



# INTERNATIONAL VIRTUAL BROKERAGE EVENT EUROPEAN GREEN DEAL CALL

Workshop 3: Area 8 - Zero-pollution, toxic-free environments  
23 October 2020

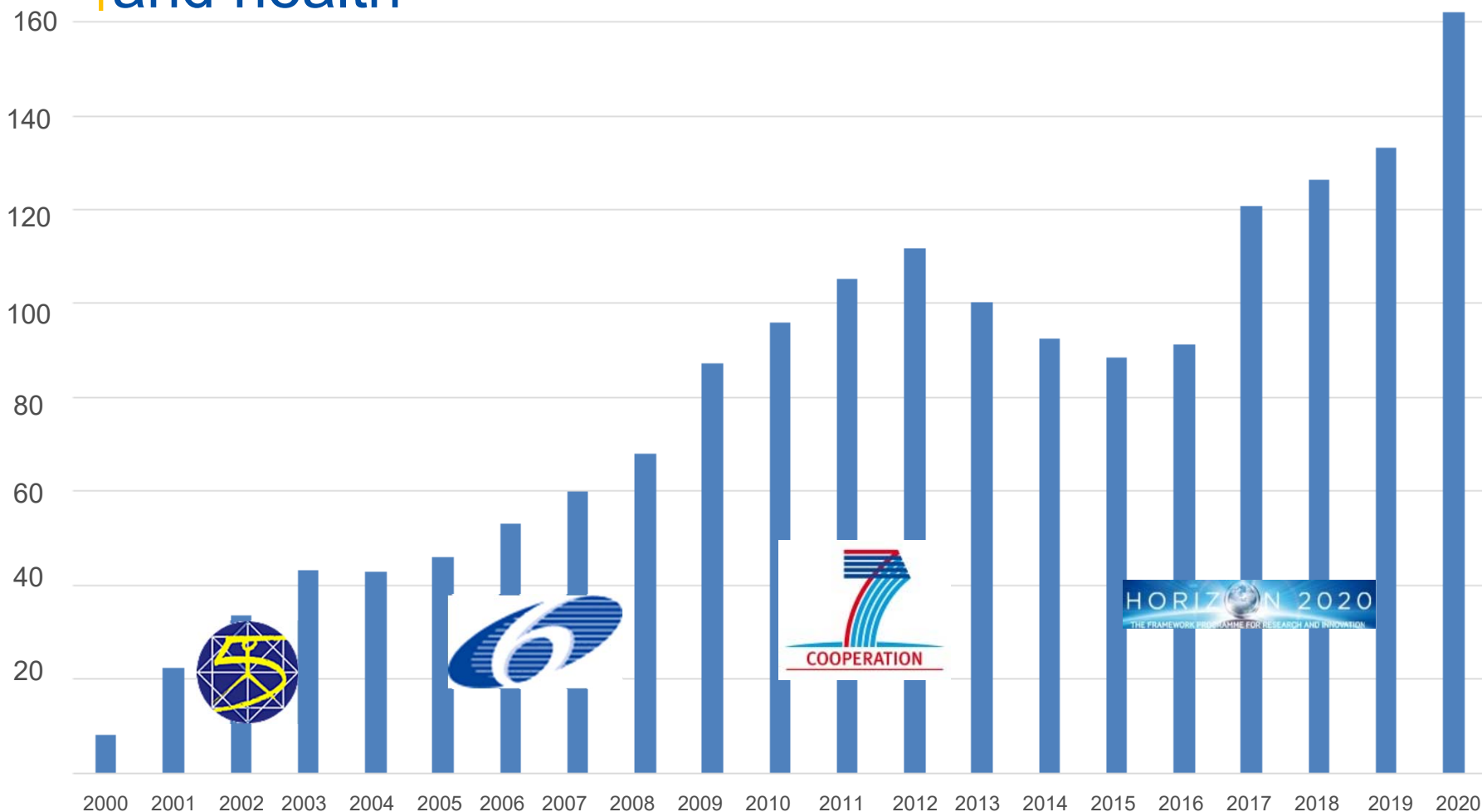
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# Agenda

- Welcome and background
- Topic 8.1: Innovative, systemic zero-pollution solutions to protect health, environment and natural resources from persistent and mobile chemicals
- Topic 8.2: Fostering regulatory science to address chemical and pharmaceutical mixtures: from science to evidence-based policies

# More than 20 years supporting research on environment and health

€ million



TR participation:  
13 institutions in FP7  
(E&H research)

Over 500 projects funded; received over 1.8 billion euros from FP5/FP6/FP7/H2020 (1998-2018)



# Research on chemicals in the EU



- Chemical safety: 101 projects, € 515M
- Nanosafety: 78 projects, € 285M

## Relevant ongoing activities:

- Microplastics call
- European Human Biomonitoring Initiative
- Horizon Europe Partnership for the Assessment of Risks from Chemicals (PARC)



Topic LC-GD-8-1-2020:  
Innovative, systemic zero-pollution solutions to  
protect health, environment and natural  
resources from persistent and mobile chemicals

# Why are persistent and mobile chemicals a concern?

- Persistence combined with mobility in the environment:
  - ✓ High risk to contaminate water resources
  - ✓ Difficulties and high costs to remove with water treatment
- Criteria proposed by German Federal Environment Agency UBA
- Starting to be used under REACH
  - ✓ Chemicals Strategy for Sustainability Towards a Toxic-Free Environment: *The Commission will introduce endocrine disruptors, persistent, mobile and toxic and very persistent and very mobile substances as categories of substances of very high concern*
- Two substances identified as Substances of Very High Concern (SVHC) also on the basis of P and M properties

Umwelt   
Bundesamt



# The example of PFAS

- Very large group of chemicals (> 4700), used in many applications
- Only a small fraction is currently restricted in the EU and internationally
- The restricted substances have been replaced by alternatives belonging to the same group
- The alternatives are now under scrutiny and show concerns due to persistence, mobility and, in some cases, toxicity
- The Chemicals Strategy includes actions on PFAS and on persistent and mobile chemicals in general



# The EU Chemicals Strategy - PFAS

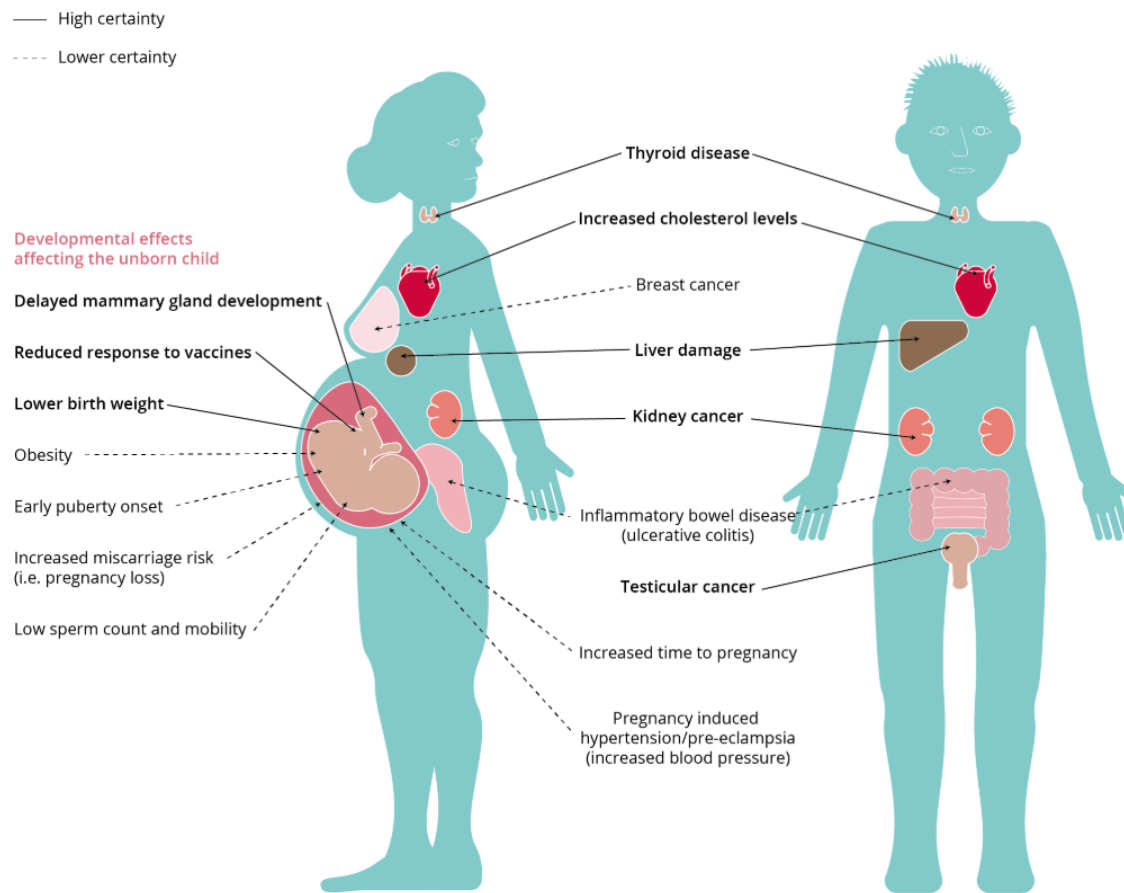


- The Commission will:
  - ✓ ban all PFAS as a group in fire-fighting foams as well as in other uses, allowing their use only where they are essential for society;
  - ✓ address PFAS with a group approach, under relevant legislation on water, sustainable products, food, industrial emissions, and waste;
  - ✓ address PFAS concerns on a global scale through the relevant international fora and in bilateral policy dialogues with third countries;
  - ✓ establish an EU-wide approach and provide financial support under research and innovation programmes to **identify and develop innovative methodologies for remediating PFAS contamination in the environment and in products**;
  - ✓ provide research and innovation funding for safe innovations to substitute PFAS under Horizon Europe.



# Potential health effects

Figure 1. Effects of PFAS on human health



Source:  
European Environment Agency

# Key issues in addressing the risks of PFAS

- Very high number of chemicals and very limited information on the specific substances: need to address them as a group
  - ✓ A group of Member States is working on a restriction proposal
- Need for analytical methods to be able to measure the whole group of PFAS in different matrixes, and at low concentration
- Need for data on environmental concentrations and on biomonitoring, especially for the « novel » PFAS
- High number of contaminated sites, costs and technical difficulties of remediation
- Waste management: industrial waste, waste water, excavated soils, consumer goods



# Topic 8.1

## Call requirements

## Specific Challenge

- A recent Eurobarometer survey (2020) showed that a large majority of respondents are worried about the impact on their health of chemicals present in everyday products
- The European Green Deal includes a commitment to a zero-pollution ambition for a toxic-free environment. In this context, it specifically mentions the need to rapidly address the risks posed by hazardous chemicals and, more specifically, very persistent chemicals
- Pollution from persistent and mobile chemicals is often a systemic problem, as it is driven by factors closely related to the prevailing ways of production and consumption and is reinforced by missing appropriate (bio)remediation and monitoring techniques for the environment
- An example of these very persistent chemicals is per- and polyfluoroalkyl substances (PFAS)
- They are an increasing concern as they are persistent in the environment, very mobile, toxic and can bioaccumulate
- The overall costs to society from PFAS alone as an example are estimated by one source to be € 52-84bn across Europe (Nordic Council of Ministers, 2019), which is likely to be an underestimate, as it includes only a limited range of health effects.

# Scope-1

- Establishing new knowledge, exploring the feasibility of new or improved technologies and demonstrating innovative solutions to protect health, environment and natural resources from persistent and mobile chemicals
  - ✓ Advance our knowledge on health impacts and environmental effects
  - ✓ Address and preferably prevent a specific pollution problem
  - ✓ Solutions should lead to cost-effective prevention, monitoring and, as a last resort, to mitigation or elimination of the issues
  - ✓ Understanding of environmental fate and help prevent negative impacts from persistent and mobile chemicals (and, where relevant, their precursors) on humans and the environment
  - ✓ May include appropriate technologies, business, governance and social innovation aspects and the demonstration of innovative solutions in a relevant environment (TRL 4-6)
  - ✓ May consider analytical methods and monitoring, enabling to quantify entire groups of persistent and mobile chemicals in food, soil or drinking water

# Scope-2

- The successful projects should include elements (one or several), such as:
  - ❖ gain insight to the uses, sources and environmental fate of persistent and mobile chemicals;
  - ❖ development of new cost-effective high-resolution methods to analyse and model the presence of persistent and mobile chemicals products/materials and in different media;
  - ❖ environmental and human (bio)monitoring of persistent and mobile chemicals;
  - ❖ gathering of toxicity and toxico-kinetic information (including animal-free approaches such as in vitro and in silico approaches) in order to allow characterising risks to human health and ecosystems, including at low environmental levels and combined/cumulative exposures;
  - ❖ detection and identification of specific pollution problems and their sources;
  - ❖ research and development of (bio)remediation technologies of soil and water (including sources of drinking water) contaminated by persistent and mobile substances and their precursors;
  - ❖ development and improvement of models to predict and assess long-term trends and risks for persistent mobile substances and propose preventive solutions;
  - ❖ development of best practices for the management and treatment of waste, soil and water containing persistent and mobile substances, in line with the ambitions of the Circular Economy Action Plan.
- Proposed solutions should be suitable for real life challenges, environmentally sustainable, cost-effective and easily implementable to encourage their uptake.
- Close consultation or collaboration with potential end-users of the expected results during the project lifetime is recommended.

# Expected impact

- Provide a **foundation for prevention and mitigation solutions** based on better understanding the sources and distribution of the targeted chemicals, access to models of their **environmental fate** and degradation pathways and improved understanding of **relevance for human and environmental** health of the problem of emerging and persistent pollution;
- Provide **solutions and support decision making** for addressing large-scale diffuse contamination of water and soil with persistent and mobile chemicals (including for combinations of pollutants) in an integrated manner;
- Contribute to **achieving a toxic-free environment** through solutions for better load reduction, (bio)remediation and detection technologies, including real time monitoring approaches;
- Improve **risk assessment** to facilitate optimal risk management and preventive solutions;
- Support **policy development, regulatory action and risk communication** with **FAIR data** of regulatory relevance;
- Support **actions deriving from several EU documents** on persistent and mobile chemicals, the upcoming Zero Pollution Action Plan, and the aims of the new Circular Economy Action Plan to minimise the presence of substances that pose problems to human and environmental health.



# Information in footnotes/call conditions

- All chemical monitoring data resulting from the projects must be shared via Information Platform for Chemical Monitoring IPCHEM.
- For human biomonitoring activities procedures and the network of reference laboratories established by HBM4EU (<https://www.hbm4eu.eu>) should be used when relevant and possible.
- Wherever relevant, applicants are invited to make use of the services offered through Copernicus data, in particular the Copernicus Climate Change and Atmosphere Services, for better understanding the complex relationships between pollution and climate change.





# Instrument and budget

- Type of Action: Research and Innovation action
- Available budget: 40 M€
- The Commission considers that proposals requesting a contribution from the EU of between EUR 8 to 12 million would allow the specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Topic LC-GD-8-2-2020  
Fostering regulatory science to address  
combined exposures to industrial chemicals  
and pharmaceuticals: from science to evidence-  
based policies

# Why are chemical mixtures of concern?

- Humans and wild organisms are exposed to variety of chemicals, occurring in combinations – ‘mixture’; never to just single chemical
  - ✓ Intentional mixtures: e.g. in production processes and products (paint, glue, detergents, pesticides); reasonably well managed in the EU chemicals legislation
  - ✓ Unintentional/coincidental mixture: arising spontaneously in the environment, variable, unknown composition; not sufficiently addressed in the EU chemicals regulation
- Effects of mixtures occur at levels considered ‘safe’ for the individual chemicals on their own

# Key issues in addressing the risks of chemical mixtures

- Information/knowledge on toxicity and exposures
  - ✓ Some progress achieved - REACH registrations, monitoring and making data available (IPCHEM) – but gaps remains
- Methodologies for risk assessment
  - ✓ Methodologies exists (Concentration addition as a default option; Cumulative Assessment Groups; probabilistic modelling of exposures) but further development/improvement needed
- Risk management approaches
  - ✓ Suggestions exist (priority mixtures; cumulative assessment groups; effect based monitoring; applying Mixture Assessment Factor), but further development of concepts is needed
- Legal requirements for mixture risk assessment
  - ✓ Some exists but more is needed

# Some examples of the needs from policy point of view











- Filling information/knowledge gaps
- Improving risk assessment methodologies
- Further development of risk management approaches and concepts
  - ✓ Identify priority mixtures
  - ✓ Mass flow of chemicals – proof of concept
  - ✓ How to implement Mixture Assessment Factor – what magnitude, how to apply it (one or several different MAFs)
  - ✓ Assess and compare different regulatory approaches and suggest how different methods could work together

# The new Chemical Strategy: Chemical mixtures

- The Commission will:
  - ✓ assess how to best introduce in REACH (a) mixture assessment factor(s) for the chemical safety assessment of substances;
  - ✓ introduce or reinforce provisions to take account of the combination effects in other relevant legislation, such as legislation on water, food additives, toys, food contact material, detergents and cosmetics;
  - ✓ improve the assessments of the mixtures used in the manufacture of tobacco and related products by using where possible existing EU agencies.



## EU funded chemical mixture projects - examples

Project logo	Title	Links
	Integrating epidemiology and experimental biology to improve risk assessment of exposure to mixtures of endocrine disruptive compounds	 <a href="#">Policy brief</a> 
	Solutions for present and future emerging pollutants in land and water resources management	
	Euromix	 
	European Human Biomonitoring Initiative	

Statement on advancing the assessment of chemical mixtures and their risks for human health and the environment



Current EU research activities on combined exposure to multiple chemicals



# Topic 8.2

## Call requirements



# Specific Challenge

- New **Chemicals Strategy for Sustainability**
- Growing concern about the **occurrence of pharmaceuticals** in the environment.
- Humans, wildlife and domestic animals are **exposed to combinations of different chemicals** via air, water (including the marine environment), food and feed, consumer products, materials and goods.
- Scientific **understanding of combination effects has progressed** in recent years and approaches for risk assessment and management of unintentional mixtures and combined exposures to chemicals are available.
- In parallel with the development and implementation of regulatory approaches, there is a **need to improve the scientific knowledge base**.
- Current knowledge shows that exposures to combinations of chemicals pose **risks** to ecosystems and human health that may **not be sufficiently managed** under existing regulations.
- There is a need to **advance regulatory science** to provide policy-makers and risk assessors with applicable approaches, methods and tools and to **study** the effectiveness and efficiency of **policy approaches**.
- The **effects of exposure** of humans and the environment to combinations of chemicals should also be further explored.



# Scope

Demonstrating how new tools and methodological approaches from regulatory science workable in a regulatory context can be applied to identify, quantify and prevent harmful co-exposures to industrial chemicals and pharmaceuticals.

The applicants can address some or all of the following:

- Development of **tools and analytical methods to detect and measure complex mixtures** in various environmental compartments;
- **Comparisons** of different possible **regulatory approaches** to manage unintentional chemical mixtures and co-exposures, regarding effectiveness, workability, cost-effectiveness and benefits to society and business;
- Estimations of the degree to which **regulatory practices/approaches underestimate** (or overestimate) **risks** related to chemicals exposure;
- Develop and apply modelling, statistical approaches and other relevant methods to **identify and study the health impacts on human populations and the environment of exposures** to combinations of different chemicals
- Scientific **case studies** to identify **safety margins** for specific unintentional exposures to combination of chemicals to protect human and ecosystems health, while taking into account **chronic exposures** over longer time scales;
- **Effects on humans**, in particular on vulnerable sub-populations, from combined (chronic) exposure to low levels of pharmaceuticals via the environment, taking account inherent pharmacological properties and the potential for combined effects from co-exposures;
- Analysing EU data sources to generate **insights on real-life and potential exposure combinations, typical exposure routes and uses**;
- Development, improvement and validation of **models for predicting (chronic) exposure** to combinations of chemicals, which can be applied in a **premarket stage** and possibly already at the **design phase of chemicals** and materials **as well as retrospectively**.

# Expected impact

- Scientific evidence to **enable prevention and/or mitigation of co-exposure** to pharmaceuticals and industrial chemicals in the environment and the technosphere;
- Support the implementation of existing **risk assessment and risk management approaches** to reduce the most critical exposures, including the setting of limit values for exposures, taking into account co-exposures;
- Support the **assessment of new regulatory approaches** such as, e.g. Mixture Assessment Factors;
- Support activities on combined exposures as relevant for the **Strategic Approach to Pharmaceuticals in the Environment** and as to be defined in the forthcoming **Chemical Strategy for Sustainability**;
- Selected projects under this topic are strongly encouraged to **continuously share information and participate to joint activities** to optimise synergies to address policy-relevant knowledge gaps.

# Information in footnotes/call conditions

- All chemical monitoring data resulting from the projects must be shared via Information Platform for Chemical Monitoring IPCHEM.
- For human biomonitoring activities procedures and the network of reference laboratories established by HBM4EU (<https://www.hbm4eu.eu>) should be used when relevant and possible.
- In this context the term 'industrial chemicals' is used to identify chemicals of anthropogenic origin, e.g. including pesticides, biocides, cosmetics etc.



# Instrument and budget


- Type of Action: Research and Innovation action
- Available budget: 20 M€
- The Commission considers that proposals requesting a contribution from the EU of between EUR 4 to 6 million would allow the specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

## Useful links

- Green Deal call overview
- DG R&I environment and health website
- Call topic
  - ✓ 8.1
  - ✓ 8.2



*İlginiz için teşekkür ederiz!*



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