The First Feminine-Care Standard

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THE CLAIM

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No government sets a heavy-metal content limit for a menstrual device in any jurisdiction. HMTc has published what is, to our knowledge, the first standard that does: it reads across the strictest mucosal-contact health limit any government has drawn, holds device forms to the same values by disclosed read-across by analogy, and tests every certified lot against them.

Abstract

Heavy Metal Tested and Certified has published a heavy-metal-safety standard for menstrual and intimate-care products, tampons, pads, cups, discs, and period underwear, and the intimate cosmetics alongside them, douches, washes, wipes, and deodorants. To our knowledge it is the first standard anywhere to place per-analyte heavy-metal limits on this category. No government sets a heavy-metal content limit for a menstrual device in any jurisdiction, because device law asks whether a material is biocompatible, not how much lead it contains; and the cosmetic limits that do exist were written for skin, not for the vulvovaginal mucosa these products actually contact. In 2024 a peer-reviewed study measured lead, cadmium, and arsenic in every tampon it tested.

The standard is written on a mucosal basis and reads across the strictest mucosal-contact health limit a government has drawn, never inventing a number of its own. Cosmetic forms bind sovereign cosmetic contaminant limits directly; device forms, for which no government sets a content limit, carry the same values by disclosed, conservative read-across by analogy. Every analyte on the panel carries an enforceable ceiling, nine firm read-across limits plus inorganic arsenic and methylmercury bounded by their parent totals, and every certified lot is tested for the full panel by mass spectrometry. The mark certifies heavy-metal safety only, and states the presence-versus-dose evidence honestly rather than as alarm.

A standard written for the surface, not the shelf

The reason this category needed its own standard is a matter of anatomy, and it is the point the whole standard turns on. Contaminant regulation treats the body as either a gut or a skin. Food limits assume the metal is swallowed, buffered by stomach acid, and subject to the fractional absorption of the digestive tract. Cosmetic limits assume the metal sits on intact skin, whose outer keratin layer is a genuine barrier that most metals cross slowly and incompletely. The vulvovaginal mucosa is neither. It is a thin, non-keratinised, richly vascularised epithelium, kept moist and, during use, in prolonged and occlusive contact with an absorbent or collecting device. Clinical medicine delivers drugs systemically by this route precisely because it is so permeable, and because a portion of what crosses it reaches the bloodstream without the first-pass hepatic metabolism that would clear an equivalent swallowed dose [4]. A limit calibrated to skin, or to a fraction of an eaten dose, does not describe what this surface does with a metal held against it for four to eight hours.

So the standard is written on a mucosal basis and never on a dermal or dietary one. That single decision is what makes it specific to feminine care rather than borrowed from cosmetics: it accounts directly for the fact that the vaginal mucosa absorbs more readily than skin, and it refuses to import a skin-calibrated number as though the two surfaces were equivalent. Everything downstream, which frameworks the standard reads across and which it rejects, follows from putting the absorptive route first. The fuller argument for why the gap exists, and why a certification program is the instrument that can close it, is set out in the companion briefing, The Mucosal Gap; this briefing is about the numbers that gap now has.

What the standard sets

The category divides into two instrument families that share the mucosal basis. The law treats them differently, and the standard is explicit about that difference rather than papering over it.

The intimate cosmetics, douches, intimate washes, feminine wipes, and feminine deodorants, are cosmetics, so sovereign cosmetic contaminant limits apply to them directly, and the standard reads across the strictest one for each metal. The menstrual devices, tampons, pads, cups, discs, and period underwear, are regulated as medical devices, and no government sets a numeric heavy-metal content limit for the finished device. Rather than leave those cells blank, the standard reads a limit across by analogy: for each metal it adopts the strictest health-based limit any government has set for an article in the same kind of prolonged mucosal contact, and holds the device to that number. The analogy is disclosed, not hidden, and it is deliberately conservative, so a device is measured against a real health-based ceiling rather than against nothing. Every certified lot of either family is tested for the full analyte panel by mass spectrometry, sampled component by component, with a tampon's applicator tested as a distinct component. The outcome is that every analyte in the panel carries an enforceable ceiling: nine firm read-across limits, plus inorganic arsenic and methylmercury bounded by their parent totals and measured on every lot. No cell is a bare pass-through control, and none is a number HMTc originated; each is a disclosed read-across to a named government limit.

The health-based values, and the government framework each is read across from, are these. For the cosmetic forms they bind directly, a cosmetic limit applied to a cosmetic; for the device forms the same values are carried across by analogy, as the closest health-based limit for an article in comparable prolonged mucosal contact:

Analyte	HMTc reference limit (µg/kg)	Read across from	Why this framework
Lead (Pb)	500	German BVL 2017, toothpaste (mucosal-contact) tier	The one place a government draws a stricter cosmetic line for a mucosal-contact product; 500 against the general-cosmetic 2000 [8]
Cadmium (Cd)	100	German BVL 2017, general cosmetic	Strictest sovereign cosmetic value for a trace contaminant [8]
Total arsenic (tAs)	500	German BVL 2017, general cosmetic	Strictest sovereign cosmetic value [8]
Total mercury (tHg)	100	German BVL 2017, general cosmetic	Strictest sovereign cosmetic value [8]
Nickel (Ni)	10,000	Korea MFDS cosmetics standard	The only sovereign cosmetic nickel content limit any government publishes [9]
Total chromium (Cr)	50	Australia, sovereign chromium limit	Total-chromium value carried across from the strictest government limit (Australia) [12]
Hexavalent chromium (Cr-VI)	5	EU 2009/48 toy-safety migration	Health-based limit for the toxic chromium species in a mouthed article [10]
Tin (Sn)	3,750,000 (3,750 mg/kg)	EU 2009/48 toy-safety migration	Health-based migration limit for an article in mouth contact [10]
Aluminium (Al)	560,000 (560 mg/kg)	EU 2009/48 toy-safety migration	Health-based migration limit for an article in mouth contact [10]
Inorganic arsenic (iAs)	bounded by tAs	reflex speciation	Speciated on any elevated total arsenic; cannot exceed its parent total
Methylmercury (MeHg)	bounded by tHg	reflex speciation	No formation pathway in a fibre, polymer, or aqueous product; bounded by the total-mercury control

Inorganic arsenic and methylmercury carry no independent ceiling. Each is the toxic species of a parent total, bounded above by that total, since a species cannot exceed the total it is part of, and measured on every lot; the standard resolves them by reflex speciation of any elevated total rather than by a separate number of their own. Methylmercury has no formation pathway in a fibre, a polymer, or an aqueous wash, so in these products it is expected at or near zero, and that expectation is checked against the total-mercury result every lot rather than assumed.

Where every number comes from

The design rule for the whole matrix is a single sentence: adopt the strictest applicable value from the two most defensible health frameworks for mucosal-contact articles, and invent nothing. The two frameworks are mucosal-contact cosmetics and children's toy safety, and each earns its place for a specific reason.

The mucosal-cosmetic framework is the German BVL 2017 guidance on technically avoidable heavy-metal contents in cosmetics [8]. It is the one place a regulator has drawn a stricter contaminant line for a cosmetic on the explicit ground that the product meets a mucous membrane: it holds lead in toothpaste to 500 micrograms per kilogram against 2000 for general cosmetics, because toothpaste contacts the oral mucosa and is partly swallowed. The standard takes that toothpaste tier for lead, on the reasoning that the vaginal

mucosa is at least as permeable as the oral, and takes the strictest general-cosmetic BVL value for cadmium, total arsenic, and total mercury. Nickel has no BVL contaminant line, so it is read across from the only sovereign cosmetic nickel content limit any government publishes, the Korea MFDS cosmetics standard [9].

The toy-safety framework is EU Directive 2009/48/EC [10]. It earns its place because it is one of the most developed health-based limit sets for an article that is deliberately placed in prolonged mucosal contact: it governs the metals a child may take in from mouthing a toy, and it derives its migration limits from tolerable daily intakes rather than from what industry finds convenient. Where no cosmetic contaminant line exists for a metal, the standard reads across the toy-safety value: hexavalent chromium, tin, and aluminium come from 2009/48, and total chromium is read across from the Australian government chromium limit. One methodological point matters here and is worth stating plainly. The 2009/48 numbers are migration limits, measuring how much metal leaches out of an article under test, and the standard applies them as content ceilings, on the total metal in the finished product. Because the content of a product is always at least as high as what can migrate out of it, using a migration limit as a content ceiling is conservative by construction: a product that passes on total content would pass by a wider margin on migration. The standard errs toward the health value, not away from it.

Every cell in the matrix is therefore a disclosed read-across to a named, published limit, with the direction of every choice toward the stricter number. Nothing in the standard is a value HMTc originated. That is the property that makes it defensible: a reader can check each number against its source document, and the certifier's discretion is limited to which existing government line applies, not to what the number is.

The evidence the numbers answer to

The anchor evidence is Shearston and colleagues, published in Environment International in 2024 [1]. The study digested thirty tampons spanning fourteen brands and eighteen product lines, bought in the United States, the European Union, and the United Kingdom, and measured sixteen metals and metalloids by mass spectrometry. It reports that it is, to the authors' knowledge, the first study to measure metals in tampons at all. Lead was present in every one of the sixty subsamples, at a geometric mean of about 120 micrograms per kilogram, a median of 173, and a maximum of 468. Cadmium was present in every subsample; total arsenic in all but three. The authors found higher lead in non-organic than in organic products and higher lead in products bought in the United States than in Europe, and reported that no product category was consistently lower across all sixteen metals. The authors are explicit that lead has no known safe exposure level, and equally explicit about the limit of their own finding: they measured total content by dissolving the whole product, not the dose that leaves it during use, and they did not speciate the arsenic or mercury.

That honest boundary, presence established and dose not yet quantified, is corroborated and extended by the rest of the literature the standard rests on. A systematic review prepared for the United States Food and Drug Administration's device centre in 2024 reached the same qualitative conclusion across the wider published record [2]. A mechanistic mass-balance model of lead released from a worn tampon, published in 2026, is careful to show that only a small fraction of the lead in a product reaches tissue in its baseline scenario [3]; that cuts both ways, establishing that a real, quantifiable pathway from product to body exists while showing that its magnitude depends on release rate, permeability, and wear time rather than on content alone. A 2025 leaching study measured lead and arsenic moving out of tampons, pads, cups, and period underwear into simulated vaginal fluid, which is the step from presence toward exposure that the Shearston totals could not take [6]. A full-panel screen across tampons, pads, cups, and other intimate

products extended the measured panel to aluminium and tin and anchors those cells [5], and an earlier tampon-chemistry study corroborates the presence of lead, cadmium, mercury, chromium, arsenic, and nickel across the form [7].

The honest reading of this body of work is neither dismissal nor alarm. Presence is established across brands and markets, not as an outlier but as the ordinary case; the absorptive route is established well enough that medicine relies on it; and the resulting dose is not yet fully quantified. A standard has to be correct under both the optimistic and the pessimistic reading of that remaining uncertainty, which is exactly why it tests every lot and reads across health-based limits rather than waiting for a number that may take a decade to settle.

What the standard does not claim

A category this sensitive is easy to overclaim in either direction, so it is worth stating plainly what the mark asserts and what it does not. The Heavy Metal Tested and Certified mark certifies heavy-metal safety, and nothing else. It is not a statement that a product performs well, that it is healthy, that it is free of every other chemical of concern, or that products without the mark are unsafe. No analytical method can certify the absence of an element, and the standard makes no claim of absence: a certified product is one whose metal content was measured, lot by lot, and fell below the strictest limit its exposure route warrants, whether that limit applies to the product directly, as it does for the cosmetic forms, or is carried across by analogy from the closest health-based article limit, as it is for the device forms, for which no government sets a content number of their own.

The framing is harm reduction, not fear. The evidence does not support telling anyone that menstrual products are dangerous, and this briefing does not. It supports the more modest and more useful position that the metals are measurably present, the absorptive route is real, the regulatory rulebook is empty for the devices and skin-calibrated for the cosmetics, and a person is entitled to choose a product whose metal content was actually checked against a health-based limit by a party with no incentive to find it clean.

Common questions

▼ Is this really the first heavy-metal standard for feminine care?
To our knowledge, yes, in the specific sense that matters: a published, per-analyte set of heavy-metal limits for menstrual and intimate-care products, tested lot by lot. Governments regulate menstrual devices for biocompatibility and intimate cosmetics for skin contact, but neither sets a heavy-metal content limit calibrated to the vaginal mucosa, and the anchor study reports that metals in these products had not been measured at all before 2024. If an equivalent standard exists elsewhere, the claim is easily corrected; the standard does not depend on being first, only on being right.

▼ Why read a menstrual-product limit across from a toy-safety directive?
Because children’s toy safety is one of the most developed health-based limit sets for an article deliberately placed in prolonged mucosal contact, and its limits are derived from tolerable intakes rather than from industrial convenience. Where no cosmetic contaminant line exists for a metal, the toy-safety value is the most defensible published number to adopt. The alternative is to invent a limit, which is exactly what the standard refuses to do.

▼ Does a certificate mean the product contains no heavy metals?

No. It means the product was tested and met the standard: for a cosmetic form, below the strictest mucosal-contact limit any government sets for that metal; for a device form, below the same limit carried across by analogy, because no government sets a content limit for the device itself. It is a statement about testing and limits, not about zero, and no honest program can claim zero.

▼ Why set a content ceiling using a limit that was written for migration?
Because it is the conservative direction. A migration limit describes how much metal can leave an article; a content ceiling describes how much is in it. The content of a product is always at least as high as what can migrate from it, so a product that passes on total content passes by a wider margin on migration. Applying the migration value to content holds the product to a stricter test than the original limit demanded.

References

Works cited in this briefing's text, in first-appearance order. This is not the full evidence base for the underlying standard; it is only what the prose above draws on. Every range in the briefing is a model built on one of these published anchors. Where a work carries a DOI or a public URL, its title and domain link to it; primary legal documents and published standards are named but not linked to a corpus record.

[1] Tampons as a source of exposure to metal(loid)s — PEER-REVIEWED

Shearston JA, Upson K, Gordon M, et al. Environment International, 2024. Sixteen metals and metalloids in 30 tampons (14 brands, 18 product lines; US/EU/UK) by ICP-MS. Lead in 60/60 subsamples (geometric mean about 120 µg/kg; median 173; maximum 468); cadmium 60/60; total arsenic 57/60. Reports total content, not exposure; arsenic and mercury not speciated. · doi.org

[2] Contaminants in Vaginal Tampons: A Systematic Literature Review — GOVERNMENT

International Consulting Associates, Inc., final report prepared for the U.S. FDA Center for Devices and Radiological Health (CDRH), Version 5.0, December 2024. Systematic review corroborating the presence of lead, cadmium, arsenic, and other metals in vaginal tampons across the published literature.

[3] Integrating experimental data and mechanistic modeling to assess potential lead exposure from tampon use — PEER-REVIEWED

Ellison CA, et al. Toxicological Sciences, 2026. Mass-balance model of lead released from a worn tampon across menstrual-fluid fractions and vaginal tissue; the baseline scenario estimates that only a small fraction of product lead reaches tissue. · doi.org

[4] The vagina as a route for systemic drug delivery — PEER-REVIEWED

Hussain A, Ahsan F. Journal of Controlled Release, 2005. Review establishing the vaginal mucosa as a high-permeability route used clinically for systemic drug delivery, with partial avoidance of hepatic first-pass metabolism.

[5] Development of a generic safety assessment strategy for feminine intimate products — PEER-REVIEWED

Marcelis Q. PhD thesis, Vrije Universiteit Brussel, 2024. Full-panel metal screen across tampons, pads, cups, and other intimate products; extends the measured panel to aluminium and tin and anchors those cells.

[6] Leaching of lead and total arsenic from menstrual products into simulated vaginal fluid — PEER-REVIEWED

Nic Corcráin, 2025. Measures lead and arsenic migrating out of tampons, pads, cups, and period underwear into a vaginal-fluid surrogate; the step from measured content toward exposure. Full citation to be confirmed at publication.

[7] Tampon metal chemistry (lead, cadmium, mercury, chromium, arsenic, nickel) — PEER-REVIEWED

Carlin, 2020. Corroborating measurement of the toxic-metal panel across the tampon form. Full citation to be confirmed at publication.

[8] Technically avoidable heavy-metal contents in cosmetics (BVL, 2017) — GOVERNMENT

German Federal Office of Consumer Protection and Food Safety (BVL). Technically-avoidable-contaminant guidance for cosmetics: lead 2000 µg/kg for general cosmetics but 500 for toothpaste, a mucosal-contact product; cadmium 100, total arsenic 500, total mercury 100. · openagrar.de

[9] Korea MFDS cosmetics safety standards (trace metals) — GOVERNMENT

Republic of Korea Ministry of Food and Drug Safety. Sets the only sovereign cosmetic nickel content allowance (10000 µg/kg) used as the read-across anchor for cosmetic nickel.

[10] Directive 2009/48/EC on the safety of toys (Toy Safety Directive) — REGULATION

European Parliament and Council, 2009. Health-based migration limits for metals in articles children place in the mouth, derived from tolerable intakes; the read-across anchor for hexavalent chromium, tin, and aluminium. · eur-lex.europa.eu

[11] 21 CFR Part 884; Regulation (EU) 2017/745 on medical devices; ISO 10993-1 — REGULATION

U.S. FDA, European Parliament and Council, and the International Organization for Standardization. The device-law basis on which menstrual devices are evaluated for biocompatibility rather than heavy-metal content, and on which no numeric content limit for the finished device exists.

[12] Australian total-chromium limit — GOVERNMENT

Australian government total-chromium limit (total Cr 50 µg/kg); the read-across anchor for total chromium. The specific instrument is named in the live standard page derivation table (binding column AU). Full citation to be confirmed at publication.

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The fields an indexing service reads. Title, named first author and year are the three that carry the record; a briefing missing any one of them is treated as carrying no metadata at all.

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