Meeting with AnimalhealthEurope on PFAS and Essential Uses
7 February 2022, Microsoft Teams

Participants
AnimalhealthEurope: [redacted]
DG GROW: [redacted]
DG ENV: [redacted]

- AnimalhealthEurope represents the interests of the European animal medicines industries (a sector not covered by CEFIC). The association requested the meeting to raise COM awareness on the interactions between REACH and the veterinary medicinal products (VMP) legislation. The VMP legislation is based on market authorisations, which include an assessment of the manufacturing process, a risk assessment for HH, Animal health and ENV, and pharmacovigilance measures once an authorisation is granted.
- Regarding essential uses (ESU) and REACH, industry referred to 2 cases of interface of legislation: TritonX-100 and PFAS. Industry is concerned about restrictions under REACH because predictability is key for their investments and changes in one substance have strong implications in their market authorisations for VMP. A VMP needs 10 to 15 years to be developed and if REACH restricts an active ingredient, simple substitution is not feasible because the procedure of the development of the VMP product should restart.
- COM informed industry about the timeframe of the REACH revision and the different consultations foreseen. Industry seemed well aware and active.
- Regarding PFAS, COM explained the different procedural steps of the ongoing restriction and invited industry to provide information all along the process: to the 5 MS preparing the Annex XV dossier, then to ECHA and later to COM. COM clarified that the regulatory measures on PFAS will be based on the current legal framework, not on the future provisions on ESU. Industry is aware, but to ensure predictability, needs to follow current discussions on ESU.
- Industry explained that it is currently gathering information from their suppliers on PFAS contained in the packaging of VMPs and on inhalation anesthetics , antiflammatory agents and parasites medicines. Answering to COM questions, industry confirmed that under VMP legislation there is (1) an environmental risk assessment (tiered-approach) and (2) an assessment of the packaging – limited to the interaction with the active substances.