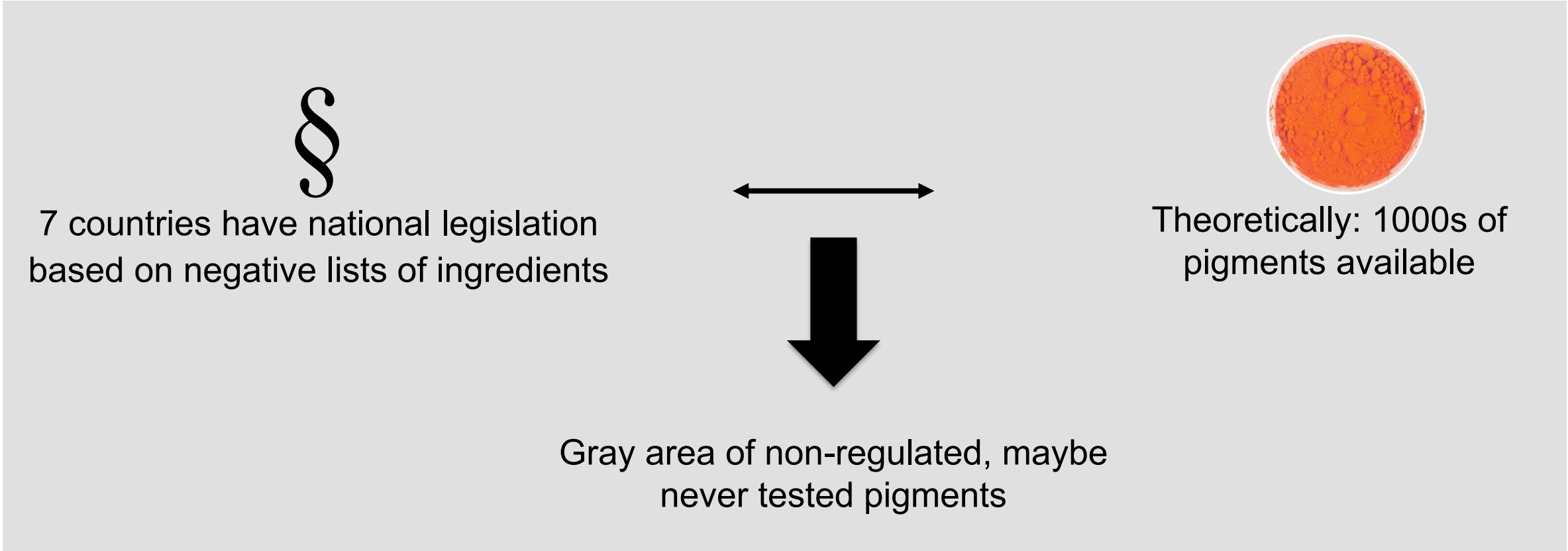




# **ESTP perspective on the REACH restriction: Interventions and open questions**

Ines Schreiver, co-chair of the ESTP

# Past state of legislation in the EU

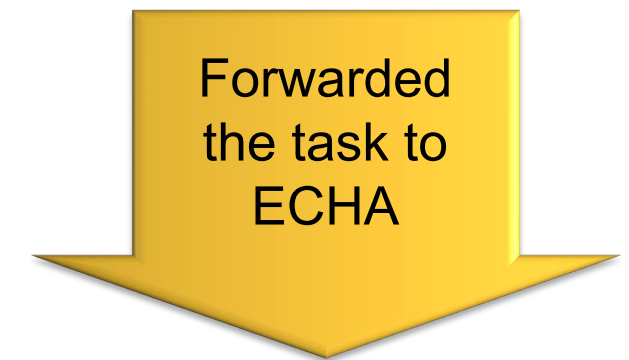


Exception: Spain = approval of pigments necessary, Norway = Positive list for preservatives

**True safety only with positive lists of non/least dangerous ingredients**

# Why REACH?

- Since 2003 non-binding resolution ResAP(2003) / ResAP(2008)1
  - Only some 7 countries implemented national laws
- Since then: EU wide regulation was targeted by the European Commission
- Joint Research Center (JCR) report on tattoo inks and safety
- European Commission decision against tattoo legislation:
  - *“it would be **difficult and time consuming to negotiate** such legislation EU-wide as the hygiene and certification aspects are normally within the jurisdiction of local and regional authorities, although the existence and the nature of these requirements varies substantially among Member States”.*
- REACH restriction means minimal need for negotiations with national legislative parties – easy to push through



# Timeline of the REACH restriction on tattoo inks

<b>Oct. 2017</b>	Publishing of first restriction draft from ECHA
<b>June 2018</b>	End of 1st public hearing (1st ESTP commented)
<b>Dec. 2018</b>	Publishing of RAC /SEAC opinion on the restriction
<b>Feb. 2019</b>	End of 2nd public hearing (2nd ESTP commented)
<b>Spring 2019</b>	Final draft was given to the EC
<b>2020</b>	EC amended the draft, consultation (Letter to the European Ombudsman), approved by Member States
<b>2021</b>	4th of January, REACH restriction (Open Letter to the EC) went into force
<b>2022</b>	<b>4th January</b> , 12 month transition time passed, all <b>requirements must be fulfilled</b>
<b>2023</b>	<b>4th January</b> , 24 month transition time passed, <b>Pigment Blue 15:3 &amp; Green 7 are fully banned</b>

RAC= Risk assessment committee  
 SEAC = Socio-economic analysis committee



# ESTP demanded..

- EU wide tattoo **legislation** instead of REACH restriction (leaves option for true positive list in the future)
- **Hazard & exposure** related ban of substances
- **technical achievable levels** of certain impurities
- Inclusion of the CEN documents on hygiene (can immediately improve infection risks)
- No lists of pigments but rather dangerous structures / cleavage products (e.g. carcinogens cleaved from azo pigments) -> slight chemical modifications are no work-around of a ban of dangerous pigments
- Full labelling of ingredients (**European Commission integrated this in the final restriction**)
- Agreement on **minimum toxicology requirements** (does not provide full safety testing/ better than current state of safety for consumers)

# What are the disadvantages of a REACH restriction?

- Is made for bulk chemicals or mixtures
- First attempt to regulate a full product group like this
- Includes wrong limits for less harmful or non-skin relevant toxicity endpoints (skin irritants, eye irritant and eye damaging)
- REACH restrictions are not designed to have positive lists of non-harmful ingredients
- Major side effects will not be prevented by the restriction (bacterial infections, allergies, granuloma, sarcoidosis, photosensitivity, neurosensitivity with pain)
- Likely prevents the implementation of EU wide positive lists for the future

**REACH restriction by law: assessment of the hazards and risks of the covered substances**

**Not fully the case with tattoo inks!**

# REACH tattoo restriction = / ≠ hazard based approach

## 1) Inclusion of harmonized classified substances (CMR, sensitizer,.. )

- Are listed by the ECHA after submission of an “(un)safety assessment“ dossier
- Proof of harm towards humans is given

## 2) Tattoo restriction = link to cosmetic directive

- lots of substances in the negative lists with no dossiers and information why they ended up in this lists (also admitted by the SEAC!)
- Sometimes only listed because the industry did not provide safety data

—————> Often no traceable data on hazards of the lists from the cosmetic directive!

**ESTP @ EC: Is this legally possible? No answer.**  
(but: likely only filing a law case would provide clearness)

# Ban of Cu-Phthalocyanine Blue 15 and Green 7 under REACH

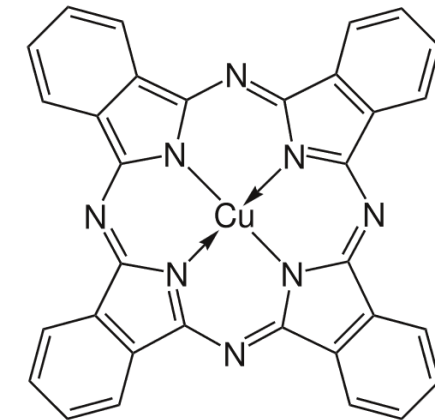
- Most used blue and green pigments
- Little public data on hazards
- Pigment blue 15: most toxicity data exist with no major concerns seen

Banned in annex II of the cosmetic directive „**when used as a substance in hair dye products** “ -> annex II banned for use in tattoo inks!

## Why is it listed?

- > Call for evidence of safety to use certain dyes for hair dying
- > No data was submitted
- > these pigments are no dyes! Not useful for hair dying
- > industry had no interest in spending money on safety dossiers

**ESTP opinion: Derogation for Pigments Blue 15 and Green 7 (C.I. 74160, C.I.74260) must be implemented**





# Can we *safe the pigments*?

Cosmetic Directive	Blue 15:3	Green 7
Annex II	listed	listed
Annex IV	listed for long term skin contact (allowed according to REACH)	NOT listed for long term skin contact (not allowed according to REACH)

As written by SEAC: Submit safety data of the pigments -> delete from Annex II

- REACH restriction: Once cosmetic directive is changed, 18 month transition time to apply to the REACH restriction on substances in tattoo inks and permanent make up
- Green 7: Also banned by application caterogy in Annex IV of the cosmetic directive, would need to change Annex IV as well

**Pigment Blue 15:3 could be safed!**

# Can we safe the pigments?

## *How to delete a pigment from Annex II*

- SCCP committee set guidelines on which data to provide

[https://ec.europa.eu/health/archive/ph\\_risk/committees/sccp/documents/out224\\_en.pdf](https://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out224_en.pdf)

- Data on mutagenicity/genotoxicity/carcinogenicity of "Dyes" and reaction products with oxydative substances must be provided
- in total 6 *in vitro* tests per dye/pigment:
  - Bacterial Reverse Mutation Assay (OECD 471)
  - In Vitro Mammalian Chromosome Aberration Test (OECD 473)
  - In Vitro Mammalian Cell Gene Mutation Test (OECD 476)
  - DNA Damage and Repair/Unscheduled Synthesis in Mammalian Cells in vitro (OECD 482)
  - In Vitro Mammalian Micronucleus Test (UK-EEMS)
  - In Vitro Syrian Hamster Embryo (SHE) Cell Transformation Assay (OECD TG495).
- eventually, also *in vivo* tests might need to be carried out, e.g. if positive result occur in the *in vitro* assays

# Can we safe the pigments?

## *How to delete a pigment from Annex II*



- expert, commercial laboratories should be able conduct these tests
- knowledge / data already exist with pigment manufacturers?
- Experts in writing safety dossiers needed

**Who are the experts on how to compile such a dossier for hair dye pigments?**

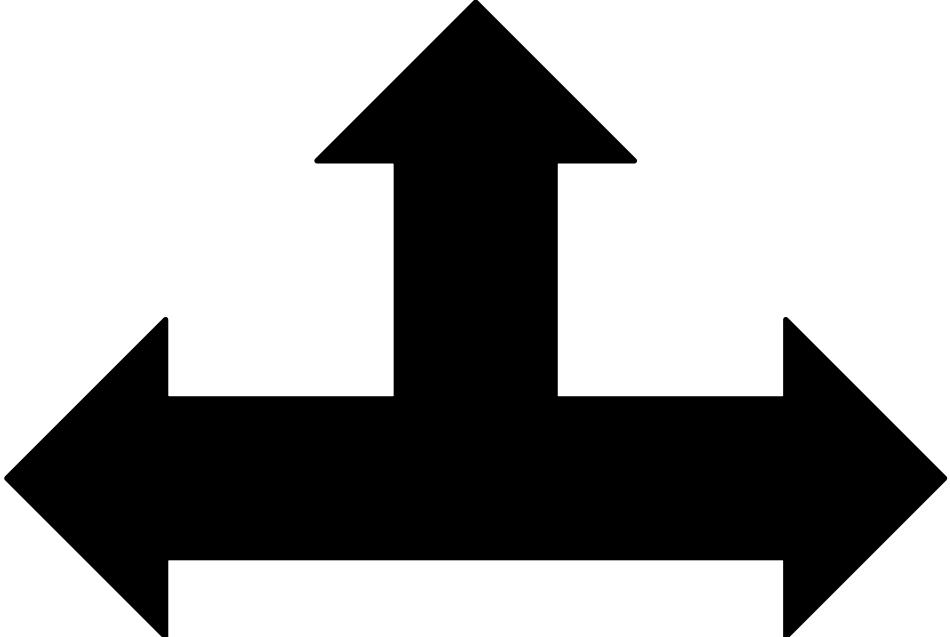
**Who would pay for this?**

**Who would join forces?**

# Future of tattooing in Europe

**Live with REACH:** All tattoo inks are dopted, other non-banned and non-tested pigments are used, in hope that raw materials fulfilling all criteria exist

**Work around REACH:** Inks are illegally used – "art colors"



**Damage reduction of REACH** -> At least safe some pigments and ingredients

*My personal note:* These inks already exist, but young professional artist & costumers do care about ink safety- a complete illegal market is not realistic

**Thanks to all involved parties, board members and the ESTP to help compiling the extensive comments to ECHA/EC!**

**Thank you for your attention!**