ECHA proposes a restriction on substances in tattoo inks

Summary

The European Chemicals Agency (ECHA), at the request of the European Commission (EC), submitted a report proposing a restriction on substances in tattoo inks. The submission is together with the Norwegian Environment Agency, Istituto Superiore di Sanita, and the Danish Environmental Protection Agency. The German Federal Institute for Risk Assessment (BfR) and Federal Institute for Occupational Health and Safety (BAuA) also contributed to the development of the proposal.

Studies have reported a large number of mild and a small number of skin complications requiring medical treatment as a result of tattoo inks injected into the skin, i.e., tattoos or permanent make-up (PMU). Tattoo inks tend to contain colourants not specifically developed to be injected into human skin and as a result, some may contain impurities with hazardous properties, such as carcinogenic, mutagenic or reprotoxic. Tattoo inks do not remain permanently at the tattoo site and are known to distribute in the body. Studies have found colourant particles in different organs such as the lymph nodes and the liver. The available information for certain hazardous substances indicate that risks for human health cannot be excluded.

The public consultation on this proposed restriction will start on 20 December 2017 and end on 20 June 2018. However, the rapporteurs of ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) would welcome any early comments by 16 February 2018, to assist them in the first discussion of the restriction proposal.

SUGGESTED RESTRICTION

Scope

The proposal aims to restrict the intentional use of certain substances in tattoo inks or to impose concentration limits for selected substances. These substances include those with harmonised classifications[1] as carcinogenic, mutagenic, reprotoxic, skin sensitising/corrosive/irritant, eye damaging/irritant as well as other substances prohibited in cosmetic products (under the Cosmetic Products Regulation)[2] and selected impurities. A number of colourants, which do not currently have alternatives or where information is insufficient to demonstrate risk from them, are exempted.

Two restriction options (RO1 and RO2) with the same scope are proposed. They differ in terms of the proposed concentration limits and how the links with the Cosmetic Products Regulation annexes are managed.

Reasons for action

It is estimated that 12% of European citizens are tattooed and that the prevalence in the younger generations (18 - 35 year olds) may be double that. Tattoos may be injected into the dermis or other parts of the body (e.g., submucosal, intraocular, or under the tongue) of consumers. Cosmetic tattoos, also known as PMU, are used to resemble make-up (JRC,

[1] As per Annex VI to the Classification, Labelling and Packaging Regulation (EC) No 1272/2008
[2] Regulation (EC) 1223/2009

2016b). It is estimated that between 3-20% of the general population, depending on the Member State, may have PMU procedures carried out.

The health effects reported after tattooing are mainly skin problems, 68% of persons being tattooed reported skin issues in one survey.[3] However, the pigments in tattoo inks are known to migrate from the tattoo site. Animal and human studies have shown that colourant particles migrate to regional lymph nodes. Animal studies have shown colourant particles are transported to the liver, suggesting their distribution via the blood system and potentially exposing internal organs to substances with hazardous properties. In the same survey by Klugl et al, 6.6% of tattooed persons reported systemic reactions after tattooing. The adverse effects associated with exposure to chemicals in tattoo inks can be grouped in: non-infectious inflammatory (e.g., plaque-like, papulo-nodular pattern, ulcerating patterns, hyperkeratotic, photosensitivity, other urticarial-like reactions, lymphopathic pattern, neurosensory reactions), systemic, malignant, reproductive and developmental.

The available information for certain hazardous substances in the scope of the proposed restriction indicate that risks for human health cannot be excluded and action is required on Union-wide basis. Currently, tattoo inks are considered as general consumer products and hence, regulated under the General Product Safety Directive (92/59/EEC) in the European Union (EU). Dedicated legislation exists in seven EU Member States (MS) and two members of the European Economic Area (EEA). Three EU MS have notified the EC of their intention to introduce national legislation. MS national legislation are largely based on the Council of Europe (CoE) resolution on requirements and criteria for the safety of tattoos and PMU (ResAP(2003)2 or ResAP(2008)1). This restriction proposal has built on these existing laws.

Consequences of the action

The restriction would create obligations for tattoo ink manufacturers, importers and distributors to ensure that tattoo inks not meeting the requirements of the proposed restriction are not placed on the EU market after its entry into force (assumed to be in 2021). It also puts the onus on tattoo artists and PMU practitioners to ensure that non-compliant inks are not used in tattoo or PMU procedures.

Several surveys have shown that the majority of tattoo inks currently on the market meet the CoE recommendations and requirements of MS national regulation. As both restriction options (RO1 and RO2) propose concentration limits that are similar or higher than those enforced by MS national legislation, it is expected that a high proportion of tattoo inks and PMU currently on the EU market will also meet the proposed requirements.

Given the similarities with MS national legislation, the proposed restriction is expected to be enforceable and manageable for many actors in the supply chain. The incremental substitution costs estimated to be incurred by downstream users of tattoo ink in the EEA as a result of the proposed restriction are about €4.4 million annually (in 2016 values). Incremental enforcement (analytical testing and administrative) costs are estimated at €235 000 annually for the EEA. The costs of the proposed restriction per one litre of non-compliant tattoo ink removed from the market are estimated at €60.

[3] Klügl, I., Hiller, K.-A., Landthaler, M. & Bäumler, W., 2010. *Incidence of Health Problems Associated with Tattooed Skin: A Nation-Wide Survey in German-Speaking Countries.* s.l.:Dermatology

Many formulators are small or micro enterprises. Those not already compliant with the CoE resolutions would experience the largest regulatory burden from the proposed restriction options but costs are expected to be passed on end-consumers. On an individual level, the increase in the prices of tattoo inks are expected to be less than €1 per tattoo or €4 per PMU, which is negligible compared to an average price of tattoo or PMU. Therefore, the analysis suggests that the proposed restriction would be unlikely to exert disproportionate costs to the individual consumer and society as a whole.

The restriction is expected to provide benefits because of avoided cases of non-infectious inflammatory, systemic, reproductive, developmental, carcinogenic adverse effects. The report demonstrates that very few avoided cases are necessary (e.g., 320 – 1 050 avoided cases of tattoo removal due to non-infectious inflammatory complications) for the benefits to exceed the costs of the proposed restriction options. The conclusions hold true also when taking into account uncertainties.

Therefore, the proposed restriction options are deemed to be affordable, cost effective and likely to be proportionate to the risk. The submitted report also demonstrates that the restriction options are practical and monitorable.

SPECIFIC INFORMATION

Stakeholders are invited to submit specific information, in addition to general comments on the overall dossier:

1. The proposed restriction limits the use of a range of chemicals with severe human health hazardous properties in tattoo and permanent make-up inks. For some impurities that are known to be regularly detected in these inks, such as heavy metals, PAHs and methanol, there is a need to carefully consider the feasibility of newly proposed limit values. Will you face difficulties finding or formulating tattoo and permanent make-up inks on the EU market meeting the concentration limits listed in the table below? If you expect to face difficulties, please clarify for which impurity (ies) and what concentration limit(s) would be achievable and what time would be needed to be able to formulate compliant inks.

Substance name	EC#	CAS#	Proposed concentration limit (% w/w)
Mercury	231-106-7	7439-97-6	0.00002
Nickel	231-111-4	7440-02-0	0.001
Tin	231-141-8	7440-31-5	0.005
Antimony	231-146-5	7440-36-0	0.0002
Arsenic	231-148-6	7440-38-2	0.0000008
Barium*	231-149-1	7440-39-3	0.84
Cadmium	231-152-8	7440-43-9	0.00002
Chromium‡	231-157-5	7440-47-3	0.00002
Cobalt	231-158-0	7440-48-4	0.0025
Copper*	231-159-6	7440-50-8	0.05
Zinc*	231-175-3	7440-66-6	0.23
Lead	231-100-4	7439-92-1	0.00007
Selenium	231-957-4	7782-49-2	0.0002
Methanol	200-659-6	67-56-1	10.9
Individual polycyclic aromatic hydrocarbons (PAH) with harmonised classification as carcinogenic or mutagenic			0.0002

Notes: *Soluble. ‡Chromium (VI).

2. Previous consultations have indicated that there are no technically feasible and safe alternatives for two specific pigments which are covered by the scope of the proposed restriction: Pigment Green 7 (CI 74260, EC 215-524-7, CAS 1328-53-6) and Pigment Blue 15:3 (CI 74160, EC 205-685-1, CAS 147-14-8). Would you agree with this? How long will it take to develop alternatives to these two pigments?

3. The colourants listed below are banned in hair dyes (Annex II Cosmetics Regulation). Are they used in tattoo inks or permanent make-up? If so, can these colourants be substituted by safe alternatives available at similar market prices?

Substance name	Substance market name	EC #	CAS #
1,4-bis(p-tolylamino)anthraquinone	Solvent Green 3, CI 61565	204-909-5	128-80-3
Dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)amino](4-hydroxy-2-sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt	Fast Green FCF, CI 42053	219-091-5	2353-45-9
6-chloro-2-(6-chloro-4-methyl-3-oxobenzo[b]thien-2(3H)-ylidene)-4-methylbenzo[b]thiophene-3(2H)-one	VAT Red 1, CI 73360	219-163-6	2379-74-0

Disodium 3-[(2,4-dimethyl-5-sulphonatophenyl)azo]-4-hydroxynaphthalene-1-sulphonate	Red, CI 14700	224-909-9	4548-53-2
N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	Pigment Red 5, CI 12490	229-107-2	6410-41-9
Calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	Pigment Red 63:1, CI 15880	229-142-3	6417-83-0
1,2-dihydroxyanthraquinone	Pigment Red 83, CI 58000	200-782-5	72-48-0
1-hydroxy-4-(p-toluidino)anthraquinone	Solvent Violet 16, CI 60725	201-353-5	81-48-1
Sodium 4-(2,4-dihydroxyphenylazo)benzenesulphonate	Acid Orange 16, CI 14270	208-924-8	547-57-9
4-(phenylazo)resorcinol	Solvent Orange 1, CI 11920	218-131-9	2051-85-6
Tetrasodium 6-amino-4-hydroxy-3-[[7-sulphonato-4-[(4-sulphonatophenyl)azo]-1-naphthyl]azo]naphthalene-2,7-disulphonate	Food Black 2, CI 27755	218-326-9	2118-39-0
1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol (Pigment Red 4; CI 12085) and its salts when used as a substance in hair dye products, 1-[(2-Chloro-4-nitrophenyl)azo]-2-naphthol and its insoluble barium, strontium and zirconium lakes, salts and pigments, Pigment red 4	CI 12085/Red	220-562-2,	2814-77-9
Trisodium 3-hydroxy-4-(4′-sulphonatonaphthylazo)naphthalene-2,7-disulphonate (Acid Red 27; CI 16185) when used as a substance in hair dye products, Trisodium 3-hydroxy-4-(4'-sulphonatonaphthylazo)naphthalene-2,7-disulphonate	CI 16185 / ACID RED 27	213-022-2	915-67-3
Ethanaminium, N-(4-((4-diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethyl-, hydroxide, inner salt, calcium salt (2:1) (Acid Blue 3; CI 42051) when used as a substance in hair dye products, Ethanaminium, N-(4-((4-(diethylamino)phenyl)(5-hydroxy-2,4-disulfophenyl)methylene)-2,5-cyclohexadien-1-ylidene)-N-ethylhydroxide, inner salt, calcium salt (2:1) and its insoluble barium, strontium and zirconium lakes, salts and pigments	CI 42051 / ACID BLUE 3	222-573-8	3536-49-0
2-(6-Hydroxy-3-oxo-(3H)xanthen-9-yl)benzoic acid; Fluorescein and its disodium salt (Acid Yellow 73 sodium salt; CI 45350) when used as a substance in hair dye products, Disodium 2-(3-oxo-6-oxidoxanthen-9-yl)benzoate	CI 45350/ Yellow	208-253-0	518-47-8
	CI 45350/ Yellow	219-031-8	2321-07-5
4′,5′-Dibromo-3′,6′-dihydroxyspiro[isobenzofuran-1(3H),9′-[9H]xanthene]-3-one; 4′,5′-Dibromofluorescein; (Solvent Red 72) and its disodium salt (CI 45370) when used as a substance in hair dye products, 4',5'-Dibromo-3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one and its insoluble barium, strontium and zirconium lakes, salts and pigments	CI 45370 / SOLVENT RED 72/ Orange	209-876-0	596-03-2
		224-468-2	4372-02-5
2-(3,6-Dihydroxy-2,4,5,7-tetrabromoxanthen-9-yl)benzoic acid; Fluorescein, 2′,4′,5′,7′-tetrabromo-; (Solvent Red 43), its disodium salt (Acid Red 87; CI 45380) and its aluminium salt (Pigment Red 90:1 Aluminium lake) when used as a substance in hair dye products, Disodium 2-(2,4,5,7-tetrabromo-6-oxido-3-oxoxanthen-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	CI 45380/ Red	239-138-3	15086-94-9
	CI 45380 / PIGMENT RED 90:1 ALUMINUM LAKE	240-005-7	15876-39-8
	CI 45380 / ACID RED 87	241-409-6	17372-87-1

2',4',5',7'-Tetraiodofluorescein, its disodium salt (Acid Red 51; CI 45430) and its aluminium salt (Pigment Red 172 Aluminium lake) when used as a substance in hair dye products, Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl)benzoate and its insoluble barium, strontium and zirconium lakes, salts and pigments	CI 45430 / PIGMENT RED 172 ALUMINUM LAKE	235-440-4	12227-78-0
	CI 45430 / ACID RED 51	240-474-8	16423-68-0
Disodium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	CI 15865/Red	222-642-2	3564-21-4

4. Are the following colourants used in tattoo inks or permanent make-up? Do they have substitutes at similar market prices? How long will it take to identify substitutes? Is it possible for industry to comply with the proposed concentration limits for these pigments?

Substance name	Other regulatory process names	EC#	CAS#	Proposed concentration limit
Acid Green 16	sodium 4-{[4-(diethylamino)phenyl][4-(diethyliminio)cyclohexa-2,5-dien-1-ylidene]methyl}naphthalene-2,7-disulfonate	603-214-8	12768-78-4	0.1% w/w
Acid Red 26	Disodium 1-(2,4-dimethylphenylazo)-2-hydroxynaphthalene-3,6-disulphonate	223-178-3	3761-53-3	0.1% w/w
Acid Violet 17	Hydrogen [4-[[4-(diethylamino)phenyl][4-[ethyl(3-sulphonatobenzyl)amino]phenyl]methylene]cyclohexa-2,5-dien-1-ylidene](ethyl)(3-sulphonatobenzyl)ammonium, sodium salt	223-942-6	4129-84-4	0.1% w/w
Basic Red 1 , Basic red 1	9-[2-(ethoxycarbonyl)phenyl]-3,6-bis (ethylamino)-2,7-dimethylxanthylium chloride	213-584-9	989-38-8	0.1% w/w
Disperse Blue 106	Ethanol, 2-[ethyl[3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]phenyl]amino]-	602-285-2	12223-01-7	0.1% w/w
Disperse Blue 124	Disperse Blue 124	612-788-9	61951-51-7	0.1% w/w
Disperse Blue 35	C.I. Disperse Blue 35	602-260-6	12222-75-2	0.1% w/w
Disperse Orange 37	Propanenitrile, 3-[[4-[2-(2,6-dichloro-4-nitrophenyl)diazenyl]phenyl]ethylamino]-	602-312-8	12223-33-5	0.1% w/w
Disperse Red 1	2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]ethanol	220-704-3	2872-52-8	0.1% w/w
Disperse Red 17	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	0.1% w/w
Disperse Yellow 9	N-(2,4-dinitrophenyl)benzene-1,4-diamine	228-919-4	6373-73-5	0.1% w/w
Pigment Violet 3	4-[(4-Aminophenyl)-(4-methyliminocyclohexa-2,5-dien-1-ylidene)methyl]aniline	603-635-7	1325-82-2	0.1% w/w
Pigment Violet 39	Methanaminium, N-[4-[bis[4-(dimethylamino)phenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, molybdatephosphate	264-654-0	64070-98-0	0.1% w/w
Solvent Yellow 2	4-dimethylaminoazobenzene	200-455-7	60-11-7	0.1% w/w

5. Do you have information on the percentage of tattoo inks that are already compliant with the proposed restriction, national legislation already in place or the Council of Europe resolution ResAP(2008)1?

Early Comments preferably by 16 February 2017

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 20 December 2017. Interested parties can comment on the proposed restriction report using the ECHA website. Although the public consultation concludes on 20 June 2018, the rapporteurs of

PUBLIC CONSULTATION

RAC and SEAC would appreciate receiving early comments by **16 February 2018** and additional comments by **20 June 2018** to better assist them as they develop their opinions.

The final opinions of both Committees are scheduled to be available by December 2018. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the proposed restriction in the Annex XVII of the REACH Regulation.

Further information on the purpose, objectives, and process of the public consultation on restriction proposals is available in the Public Consultation Guidance http://echa.europa.eu/docu ments/10162/13641/public_consultation_guidance_en.pdf

Please note: Information arriving after the closing date of the Public Consultation (or via other channels, e.g., emails) will not be taken into account by RAC and SEAC.