

**COMMISSION REGULATION (EU) 2020/2081
December 14, 2020
Amendment to Annex XVII to Regulation (EC) No
1907/2006 (REACH) Registration, Evaluation,
Authorization and Restriction of Chemicals
as regards substances in tattoo inks or permanent
make-up**

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Main regulatory sources

- RAPEX → Directive 2001/95/EC of the European Parliament and of the Council concerning the obligations of the producers to place products on the market only if they are safe.
- Labelling → Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.
- ResAP (2003)2 on the safety of tattoos and permanent make-up.
- REACH → Regulation (EC) No 1907/2006 of the European Parliament and of the Council, concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- ResAP (2008)1 → Superseded ResAP (2003)2 recommending a number of provisions relating to tattooing practices and the chemical composition of mixtures for tattooing purposes to ensure that they do not endanger the health and safety of the public.
- Only seven Member State have implemented a national legislation based on the above.

Appraisal Scheme

1. March 2015: Assignment from The EU Commission to ECHA (European Chemicals Agency) to set a dossier **assessing the risks** to human health of certain chemicals contained in mixtures used for tattooing purposes
2. Commission asked for Union-wide action beyond the national measures already in place and beyond the measures based on the general safety requirements laid down in Directive 2001/95/EC
3. ECHA prepared the “Annex XV Dossier” gathering the opinions of other commissions (RAC/SEAC/EU Commission) proposing relevant Restrictions



Key points:

- (i) risks to **human health** due to exposure to certain hazardous chemicals;
- (ii) a **harmonized high level** of protection to human health;
- (iii) **free movement of goods** within the Union.

The Annex XV Dossier (Restrictions Proposals)

- Proposition of restrictions:
 - prohibiting the placing on the market and the use of mixtures for tattooing purposes if they contained any substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council in some hazard classes: Carcinogenicity. Mutagenicity toxicity, skin corrosion or irritation, serious eye damage etc.
- New labeling requirements:
 - Statement for tattooing purposes;
 - unique reference number for identifying the specific batch;
 - to list any ingredients classified as hazardous to human health (even if not covered by the restriction proposal);
 - to indicate the presence of nickel and chromium

■ Proposition RO1

■ Proposition RO2

Restriction Option RO1

“Dynamic” approach



restriction to be applied **not only** to substances currently listed in those Annexes, but also to substances listed in Annexes II and IV to Regulation (EC) No 1223/2009 at any time in the future (without starting a further restriction process or the amendment of Annex XVII to Regulation (EC) No 1907/2006).

Dynamic restriction also for substances classified under Regulation (EC) No 1272/2008



Lighter than RO2

Restriction Option RO2

“Static” approach



restriction to be applied only to substances restriction only to substances currently listed in Annexes II and IV to Regulation (EC) No 1223/2009



Dynamic restriction also for substances classified under Regulation (EC) No 1272/2008

EU Commission Opinion on Restriction Proposals

- unacceptable risk to human health arising from certain substances in mixtures for use for tattooing purposes
- concentration threshold for a wide range of hazardous substances identified for the purposes of Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and Council of Europe resolution ResAP (2008)1 not to be used in tattooing procedures (**ban for placing on the market**)
- ancillary requirement, suppliers should be required to provide sufficient information to encourage safe use of their mixtures and to indicate the full list of ingredients
- Any future restriction should begin **to apply 18 months after** the substance has been included in Annex VI to the Regulation (EC) No 1272/2008 (sufficient time for formulators to find safer alternatives)
- It is **not necessary** to address the **availability of alternatives** for substances classified in the future, as the need to ensure a high level of protection of human health takes precedence

Commission Regulation (EU) 2020/2081 (full text)

- **Article 1:** Modification Annex XVII to Regulation (EC) No 1907/2006 as attached
- **Article 2:** The Regulation enters into force on December **January 4^o 2021**



New Annex XVII

New Annex XVII – Technical Requirements

- Ban to place on the market any substance for tattooing purposes not compliant with the new limits:
 - a) carcinogen or germ cell mutagen in a concentration equal to or greater than 0,00005 % by weight;
 - b) reproductive toxicant in a concentration equal to or greater than 0,001%;
 - c) skin sensitizer in a concentration equal to or greater than 0,001%;
 - d) skin corrosive or skin irritant, or as serious eye damage or eye irritant → 0,1 % if pH regulator - 0,01 % in all other cases;
 - e) substance listed in Annex II to REACH in a concentration equal to or greater than 0,00005 %;
- **Derogation** for Pigment «*Blue 15:3*» e «*Green 7*»: Restrictions applied from **4 January 2023**
- Any modification to Annex II or IV REACH after **4 January 2021** shall enter into force **within 18 months**

New Annex XVII – Labeling Requirements

- New labeling provisions **after 4 January 2022**:
 - (a) the statement “*Mixture for use in tattoos or permanent make-up*”;
 - (b) a reference number to uniquely identify the batch;
 - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33
 - (d) the additional statement “**pH regulator**” for substances falling under point (d)(i) of paragraph 1;
 - (e) the statement “Contains **nickel**. Can cause allergic reactions.”
 - (f) the statement “Contains **chromium (VI)**. Can cause allergic reactions.”
 - (g) safety instructions for use.
- The information shall be clearly visible, easily legible and written in the official language(s) of the Member State(s)
- Mixtures that do not contain the statement “*Mixture for use in tattoos or permanent make-up*” **shall not be used** for tattooing purposes.

Conclusions

Challenge

- The limits imposed are **quite unsustainable** for manufacturers who shall facing one of the hardest technical and regulatory challenge ever.

Derogation

- For the above reason any limitation about using pigments *Blue 15:3* and *Green 7* have been derogated to 2023
- In fact to date **there are no possible substitutes** to those two pigments.

Risks

- The risk is the vanishing of any “legal” colored tattoo (or at least anyone resulting from or combined with blue and green)
- The rise of a black market

Open Points

- Even if the Regulation purposes are totally uncontroversial – ensuring consumer safety – the decisional process is not completely agreeable



- The entire regulatory process suffered the lack of strong analytical data and affordable results about the real danger and damages related to using potential harmful ingredients (scientist have been working for years and we are still waiting for unambiguous achievements);
- All limitations provided for by the regulation represent only a potential protection, because there are no data about their effectiveness;
- Furthermore the market is still waiting for harmonized test methods (actually the one used is borrowed from the leather products test)
- There is no medical confirmation if the substances are absorbed by the human body or expelled and what is the real line between safety and harm.

Contatti



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