

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,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 68(1) thereof,

Whereas:

- (1) Annex XVII to Regulation (EC) No 1907/2006 lays down restrictions on the manufacture, placing on the market and use of certain substances on their own, in mixtures or in articles.
- (2) The number of people in the Union with tattoos or permanent make-up has been increasing steadily, in particular in the young population. The procedures used for tattooing or permanent make-up (referred to collectively as 'tattooing'), whether involving the use of needles or the application of some other technique such as micro-blading, inevitably cause an injury to the skin barrier. As a result, the inks or other mixtures used for tattooing are absorbed into the body. Mixtures used for tattooing generally consist of colorants and auxiliary ingredients such as solvents, stabilisers, wetting agents, pH regulators, emollients, preservatives and thickeners. The mixtures are introduced into the human skin, inside the eyeball or into mucous membranes. The colorants mostly remain close to where the mixture is administered, so that the tattoo or permanent make-up will remain visible. However, the soluble ingredients in the mixture are distributed within a matter of hours or days across the entire body. In consequence, the skin and other organs are exposed to the effects of those soluble substances over an extended period. Some of those substances have hazardous properties that pose a potential risk to human health. In addition, metabolism of the colorants in the skin, decomposition due to solar radiation exposure and laser irradiation may also lead to the release of hazardous chemicals from the area of the body where the tattoo or permanent make-up is located ⁽²⁾.
- (3) Mixtures placed on the market for use for tattooing purposes are products falling within the scope of Directive 2001/95/EC of the European Parliament and of the Council ⁽³⁾. Directive 2001/95/EC allows producers to place products on the market only if they are safe. Member States enforce this obligation by taking actions in respect of dangerous products on the market and notifying those actions to the Commission through the Community Rapid Information System (RAPEX). RAPEX notifications on chemicals contained in mixtures used for tattooing purposes have been increasing in recent years ⁽⁴⁾.
- (4) In 2003, the Council of Europe adopted resolution ResAP (2003)2 ⁽⁵⁾ on the safety of tattoos and permanent make-up. That resolution was superseded in 2008 by resolution ResAP (2008)1 ⁽⁶⁾. The 2008 resolution recommended a number of provisions relating to tattooing practices and the chemical composition of mixtures for tattooing purposes to ensure that they do not endanger the health and safety of the public.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ JRC Science for Policy report Safety of tattoos and permanent make-up: Final report, 2016 <https://ec.europa.eu/jrc/en/publication/euro-scientific-and-technical-research-reports/safety-tattoos-and-permanent-make-final-report>

⁽³⁾ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.1.2002, p. 4).

⁽⁴⁾ https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

⁽⁵⁾ Council of Europe Resolution ResAP (2003)2 on tattoos and permanent make-up, adopted by the Committee of Ministers on 19 June 2003 at the 844th meeting of the Ministers' Deputies - http://www.cti-tattoo.net/Documents/PDF/eu_resap_2003_2.pdf

⁽⁶⁾ Council of Europe Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up (superseding Resolution ResAP(2003)2 on tattoos and permanent make-up), adopted by the Committee of Ministers on 20 February 2008 at the 1018th meeting of the Ministers' Deputies - <https://rm.coe.int/16805d3dc4>

- (5) Based on the Council of Europe recommendations, seven Member States put national legislation in place regulating the chemical composition of mixtures for tattooing purposes ⁽⁷⁾.
- (6) On 12 March 2015, the Commission asked the European Chemicals Agency ('the Agency') pursuant to Article 69(1) of Regulation (EC) No 1907/2006 to prepare a dossier in order to assess the risks to human health of certain chemicals contained in mixtures used for tattooing purposes, and the need for Union-wide action beyond the national measures already in place in some Member States and beyond the measures based on the general safety requirements laid down in Directive 2001/95/EC. The dossier prepared by the Agency in response to the Commission's request is referred to in this Regulation as 'the Annex XV dossier'.
- (7) The Agency prepared the Annex XV dossier in cooperation with Italy, Denmark and Norway (the Agency and Italy, Denmark and Norway are together referred to as 'the dossier submitters') and with the assistance of the German Federal Institute for Risk Assessment and the German Federal Institute for Occupational Health and Safety. On 6 October 2017, the dossier submitters submitted the Annex XV dossier ⁽⁸⁾. The dossier demonstrated that the risks to human health due to exposure to certain hazardous chemicals in mixtures used for tattooing purposes are not adequately controlled and need to be addressed on a Union-wide basis to achieve a harmonised high level of protection to human health and free movement of goods within the Union.
- (8) The Annex XV dossier proposed a restriction prohibiting both the placing on the market of mixtures for use for tattooing purposes and the use of mixtures for tattooing purposes if they contained any substances classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁹⁾ in the hazard classes carcinogenicity, mutagenicity or toxicity to reproduction category 1A, 1B or 2, skin sensitisation category 1, 1A or 1 B, skin corrosion category 1, 1A, 1B, 1C or skin irritation category 2, or serious eye damage category 1 or eye irritation category 2. The Annex XV dossier also proposed the inclusion of certain substances listed in Annex II or IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ⁽¹⁰⁾ with specific conditions, and substances listed in Table 1 of the Council of Europe resolution ResAP(2008)1 based on the fact that they may either undergo decomposition to or contain residual aromatic amines classified for carcinogenicity or mutagenicity. The Annex XV dossier proposed to exclude from the restriction substances that were classified in the hazard classes carcinogenicity or mutagenicity category 1A, 1B or 2 due to effects following exposure by inhalation only and not through any other route such as dermal or oral.
- (9) In addition, the Annex XV dossier proposed a number of labelling requirements, some of them modified following advice from the Agency's Forum for Exchange of Information on Enforcement ('the Forum') during the opinion development process. The labelling requirements proposed in the Annex XV dossier included a requirement to state the fact that the mixture was for use for tattooing purposes, a requirement to specify a unique reference number for identifying the specific batch, a requirement to list any ingredients classified as hazardous to human health in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but not covered by the proposed restriction, and any ingredients covered by the proposed restriction but used in the mixture below the concentration limit set by the proposed restriction. Furthermore, an additional labelling requirement to indicate the presence of nickel and chromium (VI) was considered necessary, as these particular substances can induce new cases of skin sensitisation and potentially trigger allergic reactions in sensitised persons. The labelling requirements were proposed in order to give consumers and tattooists additional information, to facilitate implementation of the restriction, and to ensure that investigations can be properly carried out in the event of adverse health effects.
- (10) The Annex XV dossier set out two possible restriction options (RO1 and RO2), each with different concentration limits for the substances falling within the scope of the restriction. RO1 contained lower concentration limits than RO2. The two options also contained alternative approaches for handling future updates to Annexes II and IV to Regulation (EC) No 1223/2009. RO1 suggested to apply the restriction not only to substances currently listed in those Annexes (with the requisite conditions), but also to substances listed in those Annexes at any time in the future. In other words, the restriction would apply to those substances automatically without the need to start a further restriction process or to amend Annex XVII to Regulation (EC) No 1907/2006 again. This approach is referred to as 'dynamic'. RO2 suggested to apply the restriction only to substances currently listed in those Annexes

⁽⁷⁾ Belgium, France, Germany, the Netherlands, Slovenia, Spain and Sweden.

⁽⁸⁾ Annex XV restriction report-proposal for a restriction: substances in tattoo inks and permanent make up- October 2017-ECHA with Denmark, Italy and Norway-<https://echa.europa.eu/documents/10162/6f739150-39db-7e2c-d07d-caf8fb81d153>

⁽⁹⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽¹⁰⁾ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

(with the requisite conditions). This approach is referred to as 'static'. Both options RO1 and RO2 proposed a 'dynamic' restriction for substances classified under Regulation (EC) No 1272/2008. This was on the grounds that it was necessary to ensure a sufficient level of protection against the human health risks posed by the presence of substances in mixtures used for tattooing purposes that are classified in the relevant categories under that Regulation.

- (11) On 20 November 2018, the Agency's Committee for Risk Assessment (RAC) adopted an opinion concluding that the proposed restriction, with certain modifications proposed by RAC, was the most appropriate Union-wide measure to address the identified risk arising from the various substances in question, in terms of both effectiveness in reducing the risk, practicability and monitorability.
- (12) RAC considered that all relevant health hazard classes were covered by the Annex XV dossier and agreed with the hazard assessment for the substances and group of substances. In addition to the restriction options proposed under RO1 and RO2, RAC proposed a modified version of the RO1 concentration limits. RAC considered these modifications necessary because the concentration limits for some substances in RO1 and RO2 did not provide sufficient protection. For other substances, more practicable concentration limits could be proposed, in RAC's view, while still minimising the risk for human health.
- (13) RAC did not agree with the proposal to exclude two primary aromatic amines listed in Table 1 of the ResAP (2008)1 from the scope of the proposed restriction, namely 6-amino-2-ethoxynaphthaline (CAS No 293733-21-8) and 2,4-xylydine (EC No 202-440-0; CAS No 95-68-1).
- (14) However, RAC agreed with the dossier submitters' proposal to exclude carcinogenic and mutagenic substances of category 1A, 1B or 2 that present this hazard due to effects following exposure by inhalation only. RAC considered that substances presenting such a hazard due to effects following exposure by inhalation only were not relevant in the case of intradermal exposure to mixtures used for tattooing purposes. In addition, RAC supported the modification put forward by the dossier submitters in response to advice given by the Forum during the opinion-making process. The Forum proposed to exempt substances that are gases at standard temperature and pressure, since they are not expected to be found in mixtures used for tattooing purposes due to their physical state. The only exception would be formaldehyde since the public consultation indicated that formaldehyde can be found in tattoo inks in a dissolved state. RAC also agreed that risks of exposure by tattoo artists to mixtures administered by them for tattooing purposes are out of the scope of the Annex XV dossier.
- (15) RAC did not support the dossier submitters' proposal for exclusion from the scope of the restriction of 21 colorants (19 non-phthalocyanine and 2 phthalocyanine pigments). Those colorants are banned by Annex II to Regulation (EC) No 1223/2009 for use in hair colours. However, the blue phthalocyanine colorant (Pigment Blue 15:3) is allowed by Annex IV to that Regulation for use in other cosmetic products while the green phthalocyanine colorant (Pigment Green 7) is allowed for other cosmetic products other than eye products. RAC considered that the risk of cancer and possible non-carcinogenic hazards could not be ruled out for the majority of these colorants, primarily due to the lack of adequate information on their hazard properties and on the risk for human health. Moreover, RAC noted that during the public consultation stakeholders pointed out that only two of these colorants, namely the two phthalocyanine-based colorants Pigment Blue 15:3 and Pigment Green 7, were essential for tattooing on account of the fact that there were no safer and technically adequate alternatives available for them.
- (16) RAC supported a dynamic link with both Regulation (EC) No 1223/2009 and Regulation (EC) No 1272/2008 as such links provide greater protection for human health.
- (17) RAC agreed with the dossier submitters that, as regards the date when the new restriction should begin to apply, a transitional period of 12 months would allow sufficient time for actors in the supply chain to meet the new requirements.
- (18) On 15 March 2019, the Agency's Committee for Socioeconomic Analysis (SEAC) adopted an opinion, indicating that the proposed restriction, with the modifications proposed by RAC and SEAC, was the most appropriate Union-wide measure to address the identified risks in terms of its socioeconomic benefits and socioeconomic costs. SEAC reached that conclusion based on the best available information, taking into account that the significant benefits to society, in terms of the adverse skin effects and other health impacts that would be avoided, were likely to be higher than the compliance costs for industry. Moreover, SEAC concluded that the restriction would not have a significant negative economic impact on the supply chains affected, that it would be affordable in terms of price increases to consumers and that the restriction would minimise risks of regrettable substitution.
- (19) SEAC agreed with the conclusions in the Annex XV dossier and with RAC that a transitional period of 12 months seemed reasonable and sufficient to enable actors involved in the supply chains to comply with the restriction.

- (20) SEAC also supported creating a dynamic link with Regulation (EC) No 1272/2008 that would take into account any future changes to the classification of substances listed in Part 3 of Annex VI of that Regulation on the grounds that it would produce human health benefits more quickly. With regard to future changes to Annex II or Annex IV to Regulation (EC) No 1223/2009, SEAC expressed a slight preference for a static link. In SEAC's opinion, although a static link may result in a delay in achieving the health benefits provided by the restriction, it would allow for a proper scientific scrutiny of the concentration limits appropriate for the specific use of the substances in tattooing procedures, and also for a proper assessment of the availability of alternatives.
- (21) SEAC agreed with RAC that it was appropriate to restrict the 19 colorants banned in cosmetic products as, according to the information available, some are not currently used for tattooing purposes and there are alternatives available. However, for Pigment Blue 15:3 and Pigment Green 7, comments raised during the public consultation indicated that there were no safer and technically feasible alternatives available to cover this spectrum of colours. As regards Pigment Green 7, comments indicated that it was largely replaced by the brominated Pigment Green 36 although RAC considered that Pigment Green 36 was not a less hazardous alternative. Therefore, SEAC recommended a time-limited derogation of 36 months for both pigments considering the time needed by manufacturers to reformulate the mixtures. In addition, SEAC supported the exemption for gases at standard temperature and pressure in line with RAC's conclusion that such gases are not expected to be found dissolved in mixtures for tattooing purposes. Based on information from the public consultation SEAC also supported the exclusion of formaldehyde from that exemption.
- (22) SEAC supported the inclusion of labelling requirements and recommended the alignment of the labelling requirements with the requirements of Regulation (EC) No 1272/2008, to prevent duplication of information.
- (23) The Forum was consulted on the proposed restriction in accordance with Article 77(4)(h) of Regulation (EC) No 1907/2006 and its recommendations have been taken into account.
- (24) On 11 June 2019, the Agency submitted the opinions of RAC and SEAC ⁽¹¹⁾ to the Commission.
- (25) Taking into account the Annex XV dossier and the RAC and SEAC opinions, the Commission considers that there is an unacceptable risk to human health arising from certain substances in mixtures for use for tattooing purposes above specific concentration limits. The Commission also considers that the risk needs to be addressed on a Union-wide basis.
- (26) The Commission agrees with RAC and SEAC that, above a certain practical concentration threshold, a wide range of hazardous substances identified for the purposes of Regulation (EC) No 1272/2008, Regulation (EC) No 1223/2009 and Council of Europe resolution ResAP (2008)1 should not be used in tattooing procedures. Moreover, the restriction should also ban the placing on the market of mixtures for use for tattooing purposes if they contain any such substance above the specified practical concentration threshold. By way of an ancillary requirement, suppliers placing mixtures on the market for use for tattooing purposes, within the parameters permitted by the restriction, should be required to provide sufficient information to encourage safe use of their mixtures.
- (27) The Commission agrees with RAC and SEAC that the restriction should not apply to carcinogenic and mutagenic substances with harmonised classification due to effects following exposure by inhalation only. The same analysis applies to reproductive toxicants even though no reproductive toxicant is currently classified due to inhalation exposure only. Therefore, reproductive toxicants with harmonised classification due to effects following exposure by inhalation only should also be excluded from the scope of the restriction.
- (28) The Commission agrees with RAC and SEAC that the restriction should not apply to gaseous substances other than formaldehyde as they are not expected to be present in that state in mixtures used for tattooing purposes.
- (29) The restriction should cover not just substances currently classified in the relevant hazard categories in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but also substances classified in those hazard categories at any point in the future, following an amendment to that Part adding or changing the classification of a substance. Classification under Regulation (EC) No 1272/2008 is based on a careful assessment of the hazard properties of substances. The way that mixtures are administered for tattooing purposes i.e. by introducing them into a part of the body also gives sufficient indications about the potential exposure to these substances. In summary, both the potential hazard (s) of the substances and the way people are exposed to them leads to the conclusion that these substances present a general level of risk to human health that is unacceptable and needs to be addressed by this restriction in accordance with the requirements set out in Title VIII of Regulation (EC) No 1907/2006.

⁽¹¹⁾ Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 20 November 2018) and SEAC's opinion (adopted 15 March 2019) <https://echa.europa.eu/documents/10162/dc3d6ea4-df3f-f53d-eff0-540ff3a5b1a0>

- (30) For any substance that subsequently comes within the terms of the restriction as a result of a subsequent amendment to Part 3 of Annex VI to Regulation (EC) No 1272/2008, the restriction should begin to apply to that substance when the classification in that Part begins to apply. This is usually 18 months after the substance has been included in Annex VI to that Regulation. The 18-month period will provide sufficient time for formulators to find safer alternatives, in particular in those cases that might otherwise lead to regrettable substitution. It is not necessary to address the availability of alternatives for substances classified in the future, as the need to ensure a high level of protection of human health takes precedence over considerations related to technical and economic feasibility of alternatives as regards substances used in tattoo inks.
- (31) Similarly, the restriction should cover not only substances currently listed with the relevant conditions in Annex II or Annex IV to Regulation (EC) No 1223/2009 but also substances listed with any of those conditions at any point in the future, following an amendment to those Annexes listing or changing the listing of a substance. If the substance raises sufficient safety concerns to be restricted in cosmetic products applied on the skin, it must raise at least the same safety concerns when present in mixtures administered for tattooing purposes, which are introduced through the skin into the human body. It is not necessary to address the availability of alternatives for substances falling within the scope of the restriction in the future as the need to protect human health takes precedence over considerations related to technical and economic feasibility of alternatives.
- (32) Nevertheless, as regards those substances that subsequently come within the terms of the restriction as a result of a future amendment to Regulation (EC) No 1223/2009, an additional period of time should be allowed, after the relevant amendment takes effect, in order to give formulators time to adapt to the consequences of the substance coming within the terms of the restriction or to find a safer alternative to it. This is because the assessment required before a substance can be listed in Annex II or Annex IV to Regulation (EC) No 1223/2009 does not allow for specific scrutiny of the substance as regards its effects in mixtures placed on the market for use for tattooing purposes. The additional period of time should be set at 18 months after entry into force of the relevant amendment of Annex II or IV to Regulation (EC) No 1223/2009.
- (33) RAC recommended a reduced concentration limit of 0,01 % for substances classified in the hazard classes skin or eye irritant, skin corrosive or serious eye damage on the basis that the 0,1 % limit proposed by the dossier submitters did not provide sufficient protection in the case of a mixture administered intradermally. During the SEAC consultation it was highlighted that, for some acids and bases used as pH regulators in tattoo mixtures, a concentration of 0,01 % or lower may not be sufficient to achieve their function of adjusting the pH of the mixture. Acids and bases exhibit their irritant or corrosive properties because of their extreme pH values. However, the irritancy or corrosivity of a mixture containing such acids and bases will depend mostly on the overall pH of the mixture itself, rather than on the pH and concentration level of individual substances within in. In the light of these factors, it is appropriate to specify a concentration limit of 0,1 % for irritant or corrosive substances when they are used as pH regulators.
- (34) Currently, labelling requirements for mixtures used for tattooing purposes are not harmonised across the Union. Given the inherent health risks related to substances in tattoo mixtures and the increasing number of people seeking tattoos and permanent make-up, harmonisation of what is written on the packaging is required to ensure proper implementation of the restriction, and thus establish confidence in a Union-wide market of safe products for tattooing purposes, allow essential monitoring and enforcement by authorities, and address and prevent fragmentation of the internal market.
- (35) The Commission considers that, to ensure proper implementation of the restriction and permit direct traceability in case of adverse health effects, a mixture placed on the market in the Union for use for tattooing purposes should be marked with a list of substances added during the process of formulation and present in the mixture for use for tattooing purposes. For the same purpose, the tattooist should provide information marked on the packaging, or included in the instructions for use, to the person undergoing the procedure. The requirement to indicate a full list of ingredients serves to address a possible patchwork of national rules, achieve economies of scale for formulators and harness the full benefits of market harmonisation. Moreover, providing such a full list is also necessary to ensure that the restriction of an extensive list of substances is practically enforceable, monitorable, and effective throughout the Union. The common nomenclature proposed will make it possible to identify the substances by using a unique name in all the Member States. This will enable consumers to easily recognize substances which they have been advised to avoid (for example because of allergies).
- (36) To complement the full list of ingredients and any potential labelling requirements under Regulation (EC) No 1272/2008, the Commission agrees with RAC and SEAC as regards the other pieces of information that should be marked on mixtures for use for tattooing purposes, in particular the unique batch number, the presence of any nickel and chromium (VI), and further safety information on the packaging or in the instructions of use. The Commission also considers that the presence of pH regulating substances should be specifically marked.

- (37) To facilitate compliance of tattooists with this restriction, only mixtures that are marked with the statement 'Mixture for use in tattoos or permanent make-up' should be used for tattooing purposes.
- (38) Taking into account the Annex XV dossier, the opinions of RAC and SEAC, the socioeconomic impact and the availability of alternatives, the Commission concludes that the restriction proposed in the Annex XV dossier, with the modifications described, is the most appropriate Union-wide measure to address the risk identified to human health, without imposing a significant burden on suppliers, tattooists or consumers.
- (39) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the new restriction. The Commission considers that a period of 12 months is sufficient for laboratories to establish, and gain the necessary experience with, the analytical methods developed or being developed by the Member States and other stakeholders for checking compliance with the restriction.
- (40) The Commission agrees with SEAC's recommendation that a longer period should be allowed for Pigment Blue 15:3 and Pigment Green 7 because of the lack of safer and technically adequate alternatives and the time needed by manufacturers to reformulate their mixtures. The Commission considers, that 24 months is sufficient to find safer alternatives and to remove mixtures placed on the market for use for tattooing purposes containing these pigments from the market.
- (41) Mixtures placed on the market for use for tattooing purposes are administered for a variety of reasons, including both aesthetic and medical reasons. Such mixtures may fall within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council⁽¹²⁾. When placed on the market or used exclusively for medical purposes within the meaning of Regulation (EU) 2017/745, the restriction established by this Regulation should not apply to them. In order to ensure a consistent regulatory approach between Regulations (EU) 2017/745 and (EC) No 1907/2006 and to guarantee a high level of protection of human health, when the placing on the market or use of such mixtures may be for both, medical and non-medical purposes, the specific obligations and requirements laid down in both Regulations should apply cumulatively.
- (42) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (43) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹²⁾ Regulation (EU) 2017/745 of the European parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

<p>75.</p> <p>Substances falling within one or more of the following points:</p> <p>(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:</p> <ul style="list-style-type: none"> — carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation — reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation — skin sensitiser category 1, 1A or 1B — skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2 — serious eye damage category 1 or eye irritant category 2 <p>(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*)</p> <p>(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex</p> <p>(d) substances listed in Appendix 13 to this Annex.</p> <p>The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.</p>	<p>1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:</p> <p>(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:</p> <ul style="list-style-type: none"> (i) 0,1 % by weight, if the substance is used solely as a pH regulator; (ii) 0,01 % by weight, in all other cases; <p>(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:</p> <ul style="list-style-type: none"> (i) “Rinse-off products”; (ii) “Not to be used in products applied on mucous membranes”; (iii) “Not to be used in eye products”; <p>(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;</p> <p>(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.</p> <p>2. For the purposes of this entry use of a mixture “for tattooing purposes” means injection or introduction of the mixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as</p>
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permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
 - (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
 - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
 - (a) the statement "Mixture for use in tattoos or permanent make-up";
 - (b) a reference number to uniquely identify the batch;
 - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

	<p>(d) the additional statement “pH regulator” for substances falling under point (d)(i) of paragraph 1;</p> <p>(e) the statement “Contains nickel. Can cause allergic reactions.” if the mixture contains nickel below the concentration limit specified in Appendix 13;</p> <p>(f) the statement “Contains chromium (VI). Can cause allergic reactions.” if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;</p> <p>(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.</p> <p>The information shall be clearly visible, easily legible and marked in a way that is indelible.</p> <p>The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.</p> <p>Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.</p> <p>Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.</p> <p>8. Mixtures that do not contain the statement “Mixture for use in tattoos or permanent make-up” shall not be used for tattooing purposes.</p> <p>9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).</p> <p>10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.</p>
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(*) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).;

(2) the following Appendix 13 is added:

Appendix 13

Entry 75- List of substances with specific concentration limits:

Substance name	EC No	CAS No	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 %

Substance name	EC No	CAS No	Concentration limit (by weight)
Barium **	231-149-1	7440-39-3	0,05 %
Cadmium	231-152-8	7440-43-9	0,00005 %
Chromium‡	231-157-5	7440-47-3	0,00005 %
Cobalt	231-158-0	7440-48-4	0,00005 %
Copper **	231-159-6	7440-50-8	0,025 %
Zinc **	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 %
Polycyclic-aromatic Hydrocarbons (PAH), classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen or germ cell mutagen category 1A, 1B or 2			0,00005 % (individual concentrations)
Methanol	200-659-6	67-56-1	11 %
o-Anisidine **	201-963-1	90-04-0	0,0005 %
o-toluidine **	202-429-0	95-53-4	0,0005 %
3,3'-dichlorobenzidine **	202-109-0	91-94-1	0,0005 %
4-methyl-m-phenylenediamine **	202-453-1	95-80-7	0,0005 %
4-chloroaniline **	203-401-0	106-47-8	0,0005 %
5-nitro-o-toluidine **	202-765-8	99-55-8	0,0005 %
3,3'-dimethoxybenzidine **	204-355-4	119-90-4	0,0005 %
4,4'-bi-o-toluidine **	204-358-0	119-93-7	0,0005 %
4,4'-Thiodianiline **	205-370-9	139-65-1	0,0005 %
4-chloro-o-toluidine **	202-441-6	95-69-2	0,0005 %
2-naphthylamine **	202-080-4	91-59-8	0,0005 %
Aniline **	200-539-3	62-53-3	0,0005 %
Benzidine **	202-199-1	92-87-5	0,0005 %
p-toluidine **	203-403-1	106-49-0	0,0005 %
2-methyl-p-phenylenediamine **	202-442-1	95-70-5	0,0005 %
Biphenyl-4-ylamine **	202-177-1	92-67-1	0,0005 %
4-o-tolylazo-o-toluidine **	202-591-2	97-56-3	0,0005 %
4-methoxy-m-phenylenediamine **	210-406-1	615-05-4	0,0005 %
4,4'-methylenedianiline **	202-974-4	101-77-9	0,0005 %
4,4'-methylenedi-o-toluidine **	212-658-8	838-88-0	0,0005 %
6-methoxy-m-toluidine **	204-419-1	120-71-8	0,0005 %
4,4'-methylene-bis-[2-chloro aniline] **	202-918-9	101-14-4	0,0005 %

Substance name	EC No	CAS No	Concentration limit (by weight)
4,4'-oxydianiline **	202-977-0	101-80-4	0,0005 %
2,4,5-trimethylaniline **	205-282-0	137-17-7	0,0005 %
4-Aminoazobenzene **	200-453-6	60-09-3	0,0005 %
p-Phenylenediamine **	203-404-7	106-50-3	0,0005 %
Sulphanilic acid **	204-482-5	121-57-3	0,0005 %
4-amino-3-fluorophenol **	402-230-0	399-95-1	0,0005 %
2,6-xylidine	201-758-7	87-62-7	0,0005 %
6-amino-2-ethoxynaphthaline		293733-21-8	0,0005 %
2,4-xylidine	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 %

Substance name	EC No	CAS No	Concentration limit (by weight)
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 %

** Soluble. †Chromium VI.