PFAS regulation, data, collaboration. Presentation 9/7/2021 at the Flemish Parliament (minor corrections 15/07/2021)

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Corrections 2021-07-15

- ▶ point 3.2: GLP CLP
- ▶ point 6: last line was partially missing

1) Disclaimer - Status of the person speaking

- ► I am working for the Federal public service Health, food chain safety and environment
- ▶ I have been invited as expert, thus the views here do not represent the views of the FPS or the Federal government.
- ▶ I am expert on Federal, EU and international chemicals policy at the DG Environment of the FPS, with an environmental science background and represents Belgium in various international expert committees on chemicals including at ECHA and OECD.
- ▶ I will give my personal expert opinion within the limits of the duty for civil servants to exercise discretion

2) Presentation objectives

I have been reading with attention the presentations to this Committee from last week and will avoid repeating various scientific aspects regarding PFAS: they highlight very well the great concerns linked to this group of substances. My main focus will be on the <u>regulatory managment</u> on the PFAS as a group, the present <u>actions and possible ways forward</u>.

- Legally recognised hazards and Evolution of the PFAS regulation
- ► EU & international PFAS regulation
- Competence/jurisdictions in Belgium
- ► Federal actions on PFAS
- Cooperation federal/regions
- Expert opinion on future developments
- Conclusions

3) Specific PFAS hazards legally recognized

3.1) POP (Stockholm convention, Persistant organic pollutant)

- ▶ PFOS+related
- ► PFOA+related
- soon (very likely) PFHxS

3.2) Harmonised classfication (CLH) under the EU CLP regulation

System used for hazards classification related to the available evidence, example of Carc. substances:

- Category 1A Known to have carcinogenic potential for humans. Largly based on evidence from humans.
- Category 1B Presumed human carcinogens. Largly based on well performed animal studies.
- ► Category 2 Suspected human carcinogens. Human+animal evidence but not sufficient for 1A or 1B

3.2) Harmonised classfication (CLH) under the EU CLP regulation

Various long-chain:

- ▶ PFOS and related: Carc. 2, Repr. 1B, Lact., Acute Tox. 4 swallowed & inhaled, STOT RE 1 liver, Aquatic Chronic 2 -> may damage the unborn child, causes damage to organs through prolonged or repeated exposure, toxic aquatic life (long lasting effects), harmful if swallowed, harmful if inhaled, suspected of causing cancer, may cause harm to breast-fed children.
- ▶ PFOA (perfluorooctanoic acid): Carc. 2, Repr. 1B, Lact., Acute Tox. 4 swallowed & inhaled, STOT RE 1, Eye Dam. 1 -> may damage the unborn child, causes damage to organs through prolonged or repeated exposure, harmful if swallowed, serious eye damage, harmful if inhaled, suspected of causing cancer and may cause harm to breast-fed children.

3.2) Harmonised classfication (CLH) under the EU CLP regulation

- ► PFNA and PFDA presumed developmental toxicants, also Repr. 2 (Suspected of damaging fertility)
- ▶ PFDA, PFD-A, PFD-S: Carc2, repr 1B, Lact.
- PFNA, PFN-S, PFN-A: Carc. 2; Repr. 1B; Lact.; Acute Tox. 4 swallowed & inhaled; STOT RE 1; Eye Dam. 1
- ▶ PFHpA: perfluoroheptanoic acid : BE CLH dossier (dec.2020) : RAC agreed on STOT RE1 et Repro 1B

3.3) REACH candidate list of SVHC (substances of very high concern)

- ► PFHxS: vPvB
- ▶ PFOA: Toxic for reproduction, PBT
- Several C9-C14 (Toxic for reproduction, vPvB,...)
- ► ELOC: PFBS, GENx

3.4) Conclusion on legally recognized hasards

- in-depth scientific examination for this, new hazards will possibly be added to this list (e.g. immunotoxicity)
- this is clearly an underestimation of the hazards amongst the 6000 known PFAS, not feasible to classify all of the individually with the present categories

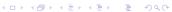
4) Evolution of the regulatory and scientific approach of PFAS

- regulating one-by-one those with a demonstrated risk (PBT,vPvB)
- substitution by industry from long-chain -> short-chain
- ▶ inventory of the PFAS sunstances (OECD, ECHA)
- from (P)ersistance, (B)ioaccumulation, (T)oxicity to P+(M)obility (gradual recognition of the M)
- looking for the arrow-head: end degradation products
- ELOC / SVHCID
- restricting groups of PFAS having the same arrow-head
- acknowledgment of the full extension of the problem at the political level
 - ubiquity, persistency, difficulty to remediate soils, to treat water, new hasards being discovered
 - impossibility to have the classical (eco)toxicological data on 6000 substances
 - unknowns aknowledged, no hope to resolve them, expected irreversible damage
 - difficulties to obtain data on the extremely high number of uses, as well as on emissions

4) Evolution of the regulatory and scientific approach of PFAS

- rise of the essential uses concept
- Belgian Request for a EU PFAS strategy in 2019 (with 11 countries, CIMES-GICLG)
- Requested also by the EU Council and Parliament
- ▶ PFAS strategy proposed by the COM in 2020
 - Ban all non essential uses
 - non-legislative and does not require the Council's approval, member states will largely be responsible for the enforcement of new regulatory measures stemming from it
 - will largely depend on the way it is translated into specific instruments (REACH,CLP,etc)
- ▶ BE declared in favour of an ambitious EU PFAS strategy, e.g.
 - ► EU Council 10/2020
 - ► EU Council 03/2021
 - CIMES-GICLG 08/07/2021

- ▶ 2006: Use of PFOS in products restricted (Directive 2006/122/EC). Derogations: amongst others photolytography, chromium (VI) plating, hydraulic fluids for aviation, firefighting foams already on the market until 2011. Obligation of inventory (on derogations, on AFFF stocks)
- **2009**:
 - Perfluorinated chemicals and the transition to safer alternatives was recognized as an issue of concern under SAICM (ICCM2, May 2009)
 - PFOS is added to the REACH regulation (EC 552/2009, Annex XVII of EC 1907/2006)
 - PFOS,salts and POSF added to Annex B of the Stockholm Convention as a POP (Persistent Organic Pollutant) with acceptable purposes and specific exemptions. As a result, measures must be taken to restrict the production and use of PFOS.
- ▶ 2010: PFOS,salts and POSF: Maximum permissible level of PFOS is reduced, subject to some exceptions —> listed in Annex I of the POP regulation by the regulation 757/2010 in force since 26 august 2010
- ▶ 2013: PFOA was added to the REACH candidate list of substances of very high concern



2015:

- PFOA and related components are added to the list of substances to be evaluated within the framework of the Stockholm Convention.
- PFNA is added to the REACH candidate list of substances of very high concern.

2017:

- PFDA and PFHxS were added to the REACH candidate list of substances of very high concern.
- ▶ PFOA and salts are added to Annex XVII of REACH.
 - 2020: may no longer be marketed as a substance; constituent of other products -> restricted to permitted concentration.
 - 2022: restriction for use in semiconductor manufacturing equipment and latex printing inks.
 - 2023: restriction for use in protective clothing, membranes for medical textiles, filtration in water treatment, production processes and waste water treatment.
 - ▶ 2032: restriction for use in medical devices (other than those covered by Directive 93/42/EEC).

2019:

- further restriction of uses of PFOS (EU POPs Regulation 2019/639). Limited exemptions (all end in 2025): If the quantity released into the environment is minimised, manufacturing and placing on the market is allowed for uses as mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems.
- Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds are listed in Annex A of the Stockholm Convention with specific exemptions. As a result, measures must be taken to eliminate the production and use of PFOA.

2020:

► The European Commission included perfluorooctanoic acid (PFOA), its salts and PFOA-related substances under Part A of Annex I under EU POPs Regulation. This amendment is in force since 4 July 2020 while the REACH Annex XVII entry 68 was removed. Some exemptions (all will end in 2025): photographic coatings applied to films, invasive and implantable medical devices, textiles for oil- and water-repellency for the protection of workers (see text for the details).

2021:

- Restriction of tridecafluorooctyl silanetriol and derivatives in sprays (TDFAs) becomes effective
- ▶ Restriction proposal of PFAS C9-C14 (PFNA up to and including PFTDA), as well as their salts and precursors, was adopted by the Member States in the REACH Committee. Belgium voted in favour of the restriction proposal and submitted a statement along with the vote to indicate the need for ambitious and effective regulatory action on these substances, including an export ban. The restriction will enter into force within 18 months (from the date of publication). A proposal to include these substances in the Stockholm Convention on POPs will shortly be considered.

6) Some existing cooperation organs in BE between the federal, regions and communities

- CIMES-GICLG: Joint-Interministerial Conference on Environment and Health
 - competent ministers (federal, community and regional) in the fields of the environment and health
 - general lines of priority and the implementation of NEHAP, may take other decisions on environment and health on a case-by-case base like the PFAS Belgian position
 - Coordination by the National Cell Environment-Health
- ► CCPIE-CCIM: Coordination Committee for International Environmental Policy.
 - Cooperation agreement on international environmental policy between the Federal State
 - Representatives of the Ministers, environment administrations and agencies + Foreign Affairs and Development Cooperation + Permanent Representation of Belgium to the EU
 - ► A number of Steering Committees (chemicals, water, etc)
 - Ad hoc decisions with other Ministers with other competences are possible
 - Existing CCPIE-CCIM ad hoc group, limited to short-chain data collection, no policy coordination
 - BCR: Belgian REACH Committee (cooperation agreement)

General principle

- ▶ Placing on the market: federal
 - main instrument: Law related to the products norms 21 dec. 1998
- Production and use: regional
- https://www.health.belgium.be/en/environment/ environmental-policy/environmental-stakeholders/ role-federal-and-regions

International & EU regulations, implementation at Belgian level

- ► Often shared competence federal/regions
- Stockholm Convention (POP): shared competence between the federal government and the regions
- ► For the Rotterdam Convention (PIC): federal competence
 - ▶ implemented in regulation (EU) No 649/2012
 - List of chemicals subject to export notification procedure, PFOS
- SAICM (Strategic Approach and sound management of chemicals and waste): shared competence between the federal government and the regions
- ▶ REACH: shared competence between the federal government and the regions, cooperation agreement, belgian REACH committee + Scientific Committee
- ► CLP regulation: federal, used in regional regulations

International & EU regulations, implementation at Belgian level

- ► Product policy (norms on placing of the market of construction materials, paints, detergents) and ecolabel: federal
- Food safety
- Food contact materials
- Circular economy: shared federal/regions
- OSPAR & Marine protection: federal
- Recovery and resilience facility: chemicals substitution -> federal project
- ► Other to mention, not well explored for PFAS aspects until now (Biocides, Plant protection products, Medical devices, Medicines, Cosmetics, Detergents)

At regional, provincial, community and communes level, amongst others those are relevant for the PFAS:

- water, soil, air protection
- nature protection & conservation
- ▶ industrial activities control & environmental permits
- water production
- prevention for health (risk factors)
- interventions on indoor air quality
- waste policy and definition of end of waste status
- regional recovery plans about chemicals

Very important:

Federal and regional inspection services

8) Focus on some regulations, conventions and actions relevant to PFAS

8.1) Focus on some regulations, conventions and actions relevant to PFAS

International level

- SDGs particularly relevant for PFAS
 - SDG 6: Ensure availability and sustainable management of water and sanitation for all
 - ▶ SDG 12: Ensure sustainable consumption and production patterns
- ► SAICM (Strategic Approach and sound management of chemicals and waste)
 - voluntary
 - PFAS issue of concern under SAICM (ICCM2, Resolution II/5, May 2009)
 - adopted at ICCM2 called for their eventual elimination, but instead their production and use has increased, including short-chains
 - while production and use of PFOA and PFOS has dropped in the USA and Europe, they continue to be produced in countries such as China and India and to be applied to products in the global supply chain

8.1) Focus on some regulations, conventions and actions relevant to PFAS

International level

- SAICM future beyond 2020 for consideration and adoption at the next session of the International Conference on Chemicals Management (ICCM5)
- ► OECD/UNEP Global PFC Group:
 - est.2012, BE federal expert
 - promotion stewardship programmes and regulatory approaches to reduce emissions and the content of relevant perfluorinated chemicals of concern in products and to work toward global elimination, where appropriate and technically feasible

8.1) Focus on some regulations, conventions and actions relevant to PFAS

International level

- Stockholm convention
 - ► Federal pilot & scientific expertise
- OSPAR (north-east atlantic protection convention)
 - https://www.health.belgium.be/nl/milieu/onze-Noordzee
 - move towards the cessation of discharges, emissions and losses of hazardous substances which could reach the marine environment
 - ▶ BE pledged since years for a PFAS ban
 - ▶ 3M requested in 2017 the retrieval of the PFBSF from the list of substances of possible concern (a precursor of PFBS, a short-chain PFAS). This was refused by BE, and finally in OSPAR in 2019. In 2019 PFBS entered in the REACH candidate list (ELOC SVHC)
 - polluter pays principle in the convention, not certain if/how this could apply to the pollution coming through the Schelde
 - OSPAR convention requires application of BAT (best available techniques), this might be linked to environment permits
 - methods being developed for planned PFOS measurements in BE waters

8.2) Focus on some regulations, conventions and actions relevant to PFAS

EU-derived

8.2.1) European Commission PFAS strategy

- part of the Chemicals strategy of the Green Deal
- ban all PFAS as a group infire-fighting foams as well as in other uses, allowing their use only where they are essential for society;
- address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
- address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries -> ex. POP, SAICM,GLH
- establish an EU-wide approach and provide financial support under research and innovation programmes to identify and develop innovative methodologies for remediating PFAS contamination in the environment and in products;
- provide research and innovation funding for safe <u>innovations to</u> substitute PFAS under Horizon Europe.
- in addition, the chemicals strategy mentions: to ensure that hazardous chemicals banned in the European Union are not produced for export

8.2.2) REACH & chemicals

- ► AFFF restriction by ECHA (proposal 1/10/2021)
- Overview of the general restriction being prepared by NO,SE,DK,DE,NL
 - properties that leads to the concern: vP, often B, many M, recognised hazards for some, growing probabilities of known and unknown effects including some without standard tests, cocktail effects
 - consequences/costs of the production/use/emission/exposure:
 - increasing levels in the env (-> bioavailability), often quasi irreversible at human scale; biomagnification; contamination of ground-surface-drinking-marine water
 - difficult removal in soils and water; long-range transport
 - ▶ intergenerational effects, transfer mother/offspring transfer
 - restrict all manufacturing, use, marketing related to non-essential uses. May include specific conditions on exemptions (technical, labelling)
- ▶ PFHxA restriction: RAC opinion issued,now 60 days on SEAC draft opinion
- ▶ BE actions: active policy positions on PFAS, contributing data to the restrictions, BE positions at the REACH Committee on restrictions, Federal experts at PBT -EG, RAC, SEAC, substances evaluation



8.2.3) CLP

- classification, labelling and packaging (substances, mixtures, articles). Hazard based.
 - https:
 //echa.europa.eu/en/regulations/clp/understanding-clp
- Classification of substances:
 - BE/federal participation to the committees
 - Perfluoroheptanoic acid (PFHpA): Belgian/federal CLH dossier (dec.2020) -> Risk Assessment Committe at ECHA agreed on STOT RE1 et Repro 1B
- Definition of new hazard classes (mainly due to PFAS but not the only):
 - ► Endocrine disruptors (possibly in 2022)
 - ► PBT/vPvB
 - ► PMT/vPvM
 - direct effect on REACH foreseen due to the new approach in the CSS: a generic approach to risk management, excluding the most <u>hazardous</u> ones from consumer products (not risk, not evaluated one-by-one)

8.2.3) CLP

- ▶ In parallel to CLP: introducing the new hazards in the UN GHS:
 - globally harmonised system of classification and labelling of chemicals
 - if EU does not succeed, exceptions allowed under WTO for health/env
 - introduce directly there more specific categories for neurotox and immunotox (presently under CLP under the Single target organ toxicity hasard).

8.2.4)

- ► POP regulation
 - relevant for PFOS including provisions on soil remediation that are directly applicable in Flanders
 - the compulsory thresholds for soil remediation might be higher than the ones encountered in Zwijndrecht?
- ► Ecolabel
 - Proposal by the federal parliament
- ► RRF
 - PFAS might be one of the priority groups for financing r&d on alternatives
- ▶ PARC (Partnership for the Assessment of Risk from Chemicals)
 - research project which includes PFAS
 - financial contribution
 - > actions on immunotoxicity foreseen
 - one voice for BE in governing board

8.2.5)

- Europe's Beating Cancer Plan
 - https://ec.europa.eu/info/strategy/priorities-2019-2024/ promoting-our-european-way-life/european-health-union/ cancer-plan-europe_en#flagship-initiatives
 - includes an action on reducing exposure to carcinogenic substances
- authorisation of plant protection products, biocides, pharmaceuticals, medical devices
- some contain PFAS, this subject as not yet been discussed
- drinking water directive
 - fed involved for food industries and bottled water
 - ▶ limits (from 2026) of sum of 20 PFAS or Total PFAS
 - to be considered in comparison to new EFSA CONTAM recommendations on 4 PFAS including PFOS
- Workers protection: If not CLH -> not in SDS (thus the majority of the PFAS) -> supply chain

8.3) Focus on some regulations, conventions and actions relevant to PFAS:

National initiatives

- NAPED: many PFAS are suspected ED
 - Prevention actions (awareness-raising and training for different target groups: workers, general public, etc.)
 - Regulatory actions (modification of the Code on well-being at work, implementation of a traceability system for products containing EDs, stricter control of imported products, etc.)
 - Actions concerning scientific research (e.g. study of the endocrine disrupting properties of PFAS via in vitro tests, possibly financed by BELSPO funds). This would allow additional regulatory measures to be taken in case newly identified risks are not taken into account by the general PFAS restriction prepared at European level.
- Enforcement/inspections
 - Federal competency for placing on the market for REACH and CLP
 - ▶ Often inspectors reports are prepared but the public prosecutor's office does not take it up, this is linked to the need to prioritize due to the lack of resources in the judicial power in Belgium
 - At the federal level, the Products Norm Law was modified to allow administrative sanctions in those cases.



8.3) Focus on some regulations, conventions and actions relevant to PFAS:

National initiatives

- ▶ Belgian Federal parliament resolution (25/6/2021)
 - https://www.lachambre.be/flwb/pdf/55/1546/55K1546004.pdf
 - requests to the Federal government (in cooperation with the regions'competence):
 - Labelling for PFAS and products being placed on the market and containing PFAS associated with the most significant emissions and risks
 - In vitro tests of PFAS covered by REACH
 - Support EU research on PFAS chemical structures, their analytical methods, toxicological tests
 - ▶ To support the extension of the Ecolabel prohibition for PFAS to additional categories (presently: textiles, furniture).
 - To support ambitious restrictions of PFAS in REACH, for all non-essential uses including consumer goods.
 - To support at EU level a study for improving recycling of products containing PFAS
- ► Inventory of civil protection & army sites

9) Information exchange procedures and coordination - CIMES 8/7/2021

- ▶ the development of a <u>co-ordination strategy</u> between entities to <u>eliminate PFAS</u> pollution in Belgium and to limit the use of these substances to an absolute minimum, to essential uses.
 - group of experts and policy advisors (6 months)
 - strategy (harmonisation and optimisation) for a coherent and integrated approach between the different levels of competence
 - act as a <u>national advisory body</u> with an exchange of information and data on the measures already taken and to be taken regarding PFAS
- sharing of early warning information between CIMES members
- study of the resolution adopted by the Federal Parliament on 25 June 2021 and its possible implementation means
- support a strong ambition in the discussions on the operationalisation of the implementation of the <u>European Chemicals</u> Strategy for Sustainability.

10) Information and data needs for the EU general restriction, and possible contribution from the regions

- ▶ On monitoring data (both human and environmental): as part of the work for the PFAS restriction we are currently collecting monitoring data (in work package 6). For example we had close contacts with some Belgian researchers (Univ Antwerp). These data will be used in the restriction dossier to underpin the need for measures as there is an unacceptable risk. New data are still welcome (preferably before end of August). For more information on WP6, you could contact: kristin.larsson@kemi.se
- Emission data: difficult to get presently under the REACH process. Under the PFHxA this was a big difficulty but the solution is to make a qualitative estimation in a worst-case approach. The 5 MS will start a second consultation round on 19/7/2021. Data on emissions during production and in different applications are needed. Contributions from industry are certainly to be expected. Measurements made by the regions as well as the ceilings in the environment permits might make a good contribution if consolidated. In any case this will have to extrapolated to the EU level.

10) Information and data needs for the EU gneral restriction, and possible contribution from the regions

- Remediation and water purification costs: this is part of the socio-economical analysis. Here also regions have data and can contribute by prospective calculations together with the water producers.
- Measurements in agricultural and animal products: this is not directly part of the restriction. However those could help in substantiating the risks and costs -> AFSCA-FAVV data
- ► Substances, mixtures and articles placed on the market: Federal market studies might help
- Regional data are essential for reporting obligations for POP (EU, art 13 POP regulation, and National Implementation Plan Stockholm Convention, article 15 Stockholm Convention on production and import).

11) Conclusions

- ▶ Information is available on unacceptable costs and effects that are likely if generalized use of PFAS continues. Drinking water is a particular concern.
- ▶ PFAS case involves decisions with irremediably incomplete scientific information and where there are indications that the possible effects are inconsistent with the chosen level of protection of health and environment in the EU
- ▶ PFAS policy in the EU is taking the direction of an increased protection of health and environment, within a circular economy with non-toxic lifecycles

11) Conclusions

- Important: synergies between regulations (e.g. REACH and drinking water directive).
- Upstream measures, grouping, precautionary approach, safe by design and essential uses definition are appropriated tools because a substance-by-substance approach for risk assessment/management of PFAS is not feasible while regrettable substitutions are possible.
- ► However, there is already a <u>legacy of pollution to manage</u>, for which monitoring will be needed for many years
- Use conditions and environmental permits have also a role for minimizing releases from accepted essential uses until substitutes are developed.
- Monitoring in the environment is also useful for ensuring that the upstream measures are working.

11) Conclusions

- Within the proposed measures, a particular attention is needed to imported articles (thus analytical methods and enforcement) for ensuring a level playing field for EU industry
- Building and sharing expertise, collaboration and making investments in green/sustainable chemistry is crucial for correct substitution of PFAS uses. Environmental, health and sustainability criteria are to be used for orienting investments.
- ▶ Most efficient measures according to my expert opinion:
 - Contribution to REACH restriction + ambitious essential uses definition
 - CLP new categories
 - Strict environmental permits
 - Enforcement
 - Innovation for substitution