CCQM KCWG Task group on Broad scope CMCs

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1. Introduction

The Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) strategy provides the structure for National Metrology Institutes/Designated Institutes (NMIs/DIs) to develop and maintain capabilities using a defined set of key and supplementary comparisons. The technical working groups (WGs) of the CCQM have developed additional strategies that allow the design of comparisons to reach beyond the explicit measurement challenge of those comparisons. This approach has led to the possibility of describing the calibration and measurement capabilities (CMCs) of NMIs/DIs in a wider sense in an attempt to optimise Appendix C of the key comparison database (KCDB). In this report these CMCs are described as broad scope CMCs.

The WGs that have already made some advances in the development and implementation of such strategies include the Organic Analysis Working Group (OAWG), the Inorganic Analysis Working Group (IAWG) and the Gas Analysis Working Group (GAWG) (Appendix A). Especially, the OAWG already has published some of these broad scope CMCs. The IAWG has made considerable advances in developing the strategy to support a broad scope of CMCs with a finite number of comparison studies. However, broad scope CMCs in the true sense, i.e., CMCs that describe a group of elements for a broadly described range of matrices over large concentration ranges have not been attempted yet. In the GAWG, the number of gas components and matrices form a more defined measurement space than in the OAWG and IAWG. The work of this group in the area of broad scope CMCs has focused on optimising the description of CMCs in

terms of more broad concentration ranges with the appropriate uncertainty claims based on the performance in comparison studies.

The Key Comparison Working Group (KCWG) of the CCQM and its members have found that it is becoming important to understand these different approaches being applied by the WGs for the review of broad scope CMCs. It has also become important to investigate the possibility of harmonising the philosophies and approaches between the WGs to make the review of these broad scope CMCs easier for the KCWG members. With this goal in mind, the KCWG has formed a task group to review the different approaches to broad scope CMCs used by the different WGs in an attempt to harmonise or at least understand the different approaches better. This review will also serve to make it easier for the newer WGs to formulate broad scope CMCs in their areas as supporting evidence from future comparison studies becomes available.

The terms of reference of this newly formed KCWG Task Group are as follows:

To draft advice for the CCQM KCWG, which in turn will make recommendations to the CCQM Strategic Planning Working Group (SPWG) and then CCQM, on:

a) The current status of the guidance documents on broad claim CMCs developed by the CCQM WGs and the need and possibilities for further harmonisation;

b) How broad scope CMCs for Chemistry and Biology could be defined/represented in a harmonised way;

c) How broad scope CMCs for Chemistry and Biology can be integrated into the KCDB 2.0 platform, and any eventual platform modifications and estimated financial implications to achieve this;

d) The current approaches regarding inclusion of information on repeat analyses in key comparison (KC) reports, following initial sub-optimal performance in the KC; the use of such information as well as reports of corrective actions in CMC review; the need and proposals for harmonisation of these approaches, if the need is ascertained, across the CCQM WGs and in the CMC review process.

2. Discussion

The discussions in the task group focused on the following four topics concerning broad scope CMCs as developed in the three technical working groups (WG), i.e., the OAWG, IAWG and GAWG that have already published broad scope CMCs or intend to publish broad scope CMCs in the near future:

- The different types of broad scope CMCs;
- How to write broad scope CMCs;
- The evidence/support required for broad scope CMCs; and
- How to handle sub-optimal performance in comparison studies as it relates to broad scope CMCs.

2.1 The different types of broad scope CMCs

The OAWG formulates broad scope CMCs according to three types, i.e., high purity materials, solutions and matrix CMCs. At the moment, the broad scope matrix CMCs covers four types, namely organic solutions, soils/sediments/ores, biological materials and food, where CMCs claimed may be guided by the different sectors of the AOAC food triangle.

The IAWG has not published any broad scope CMCs in the true sense of the word yet, i.e., where one CMC includes a range of analytes and matrices over a large concentration range. The broad scope approach has only been used to gain support for a wide range of CMCs from a limited set of comparisons and are categorised by different analytical challenges based on the following:

- Analyte group:
  The IAWG has divided the periodic table into seven (7) analyte groups, i.e., Groups I and II, the transition elements, the platinum group elements (PGEs), metalloids/semi-metals, non-metals, halogens, and the rare earth elements (REEs). A few additional specialised analyte groups have also been identified, such as inorganic species, proteins, etc.
- Sample matrix:
  Here six (6) main groups have been identified, i.e., water/aqueous solutions, high silica content, high salt content, high organic content, difficult to dissolve metals and highly volatile matrices.
- Analytical technique:

The analytical techniques used most by the members of the IAWG include inductively coupled plasma optical emission spectrometry (ICP-OES), inductively coupled plasma-mass spectrometry (ICP-MS), instrumental neutron activation analysis (INAA), etc.

- Calibration strategy:

  The different calibration strategies used by the IAWG include isotope dilution, external calibration, standard addition, etc.

- Concentration range:

  To simplify the description of the core capability of the group and due to the large dynamic working ranges of the analytical techniques that are typically used by the group the concentration ranges for the measurement capabilities are divided into two parts, i.e., the low range of < 50 mg/kg and the high range of > 50 mg/kg.

The GAWG still presents their CMCs as one component per matrix or as a multi-component mixture per matrix through the group identifier symbol. For some components the matrix has been extended to include both nitrogen and synthetic air. The concentration ranges have now been extended to cover the complete concentration range per gas component in two parts: one part where the uncertainty can be reported as relative (high concentration range) and the second part where the uncertainty is reported as absolute (low concentration range) as per the GAWG strategy.

2.2 How to write broad scope CMCs

The OAWG has developed spread sheet templates for writing broad scope CMCs to cover category 1 for high purity claims and category 11 for food. The group is in the process of developing a template for category 10 (Biological fluids and materials). The templates follow the fourteen (14) service categories of the CCQM. The templates provide guidance for the writers in terms of the analytes, matrices and concentration ranges that could be claimed for the CMCs based on the comparisons that could be used for support for the CMCs in the specific categories. The templates also import the support based on the How Far the Light Shines (HFTLS) statements from different comparison studies for a particular CMC claim to facilitate the easy review of the CMC.

Issues identified:

- The possible issues that the OAWG has identified in terms of creating broad scope CMCs in the KCDB 2.0 are that if the claim is very broad it could become difficult to enter the details of all the Certified Reference Materials (CRMs) of the NMI/DI that falls within the CMC. The difficulties with entering the CRM details in a broad scope CMC claim include the fact that the matrices and analytes, as well as concentration ranges of the CRMs that fall within the CMC claim could be more specific than the scope of the claim on the one hand. On the other hand, the number of CRMs that fall within the CMC claim could be large and the specifics of the different CRMs in terms of matrix, analyte, concentration and associated uncertainty could be diverse.
- There could also be more than one source of traceability, because different calibrants from different other NMIs/DIs could possibly be used for the CMC.

SM commented in the meeting that there is no technical limitation in the KCDB 2.0 as well as the format of the CMC submission web form to declare more than one source of traceability for a CMC (usually the source of traceability is indicated by the acronym of the institute that provides the highest link to the SI for the CMC being declared.)

Question: The IAWG especially asked whether the OAWG could share their templates with the other technical WGs.

The IAWG still enters CMCs as an element per matrix per CMC entry. In future, it is envisaged that a broad scope CMC could include a group of elements (the specific elements could be included in a list as part of the definition of the analyte) as applied to the broad matrix as described in the strategy of the IAWG, e.g., high organic content.

Questions:

- Will it still be possible for customers to search the KCDB 2.0 for a specific element in a broad scope CMC?
- How will it be handled in the KCDB 2.0, if more than one CCQM service category falls within the broad scope matrix of the CMC claim?

SM commented that it will still be possible to search the database for a specific element when a list of elements is specified in the definition of the analyte for a broad scope CMC.

As already stated, the CMCs of the GAWG are written as one component per matrix or a multi-component mixture per matrix and the concentration range is usually divided into two parts: one with a relative uncertainty claim and the other with an absolute uncertainty claim. Where it is technically possible, the matrices of CMC claims have been broadened to include both nitrogen and synthetic air for a specific component.

2.3 Supporting evidence for broad scope CMCs

The OAWG has divided broad scope CMCs into three classifications:

Classification 1: Homologues with identical functional groups and common classes with a well-defined range of structural variation in a simple matrix, e.g., polychlorinated biphenyls (PCBs) at mass fraction 100 µg/kg to 100 mg/kg in a soil matrix.

Supporting evidence required: One applicable Track A Model 1 key comparison with an additional key comparison or recent pilot study, but not a pilot study organised in parallel to a key comparison.

Classification 2: Classes of analytes with greater structural diversity, covering a subset of the HFTLS statement, e.g., mass fraction purity of low polarity pesticides ($pK_{OW} < -2$) with a molar mass range 200 to 500 g/mol.

Supporting evidence required: One Track A Model 1 comparison with an additional key comparison (also Regional Metrology Organization (RMO) supplementary comparison) covering the sectors of the ‘organic analysis space’ relevant to the entire scope of potential measurands.

Classification 3: Broad scope claim covering entire or major subset of the HFTLS statement, e.g., mass fraction purity of organic compounds of low polarity ($pK_{OW} < -2$) with molar mass range 200 to 500 g/mol.

Supporting evidence required: One Track A Model 1comparison with 2 additional key comparisons, one may be a recent pilot study, but not a pilot study organised in parallel to a key comparison.

Discussion focused on the use of support from pilot studies. Consensus was reached on the requirement for a published, readily available report for the pilot study with an agreed reference value for the applicable review of CMCs. For OAWG, while the use of pilot studies as evidence is possible under the current guidance, institutes were made aware of the limitations involved in their use and these are specifically stated in the guidance.

The IAWG makes use of a record of participation that can be prepared as a table but is also required to be a graphical representation as a visual aid to make it easier to review the capability of the NMI/DI. The record of participation is prepared per analytical technique. The requirements for the record of participation to support CMC claims include at least ten (10) points from at least 3 comparisons over the past 10 years and must contain data from the past 5 to 7 years. Ninety per cent (90%) of the points on the record of participation must fall within -1<DOE<1. The core capability (CC) table (per analytical technique) summarises the specific analytical challenges of the analytical technique that was mastered by the NMI/DI.

Issues related to claiming broad scope CMCs for inorganic analysis based on the evidence/support available:

- What is the best uncertainty convention to use?
- Can comparison results from one element in a group really be applied as sufficient evidence for all the elements in the analyte group?
- How to extrapolate the results for one element in a comparison to an applicable concentration range and uncertainty claim for the group of elements in the analyte group?

Issue that arose since the last meetings of the KCWG and the task group is a case where an NMI/DI claimed support for a number of elements using the core capability approach but did not participate in the most recent comparisons for some of the elements, i.e., the case of Pb in CCQM-K145. More discussion on using this rule to claim broad scope CMCs may be required and it may be determined that NMIs/DIs will need to report results for all of the analytes in the comparison. This could possibly be clarified in the HFTLS statement as well.

The GAWG has divided the comparison studies being organised by the group into three (3) types:

- Track A: to establish measurement equivalence for core competencies (i.e., gravimetry, verification, purity analysis), the comparison has two (2) HFTLS-statements.
- Track C: analytical challenge, the comparison usually has one very specific HFTLS-statement.
- Track D: new areas, pilot studies that usually does not have a HFTLS-statement and cannot be used to support CMC claims.

The group makes use of two types of schemes for the use of comparisons to support CMC claims: the default scheme and the flexible scheme.

The default scheme utilizes a one-to-one relationship between the CMC and the HFTLS-statement of the comparison. The HFTLS-statement is divided into a lower bound (LB) part of the CMC claim where the uncertainty claim will be absolute and an upper bound (UB) part of the CMC claim where the uncertainty claim will be relative. Each key comparison has a separate support document for CMC claims that summarises the HFTLS-statement and the performance of the participants to make it easier for writers to formulate their CMCs and for reviewers to review the CMC claims. If the comparison result of the institute agrees with the Key Comparison Reference Value (KCRV), the participant can use their reported uncertainty for the CMC claim. If the comparison result does not agree with the KCRV, the uncertainty of the CMC claim must be calculated as a quadrature of the reported uncertainty and the difference of the result of the participant from the KCRV.

Discussion point: How to approach it if the u(KCRV) calculated is larger than the reported uncertainty of the participant. JC mentions that the uncertainty that participants can claim for their CMCs are discussed when the comparison results are discussed if this is an issue. The discussions could include the requirement for specific additional information that the NMI/DI has to provide for support of the uncertainty claim of their CMC. The issue of the dark uncertainty of the u(KCRV) if the results from participants are discrepant and the effect of a small number of participants on the estimation of the KCRV and its uncertainty was also discussed. These issues will also be brought to the attention of the ad hoc CCQM working group that will review and update the CCQM document on the estimation of the consensus KCRV (CCQM/13-22).

The flexible scheme is based on the support for a group of core gas components with a track record of performance of the NMIs/DIs. The historical data of the performance of institutes in CCQM key comparisons were reviewed in 2010 to come up with the strategy for the flexible scheme. The capability of the NMI/DI is based on the pooled performance from the last three (3) Track A comparisons. NMIs/DIs can use the two schemes interchangeably depending on the best support for their respective CMCs. There are three (3) criteria for participation in the flexible scheme:

- Participation in the last three (3) Track A comparisons. One Track A comparison is organised every three (3) years.
- The NMIs/DIs need to maintain a track record of good performance in the Track A comparison. A spread sheet is maintained for the flexible scheme with the performance of the NMIs/DIs.
- The NMIs/DIs need to implement and maintain a quality system in accordance with ISO/IEC 17025 and ISO 17034.
    - Monitored by the quality system review process of the RMO

2.4 How to handle sub-optimal performance in comparisons with respect to broad scope CMCs

The OAWG makes use of different approaches to handle the sub-optimal performance of NMIs/DIs depending on if the institute already has published broad scope CMCs or not. If the NMI/DI has published broad scope CMCs, corrective action could be supported by additional measurements from the NMI/DI to conform the capabilities of the published CMCs with peer-review of the quality system and corrective actions within 1 year of the KCRV being determined. As the timescale from initial disclosure of results to finalisation of the KCRV can take several years, where failure of the Institute is clear cut, the Institute should initiate its quality review and apply corrective measures as soon as possible before the comparison report has been finalised. If the NMI/DI does not have published broad scope CMCs, the best approach to corrective action is for the NMI/DI to participate in another CCQM comparison.

The IAWG follows quite a strict policy that the NMI/DI needs to participate in a subsequent comparison to reconfirm its measurement capabilities. The GAWG has the same policy also when the NMI/DI is making use of the flexible scheme for

the support of CMCs. However, the NMI/DI has the option to change to the default scheme until the expected performance in the flexible scheme has been restored.

3. Conclusions:

The conclusions from the discussion so far in the task group is to confirm the initial findings from the survey done in the KCWG (SPWG20-38). The different CCQM WGs are at different stages of working out their own fit-for-the purpose approach and criteria towards the concept of broad scope CMCs (or CMCs indicating core competencies) in their assigned measurement space. Only the OAWG has properly reviewed published broad scope CMCs in the true sense of the expectation of the concept so far, i.e., CMCs that cover a range of analytes, over a range of matrices over a large dynamic concentration range with an appropriate uncertainty claim.

The broad scope approach to support the measurement space of the IAWG with a finite set of comparisons is now becoming well-developed and reasonably mature. However, the group still has questions about how to extrapolate comparison results from a few elements to the full set of elements in an analyte group, how to extrapolate the concentration range from the comparison study to the CMC claims and the same for the uncertainty claim.

Due to the well-defined measurement space of the GAWG in terms of the components and the matrices, the focus of the broad scope approach has been to extend the concentration ranges of the CMC claims and most CMC claims can now be reported as two CMC claims per component and the matrices have been broadened to some limited extent.

Limited (or partially) broad scope CMCs exist in the measurement space under the charge of the Electrochemical Analysis Working Group (EAWG) (pH), the Nucleic Acid Analysis Working Group (NAWG) (genetically modified organisms (GMOs)) and the Protein Analysis Working Group (PAWG) (peptide, protein purity). However, especially in the field of the PAWG and the NAWG the broadness of the CMC claims is based on the complexity of the measurement space and cannot be classified as broad scope CMCs in the same technical sense as in the OAWG and potentially in the IAWG.

4. Recommendations:

- Make this report available as open access on the KCWG website.
- Update the CCQM KCWG Guidance document on the review of CMCs to expand on the current guidance on broad scope CMCs available based on the generic information summarised in this report.

- Encourage the CCQM technical working groups to develop HFTLS-statements for planned comparisons as far ahead as possible during the protocol drafting stage. The protocol should attempt to define the scope for broad scope CMCs by describing how the analytes measured in the comparison can be expanded to cover a range of analytes and different matrices and should discuss how the concentration ranges and reported uncertainties could be extrapolated.
- CCQM SPWG to be consulted about the fact that the CIPM MRA rule that a CMC claim is only allowed to have one source of traceability could be problematic for broad scope CMCs including a range of analytes where the source of traceability of the different analytes could be from different high purity materials or calibration solutions from different other NMIs/DIs.
- Propose to the CCQM SPWG to review the service categories of the CCQM in view of recent developments, current issues and broad scope CMCs.
- Ask the KCDB Office for the development of the database to make it possible to select more than one service category for a broad scope CMC claim.
- Request for an example to be included in the KCWG guidance document to show how CRMs should be included and the Uncertainty of Measurement reported when you write/create a broad scope CMC.

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Appendix A:

Observations on approaches adopted by CCQM WGs on broad scope CMCs

1. Different CCQM WGs are in different stage of working out their own fit-for-the purpose approach and criteria towards the concept of broad scope CMCs (or CMCs indicating core competencies) in their assigned measurement space.

    a) Comprehensive set of criteria for making/reviewing broad scope CMCs was developed under the purview of GAWG, IAWG and OAWG. In the past few years quite some members of these WGs also made some broad scope CMCs demonstrating their core competencies in the measurement space under these WGs.
    b) Limited (or partially) broad scope CMCs existed in the measurement space under the charge of EAWG (pH), NAWG (GMOs) and PAWG (peptide, protein purity). The concerned WGs are in the process of developing/refining their criteria for making broad scope CMCs.
    c) Though no broad scope CMC was made under the purview of Cell Analysis Working Group (CAWG) and Surface Analysis Working Group (SAWG) for the time being, they are developing guidelines defining evidence for supporting broad scope CMCs.

2. Different follow up action plans for sub-optimal performers ranging from participation in subsequent/bilateral comparisons to satisfactory corrective actions documented in peer review reports.

3. Other suggestions: periodic on-site/virtual peer review will be helpful towards the harmonization of the standard in making/reviewing the broad scope CMCs.

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Summary Table on CCQM WG's approach towards broad claims

	Criteria for broad claims	Supporting evidence required in the criteria	Actions on Failure on Subsequent CCQM Comparisons following the broad claims	Other proposals/remarks
EAWG	The EAWG KC guideline has a sort of "broad scope" for pH, but it is very specific and limited. Currently, there is no need to have full broad claims in the electro analysis field. There are commonly-used a limited of pH standard solutions. These solutions are categorized into two buffers: core capability buffers (easier to measure with primary method) and extended capability buffers (more difficult to measure with primary method). The EAWG KC guideline says "NMIs successfully participating in including both extended capability buffers , may justifiably claim a complete pH measurement range from approximately 1.2 to 10.5,	NA	NA	EAWG is currently capable of conducting the required KCs regularly, and performing subsequent/bilateral comparisons if needed. Therefore, bad performance in an KC cannot be compensated by corrective actions. However, existing "broad pH-CMCs" (see left) might remain valid, if they are supported by the overall performance of an institute in preceding comparisons.

	provided the claimed uncertainty is justified". There has been no been to define broad claims for conductivity and coulometry yet.			
GAWG	Yes. Comparisons are divided into classes: Track A, Track C, and Track D, in alignment with other CCQM working groups. A flexible scheme to support CMCs can be used for Track A. NMIs can choose to adopt the flexible scheme if they meet the 4 criteria: 1. The NMI shall have participated in at least three key comparisons organized by GAWG. 2. The NMI shall participate in at least one key comparison in Track A every three years when available through the GAWG. 3. NMI must establish a link between CMCs and performance in Track A comparison in accordance	CMC claims for all core competencies are evidenced by: a. The guidelines for the default scheme for Track A with the exception that CMCs for individual components shall be evidenced by a dedicated key comparison. b. The last **three** key comparisons in Track A. c. Future Track A comparisons shall involve a simple mixture. The Track A list of comparison will be reviewed by the GAWG yearly.	If an NMI ceases to meet these criteria for submitting flexible CMCs, it shall resubmit all CMCs for track A within established HFTLS statements under the default scheme in the upcoming cycle. NMIs that do not meet these criteria shall use the default scheme.	Track A comparisons shall be organized by GAWG. Track A comparisons shall have two HFTLS statements: one for default scheme and a second for a broad statement for use under the flexible scheme. The pooled performance of the last three Track A comparisons will be used for the flexible scheme. If an NMI does not demonstrate equivalence with the KCRV, the value of the uncertainty used for the pooled uncertainty is the submitted uncertainty added in quadrature to the difference between the submitted value and the KCRV.

	with GAWG/09-07. The NMI shall have a quality system in accordance with ISO/IEC 17025 and IDO 17034 and a measurement capability that covers all CMCs.			NMIs can choose between default scheme and flexible scheme. Periodic onsite visit by peers is required.
IAWG	Yes. Criteria set out for different analyte groups such as alkali and alkaline earth elements, transition elements. Sample matrix categories developed based on analytical challenges, e.g. high silica content, high organics content. Broad scope CMCs can be submitted by grouping multiple analytes and/or matrices (matrix challenges), concentration ranges based on the CC table	Use of the CC System and HFTLS in KC reports as evidence to support broad scope CMCs. Record of participation (per technique) - NMI/DI should participate in at least three studies (that can support the broad CMC) over a period of 10 years. Contains no fewer than 10 points in the past 5-7 years. No less than 90 % of the points are between -1 and +1	As per CCQM guidelines, any problems identified after reporting deadline cannot be corrected, i.e. original results should be used to support CMC-claims. To show that initial analytical problems encountered have been successfully resolved, Institute should participate in bilateral or supplemental comparison. For subsequent CMC claims: Use Broad Scope approach, i.e. supporting evidence from several KCs (including KC where unsatisfactory results were reported).	
OAWG	Yes, have started having broad claims in 2014. Criteria set out for pure materials, calibration solutions, matrix materials. A broad scope CMC claim will	a) Classification 1: Track A Model 1 key comparison + 1 additional purity /calibration solution/ matrix key comparison or recent pilot study	Find out the root causes. Upon satisfactory corrective actions carried out within 1 year from conclusion of KCRV, the broad claims remain in the	Different institutes used different ways in linking their services to broad claims, eg. a few institutes have broad claims in high purity chemicals and only NIST listed SRM

	normally fall into one of the following three classifications: a) Classification 1: Homologues with identical functional groups and common classes with well-defined range of structural variation b) Classification 2: Classes of analytes with greater structural diversity, covering a subset of the HFTLS statement c) Classification 3: Broad scope claim covering entire or major subset of the HFTLS statement	b) Classification 2: Track A Model 1 key comparison + 1 additional purity/calibration solution/ matrix key comparison covering the sectors of the 'organic analysis space' relevant to the entire scope of potential measurands. c) Classification 3: Track A Model 1 key comparison + 2 additional purity/calibration solution/matrix comparisons (no more than 1 recent pilot study) Institutes providing the source of traceability for calibration solutions or matrix materials broad claims must have demonstrated successful participation in purity comparisons or have broad claims for neat organic compounds with similar range of polarity and mass range. Non-Track A CCQM comparisons are non-mandatory.	KCDB. If not, broad claims will be greyed out and deleted. Corrective actions covered in peer review reports are acceptable. When several institutes did not demonstrate successful participation and another batch of material was immediately available from the Coordinating Institute, the CCQM WG rolled out the CCQM-Kxx.1 or 2 KC for participation of the sub-optimal performers. CCQM-Kxx and CCQM-Kxx.1 should not count as two KCs for broad claims	numbers under "Mechanism(s) for Measurement Service Delivery", as well as the ranges of certified values & MU. A team of experts to look at broad CMC submissions earlier would be useful. This can be conducted via virtual meetings.

CAWG	Developing guidelines defining evidence for supporting broad scope CMC claims No broad scope CMCs for the time being			
NAWG	11 CMCs in GMO areas based on CCQM-K86 series, some of them are broad claims several spaces for NAWG to explore (single nucleotide, small indel measurements, RNA measurements) which may allow broad scope claims in the future criteria for broad claims – under discussion	CCQM comparisons		
PAWG	currently only broad scope claims for peptide and protein purity based on track A no plans in next 5 years expanding to other areas	Track A key comparisons and supplementary information		
SAWG	Currently SAWG does not have broad scope claims.			There are some activities that may lead to broad scope claims within the next five years. Therefore, the criteria and corrective actions need to be defined.