

Peptides, SARMs, and Research Chemicals

Category 26 · Manual v1

Method v2.1: ICH Q3D read-across. Metal safety only.

AUTHOR AND PUBLISHER

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About this manual

The Category 26 program manual. Seven metals (Pb, Cd, tAs, tHg, Ni, Sn, Cr) are read across from the ICH Q3D elemental-impurity limits. Aluminium uses the FDA injectable limit (25) for the injectable and nasal standards and the EU drinking-water limit (200) for raw powders and oral SARMs. Inorganic arsenic, methylmercury, and hexavalent chromium are capped at their parent totals and tested on every lot. Scope: metal safety only, not efficacy, legality, or approval status. The manual DOI is not deposited in this edition.

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Contents

Part 1: Why this manual exists

- 1.1 Drive down contamination
- 1.2 Protect consumers
- 1.3 Protect brands who enter
- 1.4 Remain legally defensible
- 1.5 Become the de facto standard

Part 2: Program lifecycle and instruments

- 2.1 The governing rule
- 2.2 Program flow
- 2.3 The analyte panel
- 2.4 Certification status framework
- 2.5 Measurement uncertainty
- 2.6 CAPA
- 2.7 Remediation
- 2.8 The mark
- 2.9 Standards ratchet

Part 3: Category 26 Standards Register

- Five standards and their house DOIs

Part 4: Lot Testing Schedule

- 4.1 Product risk tiers
- 4.2 The Testing-Frequency Matrix
- 4.3 Baseline
- 4.4 Surveillance by status
- 4.5 Species
- 4.6 Sampling and chain of custody
- 4.7 Lab-informed schedule
- 4.8 90% stay-in-program certification gate

Part 5: Method and glossary

- 5.1 How every limit is set
- 5.2 What this manual does not do
- 5.3 Glossary
- 5.4 References

Why this manual exists

The Heavy Metal Tested & Certified program for peptides, SARMs, and research chemicals is governed by five co-equal objectives. None may be sacrificed to advance another. The ruling is `docs/governance/hmtc--governing-principles.md`, the file named by the readiness manifest.

Limits do not derive from the Heavy Metal Index. Every published number traces to a named instrument or a disclosed read-across already on the standard record [1][2][3][4].

Certification is metal safety only. It does not certify efficacy, legality, or approval status.

1.1 Drive down contamination

The program exists to lower the heavy-metal burden in products that reach people. A mark that does not change what is in the vial, the powder, or the oral dose is not the work.

1.2 Protect consumers

Limits, lot testing, and the mark are instruments of consumer protection for one attribute: the metal content of the tested lot. A certificate that cannot be trusted does not protect anyone.

1.3 Protect brands who enter

A brand that enters in good faith, tests honestly, and stays inside the published rules is not set up to fail. Certification is offered only when the program has at least 90% confidence the brand can remain in the program.

1.4 Remain legally defensible

Claim-surface ceilings are disclosed read-across only. Seven metals are read across from the ICH Q3D elemental-impurity limits [1][2]. Aluminium uses the FDA injectable limit (25) on the injectable and nasal standards and the EU drinking-water limit (200) on raw powders and oral SARMs [3][4]. Species never replace the parent total. Nothing is invented.

1.5 Become the de facto standard

The program is written to be the instrument a laboratory, a brand, and a regulator can actually use for metal safety. It is not an approval, an efficacy claim, or a statement that the product is lawful to sell.

Program lifecycle and instruments

This Part is how a Category 26 SKU enters, is assigned a status, and is held to the mark. Except where a defined term states otherwise, every requirement is normative. The five live standard pages remain the derivation of each cell.

2.1 The governing rule

Certification is limit-relative and binary at the limit. For every numeric ceiling the applicable limit is the disclosed read-across on the live standard (Method v2.1). Limits do not derive from a distribution of measured values. A product is Certified only when every numeric ceiling is met at or below 100% of its published limit, confirmed under the measurement-uncertainty decision rule (section 2.5). There is no band above the limit that still earns the mark.

The eight numeric ceilings are lead (Pb), cadmium (Cd), total arsenic (tAs), total mercury (tHg), nickel (Ni), tin (Sn), aluminium (Al), and total chromium (Cr). Inorganic arsenic, methylmercury, and hexavalent chromium do not carry a separate numeric ceiling. Each is capped at its parent total and tested on every lot. They never replace the parent total. All claim analytes are equal at the gate.

Certification is metal safety only. It does not certify efficacy, legality, or approval status.

2.2 Program flow

1. Baseline (three lots). Every SKU is tested across a minimum of three production lots, on the eight numeric ceilings and the three species, before any status is assigned. A single passing lot certifies nothing. The entry decision is taken from the worst-performing lot.
2. Expedited baseline (prior-data credit), optional. Qualifying ISO/IEC 17025 results from the preceding 12 months may credit up to two lots, per analyte actually measured. Not available on the Confidential Remediation Track.
3. Entry. A lot above any published HMTc ceiling is not certified and enters Remediation.
4. Status assignment. The product is assigned Certified or Remediation from the baseline, then maintained through surveillance. Suspension and Revocation follow section 2.4.
5. Schedule assignment. The Lot Testing Schedule is written after application, from the brand laboratory's stated panel, limit of quantification, measurement uncertainty, and capability (Part 4).

2.3 The analyte panel

The panel is eight numeric ceilings plus three species. Lead, cadmium, inorganic arsenic, and mercury may be named as priority toxics for toxicological clarity. That label is not a status ladder. Every claim analyte is equal at the gate: at or below 100% of its published ceiling, or, for a species, at or below its parent total. An exceedance on any metal removes the mark and moves the SKU to Remediation. No metal has a transitional band or an allowed overage.

Inorganic arsenic, methylmercury, and hexavalent chromium are capped at total arsenic, total mercury, and total chromium. Each species is tested on every lot. The species result never replaces the parent total. Both must be met.

2.4 Certification status framework

Four statuses. Status attaches to the product, not the brand. The mark is permitted only while the product is Certified.

Status	Meaning	Mark	Condition
Certified	Full compliance	Permitted	Every numeric ceiling at or below 100% of its published limit, and every species at or below its parent total, confirmed under section 2.5.
Remediation	Not certified, applicant or corrective	Withheld / removed	The product does not meet every published ceiling, or is a new applicant not yet at 100%. This is not a softer certification and not an allowed overage. The SKU is not listed as certified and the mark is not displayed.
Suspension	Certification halted, hard stop	Removed	A data-integrity failure, or failure to execute testing, CAPA, or directives. The mark is removed from units and marketing immediately.
Revocation	Permanent termination	Removed	Willful misconduct, data fraud, concealment of a known exceedance, or persistent unremediated suspension. Re-entry by full re-application only.

The Certification Mark shall not be used on any product, packaging, or marketing unless the product is Certified. A product above any published ceiling, at any margin and on any metal, is not Certified and does not display the mark.

Suspension reinstatement does not require a fresh baseline. It requires a completed CAPA with verification of effectiveness, a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval.

2.5 Measurement uncertainty

Every result is read with the laboratory's expanded measurement uncertainty at coverage factor $k = 2$ (95%). Pass only when the result plus the uncertainty is at or below the limit. Fail when the result minus the uncertainty is above the limit. Anything between is borderline and requires confirmatory action before a status issues. A borderline result alone shall not certify. Testing into compliance is prohibited.

2.6 CAPA

CAPA windows scale with certification status, not with analyte class. A product in Remediation has a 12-month default to return to Certified. A CAPA closes only after verification of effectiveness and Operator approval.

Status	Initiate	Full plan	Containment
Remediation	10 business days	30 calendar days	as needed
Suspension (hard stop)	2 business days	10 business days	Immediate (within 48 hours)

2.7 Remediation

The Confidential Remediation Track is a confidential entry-and-support pathway for products not yet at 100% of every published ceiling. It is not a certified status and displays no mark. Concealment of a known exceedance is grounds for revocation. Confidentiality never delays a recall, never overrides a reporting duty, and never withholds evidence from a regulator who asks.

2.8 The mark

The mark may be used only on Certified product. Claims of heavy-metal free, no toxic metals, or 100% safe are prohibited. The mark certifies metal safety of the tested lot against the published ceilings, under ongoing surveillance. It does not certify efficacy, legality, or approval status.

2.9 Standards ratchet

A published limit tightens only through the Standards Ratchet: a stated trigger, a capped step, and a dated edition. Limits do not loosen because a brand found them inconvenient. The subcategory page, not this manual, is the live derivation of each cell.

Category 26 Standards Register

Five live standards. Cert-ready means the page carries a house DOI under prefix 10.83138. 5 of 5 are cert-ready. Ceilings are not reprinted here. Aluminium on the parenteral group is 25. Aluminium on the oral group is 200. Both figures are read from the compiled records.

Injectable anabolic-androgenic steroids (AAS)

/standards/aas-injectable · aas-injectable · parenteral
10.83138/hmtc.std.26.aas-injectable

Injectable peptide hormones (GLP-1 analogs, GH secretagogues, synthetic peptides)

/standards/peptides-injectable-hormones · peptides-injectable-hormones · parenteral
10.83138/hmtc.std.26.peptides-injectable-hormones

Nasal/sublingual/troche gray-market peptide preparations (mucosal route)

/standards/peptides-nasal-sublingual · peptides-nasal-sublingual · parenteral
10.83138/hmtc.std.26.peptides-nasal-sublingual

Raw AAS / peptide powders (pre-formulation)

/standards/research-chem-raw-powders · research-chem-raw-powders · oral
10.83138/hmtc.std.26.research-chem-raw-powders

Oral SARMs

/standards/sarms-oral · sarms-oral · oral
10.83138/hmtc.std.26.sarms-oral

Lot Testing Schedule

Certification is a standing obligation for as long as the mark appears on a product. The five subcategory standards are the live taxonomy.

The eight numeric ceilings and the three species are tested on every lot. Inorganic arsenic, methylmercury, and hexavalent chromium are capped at their parent totals. Product surveillance is not a reason to drop a metal or a species.

4.1 Product risk tiers

All five standards are held to every-lot testing. Several products are injected, or may be reconstituted for injection, and the nasal and sublingual preparations are treated with the parenteral ceilings. The Program Operator does not assign a lighter calendar to any of the five.

Risk class	Standards
Every lot	Injectable anabolic-androgenic steroids; injectable peptide hormones; nasal and sublingual peptides; raw powders; oral SARMs

The Program Operator may add hold-and-release or third-party sampling on documented rationale. The Operator may not drop an analyte from the every-lot panel.

4.2 The Testing-Frequency Matrix

This is the starting grid. The assigned schedule is written after the lab-informed review in section 4.7. Certified is the only status that carries the mark. Remediation carries no mark. Every claim analyte is equal at the gate. These rows set the testing regime. They do not override the status decisions or deadlines in Part 2.

Certification status	Testing	Hold and release	Independent sampling
Certified	Every lot	not required	yes, per schedule
Remediation	Every lot	mandatory	Operator-directed third-party sampling

Any exceedance, or any species above its parent total, takes the Remediation testing row. There is no transitional overage and no analyte-class exception. A data-integrity failure is Suspension under section 2.4, not a stay on the Remediation row. Concealment of a known exceedance is Revocation under section 2.4.

4.3 Baseline

Every SKU shall undergo baseline testing across three production lots before any certification status is assigned. Status is assigned from the worst-performing lot. Each lot runs the eight numeric ceilings and the three species.

Qualifying prior ISO/IEC 17025 data from the preceding 12 months may credit up to two lots, per analyte actually measured. This pathway is not available on the Confidential Remediation Track.

4.4 Surveillance by status

Certified: every lot, with independent sampling on the assigned schedule. A numeric result at or above 80% of its published ceiling triggers confirmatory testing and Operator notice.

Remediation: the product carries no mark and is not listed as certified. Corrective action is mandatory.

Surveillance is every lot, with mandatory hold-and-release and Operator-directed third-party sampling. Return to Certified requires the product to meet 100% of every published ceiling, and every species at or below its parent, across a run of consecutive lots set by the Program Operator, plus completed CAPA with verification of effectiveness.

Suspension: a data-integrity failure, or a failure to execute testing, CAPA, or directives. Stop-ship and mark removal are immediate. CAPA is initiated within 2 business days, with a full plan within 10 business days, and containment Immediate (within 48 hours). Reinstatement does not require a fresh baseline. It requires a completed CAPA with verification of effectiveness, a run of consecutive compliant lots set by the Program Operator, restored data integrity, and formal Operator approval.

Revocation: willful misconduct, data fraud, concealment of a known exceedance, or persistent unremediated suspension. Re-entry is by full re-application only. The testing row does not keep a revoked product in Remediation.

4.5 Species

Inorganic arsenic is capped at total arsenic. Methylmercury is capped at total mercury. Hexavalent chromium is capped at total chromium. Each is tested on every lot. The species result does not replace the parent total. Both ceilings must be met. Failure to test a required species renders the lot ineligible.

4.6 Sampling and chain of custody

Certification testing is lot-based composite sampling with a complete custody record from collection through laboratory receipt. A custody breach invalidates the result. Testing is ISO/IEC 17025 for the methods and matrices in scope. The limit of quantification for each numeric ceiling must sit at or below the published limit. Where it does not, a non-detect is indeterminate. Results are reported as structured data, with measurement uncertainty, on the as-sold basis. PDF-only submissions are not accepted.

4.7 Lab-informed schedule

The frequency matrix is not assigned by itself. After application, the Program Operator reads what the brand's laboratory actually states and writes the schedule from that evidence.

Input	What is read
Panel	Does the lab quantify every numeric ceiling and the three species on this matrix?
LOQ	Is each numeric ceiling's limit of quantification at or below the published limit?
MU	Is expanded uncertainty reported at $k = 2$?
Capability	Can the lab report inorganic arsenic, methylmercury, and hexavalent chromium on every lot?
Accreditation	ISO/IEC 17025 for the methods and matrices in scope?
Turnaround	Can hold-and-release be met when the Remediation row applies?

Decision owner: Program Operator.

A brand is not certified against a fantasy grid. If the laboratory cannot support the published panel, the limits of quantification, the uncertainty, or the three species on every lot, the SKU stays uncertified until the capability exists.

4.8 90% stay-in-program certification gate

The program certifies only if there is at least 90% confidence the brand can remain in the program. A one-lot pass that will fail the next lot is not a certification. This gate protects brands who enter as much as it protects consumers.

Input	Read as
Baseline lots	three-lot record, worst lot, not the best lot
Headroom	distance to the published ceiling, not a knife-edge pass
Lab capability	the lab-informed schedule inputs above
Species	inorganic arsenic, methylmercury, and hexavalent chromium on every lot
Schedule feasibility	can the brand actually test every lot?
CAPA capacity	can the brand open and close CAPA on the published windows?

Decision owner: Program Operator. Pass means at least 90% confidence the brand can remain under the assigned schedule. A knife-edge baseline, a laboratory that cannot support the schedule, or a doubt about data integrity is not a certification.

Method and glossary

5.1 How every limit is set

The method is a disclosed read-across, not an invented ceiling and not an unbounded control.

Seven metals (lead, cadmium, total arsenic, total mercury, nickel, tin, and total chromium) are read across from the ICH Q3D elemental-impurity limits [1][2]. Injectable anabolic-androgenic steroids, injectable peptide hormones, and nasal or sublingual preparations take the parenteral concentrations. Raw powders and oral SARMS take the oral concentrations.

Aluminium is not an ICH Q3D analyte. It uses the FDA injectable limit (25) on the injectable and nasal standards [3]. It uses the EU drinking-water limit (200) on raw powders and oral SARMS [4].

Inorganic arsenic, methylmercury, and hexavalent chromium do not carry a separate numeric ceiling. Each is capped at its parent total and tested on every lot. The species never replaces the parent.

Every figure above is the value already published on the standard record. This manual does not add a ceiling. Occurrence data carry no compliance weight [5].

Certification is metal safety only. It does not certify efficacy, legality, or approval status.

5.2 What this manual does not do

This manual does not reprint the per-analyte ceiling table. The five live standard pages are the derivation of each cell, and Part 3 lists them with their house DOIs. A change to a cell is made on the standard, then reflected here at the next edition.

5.3 Glossary

percent of limit: A single analyte's measured value divided by its applicable numeric ceiling, as a percentage. Used only as an operational testing trigger (the 80% confirmatory trigger). It is not a certification ladder.

Certification status: The product-level lifecycle: Certified, Remediation, Suspension, Revocation. Certified means every numeric ceiling is at or below 100% of its published limit, and every species is at or below its parent total, under the measurement-uncertainty rule. The mark is permitted only then. Remediation is not certified and carries no mark. Suspension halts certification. Revocation is permanent. No band above the limit keeps the mark. All claim analytes are equal at the gate.

priority toxics: Plain-language name for lead, cadmium, inorganic arsenic, and mercury, used only for toxicological clarity. It is not a status ladder and does not change the certification gate.

CAPA: Corrective and preventive action. Windows scale with status.

read-across: A disclosed mapping from the named instrument on the standard record. For this category, the seven metals map from ICH Q3D, and aluminium maps from the FDA injectable limit or the EU drinking-water limit, by standard.

native basis: The form in which the product is sold. Every Category 26 standard is as sold.

metal safety only: The only attribute the mark speaks to. Not efficacy, not legality, and not approval status.

5.4 References

[1] International Council for Harmonisation. ICH Q3D guideline on elemental impurities, Table A.2.2 Option 1 concentration limits, oral and parenteral.

[2] United States Pharmacopeia. General Chapter 232, Elemental Impurities: Limits. General Chapter 233, Elemental Impurities: Procedures.

[3] U.S. Food and Drug Administration. 21 CFR 201.323, aluminum in large volume parenterals. The injectable and nasal standards record this ceiling as 25.

[4] European Union drinking-water aluminium limit, source id eu20202184_al_drinking_water_200. The raw-powder and oral SARM standards record this ceiling as 200.

[5] Heavy Metal Index, literature baseline. <https://heavymetalindex.com>. Cited one way, outbound only. The Index does not set these ceilings.

Edition record

Manual v1 is current. The house DOI suffix hmtc.manual.peptides-sarms-and-research-chemicals is reserved for deposit. This edition does not carry a manual DOI.

Edition	Date	Status	DOI	What changed
Manual v1	2026-10-12	current	not yet deposited	First Category 26 Program Manual. Five standards, ICH Q3D read-across for seven metals, FDA injectable aluminium (25) on injectable and nasal standards, EU drinking-water aluminium (200) on raw powders and oral SARMs. Species capped at the parent total and tested on every lot. Metal safety only.

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