European Commission

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Title: Fostering regulatory science to address chemical and pharmaceutical mixtures: from science to evidence-based policies

Challenge:

Under 'Towards a zero-pollution ambition for a toxic free environment', the European Green Deal will propose a new Chemicals Strategy for Sustainability, aiming at better protection of both humans and the environment against hazardous chemicals. In addition, there is growing concern about the occurrence of pharmaceuticals in the environment and several knowledge gaps are identified in EU Strategic Approach to Pharmaceuticals in the Environment[1].

Humans, wildlife and domestic animals are in general exposed to mixtures of different chemicals via air, water (including the marine environment), food, consumer products, materials and goods. The scientific understanding of mixture effects has progressed in recent years and approaches are available how to better regulate combined exposures to chemicals.

In parallel with the development and implementation of regulatory approaches to better protect human health and the environment from risks of chemical mixtures, there is a need to continuously improve the scientific knowledge base. Current knowledge shows that combined exposures pose risks to ecosystems and human health, and that these risks are not sufficiently managed under existing regulations. Accordingly, there is a need to advance [regulatory] science, thereby providing policy-makers and risk assessors with methods and tools. It is also

[1] Section 5.6 of the Commission Communication on the EU strategic approach to pharmaceuticals in the environment COM(2019) 128 final, 11.03.2019.

important to study the effectiveness and efficiency of different policy approaches, and to continue exploring human and environmental exposure to mixtures and associated effects.

Scope:

This topic calls for applied research studies, demonstrating how regulatory science can apply new tools and methodological approaches based on the latest scientific evidence, to quantify and prevent harmful co-exposures to industrial chemicals and pharmaceuticals.

The applicants can address some or all of the following:

(i) Evidence-based solid case studies of which safety margins would actually protect people, including vulnerable groups, and ecosystems, while taking accumulated exposure into account over a longer time scale;
(ii) Develop and apply modelling, statistical approaches and other relevant methods to study the impacts of chemical mixtures on human populations and the environment, e.g. through linking particular cases identified and effects on the wider population and on ecosystems;
(iii) The possible effects on humans of (chronic) exposure to low levels of pharmaceuticals via the environment, taking account of the potential for combined effects from multiple substances, and of vulnerable sub-populations
(iv) Improvement of models for (chronic) exposure to mixtures, which can be applied in a premarket stage (risk assessment, authorisation and restriction of chemicals), and possibly already at the design phase of chemicals and materials, to predict contribution to combined and overall exposure/risk/toxicity;
(v) Validation of models for (chronic) exposure to mixtures through actual testing and sampling;
(vi) Estimations of the degree to which current regulatory practices/approaches underestimate (or possibly occasionally overestimate) risks related to chemicals exposure (based on particular case studies, modelling and overall estimations);
(vii) Comparisons of different possible regulatory approaches to manage chemical mixtures with current situation, including regarding effectiveness (improved protection of health and the environment), workability, cost-effective methods and benefits to society and business;

(viii) Improvement of the knowledge base on mixtures and their health and environmental impact, to underpin and support regulatory action

Expected impact:

- Implementation of existing and new risk assessment and risk management approaches to reduce the most critical exposures, including the setting of limit values and the introduction of new regulatory approaches such as, e.g. Mixture Assessment Factors
- Scientific evidence to enable mitigation of pharmaceutical and other chemicals (mixtures) in the environment

Research and Innovation action