# Beyond registration of REACh dossiers: an industry perspective

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# Outline

- Introduction
- REACh @BASF
- Examples: experiences and factors influencing dossier updates
- Further steps for dossier improvement
- Summary & conclusion

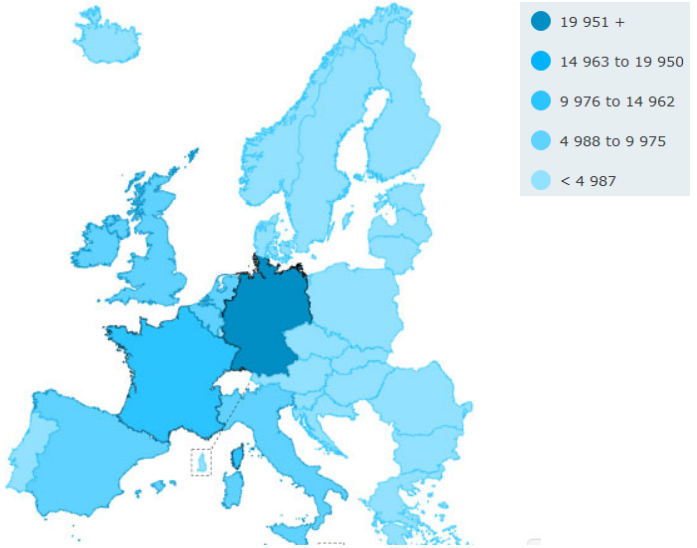
# Objectives of REACh

Ensure a high level of protection for human health and the environment

„No data, no market“
=> 97.162 registrations on 22.607 substances

Enhancement of competitiveness and innovation

**REACh**
Regulating Chemicals in Europe




Taken from EChA, 2019

Promotion of alternative test methods

Free circulation of substances on the internal market



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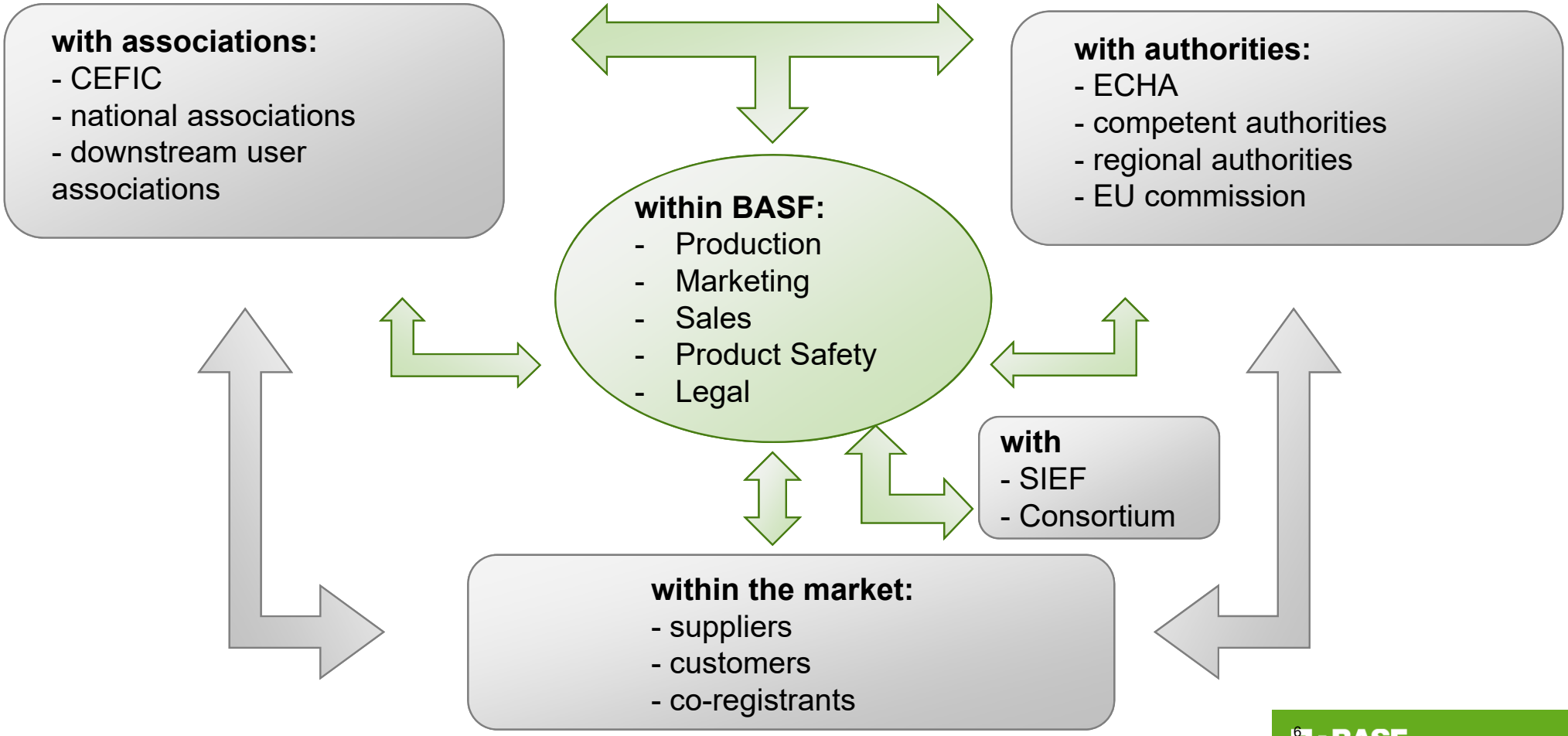
# REACh @BASF

# REACh manpower@BASF

- REACh resources @BASF
  - ~100 legal entities with active registrations
  - ~30 REACh-coordinators
  - ~90 substance-coordinators
  - **65 toxicologists, ecotoxicologists, documentalists and experts for physicochemical data**
    - *Those experts provide the main input for registration dossiers*
    - Consultants (external & internal) as additional support
    - Lab personnel not included

# REACh Communication Network



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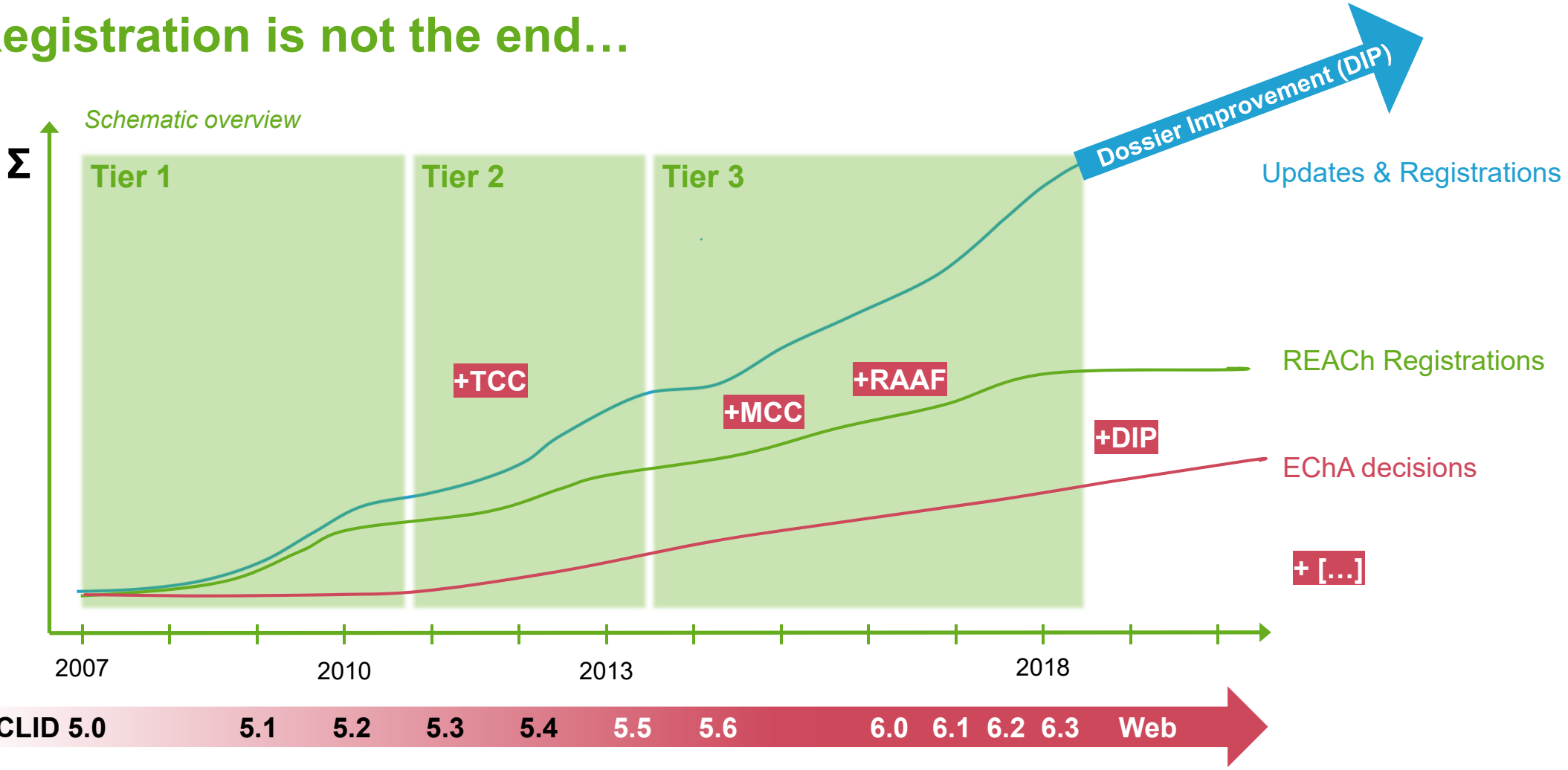
# REACh efforts@BASF

- BASF has registered approx. 2,000 substances
- BASF holds approx. 3,000 active REACh registrations
- BASF is sole registrant or LEAD registrant in ca. 50% of the registrations
- BASF ordered approx. 4,000 (eco)toxicological studies for REACh purposes since 2007. It breaks down to 1,400 *in vivo* studies and 2,600 *in vitro* studies
- On average across the last 10 years, BASF is sending ~50 submissions (registrations or registration updates) per month. This equals to 2-3 submissions per working day.
- BASF spent ca. 400 Mio€ on REACh between 2007 to 2018, i.e. 40 Mio€ per year and 3.3 Mio€ per month
  - ▶ Although registration-phase finished, annual costs remain and increase further

# Registration is not the end…




TCC: technical completeness check
MCC: manual completeness ceck

RAAF: read-across assessment framework
DIP: dossier improvement project

# Experiences and factors influencing dossier updates

# Triggers for dossier updates

Continuous pressure for dossier update

**Business driven**

- additional / modified uses
- change in substance ID
- change in production volume
- change in confidentiality claims
- change in LE (acquisitions and divestments)

**Regulatory driven**

- new relevant data / information
- changed classification and labelling
- ECHA (targeted) compliance checks
- substance evaluation
- new/modified guidances/benchmarks

**BASF has submitted more than 2,200 update dossiers to**
**BASF has received more than 800 decision letters* from**

ECHA EUROPEAN CHEMICALS AGENCY

*TP, CCh & SEv

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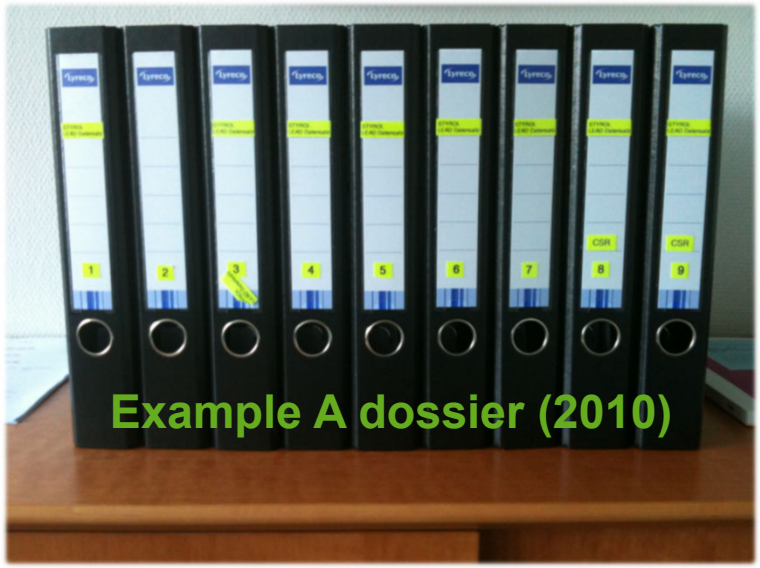
# Dossier update process is complex for industry

- Communication is key factor
- Time-consuming negotiations in consortia (particularly now for dossier improvement)
- Continuous development of IUCLID versions
- Continuous development of regulatory benchmarks (i.e. new guidance documents, new study protocols, changes in information requirements)
- Different interpretation of legal text, scientific arguments and guidance documents
- Different approaches to data gap filling, exposure assessment, CSR preparation etc.

# Example I: Complexity of dossiers




- **Example A:** REACh Technical Dossier (2010)
  - > 4,200 pages
  - > 600 references
- 3 updates: CSR increased from 819 to 865 pages (2017)
- eSDS:
  - 68 pages, 54 pages thereof: use information & scenarios
  - after updates : 90 pages, 71 pages thereof: use information & scenarios
- **Example B:** read-across justification (tox); category
  - 2013: 45 pages
  - 2016: 51 pages
  - 2017: 102 pages after publication of read-across assessment framework (RAAF) and discussion with EChA

**Many dossiers are complex; adaptation of current standards takes time**



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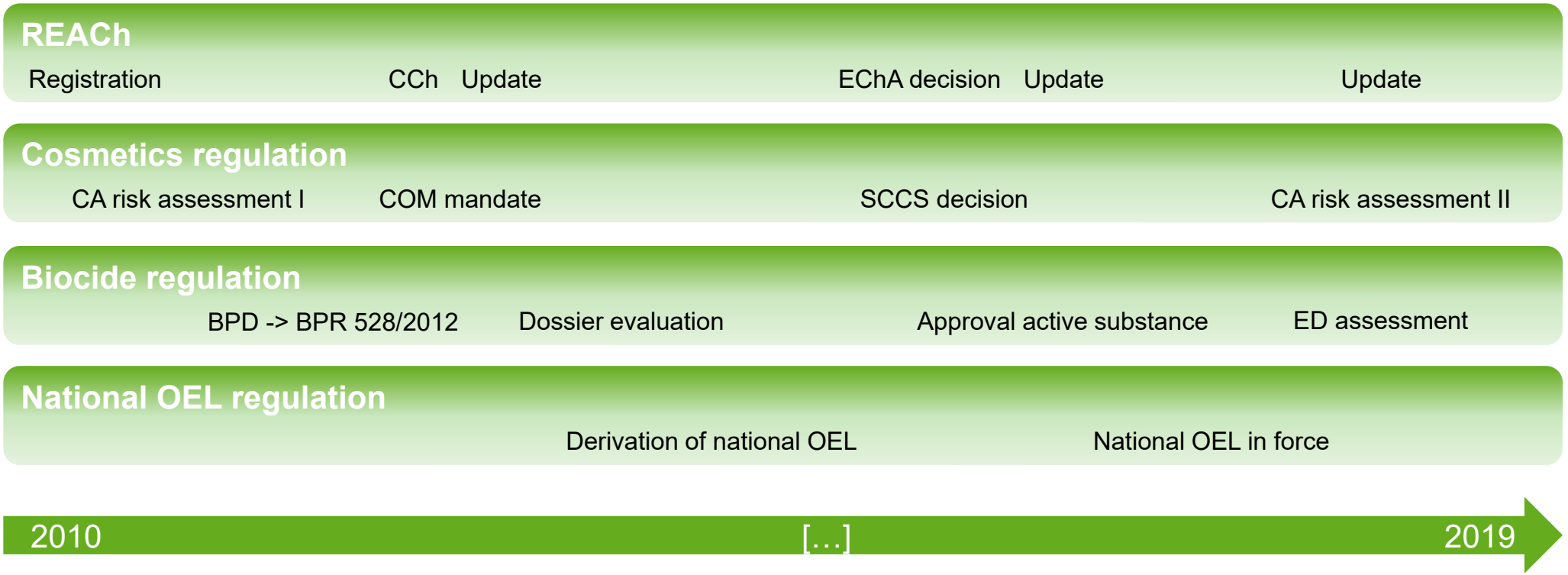
# Example II: Dossier improvement & safe handling of chemicals

- **Example A**: Improvement of category read-across justification (tox) from 45 to 102 pages
  - No further substance-specific data or use information were required or generated
  - Safe-levels (e.g. DNELs/PNECs etc.) and C&L was not changed
  - Category, data and justifications were discussed with authorities and accepted
  - **Conclusion: formal requirements were fulfilled, but risk assessment of category members was not changed**
- **Example B**: Improvement via new studies after non-acceptance of read-across justification
  - Results of new studies confirmed formerly non-accepted read-across arguments

**Adaptation to current standards does not necessarily lead to change in risk assessment and RMM**

# Example III: Other regulations possibly interfere with REACh

Example: substance used under REACh, as cosmetic ingredient and as biocide




**REACh updates are influenced by other legislations (e.g. safe levels)**
**Harmonization (e.g. AF) and adequate update frequencies increase efficiency**

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# Dossier quality and further steps

# Quality of REACh dossiers

Analysis of 1st retrospective UBA/BfR study (2018) based on a sample of 88 BASF SE LEAD dossiers

- Example Toxicology:
  - 4 categories: developmental tox; reproduction tox; mutagenicity; repeated dose tox
  - Manual check of each shortcoming claimed by BfR/UBA

| Result | % dossiers | % dossiers |
|---|---|---|
| Already addressed via update (>03/2014) | 39.5 | **80.2** |
| Substance under current CCh/SEv – update in preparation (2019) | 18.5 | |
| No shortcomings claimed / complex | 22.2 | |
| Claimed shortcomings not addressed, yet | 19.8 | **19.8** |

**>80% of LEAD dossiers meet quality standards (tox)**

**Focus for further dossier improvement**

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# Further steps to improve dossier quality

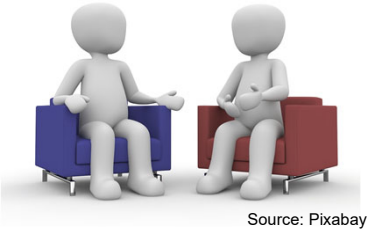
- Multi-annual (2020-2027) action plan to improve quality of REACh dossiers
  - Cooperation agreement between Cefic and EChA
  - Focus on substances located in „uncertain“ (=non-decided) pool of EChA‘s chemical universe
  - Improvement in close coordination with EChA

cefic ECHA EUROPEAN CHEMICALS AGENCY

Source: Pixabay

- Pilot project of volunteering companies (3) and EChA
  - Joint discussion of exemplary improvement strategies
  - Learning for industry, associations and authorities

# Summary



Source: Pixabay

- REACh is a success story: it increased the availability of safety information for chemicals
  - REACh is an enormous investment for industry
  - There has never been such an achievement by any chemical regulation in the world. We should be proud of what has been accomplished by legislators, authorities and industry.
- „*Dossier quality*“ is **no synonym** for „*safe handling of chemicals“ or „compliance“*
  - Standards are under continuous development; registered chemicals are handled safely despite ongoing discussions between industry and authorities
  - Communication, adequate consideration of industry input, increase of practicability and decrease of bureaucracy will make another success story for authorities, legislators and industry

# Concluding remark

- Increase of regulatory benchmarks
  - reduces speed and efficiency of updates
  - increases complexity and resource requirements (industry & authorities)
- The safety of chemicals should be the focus of updates: **Balance** between formal and science-based requirements as well as **constructive interaction** between registrants, associations and regulators required
- Balanced risk communication required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