

## **Biomet principles**

ARCHE/WCA, the founding members (NiPERA, IZA, ECI) and all new/additional members/identities (e.g. consortia, federation, company) that would like to enter their Bioavailability Tools/Models in the Biomet environment shall agree with the following principles:

- Biomet is designed to be a multi-metallic tool.
- Biomet is designed to be user friendly. Therefore all metal models included in Biomet should be based on a limited number of parameters that are readily available. The selected parameters should provide sufficient accuracy of the models.
- Biomet is designed to be available free of cost to users.
- Biomet is primarily designed to deal with compliance assessment against EU Environmental Quality Standards, such as defined under the EU Water Framework Directive. Biomet aims to be consistent with the most recent EU guidance for EQS derivation (EC, 2011<sup>1</sup>).
- The scientific principles behind Biomet are believed to be of global relevance and could be applied by metals experts outside the EU, however guidance for the implementation of bioavailability based approaches for metals may differ from that applied in Europe, or may not yet have been developed for some regions, and Biomet may not be compatible with local regulatory approaches.
- All models included in Biomet should have an equivalent level of scientific justification for their application. The technical quality and relevance of Biomet and possible new entries in Biomet should be established through review by the steering committee. The operationally-defined criteria for accepting new model entries (to be considered on a case-by-case basis) are:
  - Bioavailability models should be validated with natural waters covering a relevant range of water chemistry conditions for the region,
  - Bioavailability normalization approaches should be applicable to algae/vascular plants, invertebrates, and fish,

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<sup>1</sup> EC, 2011. Guidance Document No. 27, Technical Guidance For Deriving Environmental Quality Standards, 204 p.

- The validity of cross-species extrapolation of models to non-modeled species in ecotoxicity databases should be verified,
  - The ecological relevance of the bioavailability normalized EQS values should be checked based on a weight to evidence approach considering information such as data from field and mesocosm studies.
- Biomet will be adapted/updated according to new ruling when needed.
- All Biomet members will be made aware of peer-review publications or other publically available literature prepared or co-authored by an individual biomet member organization that critically evaluate biomet and/or utilize biomet calculations. Additionally, biomet members should be acknowledged in these publications.
- ARCHE/WCA are responsible for management/population of the Biomet website and for the further development and implementation of bioavailability tools/models in the Biomet tool.
- A fixed total amount of 4,000 € shall be invoiced annually to the founding members and new/additional members/identities for the operational costs associated with proper maintenance of the Biomet tool and website. All members will contribute an equal share to this total amount.
- Any costs for the promotion of Biomet will be in addition to the operational costs, and should be agreed by the Steering Committee.
- New/additional members/identities shall pay for the costs associated with including the additional models within Biomet.

## **Steering Committee**

- The Steering Committee agrees with the above-mentioned rules.
- Every member of Biomet is considered as a Steering Committee member.
- The following tasks are assigned to the Steering Committee members:
  - to ensure the proper quality/consistency (both technical and regulatory) of the Bioavailability Tools/Models entering Biomet,
  - to define the need, priority and timing of the updates according to the budget possibilities.
- The Steering committee is composed of representatives of the founding members (NiPERA, IZA, ECI), ARCHE/WCA and will be extended with additional/new members in case scientific/technical evidence is provided that the additional/new member is compliant with the Biomet principles (see above).
- The Steering Committee aims for unanimous consensus amongst the members regarding changes to Biomet. Only in case unanimity is not reached the steering committee will decide by quality majority (2/3) in favor of a proposal.