

MoCRA and EU 1223/2009: The Formulation Record Behind a Cosmetic Product Safety Report

What the formulation record must contain for a safety dossier to be produced by query rather than by investigation.

PREPARED FOR
COSMETICS REGULATORY, PRODUCT-SAFETY,
QUALITY, AND R&D DATA LEADERS



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WHO THIS IS FOR

This paper is written for the cosmetics regulatory or product-safety lead who has to produce and refresh a Cosmetic Product Safety Report for the European Union and hold adequate substantiation of safety for the United States, while depending on an R&D group that owns the underlying formulation data. The decision that reader owns is not which template to use, but what the formulation record must contain, at what granularity, and under what version control. It assumes familiarity with the regulations and concentrates on where the evidence chain back to the bench breaks.

Nine working days for one cell of one row

A safety assessor working through a finished body lotion asks one question, and it is not a hard one: how much of a particular impurity is present in the product as sold? The formula in front of her lists a raw material by its trade name at 3.5 percent. The impurity is not in the formula, because it is not in the recipe. It sits inside the blend the trade name stands for, at a concentration the supplier has never had to state in a form anyone can query. So the question leaves the building.

The first email to the supplier's technical service returns a certificate of analysis for a lot shipped eighteen months ago. The second returns a specification with a range where a value was wanted. The third, escalated to a regional technical manager, produces a number, with the remark that the specification was revised last year. Nine working days after a one-line question, the assessor has filled one cell of one row of one dossier.

Then multiply. A mid-sized portfolio is several hundred stock-keeping units drawing on a few thousand raw materials, and a safety report is never written once. It is revised when the preservative changes, when a fragrance house reformulates a compound, when a supplier switches grade, when a new restricted-substance entry lands. Each revision reopens the same questions to the same suppliers about the same blends. Nobody has costed that, because it does not look like a cost; it looks like the job. It is not the job. It is the recurring interest payment on a formulation record built for manufacturing and later asked to serve as evidence.

That is the argument of this paper. The Cosmetic Product Safety Report required in the European Union and the safety substantiation duty imposed in the United States are not independent compliance exercises. They are downstream artifacts of one upstream asset, the formulation record. Read literally, Annex I Part A of Regulation (EC) No 1223/2009 is a list of data fields that R&D either populated at the bench or did not. Nothing in the assessment stage creates data that was not recorded upstream. Whatever the record fails to capture, the assessor reconstructs by hand, late, against a launch date.

The sharpest version of that dependency is composition granularity. A formulation held at trade-name level cannot answer the item on impurities, traces and packaging material, and cannot support substance-level exposure at all, because the quantities the regulation asks for sit inside a supplier's blend rather than in the recipe as recorded. The same substance arriving through three raw materials is never summed. Exposure metadata behaves the same way: a product category entered casually, rather than mapped to the table an assessor will use, moves a margin of safety by more than an order of magnitude, since the SCCS Notes of Guidance assign a body lotion 123.2 mg/kg bw/day against 2.79 for a shower gel. Neither is a toxicology problem. Both are data-model problems that surface as toxicology problems, months later, in someone else's deadline.

There is a real counter-argument. Substance-level records cost money to maintain, suppliers guard blend composition as commercial property, and fragrance is protected by an accommodation the regulation itself grants. A lead who says full disclosure is unobtainable for every raw material is describing the world accurately. The answer is not to insist on the impossible but to separate what is genuinely unavailable from what is merely expensive: allergen breakdowns, restricted-substance declarations, numeric impurity limits with methods, and specification versions with effective dates are all obtainable without a full formula, and they are what makes a dossier regenerable.

This paper attempts one thing: to specify what the formulation record must contain for a safety dossier to be produced or refreshed by query rather than by investigation. It walks Annex I Part A as a data specification, maps the two regimes against each other, and sets out change-control triggers. It is not a legal analysis, and it does not tell a reader whether a given product is safe. It is also deliberately honest about the unfinished state of the American regime. FDA's cosmetic good manufacturing practice rulemaking carries no dates in its Unified Agenda timetable, the fragrance allergen labelling rule is still pre-proposal, and the talc testing proposal was withdrawn in November 2025. Building a program around final US rules that do not yet exist is a scheduling error.

The sections ahead move from obligation to data. The first two establish why the safety report is really a report on the formulation record, and read Annex I Part A as a field-by-field specification. The next two take the hardest cases: composition, impurities and fragrance, then exposure and the margin of safety. A comparison of the regimes follows, then change control, then the traceability problem when one bulk becomes many finished goods in many markets. The paper closes with the minimum data-capture specification a record must satisfy, and with the questions it cannot answer.

0.1

What this paper argues

Nothing in a safety report is created at the assessment stage. Every field it needs was either captured at the bench or is now a question for a supplier.

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- 01 The two regimes differ in prescription, not in dependency. The EU specifies the safety report's content and ten-year retention of the product information file. MoCRA specifies an outcome standard, "a reasonable certainty that a cosmetic product is safe", and leaves the evidentiary form to the statute's expert-consensus test. A company that builds only to the American standard has no checklist to audit against; one that builds to the European standard usually finds its Annex I file is adequate substantiation too.
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- 02 Quantitative composition recorded at trade-name level is the most common structural defect. Annex I Part A item 1 requires chemical identity including INCI name, CAS and EC numbers and intended function, none of which a trade name supplies. Exposure defaults compound the problem, and they are not neutral: the 12th revision of the Notes of Guidance, issued as SCCS/1647/22, fixes the category-level daily exposure figures on which every margin of safety rests, so the category field is a toxicological input rather than a marketing label.
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- 03 Change control is where dossiers rot. A reformulation that alters an active level, a preservative system, a fragrance compound, or a supplier grade changes the inputs to the safety assessment. Under EU Article 13(7) the notification must be updated without delay; under MoCRA the product listing is updated annually. The most common failure mode found in practice is not a bad assessment but a good assessment of a product that is no longer being sold.
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- 04 The remedy is structural rather than procedural. A record carrying substance-level composition, specification versions with effective dates, exposure metadata mapped to the guidance tables, toxicological points of departure with their sources, and approval evidence as linked fields turns regeneration into a query; one carrying trade names and scanned certificates turns it into an investigation, every time.
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A living document, dependent on being told something changed

1.1

What the European regime requires

Article 10 of Regulation 1223/2009 requires that, before a cosmetic product is placed on the market, the responsible person ensure a safety assessment is carried out on the basis of the relevant information and a safety report set up in accordance with Annex I. The assessment must take into account the intended use and the anticipated systemic exposure to individual ingredients in a final formulation, follow a weight-of-evidence approach, and be kept up to date in view of information generated after placing on the market. The report is not a one-time deliverable. It is a living document whose currency depends on whether anyone tells the assessor something changed.

Article 11 places the report inside a product information file that must be kept for ten years following the date on which the last batch was placed on the market, and made readily accessible in electronic format at the address indicated on the label, in a language easily understood by the competent authorities. That turns a formulation database into a records-retention obligation. A file referencing a supplier specification by a link that resolves to whatever the supplier currently publishes does not satisfy it, because the specification in force at the time of assessment is the one that matters.

1.2

What the American regime requires

MoCRA arrives at the same dependency from a different direction. Section 364d requires a responsible person to "ensure, and maintain records supporting, that there is adequate substantiation of safety" for a cosmetic product, and defines adequate substantiation as tests or studies, research, analyses, or other evidence considered, among experts qualified by scientific training and experience, sufficient to support a reasonable certainty that the product is safe.

There is no annex, no prescribed structure and no stated retention period for substantiation records. What exists is an evidentiary standard judged after the fact, most likely in an inspection triggered by an adverse event. Section 364f limits FDA's records access in a way that matters here: it does not extend to recipes or formulas for cosmetics, nor to research data other than safety substantiation data. The formula stays with the company; the substantiation does not.

Ten items, field by field

2.1

Items 1 to 10, item by item

The clearest way to see the dependency is to walk Part A item by item, asking what R&D must have captured, in what units, for each element to be answerable. Part B then requires the assessor's conclusion, the labelled warnings, the reasoning, and the credentials, with proof of qualification and a dated signature.

ANNEX I PART A ELEMENT	DATA R&D MUST CAPTURE	GRANULARITY AND UNITS	WHERE IT TYPICALLY GOES WRONG
1. Quantitative and qualitative composition	Every substance with chemical name, INCI name, CAS and EC numbers, intended function; for perfume compositions the name, code number and supplier identity	Percent w/w of each substance in the finished product, not of the raw material	Composition held at trade-name level, so the same substance entering via three raw materials is never summed
2. Physical/chemical characteristics and stability	Characteristics of the substances and of the finished product; stability under reasonably foreseeable storage conditions	Per formula version and per pack; storage conditions stated	Stability run on a development batch in a laboratory jar, never repeated for the commercial pack
3. Microbiological quality	Microbiological specifications of raw materials and product; preservation challenge test results	Per formula version and pack; specific attention to eye area, mucous membranes, damaged skin, children under three	Challenge test held against an earlier formula version after a preservative or pH change
4. Impurities, traces, packaging material	Purity of substances and mixtures; evidence of technical unavoidability for traces of prohibited substances; purity and stability of packaging material	ppm or µg/kg with method and limit of detection	Supplier certificate of analysis stored as a PDF with no extracted, queryable impurity values
5. Normal and reasonably foreseeable use	Intended use, application site, foreseeable misuse, justified in the light of warnings and labelling	Narrative tied to the label artwork version	Use description written for the marketing claim rather than the actual application pattern

Fig. 1 Annex I Part A items 1-10, read as a field-by-field data specification. Items 1-5 above; 6-10 overleaf.

ANNEX I PART A ELEMENT	DATA R&D MUST CAPTURE	GRANULARITY AND UNITS	WHERE IT TYPICALLY GOES WRONG
6. Exposure to the cosmetic product	Application site and surface area, amount applied, duration and frequency, exposure route, target population, secondary exposure such as inhalation from sprays or ingestion from lip products, and particle size	g/day, cm ² , applications/day	Product category chosen loosely, which silently changes the SCCS default exposure value
7. Exposure to the substances	Substance-level exposure derived from item 1 and item 6	mg/kg bw/day per substance	Cannot be computed at all where item 1 is at trade-name level
8. Toxicological profile of the substances	All relevant endpoints, local toxicity, skin sensitisation, photo-induced toxicity for UV absorbers, and the margin of safety based on a no-observed-adverse-effect level or a justified absence	Point of departure with study type, species, route; MoS as a dimensionless number	References cited as a dictionary entry rather than the underlying study, with read-across never substantiated
9. Undesirable and serious undesirable effects	Complaint and pharmacovigilance data, including statistical data	Counted per product and per formula version	Complaints stored against a brand rather than a formula version, so a signal after reformulation is invisible
10. Information on the cosmetic product	Human volunteer study data, other data on the finished product	Per protocol, per batch tested	Panel study run on a prototype that never became the commercial formula

Fig. 1 continued Items 6–10.

2.2

Where the chain of custody breaks

Item 8 is where the chain of custody is most often broken, and most often examined. The regulation requires the source of information to be clearly identified and read-across duly substantiated.

An assessor who writes "no concerns identified" without a point of departure, an absorption assumption and an arithmetic margin of safety has produced an opinion, not an assessment.

The assessment operates on substances, not containers

3.1 Composition granularity

Recording composition at the trade name is efficient for manufacturing and useless for safety. A trade-named raw material may be a preservative blend in a glycol carrier, a surfactant with residual ethylene oxide chemistry, or a plant extract in a solvent, and the assessment operates on the substances, not on the container they arrived in. Article 19 draws the same distinction from the labelling side: the ingredient list uses the common ingredient name from the glossary established under Article 33, in descending order of weight at the time of addition, while impurities and subsidiary technical materials not present in the final product are not ingredients. Two views, one underlying record.

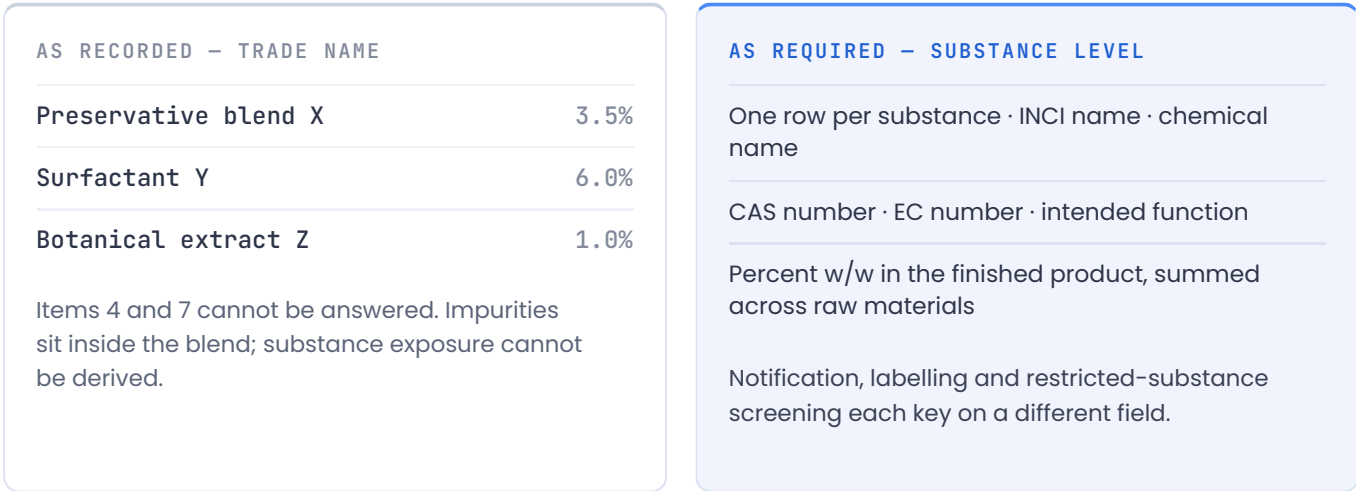


Fig. 2 The same formula, held at two granularities.

The naming layer is a standards problem with a single custodian. INCI names are assigned by the International Nomenclature Committee and published by the Personal Care Products Council in its International Cosmetic Ingredient Dictionary and Handbook; other jurisdictions incorporate it by reference, as Canada's 2024 amendment to its Cosmetic Regulations does, defining an INCI name as the name assigned in that dictionary as amended from time to time. A record holding only a trade name inherits none of this. It needs INCI name, CAS number and EC number as separate fields, because notification, labelling and restricted-substance screening each key on a different one.

3.2

Impurities and traces

Traces are governed separately. Article 17 permits the non-intended presence of a small quantity of a prohibited substance where it stems from impurities of ingredients, the manufacturing process, storage, or migration from packaging, is technically unavoidable in good manufacturing practice, and the product still conforms to Article 3. "Technically unavoidable" is an evidentiary claim about the process, so the process description and the supplier's purification capability belong in the file.

Three contamination families show why impurity data must be numeric and versioned rather than filed as a scanned certificate. Nitrosamines are prohibited under Annex II entry 410, and secondary alkyl- and alkanolamines and their salts under entry 411, an entry whose scope the Commission has itself had to refer to the SCCS for interpretation. Annex III entry 60, for fatty acid dialkylamides and dialkanolamides, sets a maximum secondary amine content of 0.5 percent in the finished product and 5 percent in the raw material, a maximum nitrosamine content of 50 µg/kg, a prohibition on use with nitrosating systems, and a requirement to keep the material in nitrite-free containers. Every one is a raw-material specification attribute, not a finished-product test result.

Two further families make the same point at state level. For 1,4-dioxane, a process residue from ethoxylation, New York's Environmental Conservation Law sets ceilings by product class of 10 ppm for cosmetic products from 31 December 2022, and 2 ppm then 1 ppm for personal care products from 31 December 2022 and 31 December 2023, limits the state confirmed as sufficient and protective on review. For heavy metals, Washington's toxic-free cosmetics act bans intentionally added lead or lead compounds, or lead at one part per million or above, from 1 January 2025, alongside ortho-phthalates, per- and polyfluoroalkyl substances, formaldehyde and formaldehyde releasers, methylene glycol, mercury, triclosan and the phenylenediamines. None of those thresholds can be screened against a record storing impurities as prose.

THE CONSEQUENCE

A threshold expressed in ppm cannot be screened against an impurity stored as prose.

3.3

Fragrance is the hardest case

Fragrance is the hardest case because the composition is deliberately withheld. Annex I Part A item 1 accepts the name and code number of the perfume composition and its supplier's identity, the regulation's accommodation of trade secrecy. That accommodation stops where restricted substances are involved. Article 19 requires perfume and aromatic compositions to be indicated as "parfum" or "aroma", but the substances whose presence must be mentioned under the "Other" column of Annex III appear in the list regardless. Commission Regulation (EU) 2023/1545 expanded that set substantially, and non-compliant products may be placed on the Union market until 31 July 2026 and made available until 31 July 2028.

The workable pattern is to require from the fragrance house, per compound code and version, an allergen breakdown at the labelling thresholds, an IFRA certificate of conformity stating the amendment level and product category under the guidance for the use of the IFRA Standards, and a declaration on restricted and CMR substances; without the full formula.



Fig. 3 What is obtainable from a fragrance house without disclosure.

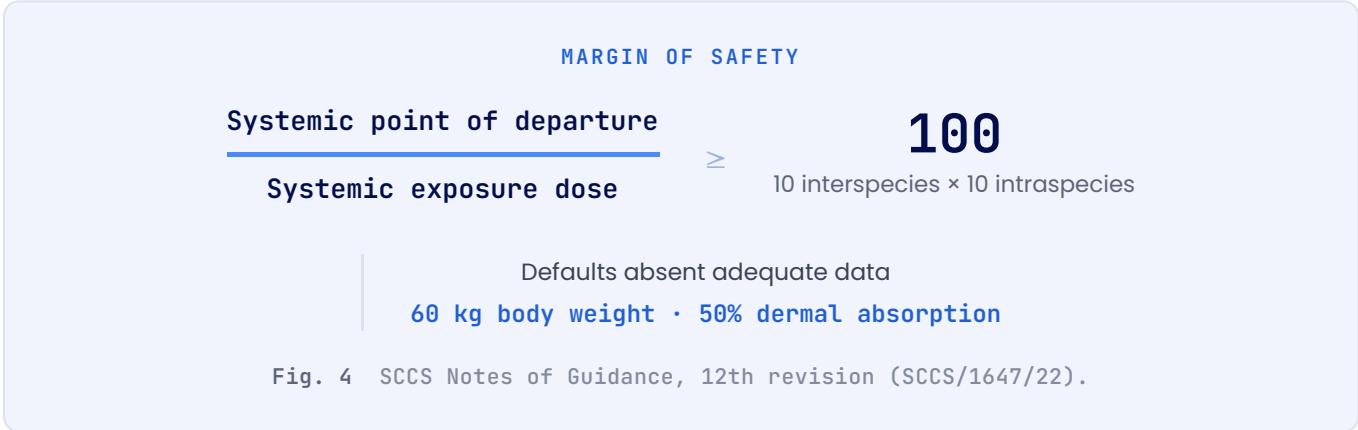
IFRA's compliance dates attach to the fragrance mixture, not the finished product: for the 51st Amendment, notified on 30 June 2023, prohibition standards applied to new creations from 30 August 2023 and existing creations from 30 July 2024, restriction and specification standards from 30 March 2024 and 30 October 2025, with the compliance date taken as the earlier of dispatch or invoice date.

Where R&D metadata becomes toxicology

4.1

How the margin of safety is built

The margin of safety is where R&D metadata becomes toxicology. The SCCS Notes of Guidance, 12th revision, calculates it as the systemic point of departure divided by the systemic exposure dose, the point of departure preferably a benchmark dose lower confidence limit and otherwise a no-observed-adverse-effect level, against a reference value of at least 100 built from factors of ten for interspecies and ten for intraspecies variability. The revision was adopted by written procedure on 15 May 2023 and published, with two corrigenda, on 22 December 2023, which matters, because a dossier assembled against the 11th revision uses different exposure defaults. Systemic exposure is computed from the daily amount applied, the substance concentration, and dermal absorption, against defaults of 60 kg body weight and 50 percent dermal absorption absent adequate data.



The consequential number is the daily exposure figure attached to the product category. The 12th revision assigns a body lotion 123.2 mg/kg bw/day at a retention factor of 1.00, against 7.82 g applied per day and a treated surface area of 15,670 cm², while a shower gel is 2.79 at 0.01 and a toothpaste 2.16 at 0.05. A product recorded as "cream" and sold as a body moisturizer has a defensible category; the same bulk described only as "emulsion" does not.

4.2

Category exposure defaults

PRODUCT CATEGORY	DAILY EXPOSURE	RETENTION FACTOR	APPLIED PER DAY
Body lotion	123.2 mg/kg bw/day	1.00	7.82 g · 15,670 cm ²
Shower gel	2.79 mg/kg bw/day	0.01	—
Toothpaste	2.16 mg/kg bw/day	0.05	—

Fig. 5 A category field that moves the margin of safety by more than an order of magnitude.

Aggregate exposure compounds the point: for substances classified as carcinogenic, mutagenic or toxic for reproduction, Article 15 requires exposure from all sources to be considered — an assessment the Commission coordinates with the SCCS, ECHA, EMA and EFSA under its guidance on overall exposure to CMR substances.

Article 10(2) constrains who may perform this work: the assessor must hold a diploma or other evidence of formal qualification awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course a member state recognises as equivalent. Annex I Part B requires proof of qualification in the file, with the assessor's name and address, the date and the signature. A defensible dossier therefore carries the credentials, the formula version assessed, the version of every supplier specification relied on, and the arithmetic.

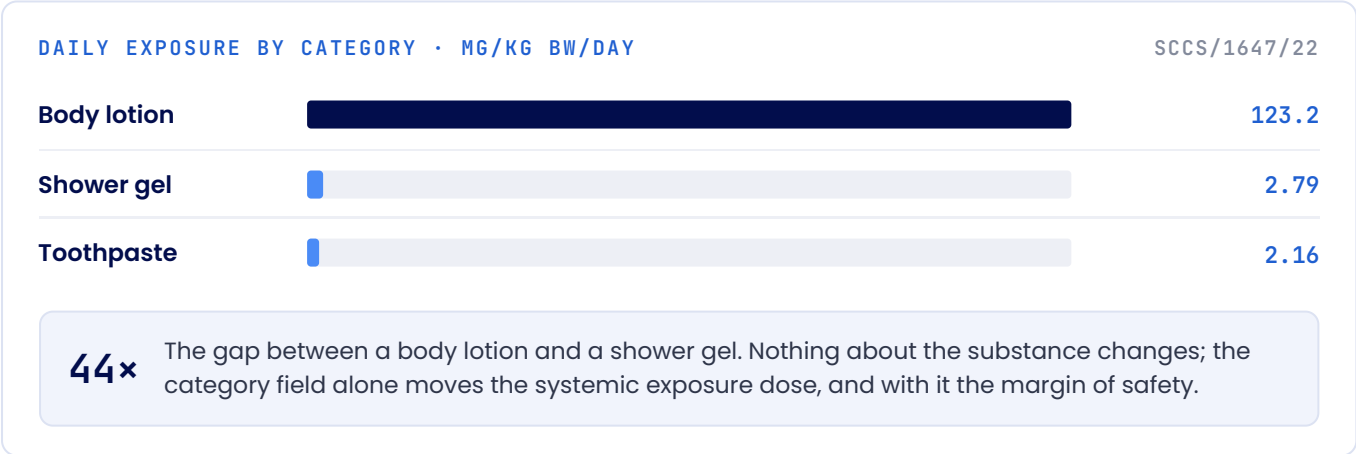


Fig. 6 Exposure defaults drawn to scale. A category entered casually is a toxicological input, not a label.

The same underlying data on different terms

5.1

The regimes side by side

Set side by side, the two regimes ask for the same underlying data on different terms. The table below maps the obligations a single formulation record has to serve.

DIMENSION	EU REGULATION (EC) NO 1223/2009	MOCRA (21 U.S.C. 364 ET SEQ.)
Safety standard	Safety assessment against Annex I before placing on the market, kept up to date after (Article 10)	Adequate substantiation of safety: evidence sufficient among qualified experts to support a reasonable certainty the product is safe (section 364d)
Accountable party	Responsible person established in the Union: manufacturer, importer, or distributor marketing under its own name (Article 4)	Responsible person: the manufacturer, packer, or distributor whose name appears on the label (section 364)
Documentation that must exist	Product information file containing the safety report, manufacturing method and GMP statement, proof of claimed effect, and animal-testing data (Article 11)	Records supporting substantiation; adverse event records; FDA records access excludes recipes and formulas (sections 364d, 364a, 364f)
Retention	Product information file kept ten years after the last batch was placed on the market (Article 11)	Adverse event records six years, or three years for qualifying small businesses (section 364a); no statutory period for substantiation
Notification or listing	Electronic notification to the Commission before placing on the market, including frame formulation and CMR identification; updated without delay on change (Article 13)	Facility registration with biennial renewal and 60-day updates; product listing with annual updates, submitted through Cosmetics Direct (section 364c)
Adverse events	Serious undesirable effects notified to the competent authority without delay (Article 23)	Serious adverse event report with a label copy within 15 business days; fragrance or flavor ingredient list on written request within 30 days (section 364a)
GMP basis	Article 8, with conformity presumed where harmonised standards apply; ISO 22716:2007 is the reference guideline	Section 364b requires GMP regulations; the rule at 21 CFR 711 has no timetable dates despite statutory deadlines of December 2024 and December 2025
Enforcement	Member state in-market control including checks of the product information file and GMP compliance, with withdrawal and recall duties on the responsible person (Articles 5, 22, 25)	Mandatory recall and suspension of facility registration (sections 364g, 364c); state-level requirements partly preempted but ingredient restrictions preserved (section 364j)

Fig. 7 One record, two sets of obligations.

5.2

One asymmetry needs stating plainly

One asymmetry needs stating plainly: the US regime remains partly unbuilt. On the current Unified Agenda, the fragrance allergen disclosure rule is still at proposed-rule stage with a projected notice date of November 2026 against a statutory deadline of 29 June 2024, and FDA withdrew its proposed rule on testing methods for detecting asbestos in talc-containing cosmetic products on 28 November 2025, stating it intends to issue a new proposal without giving a date.

What has landed is worth separating from what has not. The agency's MoCRA implementation page records the completed pieces, including the report on per- and polyfluoroalkyl substances in cosmetic products published on 29 December 2025. Registration and listing are operational: FDA's December 2024 guidance sets out the data elements, and the agency reported 16,398 active facility registrations and 1,298,361 active product listings as of 30 June 2026 on its registration and listing page.

MOCRA INSTRUMENT	STATUS	WHERE IT STANDS
Facility registration and product listing	IN FORCE	Data elements set by FDA guidance of December 2024; 16,398 active registrations and 1,298,361 active listings as of 30 June 2026
PFAS report	PUBLISHED	Report on per- and polyfluoroalkyl substances in cosmetic products issued 29 December 2025
Fragrance allergen labelling	PROPOSED	Still at proposed-rule stage, projected notice November 2026, against a statutory deadline of 29 June 2024
Good manufacturing practice	UNDATED	Rule at 21 CFR 711 carries no timetable dates, despite statutory deadlines of December 2024 and December 2025
Talc testing methods	WITHDRAWN	Proposed rule withdrawn 28 November 2025; a replacement is intended but has no date

Fig. 8 What has landed under MoCRA and what has not. A programme built on the unfinished rules is scheduled against dates that do not exist.

Which changes reopen which obligation

6.1

The trigger table

Article 10 requires the report to be kept up to date in view of additional relevant information generated after the product is placed on the market, and Article 13(7) requires the notification to be updated without delay where notified information changes. The table below sets out which changes reopen which obligation.

CHANGE	REVISIT SAFETY ASSESSMENT	UPDATE NOTIFICATION OR LISTING	TIMEFRAME	BASIS
Active concentration changed	Yes: exposure to the substance and the margin of safety both move	EU frame formulation if the hazard profile changes; US listing if the ingredient list changes	EU without delay; US annual listing update	Articles 10, 13(7); section 364c
Preservative system changed	Yes, with a new challenge test and microbiological specification per ISO 11930	Yes, ingredient list and frame formulation	Before the changed product is placed on the market	Annex I Part A items 3 and 8; Article 14 and Annex V
Fragrance compound or version changed	Yes: allergen breakdown, IFRA amendment level, and restricted-substance declaration all change	Yes if labelled allergens change under Regulation (EU) 2023/1545	EU labelling transition ends 31 July 2026 for placing and 31 July 2028 for making available	Article 19(1)(g); IFRA standards
Supplier or grade change, same INCI	Yes where the impurity profile, particle size, or purity specification differs	Not necessarily, unless a notified attribute changes	Before the affected batch ships	Annex I Part A item 4; Article 17
Packaging change	Yes: migration, stability, and compatibility are pack-specific	EU notification carries a photo of the packaging; US listing is per product	Before market placement of the new pack	Annex I Part A items 2 and 4; Article 13(2)
Claim change	Yes where the claim implies a new use, population, or exposure pattern	Label artwork and, in the EU, the notified label image	Before the new artwork ships	Articles 20 and 13(2)
Manufacturing site change	Assessment usually unaffected; GMP statement and microbiological data are	EU: address in the file; US: facility registration number on the listing	US registration updates within 60 days	Article 11(2)(c); section 364c
New restricted-substance listing	Yes: rescreen the whole portfolio	Yes where a notified CMR entry changes	By the Omnibus application date: 1 September 2025 for Omnibus VII, 1 May 2026 for Omnibus VIII	Article 15

Fig. 9 Change-control triggers, by change type.

6.2

Two silent failure modes

Two silent failure modes sit inside this table. A supplier revising a specification will typically issue a new document version without notifying every downstream safety function; if the record links to a specification document rather than a specification version with an effective date, the change passes unnoticed. And a fragrance supplied as an undisclosed compound under a code number changes composition when the house reformulates; unless the record versions the compound code, the allergen declaration on the pack can become wrong without a single line of the finished-product formula changing.

PATH ONE**A supplier revises a specification**

- 01 A new document version is issued, with no duty to notify every downstream safety function

- 02 The record links to the specification document rather than to a version with an effective date

- 03 The assessment still rests on limits that have been superseded

PATH TWO**A fragrance house reformulates a compound**

- 01 Composition changes while the compound code on the formula stays the same

- 02 The record does not version the code, so the allergen breakdown is never re-read

- 03 The declaration printed on the pack becomes wrong

- Neither event changes a single line of the finished-product formula, so neither raises a review.

Fig. 10 Two ways a current dossier goes stale without anyone editing the formula.

Properties of a formula-in-a-pack, not of a formula

7.1

Durability, packs, and period after opening

Annex I Part A item 2 asks for stability under reasonably foreseeable storage conditions, and item 4 for the characteristics of packaging material, in particular purity and stability. Both are properties of a formula-in-a-pack, not of a formula. Article 19(1)(c) makes the consequence visible on the label: the date of minimum durability, or, where that exceeds 30 months, the period-after-opening symbol in months or years. A period after opening is an assertion about the preserved system in that container with that closure, supported by preservation efficacy work per ISO 11930 and compatibility data on the actual pack.

The traceability problem appears when one bulk is filled into several formats and sold into several jurisdictions. The bulk is one formula version; the finished goods are several stock-keeping units with their own pack materials, fill volumes, artwork, notified images and applicable restricted-substance lists.

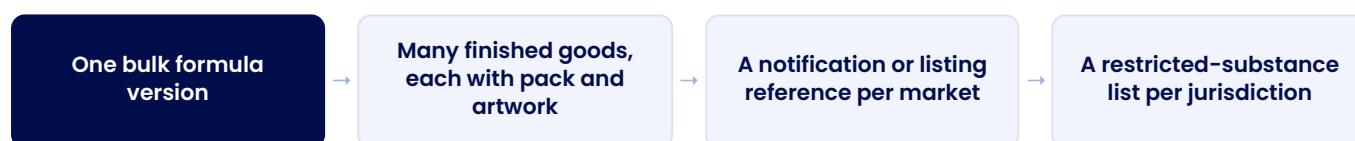


Fig. 11 A flat one-row-per-product model forces composition to be re-entered per market.

Each jurisdiction asks for its own artifact. The EU expects a product information file per product with a notified label image and packaging photograph under Article 13(2). Great Britain expects a separate notification through the Submit Cosmetic Product Notification service by a responsible person established in the United Kingdom, under the retained version of Regulation 1223/2009 enforced through the Cosmetic Products Enforcement Regulations 2013. The United States expects a listing per product with the registration number of each manufacturing facility.

7.2

One bulk, many markets

Outside those three, the requirements diverge further. China requires a safety assessment on registration or notification, with Announcement No. 50 of 2024 introducing classified management under which some qualifying general cosmetics may submit only the basic conclusions while retaining the full report on file, and a transition allowing a simplified report before 1 May 2025. California adds reporting of designated ingredients, including fragrance allergens at 0.01 percent in rinse-off and 0.001 percent in leave-on products, aligned to the EU's 2026 and 2028 deadlines. Where the mixture is classified as hazardous, poison centre notification under Annex VIII to the CLP Regulation adds a unique formula identifier that must appear in the submission and on the label, per ECHA's PCN handbook and the Commission's poison centres guidance.

The data structure that survives this is a bulk formula version with many finished-good children, each carrying its own pack specification, artwork version, notification or listing reference, and market list. A flat one-row-per-product model forces composition to be re-entered per market, and re-entry is where divergence begins.

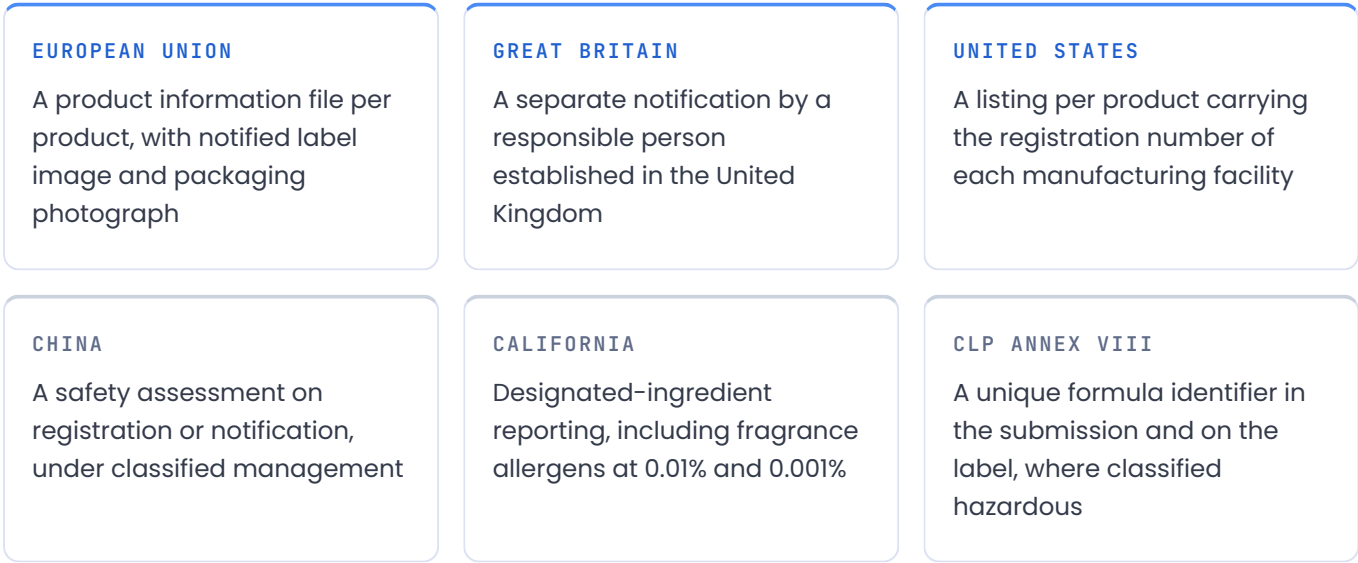


Fig. 12 Six jurisdictions, six artifacts, one record.

The minimum a record must carry

8.1

Composition, suppliers, and exposure

The following is the minimum a formulation record must carry for a safety report to be produced or refreshed without an investigation, stated as a requirement on the system, whatever that system is.

COMPOSITION

One row per substance, never per trade name, with INCI name, chemical name, CAS number, EC number, intended function, percent w/w in the finished product, a link to the raw material and its inclusion level, and the ability to sum a substance arriving through several raw materials. Nanomaterial status must be a flag, since Article 16 requires notification six months before placing on the market and Article 19 "(nano)" on the label.

RAW MATERIALS AND SUPPLIERS

Every raw material links to a specification version with an effective date, a supersession chain, an impurity table with numeric values and units, a certificate of analysis per lot, and a declaration covering restricted substances, CMR classification, and animal-testing status. Article 18's testing prohibitions and Article 11's requirement to hold data on animal testing performed, including to meet third-country requirements, key on supplier declarations.

FRAGRANCE AND FLAVOR

Compound code, version, supplier identity, IFRA certificate with amendment level and product category, allergen breakdown at labelling thresholds, and the declaration's issue date — enough to answer, per pack, which allergens must appear on the label.

EXPOSURE METADATA

Product category mapped explicitly to the SCCS exposure table entry used, amount applied per day, treated surface area, applications per day, target population, application site, and any secondary route such as spray inhalation or lip ingestion — the inputs an assessor otherwise guesses.

8.2

Studies, references, and version control

TEST AND STABILITY DATA

Every study links to the formula version and, where relevant, pack and batch: stability at defined conditions and durations, compatibility with the specific pack, preservation efficacy per ISO 11930, microbiological specification, and any human volunteer study with its protocol.

TOXICOLOGICAL REFERENCES	Per substance, the point of departure with study type, species and route, the absorption assumption and its justification, any read-across with its substantiation, and a link to the source document rather than a secondary summary.
VERSIONING AND APPROVALS	Immutable formula versions with effective dates; an audit trail recording who changed what, when and why; electronic approval carrying the assessor's identity, credentials and date; and a bidirectional link from every finished good to the formula and specification versions in force when it was assessed.
CHANGE-CONTROL TRIGGERS	The record should raise a review on any of: a substance concentration change; a preservative, pH, or emulsifier system change; a fragrance compound or version change; a supplier, grade, or manufacturing-route change; a revised supplier specification version; a pack material, closure, or fill-volume change; a claim or artwork change implying a new use or population; a manufacturing site addition; a new entry in Annexes II to VI, a new CMR classification, or a new restricted-substance threshold; an adverse event signal; and an approaching listing or notification renewal date.

8.3

A narrower position than a solution

None of this is cheap, and none of it substitutes for judgment. Substance-level composition takes negotiation with suppliers who have no obligation to help, fragrance will stay partly opaque by design, and no data model resolves what "adequate substantiation" means in an inspection that has not happened yet. The position here is narrower than a solution. Safety assessment is a reporting function over an upstream record, and the quality of the dossier is bounded by the quality of that record long before an assessor opens it.

THE ECONOMICS

A company that fixes the record once pays for it once. A company that leaves it at trade-name level pays again at every reformulation, every new market, and every regulatory list update, for as long as the product is sold.

Five open questions

1

US GMP

Section 364b directs the Secretary to establish good manufacturing practice regulations, but the rule at 21 CFR 711 carries no timetable dates in the current agenda entry, so what US GMP will require, and how closely it will track ISO 22716, remains open.

2

Fragrance allergen disclosure in the US

The statute directs FDA to identify the allergens by regulation and permits thresholds, but no proposal has issued. Whether the final list will mirror the EU's expanded set, and whether the thresholds will match the EU's, cannot be stated.

3

Talc testing methods

With the proposed rule withdrawn and a replacement announced without a date, there is no settled federal method for detecting asbestos in talc-containing cosmetics.

4

What "adequate substantiation" means in practice

The statutory standard is an expert-consensus test. Until inspection findings and enforcement actions accumulate, the amount and type of evidence FDA will accept for a given product class is a matter of professional judgment, and reasonable assessors will disagree.

5

Retention for substantiation records

MoCRA sets six and three year periods for adverse event records but is silent on how long substantiation must be kept. Aligning to the EU's ten-year post-last-batch rule is a defensible default rather than a legal requirement.

A dossier is regenerable or it is reconstructed. The formulation record decides which.

Substance-level composition, versioned supplier specifications, and mapped exposure metadata turn a safety report from an investigation into a query.

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SCAN TO BOOK

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