

Criteria for broad scope claims with the Organic Analysis Working Group (OAWG)

Introduction

This document is intended to describe the approach of the CIPM Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) Organic Analysis Working Group (OAWG) to the scoping and maintenance of broad-based Chemical Measurement Capabilities (CMCs) claims. It gives guidance on how to group analytes within a CMC claim, gives the typical minimum requirements to support such claims, prescribes how National Metrology Institutes (NMIs) and Designated Institutes (DIs) [herein referred as "Institute(s)"] would be expected to demonstrate their ongoing competence to deliver these services and suggests when broad based CMC claims should be suspended or revoked. This document should be used in conjunction with a CCQM wide guidelines on the Review of CCQM CMCs for Inclusion in the Key Comparison Database by the Key Comparison and CMC quality Working Group (KCWG).

Background

In recent years, the pragmatic use of 'How Far The Light Shines' (HFTLS) scopes for CCQM comparisons has allowed CMC claims to be made across a large range of analytes and matrix types. This has enabled the continual increase in the numbers of CMC claims within the CCQM resulting in an increased bureaucratic burden on both the individual Institutes and the Key Comparison Working Group & CMC Quality (KCWG) that oversees the process. To partially mitigate this, a strategic move has been made to allow 'Broad Scope' CMC claims that cover groups of analytes rather than the individually specified analytes of original claims. This document provides clarity for both Institutes seeking claims and reviewers on how broad a scope an Institute can claim based on its track record of CCQM comparison performance and how that claim should be worded. The establishment of broad based claims means that Institutes will be claiming wide ranging capabilities that will be tested by more CCQM comparisons than the traditional analyte specific ones. This requires each institute to have clarity in what future CCQM comparisons it is required to participate in to maintain those capabilities and what are the implications of poor performance.

Scope of Claim

A broad scope CMC claim will normally fall into one of the following three classifications:

- | | |
|-------------------------|---|
| Classification 1 | Homologues with identical functional groups and common classes with well-defined range of structural variation (In same matrix type if applicable). |
| Classification 2 | Classes of analytes with greater structural diversity (In same matrix type if applicable). |

Classification 3 Broad scope claim covering entire or major subset of the HFTLS statement

These classifications are exemplified as follows:

Classification 1

Within this classification there are likely to be two different types: a) Homologous series and b) Common classes.

a) Homologous series

A claim for a homologous series should have clear boundaries to ensure changes in molecular weight, and polarity throughout the scope of the claim remain within the same sector of the 'organic analysis space' model

Examples:

- Mass fraction purity of perfluorinated carboxylic acids $C_nF_{(2n+1)}CO_2H$ where $1 \leq n \leq 8$
- Polychlorinated biphenyls (PCBs) at mass fraction 100 $\mu\text{g}/\text{kg}$ to 100 mg/kg in a soil matrix

b) Common classes

As these groupings may contain significantly different functional groups, they will potentially cover a more varied set of analytical challenges, not least in terms of polarity and reactivity. The definition of any chemical classes used within a CMC claim must be well defined, ideally from IUPAC guidelines. If not, then this will need to be captured in more detail within the CMC claim and the definition agreed by OAWG. The range of variation allowed should be clearly stated. Combinations of common classes may be made within the same claim for a single classification.

Examples:

- Mass fraction purity of one of the 22 natural proteinogenic amino acids
- Mass fractions of steroid hormones and a molar mass range of 100 - 500 g/mol at 10 - 500 ng/g levels in human serum

Classification 2

This will typically be a more heterogeneous grouping of analytes than those found in Classification 1. They will typically have similarities in source or application area. As these groupings will provide a greater range of analytical challenge, a more extensive body of evidence is required to support the claim. Combinations of common classes and more structurally diverse analytes may be made within the same claim for a single classification.

Examples:

- Mass fraction purity of low polarity pesticides ($pK_{OW} < -2$) with a molar mass range 200 to 500 g/mol
- Mass fraction purity of natural and synthetic nucleotides ($pK_{OW} > -2$) with a molar mass range 300 g/mol - 500 g/mol including synthetic variants with F, Cl or S incorporation

- High polarity steroids ($pK_{ow} > -2$) with a molar mass range 300 -500 g/mol at mass fraction from 100 $\mu\text{g}/\text{kg}$ to 100 mg/kg in aqueous solution
- Low polarity pesticides ($pK_{ow} < -2$) with the molar mass range from 200 - 500 g/mol at mass fraction 1-15,000 $\mu\text{g}/\text{kg}$ levels in a soil matrix

The nomenclatures for this classification will normally be less well defined than those in Classification 1 and so comparison coordinators should endeavour to provide some guidance in the protocols for different classifications that might sit within the HFTLS statement.

It should be noted that for this classification, the analyte class may cover more than one of the sectors of our “organic analysis space”, for example the class of mycotoxins may cover both non-polar and polar regions and hence more than one comparison may be needed to demonstrate capability.

Classification 3

This classification will cover the entire or a subset of the HFTLS statement of the appropriate comparison and will normally represent a specific sector of the ‘organic analysis space’ model.

Examples:

- Mass fraction purity of organic compounds of high polarity ($pKOW > -2$) with molar mass range 300 – 500 g/mol
- Mass fraction of organic compounds of low polarity ($pKow < -2$) with molecular mass of 100 - 500 g/mol at mass fraction from 100 $\mu\text{g}/\text{kg}$ to 100 mg/kg in a multicomponent organic solution
- High-polarity analytes ($pKOW > -2$) with the molecular mass range from 200 - 500 g/mol at mass fraction 20-5,000 $\mu\text{g}/\text{kg}$ levels in a high fat, high protein matrix

Supporting Evidence for Broad Scope CMC Claims

The broadness of the scope of the CMC claim permitted for an Institute will be dependent on the strength of the track record of that Institute in historical CCQM comparisons. The tables below give an indication of the expected requirements for pure materials, calibration solutions and matrix materials.

Generally, older comparisons (more than 10 years from the time of measurement) may only be used as evidence if there are no newer comparisons. No more than one of such older comparisons should be counted, even if multiple numbers are provided as evidence for a broad CMC claim. There should always be evidence of continued competence, e.g. from a peer review report to indicate that the institute has maintained the relevant equipment and technical skills for the service covered by the broad scope CMC claim. Participation in all relevant Track A key comparisons that have a HFTLS statement that overlaps with a broad scope CMC is mandatory.

Pure materials			
Broad scope Classifications	1	2	3
	Homologues and Common classes with well-defined range of structural variation	More structurally diverse categories that fit within the HFTLS statement(s) of the relevant CCQM key comparison(s)	Broad claim covering subset or entire HFTLS statement
Requirements to underpin claim ♦	Successful participation in the most relevant OAWG Track A Model 1 key comparison with respect to the measurand plus 1 additional purity comparison* demonstrating uncertainty that supports the CMC claim to indicate repeat successful participation.	Successful participation across a minimum of 2 purity key comparisons demonstrating uncertainties that support the CMC claim, ensuring they cover the sectors of the 'organic analysis space' relevant to the entire scope of potential measurands. At least one must be an OAWG Track A Model 1 comparison.	Successful participation across minimum of 3 purity comparisons# demonstrating uncertainties that support the CMC claim in at least 2 different sectors of the 'organic analysis space'. At least one must be an OAWG Track A Model 1 comparison.

* Includes recent pilot study, provided there is no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim.

Includes not more than one recent pilot study, provided there are no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim. Note: Participation in a pilot study that is coordinated in parallel to a key comparison cannot be counted as evidence.

♦ An OAWG Track A Model 1 key comparison is required for all Classification broad claims. When a Track A Model 1 key comparison for the area is not available, multiple OAWG Track A and Track C key comparisons that use similar approaches but where the HFTLS do not overlap directly with the broad scope CMC may be used as evidence.

While the use of pilot studies as evidence is possible under the current guidance, institutes should be aware of the limitations involved in their use. As part of the OAWG strategic plans, the organisation of purity key comparisons is on-going. Unless there are changes to the OAWG plans where purity comparisons, such as the K148 series, are no longer organised, it remains that pilot studies cannot be counted towards the minimum number of evidences required for a broad scope claim. For example, the two P150 series pilot studies can be used as supporting evidence but cannot be counted towards the minimum number of evidences for a broad scope CMC as K55 series of purity key comparisons were being organised over the same timeframe. Institutes should refer to the most updated listing of key comparisons or pilot studies eligible for supporting CMC claims as published in the BIPM website¹.

¹ www.bipm.org/en/committees/cc/ccqm/wg/ccqm-kcwg/other-working-documents

Calibration Solutions			
Broad scope Classifications	1	2	3
	1. Homologues and Common classes with well-defined range of structural variation [^]	2. More structurally diverse categories that fit within the HFTLS statement(s) of the relevant CCQM key comparison(s) [^]	3. Broad claim covering subset or entire HFTLS statement [^]
Requirements to underpin claim ♦	Successful participation in the most relevant OAWG Track A Model 1 key comparison with respect to the measurand plus 1 additional calibration solution comparison* demonstrating uncertainty that supports the CMC claim to indicate repeat successful participation.	Successful participation across at least 2 calibration solution key comparisons demonstrating uncertainties that support the CMC claim, ensuring they cover the sectors of the 'organic analysis space' relevant to the measurand. At least one must be an OAWG Track A Model 1 comparison.	Successful participation across at least 3 calibration solution comparisons [#] demonstrating uncertainties that support the CMC claim, one being an OAWG Track A Model 1 comparison related to the claim and the other two selected to be as closely related as possible to capabilities needed for the claim.

[^] Broad scope claims for calibration solutions fall into similar categories as for pure materials but are subjected to additional considerations of the availability of calibration materials and the volatility of solvent matrix.

* Includes recent pilot study, provided there is no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim.

[#] Includes not more than one recent pilot study, provided there are no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim.

Note: Participation in a pilot study that is coordinated in parallel to a key comparison cannot be counted as evidence.

♦ An OAWG Track A Model 1 key comparison is required for all Classification broad claims. When a Track A Model 1 key comparison for the area is not available, multiple OAWG Track A and Track C key comparisons that use similar approaches but where the HFTLS do not overlap directly with the broad scope CMC may be used as evidence.

Institutes making broad scope claims risk facing the inability to deliver their broad range of services if other institutes providing the source of traceability to their services terminate their CRMs or fail to demonstrate successful participation in the relevant purity comparisons. Considering the wide impact to the services of Institutes with broad scope claims under such circumstance, these Institutes should have the ability to provide a source of traceability to themselves for such claims covering calibration solutions or matrix materials.

Broad scope claims for calibrations solutions will only be accepted where the Institutes making the claims have demonstrated capability in the assignment of purity for the generation of their own calibrants. For example, for a broad scope "Mass fraction purity of organic compounds of high polarity ($pK_{OW} > -2$) with molar mass range 300 – 500 g/mol in acetonitrile", the Institutes making the claims

must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and molar mass.

In addition to defining the scope of the analyte, broad scope claims for calibration solution should also include mass fraction ranges and potential solvents, the latter may be expressed as range of physical characteristics (e.g. boiling point range).

Matrix Materials			
Broad scope Classifications	1	2	3
	Homologues and common classes with well-defined range of structural variation in same matrix type	More structurally diverse categories that fit within the HFTLS statement(s) of the relevant CCQM key comparison(s)	Broad claim covering a subset or entire HFTLS statement
Requirements to underpin claim related to Matrix comparisons ♦	Successful participation in the most relevant OAWG Track A Model 1 key comparison with respect to the measurand plus 1 additional matrix comparison* demonstrating uncertainty that supports the CMC claim to indicate repeat successful participation.	Successful participation in a minimum of 2 key comparisons demonstrating uncertainties that support the CMC claim, ensuring they cover the sectors of the 'organic analysis space' relevant to the measurand and are as closely related as possible to the capabilities needed for the claim. At least one must be an OAWG Track A Model 1 comparison.	Successful participation across at least 3 matrix comparisons# demonstrating uncertainties that support the CMC claim, one being an OAWG Track A Model 1 comparison related to the claim and the other two selected to be as closely related as possible to capabilities needed for the claim.

* Includes recent pilot study, provided there is no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim.

Includes not more than one recent pilot study, provided there are no other recent key comparisons organised and there is sufficient evidence in the pilot study report (such as reference value) to assist in the evaluation of the claim.

Note: Participation in a pilot study that is coordinated in parallel to a key comparison cannot be counted as evidence.

♦ An OAWG Track A Model 1 key comparison is required for all Classification broad claims. When a Track A Model 1 key comparison for the area is not available, multiple OAWG Track A and Track C key comparisons that use similar approaches but where the HFTLS do not overlap directly with the broad scope CMC may be used as evidence.

Broad scope claims for matrix materials will only be accepted where the Institutes making the claims has demonstrated capability in the assignment of purity for the generation of their own calibrants. For

example, for a broad scope “Mass fraction purity of organic compounds of high polarity ($pK_{ow} > -2$) with molar mass range 300 – 500 g/mol in soil”, the Institutes making the claims must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and molar mass.

Templates aimed at guiding institutes and CMC reviewers in providing or assessing the necessary evidence for broad scope CMCs should be completed and submitted for each new claim, for CMC review or when new evidence from a relevant key comparison is available. Given the complexity within the organic analysis measurement space with respect to analyte structure, polarity, stability and the makeup of the matrix, the criteria are expectedly different, dedicated templates will be made available for various categories of CMCs and these will be updated periodically by OAWG.

Ongoing Competence

Pure Materials

Classification 1 and 2 broad scope claims should be underpinned by performance in at least 2 purity comparisons, including the relevant sector(s) related to the claims, over the cycle of the CCQM-K55 and/or CCQM-K148 series. Classification 3 broad scope claims should be underpinned by 3 purity comparisons over the cycle of the CCQM-K55 and/or CCQM-K148 series.

Calibration Solutions

Classification 1 and 2 broad scope claims should be underpinned by performance in at least 2 solution comparisons over the 10-year OAWG strategy period. Classification 3 broad scope claims should be underpinned by 3 solution comparisons over that timeframe. For all classifications, participation in the relevant purity Track A comparisons for organic compounds with a similar range of polarity and molar mass to the broad scope is required.

Matrix materials

Classification 1 and 2 broad scope claims should be underpinned by performance in at least 2 matrix comparisons over the 10-year OAWG strategy period, selecting those most relevant to the claim. Classification 3 broad scope claims should be underpinned by 3 matrix comparisons over that timeframe, selecting those most relevant to the claim. In both cases participation at least once every 5 years would be expected. For all classifications, participation in the relevant purity Track A comparisons for organic compounds with similar range of polarity and molar mass to the broad scope is required.

Non-core, i.e. non-Track A CCQM comparisons that fall within an Institute’s broad scope claims would not be mandatory, provided successful participation in all relevant Track A Model 1 comparisons has been achieved. Non-mandatory comparisons may however be undertaken by an Institute to allow enhancement of existing claims (e.g. to improve the measurement uncertainty) but unsatisfactory performance will risk suspension of related claims.

Each Institute with broad scope CMC claims should monitor which upcoming comparisons are mandatory to demonstrate ongoing competence and consider the potential impact of non-mandatory comparisons being undertaken (see an example in Appendix 1).

Should an Institute decide not to participate in one of the relevant mandated comparisons then they should proactively withdraw any claims related to this comparison. The KCWG should be notified prior to their next meeting after the date of data submission for that comparison.

Actions on failure on subsequent CCQM comparisons

1. The Institute is expected to conduct a quality investigation and implement appropriate corrective measures which can be supplied to the KCWG for consideration within 1 year of the KCRV being determined and indicating that performance of the Institute does not support their associated CMCs.
2. If these are not deemed acceptable the claim will be suspended.

The Institute should assess:

- What was the failure (e.g. extraction, chromatography, mass spectrometry, standards, etc.) and what other services or CRMs would this failure potentially effect;
- What changes have occurred that may have impacted on the failure e.g. changes in staff, instrumentation & premises; and
- Whether it was a particularly challenging analyte that requires exclusion from the broad scope claim.

On failure, the institute should review what CRMs and services have been delivered since the last successful comparison and assess whether the status of these needs to be downgraded and any customers informed.

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.

CMC submissions and reviews

The layout of current CMC submission form does not cater well for broad scope claims and the range of measurement uncertainty in broad scope CMC claims will refer to smallest and largest uncertainties seen across the scope of services and underpinned by supporting comparisons. It should be reinforced that a broad scope CMC claim should be supported by real services. The uncertainty convention field is less relevant as the range of uncertainties can be due to differences in both analyte type, analyte levels and matrix type.

Ideally broad scope CMCs should still be relatable to the underpinning services. To incorporate useful information on CRMs, calibration services etc for the external user community, it is recommended to place such information in the Comments for Publication text box of the CMC template in KCDB 2.0.

Appendix 1. Example of ongoing competence monitoring form for broad scope claims

LGC – OAWG broad scope ongoing competence requirements									
Identifier	Analyte scope	Matrix	Classification	K148.a	K159	K78.b	K148.b	K168	K148.c
				Non-polar pure organic	Biomarkers in clinical matrix	Non-polar multi component solution	Polar pure organic	Analyte in high carbohydrate food	Large mol.weight pure organic
Org-048	amino acid with molecular weight less than 300	High purity amino acids	1	Mandatory			Mandatory		
Org-060	high polarity organic compounds with Mwt between 300 and 500	Pure material	3	Mandatory			Mandatory		Mandatory
ORG-051	PBDEs PAHs PCBs Low polarity pesticides (<500Mwt) Perfluorinated carboxylic acids (<C12) Perfluorinated sulphonates (<C12)	Sludge	2	Mandatory	Not mandatory but LGC participated as part of their 10-year suite of evidence		Mandatory		Mandatory
ORG-052	PBDEs PAHs PCBs Low polarity pesticides (<500Mwt) Perfluorinated carboxylic acids (<C12) Perfluorinated sulphonates (<C12)	Soil	2	Mandatory	Not mandatory but LGC participated as part of their 10-year suite of evidence		Mandatory		Mandatory
ORG-053	PBDEs PAHs PCBs Low polarity pesticides (<500Mwt) Perfluorinated carboxylic acids (<C12) Perfluorinated sulphonates (<C12)	Sediment	2	Mandatory	Not mandatory but LGC participated as part of their 10-year suite of evidence		Mandatory		Mandatory

Revision History

No.	Version	Relevant sections	Revisions
1	2.3	"Introduction"	Added sentence: "This document should be used in conjunction with a CCQM wide guidelines on the Review of CCQM CMCs for Inclusion in the Key Comparison Database by the Key Comparison and CMC quality Working Group (KCWG)."
2	2.3	"Supporting Evidence for Broad Scope CMC Claims"	Added 2nd paragraph: "Generally, older comparisons (more than 10 years from the time of measurement) may only be used as evidence if there are no newer comparisons. No more than one of such older comparisons should be counted, even if multiple numbers are provided as evidence for a broad CMC claim. There should always be evidence of continued competence, e.g. from a peer review report to indicate that the institute has maintained the relevant equipment and technical skills for the service covered by the broad scope CMC claim. Participation in all relevant Track A key comparisons that have a HFTLS statement that overlaps with a broad scope CMC is mandatory." Added last paragraph: "Templates aimed at guiding institutes and CMC reviewers in providing or assessing the necessary evidence for broad scope CMCs should be completed and submitted for each new claim, for CMC review or when new evidence from a relevant key comparison is available. Given the complexity within the organic analysis measurement space with respect to analyte structure, polarity, stability and the makeup of the matrix, the criteria are expectedly different, dedicated templates will be made available for various categories of CMCs and these will be updated periodically by OAWG."
3	2.3	Additional notes for all three tables providing requirements to underpin broad CMC claims	Added note: "♦ An OAWG Track A Model 1 key comparison is required for all Classification broad claims. When a Track A Model 1 key comparison for the area is not available, multiple OAWG Track A and Track C key comparisons that use similar approaches but where the HFTLS do not overlap directly with the broad scope CMC may be used as evidence."
4	2.3	"CMC submissions and reviews"	Editorial change and insertion to 1st paragraph: "The layout of current CMC submission form does not cater well for broad scope claims and the range of measurement uncertainty in broad scope CMC claims will refer to smallest and largest uncertainties seen across the scope of services and underpinned by supporting comparisons. It should be reinforced that a broad

			<p>scope CMC claim should be supported by real services. The uncertainty convention field is less relevant as the range of uncertainties can be due to differences in both analyte type, analyte levels and matrix type.”</p> <p>Added last paragraph: “Ideally broad scope CMCs should still be relatable to the underpinning services. To incorporate useful information on CRMs, calibration services etc for the external user community, it is recommended to place such information in the Comments for Publication text box of the CMC template in KCDB 2.0.”</p>
5	2.4	“Supporting Evidence for Broad Scope CMC Claims”	<p>Added 3rd paragraph: “While the use of pilot studies as evidence is possible under the current guidance, institutes should be aware of the limitations involved in their use. As part of the OAWG strategic plans, the organisation of purity key comparisons is on-going. Unless there are changes to the OAWG plans where purity comparisons, such as the K148 series, are no longer organised, it remains that pilot studies cannot be counted towards the minimum number of evidences required for a broad scope claim. For example, the two P150 series pilot studies can be used as supporting evidence but cannot be counted towards the minimum number of evidences for a broad scope CMC as K55 series of purity key comparisons were being organised over the same timeframe. Institutes should refer to the most updated listing of key comparisons or pilot studies eligible for supporting CMC claims as published in the BIPM website.”</p>
6	2.4	“Supporting Evidence for Broad Scope CMC Claims”	<p>Added 4th paragraph: “Institutes making broad scope claims risk facing the inability to deliver their broad range of services if other institutes providing the source of traceability to their services terminate their CRMs or fail to demonstrate successful participation in the relevant purity comparisons. Considering the wide impact to the services of Institutes with broad scope claims under such circumstance, these Institutes should have the ability to provide a source of traceability to themselves for such claims covering calibration solutions or matrix materials.”</p>
7	2.4	“Supporting Evidence for Broad Scope CMC Claims”	<p>Revised 5th paragraph from: “Broad scope claims for calibrations solutions will only be accepted where either calibration materials from Institutes with demonstrated capability in the assignment of purity are freely available to cover the range of analytes within the CMC, or the Institutes making the claims have demonstrated capability in the assignment of purity for the generation of their own calibrants. For example, for a broad scope “Mass fraction purity of organic compounds of high polarity ($pK_{ow} > -2$) with molar mass range 300 – 500 g/mol in acetonitrile”, the Institutes making the claims providing the source of traceability must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and mass range.” to “Broad scope claims for calibrations solutions will only be accepted where the Institutes making the claims have demonstrated capability in the assignment of purity for the generation of their own calibrants. For example, for a broad scope “Mass fraction purity of organic compounds of high polarity ($pK_{ow} > -2$) with molar</p>

			mass range 300 – 500 g/mol in acetonitrile”, the Institutes making the claims must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and molar mass.”
8	2.4	“Supporting Evidence for Broad Scope CMC Claims”	Revised 7th paragraph from: “Broad scope claims for matrix materials will only be accepted where either calibration materials from Institutes with demonstrated capability in the assignment of purity are freely available to cover the range of analytes within the CMC, or the Institutes making the claims has demonstrated capability in the assignment of purity for the generation of their own calibrants. For example, for a broad scope “Mass fraction purity of organic compounds of high polarity ($pK_{ow} > -2$) with molar mass range 300 – 500 g/mol in soil”, the Institutes making the claims providing the source of traceability must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and mass range.” to “Broad scope claims for matrix materials will only be accepted where the Institutes making the claims has demonstrated capability in the assignment of purity for the generation of their own calibrants. For example, for a broad scope “Mass fraction purity of organic compounds of high polarity ($pK_{ow} > -2$) with molar mass range 300 – 500 g/mol in soil”, the Institutes making the claims must have demonstrated successful participation in purity comparisons for organic compounds with similar range of polarity and molar mass.”
9	2.4	“Ongoing Competence”	Deleted last sentence in 2nd paragraph: “Participation in relevant purity comparisons will also be required where the Institute would need to carry out in-house assessment of calibrants in order to cover the scope of the claim.” Added last sentence in 2nd paragraph: “For all classifications, participation in the relevant purity Track A comparisons for organic compounds with a similar range of polarity and molar mass to the broad scope is required.”
10	2.4	“Ongoing Competence”	Deleted last sentence in 3rd paragraph: “Participation in relevant purity comparisons will also be required where the Institute would need to carry out in-house assessment of calibrants in order to cover the scope of the claim.” Added last sentence in 3rd paragraph: “For all classifications, participation in the relevant purity Track A comparisons for organic compounds with a similar range of polarity and molar mass to the broad scope is required.”
11	2.4	“CMC Submissions and Reviews”	Deleted 2nd paragraph: “The source of traceability field, which possibly includes more than one NMI given the broadness in the scope of the CMC, is limited by the current rule that not more than one source of traceability should be cited. To circumvent such scenarios, additional supplementary information should be included to provide more information to the reviewers and customers.”

12	2.4	Appendix 1	Replaced "TBD" with "K168" and deleted the words "Mandatory" under the column. Added the wording "Not mandatory but LGC participated as part of their 10-year suite of evidence" under the column for K159.
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