

# Webinar: REACH restriction of hazardous substances in tattoo inks and permanent make-up

Questions and answers

ECHA organised a webinar on 29 March 2022 on the <u>REACH restriction of hazardous substances in tattoo inks and permanent make-up</u>.

The purpose of this document is to support the implementation of the restriction by providing technical advice to questions received during the webinar. It is presented in the form of 'questions and answers'. It does not address generic restriction issues, or other aspects of REACH, which are addressed on our <u>website</u>.

This document is based on the questions received from participants before and during the webinar. Editorial changes have been made to improve clarity and similar questions have been combined.

If you need further clarification, or if a specific question has not been answered, contact us.

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This document will not be updated. For the most up-to-date advice on restrictions, refer to our <u>support material</u>.

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## 1. Scope and implementation of the restriction

Question	Answer
What is the official application procedure to present additional data to start a new evaluation of formaldehyde and other limits to amend the restriction? What is the procedure to extend the derogation for Pigment Blue 15:3 and Pigment Green 3?	Any amendment of a REACH restriction needs to be based on the assessment of a restriction dossier.  If the European ink manufacturers want to amend a limit, the scientific and toxicological data will need to be presented in a restriction dossier to be prepared by either a Member State or by ECHA. ECHA acts after receiving a mandate from the Commission).  With regards to formaldehyde, this is a carcinogenic substance, it is the goal of the EU chemicals policy to ban carcinogenic substances from consumer products, unless their use is critical/essential for the functioning of society. It is therefore rather unlikely that any efforts to establish higher concentration limits will be successful. a first step for
	Manufacturers manufacturers should be try to find alternatives.  Regarding the derogation on Pigment Blue 15:3 and Pigment Green 7, given the length of the procedure, it is difficult to change the timelines in the current text of the regulation before Jan 2023.
If customers that are turned away by tattoo artists that want to respect rules then obtain a tattoo with inks that do not meet the conditions of the restriction (i.e. from an artist working illegally) what are the benefits?	Information campaigns for consumers to understand the risks related to non-compliant inks or backyard tattoos and allow them to take informed decisions are aimed to prevent or at least to reduce this to happen at the end of the day, consumers are free to take their decisions.
After the implementation of the restriction, how common do you expect it will be that tattoo inks will require CLP-labelling and safety data sheets?	The supplier of a hazardous mixture is required to provide a safety data sheet. It is not clear if the alternatives to the restricted substances or the other substances in the tattoo ink mixture are hazardous in some other way (not related to the restriction), which means that the mixture is still hazardous and safety data sheets will still be required.
There seems to be panic and general lack of understanding about the regulation changes for artists. Where can we access user friendly information that can be used to reassure artists and consumers alike?	Please visit ECHA's website at <a href="https://echa.europa.eu/hot-topics/tattoo-inks">https://echa.europa.eu/hot-topics/tattoo-inks</a> Inks for information and guidance on the restriction on tattoo inks Link to the webinar is available here: <a href="https://echa.europa.eu/-/reach-restriction-of-hazardous-substances-in-tattoo-inks-and-permanent-make-up">https://echa.europa.eu/-/reach-restriction-of-hazardous-substances-in-tattoo-inks-and-permanent-make-up</a>

Question	Answer
How can artists have certainty that they are using compliant inks when the manufacturers are stating compliance but the artist himself is not a chemist and cannot check the correctness of this statement?	The main responsibility for technical compliance lies with the manufacturers and importers. Moreover, the monitoring of compliance is the task of authorities enforcing the restriction. However, the artists have a partial responsibility insofar as compliance with their direct obligations is affected. For example, they should verify before use of the ink the presence of the marking 'Mixture for use in tattoos or permanent make-up' (Entry 75, paragraph 8). The artists should also verify the completeness and correctness of the information that they are supposed to communicate to the person undergoing the tattooing procedure (Entry 75, paragraph 7).
How will it be prevented that tattoo artists obtain colours illegally or from outside the EU and continue to use them?	Enforcement of EU legislation is the responsibility of the Member States competent authorities, including at the customs.
in the Netherlands we need to give all clients an 'ink passport' that shows what ink batch number etc. Is this the rule for all of the EU now?	To provide a batch number as reference is obligatory. An 'ink passport' including that number is a possible way to implement this obligation. The Netherlands are encouraged to share their experiences regarding the ink passport with other Member States.
Is a tattoo artist a downstream user when he only uses colours bought by European suppliers?	REACH Article (3) definition: downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who <b>uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities.</b> A distributor or a consumer is not a downstream user. A re-importer who is exempted from registering a substance (pursuant to Article 2(7)(c) of REACH) shall be regarded as a downstream user.  If the tattoo artist imports the mixture from outside the EU, he first becomes an importer and in that role he puts it on the EU market (he has to ensure that the importer obligations are complied with). Then he uses it and becomes a downstream user.
The proposed alternatives are likely to be less well studied than those that they will replace. Could substitution increase risks for customers rather than reduce them?	ECHA's final opinion identified some alternatives for which there is less toxicological information available and other areas where further work is recommended.
Has ECHA considered that tattoo paints are mixtures and not only raw materials such as pigments?	Yes, tattoo inks are mixtures as described in Regulation EU No 2081/2020

Question	Answer
What content should the 'safety instructions for use' mentioned in paragraph 7 (g) of the restriction have?  Why doesn't the restriction offer the option to bypass or to waive certain general concentration limits (e.g. < 0.01 % substances	Safety instructions refer to instructions for use given to the tattoo artist on how to use the ink, if there are precautions to take, for example. The exact content of form of such instructions are ot prescribed in the law. When there is no place in the package, the list of ingredients, the reference number, and the statements, can be included in the instructions for use (all labelling requirements except the marking "mixture for use in tattoos or permanent make-up" that must be on the ink bottle).  Annex XVII entry 75 specifies that substances classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B
classified as Eye Irrit. 2) based on a toxicological risk assessment?	or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2 are restricted in tattoo inks in a concentration equal to or greater than:
Why is the concentration limit of substances classified as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, and as serious eye damage category 1 or eye irritant category 2, the same, regardless of the category? Why isn't the concentration limit of category 2 substances higher (e.g. by the factor 10) than the corresponding concentration limit of category 1 substances?	(i) 0.1 % by weight, if the substance is used solely as a pH regulator; (ii) 0.01 % by weight, in all other cases. (see restriction entry <a href="https://example.com/here">here</a> ). The concentration limit is based on a concentration limit proposed by ECHA's committee for risk assessment (RAC) for skin/eye irritants and corrosives achieved by dividing by a factor of 100 the generic concentration limit (GCL) of 1% for Category 2 for skin corrosive substances or eye damage substances, deriving a value of 0.01% on the
Why is the use of substances classified as Eye Irrit. 2 (e.g. organic solvents as propan-2-ol) restricted to a concentration < 0.01 %?	basis of based on human and animal data showing 10 to 100 times higher irritant potency of intradermal compared to topical application.  RAC pointed out that these substances should not be contained in tattoo inks and for the purpose of ensuring the practicality and monitorability of the proposed restriction, a sufficiently low concentration limits are to be derived for these substances to discourage use. Therefore, similar to the other hazard classes in the scope of the restriction (carcinogenic, mutagenic, reprotoxic, skin sensitising), RAC did not propose different concentration limit for hazard categories. During ECHA's socio economic analysis committee (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, the final decision from the Commission specified a concentration limit of 0,1 % for irritant or corrosive substances when they are used as pH regulators.

Question	Answer
Medical tattooing pigments are out of the scope of the current restriction but are still being used. Why?	Tattoo inks placed in the market for medical purposes are covered by the specific requirements of the relevant EU regulation on medical devices. This regulation foresees a transparent cost/benefit assessment and imposes strict requirements for mixtures injected into the human body. Furthermore, if the inks have both medical and non-medical purpose, the obligations of REACH and the medical device regulation both apply.
What are the rules for buying pigments in England and than using them in the EU?	EU chemicals legislation does not apply to the UK. Please refer to national legislation for rules on tattoo inks and substances contained in them. Substances and mixtures imported from the UK to the EU need to comply with REACH regulation, including provisions on restriction of tatoos inks.

#### 2. Substances used in tattoo inks

Question	Answer
Which name or identifier of an ingredient shall be labelled in the absence of a common ingredient name, if neither a IUPAC name nor a CAS or an EC number are available?	The purpose of the labelling obligation is to identify the ingredients as easily and clearly as possible. If no common ingredient name is available, any other applicable name or identifier (usual name, trade name) can be used to achieve this objective.
Why is the concentration limit for formaldehyde in tattoo inks five ppm? It is permitted to be higher in food as well as in pharmaceuticals that are injected/infused? What are the risks of formaldehyde being addressed?	Formaldehyde is a carcinogenic substance for which no safe threshold can be established when injected in the human body. Pharma and food legislation contain specific requirements to address the risks of the different uses and exposure routes. It is not correct to assume that in all cases the requirements are stricter in one legislation or the other by comparing only the limit values.
Why is isopropanol restricted to 0.01 % in tattoo inks when hand sanitisers can contain much higher concentrations?	Isopropanol is restricted because it is an eye irritant. Some people do tattoos on eyeballs so the route of exposure is different compared to a hand sensitiser.

Question	Answer
How was the impact of the restriction on industry assessed? Did this assessment take into account the impacts on SMEs and the impacts on EU artists compared to non-EU artists (i.e. that can continue to use the restricted tattoo inks)?	All inks placing on the market and used in the EU must be compliant with EU Regulations. ECHA's committee for socio economic analysis (SEAC) assessed the impacts in the EU but found that the cost of the ink represents a relatively low part of the final cost of the tattoo procedure.
Does the restriction also apply to tattoo ink thinners?	Yes, the restriction applies to all ingredients added in the formulation of the tattoo ink and present in the mixture for use for tattooing purposes. Impurities are not ingredients.
Which in-can-preservatives can be used for tattoo-inks? How can ECHA support us in this respect?	In-can preservatives can be authorised under the Biocidal Products Regulation or under national schemes in a Member State of the EU if the active substance contained in the in-can preservative is under evaluation within the Review Programme of the Biocidal Products Regulation. For the first situation, the in-can preservative needs to be authorised for preservation of tattoo inks. Information on authorised biocidal products under the Biocidal Products Regulation can be found on the ECHA webpage at <a href="https://echa.europa.eu/information-on-chemicals/biocidal-products">https://echa.europa.eu/information-on-chemicals/biocidal-products</a> . For the second situation, the concerned Member State needs to be contacted as the rules are different for each Member State.
Did I understand correctly that tattoo inks that contain preservatives (biocides in PT 6) are considered as treated articles according to BPR?	Yes, that is correct.
The proposed alternatives are likely to be less well studied than those that they will replace. Could substitution increase risks for customers rather than reduce them?	ECHA's final opinion on restriction proposal on tattoo inks identified some alternatives for which there is less toxicological information available and other areas where further work is recommended.
How do you assess the dynamic restriction of substances in case of future entries in CLP Annex VI (e.g. classification proposal of the natural substance citric acid, which plays a relevant role in the human body)?	The dynamic link with CLP means that the restriction will apply automatically after the substance is classified in CLP. There is a transitional period of 18 months for the manufacturers to replace the substances if they were used.  ECHA's committees for risk assessment (RAC) and socio economic analysis (SEAC) and Member States of the EU supported the dynamic link with CLP to make sure that action to protect human health from risks related to tattoo inks reflect the latest information on serious health hazards and action is taken quickly to protect human health.

Question	Answer
If isopropanol is restricted to 0.01 % due to eye irritation, why it allowed to use up to 11 % of methanol (which is classified as Acute Tox . 3, and STOT SE 1). On what basis were the concentration limits selected?	Methanol is the only STOT SE substance included in the scope the restriction, as it is the only substance with STOT SE classifications (effects on the optic nerve and central nervous system) found to be present in tattoo inks and not covered by other group or individual assessments. A specific concentration limit was derived (by the Dossier Submitters: ECHA, Norway, Denmark and Italy, and assessed by ECHA's committee for risk assessment - RAC) for substances with predominantly threshold health hazards, for which a health risk can be evaluated in a quantitative manner with a derivation of DNELs. As described in section B.1.2.1.3 and Appendix 2 of the RAC final opinion, DNEL derivation for methanol is based on occupational exposure level of 260 mg/m3 (or 200 ppm) for an 8-hour exposure, giving an exposure of 2.6 g/person/day, equivalent to 40 mg/kg bw/day. Applying the concertation limit formula based on realistic worst case exposure scenario assumptions, a concentration limit of 11% w/w was obtained (rounded value of 10.8%), which equals RCR of 1. Thus, the entry 75 in Annex XVII (specifically Appendix 13 to this entry) lists a concentration limit for methanol of 11% by weight.
	RAC noted that the generic and specific concentration limits set in Regulation (EC) No 1272/2008 reflect to some extent the potency of the substance having harmonised classification. However, these limits are intended to be used for communication on health hazard of the mixtures, and not for risk assessment, since they were not based on risk

## 3. Pigments

Question	Answer
The risk assessment for Pigment Blue 15:3 is disputed by some stakeholders. Are there plans to prolong the transitional period for this pigment or change the conditions of the restriction?	Any change in the existing entry would require an amendment of Annex XVII following an assessment of ECHA's committees on additional information on the safety of the 2 pigments
If alternatives for the Pigment Blue 15 and Pigment Green 7 are not available when they are restricted in January 2023 what is the solution? The demand for coloured tattoos will not decrease.	Pigment Blue 15:3 and Pigment Green 7 have been given a longer transition period (until 4 Jan 2023) to allow inks formulators to find safer alternatives whilst ensuring the availability of the inks on the market in the meantime.

Question	Answer
How do the benefits of the restriction compare to the health hazards? What exactly is the health risk? Do the pigments cause cancer? How many people have been harmed in Europe because of a lack of these restrictions?	The restriction is expected to decrease chronic allergic reactions and other inflammatory skin reactions. ECHA's committee for risk assessment (RAC) concluded that more serious effects such as cancer, harm to our DNA or the reproductive system potentially originating from chemicals used in the inks cannot be excluded and could also decline. SEAC concluded that the proposed restriction is likely to be proportionate to the risk. For further information, please see RAC and SEAC final opinion.
Are you working on positive lists for pigments that do not pose a risk to human health in tattoo inks?	REACH does not work in the form of positive lists as for example the
Where can I get support to ensure that the pigments and end products that I am buying are compliant with the conditions of the restriction?	Cosmetic Product Regulation Annex IV.  All Member States have a national help desk to help with the implementation of the REACH Regulation-insert link from ECHA website
Why was the proposed transition period for Pigments Blue 15:3 and Green 7 amended at the decision making stage? i.e. shortened from three years to two years?	Two years of transitional period have been a compromise between the position of ECHA's committee for risk assessment (RAC) that – based on the evidence available - asked for no transition period and the position of ECHA's committee for socio economic analysis (SEAC) which suggested three years.
Was the standard of evidence required to 'derogate' Pigments Blue 15/Green 7 from the restriction higher because they were listed in Annex II of the CPR? Did the restriction process artificially create a higher threshold?	The Commission requested ECHA to include Annex II of the Cosmetic Product Regulation (CPR) in the scope of the restriction. The 2 pigments in question, blue 15 and green 7, were included in the Annex II of CPR because of concerns around bladder cancer from exposure to hair dyes.
In relation to CPR Annex II B15 and cancer: the hair dye fear of cancer is structural only related to azo compounds - not B15 as it is an phthalocyanine pigment. B15 is listed as suitable for prolonged skin contact since no evidence on carcinogenicity exists.	During the process of preparing the restriction, Industry failed to demonstrate to RAC that the concern around the carcinogenicity could be disregarded.
Is Pigment Green 7 restricted or not?	Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6) can still be used in tattoos until 4 <sup>th</sup> of January 2023. After that date, this substance is covered by restriction entry 75.
Where can I find list of pigments that has been restricted aside from pigment blue 15:3 and pigment green 7?	A list of all substances covered by restriction entry 75 is not provided, however a Q&A is being prepared by ECHA with more detailed information.

#### 4. Links to other legislation

Question	Answer
Why are tattoos treated like a Cosmetic Product? What justifies the "dynamic link" to the Cosmetic Product Regulation?	Tattoos are not treated like a cosmetic product but the regulatory framework applicable to specific substances under the Cosmetic Products Regulation is considered an indicator for how far the same substances should be regulated under the tattoo ink restriction. The dynamic link between the Cosmetic Products Regulation and the tattoo ink restriction should ensure a minimum level of protection. The risk of a substance used for tattooing purposes (i.e. when it is injected into the body) should not be treated more lightly than when the same substance is used for cosmetic purposes (i.e. when the substance is only in contact with the external parts of the body).

## 5. Testing and analytical methods

Question	Answer
It is difficult to find appropriate test methods for assessing compliance with the concentration limits. Are all standardised testing methods in place for all the restricted substances in tattoo inks, including, e.g., for formaldehyde? Where can recommended testing methods be found? What is the expected timeline for the publication of appropriate analytical methods for	There are no standardised analytical methods for substances in tattoo inks. At the time of the dossier development, the Dossier Submitters (ECHA, Norway, Denmark, and Italy) compiled information available on analytical methods largely based on work by the Joint Research Centre of the EU Commission (JRC) on the safety of tattoo inks and permanent make-up. See Appendix D.2 to Annex of background document,
tattoo inks?	compilation of analytical methods: <a href="https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a">https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a</a> . The Forum for Exchange of Information on Enforcement (Forum) is encouraging exchange of information on analytical methods among Member States of the EU with the ultimate goal to expand the Compendium of analytical methods for restrictions with recommended methods for substances in tattoo inks to check compliance. Data collection of analytical methods for tattoo inks is expected to be part of next Forum exercise. The information gathered will be assessed to recommend the methods that the Forum experts consider to best fit for the purposes of compliance controls with the view to update the Compendium. The Compendium of analytical methods, Forums methodology for recommending analytical methods for restrictions and an excel spreadsheet that can be used by the public to submit information on analytical methods: <a href="https://echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions">https://echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions</a>

Question	Answer
Do ink formulators need to test their inks before placing them on the market?  Who has the obligation to ensure tattoo inks meet the requirements of Annex XVII? Do I have to test for all substances?	Any company, including ink formulators, placing on the market a mixture needs to comply with the relevant obligations of this restriction. In order to comply with these requirements a supplier must be aware of the identity of the ingredients of their mixture and their concentration. Ink formulators should receive from their suppliers detailed information on the composition of the ingredients they use. In the absence of detailed information on the ingredients from suppliers it is up to the ink formulator to decide to request detailed information from their suppliers, refer to a different supplier or test their mixture to ensure compliance.
Is there a database/register of all approved products (based on EAN barcodes) that have passed the testing and are safe to be used? What is the easy way to check that an ink meets the updated legislation?	No, this database does not exist for the moment.
How can we assure that the results of chemical analysis is accurate and that substances are below the concentration limits?	The analytical methods used by chemical labs needs to be validated to ensure reliability of results. For tattoo artists, the supplier of the ink should ensure this by getting confirmation from laboratories on the analysis
Is ECHA or the Commission going to perform further toxicology studies to support the restriction?	No, this would be the responsibility of industry.

#### **6. Information and Communication**

Question	Answer
The labelling restrictions are causing the manufactures to falsely advertise because not all pigment is made for permanent makeup and vica versa. Is there flexibility on the phrase for "mixture for permanent makeup and tattoos"	The correct labelling should be: 'Mixture for use in tattoos or permanent make-up'. Therefore, the wording is sufficiently flexible. The labelling text covers situations where the mixture is either only for use in tattooing or only for use in permanent make-up. It covers also the rare cases that both uses should be indicated.
Is information in EU languages allowed to only be on the inside of a peel-off-label? For example, to have English on the outside and other relevant EU languages on the inside?	The only rule concerning the language regime is that information given must be provided in the official language(s) of the Member State of the EU (MS) where the mixture is placed on the market unless provided otherwise by the MS. Information in additional languages are therefore possible. A specific design of the marking/labelling is not regulated.

Question	Answer
Is it correct and necessary to mention restriction 75 in each and every SDS with such a component down to concentrations of 0.1% (0.01% if not used as pH regulator)? If so, why only harmonized classified substances and not self classified ones too?	Yes. If a substance or mixture covered by a safety data sheet (SDS) is subject to restriction then the restriction shall be mentioned in Section 15.1. Reference to e.g. "pH regulator" is part of the restriction conditions, not SDS contents.  If a substance in a mixture is indicated in the SDS Section 3.2, that means the SDS covers it.  The restriction applies to the substances falling within one of the points (a) to (d) of the restriction, where (a) is harmonised classified substance. Self-classified substances are not within the scope.
Does ECHA have an overview, which inks are covered by registration dossiers if the uses for tattooing are covered?	Based on a quick scan of section 3.5 Use and exposure information of latest active successful registrations, it does not appear that any substances are registered for uses in tattoo(s) under REACH. Based on a quick scan of section 3.6 Uses advised against of latest active successful registrations, it appears that a number of REACH registrants list use in tattoo inks as a use advised against. This information can be accessed via ECHA's homepage, by entering substance identifier (substance name, EC or CAS number) in the "Search our data" dialogue box. Any publicly available information, including on suppliers, is summarised under the REACH registered substance factsheet. Here is a link for example to the factsheet of Pigment Blue 15:3 (https://www.echa.europa.eu/web/quest/registration-dossier/-/registered-dossier/15491/) and Pigment Green 7 (https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/15380/)
What is the current product category for tattoo and permanent make-up ink?	For REACH registrations and Safety Data Sheet (SDS) the Product Category: PC18: Inks and toners, is the most appropriate. However it should be made very clear via the "Use name" that the use is for "tattoo ink". In addition, for the exposure assessment, the default parameters of the ECETOC TRA exposure assessment tool, cannot be used for the application of the tattoo ink.  Under the Biocidal Products Regulation (BPR), preservatives used to control microorganisms in tattoo inks, are included in Product Type 6. For further information on BPR, please see: <a href="https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr">https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr</a>

Question	Answer
Does labelling requirements include the best before date?	There is no specific reference to a 'best before date'. However, such information or an 'expiry date' could be considered as part of the 'safety instruction' referred to by Paragraph 7 (g) of Entry 75.
A recent study by Sciensano in Belgium found that almost a quarter of tattoo inks in the country breach REACH restriction thresholds (based on the samples tested). How can enforcement of the restriction be improved?	The study carried out by Sciensano was performed in samples taken on tattoo inks placed in the market before the date of the entry into application of the restriction. Transitional periods are aimed to ensure that non-compliant inks are progressively phased out from the market
Do you know how manufacturers react if they hear about the use of their pigments in tattoo inks?  What does ECHA recommend to make the communication in the supply chain better? Has ECHA received information from our suppliers after we informed them of our use of Pigment Blue 15:3 and Pigment Green 7? Could ECHA moderate a dialog between different market actors with the objective to stabilize the ink market?	ECHA has no role in the supply chain, and typically does not receive any information from the suppliers/registrants other than any subsequent updates to the registration dossier. For this reasons it is difficult for ECHA to comment on how industry should work better together, especially in regards to their communication with each other. The Commission and ECHA will decide upon the follow up after this webinar.
Before tattooing, the tattoo artist has to provide the customer with the information marked on the package or included in the instructions for use (e.g. colours used including the ingredients, lot no etc.) Does this information have to be written down for later use (e.g., in case of skin irritations) or in case of legal disputes? Is a written form optional or mandatory?	This is a matter of developing best practice models. It is not mandatory that the information needs to be delivered in writing. However, written information could be a useful part of a best practice model and help with the delivery of the information to the customer as well as with the overall monitoring of the restriction.  The goal is that tattoo artists have sufficient legal certainty as regards their activities and people who are receiving a tattoo can also feel safe. The enforcement of this restriction is a responsibility of Member States enforcement authorities.
How can tattoo studios meet the restriction requirements?	The restriction contains comprehensive labelling requirements, which suppliers of tattoo inks should meet. E.g., that the mixture is marked with the following information: a statement "Mixture for use in tattoos or permanent make-up" as well as list of all ingredients. These labelling provisions are intended to assist tattoo artists (among others) to select inks suitable for tattoo purposes and to inform the person undergoing the tattoo procedure with the information marked on the package or included in the instructions for use.
The new restriction is causing a wide disruption on the tattoo-ink	Now that the restriction is in force ECHA does not have a formal role. The

Question	Answer
market and the availability of adequate inks. This is mainly affecting tattoo-artists, most of them very small actors with a	Commission is aware of the difficulties that the Small and Medium Enterprises (SMEs) are facing. This workshop has been organised to help
very limited market power. In its Substitution Strategy ECHA also	·
refers to the SME-strategy and the need to support SMEs in	exchanges. We trust that the replies to the questions given in the
relation to the substitution of problematic chemicals. Considering this, is ECHA planning to support the substitution of tattoo-inks?	presentations and those that will be published, will be of help.
And if yes, how?	