

Welcome

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

29 March 2022

Mark Blainey
Head of Unit - Prioritisation
European Chemicals Agency



What you can expect today

- Learn about the REACH restriction on hazardous substances in tattoo inks
- Get answers to your questions
- Learn where to find more information



Programme

Time	Topic	Speaker
14.30	Introduction	Mark Blainey, ECHA
	EU Regulation on substances in tattoo inks and permanent make-up	Ana Maria Blass Rico, European Commission
	Scope of the restriction	Karin Kilian, European Commission
	Common topics of interest a) What is a REACH restriction? b) Pigment Blue 15:3 and Pigment Green 7 c) Analytical methods d) Communication in the supply chain e) Requirements for preservatives in tattoo inks	Christian Krassnig, European Commission Evgenia Stoyanova, ECHA Evgenia Stoyanova, ECHA Fesil Mushtaq, ECHA Erik van de Plassche, ECHA
15:30- 16:30	Question & answer	

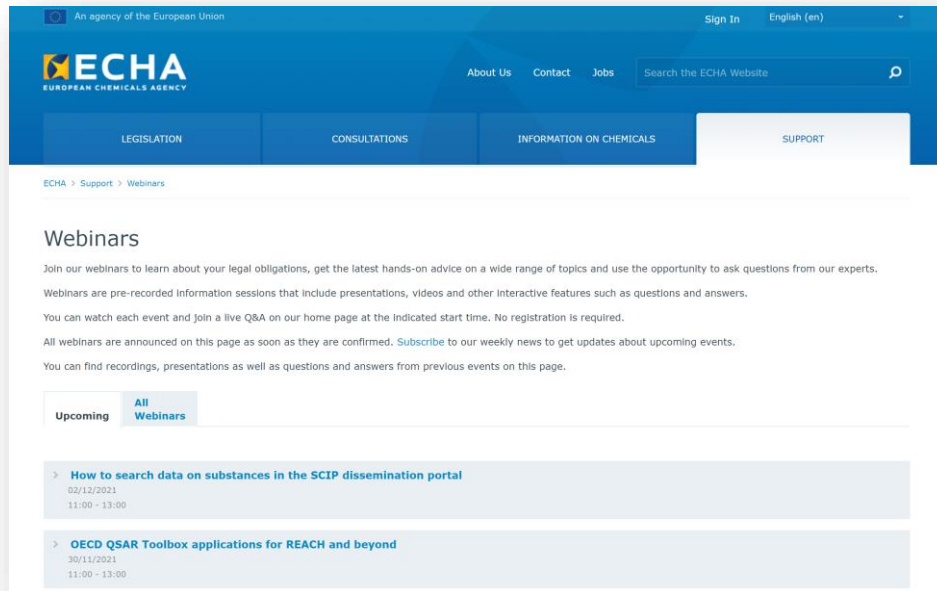
Live Q&A

- Join Q&A at: slido.com
Event code: or with QR:
- Send questions from
14:30 to 16:30 (EEST, GMT +3)
- Only questions within scope
- Questions after the webinar?
echa.europa.eu/contact



Material available

- Video recording
- Presentations
- Q&A



The screenshot shows the ECHA website's 'Webinars' page. The header includes the ECHA logo, navigation links (About Us, Contact, Jobs), a search bar, and a language selector (English (en)). The main navigation bar has tabs for LEGISLATION, CONSULTATIONS, INFORMATION ON CHEMICALS, and SUPPORT. The page content includes a breadcrumb trail (ECHA > Support > Webinars), a title 'Webinars', and introductory text explaining the purpose of webinars. Below the text is a filter section with 'Upcoming' and 'All Webinars' buttons. Two webinar events are listed:

Topic	Date	Time
> How to search data on substances in the SCIP dissemination portal	02/12/2021	11:00 - 13:00
> OECD QSAR Toolbox applications for REACH and beyond	30/11/2021	11:00 - 13:00

echa.europa.eu/webinars



EU Regulation on substances in tattoo inks and permanent make-up

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*Ana Maria BLASS RICO
European Commission*

Why a restriction?

- Tattoo fashion increasing
- Negative health effects reported
- Hazardous chemicals found in tattoo inks on the EU market
- Recommendations Council of Europe - ResAP(2003)2, ResAP(2008)1
- National legislation in some Member States
- Member States asking for harmonised rules across EU

What are the objectives?

- High level of protection of peoples' health
- EU citizens equally protected despite the country where they get a tattoo and whether the ink is manufactured in the EU or not
- Free movement of goods within the EU
- Increased awareness of informed choices for consumers (a business opportunity for companies)
- International benchmark
- Webinar to help you with the requirements

Preparatory work

- **June 2014:** Consumer Safety Network Subgroup on Tattoos and Permanent Make-up gathered representatives from EU/EFTA national authorities and stakeholders
- **September 2014:** European Commission project on "Tattoos - Permanent Make-up" to provide regulators with scientific and technical basis to decide if EU measures needed to ensure tattoo/permanent make-up ink safety and protect consumers
- **December 2015:** European Commission asked ECHA to prepare a dossier and assess risks to human health of chemicals in tattoo and permanent make-up inks, and the need for EU-wide action beyond national measures

Preparatory work (contd.)

- **October 2017:** ECHA submitted the restriction dossier prepared in cooperation with Italy, Denmark and Norway and with the contribution of Germany
- **December - June 2018:** Consultations on the proposal
- **December - February 2019:** Consultations on draft opinion
- **June 2019:** ECHA submitted the opinions of the Committees for Risk Assessment and Socio-Economic Analysis to the Commission
echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a

How the law is passed

- REACH Committee (EU Member States)
- Technical Barriers to Trade notification
- Scrutiny by the European Parliament and Council

	WORLD TRADE ORGANIZATION	G/TBT/N/EU/709
(20-2756)		7 April 2020 Page: 1/2
Committee on Technical Barriers to Trade		Original: English
NOTIFICATION		
The following notification is being circulated in accordance with Article 10.6		
1. Notifying Member: EUROPEAN UNION If applicable, name of local government involved (Article 3.2 and 7.2):		
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/		
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [X], 5.7.1 [], other:		

DATES

- Published - 15 December 2020
- Entry into force – 4 January 2021
- Entry into application - 5 January 2022
 - Pigment Blue 15:3 and Pigment Green 7 - 5 January 2023





Scope of the restriction

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*Karin Kilian
European Commission*

Scope

- Use of a mixture ‘for tattooing purposes’: 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 permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on the body
- Substances with harmonised classification under the Classification, Labelling and Packaging (CLP) Regulation
 - For carcinogenicity, mutagenicity or toxicity to reproduction, skin sensitisation, skin corrosion or irritation, serious eye damage or irritation
- Substances prohibited by the EU Cosmetic Products Regulation
- Impurities including heavy metals and PAHs, methanol and azo dyes not classified for carcinogenicity or mutagenicity but that may undergo decomposition or contain residual aromatic amines classified as carcinogenic or mutagenic

Scope (contd.)

- Restriction on the placing on the market of tattoo inks that do not meet requirements for max concentration of substances (specified in entry 75 and in Appendix 13)
- Inks not meeting requirements cannot be used for tattooing
- If several different classifications, lowest concentration limit applies
- Dynamic links with:
 - Cosmetic Product Regulation (CPR) – for new substances added to Annex II and Annex IV, restriction applies 18 months after entry into force of CPR amendment
 - CLP Regulation – for new substances with relevant classifications added to Annex VI, restriction applies at the date of application of the CLP amendment (18 months after its entry into force)

Restriction limits

Substances	Concentration limit
Classified as carcinogen or germ cell mutagen	0,00005 % w/w
Classified as toxic to reproduction	0,001 % w/w
Classified as skin sensitisers	0,001 % w/w
Classified as skin corrosive or irritant or serious eye damaging/eye irritant	0,01 % w/w
Prohibited for use in cosmetic products in Annex II of Regulation (EC) No 1223/2009;	0,00005 % w/w
In Annex IV of Regulation (EC) 1223/2009, subject to either of the following conditions in column g: rinse-off products, not to be used in products applied on mucous membranes, not to be used in eye products.	0,00005 % w/w
Listed in Appendix 13	Specific concentration limits

Labelling requirements

- Labelling requirements
 - Statement: “Mixture for use in tattoos or permanent make-up”
 - Reference number to uniquely identify the batch
 - List of ingredients in decreasing order
 - Special labelling: Ni, CrVI, pH regulators

Improved information to users

- The information must be clearly visible, easily readable and marked in a way that is indelible
- If the packaging is too small to display the information, it must be included in the instructions for use instead
- Before using the ink: tattooist must inform the customer with the information included on the package or in the instructions for use



What is a REACH restriction?

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*Christian KRASSNIG
European Commission*

Why under REACH?

- See REACH objectives:
 - Ensure high level of protection of human health and environment
 - Free circulation in the internal market

Restrictions under REACH

- Restriction is one of the possible measures under REACH to manage the risk of a substance
- To be applied if risk is not adequately controlled
- May concern manufacture, placing on the market (incl. import) or use of a substance, on its own, in mixtures or in articles
- Can be: bans, use limitations, concentration limits in mixtures or articles
- Can impose any other relevant condition, such as requiring technical measures or specific labels
- Restrictions are listed in Annex XVII to REACH

How the restriction process works

- Initiated by Commission or Member State
- Preparation of "Annex XV dossier" (ECHA or Member State)
- Information on hazards and risks, alternatives, socio-economic assessment
- Opinions by ECHA Committees for Risk Assessment and Socio-economic Analysis
- Everyone can have a say through consultations
- If risk is unacceptable: Commission prepares proposal for amendment of Annex XVII (the place where all restrictions are listed)

Changing a restriction

- It is possible to add substances in the list of restricted substances, change the concentration limits and add exemptions
- Any change is done in the same way as for the adoption of the restriction
- “Dynamic link” between restriction + CLP/Cosmetic Product Regulation
 - Does not require a proposal to begin the legislative procedure
 - Substances are automatically added to or removed from the scope of the restriction

Information needed for a restriction

- When submitting a restriction proposal, information is often requested from the public, including industry, to assist with the assessment.
- Type of information requested is outlined in **Consultation guidance**
echa.europa.eu/restrictions-under-consideration
- Hazard and exposure information is described in **Guidance on information requirements and chemical safety assessment**
echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

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Thank you



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Pigment Blue 15:3 and Pigment Green 7

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

29 March 2022

Evgenia Stoyanova
Risk Management
European Chemicals Agency



Overview

- Restriction from 5 January **2023** in a concentration equal to or greater than 0.00005 % by weight
 - Pigment Blue 15:3 (CI 74160)
 - Pigment Green 7 (CI 74260)
- Why a restriction?
- Transitioning to alternatives for the two pigments

Why these pigments?

- Both on Annex II of the Cosmetic Products Regulation (CPR): List of substances prohibited in cosmetic products
- Pigment Green 7 also on Annex IV of CPR (List of colorants allowed in cosmetic products) with condition “not to be used in eye products”

Why these pigments? (2)

- Committee for Risk Assessment (RAC) did not support the derogation of these 2 pigments due to limited information available on hazards and risks
 - Noted some known alternatives could lead to equal or greater risk
 - Noted industry comments on essential role of pigments and lack of technically feasible alternatives
- Committee for Socio-economic Analysis (SEAC) supported time-limited derogation for industry to identify and transition to safer alternatives
- European Commission decision: one additional year

Alternatives

- Risk Assessment Committee (RAC):
 - Some blue and green pigments of higher concern
 - Some pigments with expected low hazard profile but have limited (or no) specific information on hazardous properties and technical feasibility
 - Pigment Green 36 cannot be considered a less hazardous alternative to Pigment Green 7
 - See Appendix B.12 in Annex to background document to the restriction: echa.europa.eu/documents/10162/d4637427-99fd-52c0-e81e-1404f31a8e0b

Alternatives

- Resources to avoid regrettable substitution:
 - Pigments with harmonised classification for human health (CMR, SS, I/C), in the CPR (Annex II & IV with use restriction) and in Appendix 13 to the restriction entry #75 are restricted above their specified concentration limits
 - Pigments without harmonised classification
 - ECHA chemicals database: echa.europa.eu
 - PACT - Public Activities Coordination Tool: echa.europa.eu/pact

Non-classified pigments and other ingredients

- Resources to assess hazard, exposure and risk:
 - Guidance on information requirements and chemical safety assessment: echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
 - Restriction on tattoo inks: RAC and SEAC opinion and background document
 - Main page: echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180dff62a
 - Annex: echa.europa.eu/documents/10162/d4637427-99fd-52c0-e81e-1404f31a8e0b
 - B.9.3.2. Exposure estimation
 - E.g., Appendix B.11. Risk assessment of zinc

Non-classified pigments and other ingredients

- Other potential resources:
 - Federal Institute for Risk Assessment Germany: “Tattoo inks: minimum requirements and test methods”
bfr.bund.de/cm/349/tattoo-inks-minimum-requirements-and-test-methods.pdf
 - Council of Europe: “Safer tattooing. Overview of current knowledge and challenges of toxicological assessment”
edqm.eu/sites/default/files/leaflet-safer-tattooing-2018.pdf

PB 15:3 & PG7: Summary

- Restriction from 5 January 2023 in a concentration equal to or greater than 0,00005 % by weight
- Use available resources to identify long-term alternatives and avoid regrettable substitution

Analytical methods for tattoo inks

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

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Evgenia Stoyanova
Risk Management
European Chemicals Agency



Identified issues

- RAC/SEAC recommendations, based on advice from Enforcement Forum:
 - Importance of standardisation and harmonisation of analytical methods for enforcement
 - Guideline developed by enforcement authorities identifying among others a priority list of substances for enforcement and indicating appropriate analytical method(s)
 - Methods applicable to other matrices should be considered and modified
 - Information on best available analytical practices to be shared among all relevant stakeholders (e.g., through the Forum Compendium on analytical methods for enforcement of restrictions or through ad hoc guidance on tattoo inks restriction)

Analytical methods for tattoo inks

- Appendix D.2 to Annex of background document, compilation of analytical methods, p.477-491:
 - PAAs
 - PAH
 - Phthalates
 - Nitrosamines
 - Colorants
 - Common impurities

echa.europa.eu/documents/10162/d4637427-99fd-52c0-e81e-1404f31a8e0b

Recent developments

- Development and validation of analytical methods by several member states:
 - For example, Italian Ministry of Health financed two projects for enforcement for: PAAs, phthalates, preservatives, metals, and pigments
 - Leoni et al. Validation and measurement uncertainty evaluation of a GC/MS method for the quantification of nine phthalates in tattoo and PMU inks. Accreditation and Quality Assurance 2021
 - Famele et al. Quantification of preservatives in tattoo and PMU inks in the frame of new requirements under REACH Regulation. Contact Dermatitis 2022 (under review)

Enforcement Forum

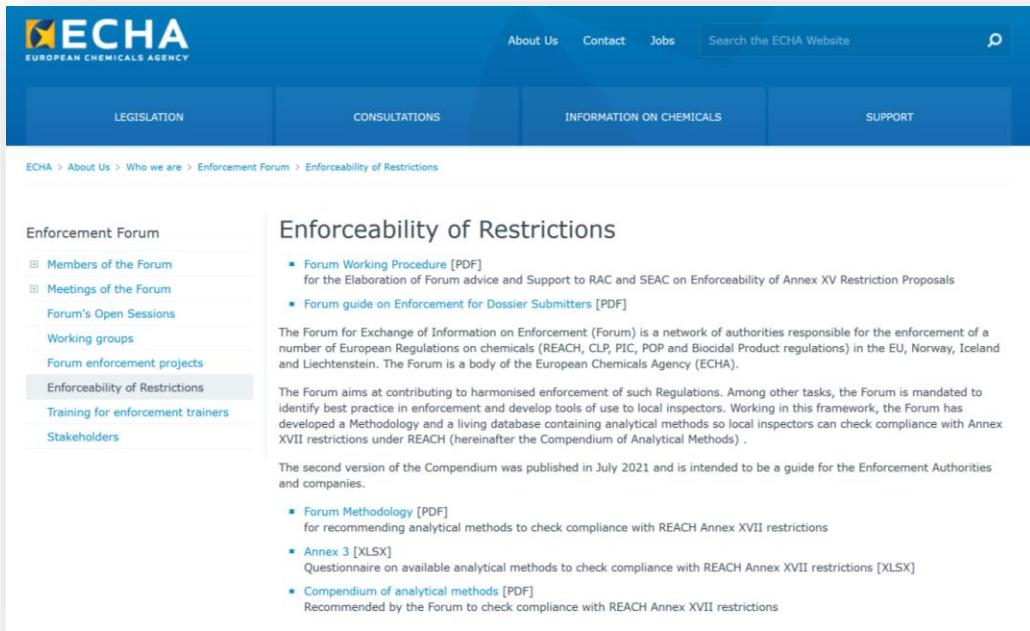
- Enforcement Forum:
 - Network of authorities for enforcement of REACH, CLP, PIC, POP and Biocidal Product regulations
 - Representatives of each EU member state, Norway, Iceland and Liechtenstein
 - Supported by ECHA's Forum Secretariat
 - Sets own work programme on specific areas of enforcement

echa.europa.eu/about-us/who-we-are/enforcement-forum

Upcoming work

- Forum is encouraging exchange of information on analytical methods among Member States with the ultimate goal to expand the *Compendium of analytical methods for restrictions* with recommended methods for substances in tattoo inks to check compliance

Further information



The screenshot shows the ECHA website interface. At the top, there is a blue navigation bar with the ECHA logo on the left and links for 'About Us', 'Contact', 'Jobs', and a search box labeled 'Search the ECHA Website'. Below the navigation bar is a secondary menu with four categories: 'LEGISLATION', 'CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The main content area has a breadcrumb trail: 'ECHA > About Us > Who we are > Enforcement Forum > Enforceability of Restrictions'. On the left side, there is a sidebar menu under the heading 'Enforcement Forum' with items: 'Members of the Forum', 'Meetings of the Forum', 'Forum's Open Sessions', 'Working groups', 'Forum enforcement projects', 'Enforceability of Restrictions' (which is highlighted), 'Training for enforcement trainers', and 'Stakeholders'. The main content area is titled 'Enforceability of Restrictions' and contains the following text and links:

- [Forum Working Procedure \[PDF\]](#) for the Elaboration of Forum advice and Support to RAC and SEAC on Enforceability of Annex XV Restriction Proposals
- [Forum guide on Enforcement for Dossier Submitters \[PDF\]](#)

The Forum for Exchange of Information on Enforcement (Forum) is a network of authorities responsible for the enforcement of a number of European Regulations on chemicals (REACH, CLP, PIC, POP and Biocidal Product regulations) in the EU, Norway, Iceland and Liechtenstein. The Forum is a body of the European Chemicals Agency (ECHA).

The Forum aims at contributing to harmonised enforcement of such Regulations. Among other tasks, the Forum is mandated to identify best practice in enforcement and develop tools of use to local inspectors. Working in this framework, the Forum has developed a Methodology and a living database containing analytical methods so local inspectors can check compliance with Annex XVII restrictions under REACH (hereinafter the Compendium of Analytical Methods) .

The second version of the Compendium was published in July 2021 and is intended to be a guide for the Enforcement Authorities and companies.

- [Forum Methodology \[PDF\]](#) for recommending analytical methods to check compliance with REACH Annex XVII restrictions
- [Annex 3 \[XLSX\]](#) Questionnaire on available analytical methods to check compliance with REACH Annex XVII restrictions [XLSX]
- [Compendium of analytical methods \[PDF\]](#) Recommended by the Forum to check compliance with REACH Annex XVII restrictions

echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions

Thank you!

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Communication in the supply chain

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hazardous substances in tattoo
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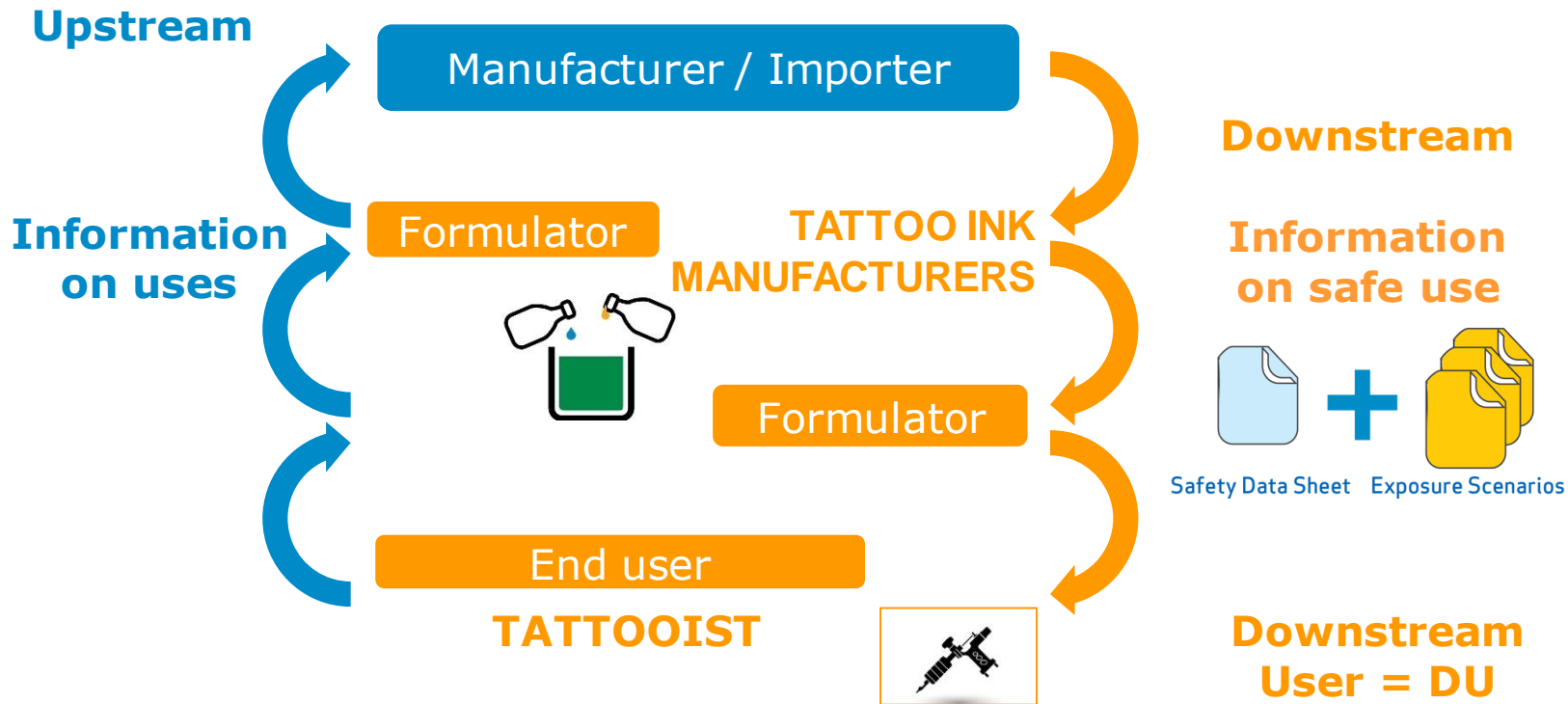
29 March 2022

Fesil Mushtaq
Exposure and supply chain
European Chemicals Agency



Supply chain communication

REGISTRATION OF PIGMENT



Receiving extended safety data sheets (SDS+ES)

Apply appropriate measures from SDS

Main information relating to risk management in Sections 7, 8 and 9 of SDS and Section 3 of exposure scenario (ES)



Check your use is covered in the ES

Your use should be included and your conditions of use should match those in the exposure scenario from your supplier

FORMULATOR CAN CHECK OWN + CUSTOMERS' USES



Implement ES conditions of use

Otherwise, contact or change your supplier to have your use covered, or take alternative action

Options if use not covered

- **Contact your supplier** to have the exposure scenario updated with your use covered
- **Change your process** to implement the exposure scenario
- **Substitute** with another substance or process or stop the activity
- **Find a supplier** providing an exposure scenario that covers your conditions
- **Prepare a downstream user chemical safety report (DU CSR)** to establish safe conditions for the use not covered by the exposure scenario received, and report that use to ECHA

Exemptions from a downstream user chemical safety report

Two situations where it is not required:



1. Total use less than 1 tonne/year



2. Substance used for PPORD

Reporting to ECHA




You need to report to ECHA if you:

- Prepare a downstream user chemical safety report
- OR
- Are exempted from preparing the chemical safety report

Ensure that your risk is controlled

You do not submit the DU chemical safety report

Information on our website

- Web pages with information specifically for downstream users have been tagged: 
 - Click the tag to retrieve relevant content
- Guidance for downstream users:
echa.europa.eu/documents/10162/2324906/du_en.pdf
- How to prepare a downstream user chemical safety report:
echa.europa.eu/documents/10162/17250/pg17_du_csr_final_en.pdf
- Q&As:
echa.europa.eu/support/qas-support/browse

echa.europa.eu/communication-in-the-supply-chain

Thank you!

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Requirements for preservatives in tattoo inks

Webinar: REACH restriction of
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inks and permanent make-up

29 March 2022

Erik van de Plassche
Chair of the Biocidal Products Committee
European Chemicals Agency



Outline

- Requirements for use of preservatives under EU legislation
 - REACH
 - Biocidal Products Regulation (BPR)
- More on legal requirements

Requirements for preservatives

- Restriction does not limit use of preservatives per se but any substance with hazardous properties that can lead to human health risk
- Some preservatives are impacted due to harmonised classification
- Preservatives subject to the Biocidal Products Regulation

Biocidal Products Regulation

- Preservatives in tattoo inks belong to product-type (PT) 6, preservatives for products during storage:
 - Approval of **active substance** for use in PT 6: example BIT
 - Authorisation of the **biocidal product**: preservative containing biocidal product authorised to preserve tattoo inks
 - Tattoo ink treated with a preservative considered a **treated article**: rules on placing on the market of treated articles

Biocidal Products Regulation (2)

- Biocides in a transitional phase:
 - **active substances** can be approved or under assessment
 - if approved → authorisation of the **biocidal product**: authorisation of the biocidal product is required → under the BPR this can be a national authorisation granted by a Member State or Union authorisation granted by the Commission
 - if under assessment → national rules in the Member State apply → these rules vary among Member States

Biocidal Products Regulation (3)

Tattoo inks are treated articles:

- Only tattoo inks preserved with preservatives approved or under assessment for product-type 6 can be placed on the EU market -> list (23 November 2021):
echa.europa.eu/documents/10162/5604808/treated_art94_data_en.pdf/c0427245-f912-84aa-978a-817ff6bc95db
- Tattoo inks preserved with some preservatives (e.g. C(M)IT/MIT, MBIT) need to be labelled according to Article 58(3): e.g. active substance name needs to be on tattoo ink label

Biocidal Products Regulation (4)

- **Approved** active substances in PT 6:
 - 11 (all have harmonised classification)
 - 7 contain conditions for treated articles (see previous slide)
- Many biocidal products authorised for use as a preservative during storage → unknown how many authorisations exist for use in tattoo inks → ECHA has asked Member States for information

Biocidal Products Regulation (5)

- Active substances in PT 6 **under assessment**: 37
- Unknown if under national rules in Member States allowed to use these active substances to preserve tattoo inks → ECHA has asked Member States for information

Biocidal Products Regulation (6)

- More information gathered by ECHA to get an overview of preservatives which can be used in tattoo inks
- ECHA continues to support meeting obligations under REACH and BPR
- More on BPR:
echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

Thank you!

echa.europa.eu/contact



Live Q&A panel

- Our panellists reply to questions until **16:30 Helsinki time** (EEST, GMT+3)
- **All questions will be answered** in a Q&A document shortly after the webinar
- Send questions at [slido.com](https://www.slido.com), event code **tattooinks22**, or with QR code:
- Questions after the webinar?
echa.europa.eu/contact

