

Berlin, 04 June 2019

## Minutes (05/2019)

### 19<sup>th</sup> HBM4EU Management Board Meeting

*Monday, 06 May 2019, from 10:00 to 18:00,  
Tuesday, 07 May 2019, from 08:30 to 09:15,  
Room No. 044, CDMA Building, Rue du Champs de Mars 21, Brussels*

Time	Item No.	Topic
10:00 – 10:34	1	<p><b>Welcome and Organisational Issues (MARIKE KOLOSSA-GEHRING)</b></p> <ul style="list-style-type: none"> <li>- Organisational issues of the meeting</li> <li>- Date and location of the next meeting: <b>MB meeting in June in Berlin</b> starting 12:00 on Wednesday 26 June 2019 to Friday 28 June 2019 15:00.</li> <li>- Joint excursion to Botanical Garden and Dinner</li> <li>- Adoption of the agenda</li> <li>- Organisation of the content meeting in September 2019</li> <li>- Future lead of WP14</li> </ul> <p><b>Decision proposal:</b> The MB is asked to adopt the proposed agenda.</p> <p><b>Decision:</b> The MB adopted unanimously<sup>1</sup> the proposed agenda.</p> <p><b>Presentation at final conference from Interreg Europe</b></p> <p><b>Information:</b> The Coordinator informed on the final conference from Interreg Europe, held at 23/24 May, for which a presentation to introduce HBM4EU was requested.</p> <p><b>Action Point:</b> PL1, Greet Schoeters, will hold the presentation if possible with respect to available flight times.</p> <p><b>Content Meeting in September:</b></p> <p><b>Information:</b> The Content Meeting back to back with the MB-Meeting in September is planned to be extended to a full day to discuss i) results of QA/QC-exercises of the 1<sup>st</sup> prioritisation round, ii) the QA/QC-approach for the 2<sup>nd</sup> prioritisation round, iii) aligned studies and laboratories (e.g. which laboratories will measure the samples of the respective study), iv) effect biomarker measurement in the aligned studies.</p>

<sup>1</sup> Unanimously: All Work Package Leaders (or a fully mandated representative) who are entitled to vote were present and voted „yes“, no objection, no abstention.

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		<p><b>Action Point:</b> PL1 agreed to organise the Content Meeting. Study owners from the aligned studies are planned to be invited.</p> <p><b>Meeting with the EU Policy Board in September:</b></p> <p><b>Action Point:</b> The Project Officer (PO) reminded of the video conference with the EU Policy Board (held at September 5<sup>th</sup>) and informed that all topics on which a need for discussion will be identified (such as the selection of effect biomarkers) should be communicated as early as possible to the EU Policy Board so the agenda can be adapted.</p> <p><b>Future lead of WP14 and WP15:</b></p> <p><b>Information:</b> WPL14 and WPL15 will inform in more detail on this topic at the MB-Meeting in June.</p> <p><b>Action Point:</b> An official mandate from the respective organisation which leads the WP stating the support of the new WPL will be supplied.</p> <p><b>Conference on EU chemicals policy 2030:</b></p> <p><b>Action Point:</b> The PO suggested to ask the ambassador to represent HBM4EU at the conference and underline the importance of HBM4EU for European chemical policy.</p> <p><b>Research and innovation days:</b></p> <p><b>Action Point:</b> The PO informed about the upcoming research and innovation days, organised by the European Commission, which will take place from 24 to 26 September. The PO will inform the MB as soon as more information (e.g. on content and participation of HBM4EU) will be available.</p>
10:35 – 10:52	2	<p><b>Mid-term Review: anything open? (Marika Kolossa-Gehring)</b></p> <p><b>Action Point:</b> Each presenter will have a final look at the presentations held at the Mid-term Review with respect to an easy accessibility of the content.</p> <p>If a presentation will be updated, it will be send by the respective presenter to hbm4eu@uba.de until Monday, 06 May to HBM4EU. UBA will provide the final version of the presentations to the PO at Tuesday morning, so the PO can share the presentations with the reviewers before the Mid-term Review.</p> <p><b>Information:</b> The PO informed that an Ethics review will be conducted at 16 May. The PO will be present at the meeting. If additional requests or needs become available, the MB will be informed.</p>

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10:53 – 13:15	3	<p><b>Annual Work Plan 2020/2021 (Rosa Lange, Lena Reiber, Marike Kolossa-Gehring)</b></p> <p><b>Information:</b> UBA presented the status regarding the current draft WP concepts as well as upcoming steps for the preparation of a consolidated AWP20/21.</p> <p>Several WPL noted, that it is important to have clear cross-linkages between the WPs and that this should be reflected in the WP concepts.</p> <p>It was addressed that if partners have only small contributions, the partners shall be asked whether they want to concentrate their resources into a “core task”. It was also proposed that partners should be given the opportunity to stay included in the mailing list of the WPs with a former small contribution, so that they can be kept informed. Several WPL stated that it would be good to have a joint view on which (overarching) objectives and project components should be prioritised in the last two project years. This would be also important for the partners as a guidance where additional resources could be allocated. The conclusions drawn from the Mid-term Review could contribute to the revision and if necessary adaption of the project perspectives.</p> <p>The PO addressed the importance of a focus on strategically and politically important results to show the added value of the initiative, because this is important in terms of the sustainability of the project.</p> <p><b>Decision:</b> The strategic decision where resources should be allocated in 20/21 needs to be taken by the Management Board. All WPL take the strategic dimension into account for the preparation of the WP concept.</p> <p>A telephone conference will be held at Friday, 07 June, 12:00 – 15:00 CEST. Here, the MB will decide on the implementation of budget neutral shifts within a partner’s budget per WP as well as on the further procedure depending on the outcome of the overview of resource needs and surpluses per WP.</p> <p>The MB agreed to shift potential surplus resources from NHCPs (which are not needed in the respective WP) to WP6, Task 6.1. The MB agreed that joint NHCP-Meetings for different regions in Europe addressing the sustainability of HBM4EU will be added to Task 6.1. These meetings should be held with NHCPs from neighbouring countries to allow for exchange and connectivity. Surplus resources from the NHCPs should be allocated to this task.</p> <p>The MB agreed on the following deadlines:</p> <ul style="list-style-type: none"> <li>• May 9th: UBA sends mail to the Consortium, informing about further procedure and send updated WP concepts including all agreed changes to the WPL</li> </ul>

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		<ul style="list-style-type: none"> <li>• May 13th: all WPL send their aligned concepts to all partners in respective WPs</li> <li>• May 24th: Deadline for partners to send their feedback to the WPL (silent agreement if no answer)</li> <li>• May 31st: all WPL send their consolidated WP concepts (incl. list of budget-neutral shifts) to UBA</li> <li>• June 7th: MB TelCo from 12:00 - 15:00 CEST</li> </ul>
13:15 – 13:55		<i>Lunch Break</i>
13:56 – 14:04	4	<p><b>Subcontract to support European General Data Protection Regulation (GDPR) related tasks from WP10 (Greet Schoeters)</b></p> <p><b>Information:</b> In May 2018 the new GDPR came into force. This regulation was new for VITO but also for HBM4EU partners and for the European Commission. VITO had to adapt the data management plan and data policy to make it consistent with the requirements for exchange of pseudonymised data. This has taken a lot of effort from the VITO team to understand and interpret the new requirements related to transfer, storage and use of personal data in line with the new data protection rules. To support VITO and the Consortium with the new challenges a subcontract should be added. Planned is a contract for 6 months and an evaluation after three months for a budget of 51,400 Euro (excl. VTA). The resources will be taken from the VITO budget.</p> <p><b>Decision:</b> It was decided that the decision will be taken together with item 9.</p> <p>To cover the resources for the subcontract, Person Months from WP10 from the budget of VITO shall be reallocated.</p>
14:04 – 14:25	5	<p><b>New partners: North Macedonia and other interested countries (Philipp Weise, Marike Kolossa-Gehring)</b></p> <p><b>Information:</b> UBA informed the MB about the current status of the exchange with countries interested in participating in HBM4EU. The Coordinator asked for possibilities where partners from candidate partner countries such as North-Macedonia can be integrated into the project.</p> <p>Examples for possibilities where new partner countries could participate:</p> <ul style="list-style-type: none"> <li>• participation at training schools for capacity building</li> <li>• WPL4: 3<sup>rd</sup> prioritization round</li> <li>• WPL12: contribute data for WP12 models (data that not fall under the quality control-scheme of HBM4EU, such as environmental data).</li> </ul>

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		<p>WPL8 stressed the importance of a clear communication that a 'deeper' involvement, for example the participation at the alignment of studies, might be not possible at this late stage.</p> <p>The PO informed the MB that all necessary documents to join the initiative need to be provided to UBA and necessary roles in the Participant Portal need to be signed, before an amendment to include the new country as partner in the initiative will be started.</p> <p><b>Action Point:</b> WPL8 will further exchange with North Macedonia to enquire more in detail, where they could participate in HBM4EU.</p> <p><b>Decision:</b> The MB agreed that partners which do not have fulfilled the above mentioned conditions for participation until September 19, so that a decision proposal can be sent to the Governing Board to decide upon at the GB Meeting at October 11, can only taking part in HBM4EU as 'associated partner'. This means, that no resources can be allocated, but the associated partner will be taken up on mailing lists of HBM4EU, can have access to project deliverables and participate at project meetings such as the Consortium Meeting if a presentation will be held. Furthermore, the associated partner can be involved in the preparation of a potential future project.</p>										
14:26 – 15:00	6	<p><b>2<sup>nd</sup> set priority substances- update and decision about age groups for analysis of UV filters (Liese Gilles, VITO)</b></p> <p>By implementing analysis of second set priority chemicals in the aligned studies HBM4EU would make optimal use of the aligned studies and the efforts already done to align fieldwork etc. We can benefit from the work already done/planned to generate additional EU wide exposure data to a limited cost. Cost for sample collection is already covered. This added value for the aligned studies can be realized with additional costs for analysis only.</p> <p><b>Decision proposal:</b> The MB is asked to decide on the implementation of analysis of UV-filters in the aligned studies (including the decision on the age group(s) in which these analysis should be implemented).</p> <p><b>Budget implications:</b> These cost estimates are not exact but to give an idea of the order of magnitude of the expected costs.</p> <table border="1" data-bbox="547 1615 1273 1809"> <thead> <tr> <th>Age group</th> <th>Total Analytical Cost</th> </tr> </thead> <tbody> <tr> <td>Children</td> <td>€99.000</td> </tr> <tr> <td>Teenagers</td> <td>€198.000</td> </tr> <tr> <td>Adults</td> <td>€247.500</td> </tr> <tr> <td>Teenagers + Adults</td> <td>€445.500</td> </tr> </tbody> </table> <p><b>Information:</b> VITO gave an overview on the decision memo.</p> <p>WPL15 suggested to use samples from Spanish children taken in the summer period for Task 15.2 for the analysis of UV-filters.</p>	Age group	Total Analytical Cost	Children	€99.000	Teenagers	€198.000	Adults	€247.500	Teenagers + Adults	€445.500
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		<p>The PO suggested to contact ECHA (due to their interest in UV-filters) to inquire where the focus of the analysis of UV-filters should be set from their perspective (e.g. in which time period and which exposure biomarkers)? This input should be considered when the decision will be taken.</p> <p>The Coordinator informed that due to the limited amount of resources in the reserve, it should be considered to reallocate resources for the analysis of UV-filters within the development of AWP20/21.</p> <p><b>Action Point:</b> Costs for analysis per sample need to be recalculated based on input from other labs. WPL9 offered to ask Task Leader 9.5 to provide a cost estimation.</p> <p><b>Decision:</b> The decision was postponed. A revised DM including the following information will be provided for the decision:</p> <ul style="list-style-type: none"> <li>• Have all biomarkers been analysed in the available datasets, and if not, which one have been analysed?</li> <li>• In which time period have samples of the available datasets been taken?</li> <li>• In which time period would studies, which indicated interest, like to take new samples?</li> </ul>
15:00 – 16:10	7	<p><b>Implementation of effect biomarkers in the aligned studies of task 8.1 (Kirsten Baken, VITO)</b></p> <p>By implementing biomarkers of effect in the aligned studies we make optimal use of the aligned studies and all the work done in WP11-13-14. Since the costs for sample collection are already covered and samples are available from the aligned studies, the implementation of effect biomarkers can be conducted with limited additional resources for post-harmonization of available health outcome data or for new analyses of biomarkers of effect.</p> <p><b>Decision proposal:</b> The MB is asked to advice on the proposals:</p> <ol style="list-style-type: none"> <li>(1) Which proposals should be further explored and are feasible to be implemented.</li> <li>(2) Can estimated PM required for the proposals be (re)allocated to the WPs as indicated in Table 12 of the Decision Memo.</li> </ol> <p><b>Information:</b> VITO gave an overview on the decision memo. It was suggested that rather than a lot of small studies, one big study should be designed to test the principle. The proposal should be revised in this regard and include information on where resources needed should come from (e.g. shifting PM).</p> <p><b>Decision:</b> The MB agreed unanimously that the overall aim of the proposal should be changed from 'studying effect biomarker to predict health effects' to 'finding evidence for exposure impact'. The</p>

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		<p>decision proposal will have to be revised while considering the points mentioned during discussion.</p> <p><b>Action Point:</b> VITO will revise the proposal and inquire which partners are interested in participating in the study.</p> <p><b>Action Point:</b> WPL14 will check storage conditions of samples with regard to requirements of biomarkers.</p>
16:10 – 16:23		<i>Coffee Break</i>
May 06, 17:00 – 18:00 May 07, 08:30 – 09:15	<b>8</b>	<p><b>QA/QC alternatives for the substances in the 2<sup>nd</sup> prioritisation list (Marta Esteban)</b></p> <p>Until we do not have an agreement on the approach to be applied for the next round of priority substances, WP9 cannot go ahead with the elaboration of a more detailed QA/QC program. This will delay the activities to be done and therefore, the availability of analytical results for the 2nd round of priority substances.</p> <p><b>Decision proposal:</b></p> <p>The MB is asked to decide the approach for the QA/QC programme to be applied for the analysis of the substances in the 2nd list of prioritisation.</p> <p>The MB is asked to consider the suitability of including analysis of glyphosate in the aligned studies, more specifically:</p> <p>(1) what percentage of quantifiable concentrations is needed to answer the HBM4EU (policy) questions? Note: Hope 2013 EU urine 56% &lt; 0.15 ng/ml; Conrad 2017: 44%-68% &lt; 0.1 ng/ml in German samples from 2011-2015.</p> <p>(2) do you agree with the need to organise a small-scale intercomparison study for determination of glyphosate (and AMPA) between the labs selected for this analysis before starting HBM4EU analysis [cost for this are approximately: &lt; 5000€].</p> <p><b>Information:</b> ISCIII gave an overview on the decision proposal.</p> <p><b>QA/QC-programme for the substances of the 1<sup>st</sup> prioritisation list</b></p> <p>As a basis for the decision, the WPL requested an overview on the current status of the QA/QC-programme for the substances of the 1<sup>st</sup> prioritisation round. As the QA/QC-programme is not yet finished, a final result cannot be provided yet. It can be foreseen that several countries might not be able to analyse samples in national laboratories. Implications and possible solutions for issues arising with respect to the analysis of substances of the 1<sup>st</sup> prioritisation round were discussed.</p>

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		<p><b>Action Point:</b> As a basis for the derivation of further steps, following information need to be compiled:</p> <ol style="list-style-type: none"> <li>1) Which studies that plan to analyse samples in the frame of the alignment of studies, can still do so, if samples cannot be analysed in the own country? This information was shared by VITO via Email on Monday 06.</li> <li>2) From ethical perspective, would it be possible to send samples in another country for the chemical analysis? This information could be requested by VITO.</li> <li>3) Which scenario (compilation of analysed biomarkers, presented by ISCIII) need to be considered for chemical analysis as a minimum to answer the respective policy questions? This information could be requested by ISCIII from the respective CGL, the EU Policy Board and from the MB (whereas not all WPL need to be approached for each substance)?</li> </ol> <p><b>QA/QC-alternative for the substances of the 2<sup>nd</sup> prioritisation list</b></p> <p><b>Information:</b> PL2 informed that the European Commission requested an overview on the capacity of laboratories in Europe to analyse the substances of the 2<sup>nd</sup> prioritisation list. However, also the analysis of selected substances of the 2<sup>nd</sup> prioritisation list need to be safeguarded. This requires two different approaches.</p> <p>The inclusion of the analysis of glyphosate was discussed. The Coordinator informed that in more than 50 % of the analysed samples from Germany from 2011-2015, glyphosate could be detected with a concentration exceeding the detection limit. An inclusion of the analysis of glyphosate should therefore be envisaged, which was also stated by several WPL. However, it was also proposed to have a more strengthened methodological evaluation for this particularly difficult compound before starting.</p> <p><b>Decision:</b> The MB agreed unanimously on option 2, described in the Decision Memo: Analysis of samples in expert laboratories. The further approach will be discussed by PL2 with the QA-unit and discussed at the MB-meeting in June.</p>
16:30 – 17:00	9	<p><b>Information about IPCHEM (Greet Schoeters)</b></p> <p><b>Information:</b> VITO informed about current issues with IPCHEM, specifically with regard to the role of the JRC and the current state of the discussion with the European Commission.</p> <p>It was suggested to first discuss the issues with the data protection officer of the EC, then with the European data protection supervisory to get their advice and to finally use the information gathered to</p>



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		<p>create recommendations (incl. 'Do's and 'Don't's) for a further procedure.</p> <p>The EC representative added that a formalisation of the cooperation (e.g. a collaboration instrument between JRC and Consortium or Coordinator) would be advisable. This collaboration instrument could also serve to get official enforcement on all hierarchy levels at JRC.</p> <p>The PO suggested to have a draft collaboration agreement ready for June MB meeting with a general framework. Other consortia have to deal with similar issues, a general solution is necessary. Even if the process is delayed, further activities post-2021 could also benefit from the data.</p> <p>Koert (VITO) offered that he and his team are available to help with any issues regarding data security. Questions can be send to the VITO management mailing address.</p> <p><b>Decision:</b> Regarding VITO subcontract (item 4): The MB agreed unanimously that the subcontract mentioned under item 4 is accepted.</p> <p><b>Action Point:</b> VITO (Koert) will develop a proposal on how to proceed.</p>
16:23 – 16:29	10	<p><b>Publications</b></p> <p><b>(1) Publication of work related to WP14 (Marieta Fernandez)</b></p> <p>The MB is asked to decide about the review publication “Exposure to Perfluoroalkyl Acids and Thyroid homeostasis: Review on epidemiological studies”</p> <p><b>Decision proposal:</b> The MB is asked to agree to the proposed publication.</p> <p><b>Decision:</b> The MB agreed unanimously to the proposed publication. WPL14 agreed to add a linkage to HBM4EU in the abstract.</p> <p><b>Information:</b> The PO reminded to add a standard sentence to each publication that funding was received by the European Commission. WPL2 referred to the publication strategy, where this standard sentence is included.</p>