Zero PM workshop, Gothenburg 7-8 February 2023

Updates and Perspective from the European Commission

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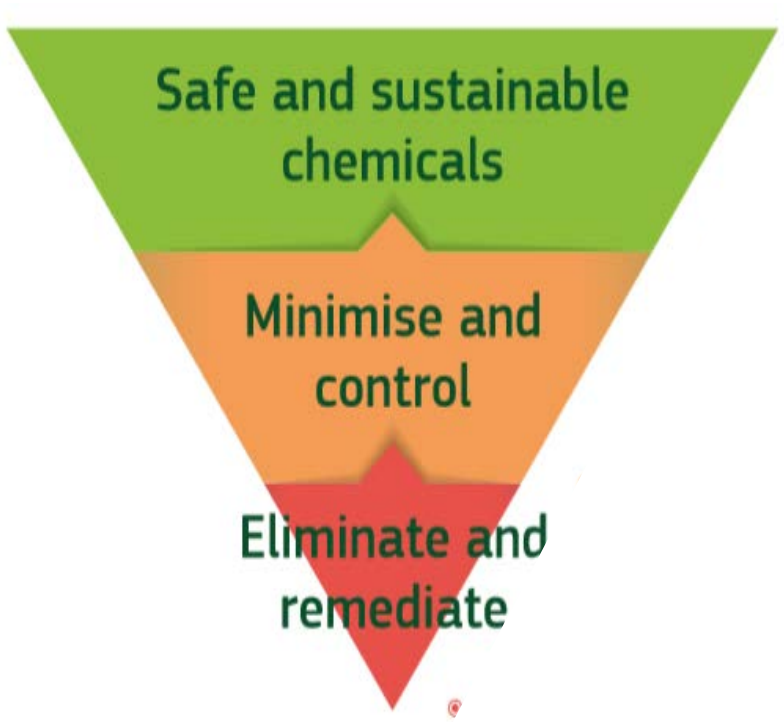
#ChemicalsStrategy
#EUGreenDeal

European Commission

2030 vision – towards a toxic-free environment



- Chemicals are produced/used in a way that **maximises their benefits to society** while **avoiding harm to planet & people**
- Production and use of **safe and sustainable chemicals** becomes the EU market norm and a global standard

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Chemicals Strategy for Sustainability

Boosting innovation

- Commission recommendation on safe and sustainable by design criteria
- Innovation and research financing
- Generic do no significant harm criteria for chemicals under taxonomy

Strengthening legislation for better protection

- CLP regulation
- REACH
- Cosmetics product regulation
- Toy safety directive
- Food contact materials legislation
- Food additives legislation
- Food contaminants legislation
- Staff working document on essential use criteria

Simplification & coherence

- Horizontal proposal on (re-)attribution of technical work on chemicals to EU Agencies
- Horizontal proposal on improving access, sharing and re-use of chemical data
- Proposal for a basic regulation of the European Chemicals Agency

Knowledge and science

- Research and innovation plan for chemicals
- Research funding
- European partnership for the assessment of risks from chemicals
- Indicator framework

Global

- Export ban on chemicals banned in the EU
- Proposal of new hazard classes to UN Global Harmonised System for Classification
- Funding for developing countries

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Information on properties of chemicals

- Horizontal: **REACH (Registration + Evaluation)**
- Sectorial: Plant protection products, biocides

REACH revision: more information on chemicals and their hazards

Identification of hazards

- Horizontal: CLP, **REACH**
- Sectorial: Plant protection products, biocides, carcinogens, mutagens and chemical agents at work

CLP revision: new hazard classes for ED, PBT, vPvB, PMT, vPvM and their harmonised classification

Managing risks

- Horizontal: **REACH (Restrictions + Authorisations)**
- Sectorial legislation on: plant protection products, biocides, cosmetics, toys, detergents, water, waste, industrial emissions, worker safety, eco-design, food contact materials, industrial accidents…

REACH revision: ED, PBT, vPvB and other substances with harmonised classification restricted for consumer and some professional uses (GRA)

Non regulatory actions

Eco-design for Sustainable Products Regulation

Taxonomy

Ecolabels

CLP Delegated act for new hazard classes

- Draft published for consultation on "Have your say" 20 September – 18 October 2022 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13578-Introducing-new-hazard-classes-CLP-revision_en

- Adoption: 19th December 2022 after CARACAL discussion and WTO TBT notification
- Publication: Q1 2023 after scrutiny period (EU Parliament + Council)
- Transitional period: 24 months for substances and 42 months for mixtures

New hazard classes => GUIDANCE (ECHA expert groups)

- Endocrine Disruptors for human health and environment Cat. 2
- Persistent Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB)
- Persistent Mobile and Toxic (PMT) and very Persistent and very Mobile (vPvM): 110 substances with harmonized C&L by 2042; out of max 700 substances.

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Setting the example globally

- Propose the **new hazard classes** for the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)**

- 43rd session of the GHS Sub-Committee (7 to 9 December 2022): discussion on the EU Proposal for new work on unaddressed hazard classes in the programme of work for the biennium 2023-2024.

- If It was agreed to start the work will during the biennium 2023-2024.

- To define by mid-2023 the scope of the mandate to OECD on the science needed to identify endocrine disruptors (EDs). Considering the state of science in testing chemicals for ED properties, the OECD mandate could focus on the currently well-described ED-related pathways, such as oestrogen-, androgen-, thyroid- and steroid modalities in both humans and the wildlife. The work by the OECD informal working group may extend beyond the end of 2024, depending on the progress of discussions. This task might, therefore, continue in the next biennium.

- To elaborate criteria for PBT/vPvB substances and PMT/vPvM substances. It is suggested to focus first on persistency and toxicity (as common properties to hazards under definition); and then on bioaccumulation and mobility. It is estimated to conclude the work on the former by the end of the 2023, and to conclude the work on the latter by end of 2024.

Adequate classification of critically hazardous chemicals

Adequate classification of critically hazardous chemicals will be ensured by:

- introducing ED, PBT, vPvB, PMT or vPvM as new hazard classes in the CLP Regulation and prioritising them for harmonised classification;
- allowing the Commission to initiate and fund more harmonised C&L dossiers, including by mandate to ECHA. ECHA could produce 250 harmonised C&L dossiers in 20 years.
- initiating harmonised C&L dossiers for several substances (grouping) ;
- Inclusion of listed SVHCs (up to the eif of the DA) into annex VI
- More than One Constituent Substances' (MOCS) rules + bridging principles (WoE);
- publishing the reasons for diverging notified self-classifications in ECHA's classification and labelling inventory, along with the names of the notifiers;
- requiring updates of notifications of self-classifications within 6 months ;

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REACH Revision/Registration

- More information on critical hazard properties (chronic toxicity, endocrine disruption, Mobility etc.) to ensure hazard identification and risk assessment but no change for Persistency (still lack of a good screening method for persistency)
- Non-animal testing
- Registration of certain polymers of concern
- More information on use and exposure
- Mixture assessment factor

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REACH Revision/Restrictions GRA

- Extend the use of the Generic Approach for Risk Management (Article 68(2) on consumer products)
  - Endocrine disruptors, PBT/vPvBs (first step?)
  - Immunotoxicants, neurotoxicants, respiratory sensitisers, STOTs (later?), PMT/vPvM (?)
- Extend to products for some professional uses => still to be decided
- Exempt essential uses : Only possible derogation?
- Implementation plan: to be discussed at CARACAL in March:
  - Stepwise approach: priority to consumer mixtures, which additional hazard classes to start with, which consumer articles (generic criteria: potential of exposure, daily uses, vulnerable people) and potential examples, initiate discussion on different types of professional uses workers like or consumers like)

The use of a most harmful chemical will only be allowed if:

- The use is necessary for health, safety or is critical for the functioning of society, and
- There are no alternatives that are acceptable from the standpoint of environment and health

REACH Revision/Restriction & Authorisation Reform

- Early information on substance that could be subject to regulatory action (One Substance One Assessment)
- Obligation for DU to submit detailed information (uses, alternatives, volume) on substance in candidate list or other regulatory lists
- Aim for a better, more informed and collegial decision on which regulatory tool(s) is/are more appropriate for a specific substance
- Simplify and acceleration of the procedure
  - Essential uses derogation but sill obligation to minimise exposure
  - Limited scope for authorisation
  - Other legislation (Occupation Health Safety, Industrial Emission Directive)
  - Derogation of general applicability
  - Upfront exemptions by authorithies

REACH - Indicative timing of actions

- Supporting actions and studies – **Q1 2021 to Q4 2022**
- Impact Assessment – **Positive RSB opinion,** IA to be updated
- Drafting proposals for revision of REACH – **2022/2023**
- Commission adoption of legislative proposal – **Q4 2023 at the latest**
- Comitology acts – **to be defined**

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TRANSPARENCY

- Stakeholders are timely informed and have access to underlying data

Initiation

- Synchronised and coordinated
- Assessments of groups of substances

Allocation

- Clear responsibilities
- Making best use of available resources and expertise
- Good governance and cooperation

Data

- Easily findable, accessible, interoperable, secure, of high quality
- Shared and reused by default

Methodologies

- Coherent
- To the extent possible harmonised
- Hazard assessment centralised under CLP Regulation

Improving coherence, efficiency and effectiveness of safety assessments across legislation

One substance, one assessment

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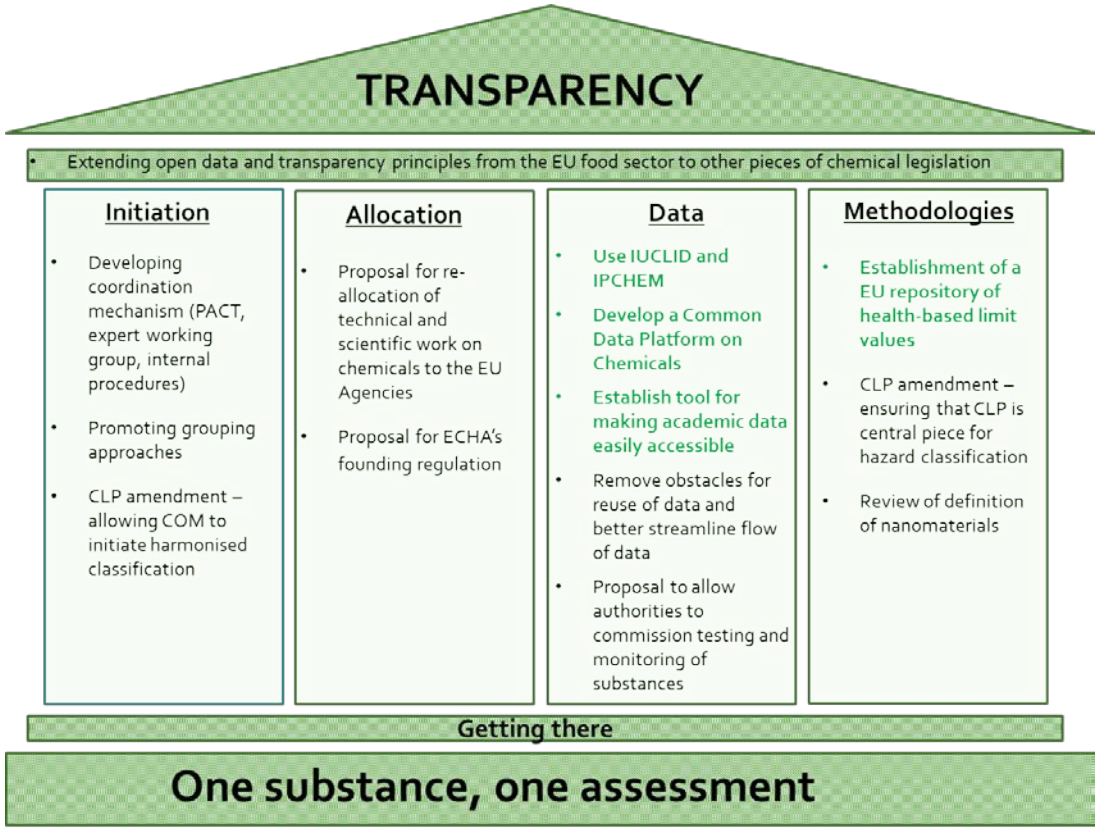
Work on data



- Common open data platform on chemicals
  - By Q2/Q4 2023
  - A single access point to data and information on chemical in the EU
- Making data available in appropriate formats
  - Progressively
  - IUCLID for hazard and use data; IPCHEM for monitoring data
- Centralised EU repository of human and environmental health-based limit values
  - Progressively (data platform)
  - To promote reuse of health-based limit values
- Tools for making academic data suitable and easily available for regulatory purposes
  - By 2023 (OECD project)

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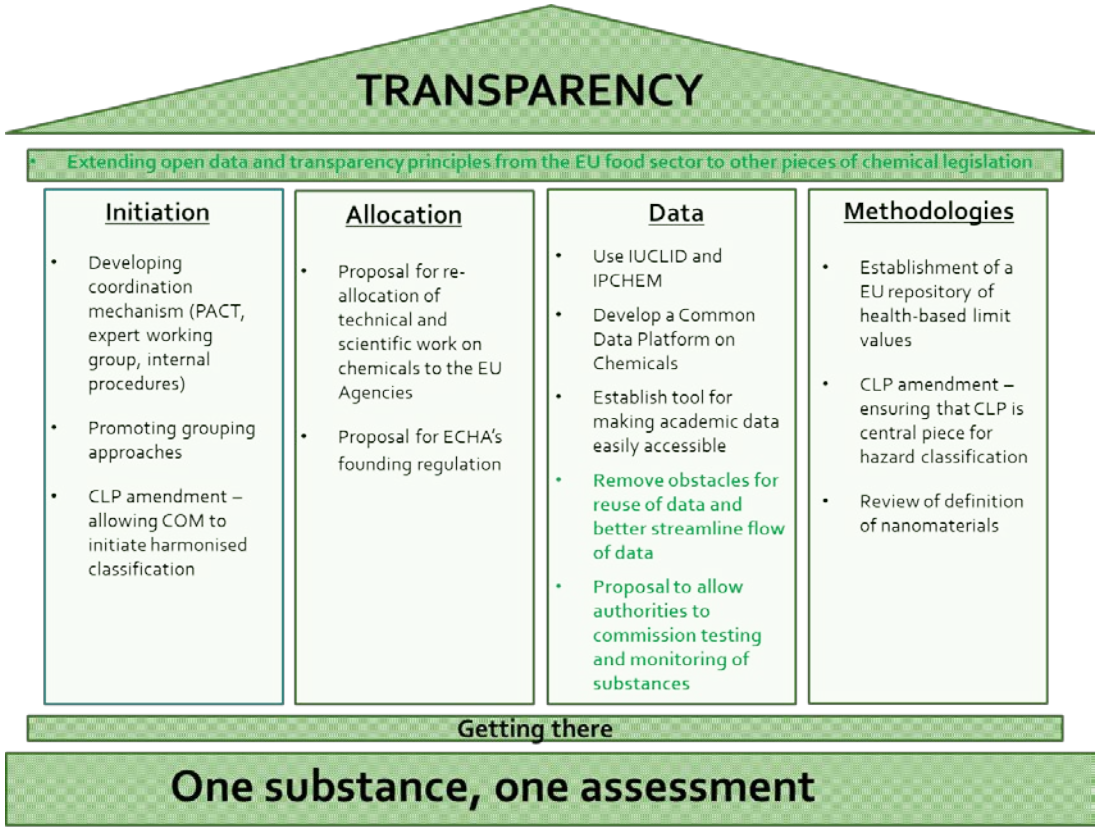
Horizontal proposal on data



- Omnibus regulation amending provisions on data handling and reporting in the individual pieces of legislation:
  - Implement the vision to streamline all data on chemicals through the EU Agencies
  - Ensure re-use of data across Agencies, services, legislation and across legislative silos
  - Extend the open data and transparency principles from the EU food sector to other pieces of chemical legislation
  - Allow authorities to commission testing and monitoring of substances
- By 2023

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In conclusion

Environmental monitoring:

- Informs every step of policy making: from evaluating our policies, to developing a strategy, to implementing the strategy, to revising the chemicals legislation
- Confirms the need to act and not only to assess the effectiveness of regulatory measures
- Provides an overall assessment of exposure of Europe's environment to (mixtures of) chemicals
- Apex, like HBM4EU project, laid some basis for the new PARC project
- possibility of using environmental monitoring for more regular data generation on wildlife exposure

… towards a toxic-free environment

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Boosting innovation

Promote the transition to safe and sustainable chemicals, materials and products

- Develop EU safe and **sustainable-by-design criteria**
- Achieve **non-toxic material** cycles in circular economy
- Establish **Research and innovation agenda** for chemicals

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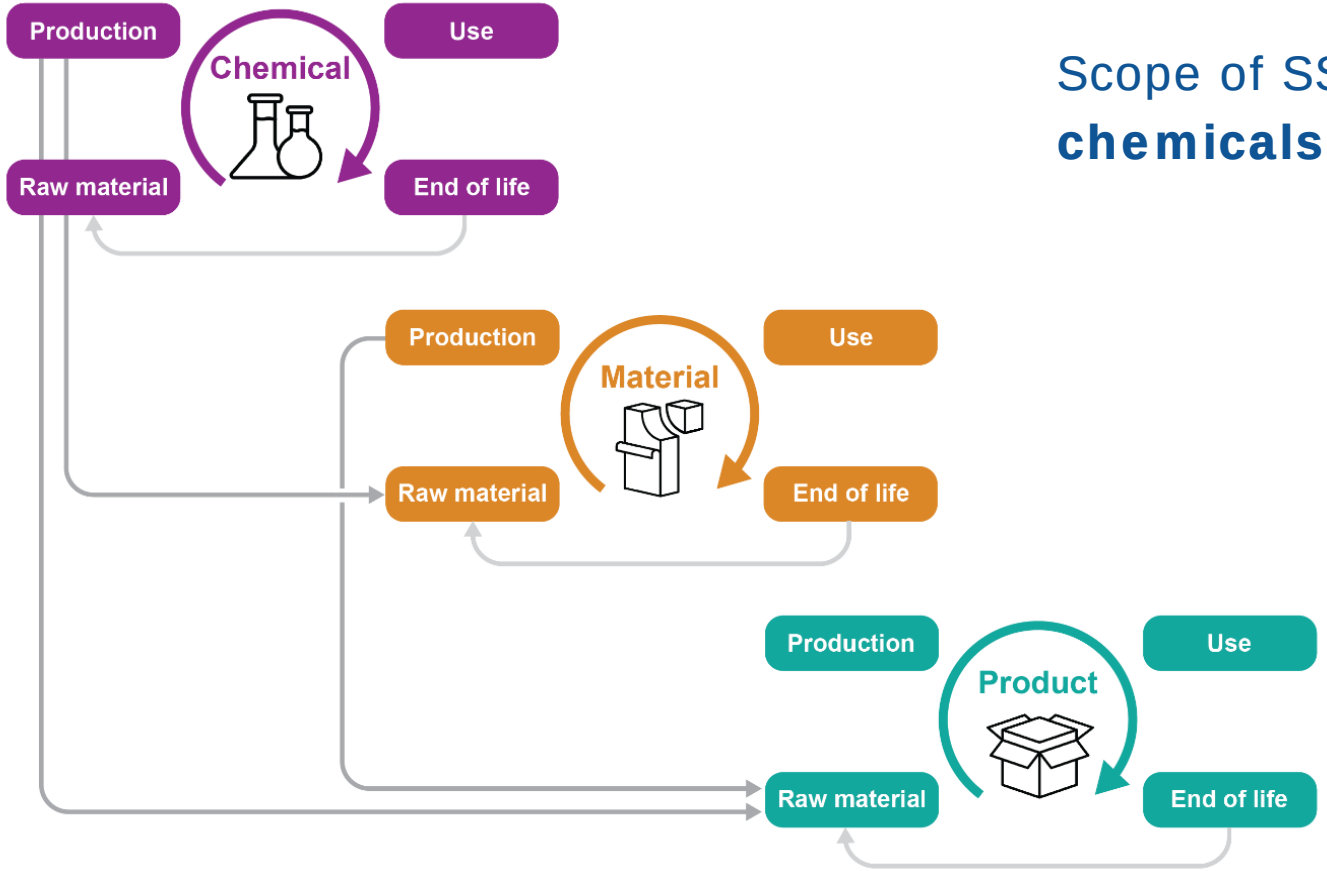
The concept

Safe and sustainable by design (SSbD) is an approach to the design, development and use of chemicals and materials that focuses on providing a **function** (or service), while **reducing harmful impacts** to human health and the environment.



Scope of SSbD:
chemicals and materials

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Other EU related initiatives

- Proposal for Ecodesign for Sustainable Products Regulation will improve EU products' circularity, energy performance and other environmental sustainability aspects
- Green claims
- Products specific (e.g. batteries)
- Sustainable finance/taxonomy
- Green public procurement
- Eco-label

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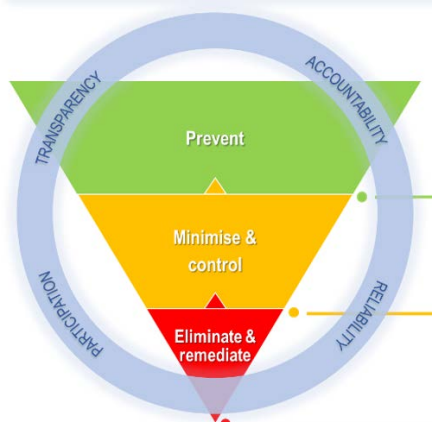
Recast Drinking Water Directive – State of Play

- Adoption by Council and European Parliament – 16 December 2020
- Publication in the Official Journal (OJ)

  http://data.europa.eu/eli/dir/2020/2184/oj – 23 December 2020
- Entry into force 20 days after publication in OJ – 12 January 2021
- Member States had 2 years to transpose into national law and to comply with provisions after date of entry into force – **12 January 2023**

Commission strategy on PFAS

- PFAS are a concern → Chemicals Strategy for Sustainability
- Ban all PFAS under REACH except for essential use
  - *ECHA to prepare a restriction dossier on all PFAS in fire-fighting foams*
  - *Preparatory work for a group restriction on all uses of PFAS (except essential uses): NL, DE, SE, DK and NO*
- Zero Pollution Action Plan for air, water and soil



Provisions on PFAS in the recast DWD

- Recast DWD
  - *'Sum of PFAS': 0.1 µg/l (compliance by Jan 2026)*
  - *'PFAS Total': 0.5 µg/l (compliance by Jan 2026)*
  - *By January 2024: COM to establish technical guidelines on analytical methods*
  - *MS can decide to use or both parameters after establishment of technical guidelines*
  - *Review Annex I & II (parametric values): at least every 5 years*
    - In light of technical and scientific progress / results of risk-based approach (data sets MS)
    - Legislative proposal (no Implementing/Delegated Act)
  - *Amend Annex III (PFAS substances): Delegated Act (COM empowered)*

PFAS: food and water related EU legislation

- COM's Zero Pollution Package proposal adopted 26 Oct 2022

  (consists of 3 elements)

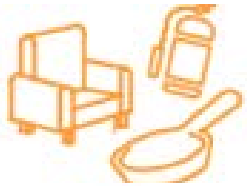
  1. **A proposal Integrated water management – revision lists of pollutants in surface water and groundwater (WFD, GWD, EQSD);**
  2. A proposal to revise the Urban Wastewater Treatment Directive
  3. A proposal to revise the Ambient Air Quality Directives.

EQSD: Environmental Quality Standards Directive
GWD: Groundwater directive
WFD: Water Framework Directive

PFAS: food and water related EU legislation

- Food Contaminants Regulation
  - *EFSA opinion: https://www.efsa.europa.eu/en/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake*
  - *Tolerable Weekly Intake of 4.4 ng/kg bw*
  - *Discussion started with MS to set maximum levels (MTC) in food*
  - *Intention of some MS to 'translate' EFSA opinion for food into drinking water parametric values for the group of 4 PFAS (PFOS, PFHxS, PFOA,PFNA)*

Surface water - 25 new emerging pollutants

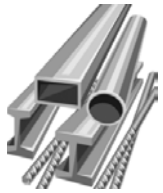


PFAS: Additional 24 substances

Bisphenol-A

Pharmaceuticals: *Macrolide antibiotics, Estrogenic hormones, Carbamazepine, Diclofenac, Ibuprofen*

Pesticides: *Triclosan, Nicosulfuron, Glyphosate, Neonicotinoids, Pyrethroids,*
of active substances in pesticides
(incl. their relevant metabolites, degradation and reaction products)



Metal: Silver

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Surface water substances – 24 PFAS

The 24 PFAS included in the (WFD, EQSD, GWD) proposal were selected based on the following criteria:

i. (eco)toxicity data and physico-chemical parameters including analytical methods;
ii. availability of the relative potency factor (RPF)
iii. (most) recent PFAS on the market;
iv. Possible coherence with other directives.

PFAS: Additional 24 substances

¤	Acronym·¤	CAS·number¤	Per–and·polyfluorinated·congeners¤
1¤	PFBA¤	375-22-4¤	Carboxylic·acid¤
2¤	PFPeA¤	2706-90-3¤	Carboxylic·acid¤
3¤	PFHxA¤	307-24-4¤	Carboxylic·acid¤
4¤	PFHpA¤	375-85-9¤	Carboxylic·acid¤
5¤	PFOA¤	335-67-1¤	Carboxylic·acid¤
6¤	PFNA¤	375-95-1¤	Carboxylic·acid¤
7¤	PFDA¤	335-76-2¤	Carboxylic·acid¤
8¤	PFUnA·or·PFUnDA¤	2058-94-8¤	Carboxylic·acid¤
9¤	PFDoDA·or·PFDoA¤	307-55-1¤	Carboxylic·acid¤
10¤	PFTrDA¤	72629-94-8¤	Carboxylic·acid¤
11¤	PFTeDA¤	376-06-7¤	Carboxylic·acid¤
12¤	PFHxDA¤	67905-19-5¤	Carboxylic·acid¤
13¤	PFODA¤	16517-11-6¤	Carboxylic·acid¤
14¤	PFBS¤	375-73-5¤	Sulfonic·acid¤
15¤	PFPeS¤	2706-91-4¤	Sulfonic·acid¤
16¤	PFHxS¤	355-46-4¤	Sulfonic·acid¤
17¤	PFHpS¤	375-92-8¤	Sulfonic·acid¤
18¤	PFOS¤	1763-23-1¤	Sulfonic·acid¤
19¤	PFDS¤	335-77-3¤	Sulfonic·acid¤
20¤	6:2·FTOH¤	647-42-7¤	Telomer·alcohol¤
21¤	8:2·FTOH¤	678-39-7¤	Telomer·alcohol¤
22¤	HFPO-DA·(Gen·X)¤	62037-80-3·¤	Ether·carboxylic·acid¤
23¤	ADONA¤	958445-44-8¤	Ether·carboxylic·acid¤
24¤	C6O4¤	1190931-41-9¤	Ether·carboxylic·acid¤

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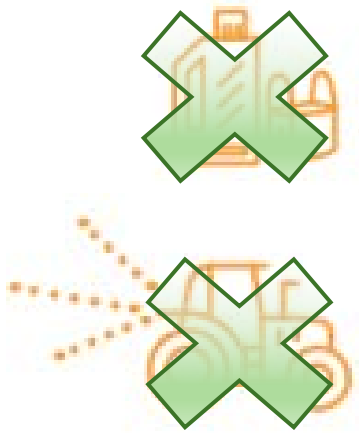
Annex I EQSD – Surface water priority substances- **deselections**

Substances that no longer pose an EU-wide risk



Carbon tetrachloride

Pesticides: *Alachlor, Chlorfenvinphos, Simazine*

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Annex I EQSD – Surface water priority substances–EQS **changes**

For 16 existing substances - In some cases more stringent in others less stringent

(Chlorpyrifos, Dioxins, Diuron, Cypermethrin, Fluoranthene, Heptachlor, Hexachlorobenzene, Mercury Hexachlorobutadiene, Nickel, Nonylphenol, PAHs, PolyBDEs, Tributyltin, Dicofol, Hexabromocyclododecane).

No.	Substance	Category of substances	CAS number	AA-EQS fw [µg/L]	AA-EQS mw [µg/L]	MAC-EQS fw [µg/L]	MAC-EQS mw [µg/L]	EQS biota [µg/kg$_{ww}$]
9	**Chlorpyrifos**	Organophosphate pesticid	2921-88-2	4,6 x 10^{-4}	4,6 x 10^{-5}	0,0026	5,2 x 10^{-4}	
41	**Cypermethrin**	Pyrethroid pesticides	52315-07-8	3 x 10^{-5}	3 x 10^{-6}	6 x 10^{-4}	6 x 10^{-5}	
34	**Dicofol**	Organochlorine pesticides	115-32-2	[4,45 x 10^{-3}]	[0,185 x 10^{-3}]	*not applicable*	*not applicable*	[5,45]
37	**Dioxins and dioxin-like compounds**	Industrial substances	This refers to the f	-	-	*not applicable*	*not applicable*	Sum of PCDD+ PCDF+ PCB-DL; [3,5 x 10^{-5}]
13	**Diuron**	Herbicides	330-54-1	0,049	0,0049	0,27	0,054	
15	**Fluoranthene**	Industrial substances (PAH	206-44-0	7,62 x 10^{-4}	7,62 x 10^{-4}	0,12	0,12	6.1
44	**Heptachlor and heptachlor epoxide**	Organochlorine pesticides	76-44-8 / 1024-57-	[1,7 x 10^{-7}]	[1,7 x 10^{-7}]	3 x 10^{-4}	3 x 10^{-5}	[0,013]
43	**Hexabromocyclododecane (HBCDD)**	Industrial substances	This refers to 1,3,5	[4,6 x 10^{-4}]	[2 x 10^{-5}]	0,5	0,05	[3,5]
16	**Hexachlorobenzene**	Organochlorine pesticides	118-74-1			0,5	0,05	20
17	**Hexachlorobutadiene**	Industrial substances (solve	87-68-3	9 x 10^{-4}		0,6	0,6	21
21	**Mercury and its compounds**	Metals	7439-97-6			0,07	0,07	10
23	**Nickel**	Metals	7440-02-0	2	3.1	8,2	8,2	
24	**Nonylphenol**	Industrial substances	84852-15-3	0,037	0,0018	2,1	0,17	
28	**Polyaromatic hydrocarbons (PAHs)**	Industrial substances (PAHs)	not applicable	not applicable	not applicable	not applicable	not applicable	[0,6] (sum of BaP equivalent, waiting for the SCHEER opinion)
5	**Poly Brominated Diphenylethers (PE**	Industrial substances	32534-81-9			0,14	0,014	0,00028
30	**Tributyltin (TBT) compounds**	Biocides	36643-28-4	0,0002	0,0002	0,0015	0,0015	1,3 µg/kg$_{dw}$ (sediment)

List of Existing PS EQS dossiers- Review
Table with the list of reviewed EQS values of existing PS. Comparison with the existing EQS values in the WFD: orange rows when proposed EQS value is stricter and green rows when the proposed EQS value is less strict than the existing one in the WFD.

Groundwater substances

PFAS: Additional 24 substances
(the same 24 PFAS as proposed for surface water)

Pesticides: additional breakdown products, non-relevant Metabolites (nrMs) to Annex I (EU-wide standards) as individual substances and as a group.

Pharmaceuticals:

- 2 additions to Annex I (EU-wide standards): Carbamazepine & Sulfamethoxazole and
- Group total standard for active pharmaceutical subst.

Add 1 (Primidone) to Annex II (MS to consider setting a national standard).

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Solvents and Chelating agents considered for the GW Watch List

No of sites with detections	Countries monitoring	Countries with detections	Countries with detections >°9°sites	Substance	CAS number	Score N°PC	% detect.	Score % N°sites	Proved gw leaching pot. score	Theoretical gw leaching score	Comb. gw leaching score	Watch List?	PMT Classifi.
203	6	4	2	Tetrahydrofuran	109-99-9	0,8	11,95	0,6	0,7	0,5	**0,6**		
174	6	6	3	1,4-Dioxane	123-91-1	1	2,28	0,3	0,65	0,5	**0,575**	WL	PMT
87	13	7	2	1,2,3-Trichlorbenzene	87-61-6	1	0,83	0,2	0,6	0,55	**0,575**	WL	vPvM
303	8	4	3	Chloroethane	75-00-3	0,8	3,15	0,4	0,6	0,5	**0,55**	WL	vPvMT
3003	3	3	3	Trifluoroacetic Acid	76-05-1	0,6	81,14	0,9	0,75	0,3	**0,525**		
152	5	3	2	Tert-butanol	75-65-0	0,6	9,16	0,5	0,55	0,5	**0,525**		
64	5	4	2	NTA	139-13-9	0,8	0,80	0,2	0,5	0,5	**0,5**		
87	4	2	2	Diisopropylether	108-20-3	0,4	4,93	0,4	0,4	0,5	**0,45**		
1443	1	1	1	Vinylchlorid	75-01-4	0,2	18,88	0,6	0,4	0,5	**0,45**		
29	9	3	1	Chloromethane	74-87-3	0,6	0,77	0,2	0,4	0,5	**0,45**	WL	vPvMT
97	10	6	3	1,3,5-Trimethylbenzene	108-70-3	1	0,62	0,2	0,6	0,3	**0,45**		
21	2	1	1	Tetraglyme	143-24-8	0,2	8,05	0,5	0,35	0,5	**0,425**		
14	3	2	1	DTPA acid	67-43-6	0,4	0,68	0,2	0,3	0,5	**0,4**		
14	10	2	1	n-Butylbenzene	104-51-8	0,4	0,15	0,05	0,225	0,5	**0,3625**		
1146	1	1	1	1,1-Dichlorethylen	75-35-4	0,2	15,46	0,6	0,4	0,3	**0,35**		
5	3	1	0	Diethylene glycol dimethyl ether	111-96-6	0,2	0,25	0,1	0,15	0,5	**0,325**	WL	vPvMT
204	13	4	2	1,1,2,2-Tetrachlorethane	79-34-5	0,8	2,57	0,4	0,6	0	**0,3**		
42	10	4	1	n-Propylbenzene	103-65-1	0,8	0,40	0,1	0,45	0,15	**0,3**		
0	1	0	0	2-Chlorethanol	107-07-3	0	0,00	0	0	0,5	**0,25**		

Substances (5) classified as **PMT, vPvMT and vPvM** should be prioritised[1]

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