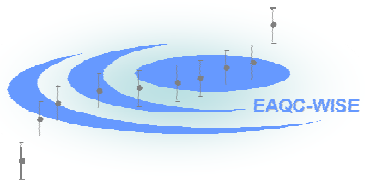

Contract n° 022603 (SSPI)

EAQC-WISE

European Analytical Quality Control in support of the Water Framework Directive via the Water Information System for Europe

Specific targeted Research Project

Scientific Support to Policies (SSP)

Deliverables number: D25

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AUTHORS:	A. Held, H. Emons, P. Taylor
AFFILIATION:	IRMM
FURTHER AUTHORS:	all project partners

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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1 Executive summary

The European Union (EU) has established a Community framework for water protection and management in order to ensure the protection, improvement and sustainable use of aquatic ecosystems across Europe. This framework is set in the Water Framework Directive (WFD).

The implementation of the WFD requires that monitoring comparability of monitoring data should be achieved at the level of the enlarged EU. Measurement data will represent the foundation of the water quality evaluation system, on the basis of which decisions will be taken on the measures required to achieve WFD environmental objectives.

Today, contrary to many other sectors, within the water monitoring community there is not a commonly shared view that achieving quality of the data is important and is a non-trivial matter. Particularly, there is a lack of awareness among decision makers.

The EU-funded project 'European Analytical Quality Control in support of the WFD via the Water Information System for Europe' (EAQC-WISE) aims to change this view and offer a Blue Print to establish a quality control (QC) system, which would for instance facilitate the provision of appropriate proficiency testing (PT) activities, reference material (RM) provision, research and training at the EU level. The ultimate objective is to develop a sustainable pan-EU quality assurance and quality control (QA/QC) system for water, biota, sediment and related soil monitoring data.

This document presents this Blue Print, in a set of recommendations towards the establishment of such a QC system.

The recommendations have been derived from research carried out in the frame of the EAQC-WISE project. Detailed reports documenting the development and detailed reasoning behind these recommendations have been issued as the deliverables of this project [1].

The recommendations have been discussed with numerous stakeholders, during the second project workshop in Brussels, June 2008 [1], at meetings of the Chemical Monitoring Activity (CMA) and other occasions. Their feedback has been incorporated into this final report.

The intention is that decision makers operating in the WFD context, in the future use the document presented here and transform it into a Guidance document under the Common Implementation Strategy.

In this document, recommendations are structured by topic (reference materials, proficiency testing, validated methods, research and standardisation and training). Additionally, there are horizontal recommendations addressing the overall structure of the quality control system (communication, expert groups).

Processes described in the recommendations are additionally visualized by a graphical representation.

2 Glossary

AOAC	Association of Analytical Communities
CA	Competent Authority
CEN	European Committee for Standardisation
CIS	Common Implementation Strategy of WFD
CMA	Chemical Monitoring Activity
CRM	Certified Reference Material: Reference Material characterised by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability [2]
DG	European Commission Directorate General
DG ENTR	Directorate General Environment
EA	European co-operation for Accreditation
EAQC-WISE	European Analytical Quality Control in support of the WFD via the Water Information System for Europe (FP6 Specific Targeted Research Project)
EC	European Commission
EC JRC	Joint Research Centre of the European Commission
EEG	European Expert Group
EPA	Environmental Protection Agency of the United States of America
EQS	Environmental quality standards [3]
EU	European Union
EURACHEM	A network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements
HELCOM	Helsinki Commission (of the Convention on the Protection of the Marine Environment of the Baltic Sea Area)
ICPDR	International Commission for the Protection of the Danube River
IEC	International Electrotechnical Commission
IKSE	International Commission for the Protection of the Elbe River
IKSR	International Commission for the Protection of the Rhine River
ISO	International Organization for Standardization
LLOA	Lower (concentration) limit of application of an analytical method
LLOA	Lower limit of application
LOD	Limit of detection of an analytical method
LOQ	Limit of quantification of an analytical method
MLA	Multi-Lateral Arrangement
MS	Member State (of the European Union)
NAB	National accreditation body

NEG	National Expert Group
NEMI	National Environmental Methods Index (USA)
NORMAN	Network of reference laboratories for monitoring of emerging pollutants related to WF requirements
OSPAR	Oslo – Paris Convention; mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic
PAH	Polycyclic Aromatic Hydrocarbon
PT	Proficiency testing – interlaboratory comparisons focused on the assessment of laboratories' analytical performance
PT-WFD	Proficiency Testing – Water Focussed Determinands; voluntary network of PT providers providing PT schemes for WFD monitoring purposes
QA	Quality assurance
QC	Quality control
RM	Reference Material: material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process [2]
SPM	Suspended particulate matter
standard	A document published by a national, European or international standardisation body, containing a technical specification or other precise criteria or procedures designed to be used consistently as a rule, guideline or defintion
SWIFT	Screening methods for water data information in support of the implementation of the WFD (former FP6 project)
TNMN	Transnational Monitoring network of the ICPDR
TSP	Training Service Provider
WFD	Water Framework Directive [4]
WFD WG of EA	a proposed group within EA that sets specifications and recommendations for the WFD sector
WG C	Working Group on Groundwater under the Common Implementation Strategy of the Water Framework Directive
WG E	Working Group on Priority Substances under the Common Implementation Strategy of the Water Framework Directive
WISE	Water Information System for Europe

3 Key actors and stakeholders in the recommendations

The project has identified a number of key actors and stakeholders for a QC system for the WFD.
These are:

Monitoring laboratories

Any laboratory that carries out measurements or operations which are used to generate monitoring data for the WFD, irrespective of its status (commercial or government owned)

Competent authorities (short: CA)

Competent authorities as defined in the Water Framework Directive (Directive 200/60/EC, Article 2(16), 3(2) and 3(3))).

National Expert Groups (NEG) on WFD-QA/QC (short: National Expert Group)

Project recommendation: Nationally or regionally formed groups of experts giving advice to the competent authorities on QA/QC issues and forming the liaison with the European Expert Group on WFD-QA/QC. Per Member State or region only one expert group is recommended.

European Expert Group (EEG) on WFD-QA/QC (short: European Expert Group)

Project recommendation: A group of experts consisting of delegates from the NEGs on WFD-QA/QC.

Subgroup on -topic-

Project recommendation: Subgroups of the European Expert Group on WFD-QA/QC dealing with a specific topic area. The subgroups should consist of those experts of the European Expert Group with relevant expertise on the topic.

Funding bodies

Bodies with the potential to provide funding for a range of activities, such as research, development of RMs, or others. Funding bodies can be national, international or EU funding bodies or groups thereof.

European Commission (EC)

The term 'European Commission' is used here without further specifying a particular Commission Service.

PT providers

Organisations (public or commercial) arranging PT schemes which are open to monitoring laboratories

RM producers

Organisations (public or commercial) producing Reference Materials, including Certified Reference Materials (CRMs).

Training service providers (TSP)

Organisations (public or commercial) offering training products and services related to WFD issues which are open to monitoring laboratories

CEN

European Committee for Standardisation

EA

European co-operation for Accreditation.

National accreditation body (short: NAB)

Bodies responsible for accreditation activities within each Member State

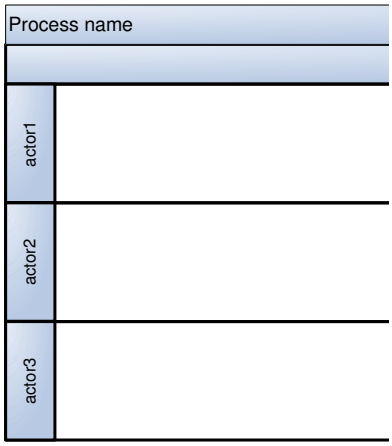
Chemical Monitoring Activity (short: CMA)

An activity mandated by the Water Directors and operating under the umbrella of both the WG E (Priority Substances) and the WG C (Groundwater). CMA consists of three main activities:

1. Activity CMA-1 – Completion and publication of the surface/marine monitoring guidance document, exchange of best practices and recommendations on monitoring programme design, sampling, selection parameters, analytical methods update, calculation methods of background concentrations, sediment and biota monitoring in support of WFD-Article 16 implementation, discussion of case studies and organisation of field trials to test methods and exchanges experiences etc. The CMA-1 Activity will provide direct support to WG E on Priority Substances and WG C on Groundwater.
2. Activity CMA-2 – Development of a common strategy for quality assurance and control of chemical monitoring data, in close connection with the progress of the EAQC-WISE project;
3. Activity CMA-3 – Evaluation of standardisation needs and appropriate actions related to them

4 Design of graphical presentations

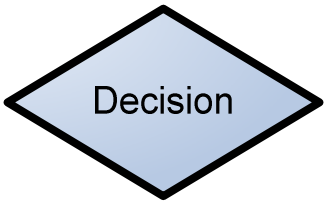
The following symbols are used in the graphical presentations of the processes:



Each process is presented as a flowchart. On top of each flowchart the name of the process is given. On the left hand side the different actors are listed. All shapes located within the horizontal band of one actor (activities, decisions etc.) are assigned to that actor.

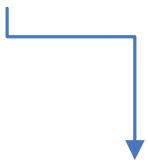
The positioning of an actor within the flowchart is purely arbitrary and does not imply any hierarchical relationship.

A rectangular shape is symbolising an activity that the corresponding actor should carry out.



A rhomboid shape symbolises a decision. Any decision in the recommendations will ultimately be accompanied by a set of decision criteria that will be provided in text format.

Cylindrical shapes represent databases.



Shapes are connected by arrows. Arrows can indicate a flow of data or information, or a sequence of actions, which is usually also accompanied with a flow of information.

5 Recommendations

5.1 Expert groups

Introduction

From the investigations conducted by the project, through questionnaires and interviews, searches on the internet and in the literature, it became apparent that there do already exist a lot of recommendable approaches for various aspects of QA/QC. There were several national or regional activities, that could serve as a model for others. Also shortcomings were noticed that differed from country to country. What was mostly lacking though was an integrated and coherent approach at the European level. Many isolated and (internationally) uncoordinated activities are going on. Due to the regional differences, a very differentiated and flexible approach towards the improvement of QA/QC for the WFD is required.

There is no need for the creation of new institutions to advance QA/QC for WFD measurements if one is able to bring together existing knowledge, ideas and best practices in a systematic way, both at the river basin, national and European level. This would create synergies and provide cost efficient solutions to many problems.

Description

In order to allow continuation of already existing activities and structures, it was felt that rigid and imposed structures and actions would actually be more disruptive than constructive. Therefore, the approach proposed by the project is a system based on expert groups – both at national and European level - that allows to react flexibly to new situations and developments and that can easily make use of existing structures. Nevertheless, it is clear that there is a great need to specify exactly the different kind of functionalities which are required, at the river basin, national and European level.

National Expert Groups (NEGs) should be created at a national or regional level, with a European Expert Group (EEG) acting as a coordination and exchange forum.

The term National "Expert Group" has to be interpreted in this context in the widest possible sense. Important is that its function and responsibilities are clearly defined and that it receives a formal mandate from the competent authority, so that its activities are formally acknowledged. It can be a group of independent experts, nominated by the Competent Authority (CA), it could as well be a particular institute in a given country, or a group of institutes, again nominated by the CA, bringing in the required expertise to fulfil its task. The actual choice of mechanism for establishing the NEGs should remain with the relevant CA and should make use of existing infrastructure as much as possible.

The expert groups should be composed of people who have different competences and come from different areas of expertise. Table 1 lists the expert profiles which one would ideally like to see assembled within an expert group. In some cases it will not be possible to have all required profiles available in every NEG. It is foreseen to compensate these shortcomings via the cooperation in the European Expert Group (EEG). At the same time one person within the expert group could provide expertise in more than one area.

Table 1: Areas of expertise recommended for members of expert groups

Area of expertise	Who could provide this expertise?
Reference Materials (RMs)	RM producer, highly experienced RM user
Accreditation	representative of EA/NAB, person working as technical assessor
Sampling	Expert monitoring laboratory, TSP, person responsible for sampling programme
Analysis of priority substances	Laboratory manager or equivalent of expert monitoring laboratory, reference laboratory or National Measurement Institute
Training	Training service provider (TSP), person from academia or national research institute
Proficiency Testing	Proficiency Testing Provider
Legislative requirements	Competent Authority (CA) or responsible at national environment agency for WFD issues

The European Expert Group (EEG) should consist of delegates of the NEGs, although care must be taken to ensure that different areas of expertise are covered. Although a smaller group of maximum 12 independent experts most certainly function more efficiently, it has to be recognised that probably all European NEGs would like to be represented in such an European Expert Group. The EEG plenum should therefore form reasonably sized topic oriented sub-groups with a high capacity to act.

Additionally, relevant stakeholders of QA/QC should be invited. A non-exhaustive list of potential stakeholders identified by the project is provided in Table 2. Inclusion of stakeholders in the NEGs is recommended, but ultimately left up to the CAs discretion.

Table 2: Stakeholders to be involved in the European Expert Group (EEG)

Stakeholder	Role of the stakeholder
European Accreditation (EA)	body representing all European national accreditation bodies
EUROLAB	the European Federation of National Associations of Measurement, Testing and Analytical Laboratories
DG Environment	European Commission Directorate General responsible for the WFD
DG Research	European Commission Directorate General responsible for research, the research framework programmes etc.
DG Enterprise	European Commission Directorate General responsible for (amongst others) standardisation and accreditation issues
CEN	European standardisation body
PT Network(s), PT providers	Representation of proficiency testing providers
Training service providers, network of TSPs	Representation of training service providers
EURAMET	European Association of National Metrology Institutes
EURACHEM	network of organisations in Europe having the objective of establishing a system for the international traceability of chemical measurements and the promotion of good quality practices

The expert groups (NEGs and EEG) will have to deal with a number of diverse tasks. Each of those is related to one or the other cornerstone of QA/QC as identified by the project. Figure 1 shows a graphical presentation of the role of the Expert Groups.

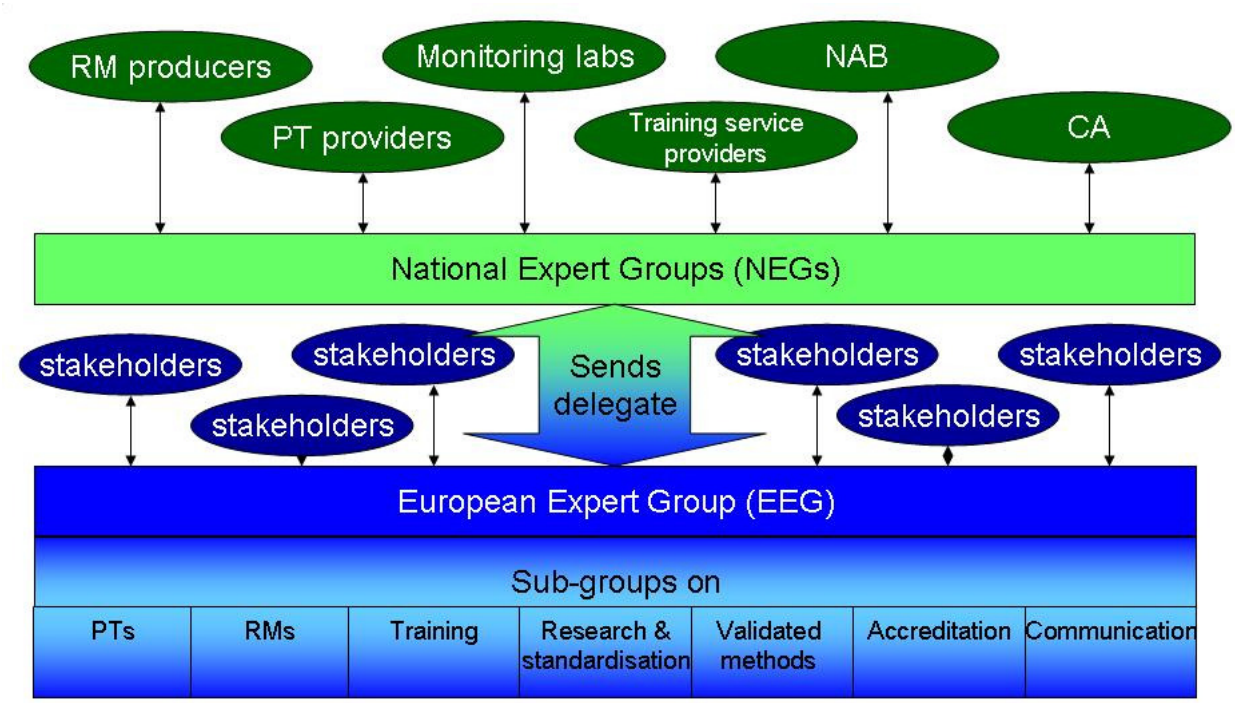


Figure 1: The role of the expert groups in facilitation of developments in different areas.

The individual tasks of the expert groups are described in the following chapters.

In Table 3 an estimate of the required working time for members of such expert groups is presented.

Table 3: Estimated time required for participation in expert groups

Task	EEG member work days per year	NEG member work days per year
Attendance of meetings	2	4
Participation to sub-group meetings	4	
Preparatory work for meetings (e.g. review of requests, evaluation of suitable QA/QC tools, updating of lists, preparation of documents, etc.)	4	4
Linking with stakeholders	4	4
Knowledge dissemination within the country	-	4

To ensure participation from all MS, obligatory participations to such expert groups would be desirable. This could be achieved through integration of this mechanism in the Common Implementation Strategy (CIS) of the WFD.

Recommendation

- Establishment of National Expert Groups (NEG) to support the competent authorities on QA/QC issues, send a delegate to the European Expert Group (EEG), provides input to and disseminates information from the EEG
- Establishment of a European Expert Group (EEG) consisting of delegates from NEGs and stakeholders, under the umbrella of the CMA or WG E (CMA), thus mandated by the Water Directors, with a clear mandate to support QA/QC for WFD, which brings together expertise in all areas of QA/QC

Recommended mandate for the expert groups

The project has identified a number of tasks that should be taken up by the expert groups. These are summarised in their proposed mandate:

Mandate National Expert Group (NEG)

- Advisory function to Competent Authority (CA) on QA/QC issues (i.e. concerning technical specifications for monitoring laboratories, interpretation of QA/QC data during data evaluation, etc.)
- Facilitate communication between all involved actors regarding QA/QC issues
- Send delegate to European Expert Group (EEG) and contribute to their tasks
- Collect information on QA/QC issues and problems from monitoring laboratories, National Accreditation Bodies, PT providers, Training service providers, RM producers, etc.
- Provide input to the database of recommended QA/QC tools
- Identify gaps and needs for QA/QC tools (e.g. PTs, RMs, training, etc.), identify the reasons for the existence of those gaps (lack of knowledge, lack of funding/resources, scientific challenge, etc.) and communicate the need to a relevant body (i.e. possible providers of the relevant tool, potential funding bodies, research programmes, etc.) at national level. If the issue has a European dimension, or cannot be solved at national level, it should be referred to the EEG.
- Early warning system: detect quality deficiencies at early stage and propose measures to CA. Provide input to the database of appropriate QA/QC tools
- The National Expert Group would be responsible to the ultimate data user (e.g. the CA) for reviewing quality control information, assessing fitness for purpose of data, for identifying areas where improvement is needed and for confirming the aspects of data interpretation (e.g. trend detection) that are directly related to quality issues.
- Send delegate to EEG and contribute to their tasks
- Definition of monitoring specifications which meet legislative needs and which can be used to define fitness for purpose;
- Determination of issues relating to analysis and monitoring of technical feasibility and disproportionate cost;

- Provision of advice to the competent authority regarding:
  - Compliance of the data with respect to the defined performance criteria;
  - Application of data screening techniques including those based on an assessment of relevant QC information as well as the more familiar “plausibility checks”;
  - Measures required for improvement in performance (from gaps that are identified as part of the continuing QC programme);
  - Advice to WISE on data collection and QC.
- Revision of the mandate, set-up and composition of the NEG in regular intervals (2-3 years) to adapt to possibly changed needs and requirements

Mandate European Expert Group (EEG)

- Advisory function to DG Environment, EEA and other relevant European bodies on QA/QC issues (i.e. concerning guidance on QA/QC, needs for legislation, interpretation of QA/QC data during data evaluation, etc.)
- Collect information on QA/QC issues and problems from NEGs, European Accreditation (EA), networks of PT providers, training providers, etc.
- Give feedback regarding their work, e.g. through relevant (voluntary) networks or other adequate channels
- Identify gaps and needs for QA/QC tools (e.g. PTs, RMs, training, etc.), identify the reasons for the existence of those gaps (lack of knowledge, lack of funding/resources, scientific challenge, etc.)
- Establish prioritised lists of needed QA/QC tools using set criteria
- Communicate the need for QA/QC tools to a relevant body (i.e. possible providers of the relevant tool, potential funding bodies, research programmes, etc.) at European level.
- Maintain a database of appropriate QA/QC tools for WFD purposes. This database should contain RMs, PT schemes, training courses and methods that have been evaluated by the EEG for their use for WFD purposes against a set of defined criteria. This database could be realised by e.g. inserting appropriate quality marks in existing databases (as e.g. COMAR for CRMs, EPTIS for PTs) but this could also be physically located in a WISE portal.
- Revision of the mandate, set-up and composition of the EEG in regular intervals (2-3 years) to adapt to possibly changed needs and requirements

5.2 Communication of QA/QC information through NEGs

Introduction

Assessments of environmental quality performed under the Water Framework Directive (WFD) must be based on monitoring data that are of known, appropriate quality. This requires the QA/QC information not only to be gathered properly but it must also be recorded, retained and communicated so that the data users are able to judge if the quality of the data is sufficient to base certain (policy) decision upon. Two conditions have to be met in order to establish the fitness for purpose of data. Firstly, analytical systems of appropriate performance must be developed and implemented (see chapter 5.5: Process for Definition of Research and Standardisation Needs). Secondly, steps must be taken to provide a robust demonstration that such analytical systems meet fit-for purpose based data quality requirements (see chapter 5.3: Proficiency testing). Consequently, adequate performance in monitoring must be both achieved and shown to have been achieved. One of the main aims of EAQC-WISE is to make recommendations on the capture, review and communication of information relating to quality assurance/quality control tools. It is also important for quality control activities to be recorded and their outcomes communicated to those who interpret data on environmental status.

The EAQC-WISE project has identified a number of points in relation to data quality and how the quality-related issues should be dealt with in the flow of data from laboratories, via the Competent Authorities (CAs) to WISE (the Water Information System for Europe). These include the need to:

- raise awareness of QC issues with data users, such that consideration of data quality is an integral part of data interpretation;
- assign clear responsibility for the definition of monitoring needs and supervision of data quality;
- provide guidance on which QA/QC features are essential for different monitoring purposes.

Discussion

Within the EAQC-WISE project the need for a commonly accepted, reliable and consistent source of expertise / advice on scientific / technical issues about data quality has been identified. In general terms, it is considered that harmonisation of practices in QA/QC across Member States should concentrate on assisting all Member States to achieve a basic common minimum standard, both in terms of what is done (QC practices) and how much of it is done (the intensity with which QC tools are applied). The aim should be to define a minimum acceptable level of QC efforts. It is proposed that this requirement can be addressed via National Expert Groups (NEGs).

Each Group would have its own clear terms of reference that are appropriate to the way in which the relevant Competent Authority manages data quality. Groups may serve several river basins or federal or local government bodies, though it is expected that Groups will be organised predominantly at national level. Group members should have a sound knowledge of current and potential analytical capabilities, be familiar with the principles and practice of QA/QC and appreciate the needs of the data user in order to be able to assess matters such as fitness for purpose and to prioritise actions that might be needed to improve data quality. The activities of the various National Expert Groups will need to be subject to coordination with respect to overall objectives and the assessment criteria used.

Expert Groups – roles, activities and participation

The communication role of the NEGs can be divided into activities prior to monitoring and after data collection.

Before monitoring commences the National Expert Group should be involved in:

- Facilitation of communication between data producers and data users on QA/QC requirements;
- Dissemination of guidance on topics including sampling scheme design and procedures and suitable analytical techniques and appropriate specific methods

After data collection, the NEG should

- Summarise QC information and review with respect to the planned data use. The NEG would be responsible to the ultimate data user (e.g. the CA) for assessing the fitness for purpose of the data, for identifying areas where improvement is needed, and for confirming the aspects of data interpretation (e.g. trend detection) that are directly related to quality issues.
- Provide (based on the assessment of QC information) advice to the competent authority regarding:
    - Compliance of the data with respect to the defined performance criteria;
    - Application of data screening techniques including those based on an assessment of relevant QC information as well as the more familiar “plausibility checks”;
    - Measures required for improvement in performance (from gaps that are identified as part of the continuing QC programme);
    - Advice to WISE on data collection and QC.

Activities of NEGs in the context of all quality-related communication are summarised in Figure 2.

The intention is that detailed QC information and other meta-data should be stored predominantly at a local level, under supervision of the national NEGs. Of course this aim should also take account of any data reporting requirements that might be specified for WISE. Where minimum data reporting requirements for QC – such as limit of detection (LOD), limit of quantification (LOQ), uncertainty etc. and other supporting information have been defined these should be adhered to. These reporting requirements are designed to provide summary information as a check on basic comparability and probably would not be sufficient to assess data quality for a completely different application. For such an assessment it would usually be necessary to access more detailed information held at a local level.

The communication between laboratories, CAs, NEGs and WISE are illustrated in Figure 3.

Compliance should be assessed via mandatory reporting requirements (of activity rather than data) to the European Commission. These might be incorporated within existing obligations of CAs.

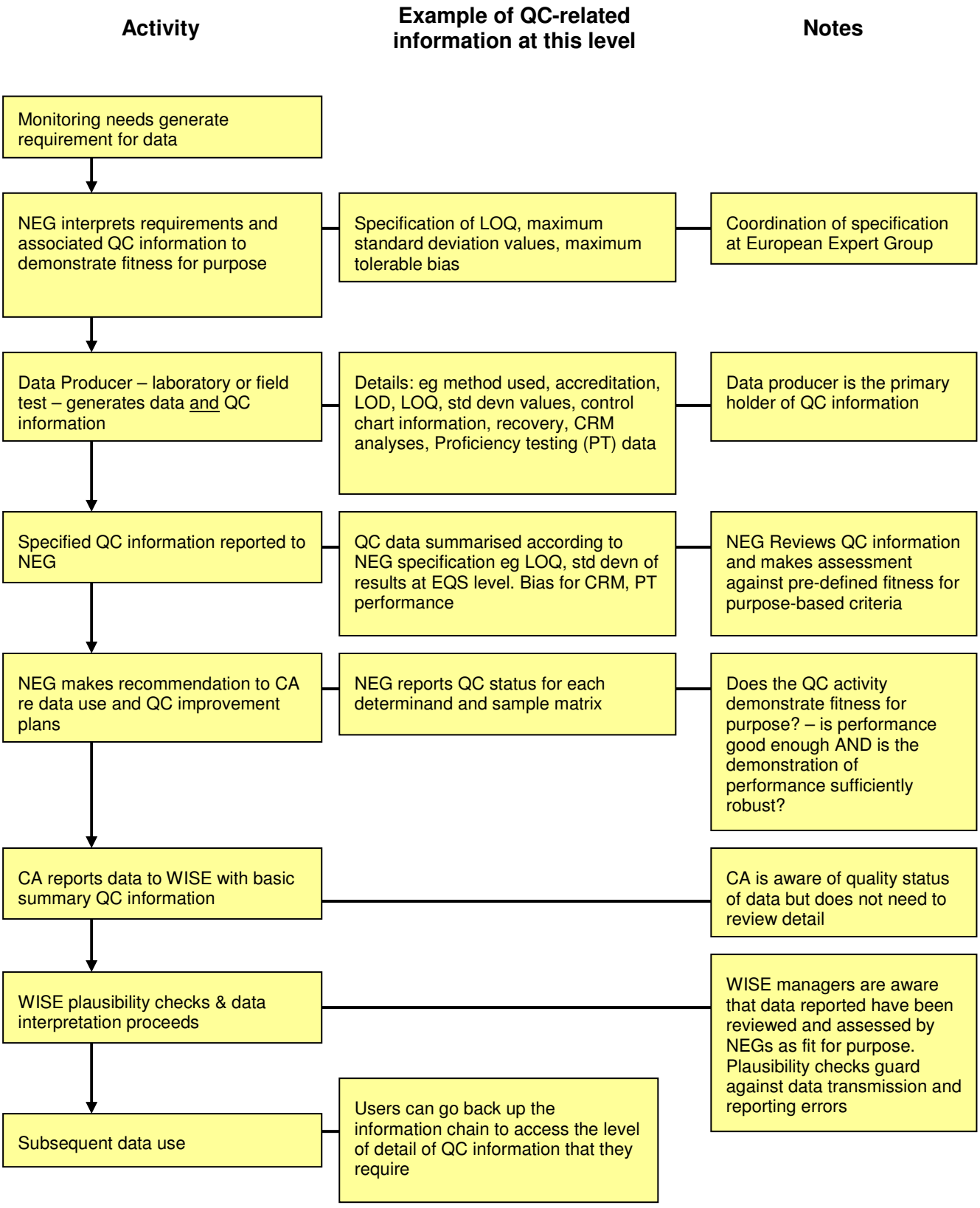


Figure 2: Illustration of the communication activities of NEGs

NEG Communication

Formulate requirements on behalf of CAs

Coordinate laboratory QC activity to meet requirements (validation, routine QC, RMs, PT)

Provide guidance on sampling and methodology

Collect and summarises key QC measures

Assess demonstration of data quality – determine QC status

Interpret QC activity for CAs

Link with other NEGs via EEG to harmonise overall approach

Figure 3: Expert Groups Communication

Recommendation

- National Expert Groups are required as a consistent source of expertise/advice on scientific/technical issues about data quality.
- National Expert Groups should be the main point of contact between WISE, CAs and monitoring laboratories on data quality related issues, they should ensure ongoing communication between these stakeholders.
- In order to facilitate the communication on data quality, the National Expert Groups should also provide the necessary background information to the involved parties, this will also help e.g. CAs to take educated and competent decisions.
- The National Expert Groups collect QA/QC related information at national / regional level and communicate that to relevant stakeholders, e.g. the CA or the EEG
- The European Expert Group should be the forum for communication between the NEGs
- The European Expert Group should foster communication between all stakeholders involved in QA/QC, through its subgroups on specific topics as well as in the plenary.
- The European Expert Group collects QA/QC related information on EU level, and communicates that to all its stakeholders as well as to all NEGs

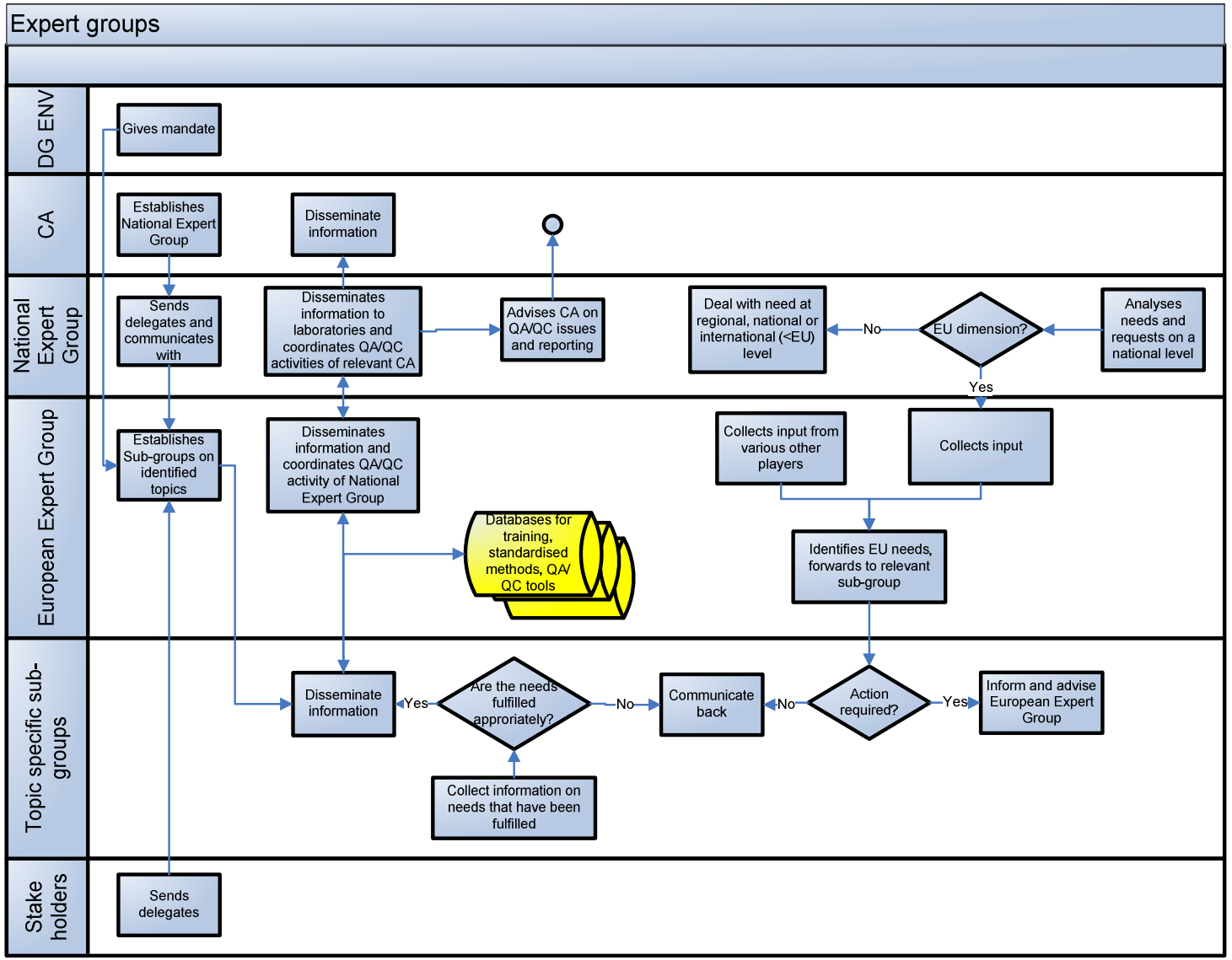


Figure 4: Flowchart showing communication between expert groups

5.3 Proficiency testing

Introduction

The pending "Commission Directive laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status" (QA/QC Directive) requires that laboratories demonstrate their competence by participation in PT schemes covering all analytes at levels of concentrations that are representative of chemical monitoring programmes carried out under the WFD. The results of participation in those programmes schemes should be subjected to performance evaluation systems as described in ISO/IEC Guide 43-1 (currently under revision and to be published as ISO/IEC 17043), or in the ISO 13528 standard or in other equivalent standards accepted at international level.

Following the work carried out within the frame of the EAQC-WISE project, a series of gaps in the field of PT have been identified. They mainly regard the following issues:

- Existence of a low number of PT providers with an uneven geographical distribution (mainly located in Northern Europe),
- Limited availability of information on organisations providing PTs suitable for WFD monitoring laboratories,
- scarce availability of schemes for emerging and/or "difficult" substances,
- scarce availability of PT schemes on sampling
- and, in particular, a lack of harmonisation in the establishment of the performance parameters, and (consequently) in the evaluation of analytical performances.

A series of recommendations can be provided mainly in relation to the needs of harmonization of PTs and availability of schemes also for "difficult" analysis regarding priority substances of the WFD list.

Two main complementary approaches are preferred, which are outlined in more detail in the following section:

- Bottom-up approach
- Top-down approach

Discussion

Bottom-up approach

Most of the gaps listed above can be filled by a self-committed network of PT providers. Such a network can provide harmonised PT schemes meeting the requirements of the WFD and ensure a comparable elaboration and evaluation of the results.

Furthermore, it is recommended that such a network should be advised by a group of external experts (e.g. from competent authorities or other scientists active in this field but not from a commercial perspective). This should ensure a high quality level, implementation of up-to-date developments and techniques, and an independent scientific control. This is an important step towards a high acceptance and sustainability of such a system.

In fact, such a "Self-committed Network of PT Providers "PT-WFD" to Support the Implementation of the Water Framework Directive" has already been founded. The official foundation of the PT-WFD Network (Proficiency Testing – Water Focused Determinands) took place in Rome – Italy on 8th October, 2008, at the premises of ENEA. The birth of this Network has been proposed, facilitated and supported under the WP 1.1 activities of the EAQC-WISE Project.

The Network is, at this initial stage, formed by 9 PT providers as ordinary members and 5 external advisor institutes, and it is open to any PT provider willing to commit to the rules of the Network as described in the technical agreement document [5]. The full list of the Network members is detailed in the table below.

ORDINARY MEMBERS – PT providers	**Country**
AQS-BW - Institute for Sanitary Engineering, Water Quality and Solid Waste Management – Universität Stuttgart	Germany
BIPEA	France
Institute Pasteur de Lille - Water and Environment Department	France
IWW - Water Centre	Germany
LGC Standards, Proficiency Testing	United Kingdom
National Institute of Chemistry	Slovenia
QualityConsult - Associazione per lo sviluppo della qualità ambientale	Italy
Quasimeme	Netherlands
VITUKI - Environmental Protection and Water Management Research Institute	Hungary

EXTERNAL ADVISORS – Experts in PT	**Country**
Aquaref - The French national reference laboratory for water and the aquatic environment	France
ENEA - Ente per le Nuove tecnologie, l'Energia e l'Ambiente	Italy
IFA-TulIn - Department for Agrobiotechnology, University of Natural Resources and Applied Life Sciences, Vienna	Austria
JRC-IRMM - European Commission Directorate General Joint Research Centre - Institute for Reference Materials and Measurements	European Commission
RWS-WD - Rijkswaterstaat Waterdienst (RWS Centre for Water Management)	Netherlands

The objective of the “PT-WFD" network is to provide harmonised PT schemes meeting the specific requirements of the WFD (in terms of analytes, matrices, and concentration levels), based on high quality criteria and organized in a harmonised and comparable way. In order to ensure consistent performance assessment, the PT providers adhering to the Network follow common rules in terms of test material typology, schemes organization/setup, data elaboration and evaluation. PT schemes run under the Network operate in accordance with the requirements of ISO/IEC Guide 43 and ILAC G13 [6], and the results will be evaluated on the basis of the internationally recognised performance evaluation systems (ISO 13528).

The self-committed Network is based on a flexible structure; the Network members are PT providers experienced with PT schemes related to WFD monitoring analyses. These PT schemes are open and available to any laboratory; they are financed by subscription fees. Whereas such activities are subject to market laws, there could also be opportunity for

public/private interaction. As an example, when some activities require research, those might be financed by public funding. The Network will keep a permanent eye on the state of the art, and will react with combined forces on new developments and gaps in the spectrum of needed PT schemes.

The presence of external experts in the PT field as external advisors within the advisory board ensures also an external scientific control of the Network operation. Being up-to-date based on regular input from external competent advisors will also increase the reputation and European recognition of PT providers in the Network.

The PT schemes in support of the WFD implementation are organized both within the individual (independent) programmes of a single PT provider under the umbrella of the Network and under joint PT programmes of Network members.

In this way, besides the harmonised laboratory performance evaluation, the Network of PT providers allows also the development of synergies among PT providers.

The value of having created such a Network lies in the potential to:

- organize PT schemes for all parameters on the Priority Substance list, including “difficult” parameters;
- organize PT schemes at European level for analytes that are analysed only by few laboratories in each country;
- guarantee a harmonised performance evaluation of European laboratories involved in WFD monitoring, thus enhancing the comparability of monitoring data obtained throughout Europe;
- decrease the cost of test samples due to co-operations among PT providers in the Network allowing a wider offer of PT schemes.
- Overcome language restrictions

This approach is regulated by the “market” rules and it is expected to exist as long as there is a market for such PT schemes.

It is recommended that the Network would be represented as a stakeholder in the European Expert Group (EEG), along with other PT providers, who fulfil the criteria of the QA/QC Directive. The PT providers should collaborate with the EEG, which would establish a list of 'recommended' PT schemes for WFD purposes, i.e fulfilling the criteria of the QA/QC Directive. This list of recommended PTs could either be published by adding an appropriate mark to existing databases of PT schemes (such as EPTIS [7]) or as a separate list, e.g. as part of the WISE portal.

PT providers may also be represented in the National Expert Groups, where appropriate.

Top-down approach

There is the possibility that some needs in terms of particular analytes/matrices/concentration levels might not be covered by any PT provider as, for instance, the market laws do not allow the organization of such schemes due to disproportionate costs.

In order to cope with this problem, it is recommended that in this case a single organizer is institutionally nominated in a top-down approach. This approach should be pursued directly by the European Commission through dedicated funds. The needs for such particular PT schemes not present on the market should be identified by the EEG. The EC itself could either organize these particular schemes (e.g. through the JRC) or publish a tender for their organization. Participation to these schemes should be free of charge but mandatory for the laboratories involved in the WFD implementation in each Member State.

The complementary top-down approach is recommended to become alternative to the bottom-up approach whenever PT providers are unable to cover a specific gap (e.g. when market forces do not support the development of necessary schemes).

This approach depends on public funding to be made available and should therefore only be used in a short term perspective limited to the start-up phase of WFD monitoring activities or the introduction of new, emerging pollutants into the monitoring schemes. Therefore, it is recommended to favour the bottom-up approach wherever possible. The top-down approach should only be a second choice and limited to crucial PT schemes that cannot be offered on a commercial basis.

Recommendation

The bottom-up approach (self-committed network following harmonised rules) shall be preferred and should be capable to guarantee a long term self sustainability.

Operation of the already existing network of PT providers should be recognized and promoted by EC, e.g. by informing Member States and recommending participation in PT schemes organized under the umbrella of the Network.

The PT-WFD Network should be represented as stakeholder in the European Expert Group on PT, along with other PT providers fulfilling the criteria of the QA/QC Directive.

With regard to the top-down approach, EC funds should be dedicated for the organization of “difficult” PT schemes only when the costs and/or risks of failure are not affordable on a market basis.

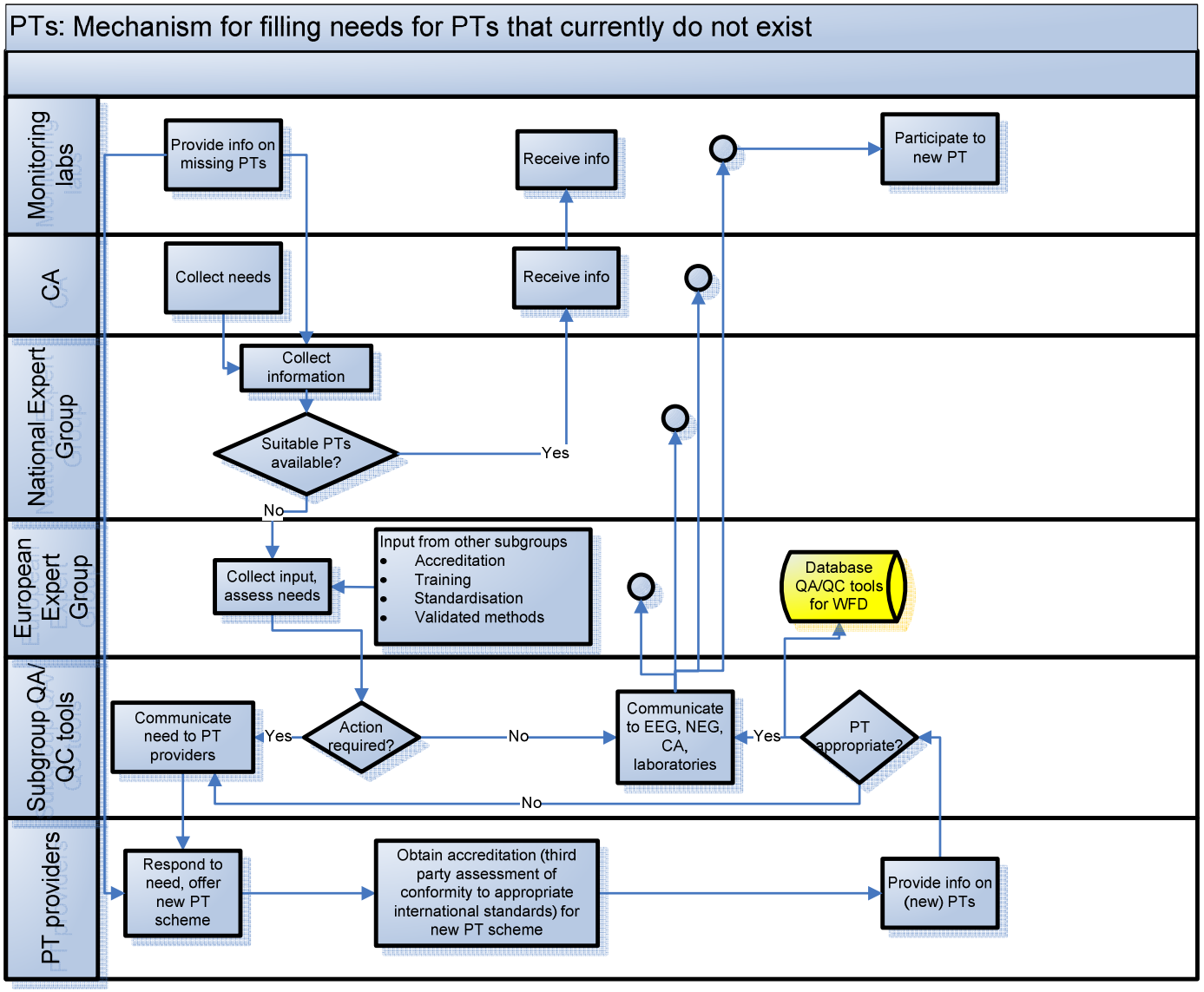


Figure 5: Flowchart showing the mechanism for identifying and filling gaps in the provision of PTs

5.4 Reference Materials

Introduction

Currently, new developments of Reference Materials (RMs), and in particular of Certified Reference Materials (CRMs)*, are mainly triggered by the initiative of RM producers, as a response to customer requests or as a response to new demands (driven by legislation, technology etc.). An assessment of the availability of CRMs for WFD chemical monitoring carried out within the frame of this project [8] has shown that these mechanisms are not sufficient to ensure the complete availability of RMs for this purpose. The following process is proposed to ensure increased availability of RMs for WFD monitoring purposes:

Discussion

The European Expert Group (EEG) and its subgroup on QA/QC tools should regularly assess the situation with regard to the availability of suitable CRMs for WFD monitoring purposes. The suitability of existing RMs should be evaluated by the group members against a set of criteria listed further below. RMs fulfilling the criteria should be collected on a list which should be made publicly available. This could either be done via an appropriate mark on the RM in existing databases for RMs (such as COMAR [9]) or via a dedicated QA/QC tools database or list on the WISE portal.

Information on missing RMs or problems with existing materials should be systematically and regularly collected from monitoring laboratories and competent authorities by the NEGs. The collected information should be checked against the list of available and recommended RMs by the NEGs. If applicable, advice is given to the origin of the request. If the request indeed indicates a problem with, or lack of, a RM, this information is passed on from the NEG to the EEG, unless the problem can be addressed at a national level. At this level this information is combined with information from other NEGs and with information on potential needs for RMs from other sources, e.g. the subgroups on accreditation, standardisation, validated methods, training, etc. as needs for new RMs might also arise from new developments in these areas. The European Expert Group should also closely monitor new developments in legislation (through liaising with corresponding Commission DGs) and emerging pollutants, to anticipate any needs for new RMs.

The combined information is then passed on to a subgroup of the EEG dealing with QA/QC tools. This group assesses the proposals and requests against a set of criteria in order to decide if and which action needs to be taken, and if so, what action. Any outcome is communicated back along the information chain to the origin of the request.

If the assessment identifies a need for a new RM, the group makes this information available to all interested RM producers. In order to do so, a list is established with CRMs for which a need has been identified. This list should also indicate priorities or urgencies that could help RM producers to start first the production of the most urgently needed materials. RM producers should provide feedback if they agree to take up the project, this should be communicated to other RM producers by the European Expert Group in order to avoid

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* The term ‘reference material’ (RM) is a generic one for various materials which are needed in measurement and testing procedures in addition to the sample to be analyzed. All materials possessing the characteristics of adequate homogeneity and stability required for calibration or quality control operations of a given measurement belong to the RMs. A subgroup of RMs is formed by the certified reference materials (CRMs). For a CRM a certificate is provided, giving for a specified property (quantity or qualitative attribute) a certified value with its uncertainty and a stated metrological traceability. Further details about these minimum quality characteristics of CRMs are explained in the corresponding ISO Guides. RMs which are not accompanied by a certificate are often simply called non-certified reference materials. But many other terms such as in-house materials, quality control materials, laboratory control materials or laboratory reference materials are also used.

duplication of work and waste of funding. The material in question would be appropriately marked on the list. In parallel, the list should be given to all possible funding bodies that could provide support to the development of a new RM.

The RM producer should develop and produce the new RM according to appropriate international standards and should be subject to accreditation.

RM producers should pass information about any new RM of WFD relevance (even if produced without being triggered by the described mechanism) to the EU subgroup on QA/QC tools.

The subgroup assesses the appropriateness of the new RM for WFD monitoring purposes against a fixed set of criteria. The outcome is communicated to the RM producer and the EEG. If the outcome is positive, and the material fulfils the criteria for a recommended RM, the new RM is entered into the QA/QC tools database. A negative outcome will trigger another action of the subgroup on QA/QC tools to initiate another attempt to produce this RM. The lists are updated accordingly.

The availability of a new RM is communicated back to all actors in this process, especially down to all involved monitoring laboratories and national accreditation bodies, via the NEGs and other appropriate communication channels.

It might occur that no RM producer responds to a need for a new RM. The subgroup on QA/QC tools needs to investigate the reasons for this and address them at the appropriate place: e.g. if it is due to a lack of funding, this needs to be communicated to potential funding bodies; if there is a scientific/ technical problem, the issue might be passed on to the subgroup on research to initiate further research on the topic, etc.

The process will only run in a sustainable way if there is a clear mandate to the expert groups to act in the way described (see chapter 5.1 Expert groups) and if the stakeholders involved are convinced of the importance of this matter.

The success of the process also heavily depends on the responsiveness of funding bodies to the proposals of the expert groups.

Criteria for appropriate CRMs to be entered in the WFD-QA/QC tools database:

- Certified property relevant for WFD (e.g. parameters mentioned in WFD or listed in priority substance list [10], identified as emerging pollutant by relevant expert group, …)
- Matrix relevant for WFD, i.e. water with appropriate suspended particulate matter (SPM) content, sediment or biota
- Concentration level relevant for WFD, e.g. in comparison to Environmental quality standards (EQS) and limits given in QA/QC Commission Directive, for other parameters: compare to range to be expected in EU waters
- CRM produced according to ISO Guide 34, preferably by an accredited RM producer

Criteria for prioritization of the list of needed RMs:

- Priority should be given to the production of such RMs where:
- There is an obvious lack of comparability in monitoring data for the parameter-matrix combination under question;
- No other QA/QC tools are available (e.g. PT schemes);
- The parameter is needed to be monitored in more than one Member State of the EU;
- The parameter is only locally relevant, but of critical importance to the status of the water bodies in that region;

- Existing CRMs for relevant parameters (as defined above) demonstrate insufficient traceability to stated and appropriate references

Despite these mechanisms, there will always be a number of parameters for which no appropriate RMs are available. This is due to the unlimited possibilities of analyte-matrix combinations, for which RMs might be requested or required, and to the limited resources that can be dedicated to their production. Moreover, there are also scientific-technical challenges which may prohibit the production of a certain RM, at least for some period of time. In this case temporary approaches have to be used by monitoring laboratories for a while, such as using stored excess samples etc..

There are existing guidance documents that can help the monitoring laboratory to overcome the lack of a CRM, [11, 12]. Also the ISO Guide 80 (in preparation) "Production of Reference Materials for metrological quality control" will provide some guidance.

PT schemes are another source of Reference Materials. Many PT providers offer their materials for use as quality control samples also after a particular PT scheme has been concluded. Although this is a valuable approach, especially if RMs of this type are otherwise not available, it has to be noted that this can potentially carry some risk for the PT provider as well as for the laboratory using them. PT materials are produced for use during a limited period of time. The validity of the data characterising this material is usually not checked beyond the time frame of the PT round. If this material is used much later, the material might have deteriorated and give false results. A laboratory that is aware of this issue might nevertheless decide to use such a PT material, but there is a possible liability problem for the PT provider.

Recommendation

- The EEG should establish a prioritized list of RMs that are currently missing for WFD purposes
- The EEG should identify new needs for RMs at the earliest possible stage
- The EEG should trigger the production of new RMs by providing information to the necessary actors (RM producers, funding bodies, research organisations etc.)
- The EEG should maintain a list of appropriate CRMs in the database with appropriate QA/QC tools for WFD
- The EEG should provide guidance and advice to the NEGs and to monitoring laboratories for those cases where no RMs are available (yet)

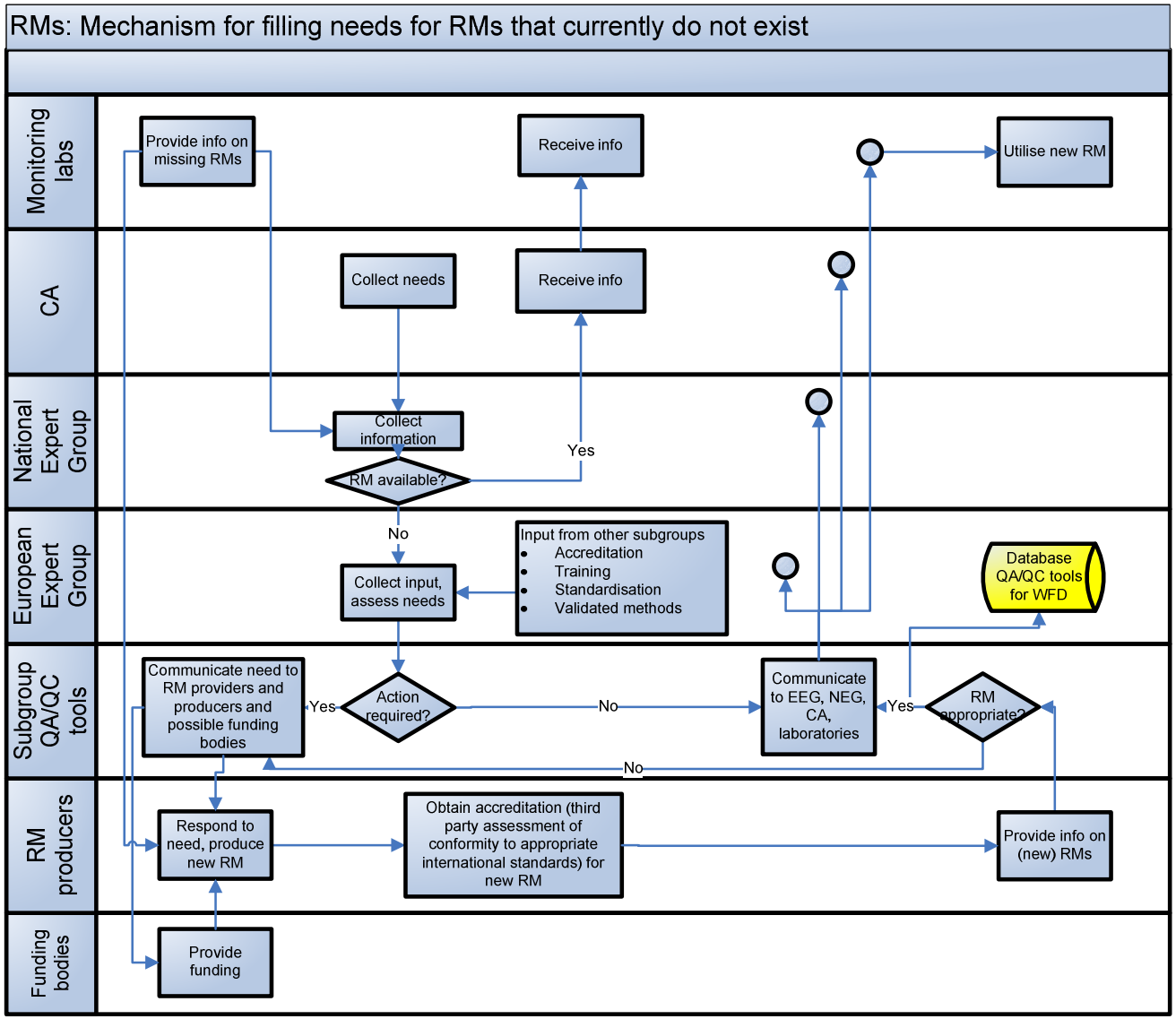

Figure 6: Flowchart showing the mechanism for identifying and filling gaps in the availability of CRMs

5.5 Process for Definition of Research and Standardisation Needs

Introduction

Analytical and sampling methods and QA/QC tools required to provide reliable data for the WFD implementation are often the product of research and subsequent standardisation. Numerous requirements arising from the implementation of the WFD are still a challenge for existing methods, and thus create the need for the development of new tools and techniques by means of research activities. Once a new tool or technique becomes widely disseminated and applied, this will usually lead to a demand for standards. Furthermore, discrepancies between already existing methods and requirements will also result in a need for improved standard methods, which means again a link back to research activities.

It is recommended to establish an institutionalised procedure how to define, prioritise and initiate such research and subsequent standardisation activities, in order to prevent duplication of efforts in EU Member States, and to facilitate the development and implementation of harmonised methods and QA/QC tools meeting the requirements of European environmental regulations.

Within the EAQC-WISE project, research needs have been derived from a representative number of completed and on-going European research projects. The needs for methods applicable to WFD-related monitoring were prioritized and the results can be found in the final report of the work package 2 of this project [13]. The process of research needs definition was carried out back-to-back with the recommendations concerning standardisation and both were prepared in close co-operation among the project partners, experts from the CMA group, and the representatives from standardisation bodies.

In addition to the prioritised list of research needs, an overview of available validated and/or standardised methods has also been established (see chapters 5.5 and 5.6) and a mandate was issued from DG ENTR to CEN for the development or improvement of standards in support of the Water Framework Directive [14]. This mandate comprises tasks ranging from research to standardisation, e.g.

- Pre- and co-normative research;
- Development of standards not yet available;
- Revision and adaptation of existing standards.

Therefore, the process that led to this mandate is a valuable and successful example of how such an approach to define, prioritise and mandate standardisation tasks as well as research needs may work in practice. In the following, the main steps of this process are sketched in a generalised way that will render it applicable to other future tasks as well.

The structure of the process is very similar for both, research and standardisation needs, as these two processes are parts of one common cycle (research – application – standardisation). The difference is that the standardisation process is already highly institutionalised while research activities are mostly driven by different actors at the national and EU level.

These differences in detail are taken into account by providing separate flow diagrams for the two processes.

Discussion

A process for definition, evaluation and prioritisation of research and standardisation needs may include the following steps:

1. WFD implementation implications – task analysis

A need for research or standardisation is usually created by a task or obligation imposed by a regulator. For instance, the process of definition of the status of the water bodies imposes increased requirements on the availability of appropriate methods for collecting information on the necessary quality elements according to the relevant legislation (WFD Annex V [4], the proposed EQS Directive [19]). The first step should be a thorough analysis of the tasks, which should result in a clear description of the tools or methods that are needed to fulfil the requirements. This should include a detailed description of the specifications (e.g. minimum performance criteria) that have to be met by the tools or methods.

This step should be organized by the EC in cooperation with the relevant expert groups under the WFD CIS and the national experts responsible for status assessment. It should also be supported by input from competent authorities of Member States reporting needs to the EC via the National Expert Groups.

2. Enquiry on existing tools and methods

This can be done in several steps:

- Literature search (scientific literature & standards)
- European expert survey

A survey should include academia, monitoring laboratories, standardisation bodies and competent authorities as well as other key stakeholders such as international river/marine commissions, networks of laboratories. A careful selection of the target audience is essential. It is recommended that such surveys will be carried out by the European Expert Group or its relevant subgroup.

3. Evaluation

It is very likely that methods or tools for the given task are already available, having however a different level of scope, applicability and quality of outputs. A detailed evaluation and assessment whether the existing tools and methods are appropriate and fit-for-purpose has to be carried out primarily by the European Expert Group in cooperation with the EC JRC and the key stakeholders (international river/marine commissions, networks of laboratories).

4. Gap analysis

Characteristics of the existing tools and methods have to be compared to the requirements derived from the first step (WFD implementation implications – task analysis). There are many factors that have to be taken into account when assessing if an analytical tool is fit for the purpose or has the potential to become a standardised method (e.g., reliability, working range and sensitivity, robustness, cost-effectiveness). It is recommended that this should be done by the EEG in cooperation with the EC JRC and the key stakeholders (international river/marine commissions, networks of laboratories).

5. Definition and classification of the work to be done

Gap analysis will lead to the definition and classification of the work to be done.

In close consultation with the relevant CEN committee, the EEG or one of its subgroups / working groups will classify the tasks according to the following proposed categories:

Tasks for fundamental research

Tasks for applied, i.e. pre-normative or co-normative research

Task for improvement or development of standards based on existing tools / methods.

Three major areas of concern can be identified: (i) making sure that for all WFD quality elements there will be methods available having performance compliant with the provisions of QA/QC Directive taking into account the respective environmental quality standards; (ii)

the tasks for the fundamental research activities should focus primarily to the newly emerging substances (and to the other substances according to the WFD Annex V, if necessary) and to development of screening techniques able to detect wide-range of substances; (iii) standardisation activities necessitate development of appropriate analytical tools sufficiently robust and easily applicable.

6. Prioritisation

Criteria for prioritisation must be derived based on the relevance of the missing tools for the proper implementation of the WFD. Furthermore, the prioritisation should allow sufficient flexibility to react on emerging issues that are not explicitly regulated in the WFD or its daughter directives.

The following criteria (in decreasing weight or relevance) are suited for a prioritisation:

- Relevance for the proper implementation of the WFD
- Relevance for the protection of environment and consumer
- Potential of the existing approach to match the requirements
- Anticipated costs in relation to existing resources and risks to be assessed / managed.
- Sustainability, environmental health & safety aspects of the approach / method.

As an example, a key priority is to ensure that the performance of analytical methods corresponds to the requirements of the adopted environmental quality standards. Furthermore, a cost-effectiveness analysis has to be carried out to ensure the economic aspects of the proposed research activities.

In case of standardisation, it should also be evaluated whether there is actually a need for a standardised method, or whether a properly validated non-standardised method would also be sufficient. The standardisation of sampling techniques and methods for determination of operationally defined parameters (or parameters where specific conventions have to be fixed in order to achieve comparable results) should be treated with highest priority.

It is recommended that this prioritisation process should be carried out by the EC with technical support by the EC JRC.

7. Feedback

It is recommended that the result of the prioritisation process by the EC is communicated to the EEG.

If standardisation needs have been defined, the regulator (EC) should mandate the relevant standardisation body (i.e. CEN) to initiate a new standardisation activity. CEN will clarify after internal consultation whether it will be possible to initiate new work item proposals for the methods or tools required. Funding possibilities would be negotiated between EC and CEN.

If research needs have been defined and prioritised, the regulator should take appropriate steps to ensure that the necessary research activities can be initiated and funded.

Ensuring sustainability of the process

The sustainability of the above mentioned process will be ensured through the regular involvement of both actors and stakeholders. The actors are the European Commission and the expert bodies under the WFD CIS (e.g. CMA) in cooperation with the EC JRC. They should make efforts to define the approaches to be used at the EU level for monitoring of WFD quality elements and ensuring comparability of results. Such actions should include advisory and guidance on the design of the monitoring networks, on the sampling and sample preparation part as well as on the analytical tools. One of the outcomes of these actions will be highlighting the needs for future research activities.

Comparison trials for monitoring approaches

In the process of implementation of the WFD, it is important to harmonise the approaches used at the national level for monitoring of WFD quality elements and to guarantee comparable results, starting from the setting up of the monitoring networks, via the sampling and sample preparation to the chemical analysis. Such harmonisation requires a close communication between the European Commission and the Member States as well as among Member States. This process should therefore be accompanied by a series of practical exercises that provide results in order to help adjusting monitoring strategies in a harmonised way.

The current idea of technical on-site Chemical Monitoring Activity (CMA) workshops aiming at comparison of different approaches in monitoring is a good example of such an approach. This approach seems to be an effective way for ensuring the establishment of coherent programmes for the monitoring of water status in line with WFD Art. 8. It is also an appropriate way to make sure that the data collected in different river basin districts will be comparable. The gaps and problems discovered during the trials serve as trigger for defining the research needs. In future therefore it will be important that more such exercises are carried out, reflecting the needs of Member States and helping to harmonise approaches and their further development on European scale.

Ensuring sustainability requires also a continuous feedback from the stakeholders. In this respect two key types of stakeholders can be identified: international river/marine commissions and networks of laboratories.

Cooperation within international bodies

Monitoring activities under international river (IKSR, ICPDR, IKSE) or marine environment (OSPAR) protection commissions can be considered as examples on joint sampling, measurement and reporting. The products of these cooperation activities, which are guided by the EU legislation as well as by the international legal treaties, are outstanding examples of practical application of multilateral harmonization protocols in the field of monitoring and assessment.

The cooperation on monitoring and assessment under the international commissions includes setting the framework for harmonization of national QA/QC approaches, which is also beneficiary for standardisation processes. The structures of analytical quality assurance and control schemes are established under international commissions and represent a unique platform not only for assuring the reliability of monitoring data but also for joint formulation of future research needs. The cooperation between those commissions on EU level can be an excellent framework for defining the research needs concerning WFD analytical QA/QC issues on a regular basis.

Networking of laboratories

A laboratory network could be a suitable tool to contribute to WDF implementation process by providing the necessary background information as well as guidance on analytical tools including QA/QC. This would be especially helpful in support of the national regulatory processes for the other pollutants. Through the network the water laboratories could have an access to information on key issues such as:

- Sampling procedures and analytical methodologies for emerging (“other” in WFD terminology) substances;
- Information and respective recommendations for internal QA/QC procedures compatible with the standardized accreditation requirements;
- Interlaboratory proficiency testing schemes;

- List of available/proposed national environmental quality standards for water, SPM, sediments and biota;
- Experience with application of ecotoxicological analyses and their combination with the results of chemical screening methods;
- General guidance on analysis of emerging substances.

There are examples of such existing or proposed international cooperation of water laboratories (TNMN under ICPDR, NORMAN – network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances).

These networks have a high potential for ensuring the sustainability of the process.

Link with other recommended processes:

The process of definition of research and standardisation needs is strongly linked to the following processes:

- Provision of validated methods. The availability of properly validated methods suitable for use under the implementation of the WFD is based on the efficient functioning of the processes “Research and Standardisation”.
- Proficiency testing. Application of the outcomes of research activities into real life requires regular quality control. This can be a two-way process as the application of proficiency testing may trigger further research needs.
- The definition of research or standardisation needs may also result in an input to the process dealing with the existence and availability of reference materials.

Practical implementation of the processes described above should be ensured by cooperation of key actors and stakeholders and should be rather problem-driven than legislation driven with the major driving force being WFD enforcement using the most effective approaches.

Recommendations

It is recommended that the need for new or improved methods, tools or standards is reported from competent authorities of the Member States to the National Expert Groups, who will collect and transmit them to the European Expert Group.

This should be followed by an investigation on existing tools (e.g. by a survey), an evaluation of the outcome and a thorough gap analysis. It is recommended that these tasks are carried out the European Expert Group or one of its subgroups.

The European Expert Group will collate these reports, analyse and define the detailed tasks. The EEG shall be mandated by EC to do this collection of information and task definition.

The same group should develop a definition and classification of the work to be done. In case of standardisation needs, this should be done in close consultation with the relevant CEN committee.

It is recommended that in a subsequent step a prioritisation of the tasks should be carried out by the European Commission (with technical support from JRC).

The prioritised task list should be communicated to the European Expert Group (and CEN, if standardisation issues are concerned)

It is the task of the regulator (EC) to provide the ground for the initiation and funding of research or standardisation activities, either by use of a tender process or as a mandated work (e.g. as mandated New Work Items at CEN).

Finally, the regulator (i.e. EC) has to decide about the implementation of the results of these process (e.g. new method or new standard) within the regulatory framework. Practical implementation of the process should be ensured by cooperation of key actors (EC, EEG and NEGs, standardisation body) and stakeholders (international river/marine commissions and networks of laboratories) and should be preferably driven implicitly by WFD implementation needs rather than explicitly by any newly defined legislation.

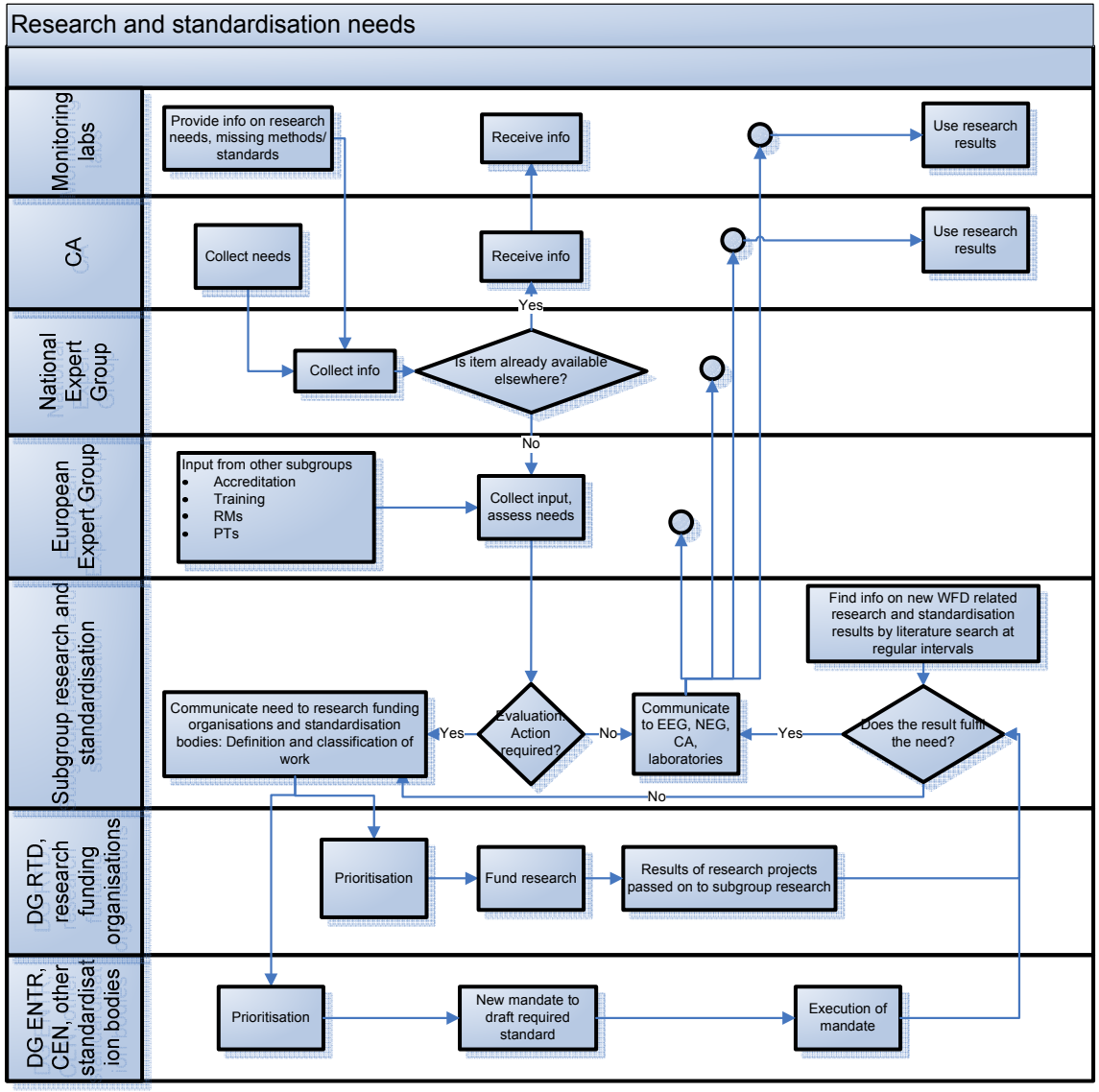

Figure 7: Process for the prioritisation of research and standardisation needs

5.6 Validated methods

Introduction

According to Article 8 and the requirements of Annex V of the Water Framework Directive (WFD), EU Member States are committed to monitor priority substances on a regular basis in all relevant water bodies and to check compliance with the environmental quality standards (EQS) set up in the “Position of the European Parliament adopted on 17 June 2008 on the Council common position with a view to the adoption of a directive of the European Parliament and of the Council on environmental quality standards in the field of water policy and amending Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and 2000/60/EC (11486/3/2007 – C6-0055/2008)”. In those cases, where the definition of EQS does not guarantee a protection against indirect effects and secondary poisoning, EQS for biota should be specified by the Member States. Furthermore, the Member States shall set up EQS for sediment or biota where it is necessary and appropriate to complement the EQS set up on Community level.

Compliance checking with EQS needs reliable data obtained by reliable methods. CEN, ISO or EPA have published standardised methods for all 46 relevant substances with the exception of C10-13 chloroalkanes. Nevertheless, these methods were not developed to meet the criteria set up for WFD EQS. In some cases, they may not represent the current state of the art, and, usually, they are a compromise in performance that is tailored to a number of different users’ goals and operational needs. But then, they are well established and have often been subjected to collaborative trials to give an illustration of their interlaboratory comparability and applicability.

To elucidate whether the existing European and International Standards are fit for the purpose of compliance checking with the proposed EQS, a survey of existing standardised methods for the determination of priority substances and Annex X compounds [10] according to the WFD was conducted [13]. The survey is an example of a first application of the process how to define research and standardisation needs (see chapter 5.5 Process for Definition of Research and Standardisation Needs). The survey focuses on EN and ISO standards and was extended to EPA and other widely accepted methods where possible. The evaluation took characteristics like performance criteria, application range and matrix into account.

The assessment of analytical methods published in the scientific literature seemed not to be feasible, since properly validated performance characteristics are often incomplete or even lacking.

Based on this survey a summary of validated methods for water, sediment, soil and biota has been established [15]. The lower limits of application (LLOA), defined in ISO/CD TS 13530, is compared with the proposed EQS for WFD priority substances to reveal their applicability for compliance checking. In this context, it has to be kept in mind that such comparisons are worst case scenarios as the limits of quantification, which can be achieved under routine conditions, are normally lower. Gaps, advantages and drawbacks of existing standards are also discussed.

It should also be noted that it is usually not mandatory to use standardised methods. It is also possible to use appropriate non-standardised methods, provided they are properly validated and meet the requirements. Nevertheless, the use of standardised methods is strongly recommended for the determination of parameters where the result depends on the applied procedure or on conventions that need to be fixed in order to achieve comparable results (e.g. so-called "operationally defined parameters"), and for sampling techniques.

Discussion

The catalogues of standardised methods are accessible via internet. A list of links to websites is provided below. The ISO and CEN websites only provide the titles of the standards and often summaries, whereas the complete EPA methods can be downloaded free of charge.

Table 4 : Access to Standardised Methods

http://www.cen.eu	On-line Catalogue of European Standards
http://www.iso.org	On-line Catalogue of ISO Standards
http://standards.mackido.com/	This is a comprehensive catalogue of international standards, their nomenclature, and their reference details (including ISO, EN, British and IEC Standards).
http://standardmethods.org/	Covers methods for the examination of water and wastewater. Standard Methods is a joint publication of the American Public Health Association (APHA), the American Water Works Association (AWWA), and the Water Environment Federation (WEF).
http://www.nemi.gov	List of all methods in the USA National Environmental Methods Index (NEMI)
http://www.epa.gov	EPA methods and guidelines; download provided via NEMI

All relevant standardised methods and additional information as regards scope, application range, lower limit of application (LLOA), and pre-treatment of samples were summarized in a table for each matrix of interest (see Deliverable D16 of this project [15]).

Furthermore, information on proposed EQS for inland surface waters as well as other surface waters and suggested data quality requirements were added. Relying on these data an evaluation of existing standardised methods with regard to analysis of WFD priority substances in surface waters for the purpose of compliance checking with the proposed EQS is given.

Although for nearly all 46 of the WFD relevant substances standardised methods for at least one matrix (water, sediment/soil, and biota/food, respectively) are existent (with the exception of C10-13 chloroalkanes), some gaps have been identified.

For the determination of pentabromodiphenylether in water only the draft EPA method 1614 is available, which specifies the determination of polybrominated diphenylethers in aqueous, solid, and multi-phase matrices as well as tissue, by gas chromatography/mass spectrometry. The procedure is well documented, but no validation data from an interlaboratory trial are included.

Hydrophobic organic substances adsorbed onto the suspended particulate matter (SPM) present in surface water samples are presumably not completely extracted by widely applied extraction techniques such as liquid-liquid extraction. As a consequence, e.g., the concentrations of such contaminants, e.g. Polycyclic Aromatic Hydrocarbons (PAHs), in surface waters, can easily be underestimated. Additionally, most standardised methods have just been validated for filtered water samples. Surveying the sample pre-treatment section of standardised methods for technical details on how to deal with SPM present in the water sample showed that in many cases none, or only inadequate, information (e.g. filtration of the sample where appropriate) was given as pointed out by Coquery et al. [16].

A further problem of standardised methods is that the application ranges often do not match the concentration range required by the WFD. The sensitivities of the methods given as the LLOA are satisfactory to conduct compliance monitoring in water only for about 60% of the substances. Using information from laboratories on limits of quantification (LOQs) would probably enhance the percentage of methods appropriate to compliance monitoring (see below) but anyhow there is a need for improvement and further development of standard methods, especially for endosulfan, pentachlorobenzene, benzo(g,h,i)perylene, indeno(1,2,3-c,d)pyrene, tributyltin compounds, para-para-DDT, aldrin, endrin, and dieldrin. For some parameters the standards would need revision with the aim of reflecting the state of the art, covering all relevant types of waters and improving sensitivity to ensure reliable compliance checking. Primarily for tributyltin compounds the detection power of the standard method is unsatisfactory. Other methods have to be re-validated by international interlaboratory trials. For C10-C13 chloroalkanes and pentabromodiphenylethers there is an urgent need to develop analytical methods suitable for compliance checking with the proposed EQS.

However, monitoring practice showed that routine monitoring laboratories have problems with the analyses of even more Priority Substances although suitable methods are actually available. An evaluation of annual averages of WFD relevant substances at 12 monitoring points along the river Elbe in Germany revealed that not all substances could be measured at the required low levels to perform compliance checking. In total, the annual averages for 14 out of 46 substances were given as less than limit of detection (LOD) with LOD higher than the proposed EQS. Hence, in case of di(2-ethylhexyl)phthalate (DEHP), hexachlorobenzene and hexachlorobutadiene, it will be necessary for the laboratories to adapt the methods in order to reduce the limit of quantification (LOQ) of the method to the required level given that the lower limit of application (LLOA) of the respective standard method is actually appropriate for the required concentration range.

On the other hand, recent inquiries amongst European monitoring laboratories undertaken by CEN and CMA showed that LOQs reported by laboratories are normally lower than the LLOA stated in the respective standard methods [17]. This denotes that compliance checking seems to be possible for qualified laboratories when applying existing standardised methods.

Summing-up this inquiry and the evaluation of standardised methods, no suitable methods are available for compliance checking for the following substances (Table 5):

Table 5: Priority substances, for which no suitable methods are existing to achieve EQS

Endosulfan	Tributyltin compounds
Hexachlorobenzene	DDT
Hexachlorobutadiene	Aldrin
Hexachlorocyclohexane*	Endrin
Pentachlorobenzene	Dieldrin*
Benzo-(g,h,i)-perylene	Isodrin
Benzo-(k)-fluroanthene	Octylphenol*
Indeno-(1,2,3-cd)-pyrene	C10-13 chloroalkanes
Pentabromodiphenylether*	

* Methods are matching the EQS for inland surface waters only

Regarding sediment and biota, only very few standardised methods are available for the analysis of priority substances, but some standardised methods for fatty food, oil or fish might be applicable for biota monitoring within the WFD chemical monitoring. Moreover, for many substances and matrices suitable (certified) reference materials are missing.

Recommendations

- It is recommended to use those methods for which it was demonstrated that the performance criteria set out in the Final draft of the 'Commission Directive laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status' can be met under routine conditions, irrespective whether these are standardised, nationally agreed or in-house methods. Suitable methods are summarised in a CMA document [18].
- The CMA list of standardised methods needs to be updated regularly. The responsibility for this task should be within the European Expert Group (EEG) / CMA.
- There is a need to develop methods for monitoring certain priority substances in sediment and biota as this is an requirement of the Position of the European Parliament [19]
- It is recommended to initiate method development on the European level to save costs and to get harmonised procedures for difficult to analyse compounds. Hence, the mandate (M424) given to CEN to develop the missing methods should be supported by Member States, e.g. by voluntary, non-financed contributions.
- All activities with regard to method development and validation should be closely embedded in the work of CMA and linked to CEN/TC 230 “Water analysis” and communicated via CMA to Member States.
- Methods included in the mentioned CMA list or in [15] should form the basis for any modifications/adjustments required to meet the performance criteria laid down in the future QA/QC Directive, wherever applicable. Starting from those methods reduces the necessary effort/cost for validation.
- Validation of new and adjusted methods should follow international accepted guidelines for in-house validation and standards/guidelines for conducting interlaboratory studies aiming at method validation. Minimum performance criteria to be achieved have to be in accordance with the requirements given in the future QA/QC Directive.

Very admissible help on method validation is given by the following links:

EURACHEM	Guide: The fitness for purpose of analytical methods (www.eurachem.org → guides and documents)
SWIFT	Deliverable D12 Part 1: Guidelines for laboratories carrying out measurements outside the laboratory where the results will be used to implement the WFD (www.swift-wfd.com → workspace → deliverables (public access))
HELCOM	Combine Manual (www.helcom.fi → manuals and guidelines)
ISO	series 5725, terms and definitions concerning quality assurance
NORMAN	NORMAN is developing a common framework to the validation of both chemical and biological methods for the respective monitoring and bio-monitoring of emerging pollutants (occurrence and effects) in a broad range of matrices [20]

- Providing an open list of analytical methods from scientific literature via Internet seems not feasible due to insufficient QA/QC information in most publications, required efforts to maintain and update this list and difficulties ensuring the quality of the information provided.
- The ´blueprint´ on QA/QC as a whole should be submitted to CMA and published as an official CIS guidance document.

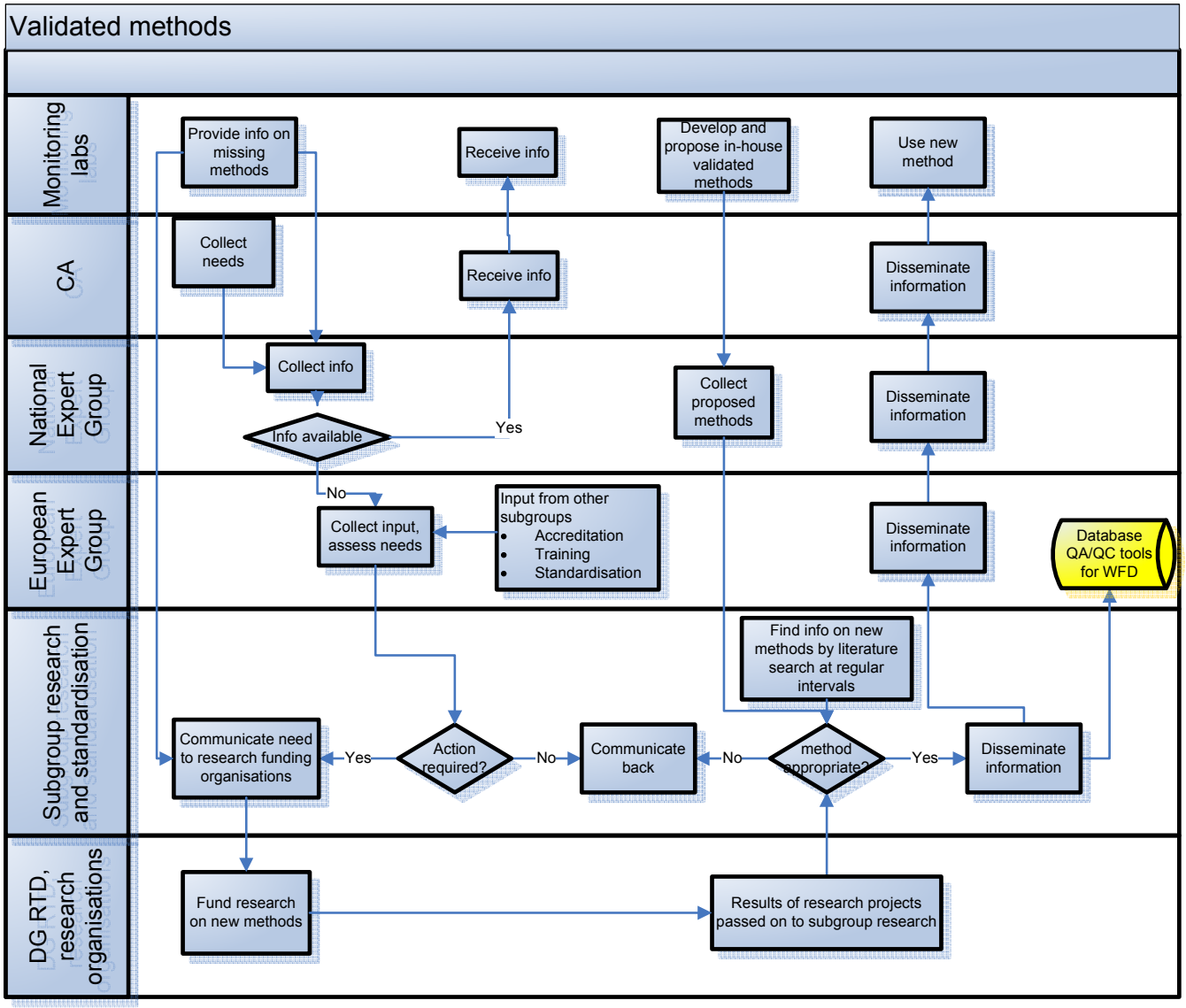

Figure 8: Process for the provision and identification of validated methods

5.7 Training

Introduction

It is important that training services and products of appropriate quality, anchorage and consistency are available to WFD monitoring laboratories in all European countries, and in all European languages. These training services and products have tp cover all QA/QC issues of importance to WFD monitoring laboratories. The subjects which are deemed to be particularly important are listed below:

- Measurement uncertainty estimation
- Method validation
- Metrological traceability and Certified Reference Materials
- External Quality Control - Proficiency Testing
- Internal Quality Control
- ISO/IEC 17025

Other subjects which are useful to WFD laboratories are statistics, general metrology and sampling.

Discussion

Training products and services of appropriate quality for laboratories carrying out measurements in support of the WFD, and its daughter directives, have been identified across the EU.

Existing products need to be monitored, and new products assessed and added to the list of appropriate products, in order for laboratories to have the most up-to-date information available.

Collaboration between TSPs on the list, and new providers, needs to be encouraged in order to ensure that gaps in the market, particularly with respect to location and language, can be filled.

The following should be noted:

* There are several providers of training products and services, and also relevant guidelines/handbooks. A list of these has been compiled as part of this project, and these have been evaluated [21].

* The most significant gaps in the provision of training products and services are the range of languages, and the location of the training provider.

* The database of training providers and products needs to be maintained in the longer-term.

Responsibility for the Process

The responsibility for the process can be divided into two groups.

Firstly, the providers of training products and services (training service providers (TSP)) have responsibilities. This group needs to ensure that clear information on those products and services offered which are appropriate to WFD laboratories, is made available to laboratories, accreditation bodies and regulatory authorities. This group also must take responsibility for collaborating effectively to ensure that provision of a wide range of training services in different locations and languages can be effectively delivered. The establishment of an informal group of TSPs should be considered.

Secondly, responsibility for the independent monitoring of the continuing suitability of existing training products and services, as well as the assessment of new products and services in

the market place needs to be taken. The ideal body to do this is an expert group, as a sub-group of the European Expert Group as described in this blueprint. The responsibility to this group should be mandated by the European Commission.

Sustainability

To ensure sustainability of this system, the two responsible groups – the TSPs and EEG – must continue to work both independently and in collaboration, both with each other as well as the laboratory community.

The establishment of a voluntary group of TSPs is recommended. This should ensure the ongoing provision of appropriate training services throughout Europe, and the provision of new services where these are needed due to location and/or language. These providers need to make the judgement based upon their views of the market as well as the broader, non-commercial aspects.

The role of the European Expert Group in assessing the continuing suitability of training services and the suitability of new products in the market, using the criteria developed within this project, is crucial. This can be maintained if it is necessary for accredited laboratories to use training products and services that have been assessed as appropriate independently. This can also be achieved by the assessment of the product or service during an audit by the National Accreditation Body (NAB), using these criteria, and by using the existing list, which must then be maintained. The NABs can feed this information into the National Expert Groups (NEGs) which can, in turn, feed the information to the EEG. By constructing and maintaining a positive list of training products and services, and making this information available to all stakeholders in Europe, this process can be sustained for many years. The possibility of some form of "accreditation" for training providers could also be considered.

Interaction with Other Processes

Interaction with other processes of the project is limited; there might be some overlap with the accreditation process and the NEGs and the EEG, especially with the subgroups on accreditation and proficiency testing.

Implementation

In order for implementation to be effective and training to be available to laboratories which is of a high quality and consistency across Europe, there must be involvement from many players, which includes TSPs, the EEG and NABs.

Consistency in the training contents is important as data is shared across the EU and the data should not only be produced using common methodology but also statistics and interpretation (e.g. uncertainty) should use a consistent basis. For the implementation to be fully effective, accredited WFD monitoring laboratories should be strongly recommended to use training products and services which are either on the list developed within this project, or assessed independently as being suitable using the project-developed criteria. This does not need to be put into legislation, but does need to be fully implemented by NABs across Europe if the implementation is to be successful.

Recommendations

- To establish a voluntary group of TSPs with responsibility for:
    - Notifying stakeholders (WFD laboratories, NABs, CAs via the Expert Groups) of new or changed training products and services;
    - Collaboration to address gaps in training provision, particularly with regard to language and geography.
    - This group could be established along similar lines to that of the network of PT providers (see chapter 5.3 Proficiency testing)

Some initial contacts have already been made with training providers in Europe with regards to establishing such a voluntary group. Representatives of eight training providers have expressed a positive interest in belonging to the proposed group, from the following countries: Bulgaria, Croatia, Finland, Netherlands, Slovakia, Sweden and the UK, as well as from IRMM (representing TrainMiC).

- To establish a Sub-group on training as of the European Expert Group, with a mandate to:
  - Collect, monitor and assess new and existing training products and services using the existing criteria developed within this project [21];
  - Communicate information on appropriate training products and services to other stakeholders (WFD laboratories, NABs, CAs, TSPs);
  - Identify gaps in the provision of training products and services and communicate of these to TSPs;
  - Maintain and develop a list of appropriate training products and services.

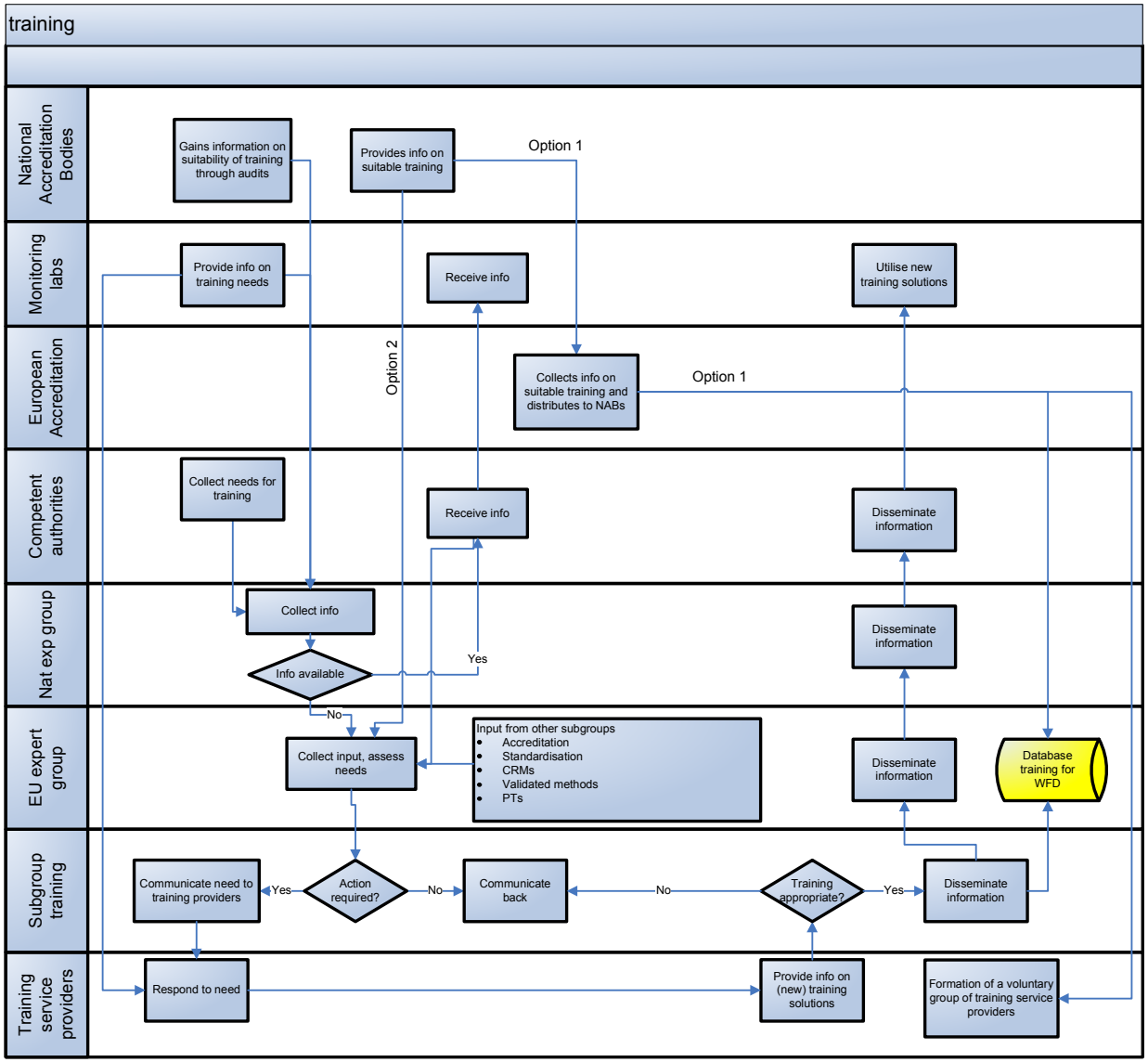

Figure 9: Training: Process for the identification of needs and the dissemination of existing services

5.8 Accreditation

Introduction

Accreditation is the most advanced system for performing external competence assessment. In 2008, a new European Regulation was issued on this, which formalises and strengthens its role. In the context of WFD monitoring, about 70% of the EU countries have mandatory accreditation according to ISO/IEC 17025 for the laboratories that provide the monitoring data.

For accreditation to work effectively, it is important that the practice of assessment is equivalent across the EU. Formally, this is done via the Multi-Lateral Arrangement (MLA) of EA. However, from the various workshops that were held during the project [1, 22], it is clear that there is still a lot of room for improvement.

The recommendations aim at creating a systemic flow of information between the different stakeholders (see Figure 10), so that further harmonisation is achieved.

Discussion

It is obviously important that the competence of laboratories that provide monitoring data is assessed by an external body, as self declaration is insufficient. Historically, there was a tradition in some Member States that such competence assessment was performed to a certain degree by some staff working for the environment ministry or environment agency (e.g. as part of a notification procedure). Nowadays, such activities are no longer seen as a core activity of such public authorities. The only credible system today is assessment of competence via a national accreditation body (NAB). This is done against the international standard ISO/IEC 17025. It is recommended that competent authorities throughout the EU require the use of this system by 2013 and accreditation should also cover the activity of sampling, which is not always the case today.

There is a series of recommendations that is made to improve the practice of accreditation in the domain of WFD monitoring. These recommendations are intended to improve the communication and interaction between different stakeholders as depicted in Figure 10: the WFD monitoring laboratories themselves, the competent authority (CA), the National and European Expert (NEG and EEG), and EA (specifically a working group within EA).

Within the competent authorities themselves, those that request the data are often not well informed on technicalities of analysis and therefore might not fully appreciate the advantages offered by the accreditation process and are less likely to interact appropriately with the NAB itself on the quality of the accreditation service delivered to the laboratories that the CA subcontracts or is otherwise responsible for. Conversely, the NAB might not be fully aware of the specific requirements of the CA or of possible inefficiencies in the accreditation service that is provided.
For that reason the CA should interact with the National Expert Group (NEG), which acts as a forum where representative(s) of the CA, those that are involved in accreditation assessment, and those performing analysis can review the current practice and address problem situations occurring during the accreditation process. It is also recommended that a representative of a reference and/or research laboratory (e.g. the National Measurement Institute) is part of this group.

To achieve harmonisation across the EU, a similar forum is required at the European level, consisting of representatives of different countries. Again, this European Expert Group (EEG) should have representatives of the different stakeholders and should have a sub-group on accreditation. Based on the input received from the various NEGs, discussions can be held and improvements and corrective actions can be undertaken, particularly linked to the most important QA/QC tools (Training, Standardisation, CRMs, Validated methods, PTs).

It is critical that the recommendations formulated by the EEG are actually followed up and thus fed into an appropriate structure of EA. For this reason it is recommended to set up a dedicated group within EA that specifically deals with the sector of environment/WFD and where pan-EU harmonisation is taking place, based on the input of the EEG. Such a group should be permanent and examples of what it would have to do are: providing guidance on how to interpret ISO/IEC 17025 for WFD monitoring, developing the criteria constituting successful PT participation, establishing common quality criteria regarding assessment practice, establishing common EU-wide minimum quality criteria applicable to technical assessors who will be carrying out assessment of an WFD monitoring laboratory, defining the different scopes for which one can be accredited (e.g. classes of compounds); identifying adequate PT schemes that can be used by accredited WFD laboratories.

An accreditation practice for WFD monitoring laboratories that is more efficient and more harmonised, will also lead to a market for QA/QC tools (like PT schemes, CRMs, training services) and the development of suppliers in this area.

Recommendations

- The national competent authority (CA) should stipulate in their contracts that WFD monitoring laboratories and sampling providers must be accredited by e.g. 2013 for all of the services they provide;
- The CA should create and run a NEG composed of representatives of the CA, of the laboratories and of those involved in accreditation assessments. This group should collect experiences (positive/negative) which the WFD monitoring laboratories have with accreditation and should relay this information to the EEG;
- The EEG should create a subgroup on accreditation to formulate preventive and corrective actions regarding the way the accreditation process is applied, and should liaise with an WFD WG of EA to ask them to formulate and specify particular accreditation requirements at the EU level;
- The National Accreditation Bodies should provide for the accreditation of WFD PT providers (ISO Guide 43, later to ISO/IEC 17043) and accreditation of RM producers to ISO Guide 34 and ISO/IEC 17025. It is recommended that at EA level, there is an agreement between National Accreditation Bodies that access to such a service is available for National Accreditation Bodies from (small) countries that cannot provide it internally.
- The National Accreditation Bodies should have a process in place to ensure that the technical assessors used in the WFD area are of equivalent competence and perform at the same quality level, within a Member State and between Member States;
- EA should set up an EA Working Group on WFD:
    - to define common EU-wide minimum quality criteria applicable to technical assessors that will be carrying out assessment of an WFD monitoring laboratory.;
    - to set up regular training events via a stable long term platform where WFD technical assessors can exchange experience;
    - to develop a series of minimal requirements for what constitutes “successful participation to an appropriate PT”, in terms of: what constitutes acceptable scores (single and cumulative), what is an acceptable frequency of participation, what are the different scopes for which one can be accredited (e.g. classes of compounds), which action will be taken by the National Accreditation Body when a result is not acceptable?
      Work on this issue has been carried out already in different international bodies, such as EE-PT, ILAC, PTCG and should be used as a basis, such as for example the guidance document ILAC-P9 [23]

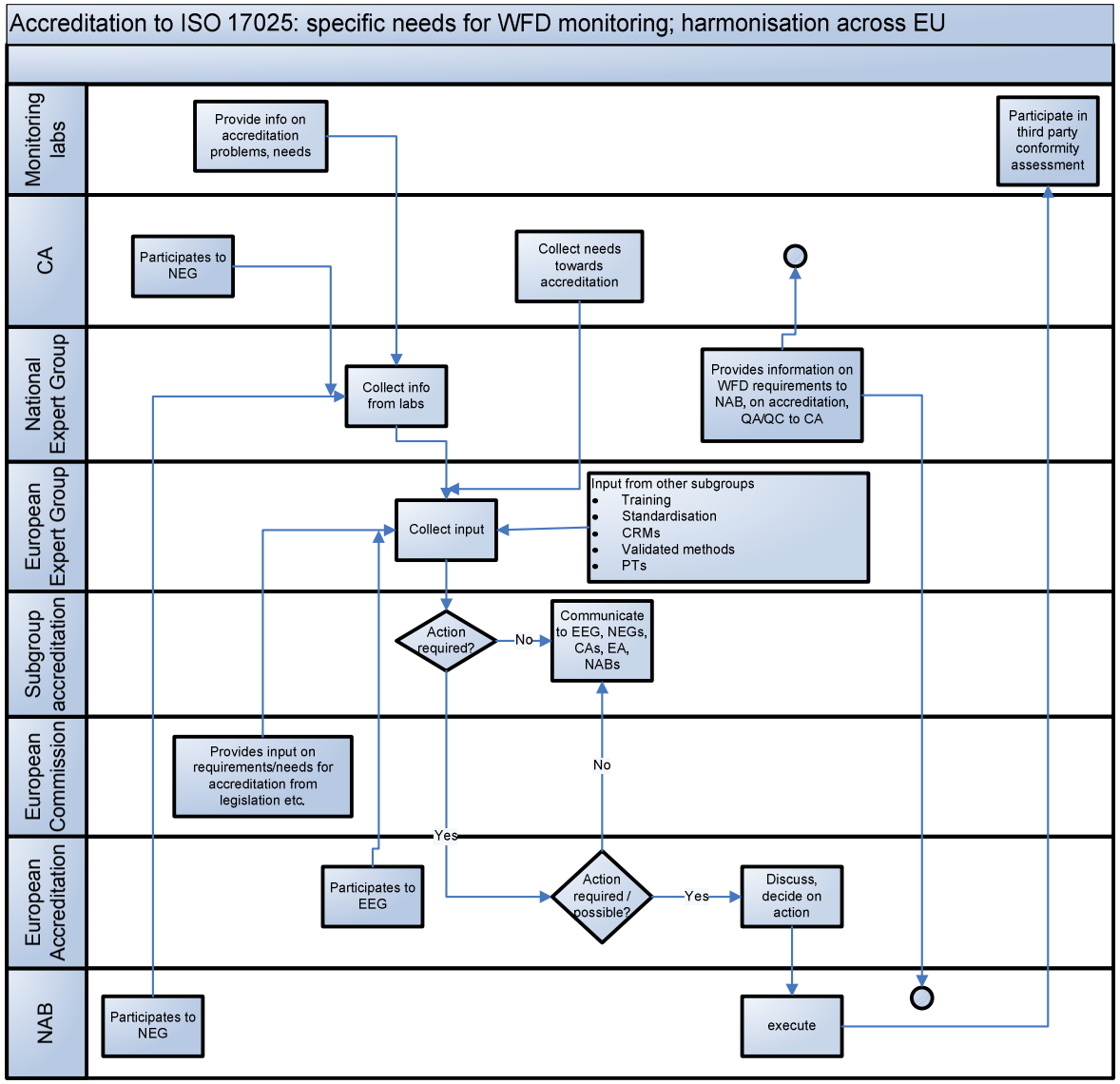

Figure 10: Harmonisation of accreditation

6 Priority recommendations

Expert Groups

- Establishment of National Expert Groups (NEG) to support the competent authorities on QA/QC issues, send a delegate to the European Expert Group (EEG), provides input to and disseminates information from the EEG
- Establishment of a European Expert Group (EEG) consisting of delegates from NEGs and stakeholders, under the umbrella of the CMA or WG E (CMA), with a clear mandate by the Water Directors to support QA/QC for WFD

Communication

- NEGs are required as a consistent source of expertise/advice on scientific/technical issues about data quality for competent authorities and monitoring laboratories. They should ensure communication between these stakeholders.
- The EEG should be the forum for communication between the NEGs, it should foster communication between all stakeholders involved in QA/QC, through its subgroups on specific topics as well as in the plenary.

Proficiency testing

- A self-committed network of PT providers following harmonised rules should be set up and maintained.
- The network(s) of PT providers should be recognized and promoted by the EC, e.g. by informing Member States and recommending participation in PT schemes organized under the umbrella of such networks.
- EC funds should be dedicated for the organization of “difficult” PT schemes only when the costs and/or risks of failure are not affordable on a market basis.

Reference Materials

- The EEG should establish and communicate a prioritized list of RMs that are currently missing for WFD purposes and identify new needs for RMs at the earliest possible stage
- The EEG should maintain a list of appropriate CRMs in the database with appropriate QA/QC tools for WFD
- The EEG should provide guidance and advice to the NEGs and to monitoring laboratories for those cases where no RMs are available (yet)

Research and standardisation

- The need for new or improved methods, tools or standards should be reported from competent authorities of the Member States to the NEGs, who will collect and transmit them to the EEG.
- A prioritisation of the tasks should be carried out by the European Commission (with technical support from JRC) and be communicated to the EEG.
- The regulator (EC) should provide the ground for the initiation and funding of research or standardisation activities

Validated methods

- It is recommended to use those methods for which it was demonstrated that required performance criteria can be met under routine conditions, irrespective whether these are standardised, nationally agreed or in-house methods.
- The EEG or CMA should update the CMA list of standardised methods regularly.
- All activities with regard to method development and validation should be closely embedded in the work of CMA / EEG and linked to CEN/TC 230 “Water analysis” and communicated to Member States.

Training

- A voluntary group of Training Service Providers (TSPs) should be established to enhance collaboration, to increase geographic and linguistic coverage of training services and to improve communication about WFD related training products
- A sub-group of the EEG on training should be established, with a mandate to collect, monitor and assess new and existing training products and services; communicate information on appropriate training products and services to other stakeholders; identify gaps in the provision of training products and services and communicate of these to TSPs; maintain and develop a list of appropriate training products and services.

Accreditation

- The national competent authority (CA) should stipulate in their contracts that WFD monitoring laboratories and sampling providers must be accredited for all of the services they provide.
- The NEG should collect experiences (positive/negative) which the WFD monitoring laboratories have with accreditation and should relay this information to the EEG.
- The EEG should create a subgroup on accreditation to propose preventive and corrective actions regarding the way the accreditation process is applied, and should liaise with the European co-operation for Accreditation (EA).
- The National Accreditation Bodies (NABs) should provide for the accreditation of WFD PT providers and RM producers. There should be an agreement between NABs that access to such a service is available for NABs from (small) countries that cannot provide it internally.
- The NABs should ensure that the technical assessors used in the WFD area are of equivalent competence and perform at the same quality level, within a Member State and between Member States;
- EA should set up an EA Working Group on WFD to define common EU-wide minimum quality criteria applicable to technical assessors; to set up regular training events; to develop a series of minimal requirements for what constitutes “successful participation to an appropriate PT”.

General recommendation

- The ´blueprint´ on QA/QC as a whole should be submitted to CMA and published as an official CIS guidance document.

7 Outlook

This blue print, the proposed system for quality assurance and quality control for WFD monitoring, represents an ambitious plan to bring together different actors and stakeholders of the WFD monitoring process in order to achieve comparability and reliability of monitoring data across the EU. Although it has been designed with much focus on chemical monitoring, the generic character of most of its recommendations and its openness to incorporate different existing structures should allow its expansion and transformation to other types of monitoring under the WFD.

The Chemical Monitoring Activity of the WFD has already agreed in its meeting in Paris, FR, on 21st October 2008, to make use of the output of this project and to develop it further into a guidance document under the Common Implementation Strategy (CIS). This CIS action, which should ultimately lead to the agreement of all Member State representatives on the future guidance document, is a process somewhere between science and policy. It is beyond the scope (and duration) of this scientific research project, but will be supported and followed up by a number of project partners.

The final step will be the implementation of the recommendations in the Member States and at EU level, leading to a coherent system for QA/QC for WFD monitoring in Europe.

The project partners of EAQC-WISE hope that their work during the last 3 years will find the support and endorsement of the Member States and are looking forward to see it being put in practice soon.

8 References

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STATUS, CONFIDENTIALITY AND ACCESSIBILITY									
Status				**Confidentiality**				**Accessibility**	
S0	Approved/Released	X		PU	public	X		Work-space	
S1	Reviewed			PP	Restricted to other programme participants (including the Commission Services)			Internet	X
S2	Pending for review			RE	Restricted to a group specified by the consortium (including the Commission Services)			Paper	
S3	Draft for comments			CO	Confidential, only for members of the consortium (including the Commission Services)				
S4	Under preparation								