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

# NORMAN Working tools & activities

## The VALIDATION protocols

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# Why validation protocols?

Background:

- Reliability and comparability of monitoring data on emerging pollutants (EP) is often limited
- Methods for analysis of EP (or their effects) are often not fully validated, not harmonised or not suitable for all relevant matrices

Objectives:

- provide structured protocols for optimisation and validation of monitoring & bio-monitoring methods for EP
- accelerate the establishment of methods which are fit for purpose
- development of three validation protocols (3 levels of "validation maturity") addressing different monitoring needs

# 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 scenarios with respect to the requirements

# Validation Procedure & Protocols

**Research method, incomplete internal validation, probably not applicable for organism, compartment or matrices of interest**

Validation Protocol V1

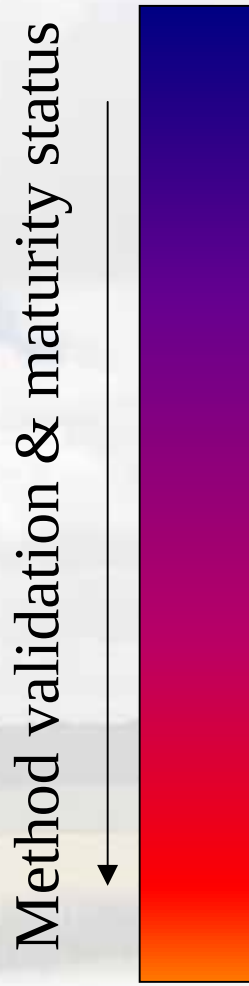
**Method applicable by research labs (complete internal validation)**

Validation Protocol V2

**Method applicable by expert labs (transferable to another lab with sufficient expertise)**

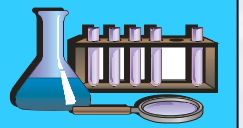
Validation Protocol V3

**Method applicable by routine labs (comprehensive external validation)**



# Scope of the validation protocols

Chemical methods



Biological methods

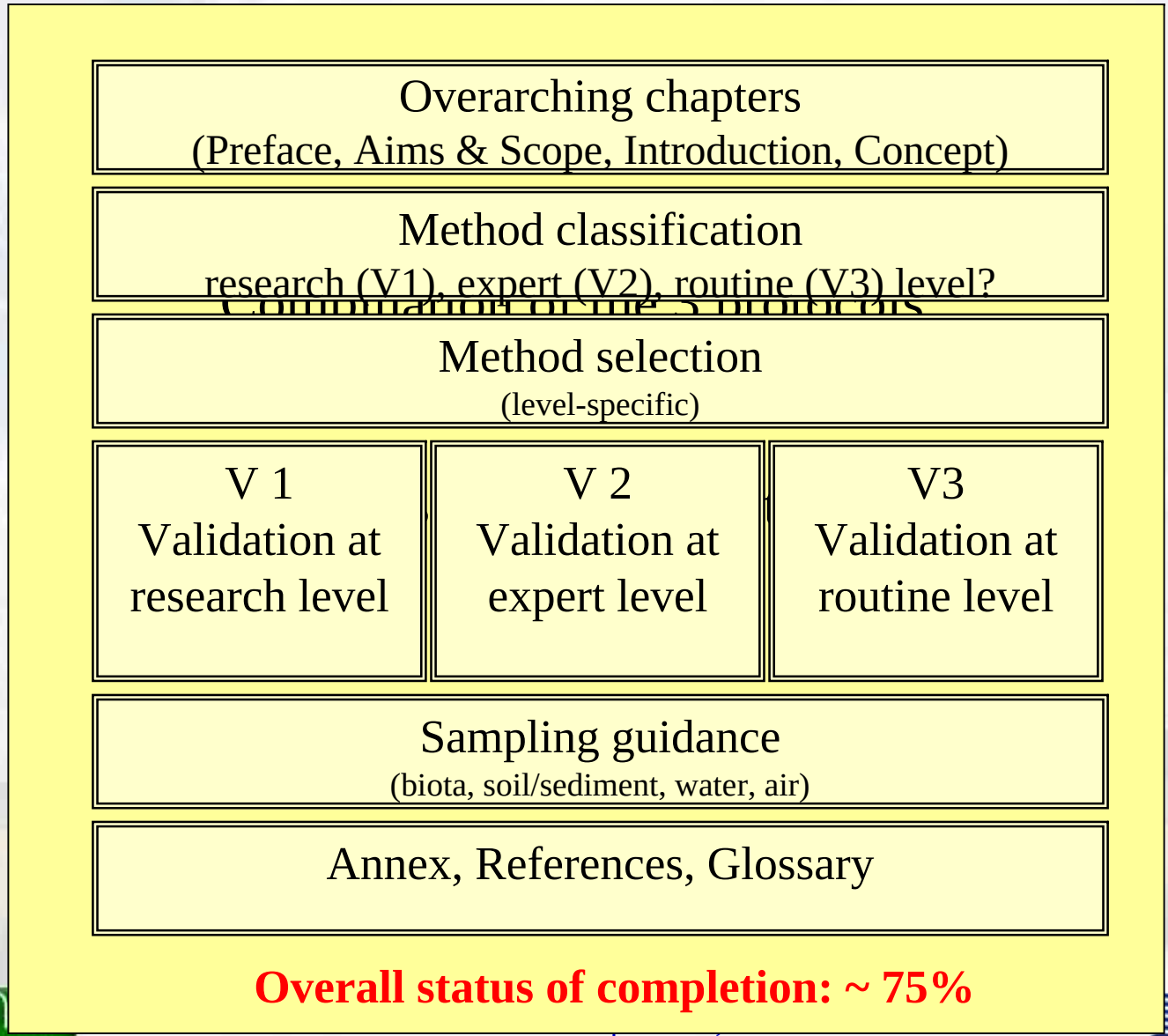
| Air | Soil & Sediment | Water | Marine systems | Biota |
|---|---|---|---|---|

! Protocols applicable to <u>all</u> types of monitoring & biomonitoring methods (chemical & biological) and environmental matrices.

# Guiding Principles

- Less specific & detailed procedures - More overarching validation principles applicable to all types of methods
- Integration of existing validation frameworks and guidelines 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 EP

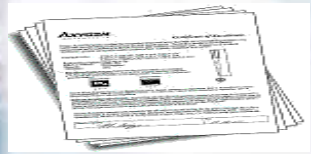
# Structure & Key Elements of the Protocols




**Overall status of completion: ~ 75%**

**Released for road-testing by CASE: Aug/Sep 2006**

# Development, Testing & Implementation of the VALIDATION protocols

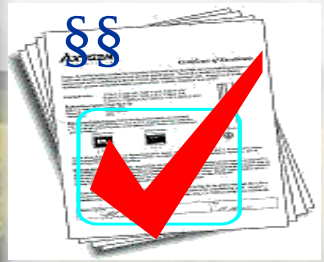


VALIDATION:
Development
of protocols

→ 3 different validation scenarios V1, V2, V3

CASE:
Test phase
of protocols

→ Inter-laboratory studies
C1, C2, C3
(matching the 3 validation protocols)




VALIDATION:
Improvement &
Implementation

→ New Work Item proposals
at CEN for development
of guidelines or CEN TR

# V1: Validation for Research Laboratories

**Selection, Adaptation, internal Validation**

## Starting point

- no method or only research methods available
- method inappropriate for matrices, compartments or organisms of interest
- rudimentary internal validation (single lab only)

## End point:

- Method appropriate for matrix, compartment or organism of interest
  e.g. sufficient sensitivity & selectivity
- complete internal validation
- no external validation
- short record of method performance

# V2: Validation for Expert Laboratories

**Method selection & external validation by „transferability study“**

## Starting point:

- Appropriate (research) method for matrix, compartment or organism of interest (sufficient sensitivity & selectivity)
- complete internal validation
- short record of method performance
- missing external validation

## End point:

- Appropriate expert method with complete internal validation
- **external validation: transferability proven**
- due to poor or unknown robustness: applicable by expert laboratories only

# V3: Validation for Routine Laboratories

**External validation, linkage of QA/QC procedures to the method**

**Starting point:**

- appropriate method with complete internal validation
- external validation incomplete
- due to poor or unknown robustness: applicable by expert laboratories only

**End point:**

- fully validated method (internal & external)
- sufficient robustness to be applicable by routine laboratories
- high degree of unambiguous documentation (SOP)
- QA/QC procedures part of method (descrition)
- realistic potential for standardisation (CEN)

# Main Tasks of the 3 Levels

## Validation at level V1 (Research Labs):

- complete internal validation (within 1 lab)
- (extending the applicability to the matrix of interest)

## Validation at level V2 (Expert Labs):

- test the principal transferability

## Validation at level V3 (Routine Labs):

- comprehensive external validation by interlaboratory method validation study (involving routine laboratories)

# Definition of Validation

Method validation is the process of verifying that a method is fit for its intended purpose,
i.e. to provide data suitable for use in solving a particular problem or answering a particular question.
This process includes:

- establishing the performance characteristics, advantages and limitations of a method and the identification of the influences which may change these characteristics, and if so to what extent, and
- a comprehensive evaluation of the outcome of this process with respect to the fitness for purpose of the method.