



science and policy
for a healthy future

First set of key indicators

Deliverable Report

D 6.1

WP 6 - Sustainability and capacity building

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1 Authors and acknowledgements

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UAntwerpen, EAA, RIVM, INSA, EEA, AUTH, MU, ISCIII, INSERM, VITO, UBA, RTD

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2 List of abbreviations

AB	advisory board
AUTH	Aristotelio Panepistimio Thessalonikis, Greece
AWP	annual work plan
DoA	description of action
EEA	European Environment Agency
HBM	human biomonitoring
HBM4EU	European biomonitoring Initiative
ISCII	Instituto de Salud Carlos III, Spain
INSA	Instituto Nacional de Saude Dr. Ricardo, Jorge, Portugal
INSERM	Institut National de la Santé et de la Recherche Médicale, France
IPChem	Information Platform for Chemical Monitoring
KSF	key strategic focus
MB	Management board
MU	Masaryk University
LNE	Flemish department for environment, Leefmilieu, Natuur en Energie, Belgium
NGO	non-governmental organisations
NHCP	national hub contact point
PTR	periodic technical report
RIVM	Rijksinstituut voor Volksgezondheid en Milieu, National Institute for Public Health and the Environment, the Netherlands
SF	stakeholder forum
UAntwerpen	University of Antwerp; Belgium
UBA	UmweltBundesAmt, German Environmental Agency, Germany
VITO	Flemish Institute on Technological Research, Vlaamse Instelling voor Technologisch Onderzoek, Belgium
WP	work package

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3 Goal and vision: why develop indicators to measure the performance and impact of HBM4EU

Within the HBM4EU project, the consortium will establish a HBM platform in the EU and will collect, provide and analyse HBM data at EU level. The impact of the knowledge generated will be amplified if the coupling of HBM activities to research activities can be sustained, allowing us to assess time trends in future years. To establish a sustainable network, WP6 is dedicated to exploring options for a sustainable HBM4EU beyond 2021.

The sustainability of the HBM initiative in Europe will depend on the successful achievement of the main objectives of the programme, *i.e.* the establishment of an EU HBM platform, the development of appropriate environment and health research studies and the transfer of the scientific knowledge to policy makers. Therefore, WP6 activities will depend on the successful implementation of all Pillars and WPs. A list of performance indicators will be established and will be related to the output of all other WPs. Efficient NHs and the involvement of all countries are important conditions for the success of this WP. Furthermore, since sustainability will only be achieved with the support of political actors and stakeholders, a close interaction between WP6, WP4 (prioritisation schemes) and WP5 (translation into policy) will take place within Pillar 1. A dedicated HBM4EU Ambassador will lobby all stakeholders regarding the ambition and subsequent achievements of this initiative.

A specific task within WP6 has been defined to measure the performance and impacts of the HBM4EU. In collaboration with the EU policy board, key institutional actors and stakeholders and leaders of large EU or national projects (see section 1.3.1), LNE and partners will develop a set of indicators capturing societal, scientific, policy and stakeholder perspectives, to measure the performance and impacts of the HBM4EU.

These indicators should capture, amongst others, performance of the research activities, impact on science, policy, and society, increased national coordination of HBM related activities, increased engagement of less experienced countries and progress towards an EU-wide HBM platform. LNE, INSERM, AUTH, UBA, INSA and RIVM will use these indicators to measure the performance and impacts of the HBM4EU and ultimately to provide a robust justification for a long-term HBM project in Europe.

An initial set of indicators was produced by M6 (June 2017). They will be revised yearly based on the acquired experience with the implementation of the initiative (D6.1, D6.2).

In this deliverable the strategy used to prioritise and select indicators to measure the performance and impact of HBM4EU, as well as the resulting first list of indicators is presented and is based on:

- ▶ Listing the overarching objectives and Specific goals of the HBM4EU initiative as input for the selection of indicators
- ▶ Defining key strategic foci that relate to the overarching objectives and specific goals of HBM4EU. These key strategic foci were agreed upon in the WP6 kick-off meeting in Berlin (2 February 2017).
- ▶ Selecting a number of criteria and indicators for each key strategic focus, that should enable us to measure the performance and impact of HBM4EU within each key strategic focus.
- ▶ Describing and applying principles to prioritize and select indicators from the long-list
- ▶ Defining first list of performance and impact indicators

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4 Setting the scene: Questions and goals to be addressed by HBM4EU

4.1 Questions to be addressed by HBM4EU¹

European citizens of all ages are exposed to a wide range of chemicals through their diet, their environment, the use of consumer products and at the work place. Exposure to chemicals (including combinations of chemicals) takes place through a variety of pathways and exposure routes, notably via dermal and oral uptake and by inhalation, with the combined exposure via all routes being the aggregate exposure.

Despite the existence of human biomonitoring (HBM) programs at national level and the large number of research and development projects ongoing both at national and European Union (EU) level, there is a clear lack of data on aggregate exposure to single substances and to combinations of chemical substances, as well as insufficient evidence-based knowledge on the link between external exposure via different routes, internal levels and human health. This knowledge is essential to inform effective policy-making to protect the EU population from the impacts of chemical exposure on health. In particular, exposure to mixtures of substances is not adequately addressed, since current risk assessment procedures assess the risks from substances acting in isolation. Furthermore, there is a lack of robust data on internal exposure. HBM data that represent national populations, as well as certain vulnerable groups and highly exposed subgroups, do exist in many European countries and these data could be used to further develop and improve chemical regulations aiming to protect human health. However, a number of factors prevent the use of these data at EU level to gain a pan-European perspective. Firstly, the data were not collected according to harmonised protocols and might therefore not be comparable. Secondly differences in the metadata characterising the datasets impede cross-dataset analyses, and finally available data are not representative of the European population.

4.2 Overarching objectives and specific goals of HBM4EU²

In order to address the abovementioned issues there is a clear need to:

- ▶ OO 1. Harmonise procedures and tools for HBM at EU level;
- ▶ OO 2. Provide and, where missing, generate internal exposure data and link this data to aggregate external exposure and the relevant exposure pathways;
- ▶ OO 3. Develop novel methods to identify human internal exposure to environmental and occupational chemicals and establish the causal links with human health effects;
- ▶ OO 4. Provide policy-makers and the general public with science-based knowledge on the health risks associated with chemicals exposure; and
- ▶ OO 5. Improve chemical risk assessment in the EU through the effective use of HBM data.

The overarching objectives will be achieved via the following specific goals (SG), to be accomplished during the 5 year programme:

- ▶ SG 1: Laying the foundations for a pan-European HBM platform that includes National Hubs and builds on existing expertise;
- ▶ SG 2: Developing a common methodology for the interpretation and use of HBM data in policymaking;

¹ See page 223 Grant Agreement (GA)

² See page 223-224 GA

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- ▶ SG 3: Harmonising and optimising the practices of national HBM programmes, including sample collection, quality assurance and data management;
- ▶ SG 4: Identifying gaps where further data are needed to inform current policy questions and designing new, targeted studies to address these knowledge gaps;
- ▶ SG 5: Including new HBM data and, where possible, existing HBM data in the European Commission's Information Platform for Chemical Monitoring (IPChem);
- ▶ SG 6: Linking external to internal exposure in order to improve exposure models for risk assessment;
- ▶ SG 7: Developing, validating, and applying exposure and effect biomarkers to improve understanding of the health risks associated with aggregate exposures;
- ▶ SG 8: Identifying chemicals of concern through novel methods for the holistic analysis of HBM samples and improving the use of HBM data in assessing exposure to and the risks of chemical mixtures;
- ▶ SG 9: Enhancing our understanding of the causal association between chemical exposure and adverse health outcomes by combining mechanistic studies with existing cohort data;
- ▶ SG 10: Promoting capacity building at national level through training and exchange programmes;
- ▶ SG 11: Engaging with stakeholders, including the general public, throughout the programme to ensure the credibility, accountability and legitimacy of activities and results.

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5 Reader's guide on key strategic foci, criteria and indicators

5.1 Key strategic foci and criteria

The overarching objectives and specific goals of the HBM4EU initiative (see 3.2) relate to

- (1) creating an impact in the fields of science (OO 2-3 and SG 6-9), policy (OO 4-5 and SG 2, 4-5) and society (SG 11) or
- (2) providing a robust justification for a long-term HBM project in Europe (OO1, SG 1, 10).

During the project communication and dissemination of results and a good project management are (additional) key goals of HBM4EU, further specified in the specific goals for year 1 (see Grant Agreement, annex 1A).

These major goals of the project can be translated into 6 key strategic foci (Figure 1).

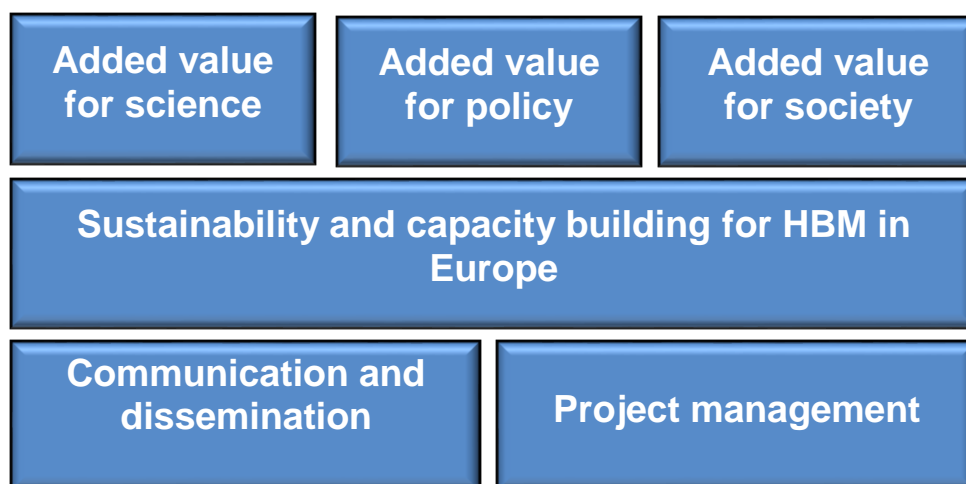


Figure 1. Key strategic foci in the HBM4EU initiative

Added value for science – A first key strategic focus is the added value of the HBM4EU initiative for science and innovation. An ambitious research programme to develop a better understanding of human exposure-response relationships can be found in pillar 3 ‘Environment and Health’ (WP11-WP16).

Criteria for an added value for science are:

- ▶ scientific productivity of the HBM4EU consortium (outputs such as publications);
- ▶ interdisciplinary cooperation;
- ▶ innovative character of the research.

Added value for policy - A second key goal of HBM4EU is to create an added value for policy through the use of HBM4EU outputs. This key strategic focus relates to the work in the science-policy pillar, more specifically to WP4 (prioritisation and input to the annual work plan) and WP5 (translation of results into policy).

Criteria for an added value for policy are:

- ▶ prioritization of chemicals for analysis and research responds to current policy questions;
- ▶ make HBM data and research results available to risk assessors and risk managers (e.g. via IPCHeM);

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- ▶ improve chemical risk assessment through the use of HBM data;
- ▶ translation of HBM4EU results into options for policy action and risk management.

Added value for society - A third key strategic focus of the HBM4EU initiative is to create an impact on societal level. This will be stimulated by engaging stakeholders, taking into account stakeholder perceptions and interacting with HBM-participants and the general public. The ultimate societal goal is the improvement and equal distribution of environmental quality, health and well-being, but also to build trust and increase understanding of the societal complexity related to environmental health risks.

Criteria for the added value for society are:

- ▶ openness towards stakeholders and taking into account stakeholder perspectives’;
- ▶ societal benefit of HBM4EU activities (awareness, improvements in health and wellbeing, trust, equal distribution of benefits, etc.)’.

Sustainability and capacity building - A fourth major goal of the project is to provide a robust basis for a long-term HBM project in Europe that can support environmental health policy. This key strategic focus relates to the work in WP6 ‘Sustainability and capacity building’ and in pillar 2 ‘HBM platform’.

Criteria for evaluating the sustainability of HBM are:

- ▶ harmonising and optimising the practices of national HBM programmes, including sample collection, quality assurance and data management;
- ▶ promote capacity building and networking through training and exchange programmes;
- ▶ laying the foundations for a pan-European HBM platform that includes National Hubs and builds on existing expertise.

Communication and dissemination - Communication and information sharing is a key success factor in achieving the aforementioned goals. All information, including research protocols, risk assessment protocols and health impact assessments, will be documented and made available through the Knowledge Hub (WP2). Results will be made available through open access publications. HBM data will be made available to the different user groups through the IPCHeM platform. Next to giving access, it is also important to inform about the project, to make it well known also to the EU population. By follow-up of indicators we aim to assess HBM4EU’s communication and dissemination objectives.

Criteria for communication and dissemination are:

- ▶ all information will be documented and disseminated through the knowledge hub
- ▶ HBM4EU results are effectively communicated to key audiences through targeted communication products and activities

Project management - It is important to safeguard the good functioning of the consortium and to monitor and evaluate whether the research activities within HBM4EU answer to the goals of the Description of Action (DoA) and Annual Work Plans (AWPs) and are positively accepted by the granting authority. Therefore, a list of output indicators related to the performance of the consortium (project management) will be included. These will be internal indicators used for internal project monitoring.

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5.2 Selection of a first list of indicators for performance and impact of HBM4EU

Within each key strategic focus, indicators were selected that can help to assess whether we achieve our main goals (the key strategic foci) and the subgoals we derive from them (criteria).

Different types of indicators can be discerned:

- ▶ **Output indicators** relate to what is directly produced or supplied by the HBM4EU consortium. These are 'easy to measure indicators that can be used to follow the progress of the programme within the short to medium term (during the programme). Output information is important to show what the activities of HBM4EU have produced, but they give no information about the actual results or consequences of the activities of HBM4EU.
- ▶ **Outcome indicators** focus on the specific changes HBM4EU is intended to achieve. Outcome and output indicators are generally defined as **performance indicators**, which relates to the effectiveness and efficiency of the project.
- ▶ **Impact indicators** focus on the ultimate impact of HBM4EU on different fields, for example health benefits, better environmental quality, but also more relevant science, transparent policy making, trust in government and industries, etc. These indicators are more difficult to evaluate mainly because of the time lag effect and multicausality.

Figure 2 illustrates the distinction between the different types of indicators.

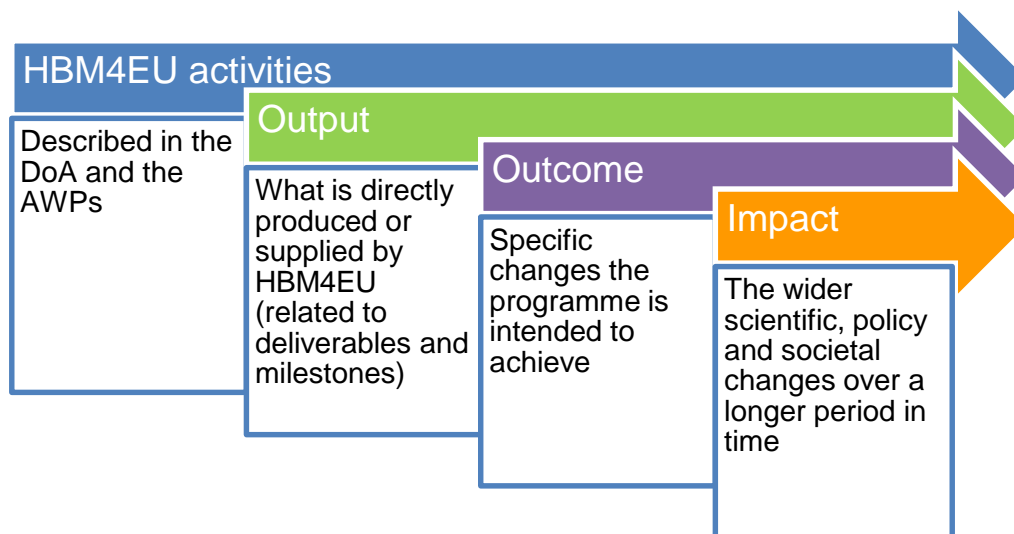


Figure 2. Types of indicators

For the first year, we aimed to define a pragmatic number of indicators per key strategic focus. This first list can be adjusted and complemented during the HBM4EU initiative. It is our ambition to not only define output indicators (low hanging fruits) but also more difficult indicators related to the outcome and impact of HBM4EU (high hanging fruits) that can give a more nuanced image of the added value of HBM4EU and towards the sustainability of HBM. These indicators can be quantitative or qualitative, depending on the subgoals/criteria that will be judged.

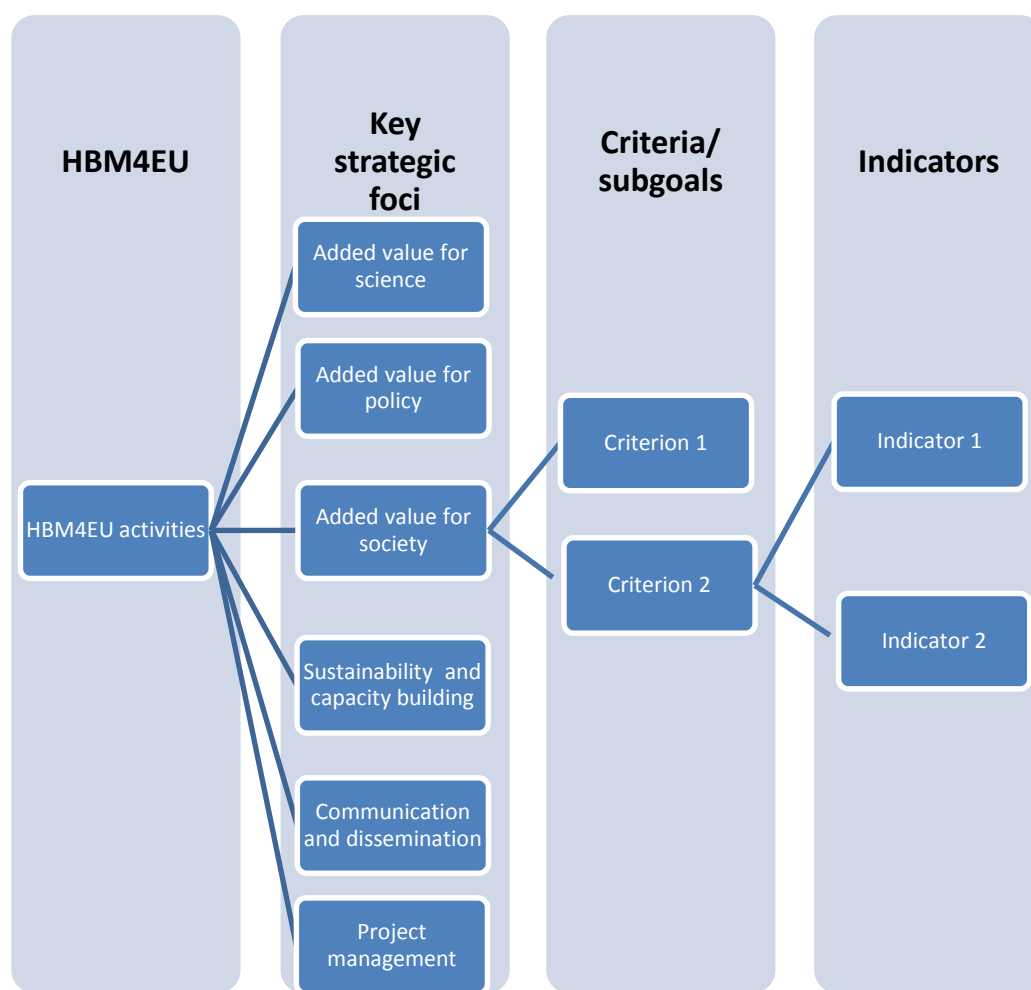


Figure 3. Relation between HBM4EU activities, key strategic foci, criteria/subgoals and indicators

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6 Setting up the first list of indicators for deliverable D6.1

Activities (partners)	Timing
1. Kick-off meeting (Berlin): agreement on key strategic foci and principle to select criteria and indicators within each key strategic focus	20/2-13/3
2. Request for input on criteria and indicators for performance and impact of HBM4EU (LNE, VITO, UA, INSERM)	20/2-13/3
3. Input from partners on 6 key strategic foci: 3.1. Added value for science (INSERM, INSA, AUTH, MU) 3.2. Added value for policy (EEA, RIVM, UBA, INSERM) 3.3. Added value for society (RIVM) 3.4. Sustainability/ capacity building (INSERM, INSA, EEA, UBA, ISCII, MU) 3.5. Communication and dissemination (EEA, ISCII) 3.6. Project management (UBA, ISCII)	13/3 – 5/4
4. Process input, adapt note for prioritization of indicators (LNE, VITO, UA, INSERM, INSA)	5/4– 20/4
5. Prioritize indicators from the long-list (all partners and EU Policy Board)	20/4 – 5/5
6. Process input from partners and consultations (LNE, INSERM, INSA)	8/5 – 19/5
7. Meeting with project partners to discuss priorities and select criteria and indicators for D6.1 (all partners)	17/5: meeting
8. Writing of D6.1 (LNE, INSERM, INSA)	8/5 – 24/5
9.1. Feed-back from the partners of D6.1 (all partners) 9.2. Feed-back from MB	24/5 – 2/6 24/5 – 5/6
10.1. D6.1 to WP leader (LNE) 10.2. D6.1 to pillar leader/coordinator (LNE)	9/6 12/6

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6.1 Creation of a longlist of indicators

At the HBM4EU kick-off meeting LNE presented a strategy to select a first list of indicators for D6.1. Key strategic foci as defined in 5.1 were agreed upon. The principle to select criteria and indicators within each key strategic focus was presented.

A core team, consisting of LNE, INSERM (WP leader), VITO (Pillar leader) and UAntwerpen (for links with the work on policy impacts conducted under task 5.5) wrote a request for input that was sent on 13/3/2017 to the partners in task 6.4A. In this first consultation phase, extensive and diverse input was received on performance and impact indicators within the 6 key strategic foci. LNE processed the input resulting in a longlist of indicators covering quite some diversity. In this first exercise scientific, policy and societal perspectives were taken into account based on the experience of the partners in task 6.4A, extended with the view of sociologists (UAntwerpen) and with input from guidance documents on project evaluation methodologies.

6.2 Prioritisation and selection of indicators from the long-list

A set of general principles for prioritisation and selection of indicators to come to a first list for deliverable D6.1 was communicated via mail and confirmed at the WP6 meeting in Brussels (17/5). An excel document containing the long-list with indicators was sent to the partners in task 6.4A and to the EU Policy Board for prioritisation of indicators within each key strategic focus.

6.2.1 General principles for the prioritisation and selection of indicators

The final list of indicators should consist of a **condense and manageable set of indicators**, in which **for each key strategic focus at least one** (and preferably more) indicator(s) will be retained.

For the prioritisation and selection of indicators we take into account:

- ▶ the **data accessibility** (how can we fill in the indicator): The assignment of a 'value' to the indicator cannot be too complex/difficult/time intensive.
- ▶ the **ownership/responsible(s)** to fill in the indicator. One or more responsible(s) should be willing and capable to fill in the indicator
- ▶ In the selection of indicators, we make a distinction between indicators that have to be filled in on a **yearly basis** and indicators that will be completed in the **mid and/or end of the project**. The indicators on a yearly basis will be mostly **quantitative** indicators, the indicators for the mid/end of the project will rather be **qualitative** indicators (and measure reflections about the (added) value of the HBM4EU project based on the different key strategic foci).
- ▶ We would like to end up with a **combination of short-term (yearly) and mid/long term (qualitative) indicators**. For the qualitative indicators we are aware of the fact that the formulation and assessment are not yet final. Therefore, we propose to adjust them after approval of the first list of indicators (deliverable D6.1).

The selected set of indicators will preferably enable us to monitor the progress in/off the project, track developments, identify possible bottlenecks and reflect on the strong and less strong aspects of HBM4EU.

This is a **work in progress**, modifications are of course possible during the yearly revisions.

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6.2.2 Prioritisation and selection process

Taking into account the abovementioned general principles, we asked all partners in task 6.4A to **score the indicators per key strategic focus (KSF)** In order to come to a short-list of indicators.

We used the following strategy:

- ▶ The total number of points per KSF equals the number of indicators in that KSF. Partners could attribute the points to the different indicators within that KSF. If they wanted to keep all the indicators, they gave them all 1 point. If they wanted to delete an indicator they were supposed to give no points to that indicator (likewise they could give more points to indicators that you thought are really useful/ important and wanted to keep in the selection).
- ▶ If partners disagreed with the formulation of an indicator, the method, timing or ownership, they could suggest a concrete reformulation
- ▶ If a partner thought that essential elements were still lacking, he could add an indicator. If he wanted this indicator to be retained in the short-list he also had to score that indicator.

The same exercise was asked to the EU Policy Board.

LNE processed the input of the prioritisation exercise:

- ▶ Scores per partner and total scores (% of total N°points per KSF; partners vs. EU Policy Board) were visualized
- ▶ General remarks were bundled per indicator (e.g. reformulate, too ambitious for the timeframe of the project, not in the scope of the project, too ambiguous, hard to measure,...)

By adding the points and bundling remarks of all partners, we had an idea of which indicators were assessed as important and which indicators were candidates to delete from the long-list.

6.2.3 WP6 meeting, Brussels

A meeting was held in Brussels (17/5/2017) with the goal to make decisions on which indicators would be retained in the first list included in Deliverable D6.1.

In preparation of this WP6 meeting, an updated list of indicators per key strategic focus (containing scores and remarks) was sent to the partners in task 6.4A. This list contained three worksheets:

- ▶ The worksheet 'green list' contained the indicators that LNE suggested to keep on the first list for deliverable D6.1. LNE also made a separation in a list of indicators to be filled in on a yearly basis and a list of qualitative indicators. We based the selection not only on the scores and remarks received during the prioritisation exercise but also on discussions and opinions raised before or during the 17/5 meeting.
- ▶ The worksheet 'red list' contained the indicators that LNE suggested to remove.
- ▶ The worksheet 'orange list' contained mostly qualitative indicators (for the mid-term and end of the project). These indicators also are important to monitor the progress in/off the project, track developments, identify possible bottlenecks and reflect on the strong and less strong aspects of HBM4EU. However, the formulation and assessment are not yet final. Therefore, it was proposed to discuss and adjust them after approval of the first list of indicators (deliverable D6.1), based on which they can be moved to the green or the red list. If a partner felt that it would be impossible to assess one of these indicators he/she could suggest changes to or removal ("red list") of the respective indicator.

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The 'green' list and the 'red' list were discussed and adapted during the meeting.

The resulting first list of indicators ('green' list) is presented in chapter 8. From this list a limited set of performance indicators that relate to the overarching objectives of HBM4EU is also presented (8.1.1). In addition, a set of indicators for internal use was selected (8.2).

In attachment, the 'orange' list can also be found. For indicators on the orange list it was agreed at the WP6 meeting (6.2.3) to discuss and adjust them after approval of deliverable D6.1. Based on this discussion, they can be moved to the green or the red list.

7 Next steps

Activities (partners)	Timing
11. Establishment of a baseline for the indicators (all partners) 12. Template to complete and report indicators (LNE, INSA, INSERM)	15/6 – 30/8
13. Consultation of national hubs (LNE, UA, VITO, INSERM) Consultation of 14. Stakeholders (EEA, EAA, LNE) 15. EU Policy Board (EEA) 16. Advisory board (UBA)	1/9 – 31/12
17. Write a report on the indicators for the first periodic technical report (LNE, INSERM, INSA)	1/12/'17 – 31/01/'18

After approval of D6.1, LNE and partners will further specify the methodology for indicators on the first list and will develop a template for the project partners to keep track of these indicators. For some indicators tracking will occur on IT systems.

LNE and partners will also organize yearly consultations of national hubs for those indicators that will have to be filled in by national hubs (through national hub contact points) (see chapter 8).

A baseline will also be established for the indicators (M9).

LNE and partners will report on the indicators in each periodic technical report.

In year 2 LNE and partners will further optimize and revise the first set of indicators and criteria to monitor the implementation of the HBM4EU and the achieved impact, which was developed in the first year. Revision and optimisation will be carried out by LNE, Inserm and EAA in collaboration with the EU policy board, key institutional actors and stakeholders and leaders of large EU or national projects. A first annual technical report will be drafted on these indicators, including a base line, by LNE and Inserm. All partners will contribute to the revision of this report in line with their own expertise. LNE and partners will also start with the preparation of the mid term report using these indicators, which contributes to a mid-term review of the performance of the initiative (M30).

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8 First list of indicators

Indicator		Method	Link with objectives	Timing	Responsible	
Key strategic focus: added value for science						
Criterion 1: Scientific productivity of the HBM4EU consortium						
<u>Output</u>	1	Number of (open access) publications with reference to funding from HBM4EU	Separate per topic to fill in indicators 9-10	OO 4	Yearly	WP2
	2	Number of oral and poster presentations at national or international conferences and workshops concerning HBM4EU	EEA to track (scientific conferences and more policy oriented events e.g. COP 21, WHO)	OO 4	Yearly	WP2
<u>Outcome</u>	3	Number of downloads of HBM4EU open access publications	Methodology to be further developed	OO 4	Yearly	WP2
	4	Cumulative number of citations of publications produced in the framework of HBM4EU	Methodology to be further developed	OO 4	Baseline - mid term - end of the project	WP2
Criterion 2: interdisciplinarity of the research						
<u>Output</u>	5	Number of HBM surveys linked with health surveys and cohorts via HBM4EU	Methodology to be further developed	OO 3 SG 6	Baseline - mid term - end of the project	WP11; National hubs
	6	Number of HBM surveys linked with food surveys via HBM4EU	Methodology to be further developed	SG 6	Baseline - mid term - end of the project	WP11; National hubs
	7	Number of HBM surveys linked with environmental data via HBM4EU	Methodology to be further developed	SG 6	Baseline - mid term - end of the project	WP12; National hubs

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<u>Outcome</u>	8	New co-author networks emerging from bibliometric studies (contacts between institutions/countries)	Methodology to be further developed	OO 4	Yearly	WP2
Criterion 3: Innovative character of the research						
<u>Output</u>	9	Number of publications with reference to funding from HBM4EU on new scientific insights (new substances that are classified as Cat B, C, D, E; mixtures, AOPs developed in the consortium with known adverse health outcome)	Input from indicator 1	SG 6 SG 7	Yearly	WP2
	10	Number of methodological publications on new methods, tools and approaches <u>developed within HBM4EU</u> (e.g. analytical methods, effect biomarkers, approaches to incorporate HBM in risk assessment, exposure modelling and data analysis tools, recruitment approaches, etc.)	Input from indicator 1	OO 3 SG 6 SG 7	Yearly	WP2
Key strategic focus: added value for policy						
Criterion 1: Prioritization of chemicals for analysis and research responds to current policy questions						
<u>Output</u>	11	Number of priority substances studied and for which new results were provided to policy makers to help answer the open questions of the scoping documents	Methodology to be further developed (priority substances includes emerging substances/mixtures)	OO 4 SG 4	Yearly	WP4
	12	Number of positive answers on rapid requests from policy makers	Tracking use via the website	SG 4	Yearly	WP4
Criterion 2: Make HBM data and research results available to risk assessors and risk managers, e.g. via IPChEM						
<u>Output</u>	13	Number of HBM data sets (regional/national/EU programmes) available through IPChEM - accessible to policy makers at the different levels of data aggregation and percentage of these datasets available to scientists at the different levels of data aggregation.	tracked under task 10.5	OO 2 SG 2 SG 5	Yearly	WP10
<u>Outcome</u>	14	Number of downloads of IPChEM data	Methodology to be further developed	SG 4	Yearly	JRC

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<u>Impact</u>	15	Number of cases/studies where multicountry data in IPCheM is used for regulatory or non-regulatory policy actions	Methodology to be further developed	OO 5 SG 2 SG 3 SG 5	Baseline - mid term - end of the project	National hubs, WP5, WP10
Criterion 3: Improve chemical risk assessment through the use of HBM data						
<u>Output</u>	16	Number of European reference/HBM values/ HBM health based guidance values <u>proposed</u> by the HBM4EU consortium	Track through the relevant WP leaders	OO 5 SG 2	Baseline - mid term - end of the project	WP5
<u>Outcome</u>	17	Number of references to HBM data or to proposed HBM reference values/ HBM health based guidance values in regulators hazard and risk assessment (by EFSA and ECHA, national governments,..)	EEA can track at EU level. NHCPs need to track at national level	OO 5 SG 6	Baseline - mid term - end of the project	EEA, National hubs through the NHCP
Criterion 4: Translation of HBM4EU results into options for policy action and risk management						
<u>Outcome</u>	18	HBM4EU helped to identify new ' regulatory ' policy actions at national/EU/international level (policy formulation and implementation)	Qualitative assessment; tracked under the webpages on the substance policy briefs	SG 2	Baseline - mid term - end of the project	WP5
	19	HBM4EU helped to identify new non-regulatory targeted policy actions at national/ EU/ international level (soft measures such as awareness raising, in addition to regulation) (policy formulation and implementation)	Qualitative assessment; tracked under the webpages on the substance policy briefs	SG 2	Baseline - mid term - end of the project	WP5
Key strategic focus: added value for society						
Criterion 1: Openness towards stakeholders and taking into account stakeholder perspectives						
<u>Output</u>	20	Number of stakeholder consultations at European and national level for input in key HBM4EU processes (e.g. prioritization process, consultation of future needs, etc.) and feedback rate (% replies received from stakeholders)	Methodology to be further developed	SG 11	Yearly	WP4

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<u>Outcome</u>	21	Stakeholder responses to HBM4EU results, e.g. NGOs/industry use HBM4EU results in their own campaigns, different stakeholders refer to HBM4EU on their website, stakeholders react on HBM4EU results, industry or other sectors and user groups seize HBM-results to undertake (voluntary) action...	Qualitative assessment - methodology to be further developed	SG 11	Baseline - mid term - end of the project	SF
Criterion 2: Societal benefit of HBM4EU activities (awareness, improvements in health and wellbeing, trust, equal distribution of benefits, etc.)						
<u>Output</u>	22	Number of HBM studies in the frame of HBM4EU in which participants receive personal feedback on test results when offered in the study design (<i>Respectful and caring approach towards HBM tested citizens</i>)	Qualitative assessment - methodology to be further developed	SG 11	Baseline - mid term - end of the project	WP7: new studies National hubs: own programmes
<u>Output</u>	23	Geographical spread of HBM activities/values (representativeness of the results across the EU)	Qualitative assessment, evaluated through IPChEM - methodology to be further developed	SG 4	Baseline - mid term - end of the project	MB, WP7
Key strategic focus: sustainability and capacity building						
Criterion 1: Harmonizing and optimizing the practices of national HBM programmes, including sample collection, quality assurance and data management						
<u>Output</u>	24	Number of selected laboratories for analysis, new methods development and QA/QC (as in WP9)	Methodology to be further developed	OO 1 SG 3	Yearly	WP9
<u>Output</u>	25	Number of chemicals for which you have at least 2 selected laboratories within Europe	Methodology to be further developed	OO 1 SG 3	Yearly	WP9
<u>Output</u>	26	Number of standard operating procedures, guidelines and harmonized questionnaires produced by the project plus number of downloads of SOP's, guidelines and harmonized questionnaires	Methodology to be further developed	OO 1 SG 3	Yearly	WP7

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Criterion 2: Promote capacity building and networking through training and exchange programmes

<u>Output</u>	27	Number of MsC and PhD dissertations published with reference to acknowledgment of HBM4EU	To be asked to all beneficiaries and LTPs	SG 10	Baseline - mid term - end of the project	WP2
	28	Number of scientific training activities within consortium, number of attendancies to these training activities, number of training materials developed and number of downloads of training materials from the HBM4EU website	EEA can provide this feedback from task 2.5 on training (training material as under the website under the header 'training')	SG 10	Yearly	WP2
<u>Outcome</u>	29	Degree of satisfaction of training activities through evaluation of training activities	Qualitative assessment - methodology to be further developed	SG 10	Baseline - mid term - end of the project	WP2
<u>Output</u>	30	Number of scientist (including students) exchanges between laboratories/countries within HBM4EU and with international programmes (NHANES, Japan, etc.) as a indicator for improved scientific networking	Methodology to be further developed	SG 10	Baseline - mid term - end of the project	MB
<u>Impact</u>	31	Partners making use of resources available in another partner-country (e.g. reference laboratory)	Methodology to be further developed	SG 10	Baseline - mid term - end of the project	National hubs MB

Criterion 3: Laying the foundations for a pan-European HBM platform that includes National Hubs and builds on existing expertise

<u>Output</u>	32	Percentage of hubs that provide input in key HBM4EU processes, in response to questions from the NHC (as an example of effective collaboration across the platform)	Methodology to be further developed	SG 1	Yearly	NHC
<u>Outcome</u>	33	Number of established HBM activities/programmes in countries aligned with or benefiting from HBM4EU (existing and new)	Methodology to be further developed	SG 1	Yearly	National hubs

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Key strategic focus: communication and dissemination

Criterion 1: all information will be documented and disseminated through the knowledge hub

<u>Output</u>	34	Number of hits for and links to the HBM4EU website and number of downloads from the online library	EEA to track	OO 4	Yearly	WP2
	35	Social media – followers on twitter/facebook/ website/ linkedin	EEA to track	OO 4	Yearly	WP2
	36	Number of reports in non-scientific traditional media (TV/radio, non-scientific press)	EEA to track	OO 4	Yearly	WP2
	37	Number of issued/requested policy briefs	EEA to track	OO 4	Yearly	WP2
	38	Number of HBM4EU events	EEA to track	OO 4	Yearly	WP2

Criterion 2: HBM4EU results are effectively communicated to key audiences through targeted communication products and activities

<u>Output</u>	39	Direct engagement with end users, including through participation in (policy) workshops, events and participation in meetings organised by other parties (not HBM4EU events or meetings)	includes participation of HBM4EU scientists in workshops and meetings of committees and expert groups involved in chemical risk management in order to directly communicate HBM4EU results	OO 4	Yearly	WP2
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The first list of indicators can be divided in:

- a list of performance indicators that relate to the overarching objectives of HBM4EU (8.1.1)
- a list of yearly indicators (8.1.2)
- a list of indicators on the mid-term/end of the project (0)

In addition, a set of indicators was defined to be used as internal indicators (7.2.).

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8.1.1 List of performance indicators

For the performance indicators listed below baselines and targets will be developed in time for the first PTR.

Indicator		link with overarching objective	Timing	Responsible
26	Number of standard operating procedures, guidelines and harmonized questionnaires produced by the project plus number of downloads of SOP's, guidelines and harmonized questionnaires	OO 1. Harmonise procedures and tools for HBM at EU level	Yearly	WP7
13	Number of HBM data sets (regional/national/EU programmes) available in IPCheM - accessible to policy makers at the different levels of data aggregation and percentage of these datasets available to scientists at the different levels of data aggregation.	OO 2. Provide and, where missing, generate internal exposure data and link this data to aggregate external exposure and the relevant exposure pathways	Yearly	WP10
7	Number of HBM surveys linked with environmental data (via HBM4EU)		Baseline - mid term - end of the project	WP12; National hubs
10	Number of methodological publications on new methods, tools and approaches <u>developed within HBM4EU</u> (e.g. analytical methods, effect biomarkers, approaches to incorporate HBM in risk assessment, exposure modelling and data analysis tools, recruitment approaches, etc.)	OO 3. Develop novel methods to identify human internal exposure to environmental and occupational chemicals and establish the causal links with human health effects	Yearly	WP2
5	Number of HBM surveys linked with health surveys and cohorts via HBM4EU		Baseline - mid term - end of the project	WP11; National hubs
11	Number of priority substances studied and for which new results were provided to policy makers to help answer the open questions of the scoping documents	OO 4. Provide policy-makers and the general public with science-based knowledge on the health risks associated with chemicals exposure	Yearly	WP4
15	Number of cases/studies where data in IPCheM is used for regulatory or non-regulatory policy actions	OO 5. Improve chemical risk assessment in the EU through the effective use of HBM data	Baseline - mid term - end of the project	National hubs, WP10, WP5

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8.1.2 List of yearly indicators

This list of yearly indicators is composed of the indicators on the first list that have to be completed yearly (see chapter 8)

Indicator		Method	link with objectives	Timing	Responsible	
Key strategic focus: added value for science						
Criterion 1: Scientific productivity of the HBM4EU consortium						
<u>Output</u>	1	Number of (open access) publications with reference to funding from HBM4EU	Separate per topic to fill in indicators 9-10	OO 4	Yearly	WP2
	2	Number of oral and poster presentations at national or international conferences and workshops concerning HBM4EU	EEA to track (scientific conferences and more policy oriented events, e.g. COP 21, WHO)	OO 4	Yearly	WP2
<u>Outcome</u>	3	Number of downloads of HBM4EU open access publications	Methodology to be further developed	OO 4	Yearly	WP2
Criterion 2: interdisciplinarity of the research						
<u>Outcome</u>	8	New co-author networks emerging from bibliometric studies (contacts between institutions/countries)	Methodology to be further developed	OO 4	yearly	WP2
Criterion 3: Innovative character of the research						
<u>Output</u>	9	Number of publications with reference to funding from HBM4EU on new scientific insights (new substances that are classified as Cat B, C, D, E; mixtures, AOPs developed in the consortium with known adverse health outcome)	Input from indicator 1	SG 6 SG 7	Yearly	WP2
	10	Number of methodological publications on new methods, tools and approaches <u>developed within HBM4EU</u> (e.g. analytical methods, effect biomarkers, approaches to incorporate HBM in risk assessment, exposure modelling and data analysis tools, recruitment approaches, etc.)	Input from indicator 1	OO 3 SG 6 SG 7	Yearly	WP2

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Key strategic focus: added value for policy

Criterion 1: Prioritization of chemicals for analysis and research responds to current policy questions

<u>Output</u>	11	Number of priority substances studied and for which new results were provided to policy makers to help answer the open questions of the scoping documents	Methodology to be further developed (priority substances includes emerging substances/mixtures)	OO 4 SG 4	Yearly	WP4
<u>Impact</u>	12	Number of positive answers on rapid requests from policy makers	Tracking use via the website	SG 4	Yearly	WP4

Criterion 2: Make HBM data and research results available to risk assessors and risk managers, e.g. via IPChEM

<u>Output</u>	13	Number of HBM data sets (regional/national/EU programmes) available through IPChEM - accessible to policy makers at the different levels of data aggregation and percentage of these datasets available to scientists at the different levels of data aggregation	Tracked under task 10.5	OO 2 SG 2 SG 5	Yearly	WP10
<u>Outcome</u>	14	Number of downloads of IPChEM data	Methodology to be further developed	SG 4	Yearly	JRC

Key strategic focus: added value for society

Criterion 1: Openness towards stakeholders and taking into account stakeholder perspectives

<u>Output</u>	20	Number of stakeholder consultations at European and national level for input in key HBM4EU processes (e.g. prioritization process, consultation of future needs, etc.) and feedback rate (% replies received from stakeholders)	Methodology to be further developed	SG 11	Yearly	WP4
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Key strategic focus: sustainability and capacity building

Criterion 1: Harmonizing and optimizing the practices of national HBM programmes, including sample collection, quality assurance and data management

<u>Output</u>	24	Number of selected laboratories for analysis, new methods development and QA/QC (as in WP9)	Methodology to be further developed	OO 1 SG 3	Yearly	WP9
	25	Number of chemicals for which you have at least 2 selected laboratories within Europe	Methodology to be further developed	OO 1 SG3	Yearly	
	26	Number of standard operating procedures, guidelines and harmonized questionnaires produced by the project plus number of downloads of SOP's, guidelines and harmonized questionnaires	Methodology to be further developed	OO 1 SG 3	Yearly	WP7

Criterion 2: Promote capacity building and networking through training and exchange programmes

<u>Output</u>	28	Number of scientific training activities within consortium, number of attendancies to these training activities, number of training materials developed and number of downloads of training materials from the HBM4EU website	EEA can provide this feedback from task 2.5 on training (training material as under the website under the header 'training')	SG 10	Yearly	WP2
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Criterion 3: Laying the foundations for a pan-European HBM platform that includes National Hubs and builds on existing expertise

<u>Output</u>	32	Percentage of hubs that provide input in key HBM4EU processes, in response to questions from the NHC (as an example of effective collaboration across the platform)	Methodology to be further developed	SG 1	Yearly	NHC
<u>Outcome</u>	33	Number of established HBM activities/programmes in countries aligned with or benefiting from HBM4EU (existing and new)	Methodology to be further developed	SG 1	Yearly	National hubs

Key strategic focus: communication and dissemination

Criterion 1: all information will be documented and disseminated through the knowledge hub

<u>Output</u>	34	Number of hits for and links to the HBM4EU website and number of downloads from the online library	EEA to track	OO 4	Yearly	WP2
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	35	Social media – followers on twitter/facebook/ website/ linkedin	EEA to track	OO 4	Yearly	WP2
	36	Number of reports in non-scientific traditional media (TV/radio, non-scientific press)	EEA to track	OO 4	Yearly	WP2
	37	Number of issued/requested policy briefs	EEA to track	OO 4	Yearly	WP2
	38	Number of HBM4EU events	EEA to track	OO 4	Yearly	WP2
Criterion 2: HBM4EU results are effectively communicated to key audiences through targeted communication products and activities						
<u>Output</u>	39	Direct engagement with end users, including through participation in (policy) workshops, events and participation in meetings organised by other parties (not HBM4EU events or meetings)	includes participation of HBM4EU scientists in workshops and meetings of committees and expert groups involved in chemical risk management in order to directly communicate HBM4EU result	OO 4	Yearly	WP2

8.1.3 List of indicators on mid-term/end of the project

This list is composed of indicators on the first list of indicators that have to be completed on the mid-term/ end of the project (see chapter 8).

Indicator		Method	link with objectives	Timing	Responsible
Key strategic focus: added value for science					
Criterion 1: Scientific productivity of the HBM4EU consortium					
<u>Outcome</u>	4	Cumulative number of citations of publications produced in the framework of HBM4EU	Methodology to be further developed	OO 4	Baseline - mid term - end of the project WP2

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Criterion 2: interdisciplinarity of the research

<u>Output</u>	5	Number of HBM surveys linked with health surveys and cohorts via HBM4EU	Methodology to be further developed	SG 6	Baseline - mid term - end of the project	WP11; National hubs
	6	Number of HBM surveys linked with food surveys via HBM4EU	Methodology to be further developed	SG 6	Baseline - mid term - end of the project	WP11; National hubs
	7	Number of HBM surveys linked with environmental data via HBM4EU	Methodology to be further developed	SG 6	Baseline - mid term - end of the project	WP12; National hubs

Key strategic focus: added value for policy

Criterion 2: Make HBM data and research results available to risk assessors and risk managers, e.g. via IPChEM

<u>Impact</u>	15	Number of cases/studies where data in IPChEM is used for regulatory or non-regulatory policy actions	Methodology to be further developed	OO 5 SG 2 SG 3 SG 5	Baseline - mid term - end of the project	National hubs, WP5, WP10?
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Criterion 3: Improve chemical risk assessment through the use of HBM data

<u>Output</u>	16	Number of European reference/HBM values/ HBM health based guidance values <u>proposed</u> by the HBM4EU consortium	Track through the relevant WP leaders	OO 5 SG 2	Baseline - mid term - end of the project	WP5
<u>Outcome</u>	17	Number of references to HBM data or to proposed HBM reference values/ HBM health based guidance values in regulators hazard and risk assessment (by EFSA and ECHA, national governments,..)	EEA can track at EU level. NHCPs need to track the national level	OO 5 SG 6	Baseline - mid term - end of the project	EEA, National hubs

Criterion 4: Translation of HBM4EU results into options for policy action and risk management

<u>Outcome</u>	18	HBM4EU helped to identify new ' regulatory ' policy actions at national/EU/international level (policy formulation and implementation)	Qualitative assessment; tracked under the webpages on the substance policy briefs	SG 2	Baseline - mid term - end of the project	WP5
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	19	HBM4EU helped to identify new non-regulatory targeted policy actions at national/ EU/ international level (soft measures such as awareness raising, in addition to regulation) (policy formulation and implementation)	Qualitative assessment; tracked under the webpages on the substance policy briefs	SG 2	Baseline - mid term - end of the project	WP5
Key strategic focus: added value for society						
Criterion 1: Openness towards stakeholders and taking into account stakeholder perspectives						
<u>Outcome</u>	21	Stakeholder responses to HBM4EU results, e.g. NGOs/industry use HBM4EU results in their own campaigns, different stakeholders refer to HBM4EU on their website, stakeholders react on HBM4EU results, industry or other sectors and user groups seize HBM-results to undertake (voluntary) action...	Qualitative assessment – methodology to be further developed	SG 11	Baseline - mid term - end of the project	SF
Criterion 2: Societal benefit of HBM4EU activities (awareness, improvements in health and wellbeing, trust, equal distribution of benefits, etc.)						
<u>Output</u>	22	Number of HBM studies in the frame of HBM4EU in which participants receive personal feedback on test results when offered in the study design	Qualitative assessment – methodology to be further developed	SG 11	Baseline - mid term - end of the project	WP7: new studies National hubs: own programmes
	23	Geographical spread of HBM activities/values (representativeness of the results across the EU)	Qualitative assessment, evaluated through IPChEM – methodology to be further developed	SG 4	Baseline - mid term - end of the project	MB, WP7
Key strategic focus: sustainability and capacity building						
Criterion 2: Promote capacity building and networking through training and exchange programmes						
<u>Output</u>	27	Number of MsC and PhD dissertations published with reference to acknowledgment of HBM4EU	To be asked to all beneficiaries and LTPs	SG 10	Baseline - mid term - end of the project	WP2
<u>Outcome</u>	29	Degree of satisfaction of training activities through evaluation of training activities	Qualitative assessment – methodology to be further developed	SG 10	Baseline - mid term - end of the project	WP2

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<u>Output</u>	30	Number of scientist (including students) exchanges between laboratories/countries within HBM4EU and with international programmes (NHANES, Japan, etc.) as an indicator for improved scientific networking	Methodology to be further developed	SG 10	Baseline - mid term - end of the project	All partners
<u>Impact</u>	31	Partners making use of resources available in another partner-country (e.g. reference laboratory).	Methodology to be further developed	SG 10	Baseline - mid term - end of the project	All partners

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8.2 List of internal indicators

These indicators are for internal performance monitoring or for test runs to see if they can be correctly accounted for (e.g. I.1 and I.2)

Indicator		Method	link with objectives	Timing	Responsible	
Output	I.1	% of open access publications with open access to the data on which the publication is based	Methodology to be further developed	OO 4	Yearly	WP2
	I.2	Number of participants with samples stored according to agreed harmonised procedures and from which samples are accessible to partners in the consortium	Methodology to be further developed	OG1 SG 3	Baseline - mid term - end of the project	WP7
	I.3	Participation of the HBM4EU Ambassador in events at EU and national level	Methodology to be further developed	SG 1	Yearly	WP6
Key strategic focus: project management						
Criterion 1: Research activities within HBM4EU answer to the goals of the DoA and AWP and are positively accepted by the granting authority						
Output	I.4	Number of new countries joining HBM4EU/countries leaving HBM4EU	Tracked under the relevant WP		Yearly	WP1
	I.5	% of deliverables per year submitted on due date and accepted by the Commission and % delay for deliverables not submitted on due date	Tracked under the relevant WP		Yearly	WP1
	I.6	% of milestones reached at due date	Tracked under the relevant WP		Yearly	WP1
	I.7	Approved project costs (PM and consumables) relative to planned project costs/year	Tracked under the relevant WP		Yearly	WP1
	I.8	Percentage of MS contribution to the overall HBM4EU costs (calculated after EC accepted costs and the resulting EC contribution)	Will be based on cost declared/cost accepted/EC payment/payments to partners		Yearly	WP1
	I.9	Conflictual management issues submitted for decision to the GB	Tracked under the relevant WP		Yearly	WP1

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9 List of Annexes

- ▶ Annex 1. Excel document containing the orange list

10 References

- ▶ Grant Agreement, Annex 1A (Work Package description WP6)
- ▶ Grant Agreement Annex 7 (Annual Work Plan WP6, first year)