

GDCh Wissenschaftsforum CHEMIE 2013  
Darmstadt, 4. September 2013

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The logo consists of the word "sofia" in a large, white, sans-serif font. To the left of the text, there is a decorative graphic element composed of several overlapping squares in shades of grey and purple, arranged in a grid-like pattern.

Society for Institutional Analysis  
Darmstadt University of Applied Sciences

## **REACH - a science perspective for the coming 10 years**

*5 Jahre REACH und weitere Beiträge  
zu einer nachhaltigen Chemie  
FG Nachhaltige Chemie*

# **Overview**

## **I. Interim Results 2011/2013**

- A Registration, Data Sharing, Evaluation**
- B Data Accessibility**
- C Authorization and Restriction**
- D Stakeholder Involvement:  
Inclusive Governance**

## **II. Retrospect 2023**

## **III. Conclusions: Self-responsibility in the Sunshine**



Page 8

Director Christel  
Musset

**Start preparing for  
2013 now**

#3 June 2013  
Issue 3

In this issue:

Second REACH registration deadline a success

Nearly 3 000 more substances registered by industry

REACH 2013 - From our stakeholders

Fair sharing of costs for active substance approval

New biocides guidance coming

Promoting substitution under REACH, CLP and the Biocidal Products Regulation

Monitoring the effectiveness of enforcement



"We are one step closer to having a database of all the main chemicals in Europe," says Kevin Pollard.

At the end of May, we together achieved another key milestone on the REACH journey towards safer use of chemicals in Europe.

REACH 2013

# I. A. Registration/Evaluation (REACH)

## Remaining Questions (Art. 54/117 II reports) ...

### ■ Quality of Registration Dossiers (*No. of Ev.Decisions 2012*)

- Substance identity (44)
- Risk Assessment: data basis, „expert judgement“ etc. (79)
  - ECHA website: non-confidential versions of evaluation decisions

### ■ Enduring incompliant dossiers: Legal consequences ?

### ■ Intermediates (of 5.500 dossiers 2388 are „problematic“)

### ■ Data sharing: few disputes; still relevant (SME's?)

### ■ Substances in Articles

- O5A → ECJ?; Imported products?

... to be answered in light of the main objective of REACH „to ensure a high level of protection of human health and the environment“

# I. B. Data Accessibility

- Overcome: *toxic ignorance*
- Transparency (Art. 15 TFEU)
  - active: Art. 119 (2: confidentiality claims assessment)
  - passive: Art. 118 (Reg. 1049/2001 + Aarhus-Regulation)
- Database: information on substances
  - Data Annex II (SDS), Art. 119(2)d
  - PBT properties / total tonnage band
  - User friendliness (→ eChemPortal, OECD)
- *C&L Inventory („clean up the mess“)*

→ Interfaces with other sectoral legislation:  
data to be used in the  
„application and implementation“ (recital 14)

## I. C. Autorisation and Restriction

- **Substances of very high concern (SVHC)**
- **Multi level Authorisation Procedure**
- **Information obligations/rights (Art. 33)**
  - Supply chain: no standard format yet  
(automotive: IMDS)
- **Substances in imported Articles**
  - even with Annex XIV substances  
(= discrimination of EU based producers)
  - different: Restrictions (Annex XVII; Art. 58(6))

# I. D. Stakeholder involvement: inclusive governance

## ■ Management Board

3 Members appointed by COM (without voting rights)

- E.g.: Advisory Group on Dissemination

## ■ Other Committees, incl. MSC, CARACAL

- Stakeholder as „Observer“

## ■ Internet-Consultations, i.a.:

- Working Programs (AWP/MAWP)
- Testing Proposals
- Candidates for the candidate list (Art. 59 (4))

## ■ Science Perspective: REACH als „laboratory“

- Democratisation of „risk knowledge“ + Feedback mechanisms
- Pluralism of perspectives + contrast information  
→ Momentum towards common welfare

## II. Retrospect 2023

# REACH: Regulative Framework enhancing learning processes

### ■ ECHA

- Autonomous role (*mature agency*)

### ■ European Commission

- REACH: *lex specialis*,  
not: „Guardian of the Regulation“

### ■ Member States

- Coordination (EU-/international Level)
- Implementation and Enforcement (national/regional)

### ■ Stakeholder

- Animate the provisions of the Regulation

# PUMA is Committed to Eliminate Discharges of Hazardous Chemicals

JULY, 2011

In line with PUMA's long-term sustainability program, the Sportlifestyle company PUMA recognizes the urgent need for reducing and eliminating industrial releases of all hazardous chemicals<sup>[1]</sup>. According to its approach based on prevention and precautionary principles <sup>[2]</sup>, PUMA is committed to eliminate the discharges of all hazardous chemicals from the whole lifecycle and all production procedures that are associated with the making and using of PUMA products<sup>[3]</sup> by 2020.

PUMA understands the scope of the commitment to be a longterm vision – with short term practice to be defined in the clarification of actions to follow. To ensure transparency, PUMA will report on the progress of this commitment in its annual PUMA Sustainability Report.

An Action Plan will be set up by PUMA within eight weeks from the time this commitment was made.



<sup>[1]</sup>All hazardous chemicals means all those that show intrinsically hazardous properties (persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB); carcinogenic, mutagenic and toxic for reproduction (CMR); endocrine disruptors (ED). This will require establishing – ideally with other industry actors – a corresponding list of the hazardous chemicals concerned that will be regularly reviewed.

Ab

Cap

Env

FAC

Key

New

Our

Pro

PUM

Sup

Sus

Who

W

# CHEMICAL WATCH

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 Global News – Multinational bodies

## Adidas joins Nike and Puma in commitment to Greenpeace

[!\[\]\(19fdbd6eaa1508fb9caf367b7a64e245\_img.jpg\) Print version](#)

31-Aug-2011

Adidas has joined major retailers Nike and Puma in committing to eliminate hazardous chemicals from its entire supply chain across the lifecycle of its products by 2020, following a second report on toxic substances in clothing brands by global NGO Greenpeace ([CW 23 August 2011](#)).

In its statement, Adidas has set out a seven week deadline to develop an action plan towards achieving this goal.

- [Adidas statement](#)
- [Greenpeace press release](#)

Translate this item  
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ZERO DISCHARGE OF HAZARDOUS  
CHEMICALS PROGRAMME

# Joint Roadmap

## Version 2

June 2013

### Mission Statement

... we work towards  
zero discharge of  
hazardous chemicals  
in the life cycle of all  
products by 2020.

2020  
13

# Joint Roadmap

## Version 2

June 2013

adidas  
GROUP

C&A

ESPRIT

G-STAR RAW

INDITEX

Jack Wolfskin

LEVI STRAUSS & CO.

LI-NING

yourM&S

new balance

NIKE

PUMA

# III. Conclusions – Self-responsibility in the Sunshine

- **REACH „learning system“ – on different levels**
  - Mechanisms of (cooperative, inclusive) learning
  - Incentives: Triggered by market impulses
  - Core: Data „traffic regulation“ (generation + transparency)
- **6th Environment Action Programme – Review COM**
  - *Shortfalls*: „The 6th EAP target ... is unlikely to be fully met“.
  - Data: concentrations of chemicals environment/humans (→ Monitoring)
  - Data: effects of exposure to complex cocktails of chemicals + EDC

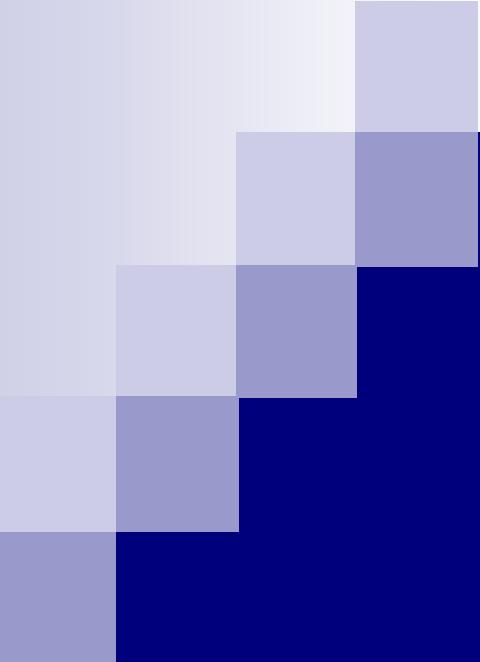
# III. Conclusions – Self-responsibility in the Sunshine

- ***Better Regulation / Smart Regulation / 7<sup>th</sup> EAP***
  - → even smarter : "... increase the chemical knowledge base and provide a predictable framework driving the development of more sustainable solutions."
- **Further enhancement (with caution)**
  - Nano-Materials
  - General Administrative Procedures on EU Level
  - Interfaces with sectoral legislation on environmental media, industrial installations and products (taking into account WTO)
  - Substances with properties without effect threshold
- ... while maintaining the regulative approach:  
***"Self-responsibility in the Sunshine"***

# Selected Literature

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- **Self-responsibility in the sunshine - Eigen-Verantwortung und Transparenz als innovationsfördernde Elemente der REACh-Verordnung,**  
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Results of research projects on REACh can be found at: <http://www.reach-helpdesk.info>.



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Society for Institutional Analysis  
Darmstadt University of Applied Sciences

**Thank you for your kind attention!**

**More information:** [www.sofia-research.com](http://www.sofia-research.com)  
[www.reach-helpdesk.info](http://www.reach-helpdesk.info)

## I. Information required

- 1) Pursuant to Articles 41(1)(a) and (b), 10(a)(vii) as well as Annex IX of the REACH Regulation, the Registrant shall submit the following information using the indicated test method:
  - a) A sub-chronic repeated dose toxicity study (90-day) with the registered substance, dichloro(dimethyl)silane (Annex IX, 8.6.2. of the REACH Regulation), in the rat, by inhalation route, test method B.29 according to Commission Regulation (EC) No 440/2008 or OECD 413. The conduct of the study shall follow a stepwise approach consisting of three steps and shall be conditional on the results obtained in these steps as described in section III.1(a);
  - b) A pre-natal developmental toxicity study with dimethylsilanediol, the relevant hydrolysis product of the registered substance, (Annex IX, 8.7.2. of the REACH Regulation), in the rat, by the oral route, test method B.31 according to Commission Regulation (EC) No 440/2008 or OECD 414.
- 2) Pursuant to 41(1)(c), 10(b) and 14(1) and (4), as well as Annex I of the REACH Regulation, the Registrant shall submit the following information in the form of an updated Chemical Safety Report:
  - a) Exposure assessment and risk characterisation for humans liable to exposure indirectly via the environment, including all relevant routes and taking into account transformation and/or degradation products (Article 14(4) and Annex I, 5.2.4):