



Network of reference laboratories and related organisations for
monitoring and bio-monitoring of emerging environmental pollutants

A common EU scheme for the validation of measurement methods

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Project objectives

- Creation of a network among European reference laboratories dealing with emerging pollutants
- The approach will foster:
 - co-operation and data transfer of environmental analysis ~~between monitoring institutes, risk assessors and regulatory bodies~~
 - validation and harmonisation of monitoring tools
 - accelerate the availability of reliable & comparable data on emerging pollutants

Subproject Validation

- Comparability and reliability of monitoring data
 - is essential for any meaningful assessment and management of environmental risks.
- Validation of methods for emerging pollutants:
 - often not satisfactory, or insufficiently documented
 - No harmonised approach to method validation
- There is a need for a harmonised European approach to the validation of chemical and biological monitoring methods
 - Cf. recent CEN/SABE policy paper on validation

Objectives

- Provide structured protocols the validation of monitoring & bio-monitoring methods for emerging pollutants
- Accelerate the establishment of methods that are fit for purpose
- Provide a method validation scheme that is flexible enough to address different types of methods and monitoring needs

A common EU scheme for the validation of measurement methods

- has been developed within NORMAN by biological and chemical experts
- is suitable for the validation of methods for monitoring of pollutants (and/or their effects) in water, air, soil, **sediment, biota...**
- is not restricted to emerging pollutants
- has taken into account existing european and international standards and guidelines wherever possible
 - E.g. on sampling, terminology, statistics, organisation and evaluation of interlabs/PTs, performance criteria, **uncertainty...**

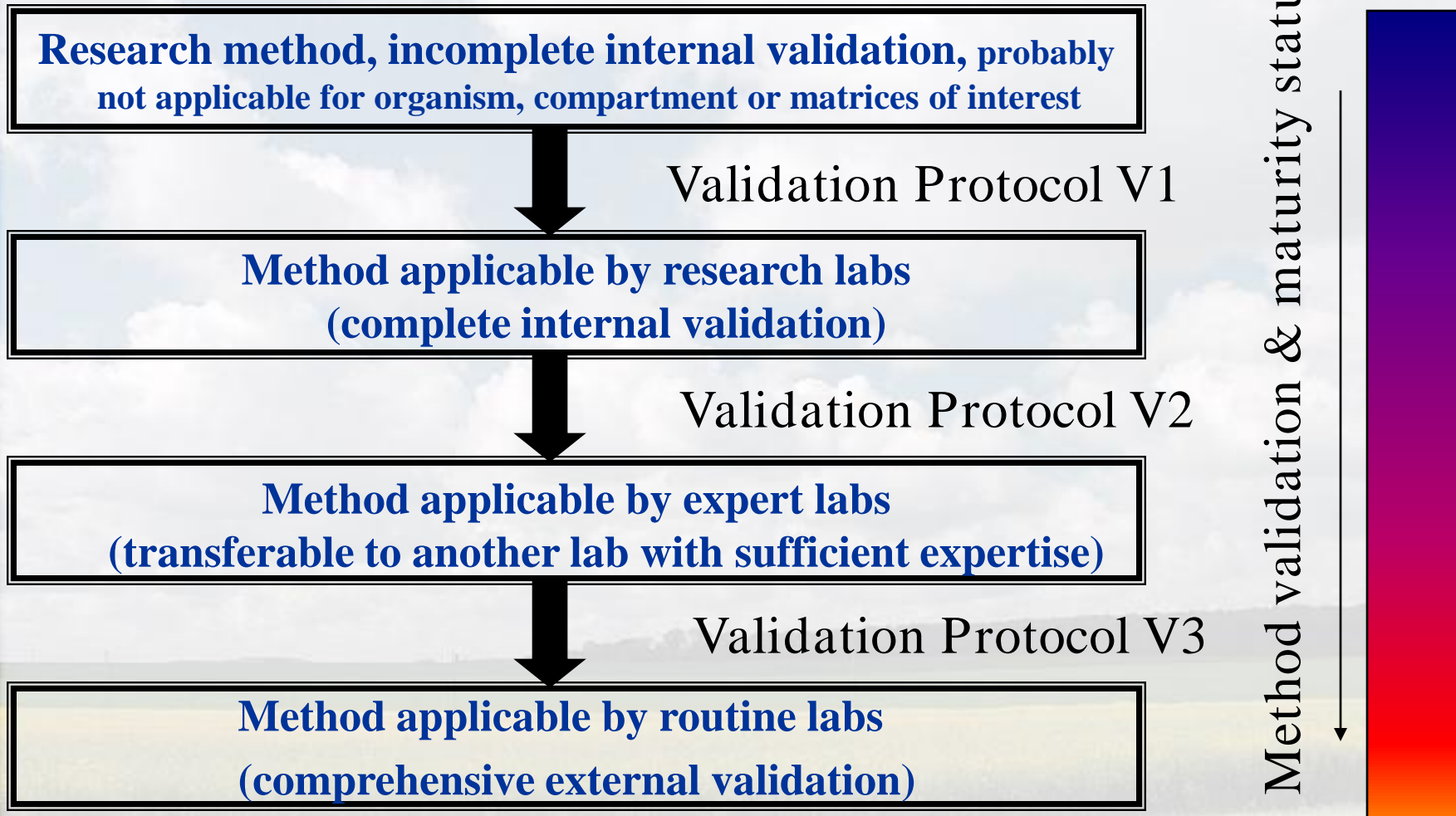
• download from www.norman-network.net



NORMAN final workshop Paris, Oct. 2008



Validation Procedure & Protocols



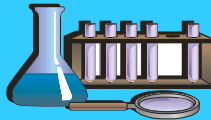
Why 3 Levels of Validation?

- European-wide monitoring is usually not needed in the initial phase of an emerging issue/pollutant
- a potential "emerging issue" may even turn out to be either
 - no problem at all
 - or only of local importance

=> method applicable by a few expert labs is sufficient
- in order to avoid the wastage of resources, our validation efforts should be adjusted to the actual needs
 - => 3 hierarchical validation levels, addressing 3 different

Scope of the validation protocols

Chemical methods



Biological methods



Air

Soil &
Sediment

Water

Marine
systems

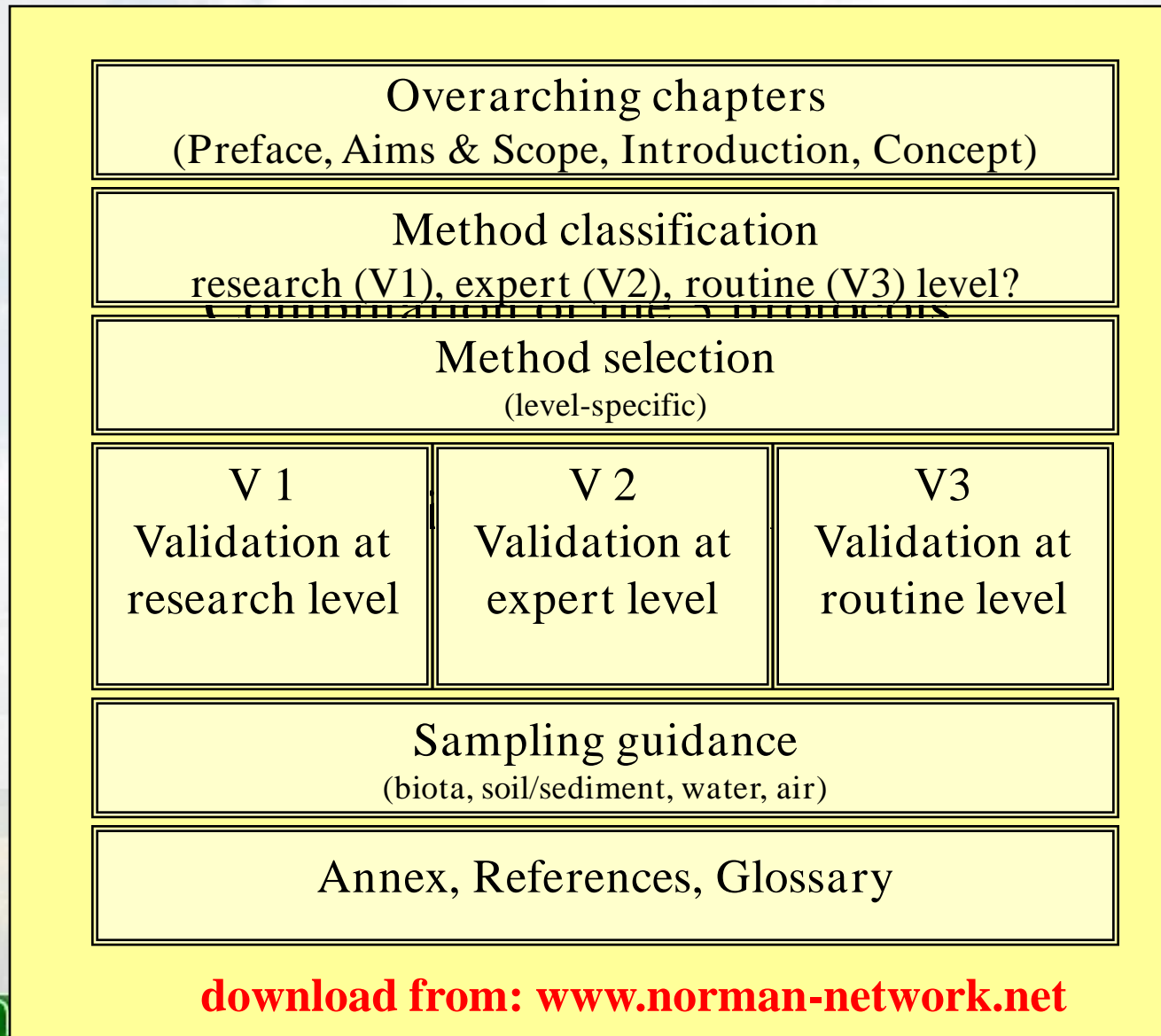
Biota

! Protocols applicable to a wide range of monitoring & biomonitoring methods (chemical & biological) and environmental matrices.

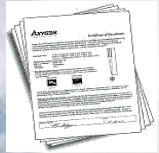
Guiding Principles

- Less specific & detailed procedures - More overarching validation principles applicable to a wide range of methods
- Integration of existing validation frameworks and approaches as far as possible (e.g. OECD, Eurachem, ICCVAM, IUPAC...)
- Use terms, criteria & procedures with a high level of acceptance in the scientific community
- Adaptation to the 3-level approach and the specific needs of monitoring labs
- Create a validation framework with enough flexibility to be applicable for all relevant validation tasks related to monitoring & biomonitoring of Emerging Pollutants

Structure & Key Elements of the Protocols



Testing the Protocols



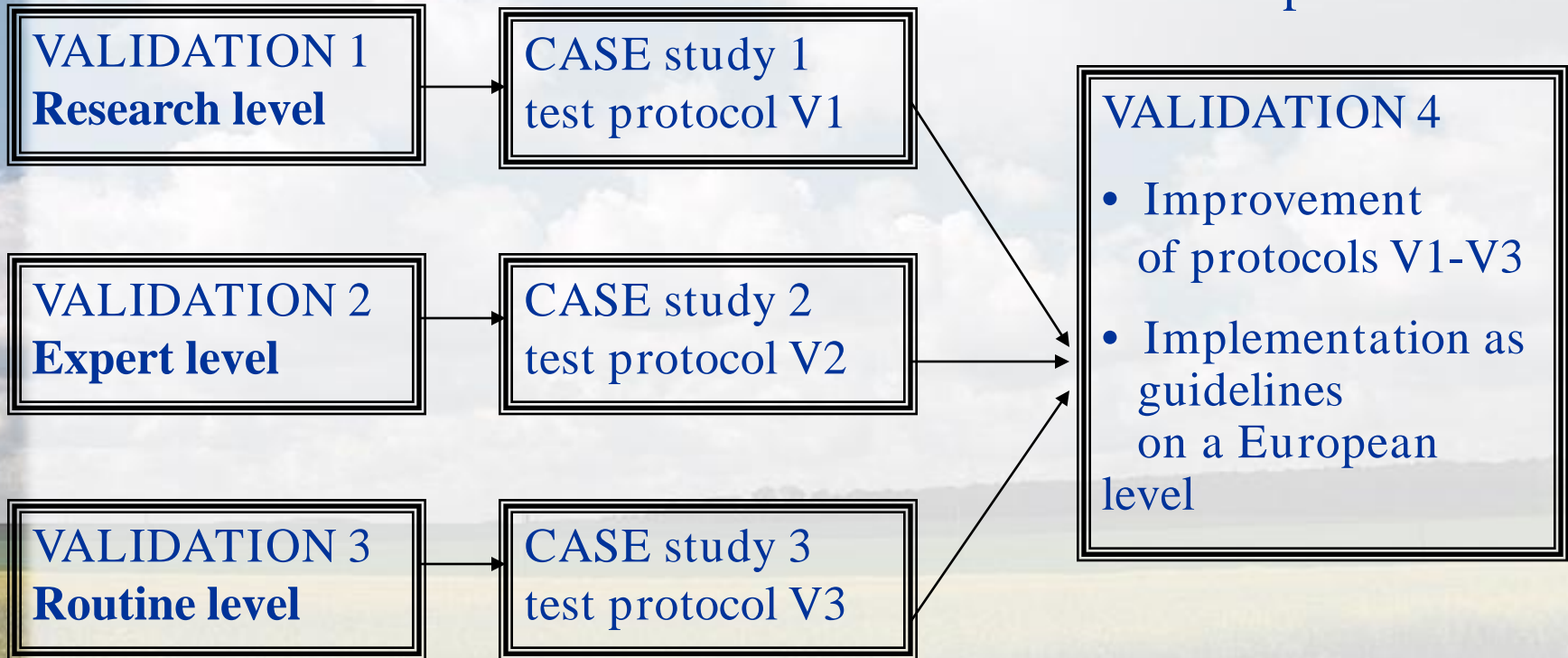
Development
of protocols



Test phase
of protocols



Feedback,
Improvement &
Implementation



Feedback from Case studies

- Protocols are clear, unambiguous, useful
- Give a good introduction to the concept of validation and the different levels
- Cover all relevant aspects of method validation
- Could be properly used to carry out the validation work in the CASE studies
- Sometimes too much details are asked for
- Some overlap / redundancies between the different chapters

Improvement of the protocols

- Removal of redundancies and overlaps especially in the requirements on documentation of method and validation results
- Structure simplified
- Increase consistency in terminology & style throughout the 3 main parts
- Additions to glossary
- Improved version will be available before end of the project (November 2008)

Implementation - Standardisation

- Initiate the implementation of the protocols in the field of European Standardisation
 - A new work item proposal for a technical guidance document will be discussed in CEN TC 230 (Water Analysis)
 - This procedure will be initiated by a proposal from the project co-ordinator to CEN
- Method validation under Mandate M 424 from DG ENTR to CEN will make use of the NORMAN validation protocols where possible

Implementation - CMA

- Propose the incorporation of the protocols in guidelines for European monitoring activities (V4.2)
 - presented to CMA group (14 May 2008)
 - Reference to the validation protocols integrated in the Guidance Document on Surface Water Monitoring

Summary

- A common framework for method validation has been developed
- The validation framework has successfully been tested in 3 case studies
- Implementation is still ongoing
 - European Standardisation (CEN)
 - CMA-related activities is still ongoing

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- UBA (Germany)
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