

Rubber as food contact material

- Status on compliance in EU

Hygienic Design Network, 02.10.2023

AVK GUMMI GROUP



AVK Ravestein - The Netherlands



AVK Sealing Technology - China



AVK GUMMI – Denmark



Anders G. Christensen – CSO/CTO AVK GUMMI Group



AVK WATER

AVK is one of the leading manufacturers of valves for Water, Wastewater Treatment, Gas, Fire Protection, HVAC & Irrigation industries worldwide.



AVK Industrial Valves

Delivering solutions within industrial valves and accessories for a broad row of industrial segments as Power Generation, Pulp and Paper, Chemical Processing, Oil and Gas, Marine, Dams & Reservoirs, Water treatment plants, Metering & Mining.



AVK Advanced Manufacturing

Manufacture components of steel, rubber, plastic, iron, aluminum and bronze as well as designing and supplying materials and handling systems for all areas of productions in all lines of business.



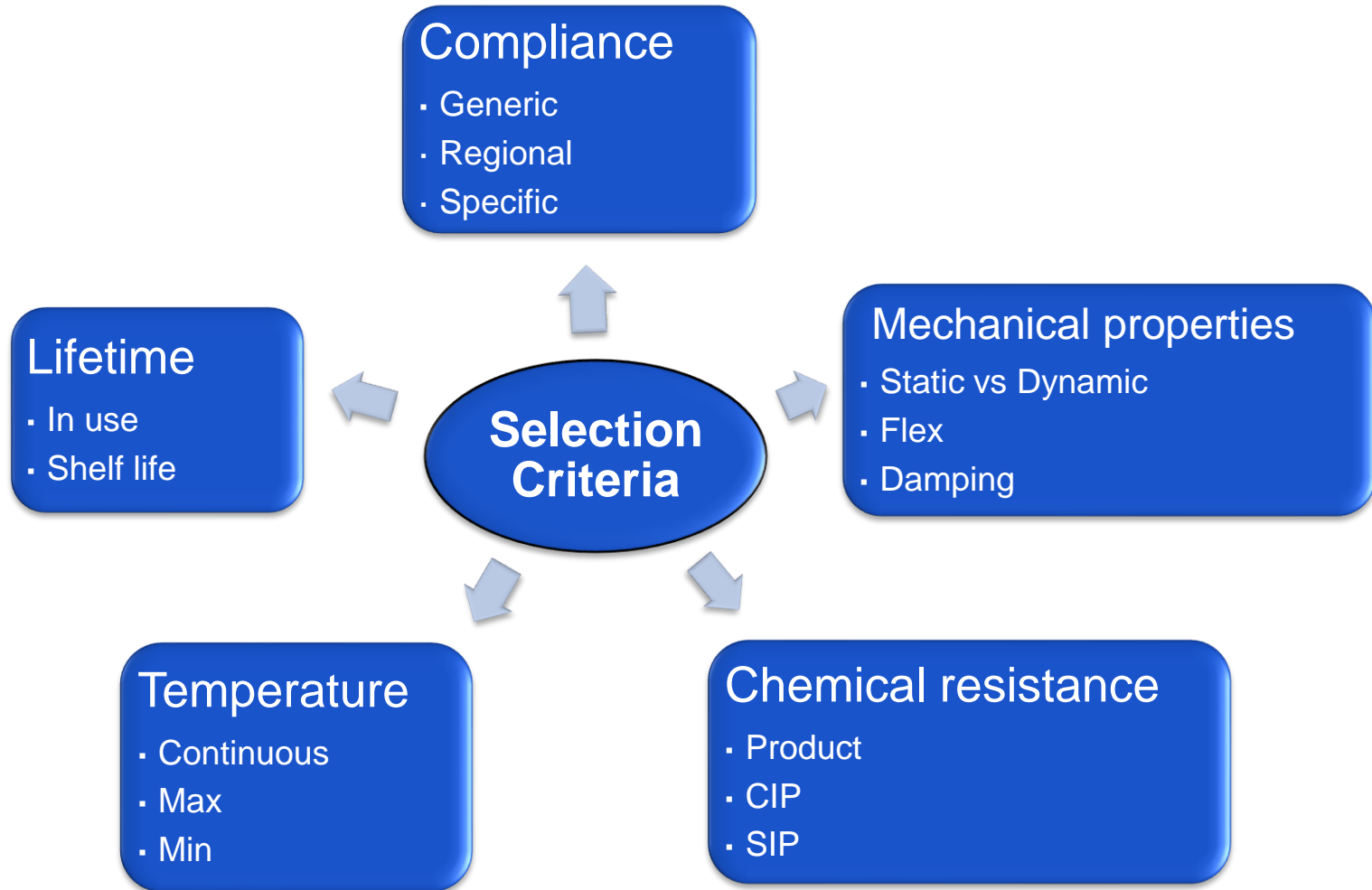


Drinking Water
Food
Technical Products
Energy
Healthcare

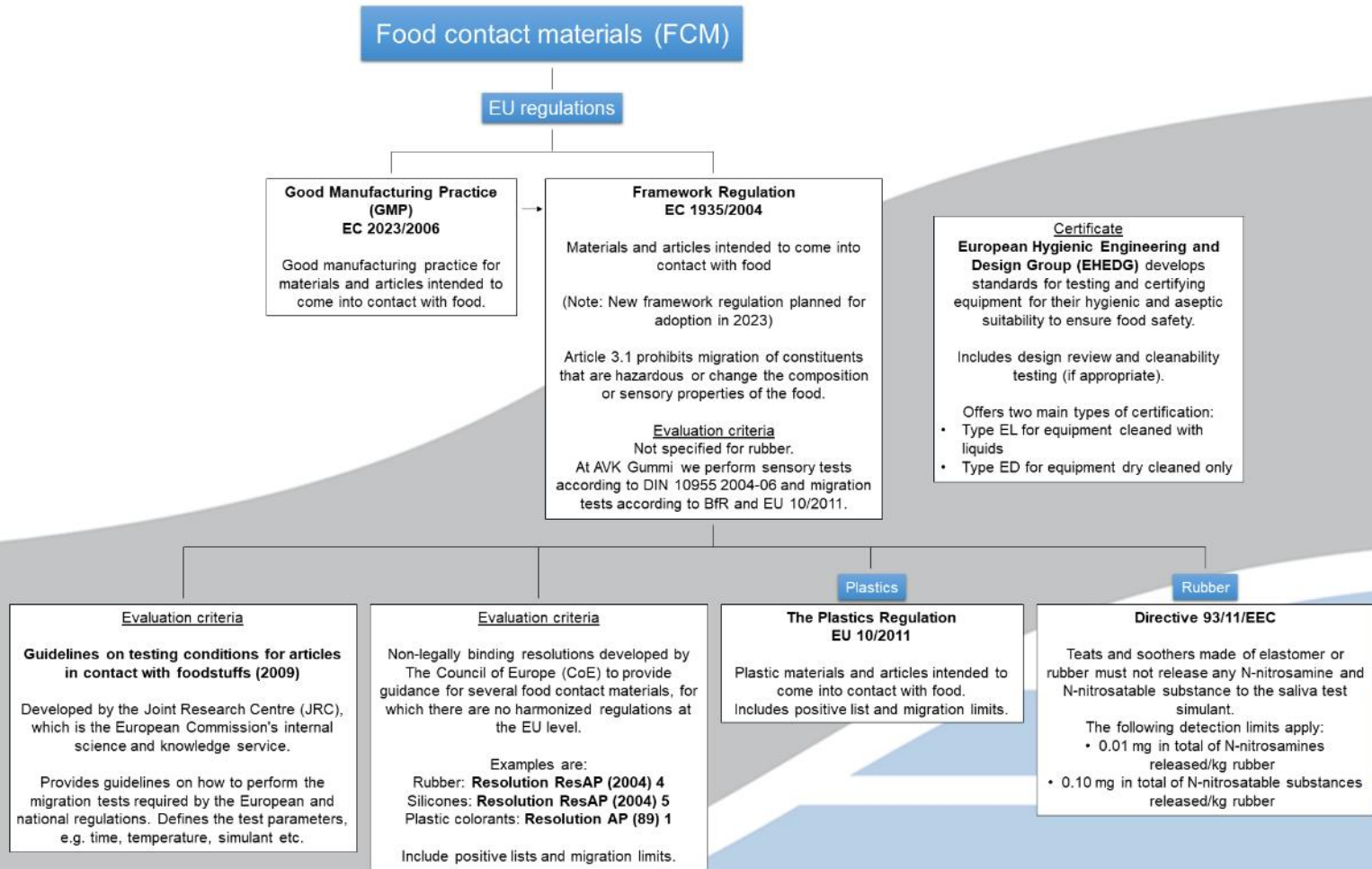


**HIGH PERFORMANCE
RUBBER COMPONENTS**
- for demanding applications

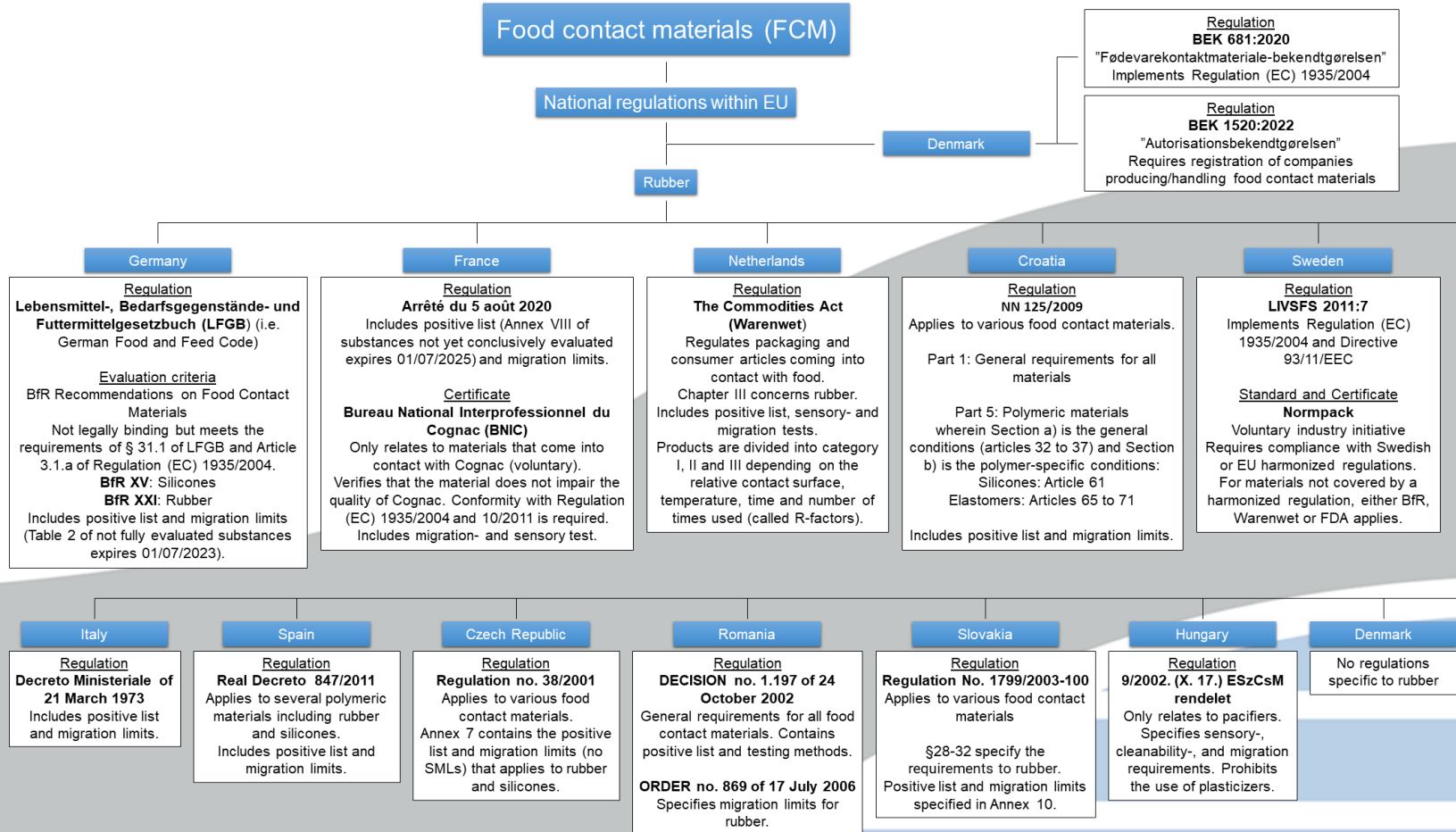
Selecting the right rubber compound



FCM Regulation in EU



National FCM Regulations in EU



EC 1935:2004

Article 3 General requirements

1. Materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
 - a) endanger human health; or
 - b) bring about an unacceptable change in the composition of the food; or
 - c) bring about a deterioration in the organoleptic characteristics thereof.



EC 1935:2004 – additional

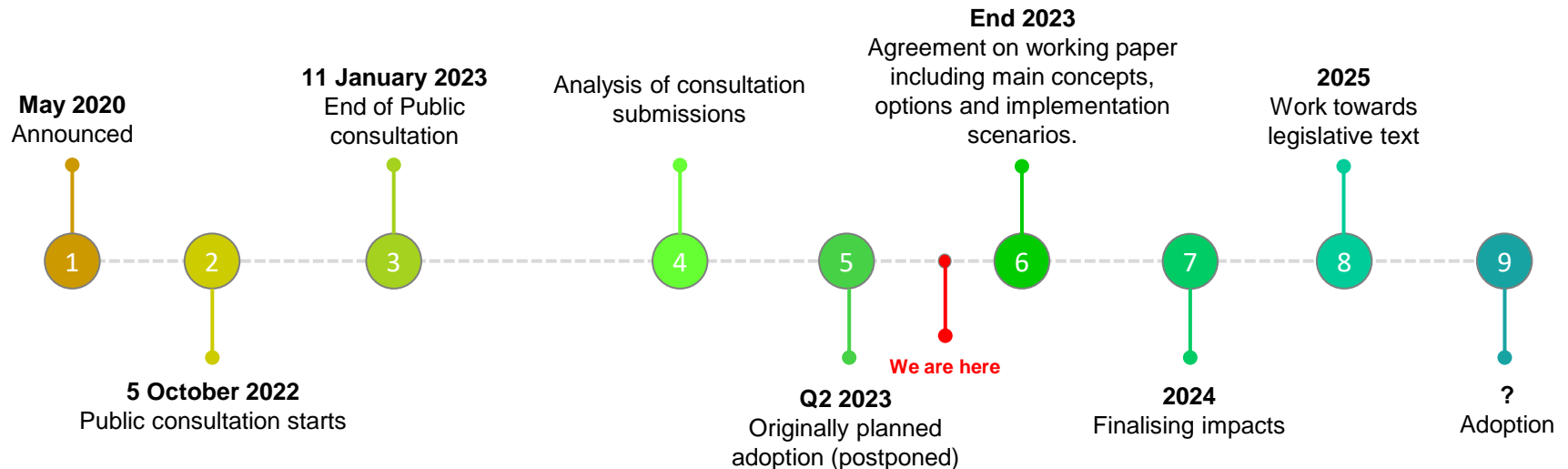


- 1) Comply with the provisions of Denmark: BEK 681:2020 and BEK1520:2022.
- 2) GMP in accordance with Regulation (EC) No 2023/2006
- 3) Sensory tests according to DIN 10955 2004-06
- 4) and
 - Compliant with positive list and migration requirements in a (EU) national regulation for rubber, or
 - Compliant with FDA positive list and total extraction and specific migration tests according to BfR XXI/XV and EU 10/2011.

EC 1935:2004 is under revision



- Main scope:
 - Prohibition of the most harmful substances
 - NIAS testing
 - Increased information sharing through the supply chain, including DoC




AVK's Certificates of Compliance



Generic:

AVK GUMMI A/S
Mosegaardsvej 1
DK-8670 Laasby



Datasheet
Compound ID EAF-75

Regulatory compliance

ADI free	Do not contain any substances originating from humans or animals.
Bisphenols	Do not contain Bisphenols as described in Regulation (EC) No 1895/2005: BPA, BADGE, BFDGE and NOGE.
Conflict Minerals	Do not contain Tin, Tantalum, Tungsten and Gold in accordance with US Law: "Dodd Frank Wall Street Reform & Consumer Protection Act", Sec. 1502 of 21.07.2010 and with Regulation (EU) No 2017/821. Additionally, Cobalt and Mica are not contained.
Food Allergens	Do not contain food allergen substances as described in Regulation (EU) No 1169/2011.
GMP	Good Manufacturing Practice in accordance with Regulation (EC) No 2023/2006.
Hazardous materials	Do not contain any hazardous substances as described in the Hong Kong International Convention for the Safe and Environmentally Sound Recycling of Ships, 2009.
ODS	Do not contain Ozone Depleting Substances in accordance with Regulation (EC) No 1005/2009.
Phthalates	Do not contain phthalates including but not limited to those listed in Entries 4-7, 33-39, and 44-46 of Annex XIV and in Entries 51 and 52 of Annex XVII to REACH Regulation (EC) No 1907/2006.
REACH	In accordance with Regulation (EC) No 1907/2006. Do not contain any substances above 0.1% (w/w) from The Candidate List of Substances of Very High Concern.
RoHS	In accordance with the Directives 2011/65/EC (RoHS 2) and 2015/863/EC (RoHS 3).


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Specific:

AVK GUMMI A/S
Mosegaardsvej 1
DK-8670 Laasby



Datasheet
Compound ID EAF-75

Compliance status

3A Sanitary Standard	Class II (Low Fat)
EC 1935/2004	BfR XXI cat. 2 migration tests. EC 10/2011 SML substance migration tests. EC 1935/2004 Article 3 organoleptic tests.
FDA 21 CFR 177.2600	177.2600 (a)-(i) including positive list and extraction in water and hexane.
GB 4806.1	Meets relevant requirements in GB 4806.1-2016, GB 4806.11-2016 and GB 9685-2016. SML substances may be disclosed for third party testing pending NDA and AVK GUMMI A/S approval.
GB 4806.11	Meets the raw material and testing requirements of GB 4806.11-2016 and GB 9685-2016. S/V ratio 1:2,2, 130 °C < 15 min, all types of food, repeated use, gaskets.
USP <87>	37 °C / 24 h MEM
USP <88>	Class VI (70 °C / 24 h + 121 °C / 1 h)

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PFAS Status



Regulatory:

- EU is working on a broad restriction on PFAS that could eliminate the use of FKM, PTFE and similar polymers – also for food contact.
- US is taking a more diversified approach, both on federal and state level.
- China has banned only few specific PFAS substances, referencing the Stockholm Convention.

Upstream supply chain - disruption:

- PFAS manufacturers have faced big lawsuits, and more are expected.
- 3M has decided to stop entire manufacturing of PFAS substances.
- Chemours and Solvay has decided to retract food contact statements.
- Review of business cases, driven by
 - Regulatory requirements
 - Significant investments
 - Risk of legal claims
 - Markets are shifting
 - Declining demand expected within FCM
 - Consumers and NGO's

PFAS - main content of proposal



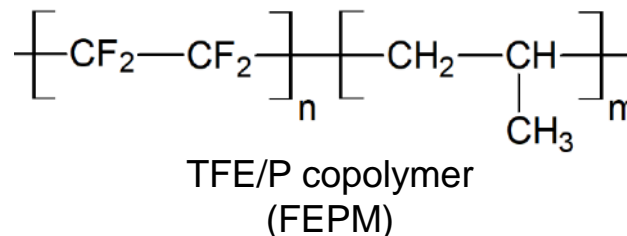
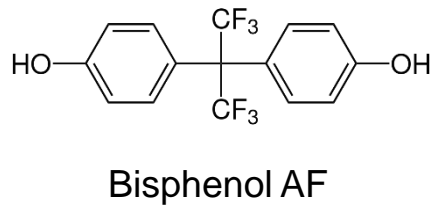
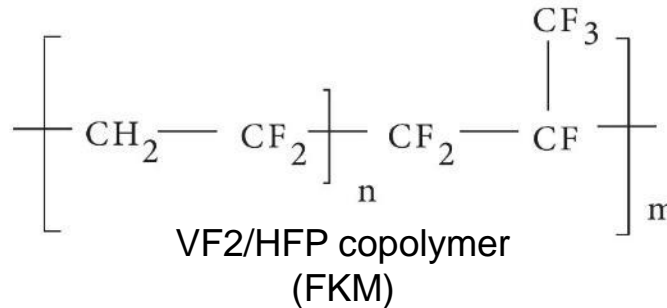
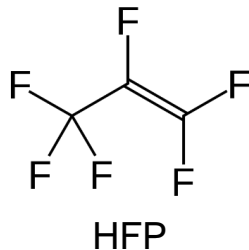
- Covers > 10,000 PFAS substances.
All PFASs in scope are either very persistent themselves or degrade into very persistent PFASs in the environment.
- Entry into force (EIF) expected July 2025
- Restriction expected to apply from 2027 – 18 months after EIF.
- 5 years derogation for FCM proposed.
- Obligation to report consumption, use and waste handling for formulators of PFAS containing mixtures.
- Obligation to maintain a management plan, annually reviewed for downstream users of PFAS containing products.

Elastomers to be affected

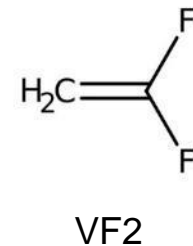
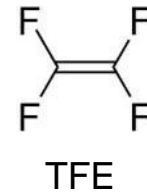
Per- and polyfluoroalkyl substances (PFASs) defined as:

Any substance that contains **at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom** (without any H/Cl/Br/I attached to it).

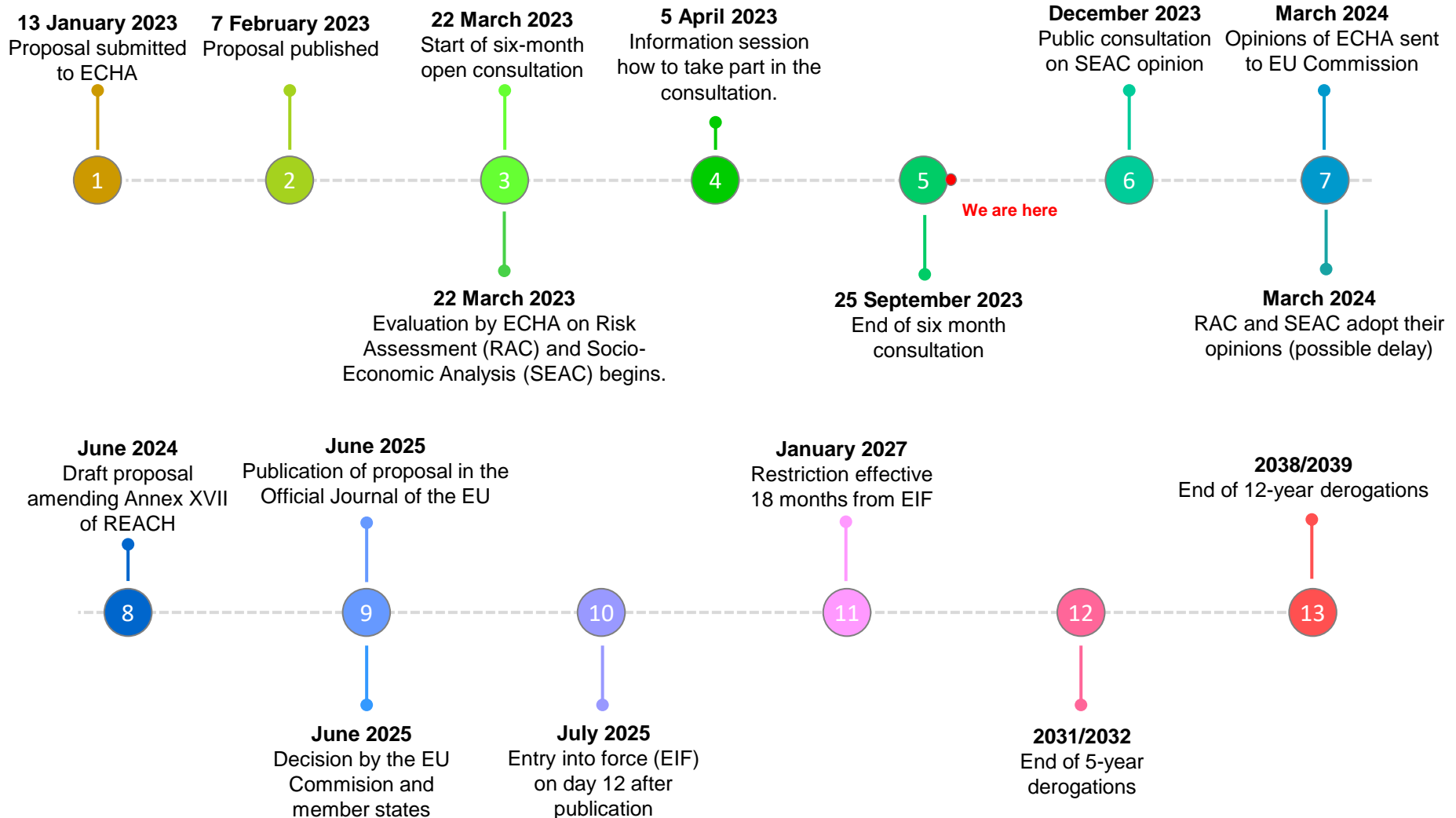
PFAS FKM



Not PFAS



Expected timeline



Preliminary feedback from RAC

General

- Agrees with grouping approach based on persistence.
- May not support the exclusion of specific non-persistent PFAS from the scope.
- Despite uncertainties, there is sufficient evidence to conclude on the intrinsic hazard of PFAS.
- Agrees that there is a concern for polymeric PFAS

Food contact materials

- FCM are among the highest uses of both small and polymeric PFAS.
- The life cycle of fluoropolymers results in emissions of monomers or short bioavailable oligomers.
- RO1 is considered as an effective measure to eliminate the risks caused by PFAS.
- Final conclusion on RO2 cannot be made yet.
- Based on available information, there are alternatives for many of those uses covered under this derogation.



Preliminary feedback from SEAC



General

- Agrees that a group restriction is an appropriate risk management option
- Non-existence of alternatives should not be used as the sole basis for justification of a derogation.
- The analyses neither facilitates evaluation of RO2 nor comparison between RO1 and RO2.
- Targeted derogations may balance the trade-offs between short-term costs and long-term benefits better than a full ban.

Food contact materials

- Higher cost of fluoropolymers may not automatically result in them being used only where high performance is required.
- SEAC agrees that alternatives do not cover the full range of applications.
- A derogation may be justified for certain applications, but not necessarily all.
- Lack of explicitly identified applications without alternatives.
- Additional emissions from RO2 may be high.
- Preliminary conclusion: The time frame (5 years) have not been thoroughly justified.



AVK's PFAS Strategy



- Global - driven by regulation, sustainability and availability.
- Assume “worst case scenario”.
- Highest performance solutions – also in future.
- To stay informed and communicate proactively.
- Without PFAS, we need to be very clear in our communication.
 - For some applications and business segments, performance will go down.
 - Outline pro's and con's of alternatives. Enable informed decisions.



What is status at AVK?

- EU is expected to ban the use of Bisphenol A, closely related to Bisphenol AF, early 2024. We are acting proactively.
- AVK has retracted EC1935:2004 compliance statement for current FKM range, due to Article 3. FDA and other compliance statements unaffected.
- We have completed qualification of first generation FKM, to comply with coming PFAS regulation, until 2027.
- Second generation FKM, to comply until 2032, is in development.
- All PFAS' are likely to be phased out





Thank you for your attention

Contact



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