

# **The REACH restriction on substances in tattoo inks or permanent make-up**

**Reflections from a consumer representative**

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# History

## National initiatives – AT and DK

- **AUSTRIA**
  - Initiation spring 2011
  - Parliamentary resolution 12/2011
  - Draft legislation summer 2013
  - Basis CoE Resolution ResAP (2008)1
  - Notification to Commission 10/2013
- **Objection by the Commission**
  - “lex specialis“ doctrine - specific law (REACH) overrides a general law (GPSD)
  - if MSs think that risks are not adequately controlled a REACH-dossier (Annex XV) is required demonstrating that “*action on a Community-wide basis is necessary*” (Art. 69 (4)) – or safeguard clause (Art. 129)



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# History

## National initiatives – AT, DK

- **Objection by the Commission (cont.)**
  - previous Commission opinion: MS are free to adopt restrictions where no restriction is included in Annex XVII (no harmonisation)
  - changed Commission opinion: process itself is harmonised – restrictions only via REACH

- **BUT REACH Article 128 (2)**

*“Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use”.*

- **Consequences?**

**Are national product laws addressing chemicals illegal? (e.g. indoor emissions, nano registries, etc.)**



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# History

## European process

- Need for EU action confirmed in 2014
- broad support for a GPSD Article 13 temporary measure based on ResAP (2008)<sup>1</sup>
- Draft ready - MS expected vote in 12/2014
- COM Services in charge of REACH prevented GPSD measure - delay of several years!!!
- JRC project
- Commission request to the ECHA to prepare a restriction dossier in 12/2015 – *“we would like to discuss with ECHA” - “grouping substances on the basis of their hazard classes”*
- Restriction proposal delivered 10/2017 (ECHA + DK, GE, IT, NO)
- Restriction adopted in 12/2020, valid from 01/2022

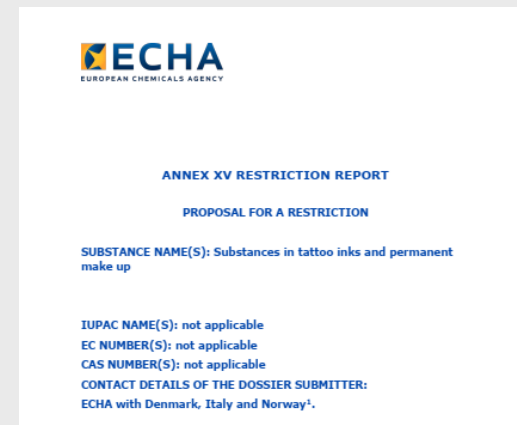


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# ECHA Restriction proposal

## Surprises...

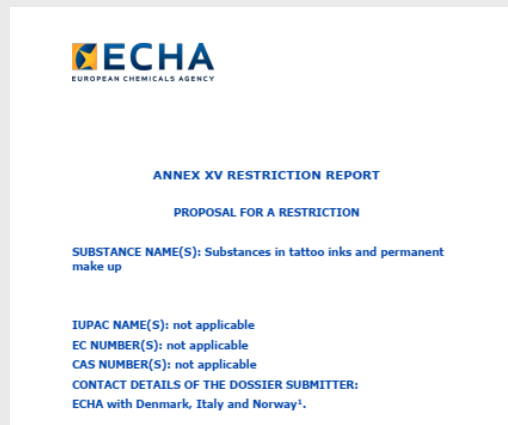
- ban of **substances with harmonised classification** CMR 1A, 1B and 2, skin sensitizers, skin irritants, skin corrosive substances, eye damaging and irritant substances
- ban of substances **prohibited** in Annex II (currently 1657 entries) of the **Cosmetics Regulation (CR)** or **restricted** in its Annex IV (list of allowed colorants):
  - not to be used in products applied on mucus membranes;
  - not to be used in eye products;
  - allowed only in rinse-off products; and
- required compliance with other conditions, such as for purity, listed in Annex IV.



# ECHA Restriction proposal

## REACH compatible?

- common understanding was that REACH follows a **substance-by-substance risk assessment approach** – not a hazard-based approach!
- Annex XV dossier for restrictions
  - shall be based on an assessment of the hazard **and risks** according to the relevant parts of **Annex I** and shall be documented in the **format** set out in Part B of that Annex for the **Chemical Safety Report**.
  - shall include **information on alternatives**
- “Chemicals Strategy for Sustainability” 12/2020 supports **“generic approach to risk management”** (= hazard based) – “default approach” for consumer products – “extend” Art. 68 (2)



# Problems related to the restriction (proposal)

## ANEC position paper 06/2018

- **bans based on hazard classes** apply only to substances with **harmonized** classifications (e.g. CMR)
- many substances do not have a harmonised classification although they fulfil the criteria for a classification
- **CLP prioritizes CMRs and respiratory sensitizers**
- other substances may be added “*on a case-by-case basis, if justification is provided*”
- e.g. sensitizers – study by RPS 2013 (textiles)

Notified classification under REACH	Number of substances
Skin Sens. 1	10267
Harmonised classification under CLP	Number of substances
Skin Sens. 1	1252



# Problems related to the restriction (proposal)

## ANEC position paper 06/2018

- CL Inventory - November 2021: Skin Sens. 1, Skin Sens. 1A, Skin Sens. 1B:
    - Notified: 15.267, Harmonised: 1.410
  - possible (partial) solution: use **industry self-classifications**, e.g. where 50% or more of the notifiers have self-classified the substances indicating these hazard classes
  - review and simplify CLP harmonisation process (e.g. introduce Commission initiative)
- 
- **(dynamic) link** to restrictions in the annexes of the Cosmetics Regulation (CR) questionable - should have been be accepted only provisionally – different kind of exposure (risks of skin injection not assessed)





# Problems related to the restriction (proposal)

## ANEC position paper 06/2018

- **ban of substances with restrictions in CR Annex IV** (positive list of allowed colorants) – but no ban of substances which are not included!
  - **absurd consequence** : if a restricted substance in this Annex is removed because of health concerns it can be used in tattoo inks
  - **problem: positive lists of substances in products** (suggested by CoE Resolution for preservatives) **cannot be established in REACH**
  - **solution: separate legislation** or **incorporation in CR** or **new legislative framework** for chemicals products
- 
- **preservatives** in theory covered by **BPR** – but skin injection not addressed!



# Restriction – final remarks

## Positive aspects 😊

- **Strengthened restriction option 1 (RO1)**
- **RO2 rejected – limits too high**
- **practical enforcement limit 0,00005 % for**
  - **carcinogenic and mutagenic substances**
  - **substances prohibited in Annex II or restricted in Annex IV of the Cosmetics Regulation**
- **practical enforcement limit 0,001 % for**
  - **substances toxic to reproduction**
  - **skin sensitisers**
- **some limits for specific substances strengthened**

**Conclusion: OK for now, but different approach needed in future!**

Committee for Risk Assessment (RAC)  
Committee for Socio-economic Analysis (SEAC)

Opinion  
on an Annex XV dossier proposing restrictions on  
substances used in tattoo inks and permanent make-up

ECHA/RAC/RES-O-0000001412-86-240/F  
ECHA/SEAC/ ECHA/SEAC/RES-O-0000001412-86-265/I

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