

# Potential regulation on tattoo inks & PMU under REACH

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and Pigment Research

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Mark Blainey  
Evgenia Stoyanova  
Risk Implementation Unit  
European Chemicals Agency



# Introduction

- Following data collection by the JRC project, the European Commission requested ECHA to prepare a restriction dossier on chemicals in tattoo inks and permanent make-up (PMU)
- ECHA is working with partner member states:
  - Denmark
  - Germany
  - Italy
  - Norway

# Outline of presentation

- ECHA and REACH
- REACH restrictions
- Tattoo inks and PMU
  - Activities in the EU leading to ECHA restriction preparation work
  - Options for addressing the risk
- Scope of ECHA/Member states work
- Restriction scope – current thoughts & reactions

## Our mission

ECHA is the driving force among regulatory authorities in implementing the EU's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness.

Help companies to  
comply with the  
chemicals legislation



Advance the safe use  
of chemicals



Provide information  
on chemicals



Address chemicals  
of concern





## Main activities

- Manage REACH, CLP, Biocides and PIC
- Disseminate information on chemicals
- Develop scientific IT tools
- Provide regulatory assistance to industry (helpdesk and guidance)
- Support enforcement
- Advise EU institutions and Member States on chemical safety
- Assist EU's international activities (UNEP and OECD; accession countries)

## Aims of REACH

- Ensure a high level of protection of human health and the environment
- Promote alternatives to animal testing
- Ensure the free circulation of substances on the internal market
- Enhance competitiveness and innovation



## Principles of REACH

- Industry responsible for safe manufacture and use
- Deal with the 'burden of the past' with a systemic program for registration of old chemicals
- Get adequate information on hazards while minimising the use of experimental animals and the costs
- Targeted activities by ECHA, Member States and the European Commission to get maximum effect
- Enforcement at national level

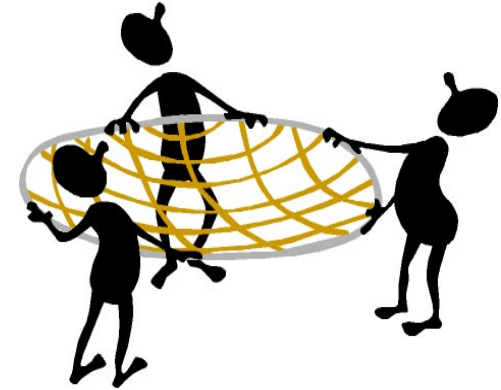


# REACH



- REACH adopted in 2006
  - **R**egistration of chemicals [“substances”]
  - **E**valuation of selected registered substances
  - **A**uthorisation of (certain) Chemicals
  - **R**estriction of (certain) **C**hemicals





## REACH restriction: Background

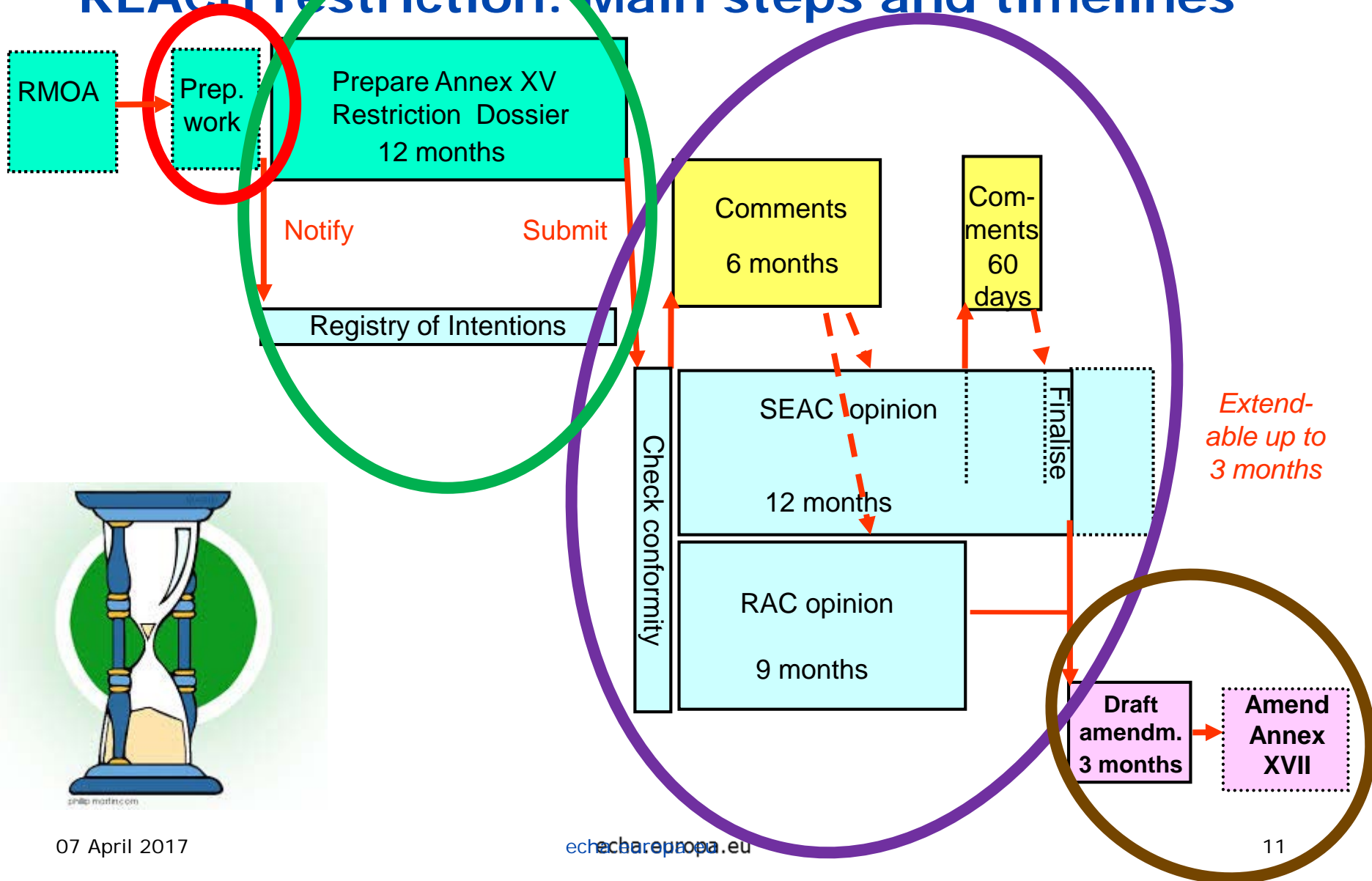
- Continues the work done under Directive 76/769/EEC
- A safety net:
  - authorisation/other Community actions are not more appropriate
  - other REACH processes do not ensure adequate control of risks
    - registration (CSR, implementation and recommendation of necessary risk management measures and operational conditions)
    - downstream obligations,
    - possible dossier or substance evaluation
- Community-wide action: the same requirements apply to whole EU from entry into force



## REACH restriction: the framework

- Any condition for or prohibition of the manufacture, use or placing on the market:
  - an unacceptable risk to human health or the environment
  - this risk needs to be addressed on a Community-wide basis
- Restrictions may be imposed on:
  - manufacture, use and/or placing on the market
  - a substance on its own, in preparation or in an article, when...
- General exemptions:
  - scientific research and development
  - risks to human health due to use in cosmetic products (dir 76/768/EEC)
  - on-site isolated intermediates

# REACH restriction: Main steps and timelines



## Tattoo inks: brief overview of work in the EU to date

- Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) concerning the safety of tattoos (2000)
- Joint Research Centre, European Commission
  - Papameletiou *et al.*, 2003. *Risks and Health Effects from Tattoos, Body Piercing and Related Practices*
  - Piccinini *et al.*, *Safety of tattoos and permanent make-up:*
    - *Compilation of information on legislative framework and analytical methods* (2015)
    - *State of play and trends in tattoo practices* (2015)
    - *Adverse health effects and experience with the Council of Europe Resolution (2008)1* (2016)
    - *Final report* (2016)
- Council of Europe
  - ResAP(2003)2
  - ResAP(2008)1
- National legislation in certain member states:
  - Belgium, Germany, France, Slovenia, Spain, Sweden, the Netherlands (and Italy)
  - Austria, Denmark and Latvia – have prepared draft legislation

# Tattoos: selected statistics

- Tattoo prevalence is increasing:
  - from 4-8% (2003) to 12% (2014), (Piccinini et al., 2015) and
  - 20-35 age group exceeding 20% in some EU member states
- RAPEX (Rapid Alert System for dangerous non-food products) notifications:
  - 153 related to chemical risks (DE, DK, FR, IT, NL, SE)
  - 8 related to microbiological risks
- Human health effects reported
  - 6% - persistent skin problems (Klugl et al., 2010)
  - 4% - persistent mild swelling, while 1% - persistent mild itching (Kluger, 2016)
  - 27% - reported complaints more than 3 months after tattoo (Høgsberg et al., 2012)
  - Photosensitivity reports: from 1.2% to 58% of tattoo complaints (Klügl et al., 2010, Høgsberg & Serup, 2012)
  - Complaints following tattoo procedure – 15% up to 3 months (Høgsberg et al., 2013) to 67.5% - up to 4 weeks (Klügl et al., 2010)

## Contributing factors

- Not only chemicals but also: ...
- Hygiene standards
- Training & development of tattoo artists
- Large “informal” sector
- Public awareness of contraindications, risks, and overall implications of getting a tattoo
- Good manufacturing practices for tattoo/PMU inks, incorporating safety assessment
- Research gaps
- Collaboration in the “supply chain” – customer, artist, suppliers, manufacturers, medical professionals and researchers

## Scope of our work

- European Commission request to ECHA to prepare a restriction proposal assessing:
  - risks of substances:
    - banned for use in cosmetic products (CPR)
    - with harmonised classifications as carcinogenic, mutagenic, toxic to reproduction, and skin sensitisers
    - in the Council of Europe resolution ResAP(2008)1
  - need for European Union-wide action beyond any national measures already in place in order to adequately control the risks to human health due to exposure from tattoo inks and PMU
  - relevant socio-economic impacts

# Scope of our work

- Defined by REACH restrictions:
  - Can specify:
    - Substances that cannot be present in tattoo inks exceeding a certain concentration
    - Labelling and substance information requirements
  - Can influence:
    - Development and standardisation of analytical methods
    - Availability of substance information
    - Safety assessment
    - Classification & labelling
    - Further research



## Scope of our work

- Defined by available resources:
  - Same timelines for dossier preparation for more than 6 000 substances
  - Data availability to conduct an assessment required by REACH

## Restriction scope: current thinking

- Tattoo inks or PMU cannot be placed on the market if they contain:
  - Carcinogenic, mutagenic and reprotoxic substances, including primary aromatic amines (PAA) and polycyclic aromatic hydrocarbons (PAH) with CMR classification
  - Skin sensitising, skin irritant, and skin corrosive substances
  - Eye damaging and eye irritant substances
  - Substances banned for use in cosmetic products as specified in the CPR:
    - Substances on Annex II
    - Substances on Annex IV (former columns 2-4)
  - Azo dyes which degrade to PAA primary aromatic amines with harmonised classification for CMR
  - Other impurities currently under investigation: barium and zinc
  - Some possible exemptions (derogations) under investigation

# Existing vs Potential restriction

Council of Europe ResAP (2008)1 (CoE) & Member State National Legislation	Potential restriction
	Differences
CMR	Potential variance in concentration limits
CPR Annex II	Potential variance in concentration limits
CPR Annex IV, columns 2-4	Potential variance in concentration limits
Aromatic Amines (CoE, table 1)	Potentially excluded: 6-amino-2-ethoxyna- phthaline (#1) & 2,4-xylidine (#27)
Pigments not allowed (CoE, table 2)	14 currently under investigation
Impurities limits (CoE, table 3)	Potential variance in concentration limits 2 currently under investigation: copper & tin
	Skink sensitisers, Skin irritants, Skin corrosives, Eye irritants, Eye corrosives

## Questions to the audience

- Labelling requirements
  - Those specified under ResAP (2008)1?
    - the name and address of the manufacturer or the person responsible for placing the product on the market;
    - the date of minimum durability;
    - the conditions of use and warnings;
    - the batch number or other reference used by the manufacturer for batch identification;
    - the list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS number (Chemical Abstract Service of the American Chemical Society) or Colour Index (CI) number;
    - the guarantee of sterility of the contents.
  - Other?

## Questions to the audience:

- Are there substances that will present a problem for industry to substitute?

## Questions to the audience

- Transitional period
  - Restrictions usually specify when they'll take effect: entry into force (publication in the official journal) + transitional period
- Transitional period is dependent on stakeholders' ability to comply with the restriction:
  - Availability of alternatives
  - Depletion of existing stock, etc.

# Thank you!

[echa-restriction-tattoo-inks@echa.europa.eu](mailto:echa-restriction-tattoo-inks@echa.europa.eu)

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