HBM4EU

science and policy
for a healthy future

Project Handbook

Version 2.3

Imprint

Editor:
Umweltbundesamt
Section II 1.2 Toxicology, Health Related Environmental Monitoring
Corrensplatz 1, 14195 Berlin
Tel: +49 8903-1427
HBM4EU@uba.de

Closing Date:
August 2018
Editorial office:
Section II 1.2 Toxicology, Health Related Environmental Monitoring
Ulrike Doyle, Rosa Lange, Kim Pack, Lena Reiber, Doreen Scheler

Version 2.3, UBA, 2018-08-06
File: HBM4EU_Handbook_20170124_V2.3

Content

1. Introduction

This internal HBM4EU Project Handbook has two main functions.
Firstly, it acts as a reference source for all Consortium members covering many of the day-to-day activities and providing links to further information where required.
Secondly, it aims to standardize various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

This Handbook is a living document and will be updated regularly throughout the project.

Please note: This handbook is for internal use only.

2. Legal Basis

The project operates within the HORIZON2020 programme.

The Grant Agreement No. 733032 with the European Union (‘the EU’), represented by the European Commission ('the Commission') is in operation. The DoA (Description of Action) (Annex 1 of the Grant Agreement) forms a part of this contract. Annex 7 ‘Annual work plan for the next year’ informed about the work plan of the first year, 2017.
The first Amendment pertaining to the deliverables was made 01 June 2017. The second Amendment of 19. April 2018 added new partners, new Linked Third Parties (LTP), a revised DoA and a revised budget. A third Amendment is under way pertaining to new LTPs, a revised DoA and a revised budget.

A Consortium Agreement (CA) has also been signed by all partners. The current version of the Consortium Agreement is dated 03. November 2016.
The Management Board of the HBM4EU project is implementing the Consortium Agreement.

3. Important Contacts

3.1 HBM4EU Coordinator

The Coordinator is responsible for the scientific and administrative management. He or she is supported by the secretariat for the administrative management, and by the Co-Coordinator, and the Management Board for the scientific management. The Coordinator is the legal entity acting as the intermediary between the Parties and the Funding Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and the Consortium Agreement.

Coordinator: Marike Kolossa-Gehring
Phone: +49-30-8903-1600, mobile: +49 173 5993297

Ulrike Doyle
Phone: +49-30-8903-1427

Nicole Kobosil
Phone: +49-30-8903-1269

Rosa Lange
Phone: +49-30-8903-1357

Kim Pack
Phone: +49-30-8903-1266

Lena Reiber
Phone: +49-30-8903-1265

German Environment Agency (UBA)
Section II 1.2 Toxicology, Health Related Environmental Monitoring
Corrensplatz 1, 14195 Berlin

POB 33 00 22, 14191 Berlin, Germany

E-Mail: HBM4EU@uba.de

Financial Management: Birgit Puppe
Phone: +49-340-2103-2366

Doreen Scheler
Phone: +49-340-2103-2375

German Environment Agency (UBA)
Unit Z 6 - Project Administration
Wörlitzer Platz 1, 06844 Dessau-Roßlau

POB 1406, 06813 Dessau-Roßlau, Germany

E-Mail: HBM4EU@uba.de

Co-Coordinator: Greet Schoeters
Phone: + 32 14 33 5167, mobile: +32 477427746

Eva Govarts
Phone: +32 14 33 5511

VITO-Unit Environmental Risk and Health
University of Antwerp - Dept. Biomedical Sciences
University of Southern Denmark - Institute of Public Health/ Dept. of Environmental Medicine

Email: HBM4EU@vito.be

3.2 Pillar Leaders

Pillar Leader for Pillar 1 Science to Policy: Greet Schoeters
Phone: + 32 14 33 5167, mobile: +32 477427746

VITO-Unit Environmental Risk and Health
University of Antwerp - Dept. Biomedical Sciences
University of Southern Denmark - Institute of Public Health/ Dept. of Environmental Medicine

Email: HBM4EU@vito.be

Pillar Leader for Pillar 2 European HBM Platform: Argelia Castaño; with co-lead Greet Schoeters

Phone: +34 918223540, mobile: +34 918223545

National Center for Environmental Health,
Institute of Health Carlos III, Calle Sinesio Delgado 4-6,
Madrid 28029, Spain

Email: castano@isciii.es or hbm4eu@isciii.es

Pillar Leader for Pillar 3 Exposure and Health: Robert Barouki

Address 1:

Phone: 33 (0)1 42 86 20 75

Unité UMR-S 1124 Inserm-Université Paris Descartes
"Toxicologie Pharmacologie et Signalisation Cellulaire"
45 rue des Saints Pères, 75270 Paris 06 France

Email: robert.barouki@parisdescartes.fr or hbm4eu.inserm@inserm.fr

Address 2:

Phone: 33 (0)1 44 49 50 55

Service de Biochimie Métabolomique et Protéomique
Hôpital Necker Enfants Malades
149 rue de Sèvres, 75015 Paris, France

Email: robert.barouki@nck.aphp.fr

3.3 HBM4EU EC Project Officer

Sofie Nørager

Scientific Officer

European Commission

DG Research & Innovation

E5 Innovative tools, technologies and concepts in health research

CDMA 00/119

1049 Brussels/Belgium

Phone: +32 229-50112

Email: sofie.norager@ec.europa.eu

4. Consortium Partners

No. (GS)	No. (LTP)	Short name	Legal Name	Cntry
1		UBA	UMWELTBUNDESAMT	DE
	1.1	IPA	INSTITUT FUER PRAEVENTION UND ARBEITSMEDIZIN DER DEUTSCHEN GESETZLICHEN UNFALLVERSICHERUNG, INSTITUT DER RUHR-UNIVERSITAET BOCHUM	DE
	1.2	UFZ	HELMHOLTZ-ZENTRUM FUER UMWELTFORSCHUNG GMBH - UFZ	DE
	1.3	IBMT	FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.	DE
	1.4	BfR	BUNDESINSTITUT FUER RISIKOBEWERTUNG	DE
	1.5	IPASUM	INSTITUT UND POLIKLINIK FUER ARBEITS-, SOZIAL- UND UMWELTMEDIZIN DER UNIVERSITAET ERLANGEN-NUERNBERG	DE
2		EAA	UMWELTBUNDESAMT GMBH	AT
	2.1	MUI	MEDIZINISCHE UNIVERSITAT INNSBRUCK	AT
	2.2	AGES	OSTERREICHISCHE AGENTUR FUR GESUNDHEIT UND ERNAHRUNGSSICHERHEIT GMBH	AT
	2.3	UMIT	UMIT - PRIVATE UNIVERSITAT FUER GESUNDHEITSWISSENSCHAFTEN, MEDIZINISCHE INFORMATIK UND TECHNIK GMBH	AT
	2.4	MUW	MEDIZINISCHE UNIVERSITAET WIEN	AT
3		SCIENSANO (former WIV-ISP (IPH))	SCIENSANO	BE
	3.1	ULg	UNIVERSITE DE LIEGE	BE
4		VITO	VLAAMSE INSTELLING VOOR TECHNOLOGISCH ONDERZOEK N.V.	BE
	4.1	UH	UNIVERSITEIT HASSELT	BE
	4.2	DOMG (former LNE)	DEPARTEMENT OMGEVING	BE
	4.3	UAntwerpen	UNIVERSITEIT ANTWERPEN	BE
	4.4	KU Leuven	KATHOLIEKE UNIVERSITEIT LEUVEN	BE
	4.5	PIH	PROVINCIAL INSTITUTE FOR HYGIENE	BE
5		SWISS TPH	SCHWEIZERISCHES TROPEN- UND PUBLIC HEALTH-INSTITUT	CH
	5.1	DFI	DEPARTEMENT FEDERAL DE L´ INTERIEUR	CH
	5.2	FOEN	FEDERAL DEPARTMENT FOR ENVIRONMENT TRANSPORTS ENERGY AND COMMUNICATION	CH
	5.3	SSPH	STIFTUNG SWISS SCHOOL OF PUBLIC HEALTH PLUS (SSPH)	CH
	5.4	AICT	ALPINE FOUNDATION FOR LIFE SCIENCES	CH
6		MOH-CY	MINISTRY OF HEALTH OF THE REPUBLIC OF CYPRUS	CY
	6,1	UCY	UNIVERSITY OF CYPRUS	CY
7		MU	MASARYKOVA UNIVERZITA	CZ
	7.1	IHIS	USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY	CZ
	7.2	VSCHT	VYSOKA SKOLA CHEMICKO-TECHNOLOGICKA V PRAZE	CZ
	7.3	IEM	USTAV EXPERIMENTALNI MEDICINY AKADEMIE VED CESKE REPUBLIKY VEREJNA VYZKUMNA INSTITUCE	CZ
	7.4	CU	UNIVERZITA KARLOVA V PRAZE	CZ
	7.5	FNUSA	FAKULTNI NEMOCNICE U SV. ANNY V BRNE	CZ
	7.6	CULS	CESKA ZEMEDELSKA UNIVERZITA V PRAZE	CZ
8		REGIONH	REGION HOVEDSTADEN	DK

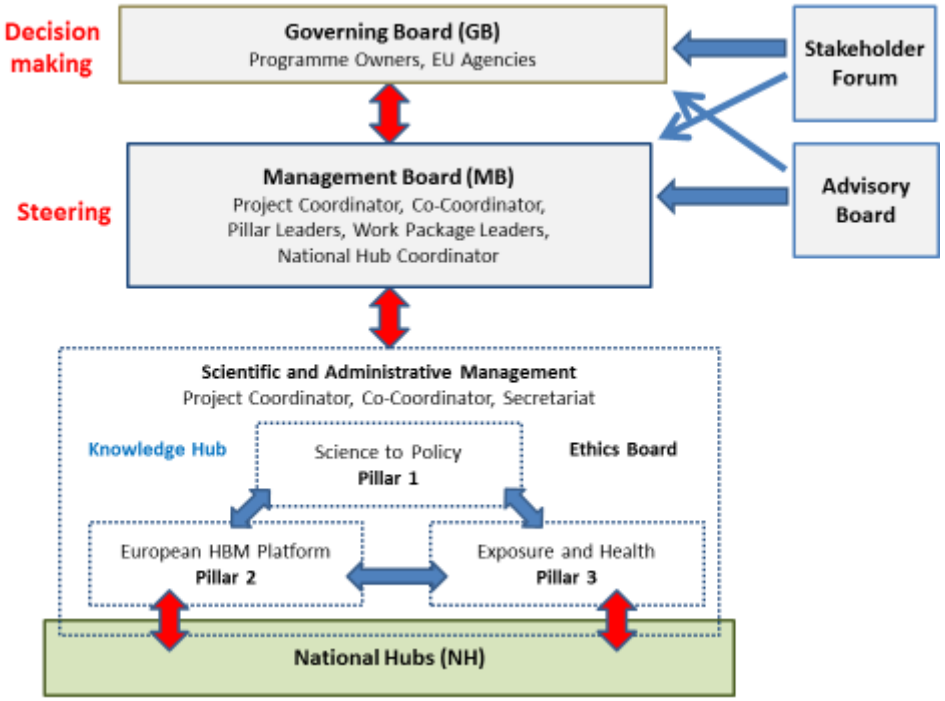
	8.1	SDU	SYDDANSK UNIVERSITET	DK
9		DTU	DANMARKS TEKNISKE UNIVERSITET	DK
10		NRCWE	DET NATIONALE FORSKNINGSCENTER FORARBEJDSMILJO	DK
	10.1	UCPH	KOBENHAVNS UNIVERSITET	DK
	10.2	AU	AARHUS UNIVERSITET	DK
11		EEA	EUROPEAN ENVIRONMENT AGENCY	DK
12		AUTH	ARISTOTELIO PANEPISTIMIO THESSALONIKIS	EL
	12.1	UoC	PANEPISTIMIO KRITIS	EL
13		UoA	ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON	EL
	13.1	HHF	HELLENIC HEALTH FOUNDATION	EL
14		ISCIII	INSTITUTO DE SALUD CARLOS III	ES
	14.1	ULPGC	UNIVERSIDAD DE LAS PALMAS DE GRAN CANARIA	ES
	14.2	IS GLOBAL	FUNDACION PRIVADA INSTITUTO DE SALUD GLOBAL BARCELONA	ES
	14.3	UGR	UNIVERSIDAD DE GRANADA	ES
	14.4	IISPV	FUNDACIO INSTITUT D'INVESTIGACIO SANITARIA PERE VIRGILI (IISPV)	ES
	14.5	EASP	ESCUELA ANDALUZA DE SALUD PUBLICA SA	ES
	14.6	FISABIO	FISABIO-PUBLIC HEALTH	ES
15		THL	TERVEYDEN JA HYVINVOINNIN LAITOS	FI
16		FIOH	TYOETERVEYSLAITOS	FI
17		INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	FR
	17.1	CEA	COMMISSARIAT A L ENERGIE ATOMIQUE ET AUX ENERGIES ALTERNATIVES	FR
	17.2	CNRS	CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE CNRS	FR
	17.3	INRA	INSTITUT NATIONAL DE LA RECHERCHE AGRONOMIQUE	FR
	17.4	ANSES	AGENCE NATIONALE DE LA SECURITE SANITAIRE DE L ALIMENTATION DE L ENVIRONNEMENT ET DU TRAVAIL	FR
	17.5	INERIS	INSTITUT NATIONAL DE L ENVIRONNEMENT ET DES RISQUES INERIS	FR
	17.6	INRS	INSTITUT NATIONAL DE RECHERCHE ET DE SECURITE	FR
	17.7	ANSP	AGENCE NATIONALE DE SANTE PUBLIQUE	FR
18		CIPH	HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	HR
	18.1	IMROH	INSTITUT ZA MEDICINSKA ISTRAZIVANJA I MEDICINU RADAI	HR
19		HSE	HEALTH SERVICE EXECUTIVE HSE	IE
20		MOH-IL	MINISTRY OF HEALTH	IL
21		UI	HASKOLI ISLANDS	IS
22		ISS	ISTITUTO SUPERIORE DI SANITA	IT
	22.1	DPH	UNIVERSITA DEGLI STUDI DI NAPOLI FEDERICO II.	IT
	22.2	IUSS	ISTITUTO UNIVERSITARIO DI STUDI SUPERIORI DI PAVIA	IT
	22.3	EPIUD	UNIVERSITA DEGLI STUDI DI UDINE	IT
	22.4	DEP	AZIENDA SANITARIA LOCALE ROMA	IT
	22.5	UNIMORE	UNIVERSITA DEGLI STUDI DI MODENA E REGGIO EMILIA	IT
23		MOH-IT	MINISTERO DELLA SALUTE	IT
24		NPHSL	NACIONALINE VISUOMENES SVEIKATOS PRIEZIUROS LABORATORIJA	LT
	24.1	LSMU	LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS	LT

	24.2	CIM	VALSTYBINIS MOKSLINIU TYRIMU INSTITUTAS INOVATYVIOS MEDICINOS CENTRAS	LT
25		MITA	MOKSLO INOVACIJU IR TECHNOLOGIJU AGENTURA	LT
26		VIAA	VALSTS IZGLITIBAS ATTISTIBAS AGENTURA	LV
	26.1	LU	LATVIJAS UNIVERSITATE	LV
27		RSU	RIGAS STRADINA UNIVERSITATE	LV
28		RIVM	RIJKSINSTITUUT VOOR VOLKSGEZONDHEIDEN MILIEU*NATIONAL INSTITUTE FOR PUBLIC HEALTH AND THE ENVIRONMENT	NL
	28.1	IRAS	UNIVERSITEIT UTRECHT	NL
	28.2	VU-E&H (former VU-IVM)	VRIJE UNIVERSITEIT AMSTERDAM ENVIRONMENT AND HEALTH	NL
	28.3	RIKILT	STICHTING DIENST LANDBOUWKUNDIG ONDERZOEK	NL
	28.4	TNO	NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK TNO	NL
	28.5	RUMC	STICHTING KATHOLIEKE UNIVERSITEIT	NL
29		NIPH	FOLKEHELSEINSTITUTTET	NO
30		NIOM	INSTYTUT MEDYCYNY PRACY IMIENIA PROF. DRA MED. JERZEGO NOFERA W LODZI	PL
31		FCT	FUNDACAO PARA A CIENCIA E A TECNOLOGIA	PT
	31.1	FMUL	FACULDADE DE MEDICINA DA UNIVERSIDADE DE LISBOA	PT
32		INSA	INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	PT
	32.1	ESTeSL	INSTITUTO POLITECNICO DE LISBOA	PT
	32.2	DGS	MINISTERIO DA SAUDE - REPUBLICA PORTUGUESA	PT
33		SEPA	NATURVARDSVERKET	SE
	33.1	KI	KAROLINSKA INSTITUTET	SE
	33.2	ULUND	LUNDS UNIVERSITET	SE
	33.3	UMU	UMEA UNIVERSITET	SE
	33.4	NFA	NATIONAL FOOD AGENCY	SE
34		NIJZ	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	SI
	34.1	CORS	URAD REPUBLIKE SLOVENIJE ZA KEMIKALIJE	SI
	34.2	UMCL	UNIVERZITETNI KLINICNI CENTER LJUBLJANA	SI
35		JSI	INSTITUT JOZEF STEFAN	SI
36		SZU	SLOVENSKA ZDRAVOTNICKA UNIVERZITA V BRATISLAVE	SK
	36.1	UKF	UNIVERZITA KONSTANTINA FILOZOFA V NITRE	SK
37		UVZ	URAD VEREJNEHO ZDRAVOTNICTVA SLOVENSKEJ REPUBLIKY	SK
	37.1	STU	SLOVENSKA TECHNICKA UNIVERZITA V BRATISLAVE	SK
38		DH	DEPARTMENT OF HEALTH	UK
	38.1	UBRUN	BRUNEL UNIVERSITY LONDON	UK
	38.2	IOM	INSTITUTE OF OCCUPATIONAL MEDICINE	UK
	38.3	UKRI (former NERC)	UNITED KINGDOM RESEARCH AND INNOVATION	UK
	38.4	HSL	HEALTH AND SAFETY LABORATORY	UK
39		NPHI	NATIONAL PUBLIC HEALTH INSTITUTE	HU
40		LNS	NATIONAL HEALTH LABORATORY	LU

GS = Grant Signatory; LTP = Linked Third Party; Cntry = Country

5. Management and Governance

The following figure illustrates the overall project management structure.



The HBM4EU European Joint Programme is structured along the following main components:

- **Governing Board (GB):** The Governing Board shall consist of the Programme Owners, the European Environment Agency (EEA), the European Chemicals Agency (ECHA), and the European Food Safety Authority (EFSA). The Coordinator supported by the secretariat takes part as a guest.
- **Scientific and Administrative Management**: the Project Coordinator and Co-Coordinator will be supported by a Secretariat and the **Management Board (MB)**.
- **Pillar 1**: Science to Policy: an activity focused on the translation of project results into policy.
- **Pillar 2**: European HBM platform: a platform providing support for field sampling and analytical work by competent national laboratories and a data infrastructure.
- **Pillar 3**: Exposure and Health: a research activity to assess the impact of chemical exposure on human health.
- **National Hubs (NH)**: a long-term network bringing together national HBM activities and ensuring that they are coordinated, feed their national needs into the European process, contribute to the objectives and learn from the work done in HBM4EU.
- **Stakeholder Forum (SF)**: 10 representatives of stakeholders from outside the project that will participate in the prioritization process and provide strategic input in order to enhance the accountability and credibility of our activities. It will be composed of stakeholders, in particular from NGOs, industry, and civil society.
- **Advisory Board (AB)**: 10 representatives including international HBM experts with knowledge and experience to contribute to the project.

The roles and members (via short name) of the various project bodies are listed below.

5.1. Governing Board (GB)

Composition: The **Governing Board (GB)** (sect. 3.2.1 DoA) will consist of the Programme Owners of the participating countries - accompanied by a technical person - to ensure political engagement, and representatives of the EU agencies EEA, EFSA and ECHA. It will convene once a year and is the highest-level decision making body of the initiative. The GB will elect a chair and set down its rules for procedures (Terms of Reference) as well as Rules for Participation during its first meeting in month 9 of the project. It will be convened by the Project Coordinator (PC) in collaboration with the Management Board (MB). External experts can be invited to the GB, as considered useful.

Role:

- Approve the annual work plans and annual summary reports.
- Be consulted on significant contractual issues such as termination or addition of new beneficiaries.
- Monitor and approve the achievement of the most significant milestones.
- Approve the ethical and legal framework and the Data Management Plan.
- Support the MB in developing a long-term sustainability plan for HBM in Europe.

The GB, whose role it is to validate the decisions proposed by the MB, such as the annual work plan, the budget, internal calls etc., will strive to reach consensus and if consensus cannot be reached, the GB will vote on different options.

Quorum and voting arrangements for the GB are set in the Consortium Agreement.

Please note: The Governing Board has its own “Terms of Reference and Rules of Procedure of the HBM4EU Governing Board”.

Meetings: once a year, starting month 9 of the project

5.2. Management Board (MB)

Composition: The **Management Board (MB)** (sect. 3.2.1 DoA) consists of the Coordinator, the Co-Coordinator, the Pillar Leaders, the National Hub Coordinator, and the Work Package Leaders except the Leader of Work Package 3 (Management Board Members). The Leader of Work Package 3 will be invited as observer when internal calls are on the agenda in order to ensure the independence of the internal calls management. The European Commission will be invited as an observer when deemed relevant.

The MB consists of 13 persons, or their fully mandated representatives:
Marike Kolossa-Gehring, Catherine Ganzleben, Greet Schoeters, Robert Barouki, Ulrike Fiddicke, Ovnair Sepai, Argelia Castaño, Hanna Tolonen, Dimosthenis Sarigiannis, Jana Klánová, Nicolas Olea, Erik Lebret, Jean-Philippe Antignac.

Role: The MB will ensure the implementation of the HBM4EU according to the overall 5-year plan of the initiative and the individual annual work plans. It will monitor progress according to the milestones and deliverables as set out in the 5-year plan and the annual work plan. The MB will ensure coordination and collaboration between the different Pillars, National Hubs (NHs), and WPs and will be responsible for the overall quality control of deliverables and reports. The MB will be in charge of adopting solutions to problems encountered during the implementation and can refer to the GB if no agreement can be found or if the solution will imply major deviations from the work plans agreed by the GB. In this case the PC is in charge of duly informing the Commission about expected deviations. The MB will oversee how resources are spent and propose changes if needed. The MB will be the entity preparing the basis for the decisions to be validated in the GB. The MB will be responsible for informing the GB about the ethical and legal framework and the Data Management Plan developed by the initiative and for seeking the agreement of the GB on these documents. The MB will also inform the GB about connections established with sister initiatives at national, EU-, and international level and can ask for the GB’s assistance in establishing contacts if needed. The MB will be in charge of any amendment to the Grant Agreement during the course of the project. Quorum and voting arrangements for the MB will be elaborated in the Consortium Agreement.

Please note: The Management Board has its own “Rules of Procedure and Terms of Reference of the Management Board”.

Meetings: bimonthly, starting month 1 of the project, 6 times a year; adapting the number of meetings to the necessary the following years.

5.3. Project Coordinator (PC)

The **Coordinator** (sect. 6.4.1 CA) shall be the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to him/her as described in the Grant Agreement and in this Consortium Agreement. The Coordinator is supported by the Co-Coordinator and the Secretariat.

If the Coordinator is temporarily not be able to fulfil her/his responsibilities within the Consortium, the Co-Coordinator shall substitute her/him, except in matters which are directly related to the responsibilities and obligations of the Main Beneficiary. The Co-Coordinator is a Work Package Leader appointed by the Management Board.

The Coordinator is responsible for:

- managing the overall Programme on a day-to-day basis, including overall contractual, scientific, ethical, financial and administrative aspects;
- fulfilling the reporting obligations under the Grant Agreement and the Consortium Agreement;
- compiling for submission to the Management Board semi-annual reports prepared by the Parties on the progress of work under their responsibility, specified by tasks and including work of their Linked Third Parties and other subsidiaries;
- consolidating the Programme planning, the progress reports, milestone reports, cost statements, budget overviews, or any other document that has to be jointly produced through the Consortium;
- monitoring compliance by the Parties with their obligations:
- monitoring compliance with ethical aspects and keeping stock of relevant ethical permits;
- ensuring financial payments to the Parties in accordance with their obligations under the Description of Action and Annual Work Plan and the internal funding rules set out in Section 7.4 of the Consortium Agreement;
- keeping the address list of Parties and other contact persons updated and available;
- collecting reports, other deliverables (including financial statements and related certifications) and specific requested documents from the Parties and reviewing their consistency and submitting them to the Funding Authority;
- transmitting documents and information connected with the HBM4EU Programme to any other Parties concerned;
- administering the financial contribution of the Funding Authority and fulfilling the financial tasks described in Section 7.3 of the Consortium Agreement;
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims;
- signing the Grant Agreement;
- ensuring implementation of decisions taken by the Governing Board in accordance with this Consortium Agreement;
- managing the Program's reserve budget according to the Annual Work Plan;
- overseeing deadlines and milestones of activities and controlling the quality of deliverables.

If one or more of the Parties is late in submission of any Programme deliverable, the Coordinator may nevertheless submit the other Parties´ Programme deliverables and all other documents required by the Grant Agreement to the Funding Authority in time.

If the Coordinator fails in its coordination tasks, the Governing Board may propose to the Funding Authority and the Parties, by a majority of two-thirds (2/3) of the votes cast representing at least two-thirds (2/3) of assigned person months on a country-by-country basis, to change the Coordinator.

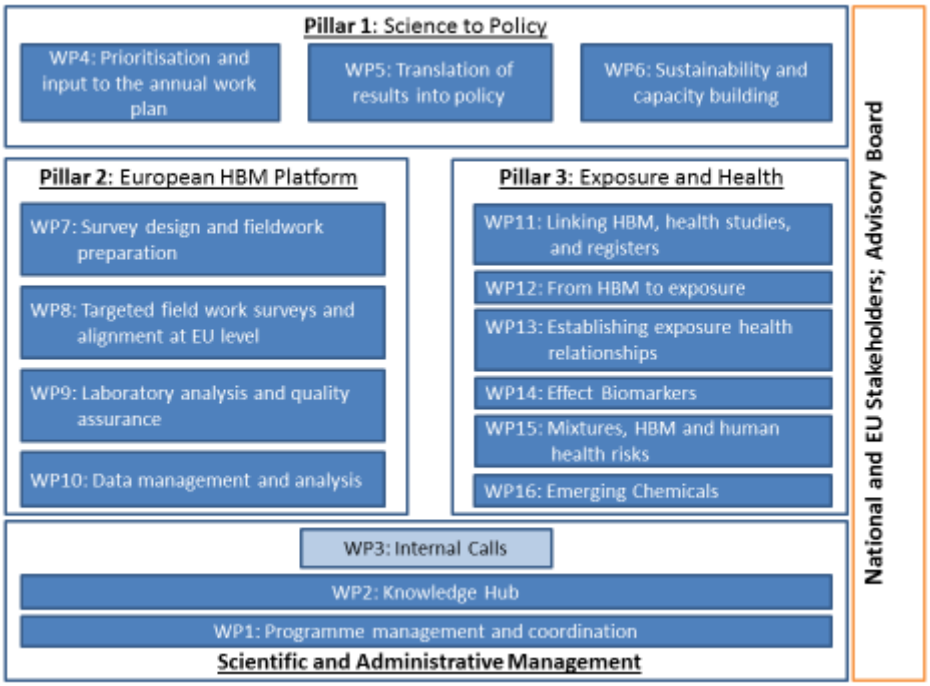
The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

The Coordinator shall not enlarge her/his role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

5.4. Pillar Leader (PL)

Pillar 1: VITO – Greet Schoeters
Pillar 2: ISCIII – Argelia Castaño, with co-lead VITO – Greet Schoeters
Pillar 3: INSERM – Robert Barouki

The following figure shows the Work packages organised in Pillars.



A **Pillar Leaders (PLs**) (sect. 6.4.2 CA) is a Work Package Leader appointed by the Management Board who will support the coordination and interaction of the Work Package Leaders within a Pillar, as well as across Pillars.

The Pillar leaders are responsible for:

- coordinating activities across the work packages of their respective pillars to deliver a coherent set of results within the pillar and promoting knowledge transfer within the pillar;
- coordinating and ensuring collaboration across pillars and promoting knowledge transfer across pillars with a view to ensuring that the overall outcomes of the HBM4EU Programme are coherent and complementary and together generate a robust and harmonized knowledge base for policy making on chemicals;
- ensuring that tasks are not duplicated and promoting complementarities and synergies;
- coordinating with the Chemical Substance Group Leaders in order to ensure that their work is fully integrated into the design and delivery of all Work Packages;
- coordinating the contributions of the Work Package Leaders to the draft Annual Work Plans;
- collecting and integrating the contributions of the Work Package Leaders to the annual reports;
- monitoring compliance of the deliverables from the Work Packages of their respective pillars with the requirements defined in the Description of Action and Annual Work Plan and report the results of this assessment to the Coordinator for discussion in the Management Board;
- collecting training needs from the pillar work packages and reporting them to the leader of Task 2.5 (RUCM);
- working collaboratively with the other Pillar Leaders, Work Package Leaders, the National Hub Coordinator, and the Coordinator.

5.5. Work Package Leader (WPL)

The following table lists the Work Packages and the actual **Work Package Leaders (WPLs)**:

WP No.	Titel	Name	Consortium Partner
1	Programme management and coordination	Marike Kolossa	UBA
2	Knowledge Hub	Catherine Ganzleben	EEA
3	Internal Calls	Charles Persoz	INSERM
4	Prioritisation and input to the annual work plan	Catherine Ganzleben	EEA
5	Translation of results into policy	Greet Schoeters	VITO
6	Sustainability and capacity building	Robert Barouki	INSERM
7	Survey design and fieldwork preparation	Ulrike Fiddicke	UBA
8	Targeted field work surveys and alignment at EU level	Ovnair Sepai	DH
9	Laboratory analysis and quality assurance	Argelia Castaño	ISCIII
10	Data management and analysis	Greet Schoeters	VITO
11	Linking HBM, health studies, and registers	Hanna Tolonen	THL
12	From HBM to exposure	Dimosthenis Sarigiannis	AUTH
13	Establishing exposure health relationships	Jana Klánová	MU
14	Effect Biomarkers	Nicolás Olea	UGR
15	Mixtures, HBM and human health risks	Erik Lebret	RIVM
16	Emerging Chemicals	Jean-Philippe Antignac	INRA
[17]	[Ethics requirements: Work Package automatically added]	[Ulrike Doyle]	UBA

The **Work Package Leaders (WPLs)** (sect. 6.4.3 CA) are responsible for the proper implementation of the obligations of their respective Work Package and its tasks according to the Annual Work Plan and the Description of Action, including timely submission of milestones and deliverables.

The Work Package Leaders are also responsible for:

- supporting the coordination and interaction of the Task Leaders within their respective Work Package, as well as across work packages;
- defining before the start of activities related to the Work Package the standards of structure, content and quality of the deliverables, reports and other documents that are to be generated within the tasks of that work package and for submitting the definition of the standards to the Management Board for approval.
- informing the Pillar Leaders and the Coordinator about any deviations from the Description of Action and Annual Work Plan and developing contingency plans;
- coordinating with other Work Package Leaders together with the Pillar Leaders with a view to ensuring that the overall outcomes of the HBM4EU Programme are coherent and complementary and together generate a robust and harmonized knowledge base for policy making on chemicals;
- ensuring good communication and the flow of information within the work package;
- identifying any bottlenecks or obstacles, as well as links, synergies and overlaps across work packages, and reporting them to the Pillar Leaders and the Coordinator;
- submitting formal reports of progress to the Pillar Leaders and the Coordinator for discussion at the Management Board meetings, and contributing the sections of the HBM4EU annual report relating to their work packages;
- cooperating with the Chemical Substance Group Leaders to ensure implementation of activities proposed in the scoping documents for priority chemicals;
- ensuring compliance within their work package with the ethical and legal framework and contributing to the ethics report by ensuring that all partners in the work package deliver required information and documents;
- contributing to the development of the annual communication plan to be developed in Work Package 2, and feeding the results of their work packages into the Knowledge Hub;
- contributing to the prioritization tasks under Work Package 4;
- developing and submitting the contribution of their respective work package for upcoming draft Annual Work Plans integrating the views of the work package participants.

5.6. Task Leader (TL)

The **Task Leaders (TLs)** (sect. 6.4.4 CA) are responsible for the proper implementation of the obligations of their respective tasks as agreed in the Annual Work Plan and the Description of Action, including timely submission of milestones and deliverables.

The Task Leaders shall be responsible for:

- supporting the Work Package Leaders in the implementation of specific task within a Work Package;
- the technical management of a task that has been assigned to him/her under a work package;
- coordinating the activities all partners involved in this task;
- coordinating scientific and research activities related to this task;
- reporting to Work Package Leaders all problems and needs related to their task ensuring good communication and the flow of information within the task;
- developing and submitting the contribution of their respective task for upcoming draft Annual Work Plans, and submitting them to the Work Package Leaders and the Pillar Leaders; integrating the views of the task participants.
- providing input to training measures.

5.7. National Hub Coordinator (NHC) and National Hub Contact Points (NHCP)

The **National Hub Coordinator (NHC)** (sect. 6.4.6 CA) is a Work Package Leader appointed by the Management Board and will in collaboration with the National Hub Contact Points (NHCP) oversee the needs and the output of the National Hubs to transfer them to the Work Package Leaders for consideration in the development of the Annual Work Plans, including the training needs of the National Hubs. The NHC will contribute to the overall coordination of training and capacity building in Work Package 6. The NHC will also be responsible for ensuring a good information flow to the National Hubs about the activities and outcome of the HBM4EU Programme. The NHC will chair and convene regular meetings of the NHCPs.

The **National Hubs (NH)** (sect. 3.2.1 DoA) will be organized according to a basic structure that will ensure the influence of national authorities and relevant research institutions on the national level. However, each country decides how their NH will be organized. Each NH will appoint a **National Hub Contact Point (NHCP)**. The NH Coordinator (NHC) (Public Health England: Department of Health – DH) will in collaboration with the NHCPs oversee the needs and the outputs of the NHs to transfer them to the WP leaders for consideration in the development of the annual work plans, including the training needs of the NHs. The NHC will also be responsible for ensuring a good information flow to the NHs about the activities and outcome of the HBM4EU. The NHC will chair and convene regular meetings of the NHCPs. The deputy for this task (Aristotle University of Thessaloniki - AUTH) will step in for the NHC when needed.

The following table gives the names of National Hub Contact Points (status: 2. August 2018).
Please also check https://www.hbm4eu.eu/about-hbm4eu/national-hubs/ for up-dates.

Country	NHCP Name	Organisation
Austria	Maria Uhl	Environment Agency Austria (EAA)
Belgium	Karen Van Campenhout	Flemish Institute for Technological Research (VITO)
Croatia	Dubravka Marija Kreković	Ministry of Health of the Republic of Croatia
Cyprus	Andromachi Katsonouri	Ministry of Health of the Republic of Croatia (MOH-CY)
Czech Republic	Jana Klanova	Masaryk University (MU)
Denmark	Lisbeth Knudsen	University of Copenhagen (UCPH)
Finland	Hanna Tolonen	National Institute of Health and Welfare (THL)
France	Robert Barouki	French Institute of Health and Medical Research (INSERM)
Germany	Petra Apel	German Environment Agency (UBA)
Greece	Denis Sarigiannis	Aristotle University of Thessaloniki (AUTH)
Hungary	Tamás Szigeti	National Public Health Institute (NPHI)
Iceland	Thorhallur Ingi Halldorsson	University of Iceland (UI)
Ireland	Health Service Executive	Health Service Executive (HSE)
Israel	Tamar Berman	Ministry of Health (MOH-IL)
Italy	Alessandro Alimonti	The Italian National Institute of Health (ISS)
Latvia	Inese Mārtiņsone	Riga Stradiņš University (RSU)
Lithuania	Sonata Juciute	Lithuanian Agency for Science, Innovation and Technology (MITA)
Luxembourg	Friedrich Mühlschlegel	Luxembourg National Health Laboratory (LNS)
Netherlands	Erik Lebret	National Institute of Public Health and the Environment (RIVM)
Norway	Cathrine Thomsen	Norwegian Institute of Public Health (NIPH)
Poland	Wojciech Wąsowicz	Nofer Institute of Occupational Health (NIOM)
Portugal	Rita Cavaleiro	Foundation for Science and Technology, I.P. (FCT)
Slovakia	Katarina Halzlova, Milada Eštóková, Michal Jajcaj	Public Health Authority of the Slovak Republic (UVZ)
Slovenia	Lijana Kononenko	Chemicals Office of the Republic of Slovenia (CORS)
Spain	Argelia Castaño	Institute of Health Carlos III (ISCIII)
Sweden	Britta Hedlund, Linda Linderholm	Environmental Protection Agency (SEPA)
Switzerland	Nicole Probst-Hensch	Swiss Tropical and Public Health Institute (SwissTPH)
United Kingdom	Ovnair Sepai	Public Health England (DH)

5.8. Stakeholder Forum (SF)

The **Stakeholder Forum (SF)** (sect. 6.3.3.1 CA) shall provide advice to the Governing Board and the Management Board on the conduct of the HBM4EU Programme that will be taken into account by the Management Board when preparing the proposal for the next Annual Work Plan. It will be composed of stakeholders, in particular from NGOs, industry, and civil society.

Its members will be appointed by the Governing Board upon proposal by the Management Board according to selection criteria prepared by the Management Board and approved by the Governing Board. The Stakeholder Forum will be convened by the Environment Agency Austria (EAA) and elect its own Chair by a majority of 50 percent of the members present and voting. It will meet once a year.

Meetings: once a year, starting month 9 of the project, back to back with GB

5.9. Advisory Board (AB)

The **Advisory Board (AB)** (sect. 6.3.3.2 CA) will provide advice to the Management Board on the conduct of the HBM4EU Programme that will be taken into account by the Management Board when preparing the proposal for the next Annual Work Plan. It will be composed of experts from large Human Biomonitoring initiatives of countries that are not participating in the HBM4EU Programme, of coordinators or representatives of other European and international projects and other relevant experts.

Its members will be appointed by the Governing Board upon proposal by the Management Board according to selection criteria prepared by the Management Board and approved by the Governing Board. The Advisory Board will be convened by the Coordinator and elect its own Chair by a majority of 50 percent of the members present and voting. It will meet as required, at a minimum once a year.

Please note: the Advisory Board has its own “Rules of Procedure of the HBM4EU Advisory Board”.

Meetings: once a year, starting month 9 of the project, back to back with GB

5.10. Ethics Board (EB)

The **Ethics Board (EB)** (sect. 6.3.3.3 CA) will assess the deliverables related to the development of an ethical, legal, and data management framework and provide quality assurance for these frameworks. It will also review the annual ethics report and ensure that all required documents are mentioned or attached. It will be composed of specialists in legal and ethical matters from the HBM4EU Programme. The Ethics Board will be convened and chaired by the Task Leader 1.5 Lisbeth E. Knudsen, University of Copenhagen, Denmark. It will meet as required, at a minimum once a year.

Meetings: as required, minimum once a year

5.11. Chemical Substance Group Leaders (CGL)

Chemical Substance Group Leaders (CGL) (sect. 6.4.5 CA) contribute to the elaboration of the Annual Work Plan by providing, in consultation with Work Package 4, advice to the Management Board on research tasks related to policy relevant questions identified under Work Package 4. They attend upon request a meeting of the Management Board prior to the development of the Annual Work Plan.

For new prioritized substances, new Chemical Substance Group Leaders will be proposed by the Management Board and appointed by the Governing Board.

The following table gives the names of the Chemical Substance Group Leaders (CGL) (status: 2. August 2018).

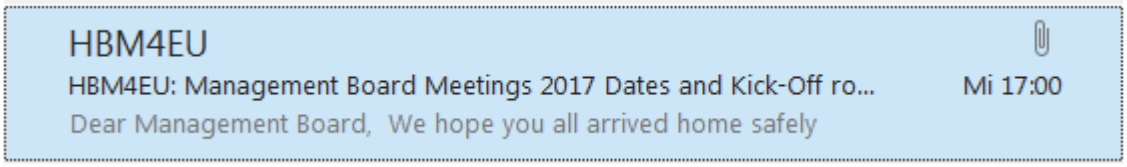
Country	Short name of Consortium Partner	Chemical Substance Group	Name
Greece	AUTH	PAHs	Denis Sarigiannis, Spyros Karakitsios
Austria	EAA	Per- and Polyfluorinated Compounds	Maria Uhl, Ingrid Hauzenberger
Finland	FIOH	MOCA & Anilines	Tiina Santonen
Denmark	UCPH		Lisbeth Knudsen
France	INSERM	Bisphenols	Robert Barouki, Elena Tarroja
Italy	ISS	Cadmium/Chromium VI	Alessandro Alimonti, Elena De Felip
Slovenia	JSI		Milena Horvat, Janja Snoj Tratnik
Czech Republic	MU	Flame retardants	Jana Klánová, Lisa Melymuk
	VSCHT		Jana Hajslova, Jana Pulkrabova
Netherlands	RIVM	Mixtures	Erik Lebret, Mirjam Luijten
Germany	UBA	Phthalates & Substitutes	Rosa Lange, Marike Kolossa
Belgium	VITO	Emerging chemicals	Greet Schoeters, Jos Bessems
Poland	NIOM	Arsenic	Wojciech Wasowicz
Sweden	KI	Acrylamide	Federica Laguzzi
Latvia	VIAA	Aprotic solvents	Normunds Kadikis
Finland	FIOH	Diisocyanates *[1]	Tiina Santonen
Hungary	NPHI	Lead & its compound	Peter Rudnai
Cyprus	MOH-CY	Mercury & its organic compounds	Andromachi Katsonouri-Sazeides
Portugal	INSA	Mycotoxins	Paula Alvito, Maria João Silva
	ESTeSL		Susana Viegas
Denmark	SDU	Pesticides, including Pyrethroids	Helle Raun Andersen
Israel	MOH-IL	UV filters - Benzophenones	Tamar Berman

*[1] It is proposed to include the diisocyanates in the aniline group.

6. Communications

6.1 Email and Email Etiquette

When sending emails it should be remembered that it is much easier to recognise the significance of an email pertaining to the HBM4EU project when this email is marked with the acronym in the subject heading. The "**HBM4EU**" should be followed then by a more specific description of the subject. For example:



As a courtesy, please include your contact details in every email that you initiate.

6.2 File Naming Conventions and Version Control

It is essential that every document circulated to other partners in the consortium includes a date and version number. This will help to avoid the situation where partners are working with old or obsolete versions of documents, or confusion when two partners accidentally work on the same document at the same time.

The guidelines below should be followed as much as possible.

- The filename should be descriptive of the contents and should include the project name first as well as the date at the end of the file name. E.g. "HBM4EU_Handbook_20161223" for the Handbook of the HBM4EU project with the status of 23rd December 2016. Please include the date as "yyyymmdd".
- Where a document is likely to be produced by various partners, please include the partners short name as file name extensions. E.g. "HBM4EU_Handbook_20161223_UD" and "HBM4EU_Handbook_20161223_BP" for different chapters of the handbook written by different persons.
- Where different versions of a document are used, the *version number* should be included in the file name at the end of the filename.
  For draft documents, the version number should start at v0.1, incrementing in 0.1 steps.
  Once the document is formally issued, the version should chance to v1.0 and then increment on 0.1 steps for minor changes.
  For a major change, the version will change to v2.0.
  E.g. the first final version of the handbook for the Kick-Off meeting in February 2017 will be named "HBM4EU_Handbook_v1.0".
- When commenting on a document provided by another partner, the file name should be changed to include the partner's short name as an extension. E.g. comments might be made to the handbook of version 1 by someone, and the file name might then look like "HBM4EU_Handbookv1.0_RB".
- Please use the *track change feature* in word when *suggesting changes* in a document.
- *Deliverables* therefore will be named as follows: "HBM4EU_D4.3_v1.0" or "HBM4EU_D4.3_v2.1" – depending on the number of amendments made - for the deliverable "Prioritisation strategy and criteria" (no. D4.3).

6.3 Participant Portal

In the case of problems with the Participant Portal of the EC, please do not contact the Coordinator, but the **EC Central Helpdesk** (EC working hours: 8 a.m. - 6 p.m. CET):

E-mail: EC-CENTRAL-HELPDESK@ec.europa.eu

When opening this ticket, you will be assigned a reference number enabling your request to be tracked.

If you send an e-mail to follow up an existing incident, please give the incident reference ("IM00xxxxxxx") in the subject line.

7. Project Website

A HBM4EU project website was set up and is regularly updated. Partners are encouraged to add a link from their own website to the HBM4EU home page. Partners will be provided with one login account in order to access the secure pages on the website and to allow updating of their organisation details:

https://www.hbm4eu.eu/

The Knowledge Hub (WP2) will deliver timely and targeted communication products to key users and audiences, serving as an entry point to the HBM4EU outputs for policy makers and other stakeholders. All technical guidelines and protocols will be available for download from an online library, accessible via the HBM4EU website. It will guarantee the visibility of the HBM4EU activities and serve as a link to other international HBM projects by providing a single interface. The Knowledge Hub will inform the public and help raising public awareness.

8. Financial

Details of the most recent budget (HBM4EU Pre-Financing) have been distributed via email on Friday 02 December 2016 00:17 CET to HMB4EU Beneficiaries.

HBM4EU timesheet templates have been distributed via email on Friday 09 December 2016 12:30 CET to all partners.

9. Reports

The **Coordinator** is responsible for:

- collecting **reports**, **other deliverables** (including financial statements and related certifications) and specific requested documents from the Parties and reviewing their consistency and submitting them to the Funding Authority
- **overseeing deadlines and milestones** of activities and **controlling the quality of deliverables** (sect. 6.4.1.3 CA).

If one or more of the Parties is late in submission of any Programme deliverable, the Coordinator may nevertheless submit the other Parties´ Programme deliverables and all other documents required by the Grant Agreement to the Funding Authority in time (sect. 6.4.1.4 CA).

The list of deliverables is to be found in Annex 1 (Part A) of the Grant Agreement.

The **Pillar Leaders** (sect. 6.4.2.2 CA) are responsible for monitoring compliance of the **deliverables** from the Work Packages of their respective pillars with the requirements defined in the Description of Action and Annual Work Plan and report the results of this assessment to the Coordinator for discussion in the Management Board (e.g. First Yearly Report of Pillar Leaders; no. D1.7 in month 9).

The **Work Package Leaders** are responsible for the proper implementation of the obligations of their respective Work Package and its tasks according to the Annual Work Plan and the Description of Action, including timely submission of **milestones and deliverables** (sect. 6.4.3.1 CA). The Work Package Leaders

are responsible defining before the start of activities related to the Work Package the standards of structure, **content and quality of the deliverables**, **reports** and other documents that are to be generated within the tasks of that work package and for submitting the definition of the standards to the Management Board for approval (sect. 6.4.3.2 CA).

The **Task Leaders** are responsible for the proper implementation of the obligations of their respective tasks as agreed in the Annual Work Plan and the Description of Action, including **timely submission of milestones and deliverables** (sect. 6.4.4.1 CA).

All reports must be submitted using the respective template, provided by the Coordinator (hbm4eu@uba.de).

9.1 Reports to the Commission

The Coordinator will submit the Annual Summary Progress Report (ASR), the Annual Work Plan (AWP) and accompanying Ethics Report, and the Periodic Technical Report (PTR) and Periodic Financial Report (PFR) alternating every half year, as well as the Final Report in month 63 (see also chapter 10 for further details).

9.2 Reports to the Coordinator

Each Party shall submit to the Coordinator a semi-annual report on the progress of work under its responsibility, specified by tasks and including work of its Linked Third Parties and its other subcontractors.

The deadlines given are June and December of every year of the project. The semi-annual reports on the progress shall be sent to the Coordinator meeting those deadlines (see also chapter 10 for further details).

9.3 Deliverables and milestones

Deliverables and milestones have to be completed on time to safeguard the proper conduct of collaboration and the transfer of funding.

Deliverables that are not written reports should be verified by a brief written summary.
For milestones an informal e-mail to the Coordinator containing a brief description and a confirmation that the milestone was achieved is sufficient.

The deadlines for deliverables and milestones are given in of Annex 1 (Part A) of the Grant Agreement (see table 1.3.2. for deliverables and table 1.3.4 for milestones). The deadlines for additional deliverables (AD) are listed in the respective Annual Work Plans (AWP). These tables also define the Lead Beneficiary being responsible. The listed project month marks the last month in which the deliverable should be submitted via Participant Portal.

The Coordinator checks the deliverables in form and content, organises reviews, and submits the deliverables. Therefore, deadlines given by the Coordinator have to be met in order to assure uploading of the deliverables according to time schedule.

A reminder will be sent to the Lead beneficiary responsible (with cc to Task and WP Leader) 7 weeks in advance to ask about the current state of the deliverable or milestone. If any deliverable or milestone due in the period is late, an explanation for this **MUST** be given to the Coordinator **seven weeks before the end of the month the deliverable or milestone is due, as well as the anticipated completion date.** The Coordinator will inform the EC officer about the delay and its reason, and ask for an extension of the deadline.

Deliverables must be submitted using the template and checklist of January 2018, provided by the Coordinator. The checklist for the Work Package Leader and Pillar Leader is meant to support the equal understanding on what should be considered during the approval process. The checklist does not need to be sent to the Coordinator but shall be archived by the Work Package Leader and Pillar Leader as a backup in case of an audit.

Quality control of the deliverables and milestones (see figure on the next page):

- A list of deliverables and milestones due in the next 2 months is on the permanent agenda of the Management Board meetings. The respective Work Package Leader will give a short information about the content and current state of the upcoming deliverables and milestones during the Management Board meeting.
- Other Work Package Leaders who are interested in the final development of the respective deliverable should give notice to the responsible Work Package Leader. They will be involved in the development of the deliverable in parallel to the Pillar Leader in the following workflow.
- The Task Leaders (sect. 5.6.) are responsible for the proper implementation of the obligations of their respective tasks as agreed in the Annual Work Plan and the Description of Action, including timely submission of milestones and deliverables. If the Task Leader is not the Lead Beneficiary, the Task Leader is responsible nevertheless to ensure timely submission.
- The Task Leader sends the Work Package Leader and the Pillar Leader the draft for discussion: **10 days before the 3rd day of the month.**
- The Task Leader sends the all over discussed and changed draft to Work Package Leader, the Pillar Leader, and Coordinator (in **cc**): **on day 3 of the respective project month.**
- **Final discussion** between Work Package Leader and Pillar Leader (Task Leader and Coordinator **cc**) and the official approval of Work Package Leader and Pillar Leader can take place until day 15 of the respective project month.
- The Work Package Leader (sect. 5.5.) who is responsible for the timely submission of milestones and deliverables sends the final draft to the Coordinator (HBM4EU@uba.de) (cc to PL and TL) **not later than day 15 of the respective month.**
- The Coordinator retains the right for a final check and layout check before submitting the deliverable/milestone and can request a revision.
- The Coordinator submits the deliverable to the European Commission via the Participant Portal and informs (from HBM4EU@uba.de) the Tasks Leader, Work Package Leader, Pillar Leader, and the Grant Signatory of the responsible author about the **date of submission to the Participant Portal** and the final form of the deliverable/milestone.
- After approval of the deliverable by the European Commission all deliverables marked as “public” will be uploaded to the HBM4EU website.

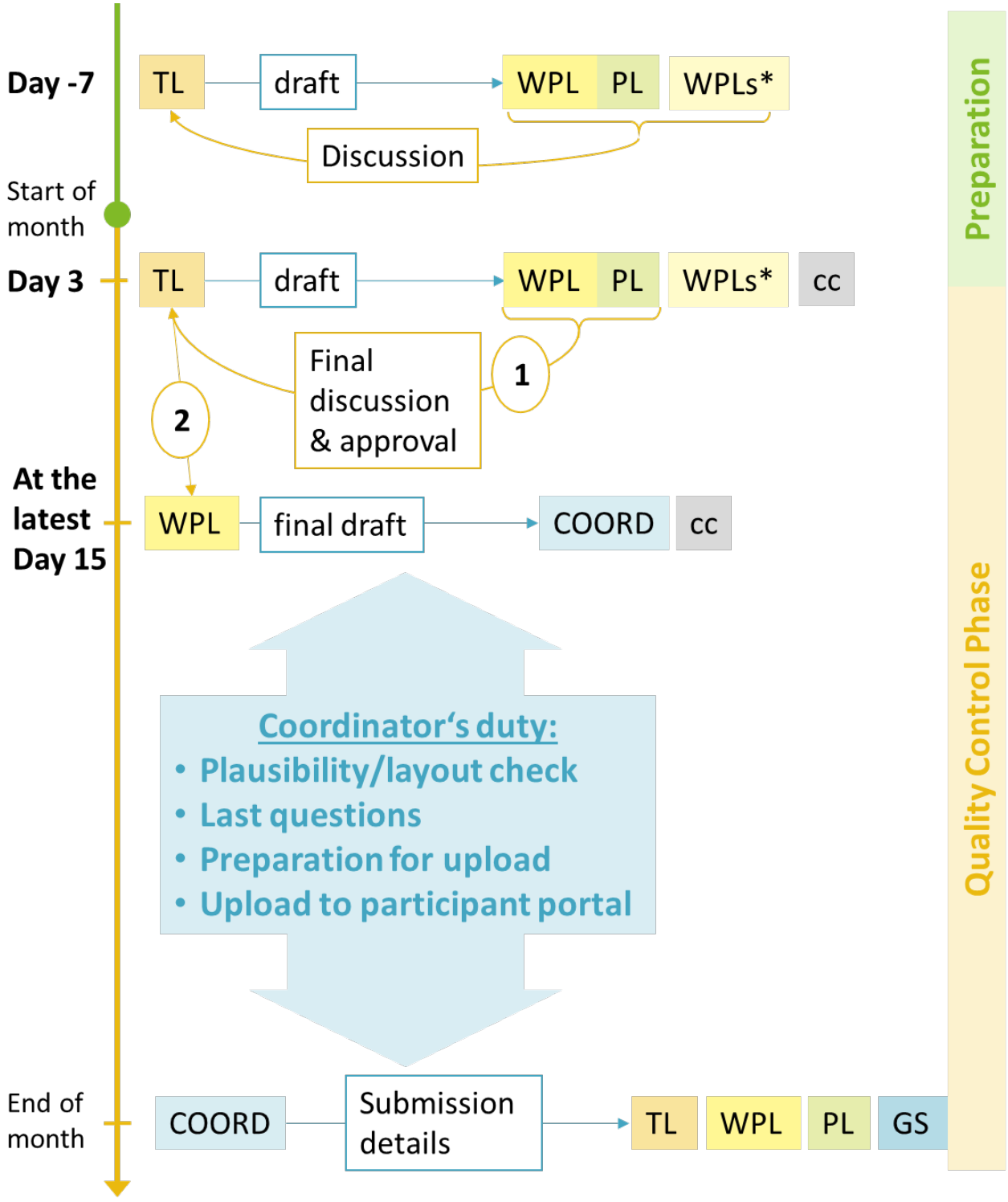


Figure: Quality control of deliverables and milestones in HBM4EU. The month referred to in this figure is the month indicated as deadline. "Day -7" therefore refers to the 7th calendar day before the start of this month. Abbreviations: TL = Task Leader, WPL = Work Package Leader, WPLs* = other Work Package Leaders that have expressed interest in this deliverable/milestone, PL = Pillar Leader, COORD = Coordinator, GS = Grant Signatory of the responsible author, cc = steps marked with 'cc' should also always go to the COORD, the TL, the WPL and the PL if they have not already been directly addressed.

10. Development of the Annual Work Plans

10.1. Background and process

The first list of prioritized substances has been developed before the start of the project, the deliverable "Prioritisation strategy and criteria" (D4.3) being the report about the second list of prioritized substances proposed for 2019-2021, and deliverable "Third list of prioritised Substances" (D4.8) will be the report about the third list of prioritized substances.

The **Annual Work Plan [AWP]** is the contractual basis and legal binding document for each project year and reporting period for all project partners. In addition to: The **Grant Agreement No. 733032 [GA]** (which is the contractual basis for the cooperation between the HBM4EU consortium and the European Commission) - as well as all additional rules and guidelines for the funding under **Horizon 2020** - and The **HBM4EU Consortium Agreement [CA]** (which is the contractual basis for the cooperation within the consortium).

The AWP defines all tasks including deliverables and milestones and necessary resources (in particular the concrete Person Months for each beneficiary) for all Work Packages - in order to achieve the overall goals of the project and to ensure sustainable and permanent HBM4EU processes across Europe. The AWP for each upcoming year is also one of the mandatory yearly reports to the European Commission as listed in the GA.

The AWP will be developed under Task 1.2 by the Coordinator in coordination with the Work Package Leaders and other persons in charge. **The timely submission of the AWP is essential -** in order to safe-guard the mandatory approval from the Governing Board (month 9 of each precedent year) and from the European Commission (month 10 of each precedent year).

The annual **Ethics Report [ER]** accompanying each AWP will address the ethical requirements as set out in the **GA**. WP17 lists the requirements for the whole duration of the project.

The **Annual Summary Progress Report [ASR]** accompanies the planned new AWP - comprising the progress of the ongoing period with regard to the objectives laid down in the current AWP.

According to our Consortium Agreement, in addition, all partners have to submit a **Semi-Annual-Report [SAR]** on the progress of work under their responsibility to the Coordinator. These reports are used to monitor the progress and the achievements made with regard to the objectives and tasks laid down in the AWP.

The coordinator must submit a Periodic Report within 60 days following the end of each reporting period. The periodic report must include a 'periodic technical report' **[PTR]** and a 'periodic financial report' **[PFR]** (see GA, Art. 20.3).

10.2. Deadlines

List of tasks and responsibilities with respective deadlines for each year (in timewise order)

Date	Task	Responsible
	Periodic Reports for the past project year to the EC:	
10 January	**A) Periodic Technical Report [PTR]:** Summaries of the work done, structured by Work Packages (Template to be sent by email to the Coordinator)	**All partners**
10 February	**B) Periodic Financial Report [PFR]:** Submission of Financial Statements [FS] for each beneficiary (if necessary, together with the Certificate Financial Statement [CFS]) within the Participant Portal	**All partners**

1 or 2 March	**The Coordinator has to submit the Periodic Reports (PTR + PFR) for the past project year within the Participant Portal.**	**Coordinator**
April 2018	Check D4.5: Second list of prioritised substances and proposed CGLs for 2019-2021 Does the planned content of the Work Package for the next AWP correspond with the content of the deliverable D4.5?	WPL
MB meeting May	Content discussion **and discussion of respective decisions** for the next AWP including the possible outcomes of the Internal Calls	MB
10 May to 31 May	The objectives, detailed content and all tasks for the next AWP - as well as person months (PM) and other direct costs - have to be discussed and agreed upon by: • Each responsible Work Package Leader; • All partners involved in the Work Package; • For the contribution of Linked Third Parties by the responsible Grant Signatories.	WPL GS LTP
10 June	**The finalised Work Package description for the next AWP (including objectives, tasks, partners, PM, travels, other direct costs) has to be sent by email to the Coordinator.** If accompanying mandatory Decision Memos for the Management Board are needed, please see page 25.	**WPL**
20 June	The Coordinator sends out the first draft of the next AWP to the MB.	UBA
End of June	**MB meeting: Discussion and agreement of the next AWP**	**MB**
July	Evaluation of the next AWP by Pillar Leaders and Chemical Substance Group Leaders (CGL)	PL / CGL
15 July	All partners have to send the Semi-Annual-Report [SAR] by email to the Coordinator (with the template provided).	All partners
31 July	PL/CGL have to send their evaluation of the next AWP to the respective WPL for their consideration (cc to the Coordinator).	PL / CGL
31 July	**WPL have to request the necessary Ethics documents** from the partners of their respective Work package and send these to UCPH (cc to the Coordinator).	WPL
August	UBA (with support of WPL) will develop the budget for the next AWP.	UBA

First week of September	**MB meeting:** **Approval of the next AWP including the budget** Approval of the ASR (short report for the ongoing year)	**MB**
10 September	**Finalisation of the accompanying Ethics Report**	**UCPH**
Second half of September	**GB meeting:** **Approval of the next AWP including the budget** Approval of the Annual Summary Progress Report by the GB	**GB**
10 October	**Upload of AWP and accompanying Ethics Report (and ASR) to the Participant Portal**	**UBA**

All reports/deliverables must be submitted using the respective template, provided by the Coordinator (hbm4eu@uba.de).

10.2.1. Overview of all deadlines for yearly reports connected to the development of the AWP

Year	January	February	March	April	May	June	July	August	September	October	November	December
2017	1	2	3	4	5	6	7	8	9	10	11	12
2018	13	14	15	16	17	18	19	20	21	22	23	24
2019	25	26	27	28	29	30	31	32	33	34	35	36
2020	37	38	39	40	41	42	43	44	45	46	47	48
2021	49	50	51	52	53	54	55	56	57	58	59	60
2022			63	Final Report								

Ethics Report 1 + 2	2nd prioritised substances list 2019-2021
AWP + ASR	
AWP + ASR + Ethics Report	3rd prioritised substances list 2020-2021
PTR to the Coordinator(10 January)	
Submission of FS/CFS (10 February)	FS = Financial Statement; CFS = Certificate Financial Statement (see chap. 10.2)
PTR + PFR (1st or 2nd March)	
SAR	

10.2.2 Overview of the deliverables pertaining to the Annual Work Plans and Ethics Reports

Month of the Project	**Deliverable No.**	**Title**
1	D1.1	First Ethics Report
9	D1.6	Second Ethics Report
10	D1.15	Annual Work Plan 2018
10	D1.16	Annual Summary Progress Report (ASR) 2017
22 – Oct. 2018	D1.17	Annual Work Plan 2019
22	D1.9	Third Ethics Report
22	D1.18	Annual Summary Progress Report (ASR) 2018
34 – Oct. 2019	D1.19	Annual Work Plan 2020
34	D1.11	Fourth Ethics Report
34	D1.20	Annual Summary Progress Report (ASR) 2019
45 – Sept. 2020	D17.1	HCT - Requirement No. 3 *
45	D17.2	POPD – Requirement No. 4
45	D17.3	A - Requirement No. 5
45	D17.4	GEN – Requirement No. 9
45	D17.5	H - Requirement No. 2
45	D17.6	OEI - Requirement No. 10
46 – Oct. 2020	D1.21	Annual Work Plan 2021
46	D1.13	Fifth Ethics Report
46	D1.22	Summary Progress Report 2020

* for the content of D17.1 – D17.6 please see page 26

10.3 SOPs for Amendments

In case of:

A) One or more project partner(s) want(s) to include new Grant Signatories and/or new Linked Third Parties and/or new subcontractors within the consortium;

B) The budget for one or more project partner(s) (acc. to GA/Annex 2) or Work Packages (acc. to GA/Annex 1) are not sufficient or already exceeded;

C) Other unforeseen circumstances with contractual and/or financial implications for the project

The responsible beneficiary has to:

1) Prepare Decision Memo(s) for the Management Board containing detailed information about the purpose/content/ estimated budget of the new partner/new task/actual situation **- if the MB agrees -**

2) Prepare all necessary documents for the Coordinator AND the European Commission to implement these contractual/financial changes **- including –**

3) Providing assistance (technical / financial / administrative) to the new partners entering the Consortium

The Governing Board shall take decisions brought forward by the HBM4EU Management Board on the following matters related to the implementation of the HBM4EU Initiative:

1) Adoption of amendments to the Grant Agreement and its annexes proposed by the Management Board to be approved by the European Commission;

2) Adoption of amendments to the Consortium Agreement, to be signed by the Parties of the Consortium (according to Section 11.4.2 of the Consortium Agreement), upon proposal by the Management Board;

3) Amendment of attachments to the Consortium Agreement upon proposal by the Management Board.

Important!

New partners (GS/LTP/subcontractor) may start with their work for the project only when all these steps are carried out.

Costs for new partners or actions cannot be declared before all contracts (GA/CA/AWP) have been amended.

Please note:

All Decision Memos must be submitted using the respective template, provided by the Coordinator (hbm4eu@uba.de).

10.4. The 'ethics requirements' that the project must comply with are included as deliverables in the Work Package 17

D17.1: HCT - Requirement No. 3 [Month 45]
1. In case human cells/tissues are obtained within the project, details on cells/tissues type and ethics approval must be provided.
2. In case human cells/tissues are obtained within another project, details on cells/tissues type and authorisation by primary owner of data (including references to ethics approval) must be provided.
3. In case of human cells/tissues stored in a biobank, details on cells/tissues type must be provided, as well as details on the biobank and access to it.

D17.2: POPD - Requirement No. 4 [Month 45]
With respect to data protection,
1. a number of identifiers (related to the environment in which the data was collected: date of collection, format, hour, location, metadata sets...) will, if merged, open the way to re-identification. These aspects must be considered and adequately documented by the applicants, in particular with respect to enabling data access to tier groups of data users at different levels of aggregation.
2. a document from the responsible data management structure/individual must be provided stating that all planned measures comply with national and EU legislation (in particular with REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016),
3. Copies of the notifications/approvals/opinions/authorisations from the relevant data protection authorities for the proposed data collection and processing as well as re-use must be provided prior to any data treatment, this being electronic or other.
4. Detailed information on the informed consent procedures that will be implemented with regard to the collection, storage and protection of personal data must be submitted on request.
5. Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation.
6. Templates of the informed consent forms and information sheets must be submitted on request.

D17.3: A - Requirement No. 5 [Month 45]
In case research on animals will be performed (yet unclear, see B2, p.220),
1. Copies of relevant authorisations (for breeders, suppliers, users, and facilities) for animal experiments must be submitted.
2. Copies of project authorisation (covering also the work with genetically-modified animals, if applicable) must be submitted.
3. In case research protocols are not defined, general information must be kept by the beneficiary in the project files on the nature of the experiments, the procedures to ensure the welfare of the animals, and how the Principle of the Three Rs will be applied. This information must be provided upon request.
4. Detailed information must be provided on why living animals have to be used as well as on which species and why that species has been chosen. In addition, information should be given on the numbers of animals to be used in experiments, the nature of the experiments, the procedures that will be carried out and their anticipated impact (e.g. potential for pain, suffering, distress) and how that has been minimised. Furthermore, details should be provided on what procedures have been implemented to ensure the welfare of the animals during their lives (e.g. husbandry, minimising harms, criteria for humane endpoints, inspection protocols). The applicant should provide evidence of awareness of relevant European legislation and regulations covering animal experimentation and that the Principle of the Three Rs will be rigorously applied.
5. If applicable, copies of training certificates/personal licenses of the staff involved in animal experiments must be provided.

D17.4: GEN - Requirement No. 9 [Month 45]
Copies of all partner ethical approvals relevant to the project must be provided whenever available.

D17.5: H - Requirement No. 2 [Month 45]
1. Information must be provided on whether adults unable to give informed consent will be involved and, if so, justification for their participation must be provided.
2. Information must be provided on how consent/assent will be ensured with respect to the participation of children and -if applicable- adults unable to give informed consent
3. If vulnerable individuals/groups will be involved, details must be provided about the measures taken to prevent the risk of enhancing vulnerability/stigmatisation of individuals/groups.
4. With respect to participants, who have indicated on the consent form that they want to receive their individual results, the applicants must take into consideration potential detrimental socioeconomic disadvantages such information can have for participants when they want to apply for private health insurance, life insurance or occupational disablement insurance, and inform the participants on such issue accordingly in the informed consent forms.

D17.6: OEI - Requirement No. 10 [Month 45]
All Material Transfer Agreements need to be provided to the European Commission.

11. Conflict Resolution

In case of a procedural, technical or financial conflict arising between partners, please address the conflict and try to solve the disagreements and tension at the lowest decision making level. Conflicts between partners can arise for many reasons: various cultural, religious or political backgrounds or simply personality clashes.

If conflict resolution does not seem to be possible, please contact the Coordinator in private to help with the conflict resolution. The Coordinator will then work to resolve the complaint to the best of both parties and seek support by Management Board Members where needed. Also the Management Board shall arbitrate and address any conflicts within the Programme and negotiate solution attempts to resolve any problem between the Consortium.

Communication with the Commission is primarily the Coordinator's responsibility. If you need to communicate with the commission directly, please let us know at the same time.

12. Publication Strategy

The Results of the HBM4EU Programme, especially quality assured Data, shall be made available to the European Commission, the EU Agencies and the governments of the participating countries of the Programme without any delay. Further publication and dissemination of the results have to be agreed with the Data owners.

The Management Board may adopt rules of conduct for the publication of jointly owned results.

Scientific publications that use HBM4EU results, including Data, shall acknowledge support and funding with the following clause: "This project has received funding from the European Unions´ Horizon 2020 research and innovation Programme under grant agreement No 733032 HBM4EU". Authors should ensure open access that grants online access free of charge for any user.

Any Party or Linked Third Party or other subcontractor can propose a publication that uses Data or other results from the HBM4EU Programme by submitting a written publication proposal to the Coordinator.

The publication proposal shall specify:

- The proposer and his or her affiliation;

- The target journal;

- A working title;

- An outline of the manuscript;

- A proposed work schedule and date of submission for publication;

- A proposed leader;

- A tentative manuscript group.

The Coordinator submits the proposal to the Management Board for decision and informs the proposer of the decision. The manuscript is prepared by a manuscript group and overseen by a leader. Authors shall be significant contributors to the design of the study including questionnaires, quality assurance protocols and programs, Data preparation, analysis, design of the publication, and/or writing. They shall be consulted by the leader at key stages and have seen and approved the final draft before submission to the Coordinator. Data and other results from the HBM4EU Programme may be used for the analysis only with written approval from the owner of these results. The owner can propose additional members to the manuscript group. The lead author shall inform the Coordinator of the publication of the manuscript.

Publications shall be made available in the Knowledge Hub and disseminated to relevant policy bodies at national and EU levels when deemed useful.

12.1 Ownership of background

Background developed by a Party or a Linked Third Party or other subcontractor of a Party will remain the property of that Party, Linked Third Party or other subcontractor, regardless of the property rights claimed with respect to results developed in this Programme, and notwithstanding the use of such Background to develop results in this Programme. For the sake of clarity, each Party may list its Background, and the Background of its Linked Third Parties and other subcontractors, related to the Programme before the start of the Programme in Attachment 1 of the Consortium Agreement, or communicate additional Background during the execution of the Programme in writing to the Coordinator for subsequent inclusion in Attachment 1 of the Consortium Agreement by decision of the Governing Board.

13. Minutes of Meetings

The chairperson of a Consortium Body shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all members within 10 calendar days of the meeting.

The minutes shall be considered as accepted if, within 15 calendar days from sending, no member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

The chairperson shall send the accepted minutes to all the members of the Consortium Body and to the Coordinator, who shall archive them. If requested the Coordinator shall provide authenticated duplicates to Parties.

Decisions will only be binding once the relevant part of the minutes has been accepted as accurately reflecting the decisions taken in the meeting.

14. List of acronyms

Note: This list of acronyms does not include the acronyms used to identify consortium partners (please see chapter 4).

AB	Advisory Board
AWP	Annual Work Plan
CA	Consortium Agreement
CGL	Chemical Group Leader
DG	Directorate General
DG RTD	Directorate General for Research and Innovation
DoA	Description of Action: Annex 1 of the Grant Agreement
EB	Ethics Board
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EU	European Union
GA	Grant Agreement
GB	Governing Board
HBM	Human biomonitoring
HBM4EU	Human biomonitoring for Europe
IC	Internal calls
IPCheM	Information Platform for Chemical Monitoring
LTPs	Linked Third Parties
MB	Management Board
NGO	Non-governmental organisation
NHC	National Hub Coordinator
NHCP	National Hub Contact Point
PAHs	Polycyclic aromatic hydrocarbons
PC	Project Coordinator
PcC	Project Co-Coordinator
PL	Pillar leader
SF	Stakeholder Forum
TL	Task Leader
WP	Work Package
WPL	Work Package Leader