

General Information	
Preliminary title of the European Partnerships	European Partnership for Chemicals Risk Assessment
Short description of the partnership	A joint research and innovation programme to support the EU/national chemical risk assessment and management authorities by providing new evidence and methodologies and stimulate their uptake in regulatory processes.
Services directly involved	DGs: RTD, SANTE, ENV, GROW, AGRI, MARE, JRC EU Agencies: EFSA, EEA, ECHA To be confirmed: DG EMPL, EU-OSHA, EMA
Context and problem definition	<p>The World Health Organization estimates the ‘disease burden’ preventable through sound management and reduction of chemicals in the environment at around 1.6 million lives per year¹ globally. Several of the Sustainable Development Goals (SDGs) relate to risks from hazardous chemicals and their management. Especially SDG target 3.9 calls for “<i>by 2030, to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination</i>”. At the same time, according to the 2019 UNEP resolution², the production and use of chemicals in the world is expected to increase threefold by 2050. The resolution emphasises the need to strengthen the science-policy interface and the global evidence base for chemicals. Horizon Europe can, by funding research on chemical risk assessment, provide solutions and contribute to reaching a sustainable Europe.</p> <p>The EU regulatory framework for chemicals is advanced by international standards. Many core pieces of legislation, protecting human health and the environment whilst ensuring competitiveness of the chemical industry, have been developed during the last decades, considerably improving the access to information on chemical properties and conditions of use. Despite this, there are concerns among citizens, civil society organisations, scientists, regulatory authorities and other stakeholders about the safety and health impacts of chemicals found in the environment, food and feed, consumer products and workplaces. According to the 2017 Eurobarometer report³, more than four in five Europeans are worried about the impact on their health of chemicals present in everyday products and nine in ten respondents are worried about the impact on the environment.</p> <p>Risk assessment agencies and regulatory bodies, at EU and national level, find themselves confronted with gaps in knowledge, information and methodology. There are knowledge gaps as regards hazards, occurrence and exposures to chemicals and chemical mixtures occurring in various media and products. Testing and assessment methods for adverse health effects need to be developed and taken-up, including non-animal methods. Existing evidence is often scattered and not accessible, new tools and methods lack validation, causing duplication of efforts and inefficient use of resources. This impedes the risk assessors from properly assessing chemical risks or advising policy makers on the scope and direction of new or existing regulatory frameworks. The uptake of scientific data and new tools and technologies in risk assessment needs stronger emphasis and acceleration, to allow the EU regulatory framework to remain a world reference. Risk communication also becomes more and more important, with risk managers as well as the public and stakeholders. An example of the growing concern and the recognised need for better collaboration is the idea of an EU</p>

¹ WHO, ‘The public health impact of chemicals: knowns and unknowns: data addendum for 2016’, www.who.int/iris/handle/10665/279001

² United Nations Environment Programme (UN Environment; UNEP) resolution on ‘Sound management of chemicals and waste’, <https://papersmart.unon.org/resolution/uploads/k1900787.pdf>

³ Eurobarometer report 468 ‘Attitudes of European citizens towards the environment’: <http://ec.europa.eu/commfrontoffice/publicopinionmobile/index.cfm/Survey/getSurveyDetail/surveyKy/2156>

	<p>Toxicology Programme launched by the French Agency for Environmental and Occupational Health Safety and now discussed with other national agencies. The present proposal for a partnership takes account of this idea, but considers the challenges faced by risk assessors to be wider and span the entire risk assessment framework.</p> <p>For many years, the EU Research Framework Programmes have funded research on the health impact of chemicals and monitoring tools and technologies. Under Horizon 2020 a closer link between science and policy was developed: HBM4EU strives at providing human biomonitoring data useful for risk assessors and managers; EUTOXRISK aims for a proof of concept for animal-free toxicology testing; new projects on testing of endocrine disruptors include the OECD validation of developed methods in their work. The new partnership would establish an even stronger link between science and policy and push forward the uptake of research results into chemical regulatory processes.</p>
Objectives and expected impacts	<p>The ultimate objective of the partnership is to support the established chemical regulatory processes and facilitate their adaptation to and preparedness for persistent or emerging challenges as described above. The aim is to strengthen European capacities in the areas of: human biomonitoring; environmental and food monitoring; toxicology and hazard assessments; exposure assessment; emerging chemicals; chemical mixtures; validation, standardisation and reference materials; risk assessment methodologies; data management and analysis; communication, dissemination and training; priority setting and sustainability. The partnership will not replace already existing mandatory reporting or monitoring schemes enshrined in EU regulations, but enrich them with new knowledge and tools where necessary. The partnership will contribute to the sustainability of the human biomonitoring platform developed by HBM4EU, by incorporating it into a wider chemical risk assessment initiative as recommended during the 2018 Human Biomonitoring conference⁴. In fine, the partnership will provide an EU-wide research platform complementing the EU chemical regulatory system, thereby strengthening the EU-MS collaborations for chemical risk assessment and management.</p> <p>The expected impacts of such a partnership are: i) structured collaboration between national (and EU) entities; ii) optimised use of available resources, better information flows and best practice sharing; iii) sound evidence base to develop, assess and implement EU policies and regulatory systems; iv) efficient knowledge-transfer and cross-fertilization between MS driving innovation; v) coherent alignment with and between national and EU regulatory bodies, stimulating prioritised and harmonised approaches to regulatory actions across sectors and countries; vi) ensure that the EU maintains the required capacities to continue to deliver world class regulation of chemicals and hold a strong international role in this area.</p> <p>The partnership will support the following EU policies or initiatives, the implementation of the outcome of the recent fitness checks and feed into the inception phase of new legislation:</p> <ul style="list-style-type: none"> • REACH regulation; • Legislation on plant protection products and pesticides residues; • Framework directive on occupational safety; • General food law and other regulations in the area of food and feed; • The water framework directive; • Commission's proposal for a regulation on the transparency and sustainability of the EU risk assessment in the food chain; • Commission Communication on options to address the interface between chemical, product and waste legislation;

⁴ www.hbm4eu-vienna2018.com/#conclusions, “Human biomonitoring in Europe – science and policy for healthy citizens”, September 2018

	<ul style="list-style-type: none"> • Commission Communication on a comprehensive European Union framework on endocrine disruptors; • Commission Communication on a European Union strategic approach to pharmaceuticals in the environment; • Commission Communication on a European plastics strategy for a circular economy; • The Commission Communication on combination effects of chemicals • The 7th Environment Action Programme and its possible follow-up; • A possible future EU strategy on the chemicals policy; • The EEA's state of the environment report. <p>In addition, the partnership will contribute to international fora, such as WHO, UNEP and OECD, dealing with chemicals, pollution and the SDGs.</p> <p>The expected timeframe of the proposed partnership would be an initial five (5) years, during which further sustainability should be prepared.</p>
Necessity test: rationale for a European Partnership	Addressing citizens' concerns about the safety of chemicals in their daily life and the environment, whilst ensuring industrial competitiveness, requires a cross-disciplinary and multi-disciplinary approach. Today's knowledge gaps that affects everybody and every place across the EU, require the combined efforts of different funding mechanisms, schemes and actors. A partnership for R&I in chemical risk assessment will incentivise the required collaboration between the risk assessment and regulatory entities, at EU and national level. Their engagement will reflect political commitment and wish to coordinate by jointly developing and implementing a European programme. Regular calls for proposals will not achieve the same level of integration, strategic programming and co-shared responsibility. With the EC's mandate on chemicals regulation, there is already a regulatory system in place spanning from national to the EU level. The proposed partnership will develop the corresponding supporting network for research and drive forward innovation.
Relevant for the following parts of Horizon Europe	Pillar II 'Global Challenges and European Industrial Competitiveness' <input checked="" type="checkbox"/> Cluster Health <input type="checkbox"/> Cluster Culture, creativity and inclusive society <input checked="" type="checkbox"/> Cluster Civil Security for Society <input checked="" type="checkbox"/> Cluster Digital, Industry and Space <input checked="" type="checkbox"/> Cluster Climate, Energy and Mobility <input checked="" type="checkbox"/> Cluster Food, Bioeconomy, Natural Resources, Agriculture & Environment <input checked="" type="checkbox"/> Cross-cluster
Currently identified links with other partnership candidates / Union programmes	<p>Information on risks posed by chemicals is important for many of the other partnerships proposed across sectors, as well as for the missions on Soil Health and Food; Cancer; Healthy Oceans, Seas, Coastal and Inland Waters. This partnership should act as a reference point for research questions related to chemical risks (complementing the available regulatory information).</p> <p>In addition, this partnership links to: i) Activities on chemical safety in JRC including IPCHEM, EFSA, EEA and ECHA ii) LIFE programme; iii) ESF+ and iv) ERDF</p>
Does the proposed partnership build on currently active ones?	The European Human Biomonitoring Initiative EJP, HBM4EU, ending 31.12.2021

Expected type and composition of partners	<p>All EU Member States will be invited to participate, as well as other European countries. The main partners shall be national organisations carrying out chemical risk assessment or regulatory enforcement mandated by the authorities in charge of chemical safety policy development. The involvement of academia and research organisations can be envisaged either through open calls on specific research topics or as Linked Third Parties to the grant signatories. Each country will have to establish a national network to ensure that information is spread, and input on research priorities gathered.</p> <p>The equivalent actors at EU level, such as EFSA, ECHA, EEA or EU-OSHA and EMA, can either be part of the governance structure to ensure alignment with their infrastructures and activities or, if rules of participation of Horizon Europe and their mandates allow so, envisage becoming partners of the initiative. Coordination with JRC activities and use of JRC databases will be managed through the governance structure.</p> <p>HBM4EU has set an example of pro-active outreach to stakeholders and citizens, joint priority setting and open knowledge sharing, which can be replicated for this new partnership. An International Advisory Board will ensure links to international activities and explore possible collaborations.</p>
Contributions and commitments expected from partners	<p>Partners will have to co-finance costs incurred by carrying out joint ‘in-house’ research or provide funds for jointly decided calls for targeted research, which they cannot themselves carry out, should they wish to use that mechanism. This may require support from national research funding organisations. Activities covered ‘in-house’ by the partnership should involve regulatory and policy uptake of new tools and methods developed and communication to citizens and stakeholders. The co-funding rate is to be discussed with the partners and their national authorities.</p>
Currently envisaged implementation mode(s)	<p><input type="checkbox"/> Co-programmed European Partnership</p> <p><input checked="" type="checkbox"/> Co-funded European Partnership</p> <p><input type="checkbox"/> Institutionalised European Partnership</p>
Justification of the implementation mode	<p>A co-funded partnership is the best instrument to support collaboration between national entities, who are not funding agencies per se, but national organisations in charge of regulatory activities, carrying out either research activities themselves or through contracts with academia or other publicly funded research institutions. A co-funded partnership allows for national arrangements between funders for the involved agencies to cover incurred costs not funded by the EU grant. A long-term sustainable partnership in Europe should not be reliant on research funds only, but needs a wider political endorsement and investments. Basing the financial contribution on costs incurred leaves it up to partners to contribute according to their means and national capacities/interests. This will ensure inclusiveness. The required synergies can be achieved by a co-funded partnership without engaging in the more complex processes of an institutionalised partnership. A co-programmed partnership does not allow for the required scientific collaboration between partners.</p> <p>The HBM4EU EJP has proven its value in fostering the necessary EU-wide coordination and collaboration across science and policy. The concept of the HBM4EU governance structure can therefore be used as a model for the new partnership. The highest governance board would involve the national and EU authorities in political charge of risk assessment and management. The aim of the governance board will be to set joint priorities and ensure alignment with policy agendas and complementary activities or programmes. The mandated national entities will then be in charge of implementing the joint programme.</p>
Proposed starting year	2022