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Model building a national human biomonitoring programme from the ground up: A framework informed by a comprehensive review of global state-of-the-art practices

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ABSTRACT

Global chemical production is projected to increase sharply by 2050, intensifying concerns about population exposure and related health and environmental risks. Human biomonitoring (HBM) provides a direct measure of aggregate internal exposure to chemicals and can act as an early warning tool for emerging health risks. There are growing international efforts to strengthen chemicals management and integrated risk assessment, including the EU's One Substance, One Assessment (OSOA) framework. Systematic HBM data are increasingly recognised as essential for translating exposure information into actionable evidence for chemical risk assessment and policy development. Several countries have established national HBM programmes, demonstrating their value for public health, regulatory decision-making, transparency for citizens and chemical safety. Yet many countries still lack such programmes despite having capable laboratories or prior scientific HBM experience. Establishing a sustainable national HBM programme requires coordinated governance, stakeholder engagement, infrastructure, technical expertise, mechanisms for linking science to policy and communication strategies. This study addresses this gap by proposing a holistic and adaptable framework, informed by best practices identified across 14 countries. The framework outlines the key elements required for the establishment and operation of national HBM programmes, including governance structures that facilitate collaboration among relevant stakeholders through either cross-ministerial steering committees or centralised coordinating bodies. It further emphasises systematic chemical prioritisation, standardised operating procedures, quality assurance and quality control (QA/QC), harmonised sample collection and processing, transparent science-to-policy translation mechanisms, integration with existing health surveys, shared infrastructure, international collaboration, and strategic bio-banking as essential components for ensuring comparability, cost-efficiency, and long-term sustainability.

1. Introduction

The World Health Organization (WHO) projects a substantial increase in global chemical production by 2050 compared to 2010 levels (WHO, 2016). In Europe alone, over 100,000 chemicals are already circulating on the market (European Commission, 2020). While this expansion supports economic development and industrial growth, it also indicates the need for effective management of chemical risks to human health and the environment. To mitigate these risks, nations have introduced regulatory requirements governing the registration, classification, and use of chemicals. Some of the most stringent legislation has been established in the EU through key legislative instruments such as the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation and the CLP (Classification, Labelling and Packaging) regulation (European Parliament and of the Council, 2008) which together aim to protect human health and the environment from harmful substances. These are supported by additional strategies under the EU Green Deal and the Chemicals Strategy for Sustainability, which promote a toxic-free environment, safe innovation, and a circular economy (European Commission, 2025). Such strategies aim to phase

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out hazardous substances, promote safer alternatives, and reduce population exposure by improving information availability and chemical tracking (Zimmermann et al., 2022).

Building on these regulatory measures, the EU has already restricted the use of many hazardous substances, including polychlorinated biphenyls (PCBs), organochlorine pesticides, and phthalates (European Commission, 2020), based on evidence of human exposure and concerns over potential health risks. Nevertheless, at a global level, the rapid introduction of new chemicals, which often includes substitutes for banned substances, means that many enter the market with limited hazard characterisation and scarce exposure information (Alves et al., 2014; Syeda et al., 2022; Tickner et al., 2019). Although the EU maintains a comprehensive regulatory framework, comprising of approximately 40 legislative instruments, challenges remain, highlighting the ongoing need for robust exposure data to support effective risk management (Fantke et al., 2022).

Accurate exposure assessment relies on multiple complementary tools, including environmental monitoring, exposure modelling, and risk estimation, to characterise sources, pathways, and potential health impacts. Within this framework, human biomonitoring (HBM) has emerged as the gold standard for assessing aggregate exposure and informing risk management (Angerer et al., 2007; Sexton et al., 2004). It does so by quantifying chemicals and/or their metabolites in biological matrices such as blood and urine (Haines et al., 2017; Louro et al., 2019). Unlike extrapolations from environmental concentrations (such as soil, air, or water), HBM directly measures chemical levels in the human body occurring from all sources and routes of exposure, offering more scientifically relevant data for risk assessments among populations (Angerer et al., 2007, 2011; Jeddi et al., 2022; Nakayama et al., 2023). It is particularly valuable for vulnerable populations, including those with occupational or residential exposures, living in hotspots, following specific diets, and children, who are more susceptible to toxins such as phthalates (Lagerqvist et al., 2015).

Over the past decade, extensive HBM research has been conducted globally, especially in Europe. Advances in the harmonisation of HBM protocols were initiated through COPHES (Consortium to Perform Human Biomonitoring on a European Scale) (Becker et al., 2014; Schindler et al., 2014) and DEMOCOPHES (DEMOnstration of a study to Coordinate and perform Human biomonitoring on a European Scale) (Schwedler et al., 2017), producing high-quality, comparable, validated HBM data and demonstrating HBM's policy relevance (Joas et al., 2012). These efforts continued with HBM4EU (2017–2022), (Ganzleben et al., 2017; Kolossa-Gehring et al., 2023), laying the foundation for the EU Partnership for the Assessment of Risks from Chemicals or PARC initiative (Kolossa-Gehring et al., 2023) to support the EU Chemicals Strategy for Sustainability and the Green Deal's Zero Pollution Ambition. In parallel, the World Health Organization (WHO) has identified that the establishment of HBM programmes are a global priority for chemical safety (WHO, 2023), reflected in World Health Assembly Resolution 76.17 and the European Environment and Health Process (EHP). The EHP HBM Partnership, launched in 2023, now includes 22 participating countries (WHO, 2025).

In addition to the past and ongoing academic HBM research projects, national HBM programmes worldwide are playing a crucial role in monitoring chemical exposures and protecting public health. The HBM programmes, typically funded by the government, involve continuous sampling and analysis of human samples to detect chemicals of concern, which are selected by each country (Ougier et al., 2021; Schindler et al., 2014). This approach provides insights into actual chemical levels in the body and their potential health impacts (Aylward et al., 2012; Bevan et al., 2012). The systematic nature of national HBM programmes enables them to generate high-quality, reliable data, which is crucial for informing public health policies and regulatory decisions more effectively than isolated HBM studies. These programmes can identify trends, assess the effectiveness of interventions, and respond to emerging health threats by continuously monitoring the population, including vulnerable groups, thereby playing a vital role in protecting public health and ensuring environmental safety (Connolly and Singh, 2025; LaKind et al., 2008; Viegas et al., 2024).

Although several countries already have well-established HBM programmes that effectively monitor and manage population exposure to hazardous chemicals, a significant number of countries, both within the EU and globally, still lack national programmes. This absence often reflects challenges such as securing sustainable funding, limited experience and expertise in HBM studies, difficulties in managing complex datasets from diverse populations, and insufficient integration between health and HBM components of surveys (Elonheimo et al., 2023). Even countries with competent local laboratories or prior participation in international HBM studies face difficulties in translating existing capacity into a comprehensive national programme. Despite these challenges, recent policy developments are increasing the importance of HBM. In particular, the EU's One Substance, One Assessment (OSOA) framework positions HBM as a key component of evidence-based chemical risk assessment, reinforcing its role beyond research and strengthening its contribution to public health and chemicals policy (Council of the European Union, 2025).

Though recent studies have established minimum requirements and practical guidance to improve comparability across HBM studies (Jeddi et al., 2025), a gap remains in the development of sustainable national programmes for assessing population exposure to environmental chemicals. To address this gap, the present study aims to develop a foundational, adaptable framework for countries seeking to establish national HBM programmes. Based on a critical review of well-established state-of-the-art HBM programmes worldwide, it evaluates programme continuity, chemical coverage, sample size, quality assurance/quality control measures, and biobank availability. The framework is designed to identify essential components for planning, stakeholder engagement, infrastructure development, and governance, while remaining adaptable to diverse national contexts. Through this approach, the study seeks to provide guidance for establishing national HBM programmes and generating evidence to inform public health and chemical safety policies worldwide.

2. Methodology

This study adopted a hybrid methodology combining systematic and targeted review approaches to evaluate existing national HBM programmes globally. A systematic literature search was conducted in Google Scholar using Boolean combinations such as “national human biomonitoring programme”, “HBM programme” + [country name], and “human biomonitoring national programmes” to identify relevant peer-reviewed publications. Although this approach identified a range of studies, it provided limited insights, as most publications focused on chemical exposure trends derived from specific HBM programmes rather than on operational aspects such as programme design, governance, or implementation. In general, not all countries comprehensively document programme structures in the academic literature, although some, such as Germany and Canada, provide more detailed reporting of their HBM activities. A small number of publications did describe structural components, including funding mechanisms, sampling frameworks, and stakeholder coordination; however, these were mainly limited to Germany, Belgium, and Slovenia.

To address this gap, the methodology was adapted to a purposive, country-specific search strategy that focused on nations with well-established national HBM programmes (such as U.S. NHANES, German GerES, CHMS, Canada, Japan and information available on EU initiatives websites like HBM4EU and PARC). This involved directly accessing respective websites, reviewing official governmental reports, and grey literature to extract programme structures, objectives, and operational frameworks. Additionally, we also conducted informal consultations with researchers in Germany, Belgium, Slovenia, and Iceland who provided unpublished insights and provided inputs on

operational details (e.g., funding mechanisms, cohort design). The synthesis of these findings informed the development of an evidence-based framework for establishing a national HBM programme. The methodology was structured into four phases: (1) defining national HBM programmes, (2) identifying and selecting relevant programmes, (3) extracting and synthesising information, and (4) developing an evidence-based framework based on the state-of-the-art practices in HBM programmes.

To distinguish national HBM programmes from standalone HBM studies, we established explicit criteria based on continuity and scope of the HBM programme. For the selection of relevant countries, a national HBM programme was defined as a government-endorsed initiative that systematically monitors population-wide exposure to environmental chemicals through repeated sampling campaigns (blood, urine) over extended periods. Key inclusion criteria included continuity of the programme (continuous/ongoing programmes), representativeness (geographic and/or demographic coverage), standardised protocols for sampling and analysis, and support or funding by the government. In addition, we also considered a small number of long-running cohort-based HBM programmes such as those in Norway and Japan that maintain substantial population reach, scientific rigour, and sustainability in follow-up, acknowledging their *de facto* role in national exposure surveillance. It was also observed that some national and regional HBM initiatives employ pooled biological sampling approaches, particularly for population-level assessment of certain chemical groups such as persistent organic pollutants (POPs), especially in resource-constrained settings (Heffernan et al., 2014; Nilsson et al., 2025; Toms et al., 2019); however, such approaches were not used as a primary selection criterion in this review due to the focus on continuous, individually based national monitoring frameworks. Exclusion criteria included standalone studies such as those targeting specific subpopulations (such as occupational workers) or limited to one-time sampling, which were excluded to focus on sustained, policy-driven efforts.

HBM programmes were studied based on predefined criteria: government funding, multi-year implementation or planning for multi-year implementation, publicly accessible data, and methodological robustness (such as QA/QC protocols). The research team initially drafted these criteria and then shared them for feedback with HBM experts/researchers involved in programme implementation and coordination in different countries in Europe. Discussions took place through informal consultations, including email correspondence and online meetings, allowing refinement of the criteria to ensure they reflected characteristics recognised as essential for national-scale HBM programmes. Data from the selected national programmes were systematically extracted and organised into the following categories: commencement of the programme, coordinating agencies, sampling frequency, target population, chemicals analysed, collection protocol, and availability of biobanks.

Comparative tables were developed to summarise and contrast the structures of existing HBM programmes (Table 1) and chemicals prioritised under each HBM programme (Table 2). Based on patterns emerging from cross-country insights, combined with the research team's knowledge of operational needs in HBM, including governance, infrastructure, ethics, and data workflows, we developed these findings into a structured framework. This approach ensured that the framework reflects both observed best practices and essential practical considerations needed to support implementation in different national contexts.

3. Results

The study identified fourteen countries with national HBM programmes meeting the specific criteria defined for this study: the United States, Canada, China, Sweden, Germany, France, Belgium, the Czech Republic (Czechia), Norway, South Korea, Japan, Slovenia, Iceland, and New Zealand. These programmes were selected based on their continuous monitoring or repeated sampling cycles to evaluate national environmental exposures and direct linkages to public health policy. Table 1 presents the insights about 14 identified HBM programmes meeting our inclusion criteria (government endorsement/funding, continuity), capturing key review aspects such as governance, sampling, and analytical priorities to extract global best practices and inform framework development. Columns are motivated by evaluation needs for comparability and policy utility: Country/HBM Survey Name for geographic context; Starting Year for longevity; Frequency of Monitoring for trend capacity; Leading Institutes for governance; Inclusion of Vulnerable Groups for equity; Major Chemical Groups for scope; Selection Method and Criteria for transparency and risk alignment; Sample Size/Design/Age/Representativeness/Collection for rigor; Sample Collection Protocol for quality; and Biobank for sustainability.

The state-of-the-art in national HBM programmes ranges from well-established initiatives, such as the U.S. NHANES, German GerES, and ESB, initiated in the 1980s and 1990s, to more recently developed programmes, such as China's CNHBM, initiated in 2017–2018 (Apel et al., 2017; Cao et al., 2021; Kolossa-Gehring et al., 2012; McQuillan et al., 2015). Within Europe, Germany launched the earliest programme in 1985, followed by the Czech Republic in 1994 and Sweden in 1993. Programmes in the United States (NHANES, 1999), Canada (2007), and France (2007) were established in the late 1990s and 2000s. Monitoring frequency varies across countries: biennial cycles in the United States, every 2–3 years in Canada and the Czech Republic, and annual cycles in China and Sweden. Programmes are primarily led by public health and environmental research institutes, including the CDC (United States), the Public Health Agency of Canada, the Chinese CDC, and the German Environmental Agency.

Most countries (such as the U.S., Germany, Norway) operate continuous, nationally representative HBM programmes. China and New Zealand were included as due to their unique characteristics and relevance. China has completed one large-scale HBM cycle and plans subsequent cycles every five years, providing insights into exposure patterns in rapidly industrialising populations (Cao et al., 2019). Unlike cross-sectional surveys, the CNHBM is a nationally representative prospective cohort, designed to follow the same participants across cycles to allow for dynamic, longitudinal datasets for epidemiologic follow-up. New Zealand's programme focuses on environmental justice considerations for Indigenous Māori populations (Mannetje et al., 2018). Canada's CHMS, by contrast, is a population-based survey in which Indigenous identity and race are self-reported rather than being design variables, enabling subgroup analyses of HBM data by population characteristics, although the sampling frame excludes persons living on reserves and other Indigenous settlements (Karthikeyan et al., 2024). Norway's national HBM programme draws participants from the Norwegian Mother, Father and Child Cohort Study (MoBa), a prospective cohort involving 114,500 children, 95,200 mothers, and 75,200 fathers (Magnus et al., 2016), with HBM conducted on a defined sub-sample through the Norwegian Environmental Biobank (Paulsen et al., 2025). Cohort-based HBM programmes, such as Norway's MoBa, German Environmental Specimen Bank (ESB) and Japan Environment and Children's Study, were included alongside predominantly cross-sectional HBM programmes to represent diverse methodologies, capturing longitudinal insights into exposure trajectories and intergenerational effects that complement the cross-sectional HBM programmes. This aligns with our selection criteria for continuity and scientific rigour, similar to other included HBM programmes, which are cross-sectional. Belgium's FLEHS, despite being limited to the Flanders region, was included due to methodological robustness, continuity, and established HBM processes.

Most programmes maintain biobanks for long-term sample storage, typically at −80°C, but several also below −150°C. Examples include the NHANES Biospecimen Programme (United States), National Microbiology Lab (Canada), centralised facilities in France, and the German Environmental Specimen Bank. Biobanks support longitudinal research, allowing for the tracking of exposure trends over time.

Table 1
Identified national HBM programmes and relevant criteria in their development. (Note: This is a non-exhaustive list; information presented reflects what was retrievable or publicly accessible at the time of compilation).

S/n	HBM survey name/ Country	Starting Year	Programme Continuity/ Cycle Frequency	Leading Public/ Research Institutes	Population Coverage and Vulnerable Groups	Major chemical groups analysed in Recent Cycles	Chemical Selection Method	Chemical Prioritisation Criteria	Target Population & Sample Size	Sample Collection Approach	Biobank
1	i) German Environmental Surveys (GerES)	1985	Every 4–10 years (main cycles)	German Environment Agency (UBA): Coordination; Ministry for Environment (BMUKN): Funding/ oversight; HBM Commission: Expert advisory body.	Population-representative sampling (GerES). Vulnerable groups inferred through demographic stratification.	More than 130 substances, i.e., heavy metals, flame retardants, phthalates, pesticides, PFAS, UV filters, chlorinated/ brominated POPs, etc.	Expert review, need for policy advice.	Environmental and health relevance, Regulatory needs (e.g., EU chemical policies), Risk assessment priorities	~1500–5000 participants; selects individuals using a nationwide, random stratified sampling method across roughly 150 unique locations in Germany	Home visits and centralised examination centres using standardised SOPs., HBM and ambient monitoring	German Environmental Survey (GerES)
	ii) German Environmental Specimen Bank (ESB)	1981	Every year	German Environment Agency (UBA): Coordination; Ministry for Environment (BMUKN): Funding/ oversight; HBM Commission: Expert advisory body.	students aged 20–29 years in defined peripheral conditions	Continuous according to needs	In agreement between BMUKN and UBA	Exposure trends, regulatory impact, policy needs	500/year, utilizes a standardized, non-probabilistic approach focusing on healthy university students aged 20–29, recruited from specific sentinel locations (Münster, Halle/ Saale, Greifswald, Ulm)	Specialized mobile examination centre (MECs) layout, known as the epiLab (mobile epidemiologic laboratory)	Specimen Bank (ESB), Rigorous pre-analytical steps (storage above −150°C) for time-trend reliability.
2	Sweden (Swedish HBM programme)	1993	Riksmaten (dietary surveys) occurs approximately every 10 years (e.g., 2010–2011 and 2023)	Swedish Environmental Protection Agency under the Ministry of Environment	Riksmaten (focus on general population), Longitudinal cohorts such as the SELMA study, focus on prenatal/child exposure.	Elements, chlorinated/ brominated/ fluorinated POPs, phthalates, flame retardants, PAHs, pesticides, bisphenols, biocide/ preservative/ antioxidant/UV filter substances	Prioritised by the Toxicological Council using HBM data; reported to SamTox.	Exposure trends, regulatory impact, policy needs	Register-based random samples collected by Statistics Sweden (Statistiska centralbyrån, SCB); stratified based on the level of education achieved, at the household level. ~1000/age group in dietary survey; 300/age group for blood & urine.	Hybrid approach combining take-home kits and outpatient clinical visits.	Managed by universities/ research institutes (e.g., Karolinska Institute)
3	Czech Human Biomonitoring Programme, The Czech Republic	1994	Periodic (originally annual; now reduced to once every several years due to funding constraints).	National Institute of Public Health (NIPH), National Centre for Toxic Compounds (Ministry of Environment and Masaryk University)	General population surveillance; children and adults included through demographic stratification	Heavy metals, pesticides, PCBs, PFAS, phthalates, PAHs, and VOCs	Alignment with National Portfolio of Actions (Ostrava Declaration, 2017), Guided by the Stockholm Convention and EU	Health risks (e.g., toxicity, persistence). - International obligations	~2000–4000 participants; cohorts', relies on a demographically stratified, quota-based sampling framework targeted at specific sentinel population group.	Hybrid approach combining school-based field-team collection (for children) and clinical health center visits (for adults)	Biobank for future use, managed by RECETOX Infrastructure (national Roadmap project)

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Table 1 (*continued*)

S/n	HBM survey name/ Country	Starting Year	Programme Continuity/ Cycle Frequency	Leading Public/ Research Institutes	Population Coverage and Vulnerable Groups	Major chemical groups analysed in Recent Cycles	Chemical Selection Method	Chemical Prioritisation Criteria	Target Population & Sample Size	Sample Collection Approach	Biobank
							regulations, expert consultations.				
4	National Health and Nutrition Examination Survey (NHANES), United States	1999	Biennial	National Centre for Environmental Health (NCEH) at the Centres for Disease Control and Prevention (CDC)	General population surveillance; children, adolescents, adults aged 60+, and Black, Asian and Hispanic populations included through oversampling.	Heavy metals, PFAS, PAHs, VOCs, pesticides, flame retardants, phthalates, PCBs, etc.	List of chemicals prepared by scientific committee, refined through public consultation and experts final call	Population exposure evidence; known/suspected health effects; reliable HBM methods; reasonable cost; discontinuation after three non-detect cycles.	~2500 participants (1/3 subsample) for HBM from overall ~10,000 examined per two-year cycle. Four-stage stratified multistage probability sampling	Face-to-face and Computer-Assisted Interviews, Home interviews, physical exams, blood and urine sampling.	Maintains a national biobank under the NHANES Biospecimen Program
5	The Norwegian Mother, Father and Child Cohort (MoBa), Norway	1999	Continuous	Norwegian Institute of Public Health	Pregnancy and birth cohort specifically targeting mothers and children to investigate early-life environmental exposures.	Heavy metals, phthalates, PFAS, PCBs, pesticides, parabens, flame retardants, bisphenols	Four-step framework: integrating EU priorities, verifying biobank sample stability, & finalising selections through expert review.	High hazard potential (EDCs/ CMRs), widespread human exposure, EU regulatory priority, and analytical feasibility	114,500 children, 95,200 mothers, 75,200 fathers. HBM sub-sample (Norwegian Environmental Biobank): NEB-I ~3000 pregnant women; NEB-II (2016–2017) 9855 mothers and 9825 fathers invited, of whom 658 mothers, 500 fathers and 671 children participated (~7% of those invited). Prospective, volunteer-based national pregnancy cohort.	Clinical collection at local maternity units/hospitals combined with postal mail	Centralized biobank
6	i) Survey of the Exposure to Chemical Compounds in Humans, Japan	2002 (comprehensive start; pilot phase from 2018)	Annual surveys, rotating across regions	Ministry of the Environment (MOE), Government of Japan; National Institute for Environmental Studies (NIES)	General adult population, with regional variations (e.g., urban, agricultural, fishery areas), to capture exposure differences.	Chlorinated dioxins (PCDDs, PCDFs, Co-PCBs); organofluorine compounds, metals, plasticisers (phthalates, bisphenols); pesticides, triclosan, parabens, cotinine, benzophenone-3	Expert consultation and pilot testing to finalise the target list.	National health priorities, exposure risk, regulatory obligations, and laboratory feasibility	Small-scale annual programme recruiting around 80–120 adults per year, totalling 606 participants across FY 2018–2024. Recruitment rotating across 5 regional blocks covering 21 regions. Adults aged 18+ (20+ prior to FY, 2024). Stratified geographic and	Fasting blood collected by medical professionals at healthcare facilities (clinics or hospitals); includes lifestyle questionnaire on diet, smoking, etc.; general health checks (blood counts, liver/	No (samples analysed per survey; no long-term biobank mentioned in the latest report available online)

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Table 1 (*continued*)

S/n	HBM survey name/ Country	Starting Year	Programme Continuity/ Cycle Frequency	Leading Public/ Research Institutes	Population Coverage and Vulnerable Groups	Major chemical groups analysed in Recent Cycles	Chemical Selection Method	Chemical Prioritisation Criteria	Target Population & Sample Size	Sample Collection Approach	Biobank
									demographic quota recruitment design executed through local administrative authorities	kidney function)	
	ii) Japan Environment and Children's Study (JECS)	2011	Intensive early sampling (child, mother), then biannual follow-ups tapering to age 13	MOE, NIES, National Center for Child Health and Development (NCCHD)	Targeted birth cohort of pregnant women, foetuses and children	PFAS, heavy metals, endocrine disruptors (phthalates, bisphenols); pesticides and VOCs; allergens (IgE-related); POPs	Expert-driven reviews, international input, and validations	Evidence-based criteria prioritising substances that accumulate in the body, readily cross the placenta, and raise significant public or scientific concern	~100,000 mother-child pairs (with ~85,000 genotyped children as of 2022); Cohort: Birth cohort (foetal stage to age 13), representative of Japanese births;	Samples collected at healthcare facilities (obstetric hospitals, clinics, and delivery centres) during routine prenatal visits and child health check-ups, with limited self-collection of urine at home. Maternal blood/ urine during pregnancy, cord blood at birth, breast milk, child blood/ urine/hair at follow-ups.	Bio-specimen repository for long-term storage, potentially convertible to full biobank post-study)
7	Belgium Flemish Environment and Health Survey (FLEHS)	2002	Every 5 years	Centre of Expertise on Environment and Health [collaboration between all Flemish universities, PIH and Flemish Institute for Technological Research (VITO)]	General population surveillance including newborns, adolescents, young adults, and older adults through age-specific sampling.	PFAS, phthalates, flame retardants, metals, VOCs, PCBs, and bisphenols	Transparent and participatory expert scoring process, with final review and approval by relevant ministries and advisory councils.	Health/exposure relevance (legal status, known effects, exposure sources, guidance values, bioaccumulation, placental transfer, margin of safety, hazard), policy relevance, technical feasibility, sampling requirements, and analytical costs.	More than 6250 Flemish citizens were included in FLEHS, a stratified random sampling of the Flemish population.	MECs and home visits for sample collection	Biobank@VITO: Population biobank storing ~70,000 samples (blood, urine, hair, nails, saliva, breast milk, etc.) from 7700 individuals across all ages. Also used in EU-wide studies.
8	Canadian Health Measures Survey (CHMS), Canada	2007	Every 2 years	CHMS is conducted by Statistics Canada in partnership with Health	General population surveillance; persons aged 3–79 in 10 provinces.	Metals, PFAS, pesticides, VOCs, flame retardants, PCBs, phthalates, bisphenols, and PAHs	Public & expert nominations combined with Chemicals Management	Health impact, exposure, public concerns, feasibility, cost, policy/treaty	~5800 individuals; nationally representative samples, cross-sectional survey	Personal interview in the respondent's home, followed by a visit to temporary	Public Health Agency of Canada's National Microbiology Laboratory (NML)

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				Canada and the Public Health Agency of Canada	Excludes reserves and other Indigenous settlements, institutionalised persons and remote regions (~3% of the population).		Plan (CMP) priorities, then filtered against selection criteria by Health Canada.	alignment, data gaps.	-representative of approximately 96%–97% of the Canadian population; Multistage, stratified probability sampling design	examination centres, at MECs.	
9	French National Biomonitoring Programme: i) Esteban: Health Study on Environment, a nationwide cross-sectional survey and ii) the ELFE birth cohort (Longitudinal Study from Childhood)	2007	Periodic cycles aligned with National Environmental Health Plans (PNSE)	Funded by the The Ministry of Health and is coordinated by the national public health agency, Santé Publique France	General population surveillance; children and women of childbearing age included through age-specific sampling (Esteban); ELFE is a targeted birth cohort	PFAS, pesticides, PAHs, PCBs, bisphenols, VOCs, phthalates, and glycol ethers	The Delphi method, validated by government agencies and PNSE's "emerging risk" group.	Health risks (e.g., carcinogenicity, endocrine disruption), exposure prevalence, policy relevance (aligned with PNSE goals).	Esteban: 2503 adults + 1104 children - ELFE: 18,000+ children (longitudinal biospecimens). - Occupational studies under PST 3 (specific cohorts). ELFE birth Cohort: Prospective, nationwide multi-center population-based birth cohort sampling frame	MECs with certified containers, temperature-controlled transport	Samples stored in national biobanks (e.g., ELFE cohort biobank). - PNSE4's PEPR program (2021–2025) funds infrastructure for large-scale biomonitoring storage.
10	Slovenia	2007	Phase-based	National Institute of Public Health (NIJZ)	Targeted sampling of children and pregnant women in high-exposure regions	Heavy metals, PFAS, phthalates, POPs, bisphenols, parabens, and pesticides	Three-step method: initial screening based on hazard data, targeting via exposure and laboratory feasibility, and final adjustments for localized concerns and policy trends.	Environmental monitoring data, toxicity, persistence, population exposure, laboratory capacity, public concerns, and international trends.	1084 (536 lactating primiparous women, 548 men), aged 18–49. Purposive sampling via gynaecologists, maternity hospitals and maternity schools across 12 study areas stratified by environment type (3 rural, 3 urban, 6 potentially contaminated); target of 50 women and 50 men per area.	Health centres with certified equipment for collection and storage	Long-term storage of blood, urine, breast milk (−20°C) and hair at central laboratory; dedicated national biobank not described in available sources.
11	The Korean National Environmental Health Survey	2009	Every 3 years	National Institute of Environmental Research,	General population surveillance; ages 3+	PFAS, phthalates, PAHs, metals, VOCs, phenols, flame retardants	Selects by evaluating K-REACH hazard profiles &	Public concerns, chemical usage & exposure level to the human body	~6000 Koreans aged 3 years and older participated in the KoNEHS	MECs and mobile units for sample collection	Centralized facilities [National Biobank of Korea

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	(KoNEHS) South Korea			Ministry of Environment (ME)			market circulation volumes, with a focus on emerging substitutes & public concerns		cycle 4 (2018–2020) at 426 sites. A two-stage proportionally stratified sampling design (geographic and socio-economic stratification)		(NBK), the National Environmental Specimen Bank (NESB)]
12	China National Human Biomonitoring (CNHBM) China	2017–2018	Every 3 years (2-year survey cycle followed by a 3-year gap before the next cycle begins)	National Institute of Environmental Health (NIEH) under the Chinese Center for Disease Control and Prevention	General population surveillance; stratified by sex, six age groups and geography (31 provinces, 152 sites).	Heavy metals, phthalates, PFAS, PAHs, benzene metabolites, and environmental phenols	Expert panel review	Health and environmental impact, emerging threats	~22,000 individuals; representative sampling, including urban and rural populations, Longitudinal cohort tracked across cycles for dynamic epidemiologic data, three-stage, stratified unequal probability sampling design	MECs; includes free physical exams and incentives for participants	Centralized facilities
13	Iceland[a]	Diet survey since 1939; HBM added in 2019–21[b]	Periodic [Every few years (aligned with national diet survey)]	Public funding. Ministry of Health, the University of Iceland and the last cycle supported by HBM4EU (Horizon)	Not specified	Cadmium, PAH and Bisphenols, Acrylamides, Mycotoxins, pesticides (Glyphosate, AMPA, Chlorpyrifos, Phytoestrogens, Neonicotinoids, etc), PFAS	Cadmium, PAHs, and bisphenols were HBM4EU priorities; others were included due to national interest and lack of prior data in Iceland.	No formal criteria; chemicals were newly analysed and chosen based on national relevance and availability of HBM4EU-approved labs.	As per the HBM4EU protocols, 200 participants from the national diet survey; urine, serum, and whole blood; REDCap questionnaire were added; information on sampling method not specified.	Linked with diet survey sampling, two phone interviews; bio-sample collection post-interview. Urine, serum and EDTA blood samples were transferred to cryo vials and kept frozen.	Samples biobanked and kept at −80°C.
14	New Zealand	2022	Proposed Annual	Environmental Science and Research (ESR)	Targeted pilot cohorts including children, older adults and Māori populations	Metals, PFAS, phthalates, VOCs, pesticides, and emerging contaminants	Stakeholder consultations	Emerging contaminants, risk trends	Small-scale pilot study targeting priority cohorts, information on sampling method not specified.	Study with proposed MECs and regional collection	Planned

Source: compiled from: United States – NHANES: (Centers for Disease Control and Prevention, 2023; Centers for Disease Control and Prevention, 2025); Canada – CHMS: (Health Canada, 2021); China – CNHBM: (Cao et al., 2019, 2021); Japan –(Ishitsuka et al., 2017), (Ministry of the Environment Japan, 2025), (Ministry of the Environment Japan, 2026); Ministry of the Environment (2025); Sweden – Swedish HBM programme: (Pineda et al., 2023; Swedish Environmental Protection Agency, 2025); Germany – GerES/ESB: (Kolossa-Gehring et al., 2012; Umweltbundesamt, 2022, 2023); France – French National Biomonitoring Programme (Esteban/ELFE) (Fréry et al., 2012; Dereumeaux et al., 2017; Fillol et al., 2021): (Fillol and Vandentorren, n.d.); (HBM4EU, 2022); Belgium – FLEHS (Schoeters et al., 2012; Schoeters et al., 2017; Van Den Heuvel et al., 2020; Van Campenhout, 2024; Environment and Health Support Center, 2025): Environment and Health Support Center, n.d.; Czech Republic – Czech HBM Programme:(National Institute of Public Health, n.d.; Černá

et al., 2012); Norway – MoBa: (Magnus et al., 2016; Paulsen et al., 2025; Brandlistuen et al., 2025); South Korea – KoNEHS: (Hong et al., 2024; Son et al., 2009); Slovenia: (Snoj Tratnik et al., 2019a; Stajnko et al., 2020; Runkel et al., 2021, 2022, 2023; Tkalec et al., 2021; Joksić et al., 2022); New Zealand: (Mannetje et al., 2018); Iceland: Based on personal communications (Eiríksdóttir, 2024).

[a] Information received based on private communications.

[b] Iceland's National Dietary Survey has been conducted since 1939 to assess the nutritional value of the nation's food intake. Human biomonitoring was added to the last survey (2019-21) for the first time.

Programmes vary in the number of substances analysed (which also differs between study cycles), from over 130 in Germany's GerES to a limited set in Iceland aligned with HBM4EU priorities. Selection of chemicals and participants is guided by public health priorities, exposure data, and emerging scientific concerns. Methods of selection include expert panel reviews (Germany, Czech Republic), stakeholder consultations (New Zealand), and Delphi methods (France). Sample sizes range from approximately 200 participants in Iceland's HBM4EU-linked survey and 1800 in Norway's Environmental Biobank substudy, through 2731 to over 5000 per cycle in Germany's GerES, to around 10,000 in NHANES and approximately 22,000 in China's CNHBM. Sampling approaches include home visits, health centres and Mobile Examination Centres (MECs). MECs or mobile units (such as trucks or vans) are equipped like clinics on wheels to deliver on-site physical exams, tests, and sample collections at convenient locations, boosting accessibility for diverse populations. For example, NHANES employs MECs and uses stratified multistage probability sampling with home interviews and physical exams, and both NHANES and China provide free physical exams and participant incentives in their HBM programme.

The chemicals analysed in recent HBM cycles are largely consistent across programmes, with primary focus on heavy metals, PFAS, phthalates, pesticides, PAHs, VOCs, flame retardants, and PCBs. These chemicals reflect shared global priorities and some distinctive regional priorities. Table 2 presents the chemicals and chemical groups included in national programmes, as well as their coverage under HBM4EU and PARC initiatives.

An analysis of existing national HBM programmes identified recurring structures, processes, and operational elements that informed a framework for countries without programmes or seeking to strengthen existing capacities. Programmes were studied across key aspects, including governance, funding, operational protocols, and infrastructure. Patterns and commonalities were identified through iterative comparison, highlighting features consistently observed across successful programmes and the challenges they addressed, forming the basis of the proposed framework.

Core elements consistently observed included the important role of strong governance structures, secure and sustained funding, establishment of dedicated national hubs and steering committees in the governance structure, technical expertise and infrastructural requirements. These findings formed the basis for an adaptable framework for establishing a national HBM programme, illustrated in Fig. 1. Conceptual synthesis of these findings achieved through iterative cross-programme analysis of structural and operational data from Tables 1 and 2 (such as governance models, funding patterns, sampling protocols, and biobanking infrastructure) identified four foundational pillars for a national HBM programme: (1) legal mandates to ensure policy support (2) sustainable funding and robust governance mechanisms (3) stakeholder collaboration involving government, research institutions, and public health agencies, and (4) operational or methodological components such as standardized recruitment, sampling, ethics compliance, QA/QC and analysis protocols and data management systems. The iterative details of programme structures highlight the necessity of these pillars to achieve national representativeness and methodological rigour. Importantly, each domain within the framework is directly linked to components identified in at least one established national HBM system. This alignment ensures that the framework reflects concrete observed patterns emerging from the review of existing programmes.

Within the framework, HBM programme development is represented as a phased, iterative process. The framework is intended to function as a continuous pathway, beginning with foundational requirements and progressively expanding as national capacity for HBM increases. Implementation typically begins with general or priority populations, while chemical selection, such as heavy metals and endocrine disruptors, is refined progressively based on stakeholders' (experts) insights, pilot studies on pollution hotspots and emerging concerns

Table 2
Major chemicals/chemical groups analysed under HBM programmes (in their latest cycles) and chemicals prioritised under the HBM4EU and PARC initiative (Note: This is a non-exhaustive list; information presented reflects what was retrievable or publicly accessible at the time of compilation.).

Major chemicals/chemical	Germany	Sweden	Czech Republic	US	Norway	Japan	Belgium	Canada	France	Slovenia	South Korea	China	New Zealand	Iceland	HBM4EU initiative	PARC
Lead	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Cadmium	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mercury	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
Bisphenols	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pesticides	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
Flame Retardant	✓	✓	✓	✓	✓	✓	✓		✓		✓				✓	✓
PFAS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓
Arsenic	✓			✓	✓	✓	✓	✓	✓	✓		✓	✓		✓	✓
PAHs	✓	✓		✓			✓		✓	✓	✓	✓	✓	✓	✓	✓
Chromium	✓	✓		✓			✓	✓	✓			✓	✓		✓	✓
POPs	✓	✓	✓			✓	✓		✓	✓					✓	✓
VOCs and Metabolites	✓	✓		✓			✓		✓		✓	✓			✓	✓
UV-filters	✓	✓				✓	✓				✓		✓		✓	✓
Solvents	✓								✓						✓	✓
Parabens	✓					✓	✓	✓	✓	✓	✓		✓		✓	✓
Tobacco Alkaloids & Metabolites	✓			✓		✓	✓	✓	✓		✓		✓		✓	✓
Acrylamide	✓		✓	✓				✓						✓	✓	✓
Mycotoxins	✓						✓		✓					✓		

Source: compiled from: United States – NHANES: (Centers for Disease Control and Prevention, 2023; Centers for Disease Control and Prevention, 2025); Canada – CHMS: (Health Canada, 2021); China – CNHBM: (Cao et al., 2019, 2021); Japan –(Ishitsuka et al., 2017), (Ministry of the Environment Japan, 2025), (Ministry of the Environment Japan, 2026); Ministry of the Environment (2025); Sweden – Swedish HBM programme: (Pineda et al., 2023; Swedish Environmental Protection Agency, 2025); Germany – GerES/ESB: (Kolossa-Gehring et al., 2012; Umweltbundesamt, 2022, 2023); France – French National Biomonitoring Programme (Esteban/ELFE) (Fréry et al., 2012; Dereumeaux et al., 2017; Fillol et al., 2021): Fillol and Vandentorren, n.d.; (HBM4EU, 2022); Belgium – FLEHS (Schoeters et al., 2012; Schoeters et al., 2017; Van Den Heuvel et al., 2020; Van Campenhout, 2024; Environment and Health Support Center, 2025): Environment and Health Support Center n.d.; Czech Republic – Czech HBM Programme: National Institute of Public Health (n.d.); (Černá et al., 2012); Norway – MoBa: (Magnus et al., 2016; Brandlistuen et al., 2025); South Korea – KoNEHS: (Hong et al., 2024; Son et al., 2009); Slovenia: (Snoj Tratnik et al., 2019a; Stajnko et al., 2020; Runkel et al., 2021, 2022, 2023; Tkalec et al., 2021; Joksić et al., 2022); New Zealand: (Mannetje et al., 2018); Iceland: Based on personal communications (Eiríksdóttir, 2024); HBM4EU: (HBM4EU, n.d.); PARC: (Partnership for the Assessment of Risks from Chemicals, 2026).

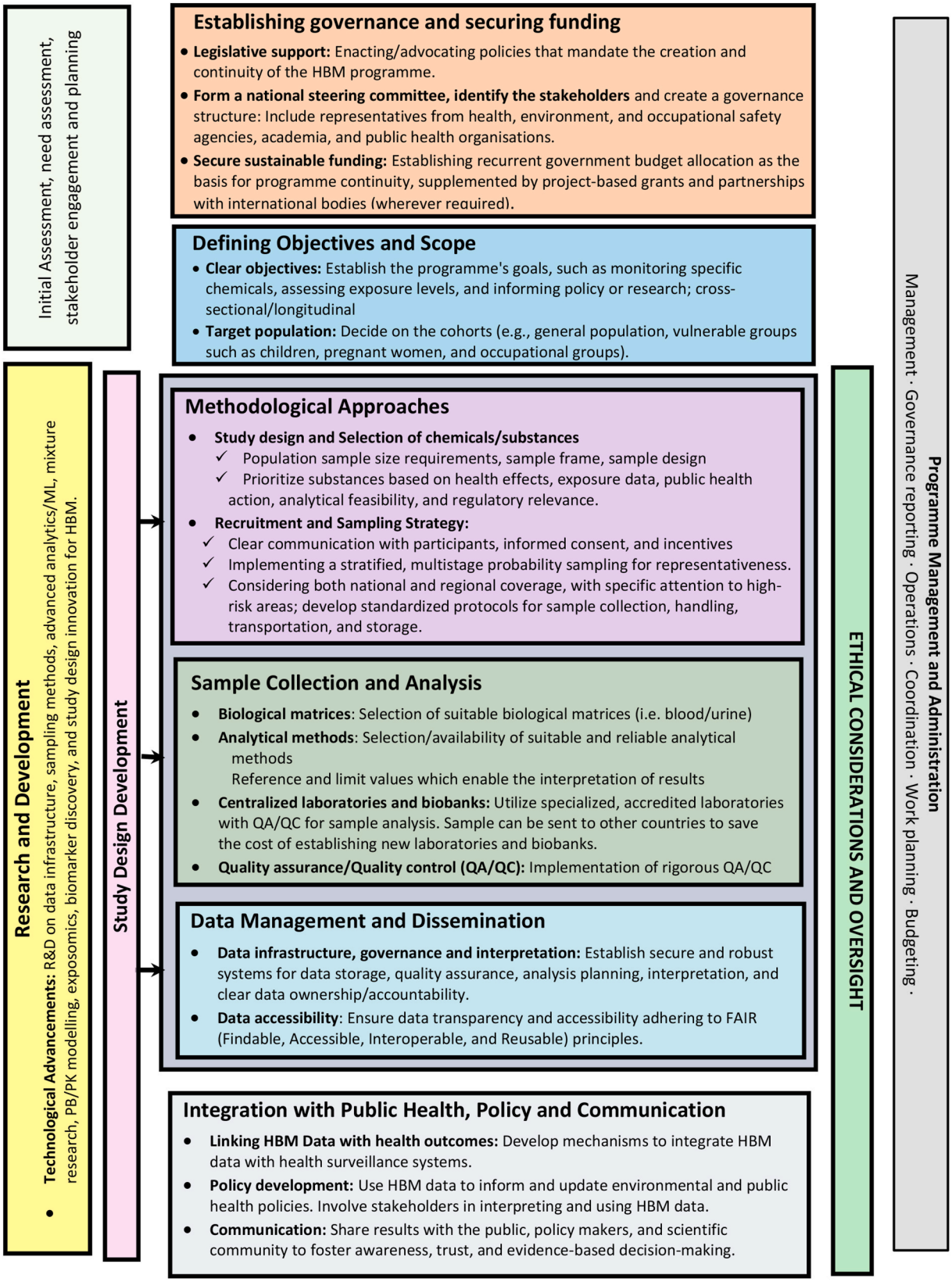


Fig. 1. Framework for establishing a national HBM programme based on the state-of-the-art practices found worldwide.

(Fig. 1).

Insights from the review also informed the design of two governance and organisational models for national HBM programme implementation (Figs. 2 and 3). These models were developed to illustrate potential roles for government ministries, research institutions, steering committees, and advisory boards in supporting programme continuity and alignment with national policies, based on best practices identified from EU HBM programmes.

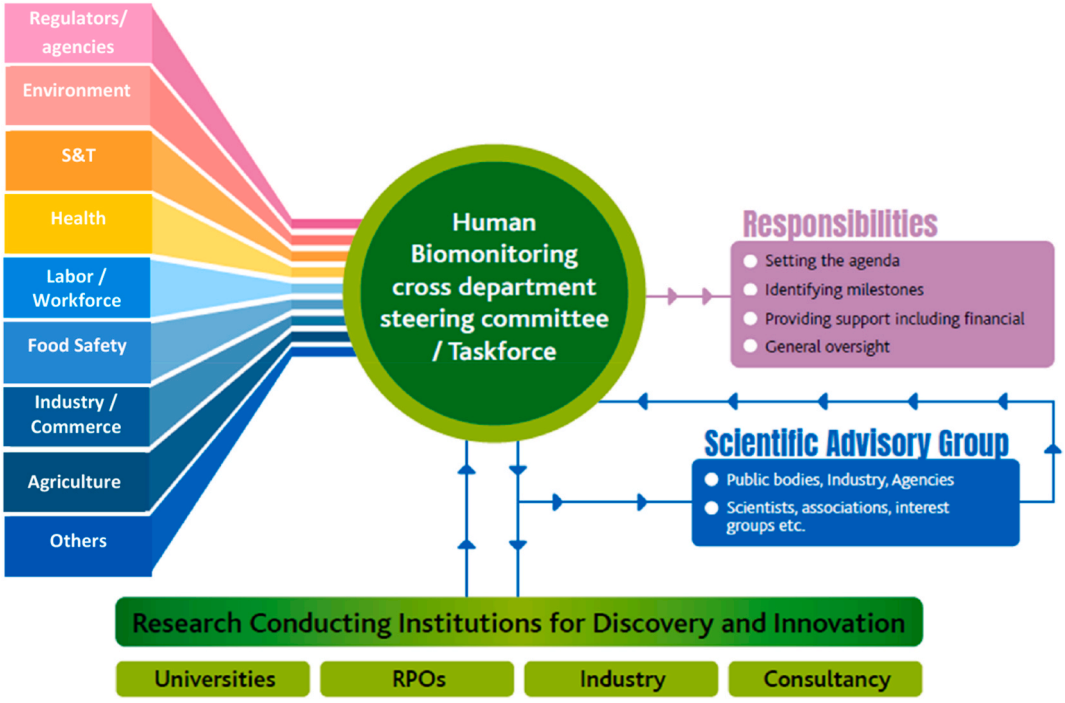


Fig. 2. Model 1: governance through a multi-agency steering committee, in which priority-setting and oversight are shared across ministries, and no single department holds sole authority. Suited to contexts where responsibility for chemicals, health and environment is already distributed across agencies. (Adapted from Connolly and Singh, 2025).
(Note- RPO: Research Performing Organisation(s); S&T: Science and Technology).

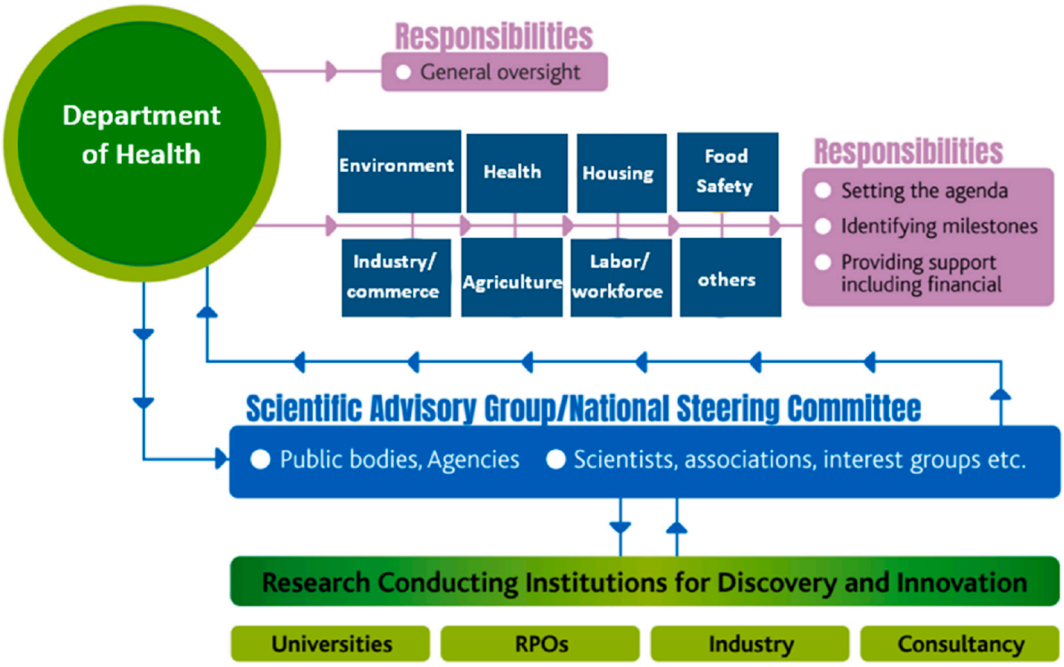


Fig. 3. Model 2: governance through a designated lead department holding primary responsibility, with other agencies engaged through formalised inter-agency coordination. Suited to contexts with limited existing cross-ministerial infrastructure, where a single accountable body accelerates establishment. (Adapted from Connolly and Singh, 2025). Note- RPO: Research Performing Organisation(s); S&T: Science and Technology.

Figs. 2 and 3 illustrate two governance models for national HBM programme implementation. Model 1 (Fig. 2) features a multi-agency steering committee responsible for national coordination, priority-setting, and programme oversight, while model 2 (Fig. 3) represents a centralised structure in which a single governmental division coordinates programme activities with partner agencies and stakeholders. Both models include an external scientific advisory group to provide guidance on emerging scientific developments and methodological issues. Stakeholder cooperation is formalised through agreements (e.g., Memorandum of Understanding), which should include

provisions for FAIR (Findable, Accessible, Interoperable, Reusable) principles and appropriate data management. These models are informed by best practices from EU HBM programmes: the multi-agency approach reflects distributed governance and cross-ministerial coordination as seen in Belgium's FLEHS and France's national HBM initiatives (Fig. 2).

In Fig. 3, the Department of Health is used purely as an illustrative example of such a lead entity; the specific ministry or department assigned this role may vary depending on the institutional framework of each country. This model is conceptually characterised by single-point leadership, supported by collaboration from other relevant stakeholders. Under this approach, one designated entity assumes primary responsibility for coordinating, delegating, and overseeing all HBM-related activities. Many existing national HBM programmes already follow this structure, where a lead institution is clearly identified and granted formal authority to manage programme operations. However, even with a centralised model, it is essential to ensure structured involvement of wider stakeholders; scientific bodies, regulators, laboratories, and ministry partners to maintain transparency, shared ownership, and strategic alignment.

4. Discussion

To the best of the authors' knowledge, this is the first study internationally to systematically collate insights for developing a framework for establishing a national HBM programme. Previous work has mainly focused on describing existing programmes; for example, Choi et al. (2015) compared nine established national HBM programmes in Europe and North America, highlighting differences in design and implementation. HBM study design requirements have been previously covered by Jeddi et al. (2025), including ethical requirements, sample collection and handling, analysis and reporting, which complements the current findings. A key gap identified during this study was the limited availability of information on programme design and implementation across countries. Such information is often scarce, fragmented, and, in some cases, available only in native languages, making it difficult to access, interpret, and compare. To address this gap, the current study examines broader programme-level considerations, including governance, funding, stakeholder engagement, infrastructure, and long-term sustainability, drawing on evidence from both publicly available and less accessible sources across national HBM programmes. The study synthesises lessons learned and common approaches into a cohesive and adaptable framework. Although national HBM programmes vary considerably in their legislative mandates, governance structures, target populations, and analytical methodologies, several recurring features emerged that appear important for programme effectiveness and long-term sustainability. The resulting framework provides practical guidance for policymakers, researchers, and institutions seeking to establish or strengthen national HBM programmes, particularly in contexts with limited prior experience.

4.1. Governance and legislative foundations

Across the reviewed countries, robust governance, sustained government funding, and clear legislative mandates were fundamental to the implementation and long-term sustainability of HBM programmes, also highlighted by Ubong et al. (2023). Legislation provides the legal basis for HBM activities and defines institutional responsibility, typically within national health or environmental ministries, while implementation may be delegated to research institutions. This governance framework ensures accountability, ethical oversight, and programme continuity.

Legislative frameworks have been central to establishing and sustaining HBM programmes in countries such as Slovenia, Belgium, and France, providing institutional support, policy continuity, and integration within national governance structures (Snoj Tratnik et al., 2019b; Schoeters et al., 2012; Dereumeaux et al., 2017). Consistent with this, regulations have been identified as a key driver for HBM implementation in occupational settings (Louro et al., 2019). More recently, the EU One Substance, One Assessment (OSOA) Regulation (EU, 2025/2455) has further strengthened this framework by promoting harmonised HBM data collection for evidence-based chemical risk assessment. Further details on legislative frameworks across countries are provided in Annexure 1.

Established HBM programmes demonstrate that cross-ministerial coordination, scientific advisory mechanisms, and multi-stakeholder engagement are critical for programme sustainability and policy translation (Keune et al., 2010; HBM4EU, 2022; Karolinska Institutet, 2025; Flemish Center of Expertise on Environment and Health, 2025). These findings align with Model 1 (Fig. 2), while stakeholder consultations in Ireland similarly highlighted the importance of institutional coordination, data integration, and long-term sustainability (Singh et al., 2025a, 2025b). Further information on national governance arrangements is provided in Annexure 2.

Model 2 (Fig. 3) represents a more centralised governance approach, where responsibility is consolidated within a single governmental body but supported by collaboration with academia, clinical institutions, and other stakeholders to ensure scientific robustness and policy relevance (Schulz et al., 2007). Regardless of the governance model adopted, effective HBM programmes depend on multidisciplinary collaboration, transparent coordination mechanisms, and stakeholder engagement to ensure programme sustainability, credibility, and public trust. Comparison of two governance models is provided in Annexure 2.

4.2. Programme design

4.2.1. Objectives and target populations

Defining clear programme objectives is the critical first step in establishing an HBM programme, as these determine the selection of priority chemicals, target populations, biological matrices, and study design (Fiddicke et al., 2021). Depending on national priorities, programmes may focus on the general population, children, occupationally exposed workers, residents near contaminated sites, or other vulnerable groups. From an environmental justice perspective, particular attention should be given to minorities and protected groups who may experience disproportionate exposures due to structural and socio-economic inequalities, and who are frequently underrepresented in population-based studies despite bearing a higher exposure burden. Targeted HBM studies can complement nationally representative surveys and address these evidence gaps.

Sampling strategies should be aligned with these objectives. Oversampling a sub-population improves precision for that group but requires survey weights if nationally representative estimates are to be reported from the same survey, and detecting differences between sub-populations requires larger samples than describing the general population, so a priori power calculations should inform sample size decisions. Detailed statistical considerations for sampling design are provided in Annexure 3.

4.2.2. Chemical selection and biological matrices

Chemical prioritisation should be guided by hazard, exposure potential, national priorities, and societal concerns, with emphasis on chemicals of high public health relevance, including carcinogens, mutagens, reproductive toxicants, endocrine disruptors, persistent organic pollutants, PFAS, phthalates, bisphenols, and flame retardants (Apel et al., 2020; Fillol et al., 2021; Schindler et al., 2014). Countries establishing HBM programmes can build on priority chemical lists developed through international initiatives such as HBM4EU and PARC while adapting them to national needs (David et al., 2020; Uhl et al., 2021; Singh et al., 2025c, 2025d). Appropriate biomarkers, biological matrices (such as blood, urine, or saliva), and analytical methods (such as LC-MS/MS, GC-MS) are critical, with validation and sensitivity being

key (Angerer et al., 2007; Apel et al., 2020; Esteban and Castaño, 2009). Analytical and logistical feasibility, influenced by sampling invasiveness, cost, and detection limits, poses challenges especially for emerging contaminants lacking toxicokinetic data (Fillol et al., 2021; Jeddi et al., 2022). Examples of chemical prioritisation adopted by different countries are provided in Annexure 4.

4.2.3. Sampling strategy and recruitment

Careful attention to the sampling frame is essential, as generalisability depends on whether participants are randomly selected from a well-defined source population that adequately represents the target population, or recruited through more limited approaches (Bates et al., 2005). Recruitment is often the most challenging aspect of HBM programmes, requiring careful planning to ensure representativeness and ethical compliance. One study identified several barriers to participation among socially disadvantaged pregnant women in a Belgian HBM study, including lack of trust in researchers, no perceived study benefits, complex study design, and difficult self-administered questionnaires, collectively contributing to the underrepresentation of this group (Morrens et al., 2017).

Programmes may initially begin with relatively small studies to establish baseline information on population chemical exposures and test recruitment, sampling, and analytical procedures. For example, the HBM4IE feasibility study recruited around 160 participants to generate baseline exposure data for the Irish population (UCD, 2026). Incentives such as small financial rewards, personal health results, or expense reimbursements can improve participation but must align with national and international ethical guidelines (Halpern, 2011; Halpern et al., 2021). Participation and contributions were encouraged across several countries, with monetary incentives provided in specific locations for HBM studies. The nature and value of incentives varied considerably across countries, ranging from vouchers and gift cards to expense reimbursements and appreciation packages (Annexure 6). While such incentives may improve inclusion of underrepresented groups, such as low socio-economic populations, they may also skew representativeness if certain groups are disproportionately motivated by the reward, as evidenced by certain studies (Resnik, 2015).

Central to all stages of an HBM programme is the need for ethical considerations, compliance and oversight. Although specific requirements vary by country, internationally recognised frameworks such as the Declaration of Helsinki for human research and, where applicable, the EU GDPR (Regulation (EU) 2016/679) provide valuable guidance for data protection, participant privacy, and responsible conduct. Throughout the programme, study protocols, participant information sheets, consent forms, questionnaires, and data protection statements must ensure pseudonymisation or anonymisation of data (Tolonen et al., 2022). Formal ethical oversight should be secured through a research ethics board or equivalent committee, either by engaging an existing board within the host institution or, where none exists, by arranging review through an accredited external committee. Approval should be obtained for all programme components prior to recruitment, and for subsequent protocol amendments and any secondary use of biobanked samples. In Canada, for example, ethics approval for all components of the CHMS was obtained from the Health Canada and Public Health Agency of Canada Research Ethics Board (Karthikeyan et al., 2024). Adhering to these ethical principles ensures that recruitment, sampling, analysis, and data management are conducted responsibly, fostering trust, transparency, and scientific rigour across diverse contexts.

Overall, clear objectives, robust methods, and evidence-based chemical selection strengthen programme governance, sustainability, and alignment with national health and environmental priorities (WHO, 2023).

4.3. Logistics, analytical capacity, and economic considerations

Successful HBM programmes require coordinated logistics encompassing participant recruitment, sample collection, laboratory analysis, data management, and communication. Adequate analytical capacity and sustained financial investment are critical for programme implementation and continuity. Although detailed cost information is rarely publicly available, evidence from national and international programmes indicates that HBM requires substantial long-term investment, with costs largely driven by sampling logistics, laboratory analyses, and participant recruitment (Joas et al., 2012; Johnson et al., 2024). A table representing reported programme costs is provided in Annexure 5.

For countries lacking accredited analytical facilities, cross-border laboratory collaborations can provide a cost-effective approach during programme establishment while maintaining analytical quality. However, such arrangements require careful consideration of national regulations governing biological sample export, together with legal, ethical, privacy, and data protection requirements to ensure compliance and participant confidentiality.

Well-established HBM programmes employ diverse sampling strategies to maximise participation and representativeness. Mobile examination centres, used in countries such as Germany and the USA, improve access to remote populations through standardised sampling procedures (Lermen et al., 2014; Fiddicke et al., 2021). However, countries with limited resources can successfully implement HBM through existing healthcare infrastructure, including hospitals, primary care facilities, and community clinics, with sampling conducted in a variety of settings depending on programme objectives.

Long-term sustainability can be enhanced by integrating HBM into existing national health surveys and surveillance systems, as demonstrated in Germany, France, the USA, and Canada, thereby leveraging established infrastructure and reducing operational costs (Joas et al., 2012; Tolonen et al., 2022). Collaboration across national and international initiatives, together with diversified funding mechanisms and support from organisations such as WHO, can further strengthen programme efficiency, harmonisation, and long-term sustainability (WHO, 2025).

4.4. Comparability across programmes

4.4.1. Laboratory quality assurance and quality control

Robust Quality Assurance and Quality Control (QA/QC) procedures are also fundamental in HBM across all stages, from sample collection, pre-processing, storage and analysis to ensure reliable and comparable data across studies, particularly through the use of specialized, accredited laboratories and cross-border collaboration to optimise resources. The HBM4EU initiative exemplifies this by implementing a QA/QC scheme involving inter-laboratory comparisons and external quality assessment schemes (EQUAS) across 84 laboratories in 26 countries, ensuring high-quality data for biomarkers like PFAS and phthalates through centralised coordination and adherence to ISO 17043 standards (López et al., 2021). Similarly, U.S. guidelines from the CDC emphasise method validation, proficiency testing, and CLIA-compliant systems to maintain data integrity in occupational biomonitoring (DeBord et al., 2022). In addition, the Centre de toxicologie du Québec (CTQ), Canada, is a public reference laboratory providing environmental, clinical, and occupational human toxicology expertise since 1972, operating under ISO/IEC 17025 and ISO/IEC 17043 accreditation, and supporting national and international HBM programmes (Institut national de santé publique du Québec, 2024). These frameworks, supported by collaborative laboratory networks and standardised protocols, enhance analytical reliability while optimising the costs through shared resources.

4.4.2. Data management and comparability

Effective data management in HBM programmes, as reflected in the

framework, is crucial and begins at the design phase and continues throughout to ensure data quality, integrity, and usability. A comprehensive data management plan, including separate databases for participant contacts, recruitment, questionnaire data, and analytical results, as well as an aliquot database tracking sample IDs, dates, types, remaining aliquots, and biobank locations, is critical (Fiddicke et al., 2021). Adherence to FAIR principles is essential to enable integration of HBM data into broader research, risk assessment, regulatory actions, and public health interventions, enhancing accessibility, transparency, and comparability (Jeddi et al., 2022). This is reflected in the final component of our framework, which emphasises integrating HBM data with public health surveillance and policy processes, as exemplified by Germany's GerES, France's Esteban, and the EU's HBM4EU initiative, strengthening evidence-based decision-making and fostering public trust through transparent communication (Dereumeaux et al., 2017; Schulz et al., 2007).

4.4.3. Study design and generalisability

Comparability is further constrained by differences in study design. Programmes vary in target population, age range, sampling frame, biological matrices, and cycle timing, so reported concentrations are not always directly comparable even where analytical methods are equivalent. Harmonisation under COPHES/DEMOCOPHES and HBM4EU addressed this through common protocols for recruitment, sampling, and questionnaire administration, showing that transnationally comparable data can be obtained where design elements are aligned in advance. Otherwise, generalisability depends on how well each programme's source population represents its target population.

4.5. Programme sustainability

Given the high costs and effort of sampling campaigns, preserving collected samples for immediate and future use is crucial, with biobanking playing a pivotal role through cryogenic preservation of biological samples (Elliott and Peakman, 2008; Kolossa-Gehring et al., 2011, 2012; Lermen et al., 2021; Malsagova et al., 2020). While sampling and chemical analysis are often standardised, storage and shipment practices vary, necessitating harmonisation to maintain sample integrity and long-term scientific value, enhanced by advanced technologies like automated storage systems (Elliott and Peakman, 2008). Biobanks, such as Germany's Environmental Specimen Bank (ESB, started 1985), collecting student samples for retrospective pollutant monitoring, and Flanders' Biobank@VITO (70,000 samples since 2002), store extensive metadata on lifestyle, environment, and health, boosting research potential (Kolossa-Gehring et al., 2011; Van Den Heuvel et al., 2020). Standardised biobanking practices in HBM have rapidly evolved over the past decade, reflecting the growing need for harmonised sample and data infrastructures to support large-scale, collaborative research.

Sustaining a programme also requires continued methodological development. Innovation in HBM extends well beyond analytical method development to include big data infrastructure, advanced analytics and machine learning, population sampling strategies, mixture and exposome research, PB/PK modelling, derivation of reference and health-based guidance values, exposure–health outcome research, biomarker discovery and validation, and advances in study design and data integration. Reliable biomarkers are often limited for emerging pollutants, necessitating ongoing investment in method development, metabolic pathway research, and biomarker validation, so that programmes remain able to detect substances entering use after their establishment.

4.6. Impact of national HBM programmes

Across the fourteen programmes reviewed, impact was evident in three domains: the development of new analytical methods, the derivation and application of health-based guidance values for risk assessment, and regulatory actions followed by measurable reductions in population exposure. Programmes with the longest continuity and most sustained funding accounted for most of the documented impacts.

4.6.1. Innovation and methodological advancement

Across the countries reviewed in the present study, discovery and innovation emerged as an important pillar within the frameworks for establishing and sustaining HBM programmes, particularly in countries with sustained funding and well-established programmes. In Belgium and Germany, for example, ongoing research investment has enabled programme adaptation, facilitating the identification of emerging contaminants, the refinement of analytical methodologies, and the harmonisation of data across international collaborations (Van Campenhout, 2024; Kolossa-Gehring et al., 2011). The Flemish Environment and Health Survey (FLEHS) has supported innovation for tracking newly introduced chemicals (Reynders et al., 2017). In Germany, a cooperation between the Federal Ministry for the Environment (BMUKN), and the German Chemical Industry Association (VCI) supported by German Environment Agency (UBA) prioritised 50 consumer- and health-relevant substances and has spearheaded the development of over 29 new urine- and blood-based analytical methods for chemicals of emerging concern, including plasticisers, flame retardants, and substances arising from consumer products and occupational settings, thereby enhancing regulatory decision-making (Kolossa-Gehring et al., 2017). These efforts highlight the necessity of sustained R&D to address knowledge gaps in exposure assessment and risk characterisation, ensuring that HBM remains a dynamic tool for regulatory decision-making.

4.6.2. Use of HBM data in chemical risk assessment

Analytical capability delivers value primarily where the resulting concentrations can be interpreted against health-based benchmarks, and national programmes have been central to developing the tools that make such interpretation possible. In Europe, HBM supports the REACH regulation by identifying hazardous chemical properties and evaluating restrictions. Health-based exposure limits, such as Derived No-Effect Levels (DNELs) or Derived Minimal Effect Levels (DMELs), required for substances manufactured, imported, or used in quantities of 10 tonnes or more per year under REACH, can be translated into biomarker concentrations known as biomonitoring equivalents (BEs; originally developed in the US) to interpret population-level health impacts (Boogaard et al., 2012; Ganzleben et al., 2017). In addition, the Human Biomonitoring Commission of the German Environment Agency established HBM I and II values for toxicological interpretation, and the HBM4EU initiative derived HBM Guidance Values (HBM-GVs) for risk assessment (Apel et al., 2017, 2020, 2023; Meslin et al., 2022), with Human Biomonitoring Health-Based Guidance Values (HB2GVs) accessible online (International Society of Exposure Science, 2025).

The practical significance of these tools is that they convert exposure measurements into statements about risk: the proportion of a population exceeding a health-based guidance value is directly interpretable by regulators, whereas a distribution of biomarker concentrations alone is not. Because HBM captures aggregate exposure from all sources and routes, such assessments reflect real-life exposure more closely than estimates extrapolated from individual environmental compartments. As noted in Section 4.1, this function is now formally recognised within the EU's One Substance, One Assessment framework, under which systematically collected national HBM data are positioned to support harmonised European risk assessment and early-warning capacity.

4.6.3. Translation into health policy and reduced population exposure

The clearest demonstration of impact is reduced population exposure following HBM-informed regulatory action. Canada documented declining lead and mercury exposure through risk management strategies (Bushnik et al., 2010; Nguyen et al., 2024; Pollock et al., 2021); Germany's GerES informed the phase-out of mercury-containing dental

amalgams for children and limits on phthalates in plastics (Göen et al., 2011; Becker et al., 2013); Sweden used data on rising PBDE levels in maternal milk to implement phased reductions in PBDE use (Lignell et al., 2015); and NHANES documented substantial reductions in blood lead following the removal of lead from gasoline and paints (Calafat, 2012; Dignam et al., 2019; Pirkle et al., 2005). These impacts are summarised in Annexure 7. German long-term data further showed declines in phthalate metabolites following EU regulation alongside rising substitute phthalates (Schütze et al., 2014; Vogel et al., 2023; Kasper-Sonnenberg et al., 2025), capturing both functions of sustained monitoring within one dataset: confirming that a measure achieved its intended effect, and detecting regrettable substitution before the replacement became established.

4.6.4. Health and economic significance

Establishing and operating a national HBM programme requires sustained investment, as outlined in Section 4.3. However, it is crucial to note that the cost of inaction can be substantially greater, including health-related costs, environmental remediation costs, and economic burdens. An example of this is PFAS, where the European Commission estimated that continued PFAS pollution in the European Economic Area could cost up to €440 billion by 2050 under baseline scenarios, with a full phase-out by 2040 saving €110 billion compared to inaction (European Commission, 2026). In the US, an analysis of five key health outcomes linked to PFAS exposure suggested a minimum annual economic burden of $5.52 billion, up to an upper limit of $62.6 billion (Obsekov et al., 2023). The Nordic Council of Ministers estimated direct healthcare costs from PFAS exposure in Europe at €52–84 billion annually (Goldenman et al., 2019). Broader work on endocrine-disrupting chemicals (EDCs) in the EU and U.S. highlights annual health costs of €157–163 billion and over $340 billion, respectively, linked to neurodevelopmental disorders, obesity, diabetes, and cancers (Attina et al., 2016; Trasande et al., 2015). Early warning indicators of chemical exposures can drastically reduce costs associated with remediation and healthcare.

Overall, this study offers a comprehensive and adaptable framework for establishing national HBM programmes, specifically designed to support different countries, including those with limited resources and/or no prior experience. Its adaptability lies in its flexible/modular structure, which allows countries to tailor each component, such as study design, analytical capacities, and data management systems and organisational structure to their own institutional, financial, and technical contexts. For instance, low-resource settings may begin with simplified sampling schemes, outsource laboratory analysis, or focus on a limited set of priority chemicals, while more established systems may integrate advanced biomarker panels, digital data infrastructures, and multi-agency governance mechanisms. In doing so, the framework enables nations to develop sustainable HBM programmes that address local needs, strengthen public health, and contribute to global environmental health monitoring by leveraging shared infrastructure and collaborative networks.

5. Conclusions

This study presents a holistic framework and the foundational building blocks required to support the development of sustainable national HBM programmes. By integrating evidence from country-level searches, government websites, grey literature, technical reports, and expert perspectives, it addresses the fragmented availability of information and provides a practical guidance for countries establishing HBM programmes. The framework outlines key considerations for governance, study design, ethics, data management, stakeholder engagement, and policy integration.

The principal recommendation is to build on existing international experience while adapting HBM programmes to national priorities, resources, and capacities. For countries with limited experience, initiating a pilot or feasibility study provides a practical pathway for iterative learning, capacity building, and gradual programme expansion. Importantly, successful implementation requires multidisciplinary collaboration among researchers, government agencies, laboratories, policymakers, and other stakeholders. By promoting knowledge transfer, collaboration, and harmonisation of best practices, this framework can support the establishment and long-term sustainability of national HBM programmes worldwide.

CRediT authorship contribution statement

Richa Singh: Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Holger Martin Koch:** Writing – review & editing, Methodology, Conceptualization. **Marike Kolossa-Gehring:** Writing – review & editing, Methodology, Conceptualization. **André Conrad:** Writing – review & editing, Methodology, Conceptualization. **Alison Connolly:** Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization.

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Appendix A. Supplementary data

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