The PFAS Restriction Proposal in a nutshell

EFSA, March 15, 2023
Why a restriction?

PFAS

Persistence

Mobility

Bioaccumulation

Toxicity, Ecotoxicity, EA/ED, Accumulation in plants, LRTP
Concerns in more detail

Properties
- Very high persistence
- Long-range transport potential
- Mobility
- Accumulation in plants
- Bioaccumulation potential
- (Eco)toxicity
- Endocrine activity

Concerns related to combinations of properties
- High potential for ubiquitous, increasing and irreversible exposures of the environment and humans;
- Difficulty to decontaminate raw water for drinking water, low effectiveness of end-of-pipe RMMs and difficulty to treat contaminated sites;
- High potential for human exposure via food and drinking water;
- Potential for intergenerational effects and delay of effects;
- Potential for causing serious effects although those would not be observed in standard tests;
- Estimation of future exposure levels and safe concentration limits is highly uncertain;
- Global warming potential.
Justification for EU-wide measure

- PFASs manufactured, imported and used in EU
- Global market with growing volumes (e.g. fluoropolymers) – many uses, e.g., FCMs
- Large variety of emission sources (across life cycle stages)
- Ubiquitous presence and increasing levels in environmental media
- No (cost) efficient remediation possible
- PFASs are mobile and cross borders
- EU internal market: level playing field

EU-wide risk reduction measures: Implement control efficiently and uniformly
Grouping approach

− Grouping based on two aspects:
  i) Chemical structure (i.e. in line with OECD 2021 PFAS definition)
  ii) Persistence
− Equivalent hazards and risks are covered
− Justified to avoid regrettable substitution
− Prevention of future exposures of PFAS which are not currently in use.
Proposed restriction: Ban

Option 1: full ban 18 months after EiF
Option 2: full ban 18 months after EiF with time-limited use-specific derogations

Ban on manufacture, use and placing on the market

- As substances on their own
- As a constituent
- A mixture
- An article

≥ 25 ppb for any PFASs
≥ 250 ppb for sum of PFASs
≥ 50 ppm * for PFASs

* 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.
## Approach to derogations

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<tr>
<th>5 years (+ transition period)</th>
<th>12 years (+ transition period)</th>
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<td>• Non-existence of feasible alternatives on market at EiF, but alternatives already identified</td>
<td>• No feasible alternatives identified so far</td>
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<td>• Alternatives not available in sufficient quantities</td>
<td>• Certification/approval of alternative cannot be achieved within 5-year derogation period</td>
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<td>• Alternative cannot be implemented by company before transition period ends</td>
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Conclusions

- **RO1: Could be proportional in medium and long-term**
  - Likely progressive increase in societal costs of continued use, which will eventually outweigh societal costs of the restriction option.

- **RO2: Also proportional, and most appropriate**
  - Balancing trade-offs between short-term and long-term vs Societal costs of continued use.
Questions?

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