Transpareo

Cosmetics checklist for the duties that apply today

Responsible person, product file, notification, labelling, claims and the fragrance allergen dates under EU cosmetics law - to tick off.

What this checklist covers

> **Nature of this checklist.** These duties apply today under existing law; no product passport act covers this industry yet. We update this list as soon as one is published.

This checklist is part of our reference on the digital product passport for cosmetics, which covers the legal position, the roles, the required data and the official documents for the whole sector; this page narrows it down to the duties you can tick off today.

Cosmetics has no product passport duty. What it has is a set of obligations that has been in force since 11 July 2013 and that already asks for most of the data a passport would show. This list sums up what Regulation (EC) No 1223/2009 asks of whoever places a cosmetic product on the EU market, plus the claims rules of Regulation (EU) No 655/2013 and the fragrance allergen amendment Regulation (EU) 2023/1545; the deadlines follow as a timeline, the official documents are linked under sources at the end, and the whole list is there to download as a PDF below.

Every item names its article. Where a duty sits with the responsible person rather than with the manufacturer, the item says so, because in cosmetics the two are often not the same company.

Which role are you in?

Tick the statement that describes you. The answer decides who carries every other item on this list, and Art. 4 leaves no product without one named person.

- [ ] A cosmetic product may be placed on the market only where a legal or natural person is designated within the Union as its responsible person.
  Art. 4(1)
- [ ] You manufacture inside the Union and do not export and re-import: you are the responsible person, unless you designate one by written mandate that the designated person accepts in writing.
  Art. 4(3)

- [ ] You import from a third country: each importer is the responsible person for the product it places on the market, and may designate another by written mandate accepted in writing.
  Art. 4(5)
- [ ] You sell under your own name or trade mark, or you modify a product already on the market so that compliance may be affected: you become the responsible person. Translating the labelling is expressly not such a modification.
  Art. 4(6)
- [ ] You only distribute someone else's product unchanged: the obligations of distributors apply to you, not the responsible person's file.
  Art. 6

Responsible person, safety report and file

The responsible person answers for compliance and holds the paperwork. Art. 5(1) is the enumeration that gives the role its content, and everything below hangs off it.

- [ ] Ensure compliance with Art. 3, 8, 10 to 18, Art. 19(1), (2) and (5), and Art. 20, 21, 23 and 24.
  Art. 5(1)
- [ ] Have the safety assessment carried out and the cosmetic product safety report of Annex I set up before the product is placed on the market.
  Art. 10(1), Annex I
- [ ] Take the intended use and the anticipated systemic exposure to individual ingredients in the final formulation into account in that assessment.
  Art. 10(1)(a)
- [ ] Keep the safety report up to date in view of additional relevant information generated after the product was placed on the market.
  Art. 10(1)(c)
- [ ] Keep a product information file with the product description, the safety report, the manufacturing method and the statement on good manufacturing practice, the proof of the claimed effect where the nature or effect of the product justifies it, and the data on any animal testing.
  Art. 11(2)(a) to (e)
- [ ] Keep that file for ten years following the date on which the last batch was placed on the market.
  Art. 11(1)
- [ ] Make the file readily accessible in electronic or other format at the address indicated on the label, in a language which can be easily understood by the competent authority.
  Art. 11(3)
- [ ] Take corrective measures, withdraw or recall immediately where a product you placed on the market is not in conformity, and inform the competent national authorities where it presents a risk to human health.

Art. 5(2)

Notification before the first sale

The notification goes to the Commission by electronic means, once per product, before it is placed on the market. It serves poison centres and market surveillance, and nothing you publish replaces it.

- [ ] Submit the category of the product and its name or names, in a form that identifies it specifically.
  Art. 13(1)(a)
- [ ] Submit the name and address of the responsible person at which the product information file is readily accessible.
  Art. 13(1)(b)
- [ ] Submit the country of origin in the case of import, and the Member State in which the product is to be placed on the market.
  Art. 13(1)(c) and (d)
- [ ] Name a physical person to contact in the case of necessity.
  Art. 13(1)(e)
- [ ] Declare the presence of substances in the form of nanomaterials, with their identification.
  Art. 13(1)(f)
- [ ] Declare substances classified as carcinogenic, mutagenic or toxic for reproduction of category 1A or 1B, with their name and their CAS or EC number.
  Art. 13(1)(g)
- [ ] Submit the frame formulation that allows prompt and appropriate medical treatment in the event of difficulties.
  Art. 13(1)(h)
- [ ] Notify the original labelling and, where it is reasonably legible, a photograph of the corresponding packaging, when the product is placed on the market.
  Art. 13(2)
- [ ] Provide an update without delay whenever any of the information notified under Art. 13(1), (3) or (4) changes.
  Art. 13(7)

What the pack has to carry

Art. 19 is the article that fills the tube. All of it has to be in indelible, easily legible and visible lettering on the container and the packaging, which is exactly why a second, digital surface earns its keep.

- [ ] The name or registered name and the address of the responsible person, which may be abbreviated as long as the person and the address stay identifiable, and the country of origin for imported

products.

Art. 19(1)(a)

- [ ] The nominal content at the time of packaging, by weight or by volume, except below five grams or five millilitres, and except for free samples and single-application packs.

  Art. 19(1)(b)

- [ ] The date until which the product, stored under appropriate conditions, continues to fulfil its initial function.

  Art. 19(1)(c)

- [ ] The particular precautions to be observed in use, and at least those listed in Annexes III to VI.

  Art. 19(1)(d)

- [ ] The batch number of manufacture, or the reference identifying the product.

  Art. 19(1)(e)

- [ ] The function of the product, unless it is clear from its presentation.

  Art. 19(1)(f)

- [ ] The list of ingredients, preceded by the term ingredients, in descending order of weight at the time they were added; ingredients below 1 per cent may follow in any order.

  Art. 19(1)(g)

- [ ] Perfume and aromatic compositions as parfum or aroma, with the substances Annex III requires named individually in addition to those terms.

  Art. 19(1)(g)

- [ ] Ingredients present as nanomaterials with the word nano in brackets after the name, and the Colour Index nomenclature for colorants where applicable.

  Art. 19(1)(g)

- [ ] Where the precautions or the ingredient list cannot practically be labelled, an enclosed or attached leaflet, label, tape, tag or card, referred to by the symbol given in point 1 of Annex VII.

  Art. 19(2)

- [ ] For soap, bath balls and other small products where even that fails, the ingredient list on a notice in immediate proximity to the container in which the product is exposed for sale.

  Art. 19(3)

- [ ] The language of the content, the durability date, the precautions and the function follows the law of the Member State in which the product is made available to the end user.

  Art. 19(5)

- [ ] The ingredient list uses the common ingredient names of the glossary provided for in Art. 33, or a term from a generally accepted nomenclature where no common name exists. It is one EU-wide nomenclature, not a per-market translation.

  Art. 19(6)

Fragrance allergens

This is the part of the label that changed most recently, and the part where the data is not yours. The composition sits with the fragrance house, so the work is the supplier declaration long before it is the artwork.

- [ ] Name individually, in the ingredient list, the fragrance allergens that Regulation (EU) 2023/1545 added to Annex III, in addition to the terms parfum and aroma.
  Regulation (EU) 2023/1545, Art. 1
- [ ] Apply the thresholds above which the substance has to be named, 0.001 per cent in leave-on products and 0.01 per cent in rinse-off products.
  Annex III, amended entries
- [ ] Read the transitional footnote of every amended entry your formulation touches; products that do not comply with the restrictions may be placed on the Union market until 31 July 2026.
  Annex, transitional footnotes
- [ ] Clear the remaining stock by 31 July 2028, the last day such products may be made available on the Union market.
  Annex, transitional footnotes

Claims and what the public may see

A claim is anything that conveys a characteristic or a function, in any medium. That includes a passport page, which is why the evidence has to be filed somewhere a colleague can find it in three years.

- [ ] Use no text, name, trade mark, picture or figurative sign that implies the product has characteristics or functions which it does not have, in labelling, in making available on the market or in advertising.
  Art. 20(1)
- [ ] Treat the common criteria as applying to any claim, irrespective of the medium or type of marketing tool used, the product functions claimed and the target audience.
  Regulation (EU) No 655/2013, Art. 1
- [ ] Judge acceptability by the perception of the average end user, reasonably well-informed and reasonably observant and circumspect, taking the social, cultural and linguistic factors of the market into account.
  Annex, criterion 1
- [ ] Support every claim, explicit or implicit, by adequate and verifiable evidence, and keep the level of substantiation consistent with the type of claim, in particular where a lack of efficacy may cause a safety problem.
  Annex, criterion 3
- [ ] Keep presentations of the product's performance within the available supporting evidence.
  Annex, criterion 4

- [ ] Make the qualitative composition, the quantitative composition limited to hazardous substances under Art. 3 of Regulation (EC) No 1272/2008, the name, code number and supplier identity of fragrance compositions, and the existing data on undesirable and serious undesirable effects easily accessible to the public by any appropriate means.

  Art. 21

Deadlines

The dates that matter for a cosmetic product. Most of them have passed, which is the point of an applies-today list; the two that have not are the allergen dates, and the file retention runs per product.

11 MARCH 2013

Animal-testing ban complete

The last transitional period of Art. 18 ends. From this day no cosmetic product may be placed on the EU market whose finished form or whose ingredients were tested on animals for cosmetic purposes, wherever in the world the test was carried out.

11 JULY 2013

The Cosmetics Regulation applies

Regulation (EC) No 1223/2009 replaces the Cosmetics Directive. The responsible person (Art. 4), the safety report (Art. 10), the product information file (Art. 11), the notification (Art. 13) and the labelling (Art. 19) all date from this day, as do the common criteria for claims of Regulation (EU) No 655/2013.

BEFORE EVERY LAUNCH

Safety report, file and notification

The safety report of Art. 10(1) and the product information file of Art. 11(1) have to exist, and the notification of Art. 13(1) has to be submitted, before the product is placed on the market. None of the three is a formality you can file after the first order.

26 JULY 2023

Fragrance allergen labelling extended

Commission Regulation (EU) 2023/1545 amends Annex III to Regulation (EC) No 1223/2009 and requires further fragrance allergens to be named individually in the ingredient list, above 0.001 per cent in leave-on and 0.01 per cent in rinse-off products. The amendment was adopted on this day and entered into force on 16 August 2023; the dates that bind follow below.

31 JULY 2026

Extended allergen declaration binding

This is the last day on which products that do not carry the extended declaration may be placed on the Union market. The date sits in the transitional footnotes to the annex of Regulation (EU) 2023/1545, one footnote per amended entry, so read the footnote of the entry that applies to your formulation.

31 JULY 2028

Old stock has to be gone

Products placed on the market before the earlier date may still be made available until this day, under the same transitional footnotes. After it, every cosmetic product on a shelf in the EU carries the extended declaration.

TEN YEARS AFTER THE LAST BATCH

The file may finally be closed

The product information file is kept for ten years following the date on which the last batch of the product was placed on the market (Art. 11(1)). It is the only retention period cosmetics law fixes, and it runs from the last batch, not from the first.

NO ACT YET

No product passport act for cosmetics

No delegated act under the Ecodesign for Sustainable Products Regulation covers cosmetics, and the first working plan of 16 April 2025 does not list them among the priority product groups. Nothing on this page is a passport duty; all of it is current cosmetics law.

Sources

The documents this checklist is drawn from, and what each one is good for. Annexes II to VI are amended several times a year, so read the consolidated version on EUR-Lex rather than the original text when you check a substance.

Document	What for
Regulation (EC) No 1223/2009	The regulation itself. Art. 4 and 5 on the responsible person, Art. 10 and Annex I on the safety report, Art. 11 on the file, Art. 13 on the notification, Art. 19 on the label, Art. 20 on claims, Art. 21 on public access.
Regulation (EU) No 655/2013	The six common criteria every claim has to meet, and the Art. 1 sentence that extends them to any medium. Worth reading before you write anything that sounds like marketing.

Document	What for
Regulation (EU) 2023/1545	The fragrance allergen amendment to Annex III. The two dates that matter sit in the transitional footnotes to its annex, per entry, not in an article.

How to prepare

Six steps in the order they pay off, from settling the role to the first published page behind the tube.

1. **Settle the role in writing:** decide per product who the responsible person is, and where a mandate is involved, hold the written designation and the written acceptance. A verbal arrangement is not what Art. 4 asks for.
2. **Complete the file:** walk the five points of Art. 11(2) per product and note which of them exists, where it lives and who updates it. The gaps are usually the proof of effect and the animal-testing data.
3. **Chase the fragrance declarations:** ask every fragrance supplier for the allergen figures at the 2023/1545 thresholds, in a format you can read as data. This is the longest lead time on the list.
4. **Audit the label against Art. 19:** go through points (a) to (g) on your three busiest packs. Where legibility is already the constraint, note it, because that is the case for a second surface.
5. **File the evidence for every claim:** one source per claim, findable without asking the person who wrote it. The common criteria ask for verifiable evidence, not for a conviction.
6. **Pilot with a handful of products:** Register for free, set up the fields of this checklist once and publish a few real products. Ingredients become rows rather than a paragraph, allergens get their own thresholds, and certificates hang on the product with their number and validity.

As of 9 September 2026. The current version of this checklist:
https://transpareo.com/en/industries/cosmetics/checklist-cosmetics