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# Role of Human Biomonitoring in REACH Regulation

## Industry Summary

Human biomonitoring (HBM) measures chemicals (or their metabolites) directly in human biological matrices, capturing uptake across inhalation, dermal and ingestion routes. Under REACH, this offers concrete evidence of real-world internal exposure that can complement personal air monitoring and modelling.

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

### Why is HBM important in REACH?

- HBM provides an integrated picture of exposure across all sources and routes and can identify uptake that may be missed when relying solely on e.g., air monitoring for exposure assessment.
- It is particularly valuable for substances with low volatility and/or relevant skin absorption, where external exposure estimates are uncertain.
- Repeated measurements can indicate whether exposure has changed over time and whether controls and risk management measures (RMMs) are effective.

### What important questions can HBM help industry answer to fulfil their REACH requirements?

- Does internal exposure occur under the claimed conditions of safe use?
- Which tasks, uses or worker/population groups show the highest internal exposure?
- Are RMMs (including PPE and policy measures) demonstrably effective in reducing total uptake?
- Do modelled estimates align with measured internal exposure, or do the underlying assumptions require refinement?
- Is there evidence of chemical substitution that shifts exposure to structurally similar alternatives with the same health effects (regrettable substitutions)?

### Why is this information critical?

- It improves the reliability of chemical safety assessments by reducing reliance on uncertain modelling, especially for dermal exposure scenarios.
- It supports targeted regulatory action (Restriction, Authorisation conditions, follow-up monitoring and enforcement) where exposure is not reduced.
- It enables evaluation of whether interventions have reduced internal exposure over time and whether additional measures (technical and/or regulatory) are needed.

Meaningful interpretation requires toxicokinetics and exposure context (tasks, timing, controls in place, non-occupational exposure sources present in different scenarios). The **FAIREHR** platform (www.fairehr.com) will provide industry with the support they need to effectively implement and use HBM.

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

# 10 Decision Criteria indicating when HBM can be used as a complementary approach in exposure assessment

1. Validated biomonitoring methods are available with sufficient sensitivity to assess the exposure of concern
2. Substance may be absorbed through the skin (e.g., have a skin notation)
3. Substance can accumulate in the body (sufficient biological half-life)
4. Substance is classified as carcinogen, mutagen or toxic to reproduction (CMR)
5. Substance is classified as neurotoxicant, developmental neurotoxicant or endocrine disruptor
6. Air monitoring or other exposure assessment approaches cannot adequately capture total exposure/total body burden
7. Internal exposure may be modified by physical stress or environmental conditions that may accelerate skin absorption
8. Oral exposure may occur through inadvertent contamination transfer (hand-to-mouth contact)
9. Exposure control relies largely on PPE and PPE effectiveness is difficult to demonstrate through environmental measurements alone
10. Aggregated exposure assessment is required due to exposure from multiple sources of exposure

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