

# **Chemicals legislation in the EU and the US – a comparison and future outlook**

**Mikael Karlsson, PhD  
Södertörn University, Stockholm  
President European Environmental Bureau**

# The precautionary principle: Core elements

- The principle is part of the TFEU, widely included in national and international law, and increasingly applied in courts
  - Charges against the principle have proven to not hold in general
1. Group or worst-case classification
    - in case of lack of data
  2. Management based on intrinsic properties
    - not necessarily on risks, not necessarily toxicity
  3. Various preventive measures
    - such as substitution, restrictions
  4. Maximin decision-making,
    - minimise probability of worst-case (if not unreasonable)
  5. Reversed burden of proof
    - needed on all points above



# Development of EU chemicals policy

Classification 1967

Restrictions, 1976

Existing, new substances, 1979



Chemical preparations, 1988

Risk assessment, 1993

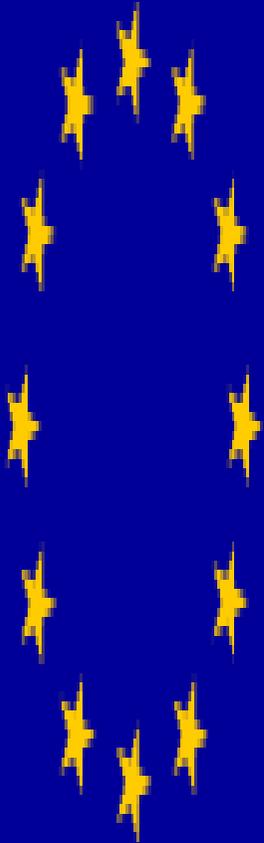
White Paper, 2001

WEEE and ROHS, 2003

REACH regulation, 2007

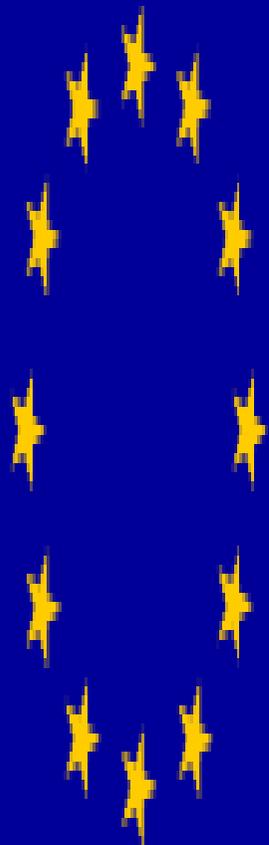
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# EU and precautionary politics



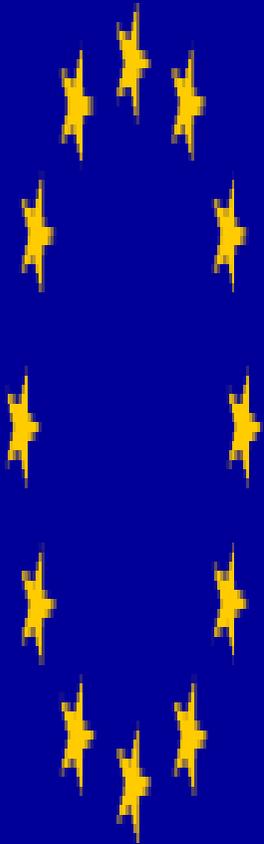
- Some elements go centuries back
- Has gradually emerged since the 1960s in various MS
- Included in the Maastricht Treaty
- Commission Communication in 2000
  - vague and contradictory
- Gradually included in secondary law and applied by the ECJ

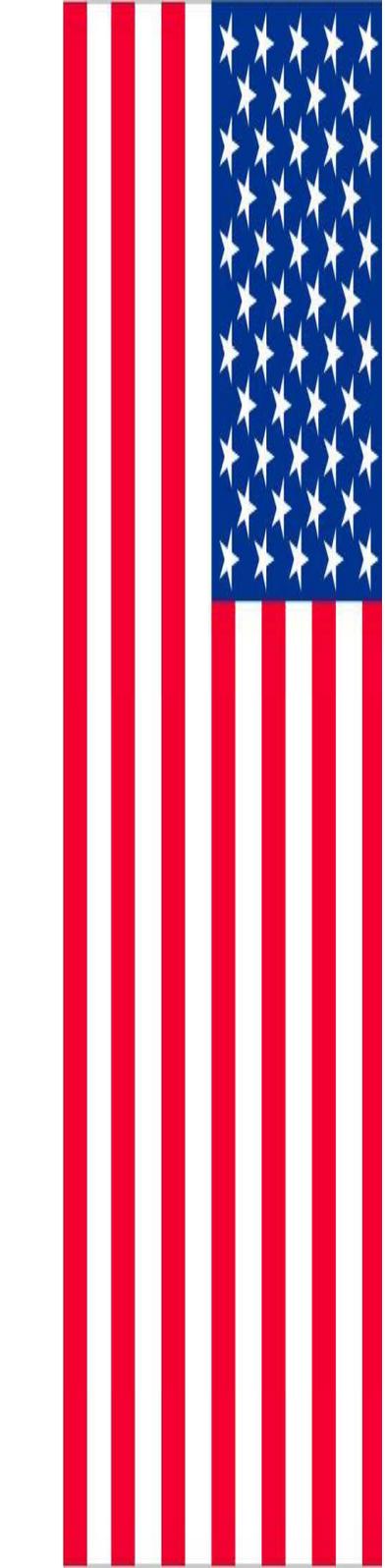
# The REACH Regulation

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- Registration
    - Preregistration included around 150 000 substances
    - First step in registration done (e.g. high volumes)
  - Evaluation
    - Substance evaluation by MS based on concerns
    - Community rolling action plan (end of this year)
  - Authorisation
    - Substances of very high concern
    - Candidate list (53 substances) and Annex XIV (6 substances)
  - Restrictions
    - Previous directive and new decisions (a handful)
    - Some phthalates and metals etc. in process

# REACH and precaution

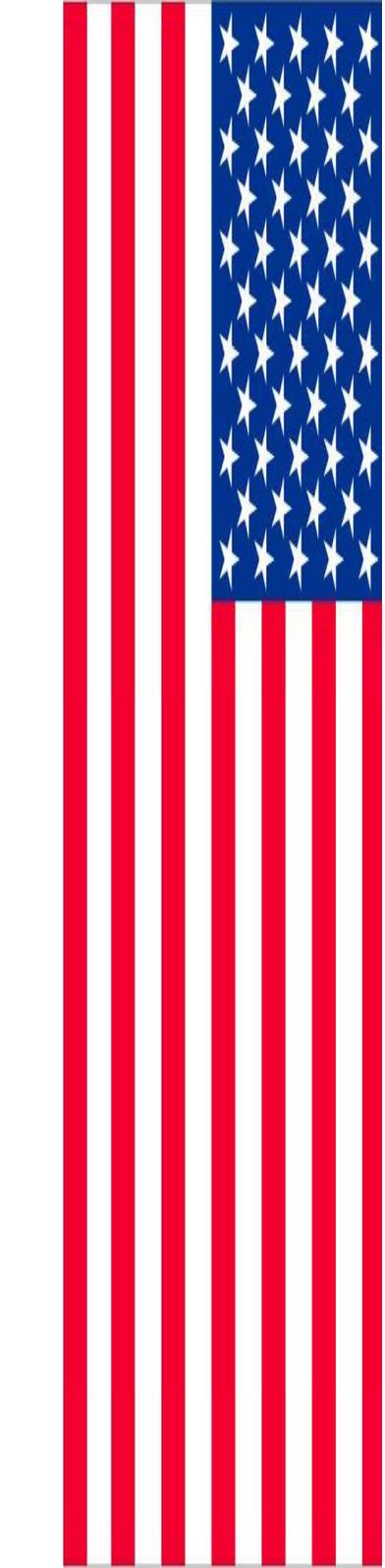
- Group or worst-case classification
  - Not generally, many substances out of REACH
  - However: 'no data, no market', alternative testing
- Management based on intrinsic properties
  - Clearly recognised (e.g. vPvB)
  - Complex process for identifying SVHC
- Various preventive measures
  - A multitude of regulatory options
  - Substitution quite weak (only some SVHC)
  - Few substances authorised compared to expectations
- Maximin decision-making
  - Relates partly to 'no data, no market'
  - Still though, strong emphasis on cost-benefit analysis
- Reversed burden of proof
  - Partially reversed, particularly not for restrictions





# Precaution and chemicals law in the US

- Food, drug and cosmetics legislation in 1938 and 'The Delaney Clause' in 1958
- Early implicit incorporation of precaution in law (CAA, CWA, ESP 1970s)
- Mentioned by courts in 1976, 1989
- Over time a development rather away from precaution
- Toxic Substance Control Act, 1976, is one example
- Strong focus on risk acceptability, CBA
- Attempts to portray norms and values as science
- Approaches to amend TSCA, including Kids safety act, and Safe Chemicals Act



# Precaution and TSCA

- Group or worst-case classification
  - No or weak stimulation of data gathering
  - EPA has a weak role, mostly voluntary measures
- Management based on intrinsic properties
  - Strong focus on the risk concept
- Various preventive measures
  - Limited regulatory options
  - EPA may not always take action even if risks identified
- Maximin decision-making
  - No, strong focus on CBA
- Reversed burden of proof
  - Very strong burden of proof on TSCA

# There is clearly room for improvements

## REACH

- Fewer exemptions and low volumes
- Higher data demands for registration
- Allow time from registration to market
- Chemicals in articles
- General and early substitution
- No bottlenecks for identifying SVHC
- Phase-out of hazardous substances
- Lower burden of proof for restrictions

## TSCA

- Operative criteria for hazardousness
- Data responsibility on companies
- Easier for EPA to require more data
- One system for all substances
- Chemicals in articles
- General substitution
- EPA to decide on preventive measures
- Regulate failing voluntary initiatives



# Future outlook

- Science and public opinion will stimulate politics, and more and new regulatory measures will emerge
- Principles for a toxic-free environment
  - Paracelsus was wrong
  - Combination effects
  - Endocrine disrupting substances
  - Kids as starting points
  - Precaution will be a key stone
- EU will continue to lead, US might follow
- Groups of MS in EU will continue to lead
- Globalised development in the area

