

Berlin, 05 August 2019

## Minutes (06/2019)

### 20th HBM4EU Management Board Meeting

Wednesday, 26<sup>th</sup> June 2019, from 12:00 to 18:00, Room No. 5, <u>Corrensplatz</u> 1, 14195 Berlin until Friday, 28<sup>th</sup> June 2019, from 09:00 to 15:00, Room No. 5, <u>Corrensplatz</u> 1, 14195 Berlin

#### Wednesday, 26 June 2019

Time	Item No.	Topic
12:00 – 12:15	1	<ul> <li>Welcome and Organisational Issues (Marike Kolossa-Gehring)</li> <li>Organisational issues of the meeting</li> <li>Adoption of the agenda</li> <li>Date and location of the next meeting:         MB meeting in September in Copenhagen         starting 12:00 on Thursday 05 September 2019         to 17:00 on Friday 06 September 2019</li> <li>Organisation of the content meeting in September</li> <li>Publishing of a paper related to the work of WP15 (A. Kortenkamp)</li> </ul> <li>Decision proposal: The MB is asked to adopt the proposed agenda.</li> <li>Decision: The MB adopted the proposed agenda (12 yes, 1 absent).</li> <li>Content meeting: Proposed was a meeting on Human exposure (EEA), Modelling (WP12), Communication (responding to the MTR advice to extent the HBM4EU outreach). The MB did not decide on a topic.</li> <li>Paper submitted by A. Kortenkamp is submitted but not published yet.</li> <li>Decision: WPL15 will provide a short decision memo and the abstract of the paper for written decision.</li> <li>HBM4EU Mid-term Review: The coordinator informed the MB about the EC's comments to the MB reply on the Mid-term Review results. The MB was informed that a second round to draft a reply will be initiated based on the comments sent from the EC.</li>

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12:15 - 14:10	2	Annual Summary Progress Report
		Information: Two PowerPoint slides for each WP pertaining to what has been reached in the last 12 months (01.07.2018-30.06.2019). This information will be used to produce the Annual Summary Progress Report (D1.20).
		Reports from the Work Packages
		WPL16 is presenting the achievements of WP16.
		WPL15 is presenting the achievements of WP15:
		Action Point: WPL2 reminded the MB that WP2 is currently producing policy briefs for the first set of substances. One will be on mixtures and WP15 is asked to provide input and what elements should be reflected in the policy brief.
		WPL14 is presenting the achievements of WP14.
		WPL13 is presenting the achievements of WP13:
		Action Point: WPL13 agreed to draft some key messages and a short text on using AOPs (what is it good for, advantages, results) for the Annual Summary Progress Report (under WP13).
14:15 – 14:50		Coffee Break
14:50 – 15:40		Annual Summary Progress Report - Reports from the Work Packages (continued)
		WPL12 is presenting the achievements of WP12: WPL12 took up the advice from the reviewers to focus on case studies instead of the computational platform. He proposed to improve the existing platform and establish case studies where possible and useful.
		WPL11 is presenting the achievements of WP11: WPL11 promoted the outcome of D11.3 with key messages and agreed to prepare some message about the advantages of combining HBM and health studies.
		Action Point: The coordinator will send the draft annual summary progress report compiled from the presentations given by the WPL. All WPL are asked to check whether the compiled information is correct and to add a paragraph with main messages, results and outcomes and how these contribute to the priorities of HBM4EU.
		Furthermore, main results and outcomes expected for 2020 and 2021 should be added to the WP description of the AWP2020/2021 (in simple words to be understood by non-experts).
15:40 – 15:45	3	Change of deliverables D14.5 and D14.6 (Marieta Fernandez)
		It is proposed to merge the two deliverables into one and to extend the deadline from June to September to enable WP14 to produce a mature

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		deliverable with the most important effect biomarkers for all the chemical families selected in the second set of prioritised substances.
		The delay will not affect any of the planned WP14 objectives or related HBM4EU short-term aims.
		Decision proposal: The Management Board is asked to approve the merge of D14.5 and D14.6 and an extension of the deadline from June 2019 (M30) to September 2019 (M33).
		Decision: The MB approved the proposed merging and extension of the deadline (12 yes, 1 absent).
15:45 – 18:20	2	Annual Summary Progress Report - Reports from the Work Packages (continued)
		WPL10 is presenting the achievements of WP10: Aggregated data can only be accessed via the HBM4EU internal pages (excel file) as IPCHEM is still not able to host aggregated data. But metadata from 94 studies are already uploaded and accessible in IPCHEM. Furthermore, WP10 received a lot of complaints about the performance of IPCHEM. Databases for pooled data analysis can be developed according to plan B: database for SPECIMEN study at IRAS, for occupational studies at FIOH, for aligned and time trend studies at VITO until a solution is available at JRC.
		WPL9 is presenting the achievements of WP9.
		WPL7 is presenting the achievements of WP7.
		WPL6 is presenting the achievements of WP6 and WP3: The MB proposed that the preparation and coordination of a new proposal should be within the sustainability task of WP6. The EC will invite a "steering group" to discuss a new proposal in September 2019.
		The MB discussed to read the proposal of ANSES and BFR on risk assessment and come to an opinion how to deal with it (integrate in the follow-up project or keep it as a separate project with a strong linkage). Good news is that a HBM4EU follow-up project is on the list of possible initiatives of the EC.
		WP3 is currently taking care of some final issues for the ICs 1 ran in 2018. As the MB did not agree on topics for a second round of calls there will be no ICs until the end of the project. If ICs should be part of the next project, the formalities and budget should be cleared at the very start.
		WPL5 is presenting the achievements of WP5.
		Action Point: WPLs shall contact the respective CGL when working on a specific substance or substance group.
18:20 - 18:30	4	Meeting Week 2019 – Poster session (Jenny Moldenhauer)
		Planned is a poster session during the Consortium meeting

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		Action Point: When interested in providing a poster please contact Lisbeth E. Knudsen until <b>15</b> <sup>th</sup> <b>September 2019</b> . Detailed information will be provided to the Consortium by e-mail.
		The MB supports the idea to encourage young scientists to present their work via a poster. The invitation to join the poster session will be sent to the whole Consortium.
		Decision: The MB decided unanimously <sup>1</sup> to follow the approach as proposed by Lisbeth. The coordinator will provide the presented details to the MB.
18:30 – 18:45	5	Alignment of HBM4EU programme components with relevant public policy processes (Catherine Ganzleben)
		WP4 was mandated by the MB to lead work on a pro-active mapping of the policy cycles for the 19 HBM4EU priority substance groups. EEA considered it possible to deliver this work without additional budget. However, EEA has since understood the scale of the task of mapping regulatory processes for the 19 HBM4EU priority substance groups. There was also an exchange on this with the EU Policy Board, who have indicated a willingness to engage in interviews in order to provide in depth information on ongoing and planned regulatory processes, such as the evaluation of substances under the Community Rolling Action Plan coordinated by ECHA. This has the potential to yield valuable information not accessible via webpages, but would also be time consuming.
		As such, EEA requests an additional budget of 60,000 € in Other Direct Costs to cover sub-contracting the work under WP4.
		Decision proposal: The Management Board is asked to decide whether or not to allocate an additional 60,000 € in ODC to EEA in 2019 to support work to align HBM4EU outputs with ongoing and future policy cycles.
		<b>Budget implications</b> : 60,000 € Other Direct Costs from the remaining EEA budget for 2020/2021 (not from the reserve).
		Decision: The MB approved the allocation of 60,000 Euro ODCs to EEA in 2019 from the ODCs originally planned for 2020/2021 unanimously.
16:40 – 17:00	6	Analysis of samples from the aligned studies (Argelia Castaño)
10.40 - 17.00		The 3rd round of the ICI/EQUAS scheme for the majority of the substance groups included in the 1st list or prioritisation will be completed by July 2019. The results obtained so far (after 2 rounds) have shown differences in the expertise of the participating laboratories and that there are difficulties in the chemical analysis of certain groups of substances. WP9 will publish the lists of the laboratories that have successfully performed the required

<sup>&</sup>lt;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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		an important issue required parameter	AS exercises for each parame remains to be decided, and the solution (biomarkers) that have to be study owners can select the lacan start.	nat is the list of minimum e analysed in the aligned
			the list of minimum required gned studies is approved, thert.	•
		minimum required p	The Management Board is as parameters (biomarkers per club fithe 1st set of priority substactudies.	hemical substance) for the
		Board unanimously labs should be encounted whenever possible,	decided to follow the recomme (for details see table below). Duraged to follow the most am but be informed that the mini 2 (scenario 1 for PAHs). WPL MB decision.	In the communication the abitious scenario (3) imum recommendation
		Group	Scenario CGL	Scenario EU-PB
		Phthalates	2	2
		Bisphenols	3	3
		PFAS	2	2
		BFR	2	2 (1)
		OFR		-
		PAHs	Mixed scenarios 2+3	1
		Information about the	ve samples analysed abroance aligned studies on the position of a laboratory abroad.	,
18:40 – 18:50	13	AOB		
		- ISES Europ	vents that HBM4EU is presen e, 04-05 July 2019, Bilthoven t week. HBM4EU results will b	(NL), will be attended by

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		Decision: The MB agreed unanimously that the travel expenses will be covered from the WP12 budget.  - Joana Lobo Vicente presented an overview on upcoming events
19:00		Self-paid Dinner (optional)  At Restaurant "Trattoria Romana", Unter den Eichen 84a, 14195 Berlin (http://www.trattoriaromana-berlin.de/)

WPL8 arrived at 16:30

## Thursday, 27 June 2019

Time	Item No.	Topic
09:10 – 09:15		Welcome
09:15 - 09:30	7	Overview reserve HBM4EU (Birgit Puppe)
		Birgit Puppe gave an overview on the actual budget in the reserve.
09:30 - 09:45	8	Annual Work Plan 2020/2021 and budget shifts (Marike Kolossa-Gehring)
		The coordinator informed the MB that the decision memos for WP14 and WP16 are missing and that the decision memo for WP15 is not sufficient. Therefore, a sound final decision on the total budget will not be possible. Furthermore, there might not be enough budget for all the requested activities. The coordinator suggested to go through the proposed activities that require additional budget and decide on priorities.
		WPL16 pointed out that all necessary information on WP16 has been sent to the coordinator but was not transferred into a decision memo.
		The coordinator explained that the responsibility of the WPL is to compile the necessary information for the WP and to provide an overview for the MB to enable the MB to decide on the proposed activities and budget (shifts).
09:45 – 11:10		Annual Work Plan 2020/2021 overview and open issues (Kim Pack, Rosa Lange)
		UBA gave an overview on the current state of the AWP generation and explicitly thanked all the WPL for the extensive work and efforts so far. A message from the EC on the importance of the AWP2020/2021 was shared with the MB. Input from the EC on the Mid-term Review and its impact on the upcoming AWPs was shared with the MB as well.
		Open issues:
		<ol> <li>Possibility of a budget ceiling per partner: The MB received a statement from the EC and discussed in detail.         Action Point: WPLs to check with their financial departments on the actual claimed versus planned costs. The national financial officers should provide written statements including a legal interpretation of the GA if personnel costs can be rejected if the budget of a partner is exceeded. For this, the MB asked UBA to provide the legal basis for the current way of reimbursement as soon as possible.     </li> </ol>
11:10 – 11:30		Coffee Break

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11:30 – 13:10	8	Annual Work Plan 2020/2021 overview and open issues (continued)	
		<ol> <li>The MB was informed on reimbursement rates (50% fieldwork for HBM studies and analysis of samples in HBM studies). The reimbursement rate for samples of cohorts in WP13 and of suspect screening in WP16 were discussed by the MB. The discussion was later continued (see Friday, 09:15 – 10:35).</li> <li>How to handle partners that have not responded to proposed budget shifts? E.g. some partners in WP1 have a lot of ODCs that cannot be claimed in WP1 have not responded to the question where they would like to shift that budget. They were reminded that no response might lead to a shift of their budgets to the overall project reserve.</li> </ol>	
		Decision: The MB decided (12 yes, 1 absent) that another e-mail will be sent to the non-responders (incl. their GS) with a clear deadline and information that no response will lead to transferring the budget to the overall project reserve.	
13:10 – 13:40		Lunch Break	
13:40 – 14:00	8	<ul> <li>Annual Work Plan 2020/2021 overview and open issues (continued)</li> <li>4) Some defined activities not assigned to a partner yet (WP8, WP9, WP10, WP14, WP15) were presented, some of them had defined resources already foreseen, others did not. UBA asked if there were other activities that need to be carried out in 2020/2021 but were not attributed to a partner yet and underlined that a defined amount of resources need to be available in order to be able to plan for these activities. The WPL have not identified additional activities not assigned yet but WPL15 is in favour of keeping a certain buffer for unforeseen circumstances.</li> <li>5) UBA presented an overview on the next steps after the MB meeting and a very rough first projection of the overall project reserve after non-neutral budget shifts.</li> </ul>	
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14:00 – 15:30	8	Annual Work Plan 2020/2021 WPs decision memos  The DMs and/or WP concepts were presented and briefly discussed for the planning of AWP2020/21.	
		Decision: The MB decided that decisions on budget-neutral shifts are not necessary as they have been agreed between the WPLs already.  Discussions and decisions will only be taken on non-neutral budget shifts.	
		Action Point: The WPL prepare their Work Package descriptions for 2020 and 2021 until July 10 <sup>th</sup> and take into account the following points:	
		<ul> <li>a) For both AWP2020 and AWP2021 Tasks, final amounts of resources (ODC and PM), Deliverables and Milestones have to be included in these descriptions. The description text itself only has to be fully</li> </ul>	

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		elaborated for 2020, it can be rough notes on the most important activities (and corresponding Deliverables and Milestones) for 2021.  b) Budget-neutral shifts: As it was suggested by the MB to now focus on the WP description text, the master table of budget-neutral shifts will not be updated anymore. Project Coordination stresses the importance of all WPL cross-checking the master table of budget-neutral shifts to see if they are informed about all shifts concerning their WP(s). Similarly, the WPL are asked to ensure that new budget-neutral shifts are agreed upon by the partner and all involved WP leaders (incoming and outgoing).  c) Activities that cannot be attributed to a partner yet: If such activities arise, Project Coordination asks the MB to flag this and the estimated resources for the activity alongside their WP descriptions.
		An email corresponding to these points was sent to the MB on July 1 <sup>st</sup> , which included both the templates to be filled out for the WP description and the related resources as well as the budget-neutral shifts master table.
		Project Coordination further underlined that WPL are experts for their own WP and carry the responsibility, including the allocation of (1) activities and (2) connected resources in their WP which includes related contact with partners and negotiations. WPLs' timely input is essential for the next steps.
From 16:00		Guided tour and joint dinner at the Botanical Garden Berlin

# **Friday, 28 June 2019**

Time	Item No.	Topic
09:00 – 09:15		Welcome (Marike Kolossa-Gehring)
09:15 – 10:35	8	Annual Work Plan 2020/2021 WPs decision memos (continued)
		Open issue (also see Thursday, 11:30 – 13:10): Reimbursement of the analysis of the samples from the Joint Survey.
		The MB decided: The reimbursement rate for analysing exposure biomarkers in samples of cohorts in WP13 is 50% and should be performed in HBM4EU qualified laboratories for priority substances. In WP14 there will be an activity on the proof of concept for biomarkers of effect in epidemiology studies and in WP16 there will be a proof of concept for the feasibility of suspect screening of pesticides. The analysis of samples for the proof of concept studies will be reimbursed at 70% as the outcome may not be directly interpretable for the participating cohort. The Joint Survey in WP15 will open the option to later integrate a targeted screening of the second set of priority substances (pesticides).
10:30 – 10:35	9	Future lead of WP14 and WP15 (Marieta Fernandez, Mirjam Luijten) Work Package 14: Nicolas Olea (WPL14) will reach the age for retirement in July 2019. Therefore, it is proposed to replace Prof. Nicolás Olea by Prof. Mariana F. Fernández, full Professor at the University of Granada, in the leadership of WP14 and Partner 14.3 (University of Granada, Spain), Nicolas Olea will still be a co-lead of partner 14.3 and support the HBM4EU consortium. An approval will not affect any of the planned WP14 objectives or related HBM4EU short-term or long-term aims.
		Decision proposal: The Management Board is asked to approve the change of the leadership for WP14.
		Decision: The MB approved the change of leadership for WP14 unanimously. Future WP Leader will be Marieta Fernandez.
		Work Package 15: Erik Lebret (WPL15) will reach the age for retirement in September 2019. Therefore, it is proposed to replace Prof. Erik Lebret by Dr. Mirjam Luijten. Erik Lebret will remain active in HBM4EU through IRAS, as PhD thesis supervisor to Ilse Ottenbros in WP15. He will also remain available in an advisory/coaching capacity to Mirjam Luijten through a subcontract with RIVM.
		Decision proposal: The Management Board is asked to approve the change of the leadership for WP15.
		Decision: The MB approved the change of leadership for WP15 unanimously. Future WP Leader will be Mirjam Luijten.

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10:35 – 10:50	10	Deliverables WP12 (Denis Sarigiannis)	
		(1) Change of scope of deliverable D12.6 "Integrated exposure modelling platform". WPL12 wants to take into account the comments of the review report that strongly recommends to avoid the work on the integrated platform, due to the complexity of the task, as well as to the sustainability issues. In addition, there is a strong need to respond to the request for copper compounds biokinetic modelling, that has been proven a challenging task, due to lack of relevant data for parameterisation.	
		Since the various modelling tools (exposure models, PBTK models) will be available as individual components, while at the same time the exposure database of WP12 is already in place, no consequences on the other WPs or on the integrated exposure assessments that are essential for answering the policy questions are expected.	
		Decision proposal: The Management Board is asked to approve the change of the scope of the work for Task 12.1 and the change of the deliverable "D12.6 - Integrated exposure modelling platform" to "D12.6 – Biokinetic modelling of copper compounds" (due in December 2019).	
		Decision: The MB approved the proposal of WP12 to follow the recommendation from the MTR and focus on case studies unanimously. The MB postponed the decision on the change of scope of D12.6 to have discussions with ANSES and EFSA first and to re-think on the chosen substance.	
		(2) Extension of the deadline for D12.5 "Report on risk characterisation ratios and evaluation of new regulatory thresholds for 1st set of priority substances" from June to December 2019: WP12 needs additional time to work (perform exposure reconstruction) of the HBM data that are now available at IPCHEM. This will allow HBM4EU to work on a larger pool of HBM data than the one that has been used in AD12.5 for exposure reconstruction. This pool of data is now available through WP10.	
		Decision proposal: The Management Board is asked to approve an extension of the deadline for deliverable D12.5 from June (M30) to January (M37) 2020.	
		Decision: The MB approved the extension of the deadline for D12.5 to January 2020 unanimously.	
10:50 – 11:00	12	Publications of work related to WP13 (Ludek Blaha)  (1) Deciphering adverse outcome pathway network linked to bisphenol F using text mining and systems toxicology approaches	

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		(2) Cadmium exposure and risk of breast cancer by histological and tumor receptor subtype in white Caucasian women: a hospital-based case-control study
		Publications of work related to WP13/WP14 (Mirjam Luijten)
		(3) Manuscript on mechanisms involved in altered hepatocellular lipid metabolism due to PFOS/PFOA exposure
		Decision proposal: The Management Board is asked to approve the publication of the proposed papers.
		Decision: The MB approved the proposed papers unanimously.
11:00 – 11:30		Coffee Break
11:30 – 12:20	8	Annual Work Plan 2020/2021 WPs decision memos (continued)
13:00 – 13:30		Kim Pack and Rosa Lange presented an updated overview on the incoming and outgoing resources for the 16 WPs (rough projection as of 28 <sup>th</sup> June 2019). Displayed was the total difference per WP in comparison to the original 5-years plan.
		Action Point Annual Work Plans: All WPLs to provide their AWP2020 and AWP2021 (full WP description incl. resources as well as other AWP parts) based on what was negotiated today until <b>10</b> <sup>th</sup> <b>July 2019</b> . Please note: proposed workplans need to be based on expected outcomes/products/results and <u>not</u> on processes.
		Final decision on the AWP2020 and AWP2021 will be taken after the AWP proposals have been provided by each WPL and a budget check has been run by UBA.
		A telephone conference will be scheduled to discuss content related questions on the AWP2020 and 2021 (second half of August 2019).
		Action Point Mid-term Review: In parallel a strategic answer to the MTR recommendations will be brought forward and submitted to the EC. Background is that the EC found the recent answer too detailed and asked for a more strategic approach.
		An e-mail from the EC described the main points that should be addressed/answered – this e-mail was sent to the MB for information.
12:20 – 13:00		Lunch Break
13:30 - 14:00	11	Transfer of budget from RIVM to RIKILT (Mirjam Luijten)
		It is proposed to transfer allocated budget from RIVM to RIKILT (both HBM4EU partners), to allow for the performance of <i>in vitro</i> experimental work on per- and polyfluoroalkyl substances (PFASs). This group of compounds is part of the first set of prioritised chemicals within

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		HBM4EU.The experimental work planned will aid strengthening and validating certain effect biomarkers from human studies (identified in WP14), by providing important mechanistic information that is currently lacking. In addition, this study will have an overall valuable contribution to the project, since it will greatly enhance the creation of AOP networks (WP13), and provide input for policy related questions (WP5).
		The budget required to carry out the <i>in vitro</i> studies is currently allocated to RIVM within WP14. However, the experimental work will be performed by a different partner (RIKILT) and consequently, the respective budget shall be provided to RIKILT. The budget will remain as such, and the sole consequence of this action is its actual transfer from RIVM to RIKILT.
		Decision proposal: The MB is asked to approve the transfer of this budget from RIVM to RIKILT (2019 and 2020).
		Decision: The MB approved the proposed budget shift from RIVM to RIKILT (10 yes, 2 abstentions, 1 absent). WPL14 will integrate the part of the budget foreseen for 2020 in the AWP2020.
14:00 – 14:40	2	Annual Summary Progress Report - Reports from the Work Packages (continued)  WPL8 is presenting the achievements of WP8: It was pointed out that for the HES-HBM activities the analysis of samples was not included. The MTR recommendations highlighted that the samples should not only be collected but also analysed. WPL11 will take care of it and integrate it into the AWP2020/2021. It was proposed to remove task 8.6 (HelpDesks) from WP8 as it is superfluous, no more resources should be allocated. WP8 will communicate to the PI of the aligned studies which laboratories have passed the QA/QC for the different substance.  WPL2 is presenting the achievements of WP2: WPL2 informed that HelpDesks are not used, this will be highlighted in D2.9. Infographics will be produced on the basis of the factsheets in 2020.  WPL4 is presenting the achievements of WP4.  WPL1 is presenting the achievements of WP1.
14:40 – 15:00	13	Inclusion of mid-term success stories in the newsletter by the WPL - following on the recommendation of the MT reviewers (Catherine Ganzleben)  Next newsletter is planned for the second week of October. WPL2 suggested to include success stories from each WP. The WPLs are asked to produce success stories for their WP until beginning of September.

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		WPL5 suggested that this can also be done by the CGLs for their substance group.
		Action Point: All WPL to send some bullet points on success to WPL2 until 12 <sup>th</sup> July 2019 and their full success stories (max. 200-500 words) until September 2019. WPL2 will send an e-mail with the details.
		<ul> <li>Policy briefs based on the scoping documents: WPL2 suggested to send all policy briefs to the MB and CGL for comments by October. Timeline will be provided to the MB by WPL2 by e-mail.</li> </ul>
		Approval of the factsheet on Cr (VI) (Catherine Ganzleben)
		Decision proposal: The Management Board is asked to approve the factsheet on CR (VI) for dissemination and citizen awareness.
		Decision: The MB decided (12 yes, 1 absent) that the decision will be taken by written decision until 12 <sup>th</sup> July 2019.
		Chlorpyrifos: The EC wanted the MB to ensure that Chlorpyrifos will be covered by HBM4EU. WPLs mentioned that this is covered in the Scoping documents.

WPL12 left at 12:45