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Role of Human Biomonitoring in REACH Regulation

Summary for Regulators

Human biomonitoring (HBM) directly measures chemicals or their metabolites in human biological matrices. Within the REACH framework, HBM provides real-world evidence of internal exposure, integrating all sources and routes (inhalation, skin, ingestion). When properly applied, it enhances the scientific robustness and credibility of chemical risk assessment and risk management under REACH.

https://www.sciencedirect.com/science/article/pii/S0273230026000516

What important questions HBM have already helped to answer within REACH?

- Are actual worker or population exposures consistent with modelled exposure scenarios?
- Are current risk management measures (RMMs) effectively controlling exposure?
- Do skin or ingestion routes significantly contribute to internal exposure?
- Are certain subpopulations at higher risk?
- Do Restrictions or Authorisations lead to measurable exposure reductions?
- Is substitution resulting in unintended exposure shifts (regrettable substitutions)?

Why is HBM information critical for REACH processes?

- It reduces uncertainty associated with exposure modelling, especially for substances with skin uptake or low volatility.
- It supports the weight of evidence regarding needs and decisions with respect to Restrictions and Authorisation.
- It provides measurable evidence of the effectiveness of regulatory risk management measures over time.
- It supports derivation and refinement of biomarker Derived No Effect Level ($DNEL_{biomarker}$) values where toxicokinetic data are available.
- It can be integrated with the Common European Data Spaces and is well positioned with the EU common data platform initiatives (ECHA).
- It supports the “one substance, one assessment” goals.

A structured, harmonised and incentivised use of HBM under REACH will strengthen the EU chemicals regulatory system and contribute to sustainable, science-driven chemical risk management.

A collaborative effort by the ISES Europe HBM Working Group and the HBM Global Network.

Where does HBM add the greatest regulatory value?

A) Supporting Hazard, Exposure and Risk Assessments

- Enables derivation of $DNEL_{biomarker}$ when human dose-response data exist.
- Provides internal dose information for more targeted risk assessment.
- Reduces uncertainty factors in DNEL derivation using internal dose metrics.

B) Enabling REACH Restrictions

HBM data have already:

- justified restriction needs (e.g. Bisphenol A in thermal paper, Per- and Polyfluoroalkyl Substances concerns).
- validated or refined exposure modelling (e.g., phthalates, aprotic solvents).
- demonstrated post-regulation exposure declines.
- identified substitution patterns within chemical groups justifying the need of regulatory action targeting group of substances.

C) Enabling REACH Authorisations

- HBM can evaluate effectiveness of RMMs, particularly when skin exposure route is relevant or personal protective equipment (PPE) is being used;
- And support risk assessment of non-threshold carcinogens where minimisation of exposure must be demonstrated.

What are the current barriers to the use of HBM and how can they be overcome?

Barriers	Action needed
Over-reliance on exposure modelling in registration dossiers	Use clear criteria for when HBM should be required or strongly recommended in exposure assessment
Limited harmonisation and implementation of $DNEL_{biomarker}$ values	Promote harmonised derivation of Biomonitoring Levels for both Occupational and General population
Absence of dedicated IUCLID sections for $DNEL_{biomarker}$ Values	Create structured IUCLID entries for $DNEL_{biomarker}$ and HBM data
Classification of occupational HBM data as “medical data” restricting accessibility	EU-wide harmonisation of occupational HBM data as "exposure data", not "medical data". Encourage use of pseudonymised and aggregated data to address GDPR concerns
Still limited availability of toxicokinetic data and validated analytical methods	Support the public access to basic toxicokinetic data, in vitro ADME data, and HBM/analytical methods as a tonnage-driven information requirement under REACH
Lack of regulatory incentives or formal requirement to submit HBM data	Foster collaboration between industry, regulators, researchers and EU agencies to ensure consistent application

Systematic integration of HBM under REACH

- Improves regulatory accuracy and underscores the necessity of regulatory measures
- Reduces uncertainties in exposure and risk characterisation
- Enables measurable evaluation of regulatory impact
- Enhances protection of workers and the general population through evidence-based policy-making
- Supports international alignment with REACH-like frameworks

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Document number: FAIREHR:2026-05-20-R