A harmonized European framework for method validation to support research on emerging pollutants

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Any investigation of environmental processes related to chemical substances or their effects depends on reliable, comparable analytical data. This also holds true for the impact of climate change on occurrence, distribution and effects of emerging pollutants, with respect to which there is particular concern regarding the reliability of analytical data, due to lack of harmonization in method validation and requirements for quality assurance and quality control (QA/QC).

We present a recent European approach to developing a harmonized framework for method validation, QA/QC and provision of environmental data on emerging pollutants. The validation approach has been tested and improved by three case studies. We outline the main concept of the validation approach as well as the results of the case studies. This European validation framework turned out to be a feasible tool to check the fitness for purpose of analytical methods and to improve the reliability of environmental analytical data, particularly for emerging pollutants.

Keywords: Analytical data; Climate change; Emerging pollutant; European validation framework; Environmental data; Fitness for purpose; Harmonization; Method validation; Quality assurance; Quality control

1. Introduction

There is general agreement within the scientific community that climate change is occurring, and effects on global and regional water cycles [1] are expected. There are an increasing number of studies suggesting that climate change will also affect the occurrence, the distribution pathways and the toxicology of environmental pollutants. Whitehead et al. [2] provided an overview of current findings and concerns on how climate change might impact the accumulation and the release of toxic compounds into surface waters. Furthermore, the toxicity of pollutants for aquatic biota can differ due to changing temperatures, dissolved oxygen levels and flow regimes [3]. Changes in temperatures and flow regimes can also affect environmental degradation pathways as a result of modified retention and residence times of pollutants in the environment. A comprehensive overview of recent findings on environmental contaminants in a warming world is available [3–5].

In summary, climate change may lead to change in the occurrence of emerging substances, their concentration levels, distribution pathways, and effects on biota in aquatic systems. Any investigation of these processes will depend strongly on the reliability of theoretical modeling and analytical results [6].

Emerging environmental pollutants pose a special challenge to environmental scientists. Once a new substance has been identified in the environment and is suspected of having an adverse effect on organisms or ecosystems within the environment, there is then a need to generate detailed, comprehensive monitoring data on the occurrence and the effects of the new substance. In particular, for emerging pollutants, there is concern regarding the availability and the comparability of data at European and international levels. Method development and validation, data gathering, effect testing and launch of monitoring campaigns are often undertaken in parallel in several countries, following different approaches, without being harmonized or synchronized. This is considered a significant hindrance to the generation of reliable, comprehensive knowledge regarding emerging pollutants and how they may be affected by changing global conditions.

We present a current European approach regarding the harmonization of data gathering, method validation and quality assurance/quality control (QA/QC). We describe details of how this approach builds on existing standards and practices and how it supports progress in environmental analytical chemistry.

2. Discussion

2.1. A European initiative to support research on emerging pollutants

In order to overcome the limitations with regard to availability, comparability and reliability of European and international results on emerging pollutants, a Network of Reference Laboratories for Monitoring and Bio-monitoring of Emerging Pollutants (NORMAN) was established under a European Union (EU)-funded coordination program in 2005, and since 2009 continued as a self-sustaining network of reference laboratories, research centers and related organizations. The objectives of this network are to:

(1) enhance the exchange of information and collection of data on emerging environmental substances;
(2) encourage the validation and the harmonization of common measurement methods and monitoring tools so that the demands of risk assessors are better addressed; and,
(3) ensure that knowledge of emerging pollutants is maintained and developed by a coordinated approach, interdisciplinary projects on collaborative, problem-oriented research and knowledge transfer [7].

2.2. The need for a harmonized approach for method validation

Often, methods used for the monitoring of emerging pollutants are not properly validated, either in-house