



Department
for Environment
Food & Rural Affairs

Substances in tattoo inks and permanent make-up

Restriction decision

by Emma Hardy MP

Parliamentary Under Secretary of State

On behalf of the Secretary of State for Environment, Food and Rural Affairs

Decision date: 30 December 2025

Preliminary Matters

- Article 69(1) of assimilated Regulation (EC) No. 1907/2006 concerning the registration, evaluation, authorisation and restriction of chemicals ('UK REACH') provides that if an appropriate authority considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Health and Safety Executive as Agency for UK REACH (referred to hereafter as 'the Agency') to prepare a dossier which conforms to the requirements of Annex 15 of UK REACH.
- In accordance with this provision, on 29 April 2021, the Defra Secretary of State, with agreement from Welsh and Scottish Ministers, made a request to the Agency to prepare an Annex 15 restriction dossier on substances with known hazards in tattoo inks and permanent make-up (PMU). This request raised concerns of a risk posed to human health from the use of these substances in tattoo inks and PMU. It raised a particular concern about the use of pigments in tattoo inks and PMU and their composition, absence of regulation, and the health effects of exposure to hazardous substances.
- The Agency's Annex 15 dossier was published on its website on 6 May 2022 ('the Restriction Dossier'). In the Restriction Dossier, the Agency provided justification that action was necessary beyond any measures already in place, and that a restriction is the most appropriate measure to address the risks identified. A restriction was proposed.

- The Agency formulated its opinions on risk assessment and socio-economic analysis of the suggested restriction in accordance with the requirements in UK REACH, and submitted its Final Opinion to the Appropriate Authorities (the Secretary of State, Welsh Ministers and Scottish Ministers) on 1 June 2023 ('the Final Opinion').
- The Final Opinion concludes that a restriction under UK REACH is appropriate to reduce the risk to human health from substances in tattoo inks and PMU. The Agency also set out the related socio-economic impact, including in relation to the availability of alternatives.
- The Secretary of State is now required to take a decision, subject to the consent requirements in Article 4A of UK REACH, on whether to propose a draft amendment to Annex 17 of UK REACH.

Purpose of this decision report

1. Under Article 68(1) of UK REACH, when there is an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances, Annex 17 of UK REACH shall be amended by regulations made by the Secretary of State which provide for the adoption of new restrictions, or the amendment of current restrictions, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles.
2. In exercising this power, the Secretary of State must take into account the socio-economic impact of the restriction, including the availability of alternatives.
3. Under Article 73(1) of UK REACH, if the conditions laid down in Article 68 are fulfilled, the Secretary of State must propose a draft amendment to Annex 17 of UK REACH.
4. The functions of deciding whether to propose a draft amendment, and of proposing a draft amendment, are subject to the consent requirement in Article 4A of UK REACH.
5. This report sets out the decision and reasons for that decision, as required under Article 130 of UK REACH. In accordance with Article 73(1), this report also sets out a detailed explanation of the reasons for divergence from the Agency's original proposal.

Agency Recommendation

6. The Agency identified that hazardous substances in tattoo inks and PMU do present a risk to human health. It is estimated that around 1.8% of people with

tattoos develop an adverse reaction of a severity that requires a doctor's consultation. The evidence to support the Agency's risk assessment included that the substances in question are carcinogenic, mutagenic, toxic to reproduction, skin sensitising, corrosive and eye damaging. There is potential risk amplification from the intradermal route of exposure, where these substances are inserted under the skin and remain in situ long term. Also, there is evidence of pigment translocation beyond the initial exposure site, including to organs such as the lymph nodes and the liver, where their activity and impact are unknown. The Agency stated that the ability of pigment particles to translocate away from the site of the tattoo means that adverse effects may occur at sites remote from the original tattoo or PMU. The Agency concluded these risks are not adequately controlled. In its Final Opinion, the Agency set out the socio-economic impact of the restriction, including in relation to the availability of alternatives. Further details regarding the contextual evidence on substances in tattoo inks and PMU can be found in the Agency's Final Opinion.

7. The Agency concluded that a UK REACH restriction is appropriate to address the risks identified. The Agency therefore proposed a restriction on the use and placing on the market of mixtures containing certain hazardous substances for tattooing procedures and PMU treatments. The Agency designed the scope of the restriction to cover a broad range of substances in order to minimise potential human health risks.
8. The Agency set out the scope of the proposed restriction in Section 2 of its Final Opinion. The Agency explored several restriction options (ROs) – RO1, RO2, RO2a and RO3 – but RO2a was the Agency's preferred option. Key aspects of RO2a include:
 - a. **Hazard classifications in scope:** RO2a proposed restricting substances classified in the GB Mandatory Classification and Labelling (MCL) list for carcinogenicity, mutagenicity, reproductive toxicity, skin sensitisation, skin corrosivity and eye damage, if present in a tattoo ink or PMU mixture at or above a specified concentration limit. The Agency's Final Opinion indicates that the risk from these substances is from their hazard profiles in addition to their specific intradermal application. As such, RO2a proposed that all substances which are classified with these hazard profiles, currently or in the future, should fall in scope;
 - b. **Cosmetic products:** RO2a also covered substances restricted from cosmetic products in assimilated Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products ('the Cosmetic Products Regulation' (CPR));

- c. **Skin and eye irritants:** Substances classified in the GB MCL list as skin and eye irritants were included within the scope of a restriction in other ROs but not in RO2a on the basis that such substances prevent infection in their function as preservatives;
- d. **Concentration limits:** RO2a proposed concentration limits from the GB MCL list and assimilated Regulation (EU) No. 1272/2008 ('the Classification Labelling and Packaging regulations' (GB CLP)). The Agency also proposed an annexed list of substances with specific concentration limits. Some of these concentration limits are higher (less strict) than those proposed in other ROs explored by the Agency in its Final Opinion;
- e. **Labelling requirements:** RO2a proposed a requirement to label tattoo inks and PMU with information including a unique reference number, list of ingredients and safety instructions for use. Other ROs included further requirements to label pH regulators and include allergen warnings for nickel and chromium (VI), but RO2a did not propose these further requirements due to uncertainty in their benefit;
- f. **Derogations for 19 substances:** RO2a included derogations for 19 substances (including pigment Blue 15:3 and pigment Green 7) that would otherwise be captured due to their status under the CPR, based on socio-economic factors and/or insufficient data;
- g. **Transition period:** RO2a proposed a two-year transition period for formulators and suppliers, with an additional one year for tattoo artists and PMU professions to use up non-compliant inks.

Conclusion

- 9. I have considered the evidence identified by the Agency, showing that hazardous and unregulated substances are prevalent in tattoo inks and PMU. Taking into account the Restriction Dossier, the Final Opinion, the socio-economic impact and availability of alternatives, I consider that there is an unacceptable risk to human health resulting from the use of hazardous substances in tattoo inks and PMU, and that the risk needs to be addressed by a restriction. As a result, I am proposing a draft amendment to Annex 17 of UK REACH.
- 10. The restriction I am proposing covers the placing on the market and use of substances described at subparagraphs 8.a and 8.b of this report. I have decided to follow the Agency's recommendations in its preferred option RO2a, except for the discrete points set out in paragraphs 11 to 13 below, where I consider it appropriate to modify the Agency's approach. In each case, the

decision to diverge is made on the basis of unacceptable risk, taking into account the socio-economic impacts including the availability of alternatives.

11. Concentration limits:

- a. I have decided to diverge from the approach to concentration limits proposed by the Agency in RO2a in the Final Opinion. Instead, I consider it appropriate to apply the lower (stricter) concentration limits as described in option RO3. I consider it appropriate to take a more precautionary approach to the permissible concentration limits. Taking into account the Agency's risk assessment, I consider that unacceptable risk would persist between the concentration limits in RO2a and RO3. This persistent unacceptable risk will therefore be addressed by reducing the concentration limits to that in RO3. In taking this decision, I have taken into account that there may be possible additional costs to industry, due to having to test for stricter concentration limits.

12. Labelling requirements:

- a. Application of the stricter concentration limits applies specific limits for pH regulators. As such, I have decided to include additional labelling requirements for pH regulators as described in the Agency's RO3. Substances with concentration limits informed by their sole use as a pH regulator will be required to be labelled as such to clearly communicate this to users. I have also decided to include a requirement to label tattoo inks and PMU containing nickel or chromium (VI) below their restriction concentration limits with allergen warnings. These labelling requirements are also described in the Agency's RO3. This labelling reflects their particular properties as common allergens, clearly communicating this to users. Both these changes support the stricter concentration limits I have decided to apply.
- b. I have decided that the labelling requirements under this restriction will apply to tattoo inks and PMU containing hazardous substances in scope of the restriction, at permissible concentrations. Applying this condition to tattoo inks and PMU that do not contain such substances would extend beyond the permissible scope this restriction.

13. Derogations for 19 substances:

- a. I have decided to restrict the 19 pigments (including pigments Blue 15:3 and Green 7) recommended for derogation by the Agency in its preferred option RO2a. This approach is considered appropriate to address the risk to human health posed by these substances in a precautionary way. In taking this decision, I have taken into account socio-economic factors including concern about the current availability of alternatives to Blue 15:3 and Green 7 pigments, which may potentially impact the longevity of tattoos using alternatives to such pigments.

- b. While the Agency did not identify evidence indicating these substances are unsafe if used in tattoo or PMU ink, they were initially included within scope of their recommended restriction due to their hazard classification, evidenced from their listing in Annex 2 to the CPR. This is the same evidence which is used to justify the inclusion of other substances within scope of the restriction. A further assessment by the Agency did not identify evidence that these 19 substances are safe for use in tattoo inks and PMU, with the Agency only concluding that it did not identify evidence that they were unsafe for such uses. At the same time, the Agency did not identify evidence that these substances were safer than the other substances in scope of the restriction. I therefore consider there to still be an unacceptable risk associated with the use of these 19 pigments.

14. This decision is taken under Article 73 of UK REACH, having obtained the consent of Scottish and Welsh Ministers.

[Signed]

Emma Hardy MP

On behalf of the Secretary of State for the Department of Environment, Food and Rural Affairs