



# EU Regulation on substances in tattoo inks and permanent make-up

## *Chances and challenges*

*2<sup>nd</sup> International Conference on Tattoo Safety*  
*Berlin 18 November 2021*

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# OUTLINE

1. Background-state of play in 2014
2. Preparatory work
3. REACH restriction
4. Legislative procedure
5. Beyond restriction of hazardous substances
6. Now what? Enforcement
7. Conclusions



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**COMMISSION REGULATION (EU) 2020/2081**

**of 14 December 2020**

**amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

- Published - **15 December 2020**
- Entry into force - **4 January 2021**
- Entry into application - **4 January 2022**
  - Pigment Blue 15:3 and Pigment Green 7, **4 January 2023.**



# 1. Background – state of play in 2014

- Tattoo fashion increasing
- Adverse health effects reported
- Hazardous chemicals found in tattoo inks in the EU market
- Lack of EU harmonised measures
- Member States asking for stricter harmonised rules



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## 2. Preparatory work

**June 2014** the Consumer Safety Network Subgroup on Tattoos and Permanent Make-up gathered representatives from EU/EFTA national authorities, and other stakeholders, such as the Council of Europe and associations of tattooists, ink manufacturers, consumers, dermatologists, etc.

**September 2014** European Commission project on "Tattoos - Permanent Make-up" aimed to provide regulators with the scientific and technical basis needed for deciding whether EU measures are needed to ensure tattoo/PMU inks' safety and protect consumers

- **Report 1-Adverse health effects and experience with the Council of Europe Resolution (2008Safety of tattoos and permanent make-up.**
- **Report 2- State of play and trends in tattoo**
- **Report 3- Safety of tattoos and permanent make-up compilation of information on legislative framework and analytical methods**

Final report published in 2016

<https://op.europa.eu/en/publication-detail/-/publication/e08d57a8-4fd0-11e6-89bd-01aa75ed71a1/language-en/format-PDF/source-240825745>



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### 3. REACH restriction

March 2015, European Commission asked the European Chemicals Agency (ECHA) to prepare a dossier pursuant to Article 69(1) of Regulation (EC) No 1907/2006 ( 'the Annex XV dossier') and assess the risks to human health of chemicals in tattoo and PMU inks, as well as the need for European Union-wide action beyond any national measures.

October 2017, ECHA submitted the Annex XV dossier prepared in cooperation with Italy, Denmark and Norway (dossier submitters) and with the contribution of German Federal Institute for Risk Assessment and Federal Institute for Occupational Health and Safety.

June 2019, ECHA submitted the opinions of RAC and SEAC to the Commission.

- <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a>

## 4. Legislative procedure

- Legislative procedure with the EU Member States
- Scrutiny by the European Parliament and Council
- TBT notification



WORLD TRADE  
ORGANIZATION

G/TBT/N/EU/709

(20-2756)

7 April 2020

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	<b>Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> European Commission <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/en/">http://ec.europa.eu/growth/tools-databases/tbt/en/</a>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:</b>

## 5. Beyond restriction of hazardous substances

- **Ancillary requirements-labelling**
  - ✓ Mixture for use in tattoos or permanent make-up”;
  - ✓ A reference number to uniquely identify the batch;
  - ✓ The list of ingredients in decreasing order;
  - ✓ Special labelling: Ni, CrVi, pH regulators;
- **Improved information to consumers**



## 6. And now, what? Enforcement!

- Enforceability – assessed by the Forum- Wide scope-analytical challenge
- ECHA opinion- Annex to BD document-“Appendix D.2 Analytical methods“- includes a table with the assessment of the enforceability of the proposed restriction and the applicability of the analytical methods listed in JRC report

**Enforcement is responsibility of the Member States**



# Conclusions

## Chances

- High level of protection of human health.
- EU citizens are equally protected independently of the country where they get the tattoo and whether the ink is manufactured in the EU or not.
- Free movement of goods within the EU.
- International benchmark.



# Conclusions

## Challenges

- **Enforcement**
  - Analytical methods
  - Online sales
- **Alternatives**

**Suggestions, ideas, concerns?**

## More info

- [https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions\\_en](https://ec.europa.eu/growth/sectors/chemicals/reach/restrictions_en)
- [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L\\_.2020.423.01.0006.01.ENG&toc=OJ%3AL%3A2020%3A423%3ATOC](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2020.423.01.0006.01.ENG&toc=OJ%3AL%3A2020%3A423%3ATOC)
- <https://echa.europa.eu/hot-topics/tattoo-inks>
- ECHA website  
<https://echa.europa.eu/nl/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a>
- JRC report  
[http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94760/wp1\\_tr\\_pubsy.pdf](http://publications.jrc.ec.europa.eu/repository/bitstream/JRC94760/wp1_tr_pubsy.pdf)



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**THANK YOU**