KCWG Report to CCQM

April 2025

Review of Chemistry and Biology CMCs during Cycle XXV (2024)

During the Cycle XXV (2024) review of the Chemistry Biology CMCs, 551 new/revised CMC claims were received from the RMOs. The breakdown of the CMC submission in terms of CCQM Service Categories, CMCs submitted by RMO and how the CMCs are applicable to the work of the different technical working groups (WGs) of the CCQM is presented in **Tables 1** to **3**.

Table 1: No. of new and revised Chemistry	y and Biology CMCs in Cycle XXV (2024)
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	2024	New
1.	High purity chemicals	54
2.	Inorganic solutions	8
3.	Organic solutions	6
4.	Gases	352
5.	Water	27
6.	рН	10
7.	Electrolytic conductivity	9
8.	Metal and metal alloys	0
9.	Advanced materials	6
10.	Biological fluids and materials	8
11.	Food	57
12.	Fuel	0
13.	Sediments, soils, ores, and particulates	12
14.	Other materials	0
15.	Surfaces, films, and engineered nanomaterials	2
	Sum	551

2024	New	<u>Revised</u>	Re-instated	Submitted during previous cycle	<u>Total</u>
AFRIMETS	1	15	0		16
APMP	90	9	0	60	159
COOMET	17	36	0		53
EURAMET	51	83	0	40	174
GULFMET	0	0	0		0
SIM	105	22	0	22	149
Sum	264	165	0	122	551

Table 2: No. of submitted Chemistry and Biology CMCs by RMO in Cycle XXV (2024)

Table 3: No. of submitted Chemistry and Biology CMCs by RMO and WG in Cycle XXV(2024)

WORKING GROUP	AFRIMETS	<u>APMP</u>	COOMET	EURAMET	<u>GULFMET</u>	<u>SIM</u>	<u>Total</u>
CAWG	0	0	0	0	0	0	0
EAWG	0	4	0	9	0	7	20
EAWG/IAWG	0	0	1	1	0	1	1
GAWG	15	86	42	151	0	58	352
IAWG	0	36	2	9	0	36	83
IRWG	0	11	0	0	0	43	43
NAWG	0	0	0	1	0	0	1
OAWG	1	28	6	2	0	5	42
PAWG	0	1	0	2	0	0	1
SAWG	0	4	2	2	0	0	8
Sum	16	159	53	174	0	149	551

The geopolitical situation that developed in Europe in 2023 has not changed. EURAMET members informed the KCWG again that they will not participate in the review of CMCs from Russia and Belarus during the review cycle XXV (2024). This decision affected 53 CMCs under JCRB review submitted by VNIIM for gas analysis. The CCQM KCWG guidelines require that 3 RMOs/reviewers actively participate in the JCRB review process for each submitted CMC. With the support of the remaining RMO TC Chairs (who enlisted their experts in Gas analysis),

the JCRB review process for Chem-Bio CMCs was not seriously impacted also for the CMCs submitted by VNIIM.

Once again, the review Cycle XXV (2024) showed a significant reduction in the time to complete the JCRB review of CMCs by using KCDB 2.0. The issue of the "premature approval" of CMCs because RMO TC Chairs accepted the CMCs during the JCRB review process when the appointed KCWG WG representatives in the specific RMO did not complete the review of his/her assigned CMCs yet was handled better by the RMO TC Chairs during Cycle XXV. During this review cycle the RMO TC Chairs also handled the acceptance of the CMC to be reviewed much better and remembered to raise their hand for the JCRB review of CMCs within the 3-week window.

The growth of chemistry and biology CMCs seems to have slowed down in recent years to a constant rate of about 400 to 700 CMCs per year from 2021. Some NMIs/DIs deleted several CMCs, and some of these deleted CMCs were replaced by a few broader scope claims. However, many other NMIs/DIs continue to show a steady increase in the number of CMC submissions. This points to the fact that the future growth rate of Chemistry and Biology CMCs is still determined by the national preference and decisions of individual members.

Update on the review of Chemistry and Biology CMCs during Cycle XXVI (2025)

During the Cycle XXVI (2025) review of the Chemistry Biology CMCs, 720 new/revised CMC claims were received from the RMOs. Also, some CMCs from previous review cycles are still in process in the KCDB in 2025. Notably, 41 CMCs from SIM from several countries cover different technical WGs and several service categories. The breakdown of the CMC submission in terms of CCQM Service Categories, CMCs submitted by RMO and how the CMCs are applicable to the work of the different technical working groups (WGs) of the CCQM is presented in **Tables 4** to **6**.

Table 4a: No. of new and revised Chemistry and Biology CMCs in Cycle XXVI (2025)

(20 March 2025)	New
1.	High purity chemicals	28
2.	Inorganic solutions	8 (+6)
3.	Organic solutions	24
4.	Gases	303 (+19)
5.	Water	162 (+6)
6.	рН	7 (+1)
7.	Electrolytic conductivity	7 (+1)
8.	Metal and metal alloys	2
9.	Advanced materials	7
10.	Biological fluids and materials	32 (+2)
11.	Food	130 (+6)
12.	Fuel	0
13.	Sediments, soils, ores, and particulates	0
14.	Other materials	10
15.	Surfaces, films, and engineered nanomaterials	0
	Sum	720

Table 4b: No. of new and revised Chemistry and Biology CMCs in Cycle XXVI (2025) (per category and sub-category)

CATEGORIES	CATEGORY NAME	NUMBER	SUB-CATEGORIES	NUMBER
			1.1 Inorganic compounds	6
			1.2 Organic compounds	13
1	High purity chemicals	28	1.3 Metals	2
			1.4 Isotopics	6
			1.5 Other	1
2	Inorganic solutions	8	2.1 Elemental	6
			2.3 Other	2
3	Organic solutions	24	3.3 Pesticides	3

CATEGORIES	CATEGORY NAME	NUMBER	SUB-CATEGORIES	NUMBER
			3.4 Other	21
			4.1 High purity	82
			4.2 Environmental	160
4	Gases	303	4.3 Fuel	51
			4.4 Forensic	5
			4.6 Other	5
			5.1 Fresh water	82
5	Wator	162	5.2 Contaminated water	6
Ŭ	Water	102	5.3 Sea water	64
			5.4 Other	10
6	рН	7		7
7	Electrolytic conductivity	7		7
8	Metal and metal alloys	2	8.3 Precious metals	2
٥	Advanced materials	9	9.4 Ceramics	5
			9.5 Other	4
			10.1 Blood serum	6
10	Biological fluids and	32	10.2 Renal fluids	1
	materials	02	10.4 Tissues	23
			10.7 Other	2
			11.1 Nutritional constituents	10
11	Food	130	11.2 Contaminants	106
			11.3 GMOs	2
			11.4 Other	12
TOTAL		I	1	720

 Table 4C: No. of 'not yet approved' CMCs submitted before Cycle XXVI (2025)

(20 March 2025)	<u>Number</u>
16. High purity chemicals	4
17. Inorganic solutions	6
18. Organic solutions	1
19. Gases	34
20. Water	6
21. pH	1
22. Electrolytic conductivity	1
23. Biological fluids and materials	2
24. Food	6
Sum	61

2025	New	Revised	Re-instated	<u>Total</u>
AFRIMETS	22	64	0	86
APMP	87	147	0	234
COOMET	35	73	0	108
EURAMET	79	101	0	180
GULFMET	0	0	0	0
SIM	49	63 (+41)	0	112
Sum	272	448 (+41)	0	720

Table 5: No. of submitted Chemistry and Biology CMCs by RMO in Cycle XXVI (2025)

Table 6: No. of submitted Chemistry and Biology CMCs by RMO and WG in Cycle XXVI(2025)

WORKING GROUP	AFRIMETS	<u>APMP</u>	COOMET	EURAMET	<u>GULFMET</u>	<u>SIM</u>	<u>Total</u>
CAWG							
EAWG		3	1	5		13 (+2)	22
EAWG/IAWG							
GAWG	63	69	70	100		1 (+19)	303
IAWG	20	86	17	47		89 (+18)	259
IRWG		6					6
NAWG		6	4	1			11
OAWG	3	64	16	27		8 (+2)	118
PAWG						1	1
SAWG							
Sum	86	234	108	180		112 (+41)	720

Issues with the sources of metrological traceability of submitted CMCs

The continued discussions on the draft document to look at issues related to establishing metrological traceability for Chemistry and Biology CMCs focuses on the complications

surrounding the definition of the measurand. This is still a very relevant issue for complex larger biological molecules where the uncertainty in terms of the definition of the measurand is a significant contributor to the measurement uncertainty. This issue complicates the establishment of metrological traceability because the measurement process involves an intricate network of measurements and therefore also a complicated uncertainty budget for the measurement result.

An action from the KCWG meeting in April 2024 was to task Dr Tang Lin Teo from HSA to develop two case studies for measurements within the OAWG measurement space where the definition of the measurand is problematic, and it is difficult to establish metrological traceability. HSA developed two (2) case studies that were shared with the KCWG members for questions and comments. All the comments received from the KCWG members were incorporated into an update of the case studies.

Re-review of existing CMC claims

The re-review strategy previously looked at CMCs that were approved before 2010. There are still 122 CMCs in the KCDB that fall into this category. The remaining "old" CMCs are split between several service categories. If we look at CMCs approved before 2015, there are 1492. The inorganic solutions and food categories had the most CMCs published before 2015.

The schedule for the re-review of Chemistry and Biology CMCs has been adjusted to include all CMCs published during or before 2015. The big technical WGs (GAWG, IAWG and OAWG) have been tasked to discuss possible service categories for re-review of CMCs during Cycle XXVI (2025) with their respective WGs. For the coming cycle, a proposal was made to re-review Cat. 5 (Water) and Cat 9 (Advanced materials) for IAWG and Cat. 11 (Food) for OAWG. The GAWG was asked to also propose the re-review of some CMCs for the upcoming Cycle XXVI in 2025.

In response to the question from the CCQM strategic planning working group (SPWG) about whether the KCWG will continue with the current approach for the re-review of CMC claims, i.e., to move the re-review schedule up to start re-reviewing all CMC claims that were approved before 2015, the KCWG has tasked the WG representatives from GAWG, IAWG and OAWG to consider what new evidence will become available to support CMC claims in 2026. The plan will be to advise NMIs/DIs on what new evidence will become available and what CMC claims will be impacted by the new evidence so that the responsibility will be returned to the NMIs/DIs to decide how they will manage their CMCs.

At the next KCWG meeting in April 2025, the WG representatives from the IAWG, GAWG and OAWG will give feedback on what evidence will become available during 2025 to support CMCs in 2026. The KCWG will also have further discussions on how to develop clear rules and guidelines in terms of the greying out of CMCs to manage the upkeep of valid CMCs in the KCDB.

Matters arising from the previous KCWG meeting (2024)

During the feedback from the JCRB Executive Secretary, the issue of comparison studies registered in the KCDB and older than five (5) years was raised. Five comparison studies were identified and discussed during the meeting. It has now been confirmed that the supplementary comparisons of SIM.QM-S3 and SIM.QM-S4 have been completed, and SIM is currently working on updating the status of these comparisons in the KCDB. It has been confirmed that CCQM-K133 has been completed and approved for equivalence. CCQM-K110 still needs to be marked as suspended in the KCDB. CCQM-K144 is progressing. An enquiry was made by the JCRB Executive Secretary at the beginning of March 2025 to identify the current "old" comparisons in the KCDB. A few additional comparisons have been identified and are being followed up on. These include CCQM-K26b.2019, APMP.QM-K90, APMP.QM-S18 and EURAMET.QM-S12.

There are still some outstanding CMCs from previous review cycles. Notably, the 41 CMCs from SIM are indicated in Tables 4 to 6 above. The rules and guidelines in terms of greying out of CMCs have been discussed extensively in the OAWG during 2024. The topic will be introduced at the KCWG meeting in 2025 by Dr Mark Lewin from the OAWG to be discussed in line with the proposed new strategy from the KCWG to return the responsibility for the rereview of CMCs to the NMIs/DIs and only play an oversight role with more strict application of rules in terms of greying out of old CMCs.

Several suggestions were made for the improvement of the KCDB and proposed to the KCDB Office for consideration:

- To remove the requirements to include a comment when a reviewer or TC Chair simply wants to approve a CMC;
- To send a notification to the writer when all the RMOs who agreed to review the CMC have completed the JCRB review of the CMC;
- To add more information about the uncertainty conventions, as discussed, to the KCDB help pages and also update the CMC webform with more clear information about the uncertainty convention;
- To allow for more than one (1), ideally three (3) rounds of revision during the JCRB review.

KCWG membership

The current KCWG membership that will be responsible for the Cycle XXVI (2025) review of Chemistry and Biology CMCs has been confirmed by the RMO TC Chairs and is presented in **Table 7**.

Table 7: Confirmed membership of the KCWG for Cycle XXVI (2025)

Name	Representation
Angelique Botha	KCWG Chair
Alvin Fung	KCWG Vice Chair
John Molloy	KCWG Rapporteur
Robert WIELGOSZ	BIPM
Stéphanie MANIGUET	BIPM
APMP	
Tang Lin TEO	TCQM Chair
Jin-Sang Jung	
Byungjoo Kim	
Kazumi Inagaki	
Kyoung Seok Lee	
Takuya Shimosaka	
EURAMET	
Teemu Näykki	TCMC Chair
Béatrice Lalere	
Bernhard Niederhauser	
Steffen Seitz	
Heidi Goenaga-Infante	
AFRIMETS	
Angelique Botha	TCQM Chair
Hanen Klich	
Ibrahim Tahoun	
Randa Nasr Ahmed Yamani	
Caleb Luvonga	
COOMET	
Yury Kustikov	TCQM Chair
Olga Efremova	
Narine Oganyan	
Alena Sobina	
Yury Kopyltsov (RF, VNIIM)	
SIM	
Bryan Calderón	TCQM Chair
José Luis Ortiz Aparicio	
Bruno C Garrido	
Patricia Grinberg	
Andreia Lima	
KCWG WG representatives	
Carla Divieto	CAWG
Alena Sobina	EAWG
Christina Cecelski	GAWG
Maré Linsky	IAWG
Philip Dunn	IRWG
Liana Dong	NAWG

Mark Lewin	OAWG
Liqing WU	PAWG
Alex Shard	SAWG
Li-Lin Tay	SAWG

Angelique Botha

CCQM KCWG Chair