

Public consultation information note

HSE proposes to restrict the use of certain substances and groups of substances that pose a risk to human health if they are present in tattoo inks and permanent make-up (PMU):

Over 4,000 substances meet one of more of the criteria that bring them into scope of this proposed restriction. This includes:

- Substances listed in Council of Europe resolution [ResAP\(2008\)1](#)
- Carcinogenic or mutagenic substances
- Substances that are toxic to reproduction
- Skin sensitisers
- Skin corrosive or irritant substances
- Substances that cause serious eye damage/eye irritant substances
- Substances that are prohibited for use in cosmetic products under the [Cosmetic Products Regulation \(EUR 2009/1223\)](#).

These criteria aim to identify substances which have the potential to cause adverse effects when inserted into skin, as is the case during tattooing and the application of PMU.

There are reports in the literature linking substances in tattoo ink and PMU to various adverse effects often collectively referred to as complications. These include allergic and other skin reactions at the site of the tattoo or permanent make-up. The evidence linking substances in tattoo ink and PMU with adverse systemic effects is less clear, though there are reports in the literature that suggest that systemic complications can occur. Complications can take weeks, months, or years to develop or may appear intermittently. In many cases, complications are mild but sometimes it is necessary for those affected to seek medical assistance and even have their tattoo or PMU removed because of the severity of the adverse effect.

It is possible to link some complications to substances in the ink (particularly when the complication is localised to the tattoo or PMU or to specific colours within a tattoo). Often it is not clear which of the many substances that may be found in tattoo inks is causing a complication. This is due to the limited number of investigations and the challenges of identifying causal agents when exposures occurred months or years before any adverse effects were apparent.

Given the uncertainties about which substances are causing tattoo and PMU related complications and uncertainties about how often complications arise, it is difficult to quantify the level of risk that is associated with tattoo ink and PMU. This restriction is therefore being proposed on the hypothesis that certain hazardous substances when used in tattoo ink or PMU have the potential to trigger complications. Since it is possible for anyone in GB who is over 18 years old to get a tattoo or PMU, this potential risk applies to any member of the adult population in GB that chooses to

get a tattoo or PMU. This action is therefore a precautionary measure to limit the impacts of this potential risk.

Currently, unlike the situation in the EU where a REACH restriction has been introduced to manage this risk, there is no legislation in GB that regulates which substances may be present in tattoo ink or PMU.

This Annex 15 dossier proposes three restriction options, referred to in this dossier as RO1, RO2 and RO3, which have the potential to manage this identified risk.

On the assumption that reducing the levels of these hazardous substances in tattoo inks will reduce the number and severity of complications, each restriction option proposes concentration limits for substances that are in scope of the restriction. These concentration limits do not necessarily reflect a level of exposure that is guaranteed to prevent ill health because it is not always possible to identify such levels from the available data. The concentration limits do indicate levels of exposure that represent a low level of risk and provide a tool for compliance monitoring.