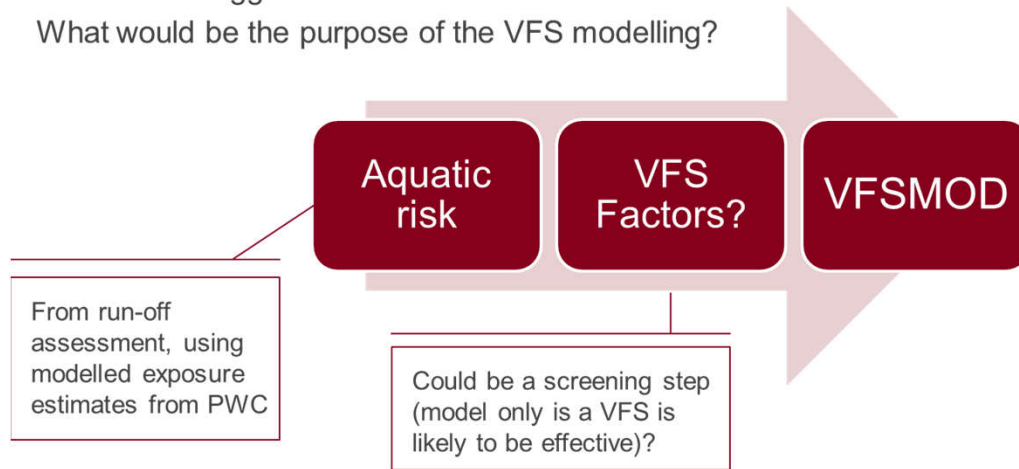


PMRA VFS Framework – Summary Slide

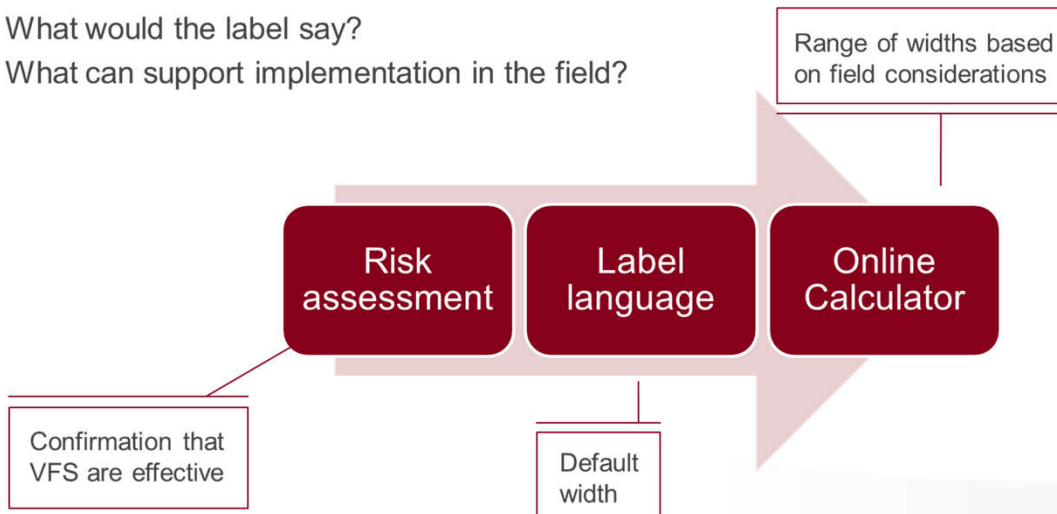
Risk Assessment

Where in the process would VFS modelling be used?
What would trigger it?
What would be the purpose of the VFS modelling?



Risk Mitigation

What would the label say?
What can support implementation in the field?



Address certain outstanding questions on modelling

- Do we have confidence in the model?
- Simpler model / adjust model for regulatory purposes?
- How can we promote harmonization in North America?
- How do we ensure version control?

Determine best direction for a draft regulatory framework for PMRA

- Solidify approach
- Gather information on field implementation
- Get feedback from end users
- Identify gaps
- Find opportunities for collaboration