'Strategy for making new HBM4EU results available from the aligned studies'

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This document provides some principles and a workflow that will be applied for public communication of newly derived HBM4EU results from the aligned studies. The same principles may also be applicable to the occupational studies, the time trend studies and the SPECIMEN study.
The strategy applies to:

- *All external communication of **EU level results** involving new HBM exposure data and effect biomarker data resulting from the aligned studies. This communication includes all types of communication products **except scientific publications!** Scientific publications should follow the procedure as outlined in the publication policy.*
- *Examples of communication products to which this strategy applies are:*
  - *Webinars, Factsheets, Research briefs, Video,…*

General principles:

- *Results cannot be withheld or influenced.*
- *All actors involved – must be informed in time and - depending on their role - have a say in the way results are communicated.*
- *All partners involved should follow the same rules, not only the scientists, also the policy makers using the results and communicating about them.*

The workflow takes into account:

- *To inform national authorities before public communication*
- *To quality assure the results – analytical (WP9, WP14) and statistical (WP10)*
- *"HBM4EU" messages are widely endorsed by the management board*

Stepwise approach for formulating the messages for communicating HBM4EU results of <u>new data</u> from the aligned studies.

E.g. Exposure levels (WP10), European reference values (WP10), geographical comparison (WP10), time trends (WP10), determinants of exposure (WP10), mixture analysis (WP15), HBM-indicators (WP5), exposure-effect biomarker associations (WP14), etc.

Why do we need communication rules?

- HBM4EU is a collaborative research effort, at the science and policy interface, involving both the national- and the EU-level. Respect for each other's role and needs is crucial, especially when communicating results.
    - *Results cannot be withheld or influenced. But all actors involved must be informed in time and - depending on their role - have a say in the way results are communicated.*
- Respecting terms and conditions of national studies feeding their data into HBM4EU.
- Quality control of the content.
- Ownership of the results: if conclusions are supported by as many partners as possible, dissemination, use and impact will be facilitated.
- Transparency and active communication (not only results, also procedures).
- Good agreements make good friends: defining procedures, timings, roles and quality requirements for communication.
    - *All partners involved should follow the same rules, not only the scientists, also the policy makers using the results and communicating about them.*

What can go wrong; what to avoid?

- Substantive errors: incorrect interpretation of data, over-generalization, ...
- Misleading visual representation of the data may wrongly stigmatize certain groups or regions.
- Data from a national study comes in the media without having informed the national data owners and responsible policy makers. Policy makers are not prepared to respond.
- Controversy because conceptual issues have not been sufficiently resolved: how to represent the data? How can countries be compared? How to compare with guidance values? Which nuances have to be included?
- Improper communication about HBM data can provoke feelings of anxiety among citizens or, on the contrary, be ignored because it does not include an adequate perspective for action or does not adequately reflect prevailing perceptions (cognitive dissonance). Risks must be adequately framed and, if possible, accompanied by a realistic action perspective.

Who should be involved?

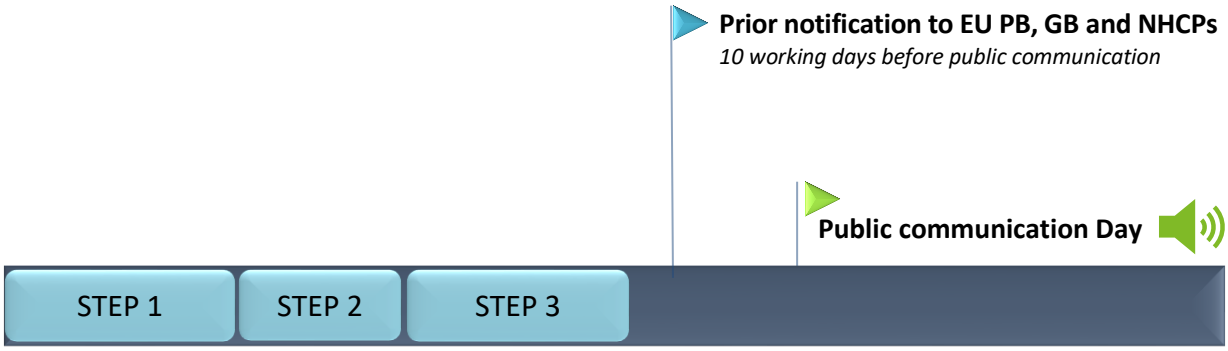
The data analyses are coordinated by WP10 (lead: VITO). Within WP10 for each substance(group) a responsible ***substance lead*** is appointed. The substance lead is advised to consult/involve PI's, WP7, 8, 9, 14 the CGL and the MB.

Other privileged partners and fora:

i) ***Data owners and partners of the national HBM studies***, to be addressed via the ***Principal Investigators*** (PI's) of the national studies.

ii) The ***EU Policy Board*** (EPB), ***Governing Board*** (GB) and ***National Hub contact points*** (NHCPs)The ***Stakeholder Forum*** (SF) and external ***national and EU networks*** (e.g. Eionet).

Communication timeline:



Step1: Quality control
Discuss and agree: Key messages, uncertainties, policy relevance

Step2: Consolidation of key messages + Develop communication plan
Target audience(s), type of communication product/channel, timeline

Step3: Validation of HBM4EU product
MB labels the communication product as HBM4EU "product/output"

Authorship of communication materials:

Communication products to which this document apply (I.e. research briefs, factsheets,..) typically do not include authors. As a standard the following should be included:

- Point of contact for more information (e-mail address).
- Name of institute of responsible person of step 1 and 2 *(described later in this document)*.

Stepwise approach for communication of EU level results:

	WHAT	WHO IS INVOLVED	WHEN	WHO IS RESPONSIBLE
1	Quality control *Key messages* *Uncertainties* *Policy relevance*	WP10 substance lead <-> PI's of national studies (+ CGL, WP9, WP14 & Statistics Working Group)	ASAP	The specific partner leading the task that delivers the result
	Dissemination and communication of national results. *To the study participants, granting authorities and national/regional government, ethics committee,…*	*PI's of national studies, NH's, funding authorities,..* ▽△	*ASAP* *(conform national requirements!)*	*PI of national studies*
2	Consolidation of key messages + Develop communication plan *Targeted audience(s)* *Type of communication product* *Timeline*	WP8 & WP10-leader[1] & coordinator knowledge hub ▽△	ASAP	The specific partner leading the task that delivers the result
3	Validation of HBM4EU product *(or conflict resolution)*	Management Board (via WP-leader & coordinator knowledge hub) ▽	4 weeks before communication day[2]	WP lead
4	Prior notification	EU PB – confidentially! ▽	10 working days before communication day	Knowledge hub
	Prior notification	GB, NHCPs – confidentially! ▽		UBA & NH Coördinator
5	*[Optional: Announcement]*	*[SF, other external fora]* ▽	*Communication day*	*Maria Uhl & Knowledge hub*
6	Communication & dissemination	Public communication and dissemination	Communication day	Knowledge hub

[1] *For results of exposure – effect biomarker associations WP14 lead should be involved.*
[2] *The MB must respond to the WP lead within 10 working days after submission of the communication product.*

Step 1: Quality control of results

The Responsible should organize a timely dialogue with the PI's of the national HBM studies whose data are used in the analysis. To discuss:

- The results of the analyses and remaining uncertainties.
- Conclusions of the results and key messages for public communication.
- Policy relevance of the results.

Also the CGL, WP9 lead and the Statistics Working Group of WP10 should be engaged in this phase as 'critical friends'.

- WP9 for quality control of the analytical data, and to be consulted when ICI/EQUAS program is mentioned in the communication.
- CGL as expert for their substance group.
- Statistical working group to consult on statistical analysis related uncertainties.

Table 1: overview of responsible persons in step 1:

Responsible	Task
WP10 lead (VITO)	Exposure levels (exposure distributions: Annual deliverable)
Substance leads in WP10	Specific research questions tackled under WP10
Protocol leads	Exposure – effect biomarker associations under WP10/WP14
WP9 lead	Quality control of the exposure biomarker analysis
WP14 lead	Quality control of the effect biomarker analysis
Statistical working group (VITO, UBA, ANSP)	European Reference Values (ERV's)
	Time trends

Communication responsibilities on country level:

In this phase, the PI's are responsible for meeting the national requirements of their studies, such as timely informing partners, commissioners or study participants about the national level results, if the study is required to do so.

Step 2: **Consolidation of key messages + develop communication plan**

The result of step 1 (key messages) should be forwarded to the competent WP leaders (WP8, WP9, WP10 and WP14) for consolidation.

A communication plan should be developed together with the EEA as coordinator of the knowledge hub. The communication plan should include:

- Assessment of the best suited communication products and channels for the selected target audience(s).
- Time schedule for validation of the output as HBM4EU product, notification, consultations (optional, if relevant) and final communication and dissemination of the results.

The knowledge hub provides templates for different types of communication products. The responsible of step 1 is responsible for feeding the results into the selected communication products.

FEEDBACKLOOP: the partners in step 1 will always be informed about the progress and final communication products that will be developed.

Step 3: Validation of the communication product as HBM4EU product (or conflict resolution in case of divergent opinions)

After agreement on the content and the communication plan in the previous steps, the products are submitted to the Management Board, by EEA as coordinator of the knowledge hub with the responsible WP leaders (WP8/WP9/WP10/WP14) in copy. The validation is explicitly listed as a point on the agenda, and minutes keep a trace of the validation status, but also of reflections made (and not only the final products).

In case of disagreement on messages or on the communication plan:

Disagreement on messages (the content) or on the communication plan (type of communication product, target audience, and timing) can occur. They might be identified by the partners in step 1 and 2 or identified within the Management Board. In these situations:

- ✓ The discussion will be given structure by listing up the different arguments;
- ✓ The Management Board concludes on the relevance of the divergence in opinions: what could be the added value of making these different perspectives public?
- ✓ If the description of the divergence is of no relevance or leading to confusion in the communication: the maximum of agreement within the Management Board will be strived for; in case of a compromise the partners of Step 1 and 2 are consulted.
- ✓ If no agreement can be found, it is up to the Management Board to evaluate the weight of the dissensus;
- ✓ A vote within the Management Board is the ultimate and decisive step on the communication (content and plan). If however more than one third of the members represents a divergent opinion, the draft communication (plan) would better return to step 1.

FEEDBACKLOOP: the partners in step 1 will always be informed about the progress and final products that will be developed.

Step 4: Prior notification [10 working days before public communication]

After validation of the communication products by the MB the communication products (*at least the key messages and timing for communication*) are sent to the EU Policy Board, by EEA as coordinator of the knowledge hub for prior notification 10 working days before public communication. Also the Governing Board (GB) and National Hub contact points (NHCPs) will

be informed about the upcoming communication by the project coordinator (UBA) and NH coordinator, respectively 10 working days before public communication. EEA as coordinator of the knowledge hub will inform UBA and NH coordinator when such communication is required.

! If relevant, the EU PB can be consulted on (specific parts) of the communication (e.g. on policy relevance).

Results should be treated confidentially by EU policy board, GB and NHCPs until public communication day.

FEEDBACKLOOP: the partners in step 1 will always be informed when a notification is send to the EU Policy Board, GB and NHCPs.

[Step 5 - optional: Announcement]

If relevant, and detailed in the communication plan, the responsible of step 1 can ask the EEA as coordinator of the knowledge hub to inform the Stakeholder forum coordinator (Maria Uhl) and other relevant external networks about the communication. This can be shortly before public communication day or at least simultaneously.

Step 6: **Public communication and dissemination**

On the HBM4EU website and other communication channels (HBM4EU social media) if relevant by EEA as coordinator of the knowledge hub.

Appendix:

Results of an inquiry conducted among the aligned studies about communication rules:

Consolidation of principles and sequence of dissemination for HBM4EU results from aligned studies. *Please indicate in the column Yes/No if you agree or if the situation applies to your data.*	NIPH	SDU	NPHI	SZU	NIOM	JSI	AUTH	EPIUD	ANSP	UBA	NFA	MU	BEA	VITO	RegionH	UI	THL	CIPH	INSA	SWISS TPH	LNS
Basic Principles: ***Indicate if you agree:***																					
The principal Investigator of the original individual studies is **responsible for timely dissemination and communication of results**[1] **to the study participants, granting authorities and national/regional government.**	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		Y	Y	Y	Y	Y	N
The **principal investigators** of the aligned studies need to be **involved** in WP10 by the substance leads (who tackle certain Research questions on EU level) **in an early stage** to discuss the results[1] of the analyses and remaining uncertainties and **to discuss and agree on conclusions and messages for public communication at European level and ensure the message is consistent with national messages**.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y		?	Y	Y	Y	Y	Y

(Table continued on next page)

	NIPH	SDU	NPHI	SZU	NIOM	JSI	AUTH	EPIUD	ANSP	UBA	NFA	MU	BEA	VITO	RegionH	UI	THL	CIPH	INSA	SWISS TPH	LNS
Sequence of dissemination: *Does any embargo apply to your data…**Please indicate below if any of these apply to your data** e.g.*																					
Results[1] need to be **communicated to the participants first** before any data can be published/reported on national and/or EU level.	Y	Y	Y	N	N	Y	N	N	N	N	N	Y	N	Y		N	N	Y	Y	Y	N
Results[1] need to be **reported on national level** before they can be published/reported on EU level.	N	N	Y	N	N	Y	N	N	N	Y	N	Y	Y	Y		N	N	Y	Y*	N	Y
Results[1] need to be **published (peer-reviewed article)** before they can be reported and used at EU level.	N	Y	Y	N	N	Y	N	N	N	N	N	/	N	N		N	N	N	N**	Y	Y
Specify if any other restriction apply to your data…..	/	/	/	/	/	/	/	/	/	/	/	/	/	/		/	/	/	/	/	/
Other restrictions?																					
Are there any time restrictions with regard to sharing national results with HBM4EU?	N	Y	N	N	N	N	N	N	Y	N	N	/	N	N		N	N	N	N	N	N
Will these restrictions delay the production of European level data?	N	N	N	N	N	N	N	N	N	N	N	/	N	N		N	N	N	N	N	N
Are there any other criteria or restrictions set by your research ethics committee approval?	/	/	N	N	/	N	N	N	N	N	N	/	N	N		N	/	N	N***	N	N

** So that National Authorities and Policy Makers are aware of the national results and prepared to respond if they come up on the national media (as nowadays information flows are quite quick).*
*** As long as the possibility to publish is safeguarded, meaning that the reporting of the results should not compromise or imperil the publication in peer-reviewed journals. ***Only the necessity to report the results to the Ethics Committee*

List of key contacts:

Principal contact point for aligned studies		
Indoor Air Quality	HU	Tamás Szigeti
POLAES	PL	Wojciech Wasowicz
Endocrine disruptors in children and associated health effects	SK	Lubica Murinova
Odense Child Cohort	DK	Tina Kold Jensen
Norwegian Environmental Biobank II	NO	Cathrine Thomsen, Line Haug
Cross-Mediterranean Environment and Health Network	EL	Denis Sarigiannis, Katerina Gabriel
Northern Adriatic cohort II	IT	Fabio Barbone
Exposure of children and adolescents to selected chemicals through their habitat environment	SI	Milena Horvat
Étude de santé sur l'environnement, la biosurveillance, l'activité physique et la nutrition	FR	Loïc Rambaud
German Environmental Survey V	DE	Nina Vogel
Pilot study in school children (Czech Republic)	CZ	Jana Klanova
Endocrine disruptors in children and associated health effects follow-up	SK	Lubica Murinova
Riksmaten ungdom 2016-17	SE	Sanna Lignel
Biomonitorización en Adolescentes	ES	Argelia Castano
Flemish Environment and Health Survey IV	BE	Greet Schoeters
European Longitudinal Study of Pregnancy and Childhood (C)ELSPAC	CZ	Jana Klanova
Copenhagen Minipuberty study (parents)/ DYMS	DK	Anna-Maria Anderssen
FinHealth study	FI	Hanna Tolonen
Icelandic National Dietary Survey 2019 - Human Biomonitoring Substudy	IS	Ása Valgerður Eiríksdóttir
Implementation of Human Biomonitoring Survey in Adults in Croatia Using HBM4EU Methodology	HR	Natasa Janev Holcer
Exposure of the Portuguese Population to Environmental Chemicals: a study nested in INSEF 2015	PT	Sonia Namorado
Environmental Specimen Bank	DE	Till Weber
ORISCAV Lux2	LX	An Van Nieuwenhuyse
Human Biomonitoring for Europe Program for Switzerland	CH	Miriam Bolz
WP leads		
WP8	DH	Ovnair Sepai
WP9	ISCIII	Argelia Castano, Marta Estaban Lopez
WP10	VITO	Eva Govarts
WP14	UGR	Marieta Fernandez

Other contacts		
Knowledge Hub Coördinator	EEA	Cathrine Ganzleben, Joana Lobo Vincente
National Hub Coördinator	DH	Ovnair Sepai
Stakeholder forum Coördinator	EAA	Maria Uhl
CGL's		
PAHs	AUTH	Denis Sarigiannis
Per- and Polyfluorinated Compounds	EAA	Maria Uhl, Ingrid Hauzenberger
MOCA & Anilines	FIOH	Tiina Santonen
MOCA & Anilines	UCPH	Lisbeth Knudsen
Bisphenols	INSERM	Robert Barouki
Cadmium/Chromium VI	ISS	Beatrice Bocca
Cadmium/Chromium VI	JSI	Milena Horvat, Janja Snoj Tratnik
Flame retardants	MU	Jana Klánová, Lisa Melymuk
Flame retardants	VSCHT	Jana Hajslova, Jana Pulkrabova
Mixtures	RIVM	Erik Lebret, Mirjam Luijten
Mixtures	THL	Hannu Kiviranta
Phthalates & substitutes	UBA	Marike Kolossa-Gehring, Rosa Lange
Emerging chemicals	VITO	Greet Schoeters
Acrylamide	KI	Federica Laguzzi
Aprotic Solvents	VIAA	Normunds Kadikis
Arsenic	NIOM	Wojciech Wasowicz
Benzophenones	MOH-IL	Tamar Berman
Lead	NPHI	Tamás Szigeti
Mercury	MOH-CY	Andromachi Katsonouri
Mycotoxins	INSA	Paula Alvito
Pesticides	SDU	Helle Raun Andersen