

Biomonitoring of Legacy & Emerging Substances of Concern – Scientific and Practical Challenges

The Use of Biomonitoring Data in REACH: Successes and Challenges

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RSC Toxicology Group & IGHC Joint Awareness Day

Biomonitoring – Human & Environmental Perspectives

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The Use of Biomonitoring Data in REACH: Successes and Challenges

- Introduction to the Chemical Assessment Unit
- REACH & CLP Regulations
- Biomonitoring Data for REACH Substance Evaluation & CLP Assessment
- Biomonitoring for Legacy & Emerging Contaminants
- Challenges Associated with Producing Robust Biomonitoring Data

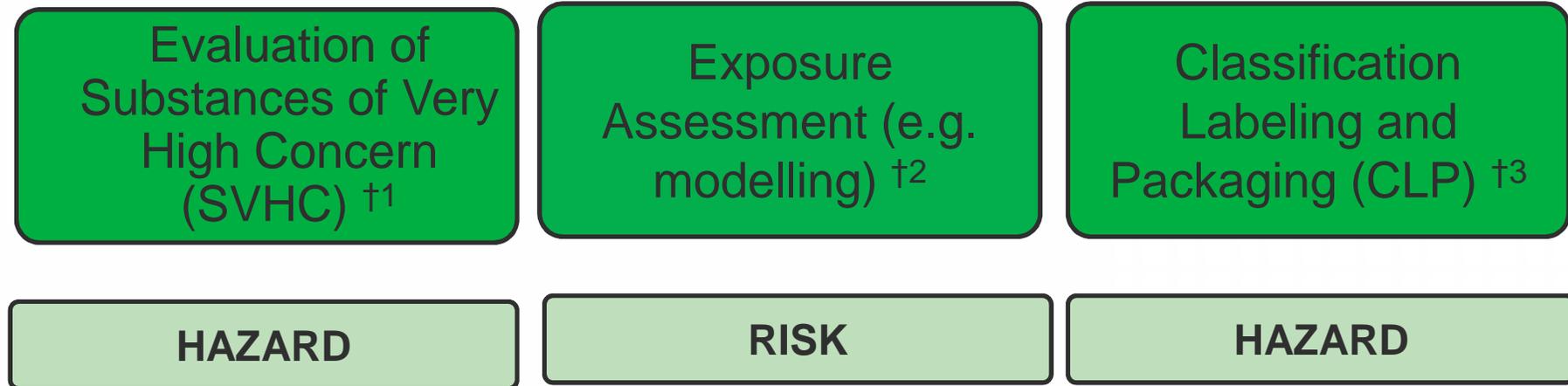
Chemical Assessment Unit (CAU)

- Review environmental sections of REACH registration and classification, labeling and packaging (CLP) dossiers
- Perform substance evaluations to clarify concerns over potential hazardous effects
- Represent UK on EU expert groups for Persistence Bioaccumulation and Toxicity, Endocrine Disruption and Nanomaterials
- Represent UK at relevant international meetings e.g. Stockholm & Rotterdam Convention
- Work closely with HSE & DEFRA (& PHE, DWI etc.)
- Contributed to European bans of a number of hazardous chemicals

What are REACH & CLP?

- **Registration, Evaluation, Authorisation of Chemicals (REACH)** (EC No. 1907/2006)
 - Protection of human health and the environment
 - Primarily industrial and consumer chemicals
 - Responsibility of the manufacturer/importer
 - Identification of hazards, which triggers exposure assessment and risk identification/management
 - Prioritised by quantities of the substance being supplied
- **Classification, Labelling and Packaging of Substances and Mixtures** (EC No. 1272/2008)
 - Alignment of the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System

Biomonitoring Data in REACH

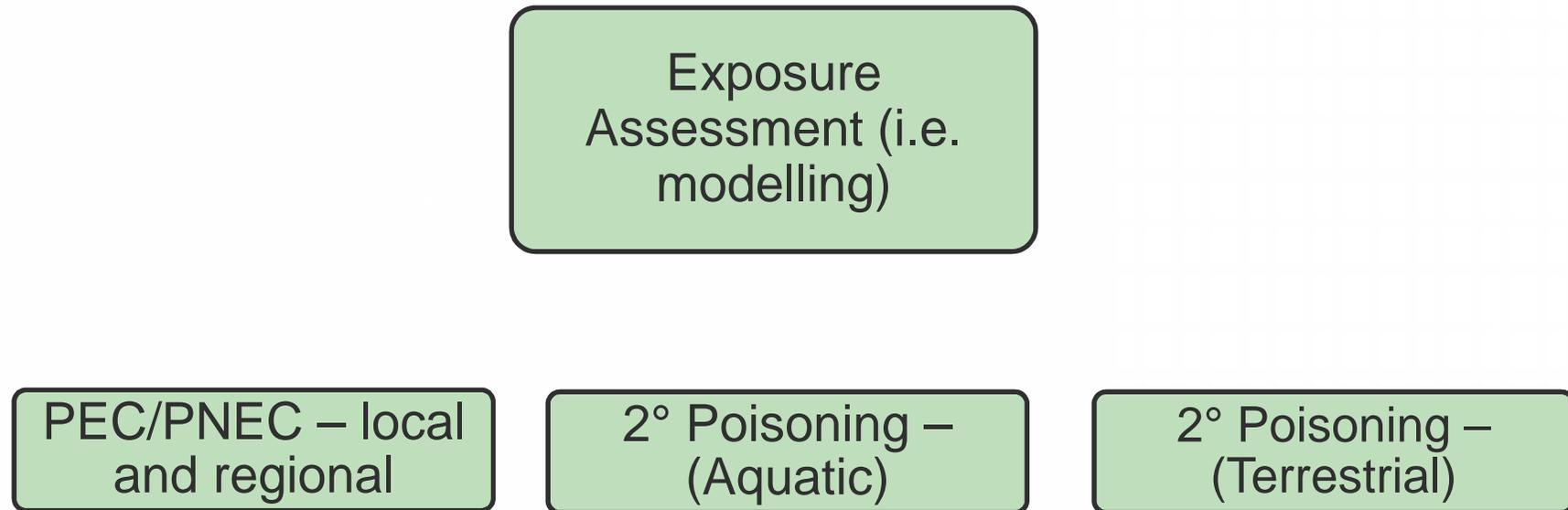


†1 REACH Regulations EC No. 1907/2006 - Article 57 & Annex XIII
Guidance documents R11, R 7 b & c

†2 REACH Regulations EC No. 1907/2006
Guidance documents R16

†3 EC No. 1272/2008 – Classification, Labelling & Packaging of
Substances and Mixtures

Biomonitoring Data in REACH – Risk Assessment

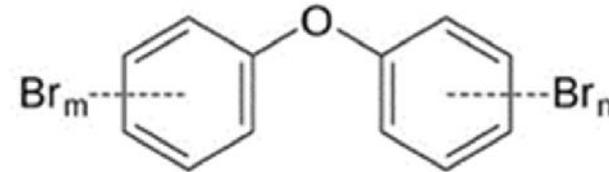


†²REACH Regulations EC No. 1907/2006
Guidance document R16.

Risk Assessment

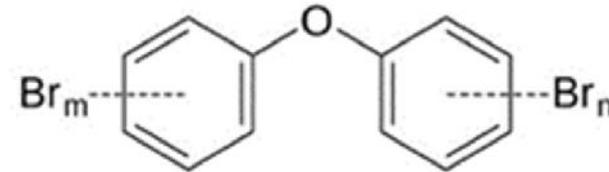
- Biomonitoring data has been used to:
 - Support modelling conclusions i.e. check the veracity of the PEC estimates from regulatory models
 - Map substance concentration data to the presence of manufacturing sites
 - Demonstrate the success of risk management measures

Polybrominated diphenyl ethers (PBDEs)



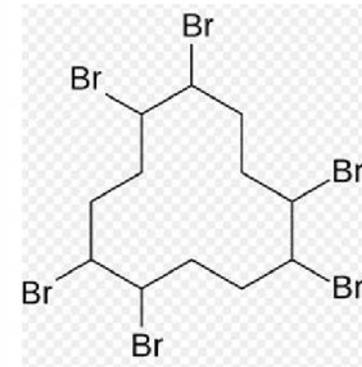
- Flame Retardants
 - Building materials, electronics, furnishings, motor vehicles, airplanes, plastics, polyurethane foams
- Known hazards – Reprotoxins & PBT/vPvB
- Biomonitoring data from fish sampled in industrialized areas of UK and The Netherlands was compared to the predicted concentrations in surrounding media

Polybrominated diphenyl ethers (PBDEs)



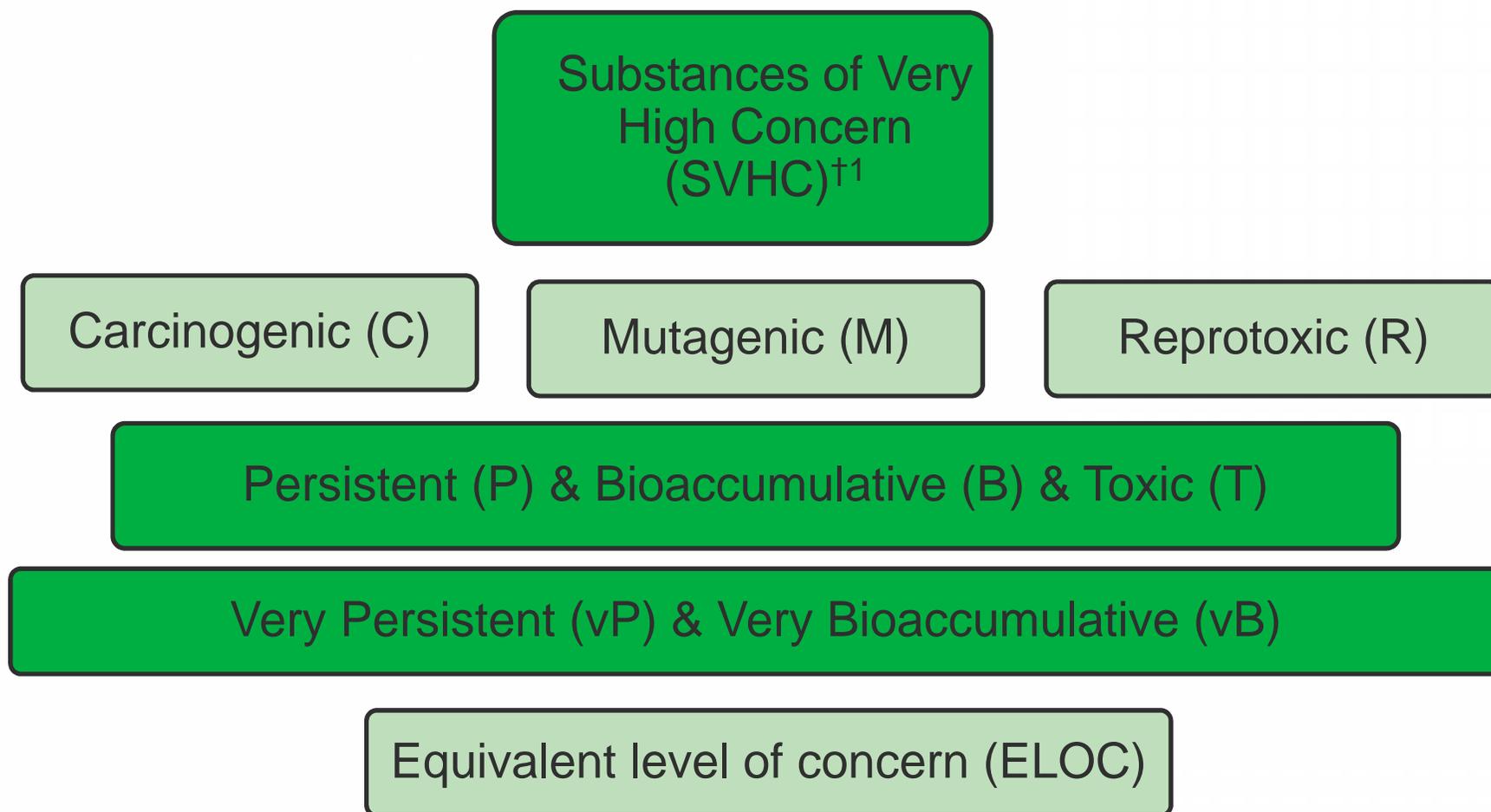
- Biomonitoring data supported the ERA models allowing the risk assessment to be conducted
- Control of DecaBDE
 - EU Candidate List (REACH Annex XIV) & Restriction (REACH Annex XVII)
 - Stockholm Convention Annex A

Hexabromocyclodecane (HBCD/HBCDD)



- Flame retardant
 - Extrusion/expansion polystyrene foams – thermal insulation in building industry
- Confirmation of presence and associated concentrations in biota samples linked to proximity of manufacturing sites
- Control of HBCD
 - EU Candidate List (REACH Annex XIV)
 - Stockholm Convention Annex A

Biomonitoring Data in REACH – Hazard Assessment



^{†1}REACH Regulations EC No. 1907/2006 - Article 57 & Annex XIII
Guidance documents R11, R 7 b & c

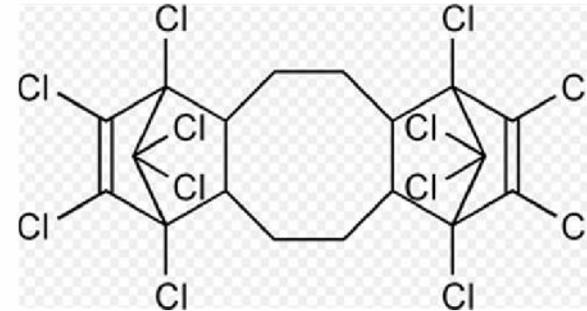
Bioaccumulation (B/vB)

- Bioaccumulation of a substance by a test organism is not in itself a hazard
- Bioaccumulation has to be considered in relation to the potential for that substance to cause long-term effects
 - Bioconcentration Factor (BCF), OECD305-I (Aqueous Bioconcentration in Fish)
 - Biomagnification factor (BMF), OECD305-III (Dietary Biomagnification in Fish)
 - Bioaccumulation factor (BAF), OECD315 & OECD 317 (Bioaccumulation in Sediment Dwelling Oligochaetes and Terrestrial Oligochaetes, respectively)

Hazard Assessment

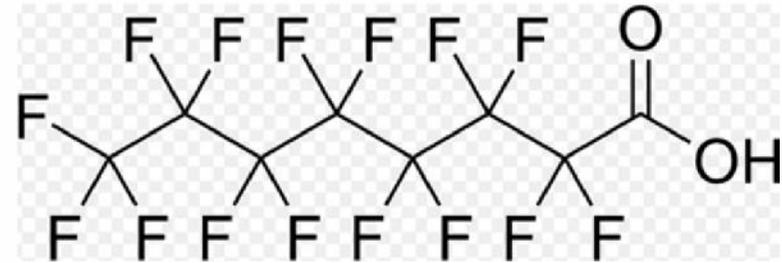
- Biomonitoring data has been used to support bioaccumulation conclusions for a number of substances:
 - Dechlorane Plus (CAS 13560-89-9)
 - Perfluorooctanoic acid (PFOA; CAS 335-67-1)
 - Cyclotetrasiloxane, (D4; CAS 293-51-6)
 - Cyclopentasiloxane (D5; CAS 541-02-6)

Dechlorane Plus



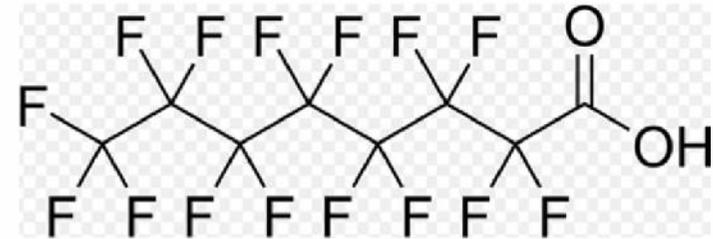
- Hazard – PBT/vPvB
- Large number of biomonitoring studies used to show:
 - Global dispersion in environmental compartments (widespread in a European scale)
 - Uptake can occur in wide range of wildlife from around the globe
 - Found to be present in top predators in regions with no human activity
 - Trophic magnification
- Control of Dechlorane Plus
 - EU Candidate List (REACH Annex XIV)

Perfluorooctanoic acid (PFOA)



- Industrial surfactant, non-stick coatings & water-proofing agents
- Hazards identified under ELOC
 - Very persistent
 - Highly mobile (Not measurable environmental B/vB)
 - Protein binding?
 - Human health CMR and Environmental ED hazards

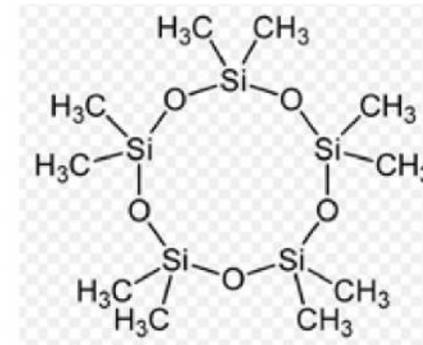
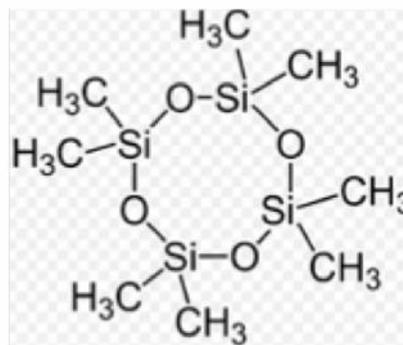
Perfluorooctanoic acid (PFOA)



- Air-breathing organisms are more likely to biomagnify PFOA compared to water-breathing organisms
- Biomonitoring data from polar bears, narwhal, beluga whale and humans
- PFOA
 - EU Candidate List (REACH Annex XIV) Restriction (REACH Annex XVII)
 - Stockholm Convention candidate for Annex A or B

D4 & D5

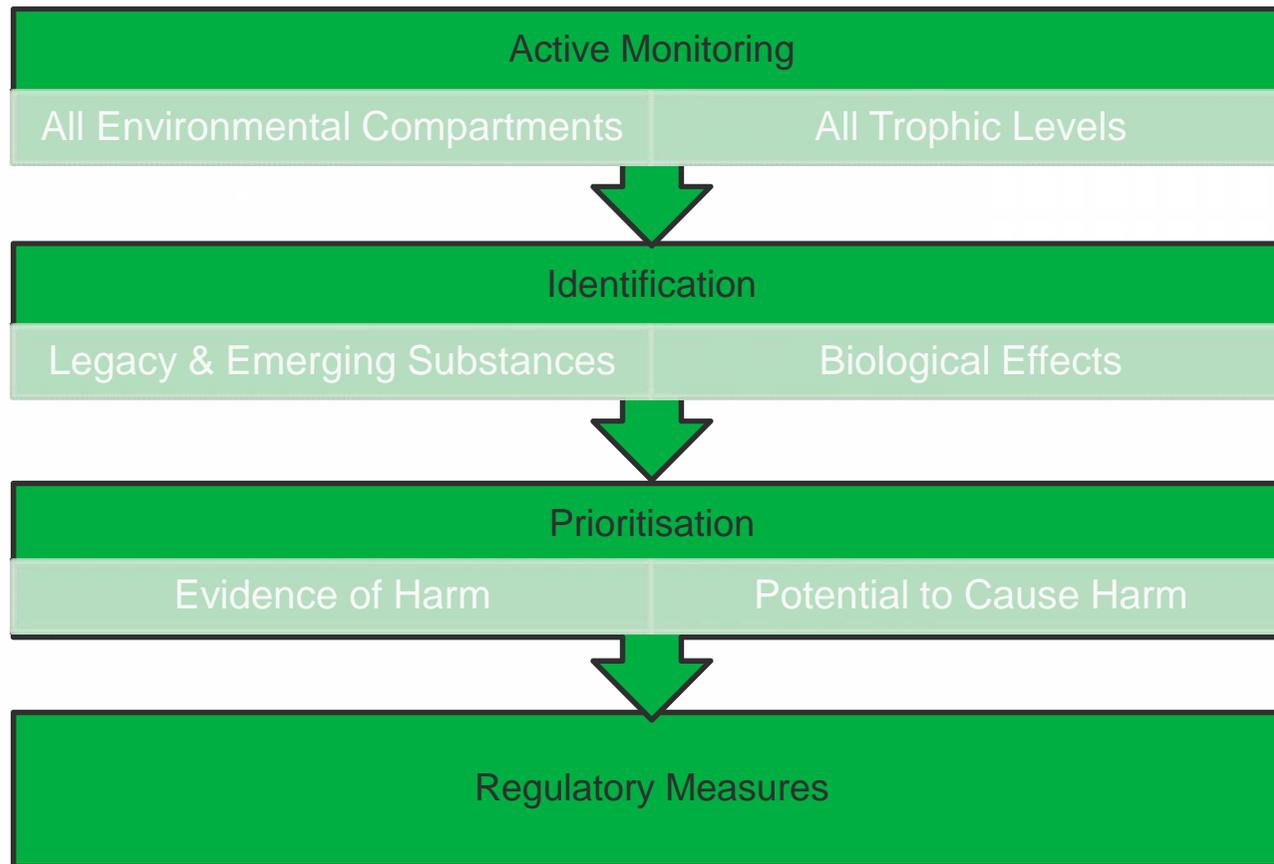
- Hazard
 - D4 – PBT/vPvB
 - D5 - vPvB
- Large number of biomonitoring studies showed:
 - Found in a wide range of organisms, including top predators
 - Measured concentrations were shown to be similar to other known vB compounds
- D4 & D5
 - EU Candidate List (REACH Annex XIV) Restriction (REACH Annex XVII) - personal care products



Classification, Labeling & Packaging (CLP)

- Biomonitoring data alone cannot be used to generate a bioconcentration factor (BCF) which is the only numerical criterion to classify a substance under CLP
 - $B > 500$, $\log K_{OW} > 4$
- Biomonitoring data can be used in a Weight-of-Evidence approach to support laboratory generated BCF data and inform CLP

Biomonitoring for Legacy & Emerging Substances



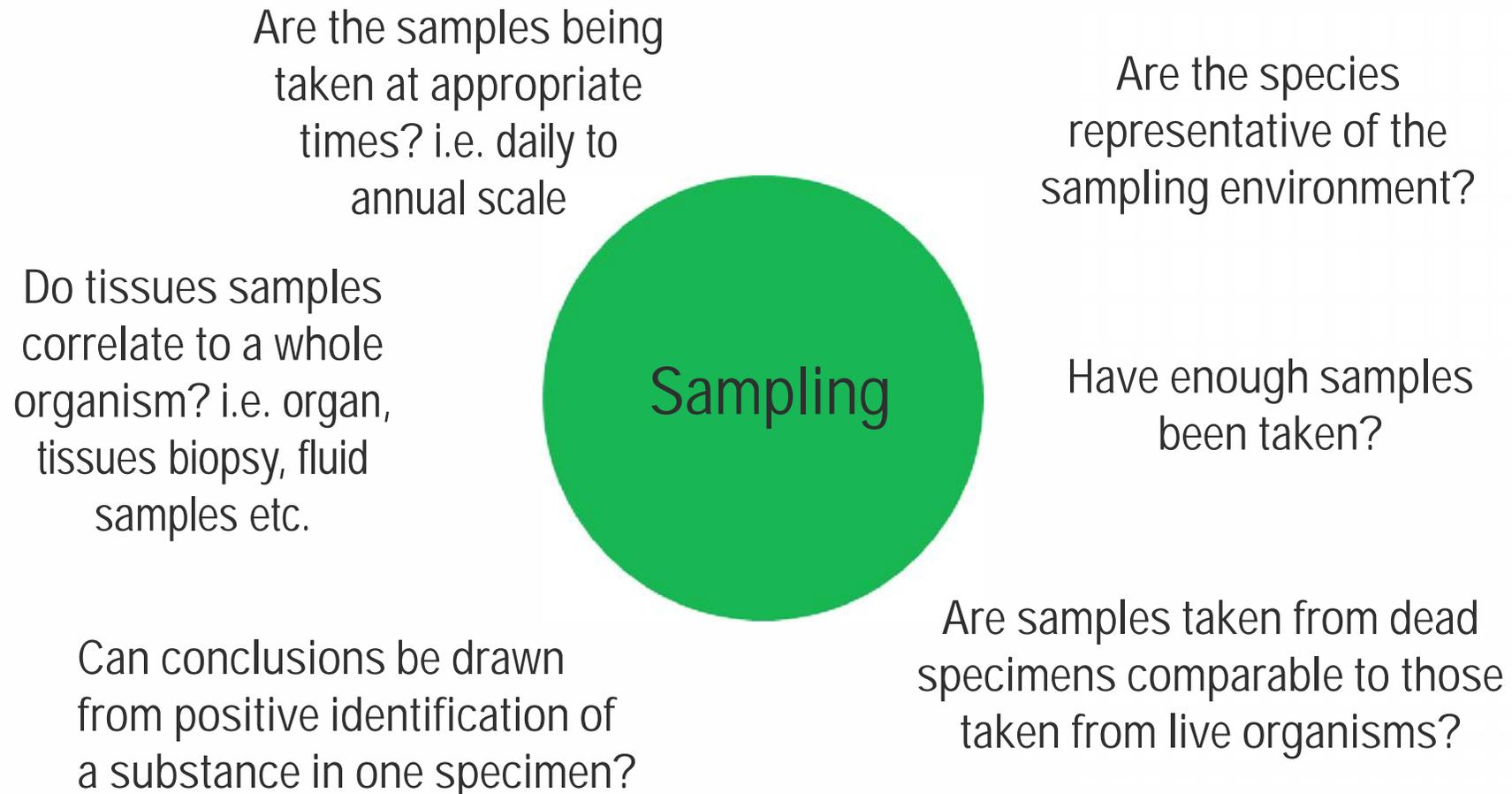
Challenges in Biomonitoring for Legacy & Emerging Substances

Sampling

Which Method
of Analysis?

Additional
Considerations

Challenges in Biomonitoring for Legacy & Emerging Substances

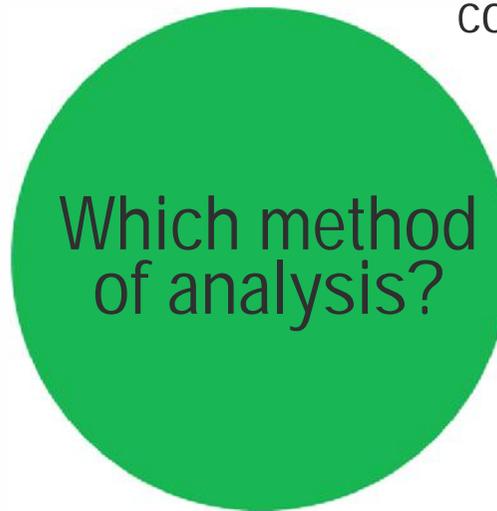


Challenges in Biomonitoring for Legacy & Emerging Substances

Biota samples are challenging to prepare for specific analysis i.e. post collection concentration and removal of interferences

Sampling procedures need to be employed that will reduce potential contamination

Is the correct analytical detection method being employed? E.g. this is often dictated by the intrinsic properties of the substance



Samples need be stored in such a way to minimise potential degradation of substances? E.g. cold storage, and stability with time should be assessed

Challenges in Biomonitoring for Legacy & Emerging Substances

Intrinsic properties of a substance and tonnages entering environmental compartments will dictate successful detection

Additional Considerations

Difficulties experienced establishing an organisms route of exposure to a substance e.g. environmental media versus ingestion via food

Organisms may migrate or move around over large distance so it can be difficult to establish sources of exposure (Manufacturing site? Ingestion of refuse from landfill sites?)

Behavioural and environmental knowledge of a species is needed

Conclusions

- As part of a weight of evidence, biomonitoring data have been successfully used to support risk and hazard assessments under REACH
- Biomonitoring data have never solely been used but can be included in an Equivalent Level of Concern argument for SVHC identification
- In a regulatory setting many challenges are associated with creating a robust biomonitoring data set that would allow it to be solely relied upon



THANK YOU FOR LISTENING
ANY QUESTIONS?