HBM4EU NEWSLETTER

Newsletter n°6 - July 2020
HORIZON2020 Programme
Contract No. 733032 HBM4EU

The legacy of HBM4EU
Research must move closer to politics

The next European research programme "Horizon Europe" must proactively foster the development of relevant legislation. One might not win a Nobel Prize for doing so - but it adds value.

The Paracelsian paradigm - often reduced to the declaration "the dose makes the poison" - is changing. Unfortunately, the effects of a harmful substance do not depend merely on the quantity in which it occurs. Which substances accompany it in the environment, and do they neutralise, modulate or even heighten its effects?

Ecosystems - and humans - are never exposed to "one" substance, but rather to a cocktail of substances. This mixture of chemicals did not exist prior to the establishment of an industrial society, producing and using chemicals. Since then tens of thousands of synthesized chemicals, and their metabolites, have been added to the mix. Organisms are, in principle, able to cope with cocktails of substances in their environment - they have had to adapt to that since the beginning of life. However, it is often difficult to determine which effects one or more additional components have in this mix. This problem stems from the fact that our - undisputedly sophisticated - risk assessment tools assess individual substances.
These tools have previously been adjusted to respond to previous challenges and to capture newly detected phenomena. For example, in the 1970s chlorofluorocarbons (CFCs) were founds to damage the stratospheric ozone layer. The comparatively clear connections between cause and effect permitted the swift global phase-out of these substances through a treaty under international law, the Vienna Convention for the Protection of the Ozone Layer and its Montreal Protocol. It is considerably more difficult to define properties like "persistence" or "accumulation in the food chain" clearly enough, to develop test methods to detect them, and to set requirements in legal instruments to oblige business to systematically test substances for these properties. It took us 23 years to describe the property "harmful to the hormone system" sufficiently clearly and comprehensively to set requirements in legislation for the protection of humans and the environment against these substances - and that work continues.

In this issue:

https://www.hbm4eu.eu/

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Federal Ministry
Republic of Austria
Climate Action, Environment, Energy, Mobility, Innovation and Technology

Dr. Thomas Jakl
HBM4EU Ambassador, Austrian Ministry for the Environment, Deputy Director General

Latest stress test

We owe the continuous development of the instruments for hazard and risk assessment not only to the advancement of scientific knowledge, but also to progress in material and product development. The latest stress test entailed the complex adaptation of test methodologies to enable the evaluation of new products, like nanomaterials. At the same time, our assessments of risks to people and the environment have now reached an unprecedented level of scientific quality - gone are the times when, at best, anecdotal evidence on the contamination of humans with specific substances was available.

Over the past few years an EU-wide programme for the systematic documentation of human exposure to chemicals has been implemented by means of human biomonitoring - HBM. The project, HBM4EU, investigates human samples (blood, breast milk, hairs, etc.) drawn from across the continent, age groups and population groups to find out whether measures taken to reduce human exposure to chemicals are effective - that is, whether concentrations in people decrease after a substance is banned - and whether new measures are needed to address emerging substances.

Robust backbone

An interaction of individual, national and concerted initiatives has so far enabled us to enhance and standardise the methodologies for the documentation and evaluation of substance properties - a precondition for their incorporation into European law. To keep pace with scientific developments, for example mixture toxicity and epigenetics, and innovation in the field of advanced materials, further work should be based on a robust, reliable and sustained foundation that can support efforts to tackle the complexity that we face today.

Under the Austrian EU Presidency, the political discussion on the required change of paradigm was initiated. The European Commission and Member States recognised this urgent need for action and took the first steps. Based on extensive preparatory work, a partnership under the future EU research programme, Horizon Europe, will institutionalise human biomonitoring as an instrument to support chemicals policies, and provide a framework for the continuous development of methods for hazard and risk assessment.

Adequate co-financing

At present, intensive work is underway to set the objectives that this partnership - the new backbone of applied research to serve chemicals policy – will achieve. Dedicating a relatively small fraction of European research funds to support the implementation of environment and health policies, through the development of test methodologies and running systematic monitoring programmes, is also an important step for social policies. Further steps must follow.

This implies that we will have to ensure adequate co-financing from national research funds in Member States. It will also be necessary to strengthen the linkages between applied research and legislation to protect human health and the environment, to ensure a solid scientific foundation.

Relevant European directives and regulations should recognise the emerging partnership as an important mechanism in the science-policy interface.

Finally, it needs to be embedded in the European institutions. Three EU agencies would be well suited for this purpose: The European Chemicals Agency in Helsinki, the European Environment Agency in Copenhagen and the European Food Safety Agency in Parma.

There is still much to be done - also for the new EU Commission - as of early 2022 the new partnership should be fit for action.

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Prof. Dr. Hans Verhagen
European Food Safety Authority

AN EFSA VIEW ON HUMAN BIOMONITORING IN FOOD SAFETY

The European Food Safety Authority (EFSA) is a European agency funded by the European Union (EU) that operates independently of the European legislative and executive institutions, including the Commission, Council and Parliament, and the EU Member States. Founded in 2002 following a series of food crises in the late 1990s, the Agency serves as a source of scientific advice and communication on risks associated with the food chain and was legally established under the General Food Law - Regulation 178/2002. The General Food Law created a European food safety system under which responsibility for risk assessment (science) and for risk management (policy) are kept separate. Most of EFSA's work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament and EU Member States.

EFSA's core responsibilities include the evaluation of food and feed products that require a safety assessment before they can be brought onto the EU market. EFSA conducts its risk assessment according to the classical risk assessment paradigm: hazard identification and characterisation, exposure assessment and risk characterisation. Dietary exposure is routinely assessed by EFSA though the combination of occurrence and consumption data. Quantitative information on the level of a chemical in food are obtained through analytical determinations and, in the case of intentionally added substances, from the producers. Dietary surveys are the primary source of food consumption data. The assessment of dietary exposure requires some degree of modelling and the method chosen usually depends on the degree of accuracy required and the availability of data.

Human biomonitoring has already occasionally been part of an EFSA mandate, such as for bisphenol A, cadmium, lead, methylmercury, deoxynivalenol. It featured in two reviews on pesticides and has been used for cross validation of exposure estimates obtained by combining occurrence and consumption data. Also, EFSA has identified human biomonitoring to be a valuable source of information in epidemiological studies in food safety risk assessments. As such human biomonitoring and the HBM4EU project are a promising development in the area of risk assessment for human health.

EFSA was happy to receive a delegation of the HBM4EU project in Parma in February 2020. On that occasion, many areas of shared interest and potential collaboration were identified and discussed, such as contaminants (e.g. heavy metals, mycotoxins, per/poly-fluorinated compounds, acrylamide), pesticides and packaging

materials (e.g. bisphenols and phthalates). Emerging substances is an additional area of mutual interest to both HBM4EU and EFSA. Mechanistically, there was interest in newer areas such as mixture toxicology, non-monotonic dose response curves, and toxicokinetics in terms of absorption, distribution, metabolism, and excretion (ADME), to which human biomonitoring could be added. In terms of access to the results of human biomonitoring activities under HBM4EU, EFSA stressed the importance of having access to individual data, and not just aggregated data.

EFSA will closely follow the developments in human biomonitoring and the HBM4EU project and is represented in the Governing Board and Policy Board, whereas several colleagues are involved in individual work packages.

HBM4EU delegation in Parma.

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Republic of Estonia
Health Board

Märten Lukk
Advisor at the Department of Environmental Health, Health Board, Estonia

NEWS FROM OUR NATIONAL HUBS - HUMAN BIOMONITORING IN ESTONIA

In Estonia, the primary source of energy is oil shale, a more polluting fuel than coal. It is mined in the Ida-Viru county in Estonia. Oil shale is a sedimentary rock that contains organic matter known as kerogen that, when heated, can produce a liquid oil very similar to crude oil. Due to our long history of using this fuel and the documented health effects in Estonia, we have discussed the need to apply new and more advanced methods to understand health impacts.

In 2015, a large study was conducted in Estonia to study the overall health effects of the oil shale industry. The study involved an analysis of pollution permits and monitoring data, coupled with the modelling of pollutant levels, to quantify the exposure of the population to pollution across the region. Extensive clinical surveys of respiratory tract-related ailments were conducted among more than 1000 children living in the counties of Ida-Viru and Lääne-Viru and the results were compared with the data on children living in the country of Tartu.

The analysis of the quality of ambient air showed a clear problem in relation to industrial pollutants, namely formaldehyde, phenol, benzene and hydrogen sulphide, for which concentration levels consistently exceeded relevant pollution limits.

An important finding was that rates of respiratory system disorders in children living in the Ida-Viru County, as well as mortality rates from circulatory system disorders, were both higher in Ida-Viru County than elsewhere in Estonia. A possible connection between oil shale mining and cancer was also seen.

In Estonia, our hope is that we can use biomonitoring to assess human exposure to oil shale specific chemicals, to characterise exposure pathways and to calculate potential risks. This can support informed decision-making on how to address health issues present in the Ida-Viru County. A proposed scoping study aims to identify relevant biomarkers that can be assessed when biomonitoring the population exposed to the oil shale sector, including both workers and residents.

The current project will support the development of a methodology for the biomonitoring of chemicals related to the oil shale industry. Many of the relevant industrial pollutants have already been studied in other countries. As such, HBM4EU offers us a unique chance to draw on the knowledge already build up on the subject in other partner countries. It is especially useful that HBM4EU has materials to help with the communication of results and possible concerns to policy makers and the general public, since this provides us with the tools to justify our interest in conducting biomonitoring in Estonia.

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YOUNG RESEARCHERS' POSTER PRESENTATIONS AT THE 2019 HBM4EU CONSORTIUM MEETING

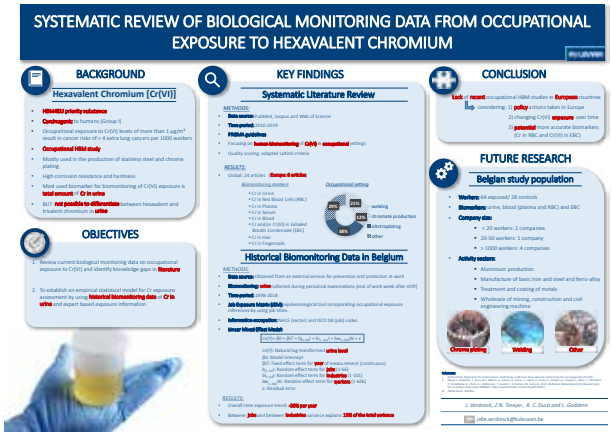
At the 2019 Consortium Meeting, young researchers were invited to present posters introducing their work. Many participants viewed the posters and engaged in lively discussion.

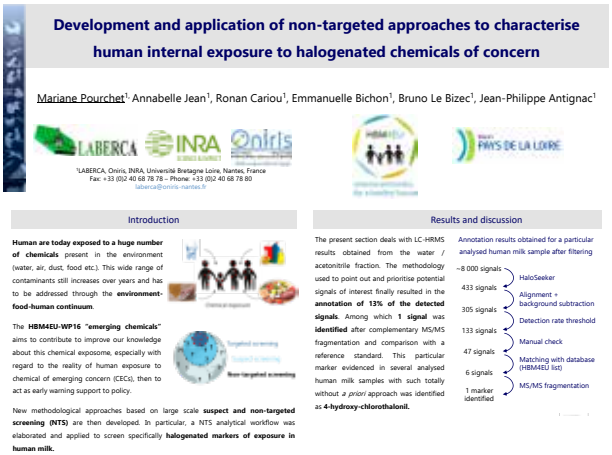
The posters were judged by Paul Scheepers, Joana Lobo and Lisbeth Knudsen in terms of content, graphical presentation and lay-out. The winning posters were:

- Jelle Verdonck's poster on a systematic review of biological monitoring data from occupational exposure to hexavalent chromium.
- Mariane Pourchet's poster on the development and application of non-targeted approaches for characterizing human internal exposure to halogenated chemicals of concern.

Thanks to all the young researchers who submitted posters! All the posters can be viewed at the HBM4EU webpage on posters.

Due to the success of last year's poster session, we will repeat this activity this year. Young researchers will be asked to provide an abstract, a short CV and a one power point slide to introduce their research. They are encouraged to reflect on the policy implications of their findings.





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UMIT
the health & life sciences university

PD Dr. med. Stephan Böse-O'Reilly
UMIT - Private University for Health Sciences, Medical Informations and Technology

HOW CAN HUMAN BIOMONITORING RESULTS BE OF INTEREST TO MEDICAL PRACTITIONERS?

Medical practitioners are in daily contact with their patients. Some patients come to the consultation worried that they may have been exposed to one or more chemical substances, even connecting their personal symptoms with those chemicals. They ask the doctor whether their blood or urine could be analysed to check for the presence of the chemicals.

As a second scenario, a patient shows up presenting multiple symptoms, and the doctor suspects that these symptoms could be caused by exposure to chemicals. Depending on the chemical, the potential source of exposure and the availability of specific laboratory methods, the analysis of blood or urine in a qualified laboratory can be helpful to answer this question.

Medical training at universities and ongoing professional training in Europe does not adequately cover environmental medicine. In some countries, a limited number of practitioners have some additional qualifications in environmental medicine. But most medical doctors are familiar neither with human biomonitoring methods, nor with potential benefits and limitations.

HBM4EU is creating an extensive amount of new knowledge about chemical stressors, including untargeted analysis of emerging substances and the effects of exposure to multiple chemicals. In my opinion, there is a clear demand and need to open this "treasure island" to medical practitioners. One option would be to organise a training workshop, invite interested doctors and ask some of our great researchers from the HBM4EU community to provide targeted lectures.

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Finnish institute for health and welfare

Hanna Tolonen
Finnish Institute for Health and Welfare, Finland

PUBLIC HEALTH AND DISEASE BURDEN PERSPECTIVE

on chemical exposures

A healthy population is a prerequisite for productive and sustainable economic development. Through the reduction of absence due to sickness, early retirement and premature mortality, we can increase workforce productive and at the same time, lower health care costs by improving overall health outcomes. This brings positive societal impacts at the level of the individual, families, and communities.

When discussing chemical exposure and potential adverse health effects, we often have a specific substance in focus. For example, evidence suggests that substances in the HBM4EU priority substance group, bisphenols, are associated with negative impacts on reproductive health, foetal development, puberty, cognitive and neurological development, as well as obesity, diabetes, cardiovascular disease and several cancers.

In terms of public health, it would be more interesting to look the problem from a health perspective, starting from a chronic disease or health outcome and asking which chemical substances might play a causal role. For example, asthma has been associated with polyaromatic hydrocarbons (PAHs), diisocyanates, hexavalent chromium (Cr(VI)) and organophosphate insecticides. In addition, phthalates, Hexamoll® DINCH, per- and polyfluoroalkyl substances (PFASs), p-Phenylenediamine (p-PDA), pyrethroid insecticides, mercury, cadmium, arsenic and lead are all suspected to have an association with asthma.

Asthma causes a significant burden of disease and economic cost both for society and for individuals throughout hospitalizations, disability, premature deaths and the costs of medication. It has been estimated that asthma affects 30 million people in Europe and one quarter of European children. In terms of other chronic health conditions, it has been estimated that 60 million Europeans have diabetes and 10-30 % of the adult population are obese, while we see around 11 million new cases of cardiovascular disease annually.

It is therefore important to be able to estimate the proportion of the burden of disease for each condition, the attributable fraction, that is caused by exposure to different substances. This would facilitate estimates of the proportion of the disease burden in Europe, and the associated economic and human costs, that could be eliminated through restrictions of harmful substances.

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NNK

Dr. Tamás Szigeti
National Public Health Center, Hungary

NEWS FROM OUR NATIONAL HUBS - AWARENESS RAISING CAMPAIGNS IN HUNGARY

New communication materials were produced in Hungary, including factsheets and posters on different chemical groups both in Hungarian and in English. So far, materials are available on phthalates, bisphenols, polycyclic aromatic hydrocarbons, flame retardants and mycotoxins.

Social media has been used to raise public awareness of harmful substances, including the official Facebook profile of Hungary's National Public Health Center and the Chief Medical Officer. Furthermore, a questionnaire was used to assess public concerns regarding chemicals at a two-day event held in Budapest in the context of the European Mobility Week in September 2019.

Awareness raising activities on human biomonitoring were also organised during the International Conference on Problem-Solving Approaches to Ensure Schoolchildren's Health, held in May 2019 in Budapest. More than 100 policy makers, public health professionals, researchers and architects participated in the event from all over Europe. Several oral and poster presentations on human biomonitoring were included in the conference programme.

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Finnish Institute of Occupational Health

Dr. Tiina Santonen
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HBM4EU CHROMATE STUDY BRINGS NEW INFORMATION

on the occupational exposure to hexavalent chromium

HBM4EU work on occupational exposure to chemicals

Occupational exposures to specific chemicals may, in many instances, be several times higher than environmental exposures experienced by the general population. Human biomonitoring provides a valuable tool for understanding human exposure to chemicals in the workplace and ensuring safety at work.

In terms of undertaking human biomonitoring studies, a typical challenge in occupational studies is the low number of workers that can be recruited in national studies. As is in the case for human biomonitoring studies assessing environmental exposure, the studies performed by different researchers in individual countries are usually not aligned with respect to sampling, analytical methodologies or data collection. This complicates the comparison of the findings and the use of the data in regulatory risk assessment at European level.

Combining results from national surveys that have used harmonized study designs and methodologies can greatly improve the usefulness of the information collected from occupational studies and deliver added value at EU level.

Within HBM4EU, we are implementing three targeted occupational studies focusing on different priority substances. The first one is an occupational study on hexavalent chromium [Cr(VI)] exposure, which began in 2018. The analysis of the results is currently ongoing and will be finished by June 2020.

Under HBM4EU, the second occupational study with two focuses, exposure to diisocyanates and exposures in E-waste handling, has been planned and will be conducted in 2020-2021.

HBM4EU chromate study brings new information on the occupational exposure to hexavalent chromium

Hexavalent chromium (Cr(VI)) is a carcinogen to which people are exposed in the workplace. Although Cr(VI) compounds are subject to authorisation under Regulation (EC 1907/2006) concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), these compounds are still widely used in different applications, especially in surface treatment of different metallic objects. In addition, workers may be exposed to Cr(VI) formed during hot processes, like welding. Although these exposures are not covered by REACH, there is a binding occupational limit value (BOELV) set under EU Directive 2004/37/EC for Cr(VI) to control occupational exposures to Cr(VI) in all processes. It is, however, unclear how well workplaces perform relative to this exposure level.

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According to preliminary results, chrome platers show the highest urinary chromium levels, which are in some cases more than 10-times higher than the levels measured in the control population. While in the control population urinary chromium levels usually remain below 1 µg/g creatinine, in surface treatment workers the levels vary from these background levels up to 10 µg/g creatinine. Interestingly, in some cases, chromium levels in samples taken from workers prior to starting their shifts were higher than in the general population. Although workers performing welding also show elevated levels, these seem to be lower than the levels seen in workers performing chrome plating.

In addition to urinary chromium, we have evaluated the capability of new, more specific HBM parameters for the assessment of Cr(VI) exposure. These include chromium levels in red blood cells and Cr(VI) levels in exhaled breath condensate. According to preliminary results, exhaled breath condensate samples show the same trend as seen in urinary chromium, whereby chrome platers show higher exposure than welders. Welders do also show elevated levels compared to the controls.

Analysis of air samples and wipe samples collected from the hands of workers will give us information on the exposure routes. This can be then used to give recommendations for how to implement risk management measures to minimise exposure to Cr(VI) at workplaces.

The HBM4EU study on Cr(VI) provides a good model that can be applied to other European occupational studies involving multiple countries.

The picture shows a laboratory technician providing a breath sample. The analysis of exhaled air has several advantages since it is a non-invasive method applicable to a large number of toxic agents. Exhaled breath samples are tested as a novel matrix for the biomonitoring of hexavalent chromium.

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RECENT PUBLICATIONS AT A GLANCE

Biomonitoring for occupational exposure to diisocyanates: a systematic review

This year, within the HBM4EU project, an occupational field study will be organized to assess di-isocyanate exposure. To prepare for this study we conducted a systematic review on biomonitoring data for occupational exposures to di-isocyanates. We aimed to:

- Identify biomarkers and matrices that have been used for biomonitoring diisocyanates and understand strengths and limitations;
- Assess current biomonitoring levels of the major diisocyanates (and metabolites) in workers; and
- Characterize potential research gaps.

After critical appraisal of all retrieved studies, we were left with 28 publications. We found large variability within and between studies and across sectors. We emphasized in the discussion the value of studies such as HBM4EU, where significant effort has gone into ensuring that results from different studies and countries within the project are comparable.

MSc Bernice Schaddelee-Scholten
TNO - Organization for Applied Scientific Research, The Netherlands

Comparison of polycyclic aromatic hydrocarbon metabolite concentrations in urine of mothers and their newborns

The aim of our study was to assess the concentration of 11 monohydroxylated metabolites of polycyclic aromatic hydrocarbons (OH-PAHs) in 660 urine samples collected from mothers and their newborns residing in two localities of the Czech Republic – Most and Ceske Budejovice – in 2016 and 2017. 2-OH-NAP was the compound present in all of the measured samples, and it was also the compound at the highest concentration in both mothers' and newborns' urine samples. Overall concentrations of OH-PAHs in urine samples collected from mothers were two times higher compared to their children. The most contaminated samples were collected in Most from both mothers (12.59 μg/g creatinine) and their newborns (8.29 μg/g creatinine). The concentrations of OH-PAHs in urine samples collected from mothers and their newborns presented in this study are comparable with those found in our previous study, and they are comparable to other studies from Poland, USA, Germany, China, and Australia.

Prof. Jana Pulkrabova
PhD, University of Chemistry and Technology, Prague

Peer-reviewed articles:

Scholten, B., Kenny, L., Duca, R.C., Pronk, A., Santonen, T., Galea, K.S., Loh, M., Huumonen, K., Sleeuwenhoek, A., Creta, M., Godderis, L., Jones, K. 2020. Biomonitoring for Occupational Exposure to Diisocyanates: A Systematic Review. Annals of Work Exposures and Health.

Peer-reviewed articles:

Urbancova, K., Dvorakova, D., Gramblicka, T., Sram, R.J., Hajslova, J. and Pulkrabova, J., 2020. Comparison of polycyclic aromatic hydrocarbon metabolite concentrations in urine of mothers and their newborns. Science of The Total Environment, p.138116.

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LOOKING FORWARD

Knowledge hub, prioritisation & sustainability

Input to consultations

Human biomonitoring is a key tool in supporting the design, delivery and evaluation of chemical regulation in Europe.

As a leader in research on exposure to chemicals and impacts on health in Europe, HBM4EU is well-positioned to provide scientific insights on key elements of different consultations.

In 2019 and 2020, HBM4EU has given input to:

- The sustainable use of pesticides directive, linked to the Farm to Fork (F2F) strategy (August 2020);
- The roadmap "Chemical's - strategy for sustainability (toxic-free EU environment)" (June 2020);
- ECHA's public consultation on PFAS (April 2020);
- European Commission's "Sustainable Food - Farm to Fork" roadmap (March 2020);
- ECHA's public consultation on setting of occupational limit values for diisocyanates (December 2019);
- EFSA's public consultation on aflatoxins in food (November 2019);
- SCHEER committee's guidelines on the benefit-risk assessment of the presence of phthalates in medical devices (April 2019).

The documents submitted channel input from the HBM4EU Management Board as well as from the Chemical Group Leads on each substance, to the different institutions.

The input provides some reflections on the work being developed and how some results may be useful for certain actions identified in the consultation or roadmap. It highlights additional aspects seen as critical from the perspective of HBM4EU and identifies relevant lines of evidence produced under the initiative.

Citizen's corner

HBM4EU has also translated the currently available 3 factsheets on bisphenols, phthalates and chromium VI into all the languages of the project. Currently, an additional 11 citizen factsheets are under consultation. The factsheets will be reviewed by the Chemical Group Leader, the National Hubs, the EU Policy Board and the Stakeholder Forum. Subtitled citizen videos are also available from the HBM4EU website, and a 3rd video is currently being prepared.

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Contributing to a sustained human biomonitoring initiative for Europe

It is an objective of HBM4EU to build the foundations of a sustainable human biomonitoring initiative for Europe. Deliverable 6.5 – Sustainability of HBM4EU in the future and related operational architecture concept: first report – identified elements that should be sustained, including:

- The National Hubs;
- The network of laboratories; and
- The alignment of studies and research activities across Europe.

These elements will be incorporated into the European Partnership for Chemicals Risk Assessment (PARC), proposed under the Commission's research funding programme, Horizon Europe. Development of the proposal is coordinated by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), with input from a Country Board that includes key players in HBM4EU, as well as an EU Board including institutional partners.

HBM4EU is involved in two processes to gather priorities for research actions to be undertaken in the context of the PARC. One online survey under the PARC:

1. A survey to identify priorities for new knowledge, tools and methods to be produced under the PARC

And in a second online survey, HBM4EU is gathering priorities on substances, that will feed into the PARC:

2. A survey for the nomination of substances for human biomonitoring under HBM4EU

For the first survey in priorities for the PARC, national and international bodies involved in chemical risk assessment and/or management are invited to contribute, including national bodies, stakeholders from NGOs, industry, trade unions and health organisations, as well as research institutions and academia.

For the second survey for the nomination of substances for human biomonitoring, the survey is limited to HBM4EU National Hubs, as well as members of the HBM4EU Stakeholder Forum and EU Policy Board. **The deadline for input to both surveys is 18 September 2020.**

The survey results will be fed into the discussions in the PARC Country Board and EU Board on priorities for research under the PARC.

More on the PARC

The objective of the PARC is to build an EU-wide research and innovation programme to support EU and national chemical risk assessment and risk management bodies with new data, knowledge, methods, networks and skills to address current, emerging and novel chemical safety challenges. The Partnership will facilitate the transition to next generation risk assessment to better protect human health and the environment, in line with the European Green Deal's zero-pollution ambition and objective of fostering a circular economy, as well as being an enabler for the EU Chemicals Strategy for sustainability. It will stimulate research and innovation in chemical risk assessment through a common roadmap set by risk assessors and risk managers in consultation with all stakeholders.

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