

Cross-Sectoral Information Session on the Cascade of REACH Restrictions in Fluorochemistry – Preserving Essential Industrial Value Chains

REACH restriction for PFHexA & related compounds (and beyond) – impact on fluorine chemistry and polymer applications

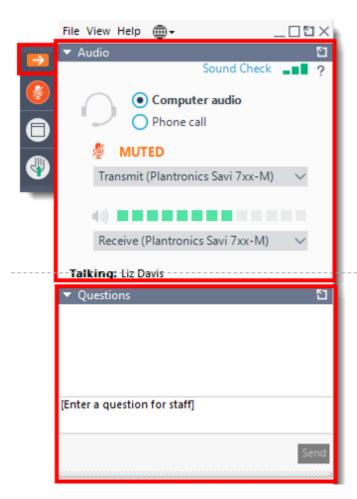
Webmeeting, 23 July 2020, 2-4 pm





Welcome to our cross-sectoral information session – some technical advices for the start

- Your microphones will remain muted throughout the session.
- Questions/comments (in German or English) can be asked via the questions tool ("Fragen").
- During the Q&A-session we will try to answer as many **questions** as possible – for unanswered questions we will try to provide a **Q&A-document** afterwards.
- The presentations will be recorded and we will provide an **event documentation** (presentation slides).







The agenda includes short introductory presentations – then questions can be discussed

- Item 1: Welcome / opening
- Item 2: Short presentations on the content, the status and the potential impacts of the REACH restriction proposal for undecafluorohexanoic acid (PFHexA), its salts and related substances as well as interconnection with other current regulatory activities
 - Introduction to the REACH restriction for PFHexA & related compounds (and beyond)
 - Essential use cases
 - Practical advices for consultation contributions

Item 3: Questions / Discussion / further Activities (Q&A)





Die Bayerischen Chemieverbände

Please note the competition law requirements – competition law notice

Please note:

It is forbidden to exchange information, to hold formal or informal discussions or to make agreements regarding

- prices, especially pricing, pricing strategies, individual discounts, etc.
- production, especially cost accounting formulas, product-specific changes in production or production costs, stocks, etc. or
- future market behaviour, in particular split of markets, boycotts of customers / suppliers, planned projects by companies with regard to technology, investments, sales, etc.

COMPETITION LAW

Important for your meeting

You have to make sure of this! 🗸

You have to avoid this! X

INFORMATION ABOUT COMPLIANT BEHAVIOR IN MEETINGS OF BUSINESS ASSOCIATIONS

As chairperson of a meeting, ensure that no competition law violations occur in meetings. Provide all attendees with a copy of this checklist and have a copy available for reference at all meetings. Observe the following rules:

PREPARATION OF MEETINGS

 Have agendas and other documents which are intended to be used in the meeting be reviewed either by a member of your team familiar with competition law or a legal counsel familiar with competition law. The discussion of issues which could result in violations of competition law must be avoided.

AT THE MEETING ✓

As Chairperson

- Limit discussions in the meeting to those topics which are on the agenda circulated before the meeting.
- · Have meetings minuted in all detail.
- Act immediately if attendees make statements which consist of contents that could violate competition law and distance yourself from respective statements:
- Instruct the participants that this topic must not be discussed.
- In certain circumstances adjourn the discussion until the competition law clearance is available.
- If the discussion continues nevertheless, have your objections minuted, interrupt the meeting or leave the meeting room; this too must be minuted.
- Report the incident to the legal department of VCI or your company.

As a participant in a meeting

- Do not engage even as a pure listener in discussions on prices, price increases, conditions, volumes, sales territories, suppliers and customers, cost or cost sharing, discounts and any other competition-relevant data.
- Do not talk to other participants about the future behavior of your company in competition (for example, production expansions, planned acquisitions etc.).

AFTER THE MEETING 🗸

- Minutes of meetings shall contain the complete contents of the meeting and shall be unambiguous.
- Have minutes reviewed either by a member of your team familiar with competition law or a legal counsel familiar with competition law.

Employees of competing companies must not, neither formally nor informally, discuss or exchange information or make arrangements, on the following items:

PRICES, INCLUDING X

- Pricing, price differentials, price strategies.
- Individual sale and payment conditions; individual discounts, credits and credit terms.

PRODUCTION, INCLUDING X

- Individual manufacturing and sales costs, calculation formulas, methods of cost accounting, numbers related to products or product groups, costs of supply, production, inventories, sales, etc.
- Production changes for example due to maintenance
- Limiting the market supply of a product.

FUTURE CONDUCT ON THE MARKET, X IN PARTICULAR

- Allocation of markets or sources of supply whether by territory or by customers.
- Relationships with individual suppliers or customers, especially if this could result in pushing them out of the market
- "Blacklists" or boycotts of customers, competitors or
- Planned projects of individual companies with respect to technology, investments, design, production and sales or marketing of certain products.





Introduction to the REACH restriction for PFHexA & related compounds (and beyond) - Overview

- A short introduction to REACH regulation
- How low molecular weight PFAS and fluorinated polymers/fluoropolymers are interconnected with each other – examples for application
- 3. REACH-restriction proposal on PFHexA the importance for users of fluorinated polymers/fluoropolymers to take part in the ongoing consultation process





The chemicals legislation is harmonized at European level – most important legal acts are the REACH and CLP regulations

Classification Labelling and **P**ackaging

Regulation 1272/2008

ensures hazard information for workers and consumers



Regulation 1907/2006

Main Goal: Protection of human health & the environment from risks by the use of chemicals

Registration **E**valuation **A**uthorization of Chemicals

In addition to REACH and CLP, there are other chemical regulations at EU level:

- Chemical Agents Directive (98/24/EG) determines occupational safety measures concerning toxicolog. & phys.-chem. properties of substances
- Carcinogens and Mutagens Directive (2004/37/EG) determines additional measures concerning CM-substances of cat. 1 and 2
- PIC ("PIC (= Prior Informed Consent) Regulation") (649/2012/EG) applies to the import and export of certain hazardous chemicals and obligations for companies wishing to export these chemicals to countries outside the EU
- Ozone Layer Regulation (2037/2000/EG) determines, among others, a production ban of substances hazardous to the ozone layer
- POP Regulations (850/2004/EG) determines, among others, a production ban pf "Persistent Organic Pollutants" (POPs)
- further **product-specific regulations**, e.g. for biocides, pesticides, cosmetics, pharmaceuticals, detergents
- further **substance-related regulations** within the EU environmental legislation framework (e.g. fluorinated greenhouse gases, explosives)





The elements of REACH include registration, evaluation, authorization and restriction of substances as well as information duties along the supply chain

SUBSTANCES

also in mixtures, articles (intended release)

Refers to: manufacturer (M), importer (I), downstream user (DU)

REGISTRATION ≥ 1 t/a

(substance dossier)

EVALUATION

AUTHORISATION

RESTRICTION

INFORMATION

wthin the supply chain (safety data sheet, "upstream" Information)

Refers to all substances and their uses => M+I

Refers to substances & groups of substances => Individual cases

Refers to substances & mixtures (also articles concerning SVHC) => M+I+DU

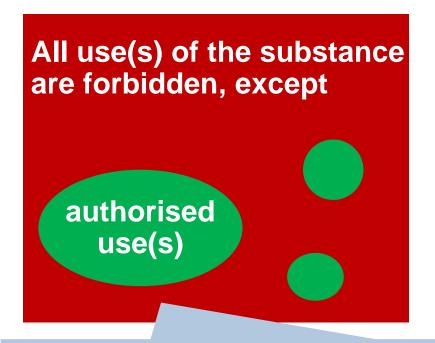
SVHC: Substance of Very High Concern



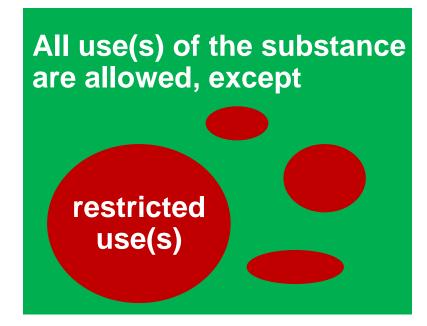


The use of substances of very high concern (SVHC) can be limited/banned by the authorisation requirement or a restriction under REACH

Authorisation: REACH Annex XIV



Beschränkung: REACH Anhang XVII



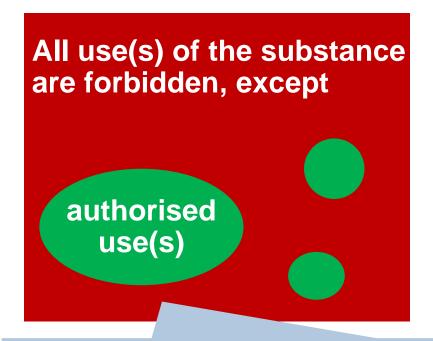
Extensive application procedure by manufacturer, importer or downstream user necessary, approval is limited in time and is subject to review



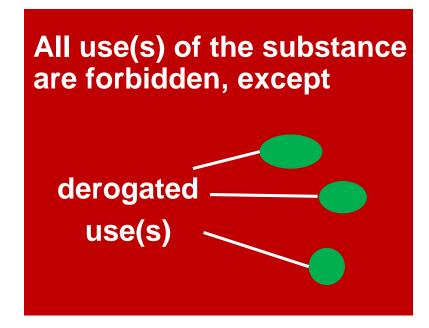


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$$_{\text{H}_3\text{C}}$$
 OH $_{\text{OH}}$ $_{\text{F}}$ $_{\text{$

PFAS: Per- and polyfluoroalkyl substances (monomeric or polymeric)

PFOA as an example for a monomeric **PFAS**

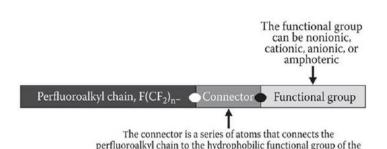




Die Bayerischen Chemieverbände

Fluorosurfactants/fluorotelomers are low molecular weight PFAS* with (per-)fluoro-alkyl chains – applications are e.g. in extinguishing foams

C6/short-chain surfactants





Class B (Flammable Liquid) Fire Fighting Foam with Shorter Extinguishing Time and Burnback Resistance

 Chemistry: Non-polymeric fluorotelomers, consisting of a fluorinated "tail" (the perfluoroalkyl chain) connected to a hydrophilic "head" (the functional group)

fluorosurfactant

Properties: low surface tension and excellent wettability



Paints and varnishes –
Construction materials coatings

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*PFAS: Per- and polyfluoroalkyl substances

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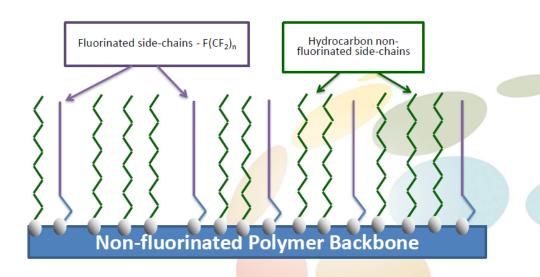


Die Bayerischen Chemieverbände

Fluorinated polymers (high molecular weight PFAS) contain fluorinated side chains – the polymer backbone, however, is not fluorinated

C6/short-chain fluorinated polymers

- Chemistry: C6/short-chain fluorinated chains attached to a non-fluorinated organic polymer backbone (e.g. C6/short-chain sidechain fluorinated polymers)
- Properties provided: Surface modification & protection, water & oil repellency, grease resistance as well as soil resistance and release







There are many (high-tech) applications for fluorinated polymers – some examples

Applications of C6 fluorinated polymers



Healthcare: Garments/Drapes that Protect Against Disease Transmission



First Responder Gear Treatments and Bulletproof Vests that Maintain Performance in Extreme Conditions



Oil/Grease Resistant Food Packaging that is Recyclable, Increases Shelf-Life, Reduces Packaging



Textiles/Carpet with Water/Oil Repellency, Stain Resistance and Soil Release and Longer Useful Life



Paints and varnishes -Construction materials coatings

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Fluoropolymers (high molecular weight PFAS) consist of (co-)polymerized (per-)fluorinated monomers – a (per-)fluorinated polymer backbone

Fluoropolymers (incl. fluoroelastomers)

- Chemistry: High molecular weight polymers with fluorinated "backbone"
- Scope of products:
- Fluoropolymers (e.g., PTFE, ETFE, PVDF, FEP)
- Fluoroelastomers (e.g. FKM) (flexible, rubber-like)
- Properties: Chemical resistance, thermal stability, resilience (elastomers)
- Polytetrafluoroethylene (PTFE) structure Tetrafluoroethylene Polytetrafluoroethylene (PTFE) (monomer) molecule Carbon atom Fluorine atom www.substech.com
- Highly stable under all types of environmental conditions
- Recent study on incineration of fluoropolymers based on BATs confirms no concern about PFOA/PFOS

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Fluoropolymers also have a huge variety of (high-tech) applications – some

examples

Fluoropolymer and Fluoroelastomer Applications



Electronics: High frequency signal transmission; smudge-resistant touch



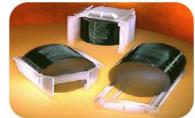
Membranes in outdoor apparel, providing a breathable barrier against wind and rain



Medical Devices: High dielectric insulators in medical equipment that relies on high frequency signals



Aerospace/Auto: Weight reducing fuel lines; heat/chemical resistant wire coatings



Semiconductor manufacturing: Providing pure environments to transport/store harsh chemicals



Highly heat/chemical resistant parts for low emission vehicles (fluoroelastomers)

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The REACH restrictions of PFAS continue to advance – perfluorohexanoic acid (PFHexA) and related compounds are currently in focus

Aug 2017: "PFOArestriction" in force Since July 2020 subject to POP regulation

March 2020: consultation for Annex-XV-Dossier "PFHexA and related substances" starts Sept 2020: Deadline for comments expires ~ 2021: Entry into force + 18 months transition period

2025: action plan to ban all non-essential uses of PFAS in the EU

- Due to their persistence, bioaccumulation / mobility and (partly) (repro-)toxic properties, low-molecular weight PFAS are in the focus of environmental regulation at the same time high-molecular weight fluoropolymers / fluorinated polymers are essential for high-tech applications due to their special properties.
- A restriction proposal for PFHexA has been available for consultation since March 2020 it refers to the manufacture, use and marketing of "C6-fluorochemistry" as a substance as such, in formulations as well as in articles and, therefore, also applies for fluorinated "C6 polymers" (or fluoropolymers with C6-PFAS-impurities).
- The proposed restriction sets **limit values for impurities at 25 ppb for PFHexA** and **1000 ppb for PFHexA-related substances** the same limit values as for the restriction for PFOA ("C-8-chemistry").
- There are **derogations** (e.g. for certain PPE risk category III and medical textiles made of nonwovens), **but many high-tech applications are left out** (such as fuel cell membranes, medical textiles or medical devices that do not consist of nonwoven but instead are woven, textile coatings (protective vests, etc.)

*PFAS: Per- and polyfluoroalkyl substances



UBA's risk assessment for PFHexA shows that there is currently no risk to human health – but it is assumed this might possibly change in the future

- The following concerns / hazardous properties are reported for PFHexA and related compounds:
 - High persistence, mobility in the aquatic environment and between environmental compartments (danger of drinking water contamination), potential for long-distance transport, accumulation in plants
 - Adverse effects in developmental toxicity studies
- All concerns are equally expected for PFHexA-related substances that can degrade to PFHexA therefore, this also applies to the degradation of precursors / migration of impurities (e.g. for side chain fluorinated polymers & fluorotelomers)
- However, these concerns are not sufficient to classify the substances as SVHC! (no CMR or PBT/vPvB).
- The UBA risk assessment (DNEL vs. exposure, dossier 2.5.2) shows that
 - the current emission and exposure pose no risk to human health and
 - exposure is unlikely to reach levels that pose a risk to human health.
- Due to the high persistence and uncertainties in long-term risks for humans and the environment, this might change in the future with increasing concentration in the environment.
- The draft dossier creator (UBA) **proposes a non-threshold approach** as with PBT-/ vPvB-substances **any emissions into the environment should be handled as an unacceptable risk.**

UBA: Federal Environmental Agency (Umweltbundesamt), responsible for the draft dossier





The dossier proposes essentially a total ban – very low limit values will be installed for PFHexA as an constituent, for mixtures and in articles

- 1. Undecafluorohexanoic acid (PFHxA), its salts and related substances¹
 - (a) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluoropentyl group with the formula C₅F₁₁- directly attached to another carbon atom;
 - (b) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluorohexyl group with the formula C₆F₁₃-.
- 2. The following substances are excluded from this designation:
 - (a) C_6F_{13} -X, where X= F;

- 1. Shall not be manufactured, used or placed on the market as substances on their own;
- 2. Shall not be used or placed on the market in:
 - (a) another substance, as a constituent,
 - (b) a mixture,
 - (c) an article

in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances.

- 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction.
- 4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.





The draft proposes some transition periods and derogations for a few uses – but many essential fields of application are left out!

Transition periods

- 5 years for hard chrome plating, photographic coatings, stocks of fire extinguishing foams (not for exercises or tests).
- 7 years for photolithographic applications and etching processes in the semiconductor industry as well as latex printing inks.
- 12 years for fire extinguishing foams for "Class B fire" in storage tanks with a surface area of more than 500 m^2 .

Derogations for

- Fire extinguishing foams for defense applications until a switch to fluorine-free alternatives is possible. (Condition: after 6 years review by the commission, after 12 months annual report on substitution activities and quantities of PFHexA and related substances used),
- Isolated intermediate products under SCC, PPE of risk category III, medical textiles made of non-wovens and agents for their re-impregnation (Condition: annual report on the identity of the substances used as well as the quantity of PFHexA and related compounds used, 12 months transition period)
- Fluoroelastomers used in the automotive and aircraft sectors there is a limit of 150 ppm for PFHexA and related substances (not for articles!)



Industry associations have expressed general and specific criticism on this wide-ranging restriction approach

- In a <u>general position</u>, the **VCI** criticizes in particular the **insufficiently derived evidence of an unacceptable risk** the latter is **mandatory for such a drastic market intervention** of a restriction procedure.
- <u>TEGEWA</u> together with <u>t+m</u> and the <u>Alliance for Telomer Chemistry Stewardship</u> have commented on the draft dossier in general and <u>raised also concerns on substance and application-specific aspects</u>.
- A list of textile applications (with around 70 additional examples (!)) for which fluorinated polymers are essential was added as an annex to the TEGEWA contribution in a first step to address the urgent need for further derogations for essential (textile) use cases.
- All association are working on a second contribution to the consultation with a focus on socioeconomic effects of the restriction.



Further applications and socio-economic impact must be carefully assessed and considered!

- The **chemical industry does not oppose a restriction for everyday items** such as rain jackets **alternatives** for water repellency **are available** for this.
- However, socio-economic impacts must be brought into focus (high-tech applications / future innovations, environmental leakage and supply dependencies, etc.) the list of essential derogations must be expanded!
- Many essential applications are niche applications of small businesses for these companies it is even more difficult to express their concerns in the current situation.
- In the **current corona crisis**, there is an urgent need to **extend rigid deadlines** of the restriction procedure, since companies are hardly able to assess such a complex situation and the effects in the value chain for resource reasons.



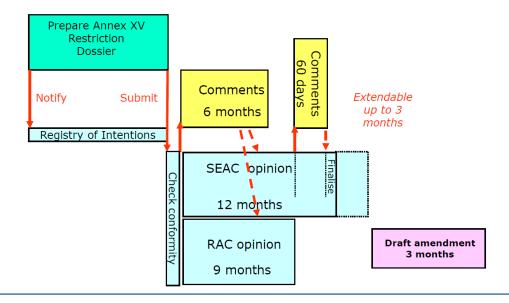


The consultation on the PFHexA dossier ist open until 25 September 2020 – affected industries / users should definitely get involved!

- For the further process it is of fundamental importance that companies / industries / users
 - carefully check their concerns regarding products and applications,

Soure: ECHA

- and get also in contact with their respective (specialist) associations / chambers and
- (above all) actively communicate their individual concerns in the public consultation.
- Participation in the consultation is still possible until 25 September 2020 it makes sense to describe the applications and (socio-economic) effects of the restriction as precisely as possible but equally well comprehensively (also to be understandable by non-specialists).





And that's not all: A data collection is currently being conducted to further restrict all PFAS in the EU!

- Currently, there is also a "<u>Call for Evidence</u>" by 5 Member States (Germany, the Netherlands, Denmark, Sweden and Norway) on per- and polyfluoroalkyl compounds (PFAS) the submission deadline ends on 31 July 2020.
- The goal is to analyze the restriction options for the manufacture, marketing and use of ALL per- and polyfluoroalkyl compounds (PFAS) in the EU!
- The "Call for Evidence" is **intended to provide further information for the development of the restriction dossier** according to REACH Annex XV.
- The **questionnaire** asks for specific **information on PFAS**, its use and function, amounts or impurities in articles, migration / release from articles, alternative substances for individual uses and reformulation costs etc.
- Manufacturers and users are called upon to check whether they are affected and whether or can contribute information on the uses of the substances/materials.
- In order to support companies and trade associations, the "Fluoropolymers Product Group", a PlasticsEurope sector group, is providing information to answer the questionnaire (Guide to Responding to Questionnaire, Factsheets).



THANK YOU FOR YOUR ATTENTION!

For a comprehensive summary please see also https://www.bayerische-chemieverbaende.de/themen-und-positionen/nachhaltigkeit/fluorchemie/