

Annex 2 - Draft Amendment for Tattoo Inks Restriction

<p>Substances¹ falling within one or more of the following points—</p> <p>(a) substances classified in the GB mandatory classification and labelling list as amended from time to time,² as any of the following—</p> <ul style="list-style-type: none">(i) carcinogen category 1A, 1B or 2(ii) germ cell mutagen category 1A, 1B or 2(iii) reproductive toxicant category 1A, 1B or 2(iv) skin sensitiser category 1, 1A or 1B(v) skin corrosive category 1, 1A, 1B or 1C substances(vi) serious eye damage category 1 substances <p>(b) substances listed Annex 2 to Regulation (EC) No 1223/2009 of the European Parliament and of the</p>	<ul style="list-style-type: none">1. Must not be placed on the market⁶ in a tattoo ink if paragraph 3 applies.2. Must not be used⁷ in a tattoo ink if paragraph 3 applies.3. This paragraph applies where—<ul style="list-style-type: none">(a) the substance is present in the mixture⁸ in a concentration, or in some other way, that does not accord with an applicable condition in column h (maximum concentration in ready for use preparation) or i (other), or both, of the table in Annex 4 to the Cosmetic Products Regulation;(b) the substance does not fall under subparagraph (a) above and is present in the mixture in a concentration equal to or greater than—<ul style="list-style-type: none">(i) 0.00005% by weight if the substance is—<ul style="list-style-type: none">(1) classified in the GB mandatory classification and labelling list as—<ul style="list-style-type: none">1. carcinogen category 1A, 1B or 2, or2. germ cell mutagen category 1A, 1B or 2;(2) listed in Annex 2 to the Cosmetic Products Regulation;(3) listed in Annex 4 to the Cosmetic Products Regulation with at least one of the following conditions specified in column g (product type, body parts) of the table in that Annex—<ul style="list-style-type: none">1. “Rinse-off products”,2. “Not to be used in products applied on mucous membranes”,3. “Not to be used in eye products”;
--	--

¹ Drafting note: see paragraph 1 of Article 3 of UK REACH for definition of ‘substance’.

² Drafting note: see paragraph 42 of Article 3 of UK REACH for definition of ‘GB mandatory classification and labelling list’.

⁶ Drafting note: see paragraph 12 of Article 3 of UK REACH for definition of ‘placing on the market’.

⁷ Drafting note: see paragraph 24 of Article 3 of UK REACH for definition of ‘use’.

⁸ Drafting note: see paragraph 2 of Article 3 of UK REACH for definition of ‘mixture’.

<p>Council on cosmetic products at [date]³ (“Cosmetic Products Regulation”)⁴</p> <p>(c) substances listed in Annex 4 to the Cosmetic Products Regulation for which a condition is specified in at least one of the columns g (product type, body parts), h (maximum concentration in ready for use preparation) and i (other) of the table in that Annex</p> <p>(d) substances listed in Appendix 13 to this Annex⁵</p>	<ul style="list-style-type: none"> (ii) 0.001% by weight if the substance is classified in the GB mandatory classification and labelling list as— <ul style="list-style-type: none"> (1) reproductive toxicant category 1A, 1B or 2, or (2) skin sensitiser category 1, 1A or 1B; (iii) 0.01% by weight if the substance is not used solely as a pH regulator and is classified in the GB mandatory classification and labelling list as— <ul style="list-style-type: none"> (1) skin corrosive category 1, 1A,1B or 1C, or (2) serious eye damage category 1; (iv) 0.1% by weight if the substance is used solely as a pH regulator and is classified in the GB mandatory classification and labelling list as— <ul style="list-style-type: none"> (1) skin corrosive category 1, 1A,1B or 1C, or (2) serious eye damage category 1; (v) the concentration limit specified for the substance in the table in Appendix 13 to this Annex, if the substance is listed in that table. <p>4. Where a substance is not listed in Appendix 13 to this Annex and falls under more than one of paragraphs 3(b)(i) to (iv) above, the lower percentage concentration limit applies to that substance. If a substance is listed in Appendix 13 to this Annex and also falls under one or more of paragraphs 3(b)(i) to (iv), the concentration limit laid down in paragraph 3(v) shall apply to that substance.</p> <p>5. Suppliers placing on the market tattoo inks containing any substance in column 1 of this entry must ensure that the packaging is marked with the following information, which must be clearly visible, easily legible and marked in a way that is indelible (but see paragraph 6)—</p> <ul style="list-style-type: none"> (a) the statement “Mixture for use in tattoos or permanent make-up”; (b) a reference number to uniquely identify the batch from which it derives;
--	--

³ Drafting note: date of entry into force of the SI adding this restriction to Annex 17 of UK REACH.

⁴ EUR 1223/2009, amended by S.I. 2022/659 and S.I. 2024/1334; there are other amending instruments, but none is relevant.

⁵ Drafting note: a new Appendix 13 will be added to Annex 17 of UK REACH, see below.

	<p>(c) the list of ingredients in the mixture, insofar as not already required to be stated on the label by Regulation (EC) No 1272/2008, in descending order by weight or volume of the ingredient as a proportion of the mixture and named—</p> <ul style="list-style-type: none"> i. in accordance with the nomenclature established in the glossary of common ingredient names⁹ established in accordance with Article 33 of the Cosmetic Products Regulation; ii. if (i) does not exist for an ingredient, with the name recommended by the International Union of Pure and Applied Chemistry (IUPAC); iii. if (i) and (ii) do not exist for an ingredient, by reference to the CAS number and EC number; <p>(d) if the mixture contains a substance falling within paragraph 3(b)(iv), the statement “pH regulator”;</p> <p>(e) if the mixture contains nickel below the concentration limit specified in Appendix 13, the statement “Contains nickel. Can cause allergic reactions.”;</p> <p>(f) if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13, the statement “Contains chromium (VI). Can cause allergic reactions.”;</p> <p>(g) safety instructions for use, including but not limited to storage instructions, expiration dates and “use by” dates, if it would be difficult to make safe use of the tattoo ink in the absence of such instructions, insofar as are not already required to be stated on the label by Regulation (EC) No 1272/2008.</p> <p>6. If the size of the package is too small to include the information required by paragraph 5, except the information in paragraph 5(a) which must be included on the label, the information must instead be included in the instructions for use accompanying the tattoo ink.</p>
--	--

⁹ Copies of the glossary of common ingredients are available from the Office of Product Safety and Standards, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET.

	<p>7. Tattoo inks that do not comply with paragraphs 5 to 6 must not be used.</p> <p>8. Before using a tattoo ink which complies with paragraphs 5 to 6, a user must provide the person undergoing the tattooing procedure with the information in paragraphs 5 to 6.</p> <p>9. This entry does not apply to—</p> <ul style="list-style-type: none"> (a) substances classified in the GB mandatory classification and labelling list under a category in paragraphs 3(b)(i)(1) or 3(b)(ii)(1)¹⁰ due to effects only following exposure by inhalation; (b) substances that are gases at a temperature of 20 °C and pressure of 101.3 kilopascals, or generate a vapour pressure of more than 300 kilopascals at a temperature of 50 °C, except for formaldehyde (CAS number 50-00-0, EC number 200-001- 8); (c) the placing on the market or use of a tattoo ink, where the tattoo ink is placed on the market or used exclusively as a relevant medical device¹¹ or relevant accessory to a medical device¹². Where the placing on the market or use of a tattoo ink is not exclusively as a relevant medical device or a relevant accessory to a medical device, the requirements of the Medical Devices Regulations 2002¹³ and this entry apply cumulatively. <p>10. For the purposes of this entry—</p> <ul style="list-style-type: none"> (a) “batch” means a specific quantity of tattoo ink produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character; (b) “ingredient” “means any substance added during the process of formulation and present in a tattoo ink, save for an impurity;
--	--

¹⁰ Drafting note: these paragraphs cross refer to the carcinogenic, germ cell mutagenic and reproductive toxicant categories to which the restriction applies.

¹¹ Drafting note: see paragraph 44 of Article 3 of UK REACH for definition of ‘relevant medical device’.

¹² Drafting note: see paragraph 45 of Article 3 of UK REACH for definition of ‘relevant accessory to a medical device’.

¹³ S.I. 2002/618.

	<p>(c) “pH regulator” means a substance which alters the pH of a mixture for tattooing purposes;</p> <p>(d) “tattoo ink” is a mixture produced for administration by intentional insertion into the skin, mucous membrane or eyeball, whereby a mark or design (a “tattoo” or “permanent make-up”, including procedures commonly referred to as permanent make-up, semi-permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation) is made on the human body.</p> <p>11. Paragraphs 1, 5 and 6¹⁴ of this entry apply after [date]¹⁵.</p> <p>12. Paragraphs 2, 7 and 8¹⁶ of this entry apply after [date]¹⁷.</p>
--	---

¹⁴ Drafting note: paragraphs in relation to placing on the market (for which a 2-year transition period applies).

¹⁵ Drafting note: date to be 2 years after entry into force of the SI adding this restriction to Annex 17 of UK REACH.

¹⁶ Drafting note: provisions relating to use (for which a 3-year transition period applies).

¹⁷ Drafting note: date to be 3 years after entry into force of the SI adding this restriction to Annex 17 of UK REACH.

Appendix 13

Entry []¹⁸ - list of substances with specific concentration limits:

Substance name	EC number	CAS number	Concentration limit (by weight)
Mercury	231-106-7	7439-97-6	0.00005 %
Nickel	231-111-4	7440-02-0	0.0005 %
Organometallic tin	231-141-8	7440-31-5	0.00005 %
Antimony	231-146-5	7440-36-0	0.00005 %
Arsenic	231-148-6	7440-38-2	0.00005 %
Barium ⁽¹⁾	231-149-1	7440-39-3	0.05 %
Cadmium	231-152-8	7440-43-9	0.00005 %
Chromium ⁽²⁾	231-157-5	7440-47-3	0.00005 %
Cobalt	231-158-0	7440-48-4	0.00005 %
Copper ⁽¹⁾	231-159-6	7440-50-8	0.025 %
Zinc ⁽¹⁾	231-175-3	7440-66-6	0.2 %
Lead	231-100-4	7439-92-1	0.00007 %
Selenium	231-957-4	7782-49-2	0.0002 %
Benzo[a]pyrene	200-028-5	50-32-8, 63466-71-7	0.0000005 %

¹⁸ Drafting note: populate with the relevant Annex 17 table entry number for this restriction.

Polycyclic-aromatic hydrocarbons (PAH), classified as carcinogen or germ cell mutagen category 1A, 1B or 2 in the GB mandatory classification and labelling list			0.00005 % (individual concentrations)
Methanol	200-659-6	67-56-1	11 %
o-anisidine ⁽¹⁾	201-963-1	90-04-0	0.0005 %
o-toluidine ⁽¹⁾	202-429-0	95-53-4	0.0005 %
3,3'-dichlorobenzidine ⁽¹⁾	202-109-0	91-94-1	0.0005 %
4-methyl-m- phenylenediamine ⁽¹⁾	202-453-1	95-80-7	0.0005 %
4-chloroaniline ⁽¹⁾	203-401-0	106-47-8	0.0005 %
5-nitro-o-toluidine ⁽¹⁾	202-765-8	99-55-8	0.0005 %
3,3'-dimethoxybenzidine ⁽¹⁾	204-355-4	119-90-4	0.0005 %
4,4'-bi-o-toluidine ⁽¹⁾	204-358-0	119-93-7	0.0005 %
4,4'-thiodianiline ⁽¹⁾	205-370-9	139-65-1	0.0005 %
4-chloro-o-toluidine ⁽¹⁾	202-441-6	95-69-2	0.0005 %
2-naphthylamine ⁽¹⁾	202-080-4	91-59-8	0.0005 %
Aniline ⁽¹⁾	200-539-3	62-53-3	0.0005 %
Benzidine ⁽¹⁾	202-199-1	92-87-5	0.0005 %
p-toluidine ⁽¹⁾	203-403-1	106-49-0	0.0005 %
2-methyl-p-phenylenediamine ⁽¹⁾	202-442-1	95-70-5	0.0005 %
Biphenyl-4-ylamine ⁽¹⁾	202-177-1	92-67-1	0.0005 %
4-o-tolylazo-o-toluidine ⁽¹⁾	202-591-2	97-56-3	0.0005 %

4-methoxy-m- phenylenediamine ⁽¹⁾	210-406-1	615-05-4	0.0005 %
4,4'-methylenedianiline ⁽¹⁾	202-974-4	101-77-9	0.0005 %
4,4'-methylenedi-o-toluidine ⁽¹⁾	212-658-8	838-88-0	0.0005 %
6-methoxy-m-toluidine ⁽¹⁾	204-419-1	120-71-8	0.0005 %
4,4'- methylene-bis-[2-chloro aniline] ⁽¹⁾	202-918-9	101-14-4	0.0005 %
4,4'-oxydianiline ⁽¹⁾	202-977-0	101-80-4	0.0005 %
2,4,5-trimethylaniline ⁽¹⁾	205-282-0	137-17-7	0.0005 %
4-aminoazobenzene ⁽¹⁾	200-453-6	60-09-3	0.0005 %
p-phenylenediamine ⁽¹⁾	203-404-7	106-50-3	0.0005 %
Sulphanilic acid ⁽¹⁾	204-482-5	121-57-3	0.0005 %
4-amino-3-fluorophenol ⁽¹⁾	402-230-0	399-95-1	0.0005 %
2,6-xylydine	201-758-7	87-62-7	0.0005 %
6-amino-2-ethoxynaphthaline		293733-21-8	0.0005 %
2,4-xylydine	202-440-0	95-68-1	0.0005 %
Pigment Red 7 (PR7)/CI 12420	229-315-3	6471-51-8	0.1 %
Pigment Red 9(PR9)/CI 12460	229-104-6	6410-38-4	0.1 %
Pigment Red 15 (PR15)/CI 12465	229-105-1	6410-39-5	0.1 %
Pigment Red 210(PR210)/CI 12477	612-766-9	61932-63-6	0.1 %
Pigment Orange 74 (PO74)		85776-14-3	0.1 %
Pigment Yellow 65 (PY65)/CI 11740	229-419-9	6528-34-3	0.1 %

Pigment Yellow 74 (PY74)/CI 11741	228-768-4	6358-31-2	0.1 %
Pigment Red 12 (PR12)/CI 12385	229-102-5	6410-32-8	0.1 %
Pigment Red 14 (PR14)/CI 12380	229-314-8	6471-50-7	0.1 %
Pigment Red 17 (PR17)/CI 12390	229-681-4	6655-84-1	0.1 %
Pigment Red 112 (PR112)/CI 12370	229-440-3	6535-46-2	0.1 %
Pigment Yellow 14 (PY14)/CI 21095	226-789-3	5468-75-7	0.1 %
Pigment Yellow 55 (PY55)/CI 21096	226-789-3	6358-37-8	0.1 %
Pigment Red 2 (PR2)/CI 12310	227-930-1	6041-94-7	0.1 %
Pigment Red 22 (PR22)/CI 12315	229-245-3	6448-95-9	0.1 %
Pigment Red 146 (PR146)/CI 12485	226-103-2	5280-68-2	0.1 %
Pigment Red 269 (PR269)/CI 12466	268-028-8	67990-05-0	0.1 %
Pigment Orange 16 (PO16)/CI 21160	229-388-1	6505-28-8	0.1 %
Pigment Yellow 1 (PY1)/CI 11680	219-730-8	2512-29-0	0.1 %
Pigment Yellow 12 (PY12)/CI 21090	228-787-8	6358-85-6	0.1 %
Pigment Yellow 87 (PY87)/CI 21107:1	239-160-3	15110-84-6, 14110-84-6	0.1 %
Pigment Yellow 97 (PY97)/CI 11767	235-427-3	12225-18-2	0.1 %
Pigment Orange 13 (PO13)/CI 21110	222-530-3	3520-72-7	0.1 %
Pigment Orange 34 (PO34)/CI 21115	239-898-6	15793-73-4	0.1 %
Pigment Yellow 83 (PY83)/CI 21108	226-939-8	5567-15-7	0.1 %

Solvent Red 1 (SR1)/CI 12150	214-968-9	1229-55-6	0.1 %
Acid Orange 24 (AO24)/CI 20170	215-296-9	1320-07-6	0.1 %
Solvent Red 23 (SR23)/CI 26100	201-638-4	85-86-9	0.1 %
Acid Red 73 (AR73)/CI 27290	226-502-1	5413-75-2	0.1 %
Disperse Yellow 3/CI 11855	220-600-8	2832-40-8	0.1 %
Acid Green 16	603-214-8	12768-78-4	0.1 %
Acid Red 26	223-178-3	3761-53-3	0.1 %
Acid Violet 17	223-942-6	4129-84-4	0.1 %
Basic Red 1	213-584-9	989-38-8	0.1 %
Disperse Blue 106	602-285-2	12223-01-7	0.1 %
Disperse Blue 124	612-788-9	61951-51-7	0.1 %
Disperse Blue 35	602-260-6	12222-75-2	0.1 %
Disperse Orange 37	602-312-8	12223-33-5	0.1 %
Disperse Red 1	220-704-3	2872-52-8	0.1 %
Disperse Red 17	221-665-5	3179-89-3	0.1 %
Disperse Yellow 9	228-919-4	6373-73-5	0.1 %
Pigment Violet 3	603-635-7	1325-82-2	0.1 %
Pigment Violet 39	264-654-0	64070-98-0	0.1 %
Solvent Yellow 2	200-455-7	60-11-7	0.1 %
(1) Soluble			

(2) Chromium VI