PFAS Restriction Proposal Under REACH

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Ales Bartl

- Ales has a broad experience in EU product regulatory law, including REACH, CLP, POPs, biocidal legislation, food law, medical devices, electronic products and product and food safety. He advises clients on regulatory compliance of a broad range of products marketed in the EU. Ales represents clients before EU and national competent authorities on compliance and enforcement issues, including withdrawals and recalls of unsafe or non-compliant products.

- Ales primarily focuses on EU regulation of chemicals and food, including representing clients in various procedures before the European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA).

Javier Jaramillo García

- Javier Jaramillo García, Ph.D., is a scientist with expertise in organic chemistry. He provides technical and scientific support to Keller and Heckman attorneys and their clients on regulatory compliance matters in the areas of food packaging and other food-contact materials. Javier supports the attorneys in evaluating the status of different types of food-contact materials under EU and Member State legislation.

- Javier advises on testing and drafts test protocols to help generate the required data to support legal opinion letters, as well as submissions to the European Food Safety Authority and to Member States authorities, such as the German Institute of Risk Assessment (‘BfR’).

Pre-publication of PFAS Restriction Proposal- Background

- Restriction proposal by 5 MS pre-published on 7 February 2023
  - PFAS have become a target for restrictions because:
    - Very high persistence (themselves or degradation products), high mobility, for some associated with bioaccumulation and other hazards (ED, ecotoxicity, CMR)
  - So far addressed individually or via sub-groups:
    - Restrictions: long-chain PFAS (C9-C14 PFCAs)
    - SVHC: all that are restricted + HFPO-DA and PFBS
    - Also via other legislation incl. POP Regulation (ex. PFOA, PFOS)

I. Choice of a Grouped Restriction

The Grouping Approach

- Principles behind grouping
  - Substances with structural similarities that trigger equivalent hazards and risks (mainly persistence)
  - Avoid regrettable substitution:
    - Avoid fostering new PFAS development
    - Prevent future exposure to currently low-used PFAS

Scope of the Group - Definition of PFAS in the Report (1)

Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

- Very wide definition, includes both short, medium, and long chain PFAS together with fluoropolymers
- Is in line with the OECD 2021 definition
- Some starting materials for fluoropolymers (like tetrafluoroethene) are excluded from the restriction based on the definition, but the fluoropolymers made from them are not

Scope of the Group - Definition of PFAS in the Report (2)

Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it).

- A subgroup of PFAS with key structural elements that make them degrade in the environment and not bioaccumulate are excluded from the scope of the restriction
- The definition of this subgroup is very narrow: *"CF_3-X or X-CF_2-X', where X = -OR or -NRR' and X'= methyl (-CH_3), methylene (- CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR'', -SR'' or –NR''R'''; and where R/R'/R''/R''' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-)"*

A Restriction with a Very Broad Scope

- Choice of a very broad scope, including:
  - Naturally occurring organofluorine substances - number mentioned as low
  - Biodegradable PFAS - acknowledged but no exemption is currently foreseen
  - Fluoropolymers - non-toxic, but key point is that they are still very persistent
- Concerns with such approach
  - Restriction detached from the actual hazard and exposure
  - **Hazard:** almost all PFAS are vP: but how about vB or T or M? Not all of them
  - Fluoropolymers: not likely to be T, B or even M
  - Also future PFAS!
  - **Exposure:** exposure to some PFAS in the group negligible

II. Scope of the Restriction

Scope of the Restriction

- PFASs shall not be manufactured, used or placed on the market as substances on their own, and in:
  - Another substance, as a constituent
  - A mixture
  - An article

  Important: this also covers imports from 3rd countries
- In a concentration of or above:
  - 25 ppb, or
  - 250 ppb, or
  - 50 ppm

Residual Concentrations (1)

- **25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFASs excluded from quantification)**
  - Targeted analysis of a PFAS in another substance, mixture or article when there is an available analytical method for the substance and reference standards for quantification
- **250 ppb for the sum of PFASs measured as sum of targeted PFAS analysis, optionally with prior degradation of precursors (polymeric PFASs excluded from quantification)**
  - Sum of all PFAS detected via the targeted analysis
  - It can be performed in the sample or after chemical degradation of the sample material (in the latter case, degradation products may occur)

Residual Concentrations (2)

- **50 ppm for PFASs (polymeric PFASs included)--if total fluorine exceeds 50 mg F/kg the manufacturer, importer or downstream user shall upon request provide to the enforcement authorities a proof for the fluorine measured as content of either PFASs or non-PFASs**
  - Applies if targeted analysis is not applicable, for example, in the case of fluoropolymers
    - In that case, a total fluorine content analysis is performed
    - As total fluorine content may also measure fluorine from other sources (inorganic and organic), if the level is exceeded more information shall be provided to the authorities regarding the percentage of fluorine detected that comes from PFAS
    - This could be either supply chain information or based on further analysis

Derogations (1)

- Entry into force of the ban: 18 months from entry into force of COM Regulation (i.e., sometime in 2027 likely)
- Limited derogations
  - Few types of substances benefit from **unlimited derogations**: PPPs, BPs, human and veterinary medicinal products, used for calibration of measurement instruments and as analytical reference materials
  - For other uses, **time-limited derogations** are foreseen when limited alternatives are available (26 in total)
- Consequence, de facto ban in all non-exempted sectors
  - Including in FCMs, irrespective of listing under Regulation (EU) 10/2011
    - Sufficiently strong evidence on alternatives (incl. consumer cookware, paper and board packaging, and plastic packaging)

Derogations (2)

- Derogations – 6,5 years from entry into force
  - Evidence "sufficiently strong" that:
    - No technically and economically feasible alternatives available; OR
    - available in insufficient quantities or cannot be implemented before end of transition period
  - Examples: polymerization aids, FCMs for the purpose of industrial and professional food and feed production (piping and tubing for drinking water, filters; seals, gaskets, tubing and pipes, expansion joints; valves, blades, etc.); not including packaging and non-stick coatings

Derogations (3)

- Derogations – 13,5 years from entry into force
  - Evidence "sufficiently strong" that:
    - No technically and economically feasible alternatives available AND potential alternatives unlikely in near future, AND
    - Certification or regulatory approval of PFAS-free alternatives cannot be achieved within a five-year derogation period
  - Examples: textiles used in protective equipment, certain refrigerants, cleaning fluids, medical devices (implantable and tubes and catheters), petroleum, and mining industries

Derogations and Interaction with Sectoral Legislation (4)

- Consequence on reliance on a derogation
  - With few exceptions, most are set to expire, goal to give time for innovation
  - Reporting obligations:
    - For PPP, BP and medical uses, report every two years to ECHA (incl. identity and quantity placed on the market)
    - For all other derogations, yearly reporting
- Potential derogations – open topics
  - Some marked as 'potential' for reconsideration after the consultation
    - Incl. aerosol propellants, semi-conductors, non-stick coatings in industrial bakeware
  - Cases where evidence was insufficient, and not inconclusive
  - Dossier submitters remain open to such derogations, provided they are supported by **additional** information

III. Way Forward with the Restriction

The Restriction Process – The Way Ahead (1)

- Restriction report pre-published on 7 February 2023
  - Now undergoing conformity check
  - Once check is validated, proposal will be published + start of **six-month public consultation (announced from 22 March 2023)**
- ECHA's Committees phase
  - RAC opinion:
    - Within nine months after the publication of the report
    - Appropriateness of the restriction for reducing the risks posed to health or the environment
    - Taking into account comments received from stakeholders

The Restriction Process – The Way Ahead (2)

- SEAC opinion: within 12 months after the publication, taking into account comments and socio-economic input from stakeholders
  - Socio-economic assessment
  - Phase 1: **two-month consultation** on the draft SEAC opinion (i.e., 1st half 2024)
  - Phase 2: SEAC revises its draft based on consultation
- RAC and SEAC issue a consolidated opinion

- <u>Commission phase</u>
  - COM prepares draft amendment to Annex XVII within three months after having received the opinions – then discussed in REACH Committee (several rounds of discussion – **still advocacy possibilities!**)
  - Final adoption: likely mid-2025

IV. Commenting in Public Consultations

Importance of Public Consultations

- Public consultations: key point
  - First six-month public consultation: usually two deadlines: 1) after one month; 2) six months
    - First deadline essential to impact RAC and SEAC opinions
  - Second two-month public consultation will be focused on socio-economic impact and will focus on derogations
- Derogations: Initially set to incl. essential uses criteria:
  - PFAS envisaged as case study for the concept
  - But: delay in the establishment of the definition
  - Result: Ad-hoc derogations, based on risk/socio-economic considerations

Inputting in Public Consultations

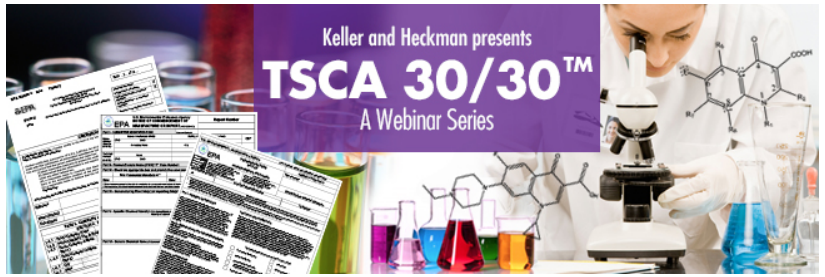
- Check Proposal + Annexes (Annexes A, B and **E** most relevant)
  - Request longer general transition period (e.g., 32 months instead of 18 months)
  - Focus on « potential derogations »: Member States lacked input, still open to add derogations
  - But not only!
    - Worth inputting on other points incl. definition, (lack of) available alternatives, rebuttal of data in the Proposal
    - Committees may (and likely will) add derogations, but also may **withdraw** some submissions
    - Need for solid data: analysis that alternatives are not available (yet), socio-economic impact of ban, risk-based data (low emissions, limited uses); be genuine and realistic (time-limited derogations)
    - Useful ECHA Guidance document Inputting to the consultation phase of an Annex XV restriction report and SEAC draft opinion under REACH
    - Comments will be made public (company name can be kept confidential)

Final Thoughts

- Several problematic elements
  - Grouping approach (do all substances in the group entail ‘unacceptable risk to human health or the environment’?)
  - P and/or M elements on their own: proxy for risk?
  - Regrettable substitution as a basis for REACH restriction?
- Neither Proposal, nor ECHA’s Committees opinions can be subject to legal challenge; only final Commission Regulation (but no suspensive effect!)
- That is why inputting in public consultation is crucial

Please join us at 1:00 PM Eastern U.S.
Wednesday, February 22, 2023
www.khlaw.com/OSHA3030

Please join us at 4:00 PM CET
Wednesday 12 April 2023
www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S.
Wednesday, April 12, 2023
www.khlaw.com/TSCA-3030

Thank You

Any questions?

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