October 2nd - 3rd

INTERNATIONAL CHEMICAL CONFERENCE 2018

CIS Center Russia

ASTANA

EU CHEMICALS REGULATIONS - REACH/CLP/BIOCIDES STATUS, CURRENT AND FUTURE ACTIVITIES

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Brexit; Titaniumdioxide; Ethanol

Enforcement Projects

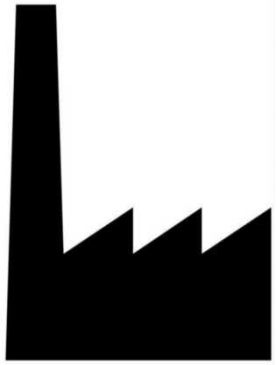
Source:Pixabay

REACH
Pre-Registrations vs. Registrations

Pre- Registrations*/ Substances/ Companies	Registrations (Chemical Safety Reports)	Substances	Substances by Country
2.7x 10^6 */ 146,000/ 65,000	89,000	21,500** EU: 95% Non_EU: 5%	Germany: 50%; UK: 14% USA: 27%; China: 15%

***Incorrect pre-registrations**: 40,000
- Non EU manufacturer/importer
- Wrong identification
- Not necessary according to annexes IV or V or since mixtures

** Estimation for registrations (2008): ca.30,000



General Deadline for Pre-Registrations. May 2008
Deadline for Registrations: May 2018

What is happening after the Countdown May 2018?

- **Sun set** for 10 year registration transition period: May 2018

Source: Pixabay

REACH Reg. in total still to be complied with

- **Consequences:**

Non-registered substances: **Immediate registration** if ≥ 1 t/a (e.g. if not exempted (e.g. cosmetics)

"No data- No market"

Continual Requirements

- Control of production/import volume
- Check of **registration status** for purchased substances
- **Update** of registration dossiers/ Chemical Safety Reports (e.g. new test results)
- Compliance with restrictions (Annex XVIII)

Authorisation/Restriction

- Substances with **SVHC*** properties: **C**arcinogenicity, **M**utagenicity, **R**eproductive toxicity: **P**ersistent, **B**ioaccumulative, **T**oxic **S**ubstances (PBTs)
- **No lower tonnage level**
- **Candidate list**: 191 substances (Sept. 2018)
- After decision→ Authorisation (time-limited); Restriction (unlimited)
  e.g. several phthalates

- **Annex XIV (Authorisation list)**
- **ATP: Reg. (EU) 2017/999**
  12 new substances → 43 substances, e.g. pitch, coal tar, high temp. CAS No: 65996-93-2:

Requirement: Application for authorisation by Manufacturers/Importers.

Latest application/use date: 4 April 2019; sunset date: Oct. 2020

After consultation and decision → Annex XVII

* **S**ubstances of **v**ery **h**igh **c**oncern

Restrictions: Existing (1)

- **Annex XVII**: Authorisation only for certain identified uses (e.g. as intermediate) or Restriction

Consequence in supply chain: threat of withdrawal of certain substances

List of several hundred chemicals restricted concerning

- Manufacture; Marketing (Consumer use/selfservice, e.g. textiles with certain azodyes releasing carcinogenic substances)

- Last ATP: No 2018/675 (2 May 2018)

Restrictions: Existing (2)

- **Special uses,** e.g.:
  Vinylchloride as propellant in sprays,
  not as monomer

- "**Lead** and its compounds shall not be placed on the market or **used** in any individual part of **jewellery articles** if the **concentration** … is equal to or greater than **0.05 % by weight**"

Source: Pixabay

Restrictions: Intentions

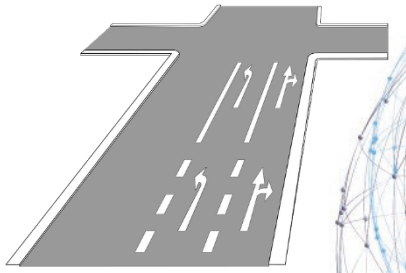
Registry of restrictions intentions:

Proposals for restrictions of substances in the candidate list by member states): at the time being: 47 substances e.g. Nonylphenol & ethoxylated deivatives

Consultation Procedure:

→ annex XVII after discussion and agreement, e.g. Lead and lead compounds in articles intended for consumer use (ongoing)

SVHC Roadmap



Source: Pixabay

- **An Action Plan for Identification** of a **large number** of substances for relevance as **SVHC**, i.e. for potential Authorisation/Restriction.

- **Goal until 2020**: Performance of Risk Management Options for 440 Substances including the currently identified SVHCs (CMRs, PBTs, vPvB*s, equivalent concern such as endocrine disruptors or sensitisers

* (very) persistent/bioaccumulative

Safety Data Sheet (SDS)

- Requirements for SDSs: REACH §§ 31-33 and Annex II (=Reg. (EC) No 2015/830)
- End of transition period (May 2017) concerning full compliance with GHS/CLP-classification and labelling
- Discussion on adaptation of the Reg. (28.09.2018)

  - Update according to GHS revision, CLP and Nanos

REACH Review (1)

- Report of EU-Commission March 2018
- Conclusion:

  - Regulation fulfills principally goals for protection

- Proposals for improvement:

  - Quality of registration dossiers
  - Quality and efficiency in practice of SDSs
  - Simplification in authorisation and restriction process
  - Equal competition conditions for EU and Non-Eu states

Report with robust conclusions: 2022

REACH Review (2)

- Extension for testing for production band 1-10 t/a and for polymers
- **Requirements of industry:**
- Support for SMEs
- Registrations: Acceptance of test results based on alternative methods
- Authorisation/Restrictions:
  - Simplifications for procedures, especially for small product volumes
  - Optimising interplay of restriction vs. authorisation

Benefits and Costs

Benefits: Estimation of potential benefits
for human health. Better work protection
€ 100 billion for human health over 25-30 y

Costs/Charges: Mainly for Registration &communication
in the supply chain): €2.3-2.6 billion for first
two registration deadlines (2008 up to 2013);
additional costs for authorisation and restrictions.
initial estimation was € 1.7 billion

Source: Pixabay

Regulation No 340/2008 with 4 amendments
e.g.“Implementing Regulation (EU) 2018/895 of 22 June 2018“:

Thoughts on Future Actions

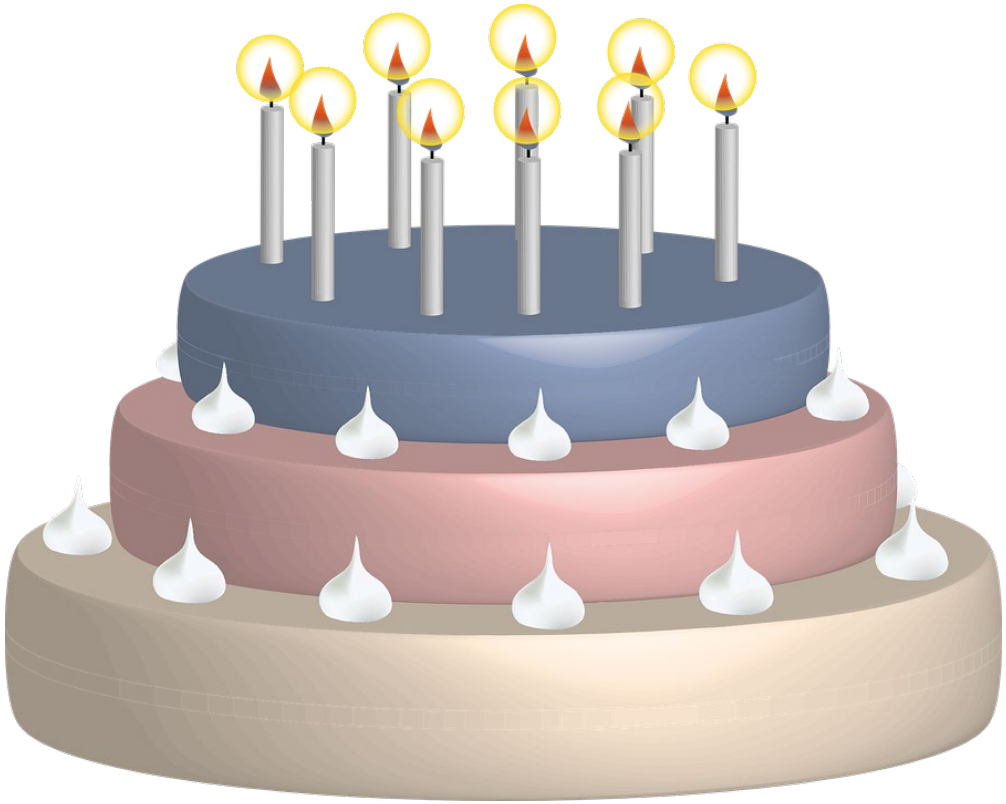
- Consultant Report on “Non Toxic Environment“:
- Identification of “ …need for an additional, overarching framework for protection of human health and the environment from harm of hazardous chemicals, i.e. a framework additional to REACH…“
- Critisims by industry:
- EU has already very stringent regulations
- “The term Non-Toxic Environment is misleading and non-scientific
- “The assessment and management of risk is missing: e.g. measures, safe use

CLP

Regulation (EU) No 1272/2008

(Classification; Labelling; Packaging)

10th Birthday Anniversary

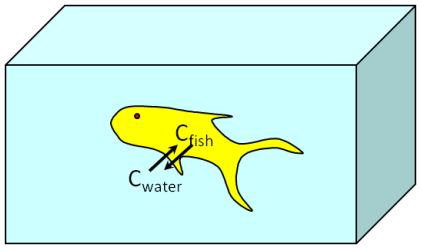


New ATPs with Highlights (1)

8.ATP (**A**daptation to **T**echnical **P**rogress; Regulation (EU) No. 2016/918); applicable latest 1 February 2018): Implementation of UN GHS Rev 5 (2013) Update e.g. of criteria for Skin and Eye effects and revised P-statements

9.ATP: (No.2016/1179); applicable latest 1 March 2018

- Table 3.2 in Annex VI with "old", i.e. non GHs classifications removed.
- New and revised entries with harmonised classification; e. .g.
  - **Copper** (II) oxide; Aquatic Acute and Chronic Category 1 with Multiplication-factor 100
  - **Lead:**
    - - **massive** (particle diameter ≥ 1mm: Generic concentration limit for Reprotoxicity:
      Developmental toxicity Category 1A: 0.3%
    - - **powder(** particle diameter <1mm): Specific Concentration Limit : 0.03%
    - - Several entries for pesticides and biocides



Preference over Generic Conc-Limit

New ATPs with Highlights (2)

- -**10.ATP** (No. 2017/776); applicable latest 1 December 2018: Further harmon-ised classifications; **first time inclusion** of **harmonised ATE-values**; e.g.
- **Nicotine**: ATE*/ LC_{50} ** 0.19 mg/l (dust/mist);

LD_{50}** 70 mg/kg (dermal);

LD_{50} 5 mg/kg

(oral) (Acute Tox.2);

H301+H311+H331 - Fatal if swallowed, in contact with skin and if inhaled

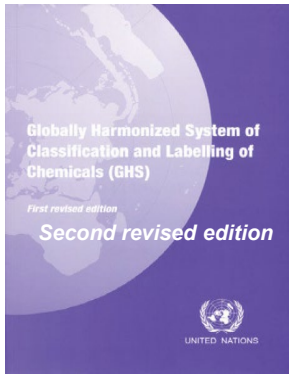
*Acute Toxicity Estimate; **Median Lethal Concentration(Dose

- **- 11.ATP** (No. 2018/69; applicable latest 1 December 2019). Names for the substances in Annex VI Table 3.1 in languages of the EU Member states
- Example Bulgarian: **холекалциферол; Витамин D3** (= Vitamin D3); Acute Tox. Category 2; H301 (inhalation); Category 3 (oral & dermal)

Sources of pictures: Pixabay

New ATPs with Highlights (3)

12.ATP (Draft 08.2018): Implementation of UN GHS Rev 6&7 (Entry into force early 2019 with transition period):



13.ATP: expected publication of draft (autumn 2018)**.**
New and revised entries, e.g. **for**
- isoeugenol: Skin Sens.1A; Specific Concentration Limit: 0.01% (use e.g. as fragrance in perfumes and as spice);
- many pesticides;

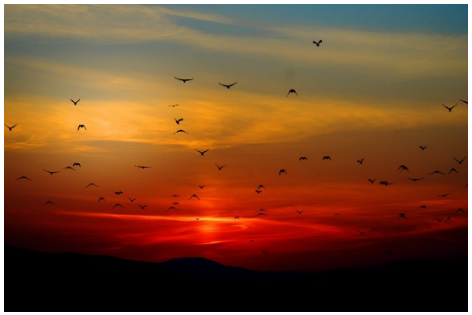
14.ATP: in preparation; new and revised entries with harmonised classification

Source: Pixabay

Conclusion: Continuous update of harmonised C&L for substances with Specific Concentration Limits and ATEs and of the criteria based on GHS-Reviews.
CLP: A living document with REACH feeding the data base for new/revised C&L

Transitional Provisions

Mixtures: Sunset for transitions



Source: Pixabay

- 01.06.2015 Classification & Labelling according to CLP (GHS)
- 01.06.2017: mixtures classified, labelled and packaged according to DPD* and marketed before 01.06.2015, no requirement for relabelling/repackaging

* Dangerous Preparation Directive (67/548/EEC)

Annex VIII

A bureaucratic monster

Poison Centres

UFI (1)
(Unique Formula Identifier)

Reg. No 2017/542

A system for **product categorisation** to be included on labels and in **SDSs**

Information on **hazardous mixtures** for **POISONS Centers**

A **16 alphanumeric code**: **X1AB-C23D-456E-F78G**

- Use of an UFI generator
- **Coding of full composition** including non-hazardous ingredients (ranges)
- Name & VAT-No of the undertaking
- **Application deadlines** for use as :

  Consumer: 2020; professionell: 2021; industrial: 2025

UFI (2)

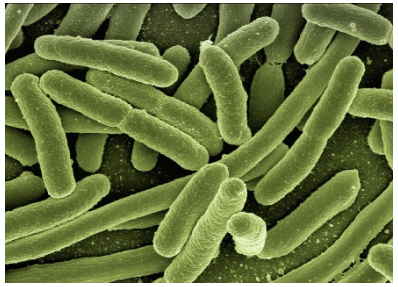
Issues/Problems:

- Central notification portal (ECHA) or national portals?
- Mixtures in mixtures
- Frequent updates of UFIs in case of change of composition/supplier/..
- Consequential update of labels and Safety Data Sheets
- Uncertainty concerning safety of CBI*
- Continuous discussions between Eu-Commission/ ECHA/Member states and industry, e.g. Workability studies for Petroleum mixtures
- Draft Guidance as of 03. 2018, but many changes expected until Dec

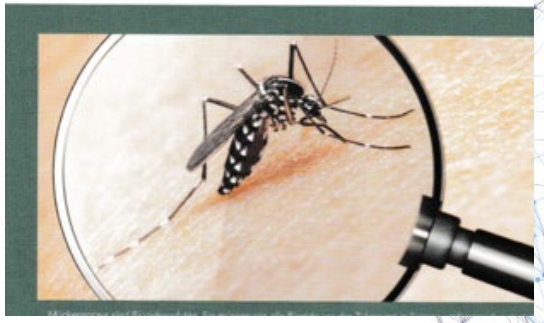
Confusion and high costs

*CBI-Confidential Business Information

Biocides



Source:
Pixabay



Source: VCI

Biocides **P**roduct **R**egulation (EU) No 528/2012
(Consolidated version of BPR: 25 April 2014)

New Features/Consequences

- Drop of important “old” active substances* due to increased regulatory pressure
- Relatively slow development/authorisation of „new“ active ingredients
- Distinctly increased requirements for

  - application

  - testing of health and environmental properties and

  - proof of efficacy

* active substance’ on the market on 14 May 2000

Hot Spots (1)
Brexit

- EU: “No cherry picking“
- Decision on 17./18. November 2018
- Hard Brexit (no agreement): A chaos
  - Desastrous consequences: e.g.registrations no more valid
- Soft Brexit: Mutual Recognition of many existing rules

Possible solution: Transition period until 2020, but only with some kind of agreement. Further negotiations concerning trade etc.

Hot Spots (2)
Titaniumdioxide

- Proposal Carcinogenicity Category 1B by France in 2015
- Discussions and new proposal Carc.2 (inhalation) by EU forum
- Proposal by industry and some member states: No Carc classification
  Rationale: no specific property by TiO2, rather unspecific property of dusts to be tackled via Occupational Exposure Limit and appropriate hazard communication concerning dust exposure

No agreement between member states by now.
Ongoing discussion

Production volume in EU: 1.1 Million tons
Use: Paint and varnishes, pladstics, ceramics, textiles, food, paper, pharmceutical and in cosmetic industry

Source: VCI

Remark: The original proposal with Carc. Cat 1→ Authorisation/Restrictions

Hot Spots (3)
Ethanol

- Proposal of Greece for an entry in the Biocide list with :

  Flammable liquid 2 & Serious Eye Irritation 2.

Request by Germany for completion of the hazard classes: i.e. discussion about

Carcinogenicity, Mutagenicity, Reproductive Toxicity

Remark: Earlier proposals by France and Finland for classifications as CMR:

→ Dropped!

Fitness Checks

European Commission

- Regulatory Fitness and Performance Programme by several EU authorities (REFIT):
- Goals/Processes:
- Indentification, assessment, performance persuit and implementation with respect to simplification and reducing regulatory costs.
- Better regulations by relying on evidence and a transparent process.
- Taking views of citizens and stakeholders into account

Reports on Poisoning & Occupational diseases (2008 - 2017), Effectiveness of CLP Regulation Study on benefits and Cumulative costs

Enforcement Projects (1) (REACH and CLP)

EU Study 2012 (ECHA/ PR 12/33**):** Inspection of 1,200 formulator companies

- **SDSs:** 52 % non compliant
- **CLP-Notification**: 25 % non-compliant

2016: EU Forum Projekt on **Child-resistant fastenings** (e.g. cleaning products, , solvents, thinner, lampoil): 797 inspections: 29% violations of regulations and 17% concerning the product

2015-2019: Sector specific EU program: **Safety Data Sheets** concerning appropriate safety/risk management measures a.o.

2020: New enforcement project to be carried out in 2020:

Focus on **restrictions** and on **CLP labelling** in **internet sales** of substances, mixtures and articles

Enforcement Projects (2) (Biocides)

- CLEEN (**C**hemicals **L**egislation **E**uropean **En**forcement Network) EuroBiocides IIIIn 2015/16 Surveillance of commerce with products treated with Biocides
- In 9 EU member states; 584 controls
- Results:
  - **High rate of non-compliance**
  - **Only 62 % of inspected goods were compliant**
  - In ca. 20 % missing of necessary information on the ingredient biocides
  - Ca.**4 % of the products had to be removed from shelves**

Sanctions

- **Sanctions: Enforcement by Member States**
  (e.g. Germany; Chemicals Law)

  – **Criminal actions**: falsification of submitted data; intentionally concealing: 1-5 years prison and/or penalties up to 100,000 €

  – **Other violations**: up to 50,000 €

Conclusion/Outlook

Advantages for CIS-Companies in complying with EU Legislation:

- ☺ Prerequisite for export business
- ☺ Strengthening competitiveness
- ☺ Proof of international competence

Thus, one relevent requirement to be succesful in EU markets is knowlegde of existing, new and forhtcoming legislation.

Finally a practical advice is to

Check regularly the ECHA website!

Annex

Fees

Source: Pixabay

- **REACH:** Reg. (EC) No 2018/895 for

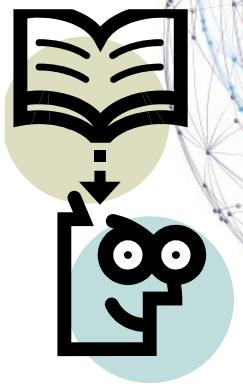
- Pre-Registration: None; Registration: 1.100-26.000 €
- Authorisation: 50.000 € (reduction for small companies)

- **CLP:** Reg. (EC) No 440/2010:
  - Application for alternative name: 400 € (< 10 employees)- 4.000 € (Standard)
  - Proposal for a C&L in Annex VI: 1.200-12.000 €
- **BIOCIDES:** Update of Reg. 427/2013: 1 January 2017
  - National Notification: 300 €
  - Authorisation: 20,000 €
  - Renewal of a substance approval: 185,000 €
  - Reduction for small Biocides companies (20-60%)

Outlook: Intention of EU for possibilities for reducing fees (EU Report 02.2013)

But, as in general life: Prices go up!

Guidance Documents/Help Desks/FAQs



REACH: 21 Guidance documents

- BDI (German Industry Federation)
- Cefic (European Chemicals Industry Association)

CLP:

- IPIECA (The global oil and gas industry association): Guidance on the application of GHS criteria to petroleum substances.

Help desks:

- European: ECHA
- National, e.g. BAUA (Germany) or UK
- FAQs: REACH, CLP, BIOCIDES

Sources/Links

- https://echa.europa.eu/guidance-documents/guidance-on-reach
- *https://echa.europa.eu/**guidance**-documents/**guidance**-on-**clp***
- *https://echa.europa.eu/**guidance**-documents/**guidance**-on-**biocides***
- *https://www.echa.europa.eu/**candidate-list**-table*
- https://www.chemsafetypro.com/Topics/EU/REACH_SVHC_Finder.html

Thank you for your attention!

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