1 January 2022
		(c) that contain other fluorinated greenhouse gases with a GWP of 150 or more. — 1 January 2025
(4)	Any self-contained refrigeration equipment, except chillers, that contains fluorinated	

all over 21 entries with subentries for different equipment/products:

- stationary refrigeration
- stationary chillers
- stationary air-conditioning equipment and stationary heat pumps
- other products and equipment

qualification requirements and certification

GREEN CHEMISTRY CHANGE MANAGER

- sector specific training requirements for certain activities
- certification scheme for workers and companies
- relevant sectors:
  - stationary refrigeration and air-conditioning equipment
  - stationary heat pumps
  - refrigeration units of refrigerated trucks and trailers
  - electrical switchgear
  - stationary fire protection equipment
  - recovery of solvents containing f-gases
  - air-conditioning systems in certain motor vehicles

- Lots of details are regulated in implementing legislation.

other obligations

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- monitoring of leakages
  - regular checks, depending on quantities of f-gases (3 to 24 months)
  - leakage detection system
- reporting and documenting obligations
  - lots of admin, e.g. in-/outgoing f-gases, protocols of checks…
- labelling of certain equipment / products
  - info that f-gas is contained
  - identifiers of the f-gas incl. GWP
  - quantities in weight or CO2-equivalents
  - and some more specialized
  - formal criteria, e.g. language, readability, position etc.

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- f-gases are completely in the scope of REACH, this can for example mean:
  - registration necessary (some are already on the CoRAP),
  - safety data sheet necessary,
  - authorisation may be relevant,
  - art. 33 information requirements (incl. SCIP) may be relevant

- A f-gas-restriction is independent of REACH
  - it can complement a REACH-restriction, but usually, it will be more specific
  - it should not double-regulate or contradict a REACH-restriction
  - qualification requirements are not usual under REACH (but not unknow, eg diisocyanates)

Interface CLP

- f-gases as substances or in mixtures are completely in the scope of CLP, this can for example mean:
  - classification and labelling is relevant
  - notification to the CLI may be relevant
  - poison-center notification may be relevant (if not only ecotox. classification)

- different definition for “placing on the market”

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- It is an ambitous global deal for greener chemistry.
- The EU is even more ambitious, especially the new proposal.
- In the EU it gives clear signals to develop new, climate-friendly solutions.
- It has a relatively wide focus, taking into account chemicals, but also the qualification of users.
- The quota-system allows a certain flexibility on the market, so that businesses can to a certain extend set priorities for the transition.
- But we see already a number of policy conflicts (e.g. safety, energy-efficiency, repairability…).
- And a growing lack of skilled workforce.

Fertilisers

GREEN CHEMISTRY CHANGE MANAGER

- Fertilisers regulated by national law
- EU rules for fertilising products
  - Regulation (EU) 2019/1009
  - since 2022 extension to organic fertilisers, before only mineral

Fertilisers

- **Fertilising product** (acc. EU regulation)

  means a substance, mixture, micro-organism or any other material, applied or intended to be applied on plants or their rhizosphere or on mushrooms or their mycosphere, or intended to constitute the rhizosphere or mycosphere, either on its own or mixed with another material, for the purpose of providing the plants or mushrooms with nutrient or improving their nutrition efficiency;

Basic structure

GREEN CHEMISTRY CHANGE MANAGER

- 7 PFCs - product function categories, e.g. Organic fertiliser (solid/liquid), inorganic fertiliser (solid/liquid…) – annex I
- 15 CMCs - component material categories, e.g. compost, micro-organisms, nutrient polymers – annex II
- Labelling requirement, general and product-specific – annex III
- Conformity assessment & Declaration of conformity

PFCs

GREEN CHEMISTRY CHANGE MANAGER

ANNEX I

Product Function Categories (PFCs) of EU fertilising products

PART I

DESIGNATION OF PFCS

1. Fertiliser

A. Organic fertiliser

I. Solid organic fertiliser

II. Liquid organic fertiliser

B. Organo-mineral fertiliser

I. Solid organo-mineral fertiliser

II. Liquid organo-mineral fertiliser

C. Inorganic fertiliser

I. Inorganic macronutrient fertiliser

(a) Solid inorganic macronutrient fertiliser

(i) Straight solid inorganic macronutrient fertiliser

(A) Straight solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content

(ii) Compound solid inorganic macronutrient fertiliser

(A) Compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content

(b) Liquid inorganic macronutrient fertiliser

(i) Straight liquid inorganic macronutrient fertiliser

(ii) Compound liquid inorganic macronutrient fertiliser

II. Inorganic micronutrient fertiliser

(a) Straight inorganic micronutrient fertiliser

(b) Compound inorganic micronutrient fertiliser

2. Liming material

3. Soil improver

A. Organic soil improver

B. Inorganic soil improver

4. Growing medium

5. Inhibitor

A. Nitrification inhibitor

B. Denitrification inhibitor

C. Urease inhibitor

6. Plant biostimulant

A. Microbial plant biostimulant

B. Non-microbial plant biostimulant

7. Fertilising product blend

PFC 1: FERTILISER

A fertiliser shall be an EU fertilising product the function of which is to provide nutrients to plants or mushrooms.

PFC 1(A): ORGANIC FERTILISER

1. An organic fertiliser shall contain:

— organic carbon (C_{org}) and

— nutrients

of solely biological origin.

An organic fertiliser may contain peat, leonardite and lignite, but no other material which is fossilized or embedded in geological formations.

2. Contaminants in an organic fertiliser must not exceed the following limit values:

(a) cadmium (Cd):	1,5 mg/kg dry matter,
(b) hexavalent chromium (Cr VI):	2 mg/kg dry matter,
(c) mercury (Hg):	1 mg/kg dry matter,
(d) nickel (Ni):	50 mg/kg dry matter,
(e) lead (Pb):	120 mg/kg dry matter, and
(f) inorganic arsenic (As):	40 mg/kg dry matter.

Biuret ($C_2H_5N_3O_2$) must not be present in an organic fertiliser.

3. The copper (Cu) content in an organic fertiliser must not exceed 300 mg/kg dry matter, and the zinc (Zn) content in an organic fertiliser must not exceed 800 mg/kg dry matter.

4. Pathogens in an organic fertiliser must not exceed the limits set out in the following table:

Micro-organisms to be tested	Sampling plans			Limit
	n	c	m	M
Salmonella spp.	5	0	0	Absence in 25 g or 25 ml
Escherichia coli or *Enterococcaceae*	5	5	0	1 000 in 1 g or 1 ml

Where:

n = number of samples to be tested,

c = number of samples where the number of bacteria expressed in colony forming units (CFU) is between m and M,

m = threshold value for the number of bacteria expressed in CFU that is considered satisfactory,

M = maximum value of the number of bacteria expressed in CFU.

PFC 1(A)(I): SOLID ORGANIC FERTILISER

CMCs

GREEN CHEMISTRY CHANGE MANAGER

ANNEX II

Component Material Categories (CMCs)

An EU fertilising product shall consist solely of component materials complying with the requirements for one or more of the CMCs listed in this Annex.

The component materials, and the input materials used to produce them, shall not contain any of the substances for which maximum limit values are indicated in Annex I in such quantities as to jeopardise the EU fertilising product's compliance with the applicable requirements of that Annex.

PART I

DESIGNATION OF CMCS

CMC 1: Virgin material substances and mixtures

CMC 2: Plants, plant parts or plant extracts

CMC 3: Compost

CMC 4: Fresh crop digestate

CMC 5: Digestate other than fresh crop digestate

CMC 6: Food industry by-products

CMC 7: Micro-organisms

CMC 8: Nutrient polymers

CMC 9: Polymers other than nutrient polymers

CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009

CMC 11: By-products within the meaning of Directive 2008/98/EC

▼M2

CMC 12: Precipitated phosphate salts and derivates

▼M3

CMC 13: Thermal oxidation materials and derivates

▼M4

CMC 14: Pyrolysis and gasification materials

▼M5

CMC 15: Recovered high purity materials

PART II

REQUIREMENTS RELATED TO CMCS

This Part defines the component materials of which EU fertilising products shall solely consist.

CMC 1: VIRGIN MATERIAL SUBSTANCES AND MIXTURES

1. An EU fertilising product may contain substances and mixtures, except [1]:

   (a) waste within the meaning of Directive 2008/98/EC,

   (b) substances or mixtures which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC,

   (c) substances formed from precursors which have ceased to be waste in one or more Member States by virtue of the national measures transposing Article 6 of Directive 2008/98/EC, or mixtures containing such substances,

CMC 6: FOOD INDUSTRY BY-PRODUCTS

1. An EU fertilising product may contain component material consisting of one of the following substances:

   (a) food industry factory lime, i.e. a material from the food processing industry obtained by carbonation of organic matter, using exclusively burnt lime from natural sources;

   (b) molasses, i.e. a viscous by-product of the refining of sugarcane or sugar beets into sugar;

   (c) vinasse, i.e. a viscous by-product of the fermentation process of molasses

CMC 4: FRESH CROP DIGESTATE

1. An EU fertilising product may contain digestate obtained through anaerobic digestion of exclusively one or more of the following input materials:

   (a) plants or plant parts grown for the production of biogas. For the purpose of this point, plants include algae and exclude blue-green algae (cyanobacteria);

   (b) digestion additives which are needed to improve the process performance or the environmental performance of the digestion process provided that:

      (i) the additive complies with the requirement set out in point 2 in CMC 1 and

      (ii) the total concentration of all additives does not exceed 5 % of the total input material weight; or

   (c) any material referred to in point (a) that has previously been digested.

2. The anaerobic digestion shall take place in a plant:

Interface REACH

- fertilisers as substances and mixutres are completely in the scope of REACH, this can for example mean:
  - registration necessary for substances / raw-materials
  - safety data sheet necessary, but also additional information (accompanying documents, art. 9, fert.-regulation),
  - authorisation should not be relevant,
  - restrictions could be relevant (e.g. ammoniumnitrate)

  - new regulation: always testing requirements for 1-100 t/a for all substances incorporated in fertilisers
    → REACH, annexes VI, VII and VIII
    → and a REACH-CSR

Interface CLP

- fertilisers as substances or mixtures are completely in the scope of CLP, this can for example mean:
  - classification and labelling is relevant
  - notification to the CLI may be relevant
  - poison-center notification may be relevant

- fert.-regulation forsees complementary / overlapping labelling., e.g.
  - name/address of the manufacturer/responsible perons
  - country of manufacturing
  - type of fertiliser
  - if relevant „EC-FERTILISERS“
  - trade name
  - concentration of certain ingredients
  - certain physical parameters
  - starting material
  - volume / mass
  - use information

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Part of the Circular Economy Package.
- Pushing the use of recycled and organic materials.
- Improving nutrition efficiency to lower input and env-impact of fertilisers.
- Conflicting objectives, e.g. Cd-concentration in PO4-fertilisers.

biocidal products

GREEN CHEMISTRY CHANGE MANAGER

- Regulation (EU) No 528/2012
  - applys since 1. September 2013
  - replaced the old directive from 1998

- Regulatory instruments:
  - approval of active substances
  - authorisation of biocidal products
  - rules for placing on the market
  - rules for treated articles

So, in practice a biocidal product is:

GREEN CHEMISTRY CHANGE MANAGER

- A substance or mixture, which
  - contains one or more active substances or produces such on the spot,
  - destroys, repeals or otherwise fights harmful organisms chemically.

- 22 product-types (annex V), e.g.
  - desinfectants for human hygiene, verterinary hygiene…
  - preservatives during storage, for wood…
  - pest control against insects, rats…
  - repellents

- Use and placing on the market only with an authorisation.

“Legalising” a biocidal product

GREEN CHEMISTRY CHANGE MANAGER

- 2-step process
  - step 1: approval of active substance(s)
  - step 2: authorisation of biocidal product

- Transitional regime for “old” active substances.
  - included in the “review”-program
    → planned to be done until 2014, recently extended until 2030
  - national rules apply
  - art.-95-listing of the supplier necessary

Active substances

GREEN CHEMISTRY CHANGE MANAGER

- approval of active substance
  - approval dossier (annex II), e.g. tox-data, uses, exposure, risk-/ efficacy-assessment, C&L…
  - evaluated by a MS-authority
  - takes pretty long, is costly
  - renewal necessary
  - included (or not) into a Union-list
  - always in combination with one or more product type(s)

Product authorisation

GREEN CHEMISTRY CHANGE MANAGER

- authorisation dossier (annex III), e.g. tox-data, uses, exposure, risk-/ effectivness-assessment, C&L, letter of access for LoA…
- different authorisation routes possible:
  - National authorisation in 1 MS only
  - National authorisation in more MS:
    - » mutual recognition in sequence
    - » mutual recognition in parallel
  - Biocidal-Product-Family (BPF)
  - Union authorisation (limited to certain PTs)
  - Same-BP-authorisation
  - Parallel-trade
  - Simplified authorisation (only for actives in annex I)
- Takes usually couple of months, costs are relevant (ECHA- or national fees)
- renewal necessary

Other elements

GREEN CHEMISTRY CHANGE MANAGER

- Treated articles
  - secondary biocidal function
  - mainly labelling requirements
- Data-sharing rules
- Advertising rules, e.g.
  “Use biocides [or PT] safely. Always read the label and product information before use.”

Interface REACH

- active substances and other co-formulants are mainly in the scope of REACH, this can for example mean:
  - registration necessary for co-formulants
  - actives used in BPs are considered as registered (art. 15, REACH)
  - safety data sheet necessary, BPR even refers to REACH
  - substances used as BPs are exempted from authorisation
  - restrictions may matter
  - some parallels between data-sharing-rules.
- REACH makes use of ED-criteria of the BPR and PPP-regulation
- ECHA manages BPR

Interface CLP

GREEN CHEMISTRY CHANGE MANAGER

- biocidal products and active substances are completely in the scope of CLP, this can for example mean:
  - classification and labelling is usually relevant
  - notification to the CLI will usually be relevant (e.g. actives)
  - poison-center notification will usually be relevant (e.g. BPs)

- additional labelling requirements based on BPR (art. 69), e.g.
  - “[nano]” / active substance(s) and concentration / authorisation number
  - certain information is not allowed, e.g. “low-risk”, “natural”, “harmless” (even a court-case on “bio”), PTs, direction for use
  - harmonized classification of actives usual
  - requirements in the authorisation dossier

- Many provisions of the BPR refer directly to CLP-classifications
  - No approval of actives classified as CMR Cat. 1A, 1B or EDs
  - Substance of concern, candidates for substitution, low-risk products…

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Phase-out of the most problematic active substances.
- 1st EU-legislation with ED-criteria.
- Simplified procedures for low-risk products.
- Procedures seem to be innovation blockers.

plant protection products

GREEN CHEMISTRY CHANGE MANAGER

- The plant-protection (pesticides) -package:
  - Regulation (EU) No 1107/2009 on the placing on the market of PPPs
  - Directive 128/2009 on the sustainable use of PPPs (+ another directive on statistics)
  - stepped into force in different steps, but everything is „active“ today
  - replace the old directive from 1991

- Regulatory instruments:
  - approval of active substances
  - authorisation of PPPs
  - rules for placing on the market
  - qualification requirements for users, suppliers and consultants

Practically a PPP is:

GREEN CHEMISTRY CHANGE MANAGER

- A mixture, which in the supplied form is composed of or contains::
  - active substance(s)
  - safener(s)
  - synergist(s)
- and which are intended to:
  - protect plants and plant products from (the effect of) harmful organisms,
  - influence the life-cycle of plants,
  - conserve plant products,
  - destroy unwanted plants or plant parts,
  - supress or prevent unwanted growth.
- Use and placing on the market only with an authorisation.

“Legalising” a PPP

GREEN CHEMISTRY CHANGE MANAGER

- 2-step process
  - step 1: approval of active substance(s)
  - step 2: authorisation of PPP

- approval of active substance
  - approval dossier (annex II), e.g. tox-data, uses, exposure, risk-/ efficacy-assessment, C&L…
  - evaluated by a MS-authority
  - takes pretty long, is very costly
  - renewal necessary
  - included (or not) into a Union-list

Product authorisation

- authorisation dossier, e.g. tox-data, uses, exposure, risk-/ effectivness-assessment, C&L…
- Authorisation-schemes:
  - national authorisation
  - mutual recognition
  - zonal authorisation
  - parallel trade
- very heavy procedures
- Takes long, costs are very high
- renewal necessary

ANNEX I

Definition of zones for the authorisation of plant protection products as referred to in Article 3(17)

Zone A — North

The following Member States belong to this zone:

Denmark, Estonia, Latvia, Lithuania, Finland, Sweden

Zone B — Centre

The following Member States belong to this zone:

Belgium, Czech Republic, Germany, Ireland, Luxembourg, Hungary, Netherlands, Austria, Poland, Romania, Slovenia, Slovakia, United Kingdom

Zone C — South

The following Member States belong to this zone:

Bulgaria, Greece, Spain, France, Italy, Cyprus, Malta, Portugal

Other elements

GREEN CHEMISTRY CHANGE MANAGER

- Lots is regulated at MS-level, e.g.
  - storage
  - placing on the market (e.g. national bans)
  - qualification-schemes
  - notification / PPP-registers

- Advertising rules, e.g.
  "Use plant protection products safely. Always read the label and product information before use."

- A long list of implementing legislation

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- active substances and other co-formulants are mainly in the scope of REACH, this can for example mean:
  - actives and co-formulants are considered as registered (art. 15, REACH)
  - safety data sheet necessary
  - substances used as PPPs are exempted from authorisation
  - restrictions may matter
- REACH makes use of ED-criteria of the BPR and PPP-regulation
- ECHA has (almost) no role, its EFSA here

Interface CLP

GREEN CHEMISTRY CHANGE MANAGER

- PPPs are completely in the scope of CLP, this can for example mean:
  - classification and labelling is usually relevant
  - notification to the CLI will usually be relevant
  - poison-center notification will usually be relevant

- CLP, annex II, part 4: Special Rule for Labelling of PPPs
  - EUH401 — “To avoid risks to human health and the environment, comply
  - with the instructions for use”

- Many provisions of the PPP-law refer directly to CLP-classifications
  - No approval of actives, safeners and synergists classified as CMR Cat. 1A, 1B or EDs

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Phase-out of the most problematic active substances.
- 2nd EU-legislation with ED-criteria.
- Reduction targets for the use of PPPs.
- Qualification requirements for users, suppliers and consultants.
- Many PPPs very controversial (e.g. neonics, glyphosate).

Cosmetic Product Regulation

- Cosmetic Product Regulation (EC) 1223/2009
- A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use
- Definition:

  " … any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;"

Regulatory instruments

- Roles and responsibilities for responsible person and distributor
- Good manufacture practice
- Safety assessment, product information file
- Pre-market notification (CPNP)
- Restriction for substances (after a scientific evaluation)
  - Prohibited substances – Annex II
  - Restricted substances – Annex III
  - Colorants – Annex IV
  - Preservatives – Annex V
  - UV-filters – Annex VI

Regulatory instruments

- Substances classified as
  - CMR cat 1A and 1B
  - CMR cat 2

  are forbidden in cosmetic products.
  → exemptions possible (based on evaluation)
- Rules for traces of prohibited substances
- Animal testing ban

Regulatory instruments

- Special labelling requirements – full declaration of ingredients (INCI)
- Rules on product claims
- Special approach for nanomaterials
- Access of information to the public
- Reporting of serious undesirable effects

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- cosmetic products mainly in the scope of REACH, this can for example mean:
  - registration necessary for raw material
  - potential conflict in relation to animals testing
  - safety data sheet necessary for raw material
  - safety data sheet not necessary for CP, if in the finished state, intended for the final user
  - so far it concerns human-health, exemptions from:
    - registration
    - restriction
    - authorisation

Interface CLP

- Cosmetics products are generally not in the scope of CLP, if in the finished state, intended for the final user
- CPR refers directly to the harmonised classification of CMR-substances (cat. 1A/B and 2) included in CLP Annex VI

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Strong hazard based focus, e.g. bans.
- Promoting the ban on animal testing.

Detergent Regulation

GREEN CHEMISTRY CHANGE MANAGER

- Detergent Regulation (EC) 648/2004
  → Proposal for a new regulation

- Scope:
  "Detergent means any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes"

  → laundry detergents / fabric softeners / dish wash detergents / surface cleaners / auxiliary washing mixtures

- Objectives:
  - Free movements of detergents
  - High level of protection for the environment and health

Detergent Regulation

GREEN CHEMISTRY CHANGE MANAGER

- Specific rules for
  - the biodegradability of surfactants in detergents
  - restrictions or bans on surfactants on grounds of biodegradability
    - » ultimate aerobic biodegradation necessary with criteria in Annex III
      - Derogation possible under strict conditions including a risk assessment
  - limitations on the content of phosphates and of other phosphorus compound

Detergent	Limitations	Date as of which the limitation applies
1. Consumer laundry detergents	Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,5 grams in the recommended quantity of the detergent to be used in the main cycle of the washing process for a standard washing machine load as defined in section B of Annex VII for water of hard water hardness — for 'normally soiled' fabrics in the case of heavy-duty detergents, — for 'lightly soiled' fabrics in the case of detergents for delicate fabrics,	30 June 2013
2. Consumer automatic dishwasher detergents	Shall not be placed on the market if the total content of phosphorus is equal to or greater than 0,3 grams in the standard dosage as defined in section B of Annex VII	1 January 2017

Detergent Regulation

GREEN CHEMISTRY CHANGE MANAGER

- Specific rules for
  - additional labelling of detergents sold to the general public
    - » Ingredient list (specified in Annex VII) in concentration ranges (descending order)
    - » Irrespective of their concentration
      - enzymes, disinfectants, optical brighteners
      - perfumes (fragrance allergens with a reference to CPR must specifically be mentioned)
      - Preservatives
    - » Website address for list of ingredients
  - medical data sheet for authorities and medical personnel (i.e. dermatologists)

are added in a concentration above 0,2 % by weight:

— phosphates,

— phosphonates,

— anionic surfactants,

— cationic surfactants,

— amphoteric surfactants,

— non-ionic surfactants,

— oxygen-based bleaching agents,

— chlorine-based bleaching agents,

— EDTA and salts thereof,

— NTA (nitrilotriacetic acid) and salts thereof,

— phenols and halogenated phenols,

— paradichlorobenzene,

— aromatic hydrocarbons,

— aliphatic hydrocarbons,

— halogenated hydrocarbons,

— soap,

— zeolites,

— polycarboxylates.

Interface REACH

- Detergents are completely in the scope of REACH, this can for example mean:
  - registration necessary,
  - safety data sheet necessary (+ medical data sheet),
  - Restrictions may be complementary
  - REACH-authorisation should not be relevant,

Interface CLP

- Detergents are completely in the scope of CLP, this can for example mean:
  - classification and labelling is relevant
  - notification to the CLI may be relevant
  - PC-notification may be relevant
  - specific requirements for liquid laundry detergents in soluble packaging

Putting in perspective to Green Chemistry

- In an early phase it was pushing substitution of phosphates.
- Demanding safety and biodegradability.
- Reducing impact on the environment.

PIC Regulation - Export of chemicals

GREEN CHEMISTRY CHANGE MANAGER

- Prior Informed Consent Regulation (EU) 649/2012
  - implements the Rotterdam Convention in the EU
  - UNEP (Geneve) and FAO (Rome) are managing the convention
  - Scope
    - » certain hazardous chemicals that are subject to the prior informed consent procedure under the Convention (the ‘PIC procedure’);
    - » certain hazardous chemicals that are banned or severely restricted within the Union or a Member State;
    - » chemicals when exported in so far as their classification, labelling and packaging are concerned

PIC Regulation - Export of chemicals

GREEN CHEMISTRY CHANGE MANAGER

- Objectives
  - international cooperation in the transfer of dangerous chemicals
  - protection of human health and the environment
  - exchange of information about
    - properties of chemicals
    - adequate storage
    - adequate transport conditions
    - use(s)
    - adequate disposal

Banned or severely restricted - Annex I

- Export notification for all chemicals in Annex I, Part 1 via
  - Check of the export notification by the competent authority of the exporting member state
  - Assignment of a RIN-number by ECHA
    - » RIN number part of the customs declaration

Banned or severely restricted - Annex I

GREEN CHEMISTRY CHANGE MANAGER

- Explicit consent requirement
  - PIC notification: chemicals in Annex I, Part 2
  - PIC procedure: chemicals under the Rotterdam Convention in Annex I, Part 3
- Export only possible
  - with valid explicit consent granted by the Designated National Authority (DNA) of the importing country outside the EU necessary
  - or granted in exceptional cases

Interface REACH

GREEN CHEMISTRY CHANGE MANAGER

- SDS necessary for export of relevant substances
  - The information on the label and on the safety data sheet shall as far as practicable be given in the official languages, or in one or more of the principal languages, of the country of destination or of the area of intended use.
- Classification and labelling for export of relevant substances
  - expiration date (for different climate zones) and production date indicated on the label, where appropriate
- REACH restriction and authorisation relevant
- Registration may be relevant for exported substances

Putting in perspective to Green Chemistry

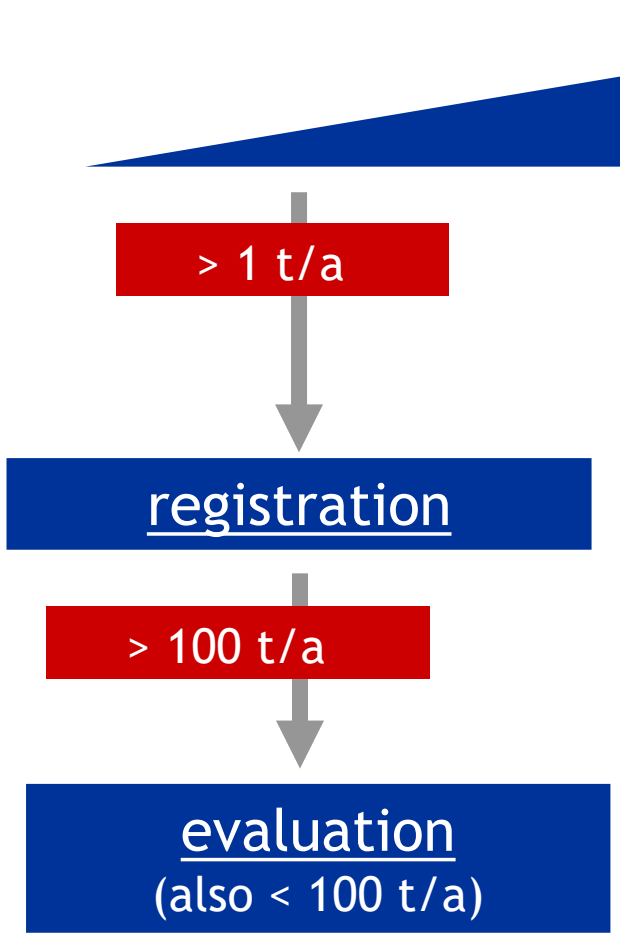
- Restricts and regulates exports of a number of problematic chemicals.
- A global framework for chemicals with some solid rules.

SCIP-system

GREEN CHEMISTRY CHANGE MANAGER

- Before we discuss SCIP, a short excursion back to the REACH-regulation

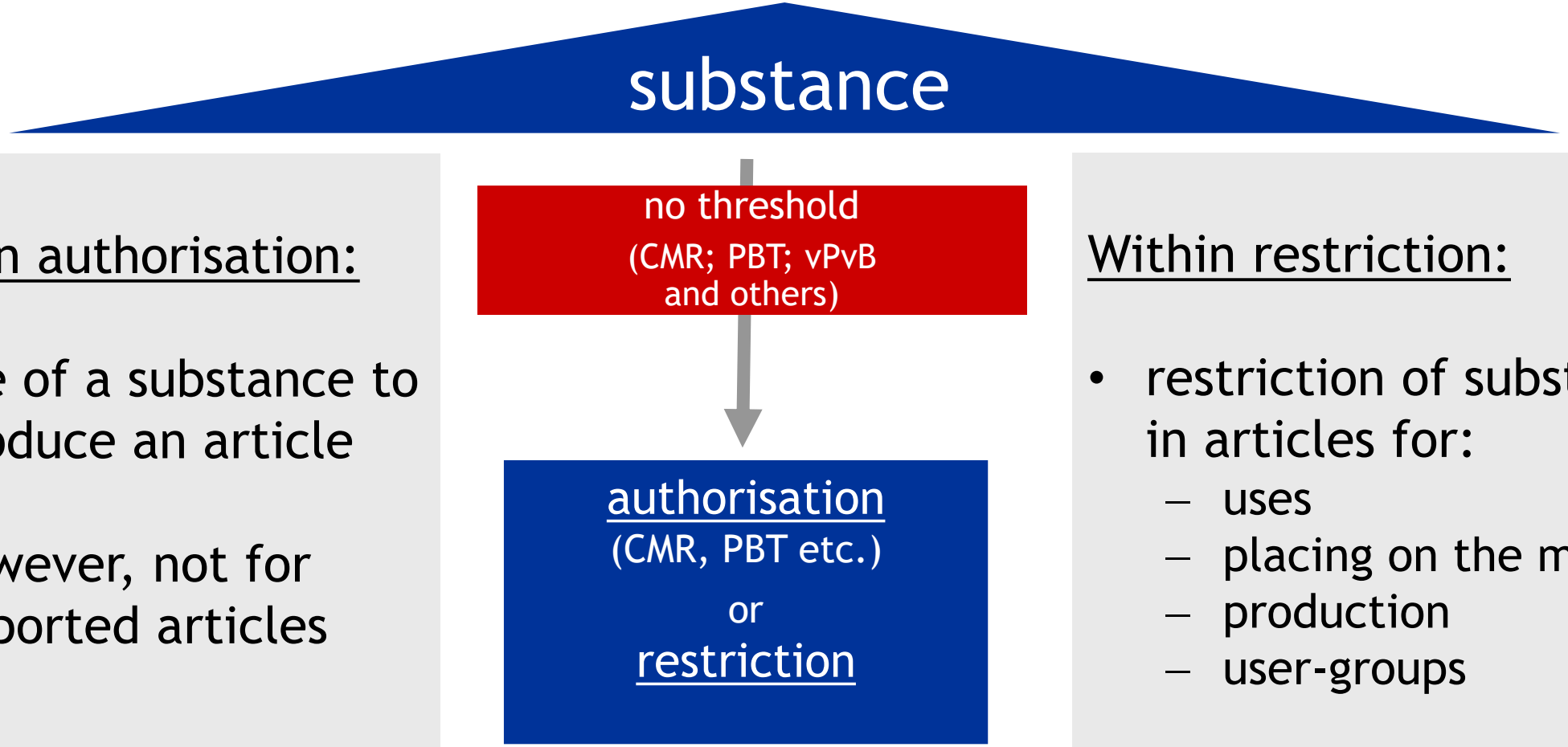
Articles under REACH



Within registration:

- use of a substance to produce an article
- and as a consequence for the CSA
- notification/registration acc. art. 7

Articles under REACH



Within authorisation:

- use of a substance to produce an article
- however, not for imported articles

Within restriction:

- restriction of substances in articles for:
  - uses
  - placing on the market
  - production
  - user-groups

Articles under REACH

GREEN CHEMISTRY CHANGE MANAGER

substance

information-flow:

- art. 33 for SVHC
- a SDS is legally not necessary for articles

no threshold

information in the supply chain

(extended) safety data sheet

notification of uses / relevant information by the DU

What are articles?

GREEN CHEMISTRY CHANGE MANAGER

3. articles:

“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;”

What are articles?

GREEN CHEMISTRY CHANGE MANAGER

3. articles:

“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;”

→ crucial criteria for the borderline to substance/mixture

Examples

GREEN CHEMISTRY CHANGE MANAGER

- laptop → complex object
- crayon → mixture/substance

- bottle → article
- bottle with benzene → article with substance

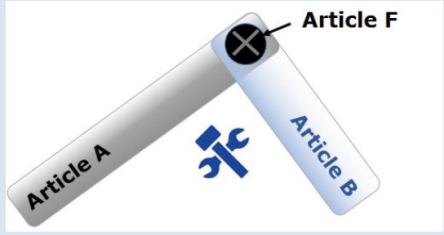
- printer-ink cartridge → article/comp.obj. with mixture
- ski-wax → mixture/substance

What are complex objects?

- There is no legal definition of “complex object”, but a consequence of the ECJ Case C-106/14
- The TGD addresses it as:

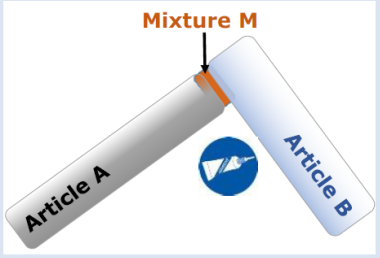
  “*any object made up of **more than one article**. In complex objects, several articles can be joined or assembled together in various manners. The more articles it is made of, the more complex an object becomes.*”

- 2 main types



A) Articles mechanically assembled (i.e. articles assembled without the incorporation of substance(s)/mixture(s))

Example(s): pair of (metallic) scissors, foldback clips



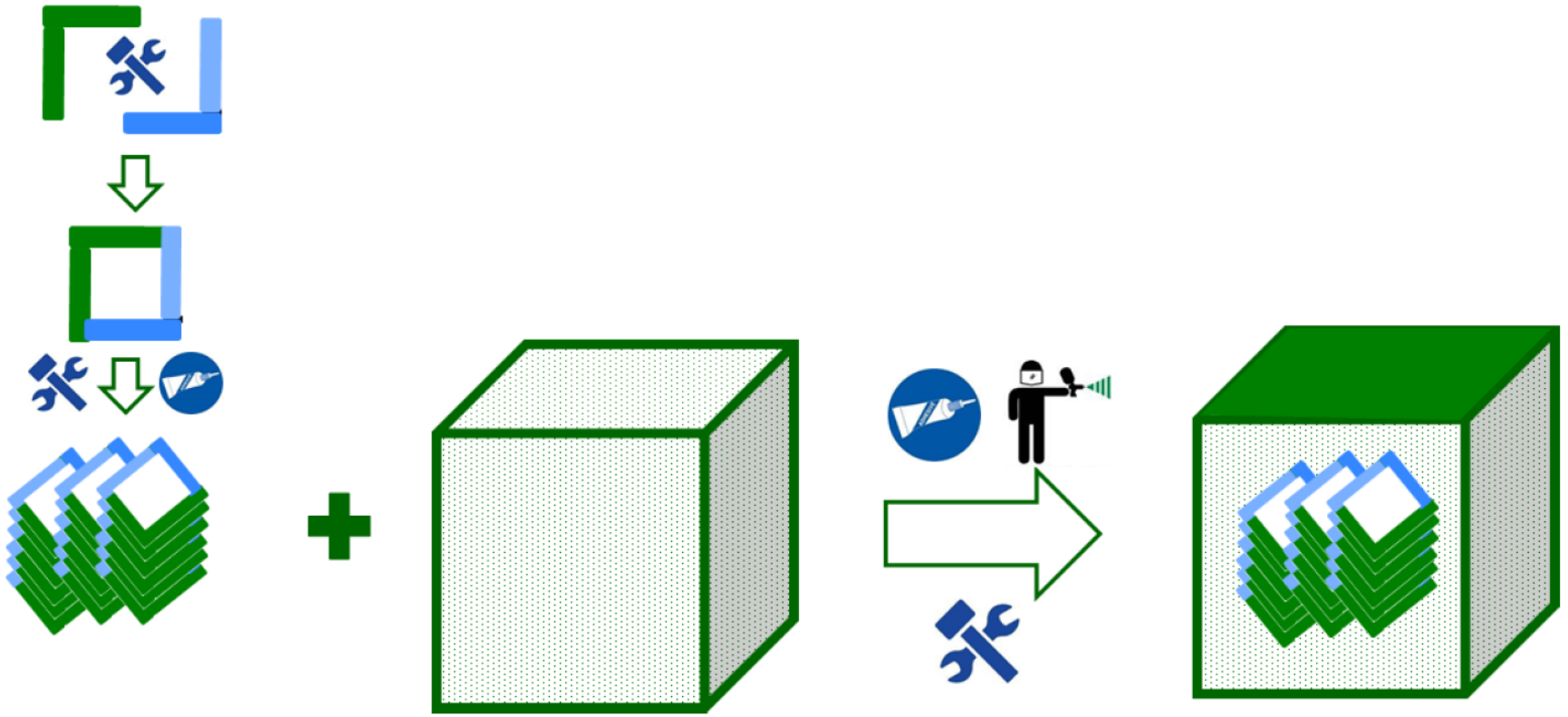
B) Joining together two or more articles using substance(s)/mixture(s)

Example(s): block of sticky notes, glued chip in a bank card, unpainted bicycle frame formed by welding together multiple steel tubes.

Complex objects

GREEN CHEMISTRY CHANGE MANAGER

- And the “Very complex object”



The candidate list and article 33

GREEN CHEMISTRY CHANGE MANAGER

- SVHC are not restricted, banned or similar. However, there is a growing market-pressure to remove such substances.

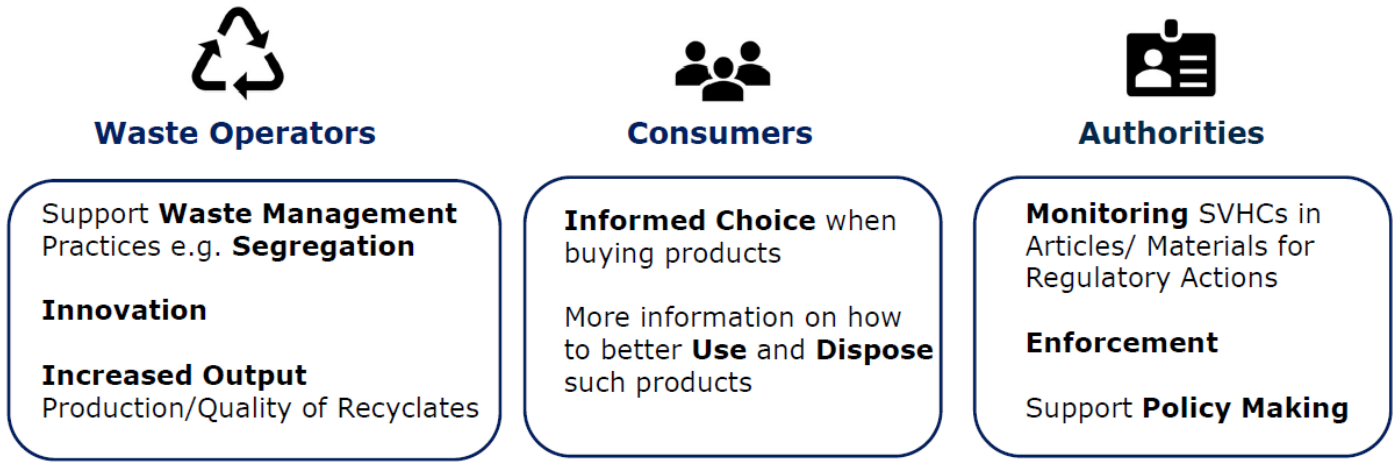
- Legally there are direct consequences related to the communication in the supply chain and on the import of articles:
  - SDS necessary for candidate substances
  - information for articles, if SVHC-content is 0,1 m% or more (article 33)
    - » active information-obligation to professionals
    - » on request to private-consumers (45 days to react)
  - need to consider complex object as well

= „extension“ of REACH?

- **SCIP** stands for “Database for information on **S**ubstances of **C**oncern **I**n articles as such or in complex objects (**P**roducts)”
- Basis is art. 9 of the Waste Frame Directive (WFD)
- A supplier of an article has to make information acc. 33 (1), REACH available
- in force since 5 January 2021
- ECHA needed to establish and maintain a database

= „extension“ of REACH?

- The main objective of the database is to improve recycling / waste-treatment



(Source: ECHA)

- ECHA has to give DB-access to waste-operators
- Also consumers can have access

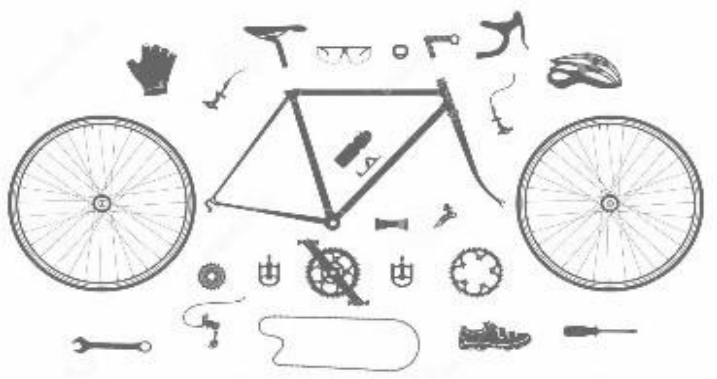
→ **Dissemination tool available since 14 September 2021**

https://echa.europa.eu/de/scip-database

WHAT needs to be notified?

- An article contains a SVHC ≥ 0,1 m%, with this we need to consider a notification for:
  - the relevant article(s) as such

  - articles in complex object(s)



Source: ECHA

WHO needs to notify?

GREEN CHEMISTRY CHANGE MANAGER

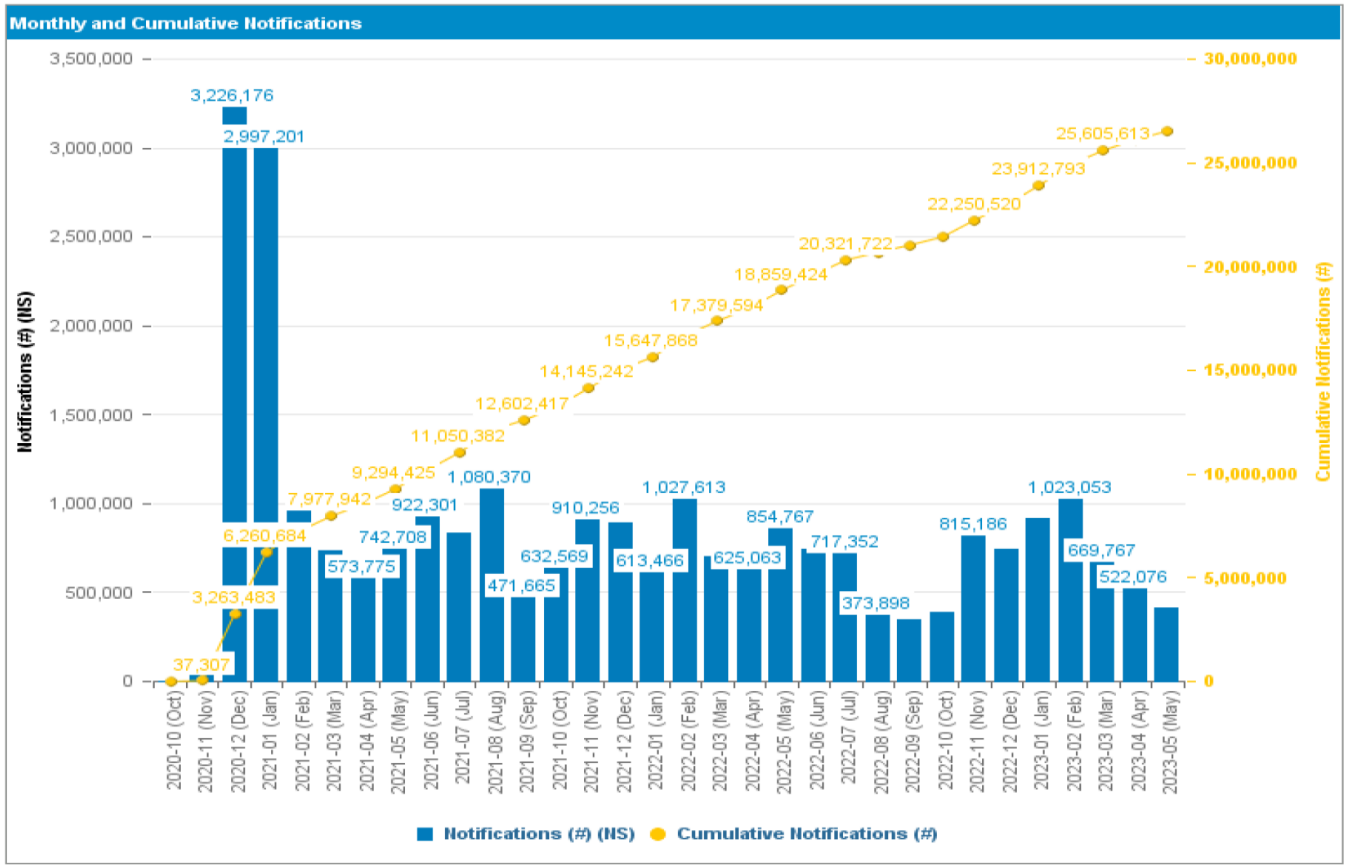
- Supplier of articles:
  - Producer of articles / complex objects
  - assembler
  - importer of articles / complex objects
  - distributor of articles / complex objects

- Supplier means every supplier, not only the one, who puts an article for the 1st time on the EU market.

- Exemptions acc. art. 2 (6), REACH, e.g. certain medical products for end-users and for pure B2C suppliers.

- A bit confusing is the situation of imports for internal use, means no supply to other EU-actors.

What to expect?



Period 26/Oct/2020 to 29/May/2023

Today >30 mio. notifications from ~10.000 legal entities

→ growing at a steady rate

Public DB contains

>10 mio. articles

~95% entries contain Pb

no numbers on activities by consumers nor waste-operators

Source: ECHA

What to expect?

GREEN CHEMISTRY CHANGE MANAGER

- Ecodesign regulation
  - sees SCIP as prototype for the Digital Product Passport
  - full material declaration

- General trend in the EU
  - more transparency demanded by:
    - » NGOs
    - » recyclers
    - » certain industrial sectors

→ SCIP is not perfect, but it certainly is a prototype for more to come.

Putting in perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- Transparent supply chains.
- Promoting recycling.
- Pushing substitution.
- Shows direction, where the EU is heading to.

Overall perspective to Green Chemistry

GREEN CHEMISTRY CHANGE MANAGER

- EU has lots of legislation on chemicals.
- Nothing is really pushing towards Green Chemistry.
- BUT nothing is really pushing away from it.
- Many elements are making chemistry greener.
- A clear(er) direction will be given by the Chemicals Strategy for Sustainability.

Conclusions

GREEN CHEMISTRY CHANGE MANAGER

- 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!

Marko Sušnik
Wirtschaftskammer Österreich
E: marko.susnik@wko.at

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Exercise

- **Let´s develop a new concrete product for the EU-market.**
- Now:
  - Analyse the relevant EU-legislation and discuss the relevance for Green Chemistry.
  - For this:
    - organise in two groups of 4;
    - you have 25 minutes working time;
    - then each group presents her results;
    - continued by a joint discussion and analysis.