WHAT IS THERE FOR PATIENTS AND WHAT ROLE FOR THEM IN POLICYMAKING?

EEB European Environmental Bureau Tatiana Santos Policy Manager: Chemicals & Nanotechnology

WHO WE ARE

• Europe's largest network of environmental citizens' organisations

- around 150 civil society organisations... including a growing number of European networks
- ...from more than 30 European countries

Over 40 years of EU environmental policy expertise

SENSITISERS IN CONSUMER PRODUCTS

Consumers are widely exposed to the substances via various consumer products such as cosmetics, toys, clothing, and detergents

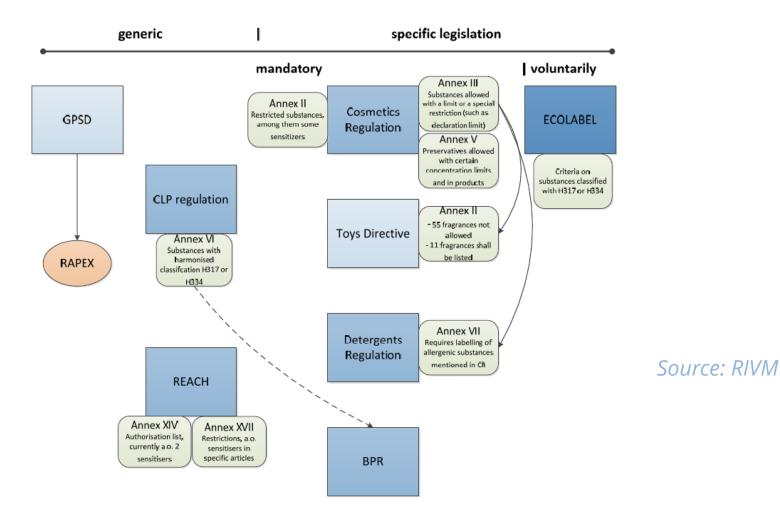
p.3



- Five main categories: metals, fragrances, (hair) dyes, preservatives and resins/solvents.
- The production and use of sensitising substances is regulated in the separate, different legal frameworks, general (eg GPSD, REACH) and sector specific (eg toys, cosmetics) legislation.



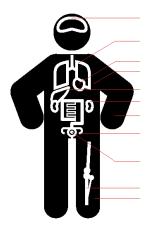
OVERVIEW OF SEVERAL EU LEGISLATION WITH RELEVANCE FOR SENSITISERS

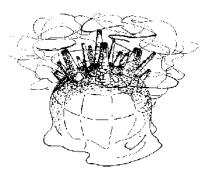


р.4

EEB'S PRIORITY CHEMICALS

No. substances	Effect
4,136	CLP- Annex VI
1,005-1,500	CMR cat 1-2 (CLP)
384	PBT/vPvB
1,500-2,271	EDCs-potential EDCs
1,364	neurotoxicants
11,091	sensitisers





Source: Risctox database. http://www.istas.net/risctox/en/

р.5



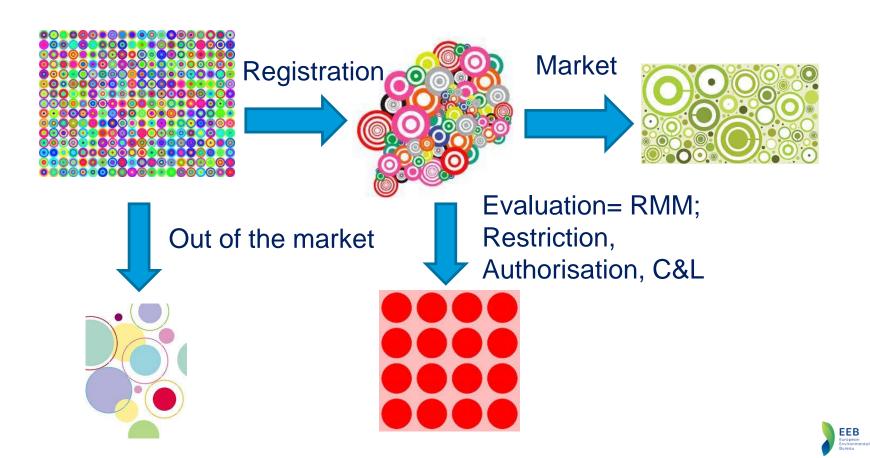
Respiratory and skin sensitisers

Effect	No of substances
Respiratory sensitisers cat 1	2,906
Respiratory sensitisers cat 1 (CLP)	231
Skin sensitisers cat 1	12,997
Skin sensitisers cat 1 (CLP)	1,252



р.6

REACH: A FILTER OF TOXIC CHEMICALS



REACH basic principles

- Goal: High level of protection from chemical risks while ensuring innovation and competitiveness
- Precautionary principle
- Substitution principle
- Shifting the burden of proof
- No data = No market
- Public right to know



REACH IMPACT ON ALLERGIES

ETUI / Sheffield University study

p.9

- Objective: assessing what could be the impact of REACH on occupational skin and respiratory diseases.
- 40 000 cases for asthma, 10 000 cases for Chronic Obstructive Pulmonary Diseases (COPD) and 40 000 cases for dermatitis could be avoided.
- Total average savings: **3.5 billion Euros** over 10 years for the EU-25.
- A great part of the skin and respiratory occupational diseases that could be avoided thanks to REACH



REACH IN A NUTSHELL



- Registration: Manufacturers and importers of chemicals (incl. sensitisers) > 1 tpa are required to register their substances to demonstrate they can be used safely
- Evaluation of <u>some</u> substances/dossiers by Member States / European Chemicals Agency (ECHA)
- Restrictions when <u>risks</u> are <u>unacceptable</u> (eg nickel, chromium VI, MDA and dimethylfumarate)
- Authorisation <u>only</u> for substances of very high concern

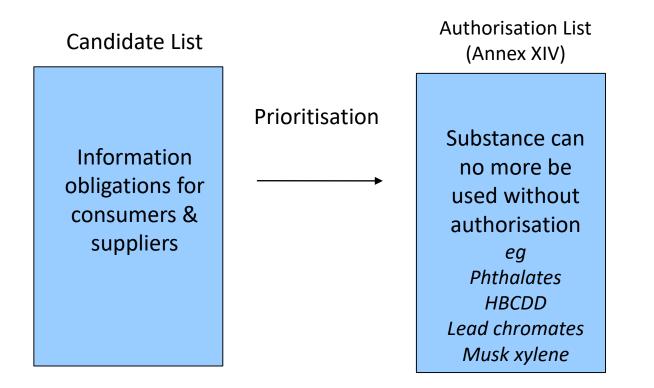




AUTHORISATION PROCEDURE

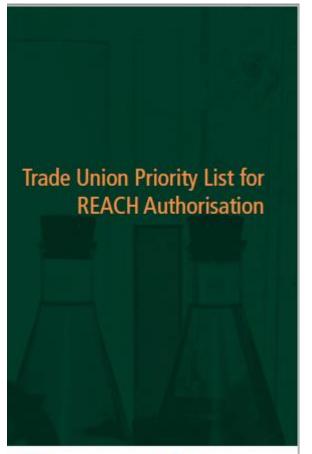
Substances of very high concern:

PBTs, vPvBs, CMRs (1A &1B), equivalent concerns (e.g. sensitisers)





TRADE UNIONS CONTRIBUTION TO THE AUTHORISATION PROCESS









instituto sindical de trabajo, ambiente y salud





Proposal of Sensitizers for SVHC identification under 57f:

Contribution to the practical implementation of REACH, in particular by proposing sensitizers as Substances of Very High Concern (SVHC) which, from a union perspective, should have priority for inclusion in the Candidate List and potentially in the Authorisation or **Restriction Lists.**





In general, it appears to be easier to justify equivalent level of concern for respiratory sensitisers when compared with skin sensitisers. Nevertheless, this should not be considered as a general rule to be applied in all cases. There may be certain circumstances which may warrant skin sensitisers becoming identified as SVHCs under the 'equivalent level of concern' route, particularly in cases where the factors and additional considerations described in this document are taken into account, particularly in cases where factors and additional this document apply.





5 Respiratory sensitisers (Article 57(f) - human health) out of 197 candidate list substances

Benzene-1,2,4-tricarboxylic acid 1,2 anhydride Cyclohexane-1,2-dicarboxylic anhydrides Diazene-1,2-dicarboxamide (C,C'-azodi(formamide)) (ADCA) Ethylenediamine (EDA) Hexahydromethylphthalic anhydride

Sensitiser coordination group: HDDA failed as skin sensitiser but committed to further work on this issue



p.14

NON-TOXIC ENVIRONMENT STRATEGY

The path towards a non-toxic environment should have certain unavoidable stretches:

- 1. closing the information gap
- 2. proper and effective application of EU environmental policy principles
- 3. preventing the risks (phase out and substitution)
- 4. need of an overall and holistic approach for the regulation of chemicals
- 5. compliance with and proper implementation and enforcement of the EU legislation
- 6. continuous reduction of health and environmental risks of chemicals and adequate control of remaining risks
- 7. Internalising the costs-economic incentives for safer products and clean production



WHAT PATIENTS COULD DO

REACH

p.16

- European associations to advocate to the sensitisers coordination group
- National associations to advocate at MS level for allergens restrictions and identification as SVHC
- Contribute to the public consultations and follow specific proposals (eg joint restriction proposal (SE and FR) on skin sensitisers and skin irritants in textile and leather articles-Jan 2019)

NTES

• Call on for a non toxic environment strategy





THANK YOU! www.eeb.org @Green_Europe @ EuropeanEnvironmentalBureau tatiana.santos@eeb.org

The EEB gratefully acknowledges the financial support from the LIFE Programme of the European Union. This communication reflects the organizers' views and does not commit the donors.