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)

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.

(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 (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-xylidine (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.