

## Report from the CCQM Organic Analysis Working Group to the 31<sup>st</sup> meeting of the CCQM (April 2025 – April 2026)

During this period the CCQM-OAWG held one hybrid meeting on 7 and 9 April 2025 at the BIPM (100 participants, 36 institutions, 39 in person), and three online meetings on 29-30 September 2025 (83 participants), and 3 November 2025 (68 participants). These meetings centred on core purity and sector-based comparisons, proposals from task groups for OAWG consideration, CMCs and proposed RMO studies. A joint OAWG-PAWG workshop on “Advances in quantitative-NMR” was held alongside the OAWG meeting on 8 April 2025 (estimated 103 participants, 40 in person). The newly established CMC-TG, in addition to the environmental sector TG, met online throughout the year to progress activities

### 1. Demonstrating and documenting the global comparability of measurements

A summary of the active OAWG key comparisons is given in Table 1. This aligns with our 10-year plan from our 2021-2030+ strategy document.

**Table 1:** Current OAWG comparisons relevant to this period

	OAWG Comparison	Coordinator	Status
	<b>Track A - Model 1</b>		
<b>K180</b>	High protein food - Metronidazole in pig muscle	BVL	<b>Published to KCDB</b>
<b>K184</b>	PAHs in sediment	NIM	<b>Published to KCDB</b>
<b>K192</b>	17 $\beta$ -Estradiol in serum	PTB/JRC	Draft A in progress**
<b>K148.c</b>	Organic Purity Assessment-Digitoxin (large MW)	BIPM	In progress ***
<b>K204</b>	Vitamins in infant formula (non-polar, mixed)	NIM	In progress
<b>TBC</b>	Multicomponent calibration solution (polar, aqueous.)	BIPM	<b>Planned for 2028*</b>
<b>TBC</b>	Pesticides in strawberry (non-polar, high carbohydrate)	KRISS	<b>Planned for 2027*</b>
<b>TBC</b>	Sirolimus in whole blood (high MW, sector 3)	LGC	<b>Planned for 2027*</b>
<b>TBC</b>	Non-polar pure organic - Quinidine	BIPM	<b>Planned for 2028*</b>
	<b>Track C - Model 2 (calibration solutions)</b>		
<b>K154.e</b>	Ochratoxin A in acetonitrile	BIPM	In progress
	<b>Track C - Model 1</b>		
<b>K203</b>	Multicomponent calibration solution (non-polar, organic)	BIPM	<b>Planned for 2026</b>
<i>K194#</i>	<i>Mass Fraction of Water in Crystalline Hydrates (Joint IAWG-EAWG)</i>	<i>VIIM</i>	<i>Draft A in progress</i>
	<b>Track D - Exploratory</b>		
<i>P259#</i>	<i>Quantification of surface functionalities on nanoparticles (Joint SAWG/OAWG)</i>	<i>BAM</i>	<i>Commencing July 2026</i>

	OAWG Comparison	Coordinator	Status
TBC	dIDMS assessment across different MS platforms	PTB & TG	Planned for 2026/27*
TBC	qNMR data processing for mixtures/crowded spectra	NRC, LGC & TG	Planned for 2027/28*

\* request for CCQM approval April 2026

\*\*3 deadline extensions from 30 Sept 2025 to 31 March 2026 (6 months) 8 external expert laboratories

\*\*\*2 extensions from 31 March to 31 May 2026 (2 months) 1 external expert laboratory

# IAWG/EAWG/SAWG comparisons, with OAWG participants

### 1.1. Comparisons where results were reviewed/reports finalised:

#### Food Sector

CCQM-K180, a Track A key comparison coordinated by BVL Germany for the determination of metronidazole (a veterinary drug residue) in pig muscle, received results from 17 participants by September 2023. Following extensive review, clarification, and two participant withdrawals, the comparison progressed through multiple OAWG reporting stages over 2024 and 2025. The OAWG approved the draft B report in November 2025. The final report was published to the KCDB on 18 March 2026.

#### Environmental sector

CCQM-K184/P235, coordinated by NIM China, assessed the determination of three PAHs: fluoranthene, benzo[a]pyrene, and benzo[ghi]perylene, in naturally contaminated river sediment, with phenanthrene subsequently added to extend the volatility and molecular mass range covered. Results were received from 17 participants for K184 and two for P235, with measurement campaign completed by June 2024. Following review, two withdrawals, and progressive reporting through 2024 and 2025, the OAWG approved the draft B report in November 2025. With the final report published to the KCDB on 5 February 2026.

### 1.2. Comparisons where measurements are underway/ draft A reports in preparation

#### Clinical Sector

- The clinical biomarker, 17 $\beta$ -estradiol in serum has been chosen as the model system for the Track A matrix comparison (**CCQM K192/ P246**) supporting NMIs with services in the clinical sector. PTB and JRC are working jointly on co-ordination of this KC and are liaising with the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), and the 2024 RELA external quality assurance scheme for clinical reference laboratories. A preliminary feasibility/ commutability study took place during June – August 2023, which informed the preparation of the study materials taking place during 2024. Homogeneity, stability and commutability of the study materials were finalised in Q4 of 2024, and samples were distributed to 12 Registered NMI participants during January-March 2025.
- Approval was granted for 8 expert laboratories, with services for 17 $\beta$ -estradiol in the JCTLM database, to also participate in the parallel pilot study in April 2025. The inclusion of the JCTLM listed reference labs was twofold: providing added rigor to the statistical assessment of the study results, which is often hampered by low participant numbers; linking the activities of the NMI and Reference lab networks on a global basis.
- Due to scheduling issues in some of the reference laboratories and difficulties encountered in reducing blank levels for the lower levels reported by participants, the final set of results were received and accepted in March 2026. The draft A preliminary report was circulated to participants in early April 2026.

## Food Sector

**CCQM-K204/P264**, is a Track A key comparison, with a parallel pilot study, for the determination of vitamin D3 in infant formula, an analytically challenging measurand given the analyte's low concentration ( $\mu\text{g}/\text{kg}$  level), non-polar character, and the complexity of the mixed protein/fat/carbohydrate matrix. The study addresses a recognised gap: the last comparable CCQM comparison in this space (CCQM-K62) was conducted in 2007 and did not include vitamin D3. The comparison aligns with the OAWG strategic plan for food sector Track A comparisons and is intended to underpin existing and planned CMCs for high molecular mass, non-polar analytes in mixed composition food matrices. Samples were to be distributed in January 2026, with preliminary results to be discussed in October 2026.

## High Purity Organics and calibration solutions

- **CCQM-K154.e** is a Track C (Model II) pilot comparison coordinated by the BIPM, focused on demonstrating competence in the gravimetric preparation of Ochratoxin A (OTA) solutions in acetonitrile, with the aim of underpinning future CMCs. Participants, primarily from the Mycotoxin Metrology CBKT, prepare OTA solutions from a BIPM-supplied stock material and return them to the BIPM for analysis. NMIs may also use their own stock. Solutions and NMI results were due by 31 March 2026 to the BIPM for analysis. Preliminary results are expected to be discussed with participants mid- 2026, with the aim to present Draft B results to OAWG in Fall 2026.
- **CCQM-K148.c/P187.c** is a key comparison and pilot study, coordinated by the BIPM, for digitoxin, a cardiac glycoside representing the high molecular weight end of the pure organic compound model. A contamination identified during initial material preparation necessitated repurification, delaying the start of the study and reducing available material, but the study proceeded with  $4 \times 50$  mg samples distributed to participants in July 2025. With 16 participants registered for the key comparison and one for the pilot. Results were due by 31 March 2026, with Draft B and final reports planned for later that year; an external expert laboratory was approved for participation as guest laboratory in the pilot study, contributing value assignment via qNMR. Due to several challenges encountered by participants, the deadline was extended to end April and again to end May 2026. However, it is anticipated that this delay will not impact finalisation of reporting.
- Coordinated by VNIIM, **CCQM-K194**, is an IAWG-EAWG comparison study that focuses on measuring the mass fraction of water in three crystallohydrates:  $\text{CaC}_2\text{O}_4 \cdot \text{H}_2\text{O}$ ,  $\text{Na}_2\text{MoO}_4 \cdot 2\text{H}_2\text{O}$ , and  $\text{C}_{12}\text{H}_{22}\text{O}_{11} \cdot \text{H}_2\text{O}$ , allowing participants to demonstrate capability across different measurement techniques and water content levels. As water content determination overlaps with organic purity assignment capabilities in the OAWG, the call was extended to OAWG members who registered for this study. With 15 registered participants in total, following a call for participation in April 2025, samples were distributed in November 2025 and results were due by end February 2026. Results will be discussed in April 2026.

### 1.3. Comparisons planned for 2026-2028

#### High purity materials and calibration solutions

- Due to challenges with NMI/DI performance in the CCQM-K78.b Track A comparison for organic calibration solutions: methoxychlor and trifluralin in acetonitrile, a follow-up Track C study: CCQM-K203/P263 Non-polar Analytes in a Multi-component Organic Solution: Mass Fraction of Atrazine (ATZ), Carbofuran (CF) and Dimethoate (DIM) in Acetonitrile (ACN) was proposed by the BIPM to the WG in April and September 2025. The follow-up study planned for 2026/27, would allow NMIs a second opportunity to support broad scope CMC claims in this space. Samples to be distributed in November 2026.
- The next model 1 KC in the WG's series of pure organic Track A key comparisons is planned for 2028. A review of OAWG Track A core key comparisons for pure materials and solutions from 2017 to 2034 identified

a gap for 2028, requiring a candidate solid organic compound of moderate molecular complexity with a molecular mass of 75–500 g/mol and low polarity ( $\log K_{ow} < -2$ ). Quinidine, an antiarrhythmic and antimalarial agent extracted from Cinchona bark, was proposed as a candidate, with its molecular weight, formula, and  $\log K_{ow}$  falling within the target parameter space. Key analytical challenges associated with quinidine, notably the presence of diastereoisomers, were discussed.

## 2. Working group activities progressing the state of the art in measurement science

Aligned with the OAWG strategic plan for 2030+ objectives to advance measurement science, the ADVANCES-TG has engaged NMI stakeholders and organised workshops in 2024 and 2025 on dIDMS and qNMR measurement techniques respectively. Outcomes of these workshops include key proposals and potential studies to be taken forward by the TG.

Following the previously reported “Advances in Mass Spectrometry and IDMS workshop”, held on 22 April 2024, the ADVANCES-TG is proposing a Track D exploratory study to assess improvements in instrumentation for IDMS methods of calibration. The study will involve dIDMS assessment across different MS platforms, aiming to evaluate the accuracy and measurement uncertainties of the double IDMS (dIDMS) technique across multiple mass spectrometry (MS) platforms.

The OAWG-PAWG held a joint workshop on quantitative nuclear magnetic resonance (qNMR) on 8 April 2025. Expert presentations were delivered by representatives from NMIJ, GLHK, INMETRO, NRC-Canada, BAM, LGC, BIPM, NIM China, and the Medicines and Healthcare products Regulatory Agency (MHRA). Discussions focused on improving accuracy in complex samples through the use of alternative nuclei (e.g. fluorine and phosphorus), refined calibration strategies, solvent suppression techniques, and external standards for low-concentration toxin analysis. The group also explored advanced data processing approaches, including deconvolution, quantum mechanical modelling, and emerging artificial intelligence applications. Progress in NMR methodologies was linked to the development of new standards for biological medicines and vaccine polysaccharides, alongside methods to enhance measurement selectivity and compare analytical approaches.

A Track D exploratory pilot study is being proposed for qNMR in 2027/28. The study will focus on qNMR data processing for mixtures and crowded spectra, evaluating the data processing approaches employed by NMIs for more complex qNMR samples, including line fitting, deconvolution, and indirect hard modelling.

The OAWG participated extensively in the session on metabolomics in the “CCQM Workshop: Metrology for (Multi-)Omics Measurements in Clinical Diagnostics” held 9–12 March 2026. Discussions for metabolomics and overall encompassed:

- Reference materials and reference methods are needed to understand performance and uncertainty of ‘omics methods and to improve interlaboratory comparability.
- Standardised approaches to QA/QC and performance are needed.
- To move towards clinical applications there is a need to establish approaches to validate ‘omics measurements.
- The different fields of ‘omics (transcriptomics/genomics, proteomics, metabolomics, lipidomics) are at different levels of metrological development and have different research and standardisation needs.
- The role of AI in ‘omics will need to be underpinned by metrological traceability.

The organising committee plans to produce a white paper capturing the workshop's key findings and identifying specific challenge areas. This will provide individual CCQM working groups with the insight needed to assess their omics-related priorities and determine appropriate next steps. The committee also recognises the need for sustained and strengthened engagement with existing standardisation and harmonisation bodies, including mQACC, the Lipidomics Standards Initiative, and BP4NTA, to better connect metrology expertise with those communities.

A Joint IRWG-OAWG is planned for 13 April 2026, bringing together international metrology experts to explore the application of Fourier Transform Mass Spectrometry (FTMS) to isotope ratio measurements through a series of presentations from international experts in the field of IR-FTMS. The workshop aims to assess the potential of FTMS technologies for high-precision isotope ratio metrology and to strengthen collaboration across the global metrology community.

### 3. Working group stakeholder engagement activities

Five OAWG Task Groups (TGs) were established for the period April 2024 – April 2027. Their primary objectives are to conduct horizon scanning, provide strategic updates, identify gaps and unmet stakeholder measurement needs, and recommend targeted comparisons to address these challenges. These TGs play a key role in shaping the OAWG strategy by ensuring it remains aligned with evolving scientific and metrological requirements.

They are the Food, Environmental, Clinical & Toxicological, Advances in Measurement Science and Knowledge Transfer Task Groups.

In addition to the 5 task groups established in April 2024. A 6<sup>th</sup> CMC Task group was established in April 2025, in response to multiple needs identified by member NMIs/DIs, RMO reviewers and KCWG representatives concerning OAWG CMC submissions and reviews.

Specific activities that have already been undertaken by the CMC-TG include:

- Production of Summary Reports for Key Comparisons finalised in 2024 or later

Summary comparison reports were compiled for CCQM-K180, K184, K159, K133, K179, K148b to guide KCWG CMC reviewers, on what different institutes may claim based on their performance in OAWG comparisons. The summary reports are a supplement to the final report and provides guidance relevant to CMC claims for 1) measurement uncertainty, 2) analyte levels and 3) specific cases of underperformance and ambiguity.

- Determine the minimum analytical and reporting requirements to determine material purity, especially as it relates to purity assignment as part of a matrix Key Comparison

The OAWG Practices and Guidelines reference document has been updated with purity requirements for calibrators used in matrix comparisons. The comparison protocol template has been updated to include traceability of calibrators linked to CMCs in the KCDB. Next steps will include updating the document with acceptable criteria for purity assignment techniques.

Other activities that are currently in progress by the CMC-TG for feedback in April 2026 meeting include:

- Produce OAWG specific CMC guidance and collate existing guidance into one document
- Review of existing CMC criteria for single and broad scope claim acceptance
- Review of CMC greying-out procedures and expectation
- Production of tools/templates to assist with CMC claim writing and review
- Review KCDB Service Categories and propose changes based on applicability to existing and future CMC claims
- Review the use of uncertainty conventions and determine whether uncertainty convention one could be retired
- Propose types and minimum data expected for evidence other than Comparisons that could be used to support CMC claims
- Review the impact of archiving studies currently approved for equivalence on existing CMCs

#### Task Group: Food Sector

- The Food Sector survey (conducted annually) of NMI planned reference measurement, CRM and PT RMs are updated together with current CMC status highlighting the current and future need for relevant comparisons across this space. This is the sector currently with the largest number of services delivered by members. Through these engagements, the next Food comparison for Pesticides in Strawberries is being proposed as the model 1 Track A comparison for 2027.

#### Task Group: Clinical and Toxicology Sector

- On-going liaison with JCTLM and the [European Metrology Network TraceMedLab](#), via Gavin O'Connor.
- On-going liaison with IFCC RELA program via Gavin O'Connor and Marina Ricci to enhance linkages in our programs.
- Through these engagements, the new Track A Model 1 comparison is being proposed for Sirolimus in whole blood.

#### Task Group: Environmental Sector

- The Task Group has engaged online during 2025 to continue to map out the environmental sector space to propose Track A studies that best accommodate maintenance of existing CMCs (sediment and water) and identify Track C or exploratory Track D studies for emerging contaminants in new matrices such as PFAS and microplastics. An NMI survey was conducted with results to be shared in April 2026.

#### Task Group for Knowledge Transfer

The OAWG has established the TG-KT to build foundational metrological capabilities for matrix reference measurements among developing NMIs, complementing the existing BIPM CBKT program which focuses on pure substances and calibration solutions. Key activities include post-comparison technical sessions, expert Q&A, guidance documents modelled on the BIPM CBKT Purity Evaluation Guidelines, and participation opportunities in Track D studies using existing comparison materials. The TG-KT membership draws from BIPM CBKT, RMOs with training programs, and both developing and advanced NMIs.

A 2025-member survey has shaped the first pilot knowledge transfer session, planned for after April 2026, which will draw on NMI experiences from the CCQM-K184 PAHs in sediment comparison. Delivered online, the session will combine an extended NMI case study with focused flash sessions on method optimisation steps, and will include practical guidance on CMC submission using K184 as a worked example. Dedicated CMC guidance sessions for developing NMIs are also proposed for 2026.

#### **4. Other WG Activities**

- OAWG members benefitted from participation in the CCQM CMC Workshop held online from 25-26 February 2026, to gain an understanding of different WG approaches for mapping KCs against CMCs, and future approaches to reviewing CMCs.
- The next OAWG meetings will be held at the new LGC premises in Guildford, Surrey, UK in November 2026.

**Maria Fernandes-Whaley and Bruno Garrido, April 2026**

**Table 2 OAWG CMC Task Group members**

<b>CCQM-OAWG Task Group on CMCs: CCQM-OAWG-TG-CMCs</b>			
<b>Name</b>	<b>Institute</b>	<b>RMO</b>	<b>Country</b>
<b>Chair</b>			
Dr Mark Lewin*	NMIA	APMP	Australia
<b>Members</b>			
Prof Gavin O'Connor	PTB	EURAMET	Germany
Dr Bruno Garrido	NRC	SIM	Canada
Dr Emily Whyte	LGC	EURAMET	UK
Dr Mine Bilsel	UME	EURAMET	Türkiye
Dr Tang Hua	NIM	APMP	China
Ms Pui Sze Cheow	HSA	APMP	Singapore
Dr Kate Rimmer	NIST	SIM	USA
Dr Simon Lobsiger	METAS	EURAMET	Switzerland
Dr Maria Fernandes-Whaley	NMISA	AFRIMETS	South Africa
Mr Abdulrahman R. AlAskar	SASO	GULFMET	Saudi Arabia
Dr Alena Mikheeva	VNIIM	COOMET	Russia
<ul style="list-style-type: none"> <li>• KCWG-OAWG representative</li> </ul>			