

Для людей и для  
окружающей среды

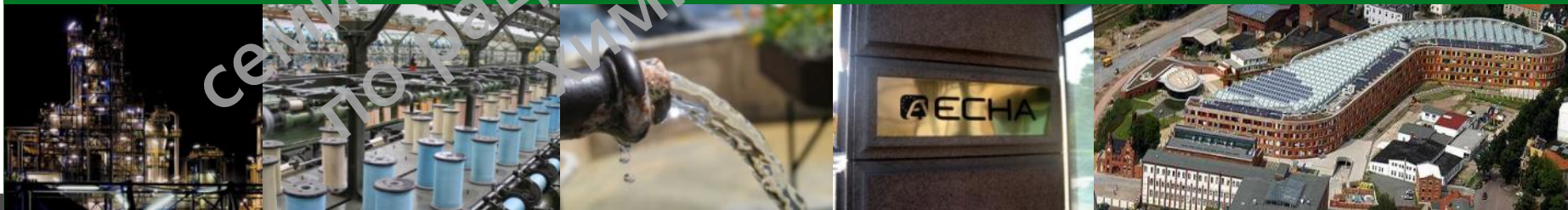
Umwelt  
Bundesamt

# REACH – Regulation of Chemicals in the EU

Chemicals Register in Belarus, Minsk 11-12 May 2017

Штефан Кацан

Немецкий федеральный ведомство по защите окружающей среды (UBA)  
Отдел VI 2.3 – Химикалии



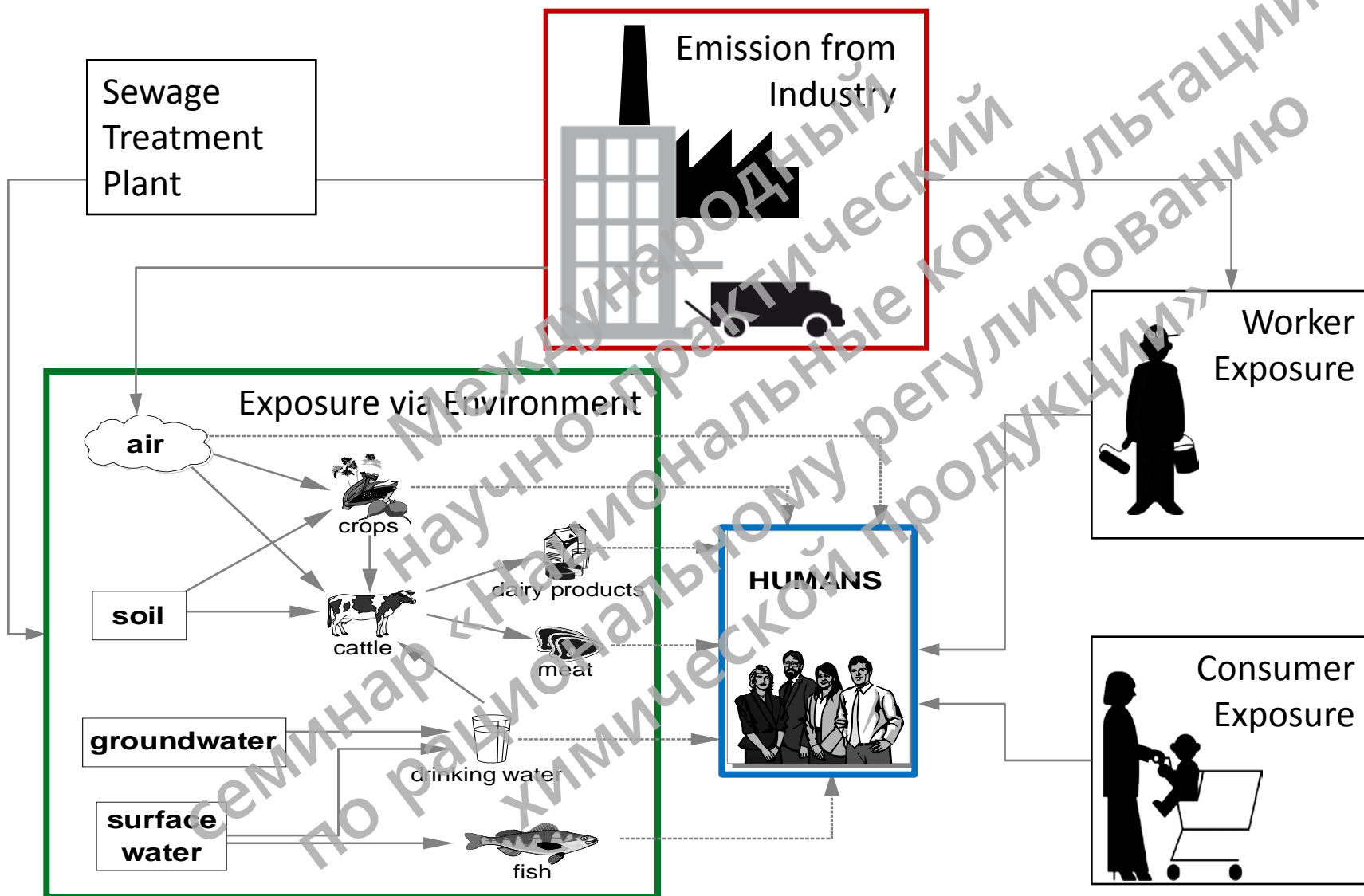
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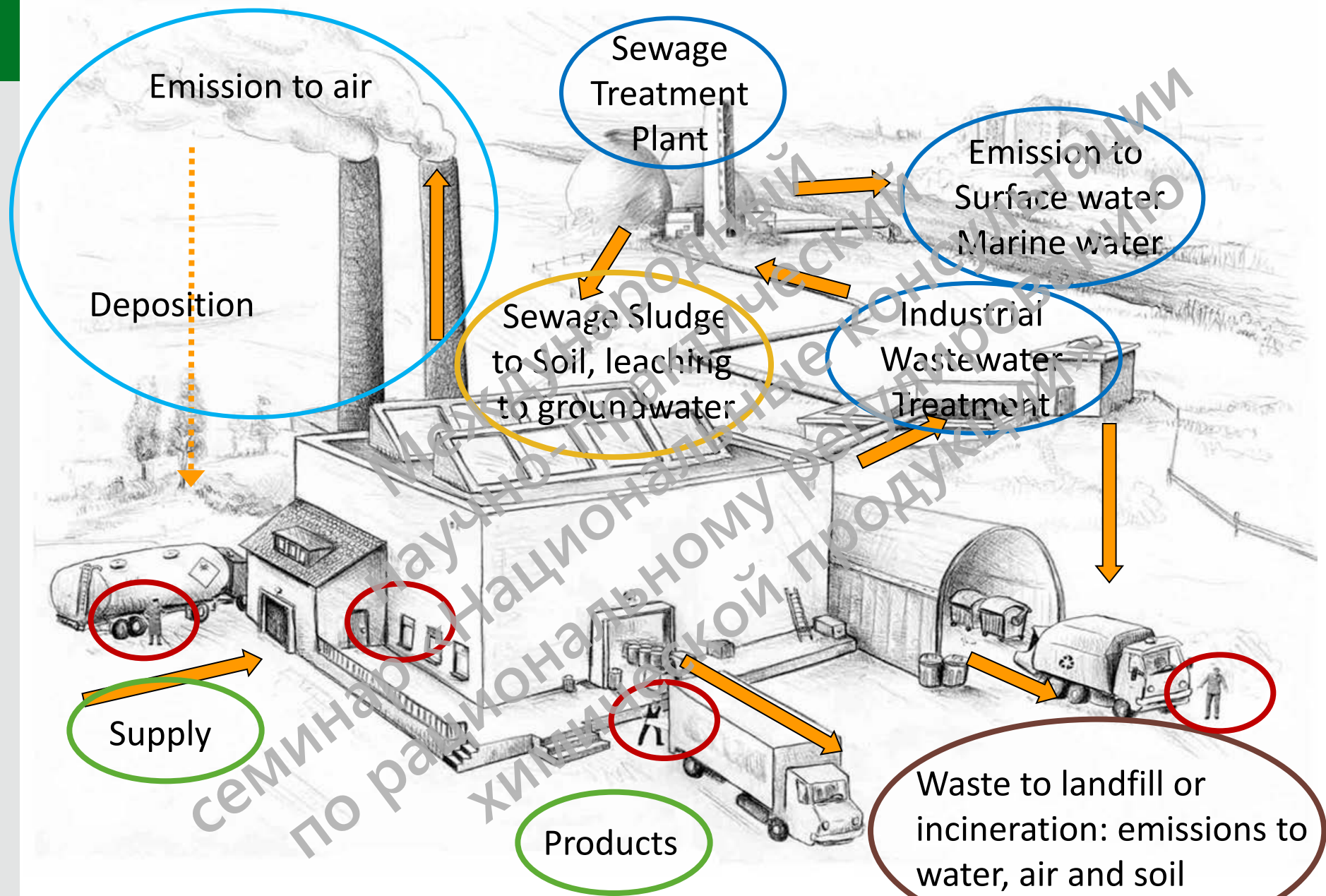
- **Introduction**  
**Вступление**

Международный  
научно-практический  
семинар «Национальные консультации  
по рациональному регулированию  
химической продукции»

## Chemicals are Everywhere



# Different regulations are needed

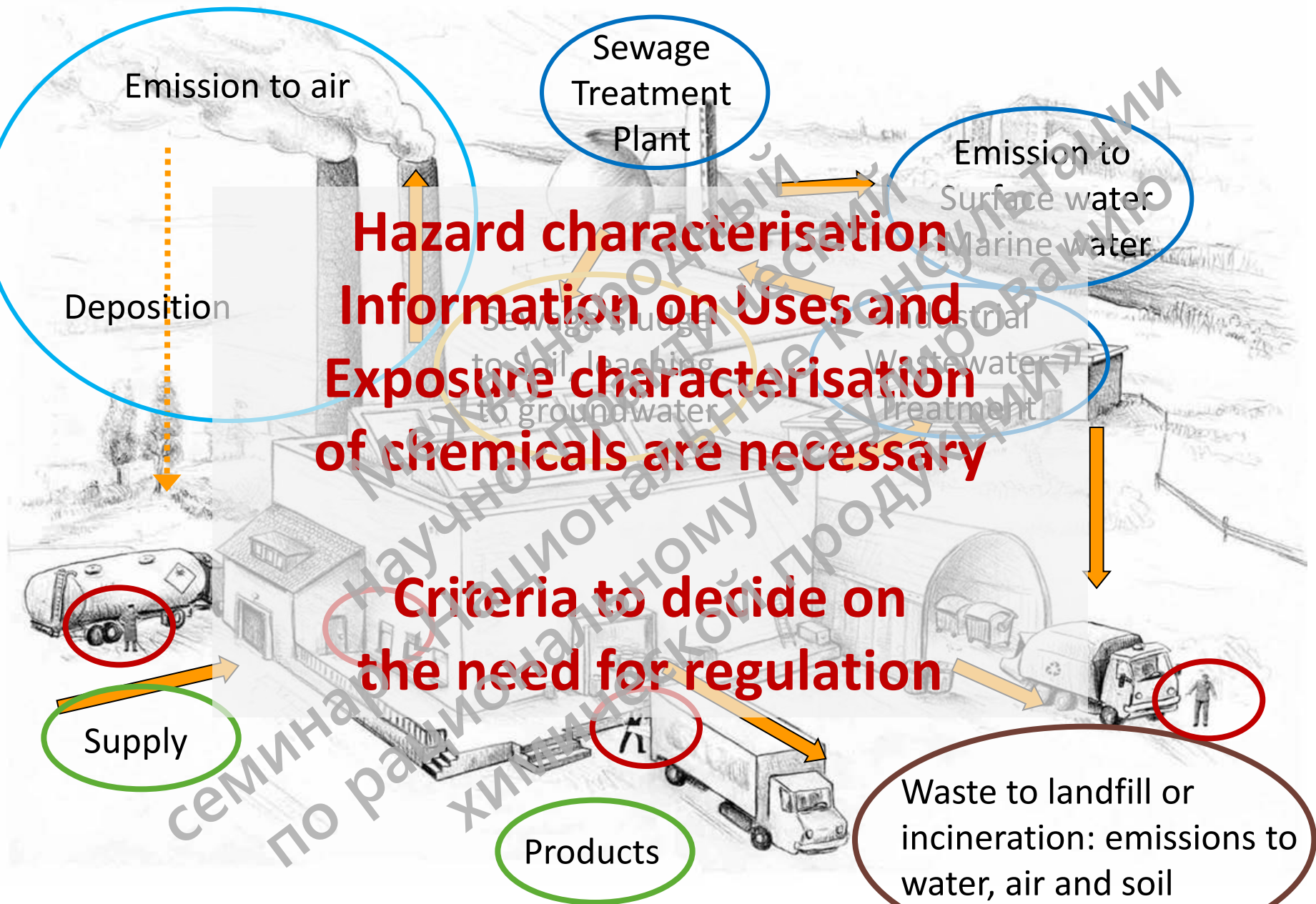




## Different regulations are needed

**Hazard characterisation  
Information on Uses and  
Exposure characterisation  
of chemicals are necessary**

**Criteria to decide on  
the need for regulation**

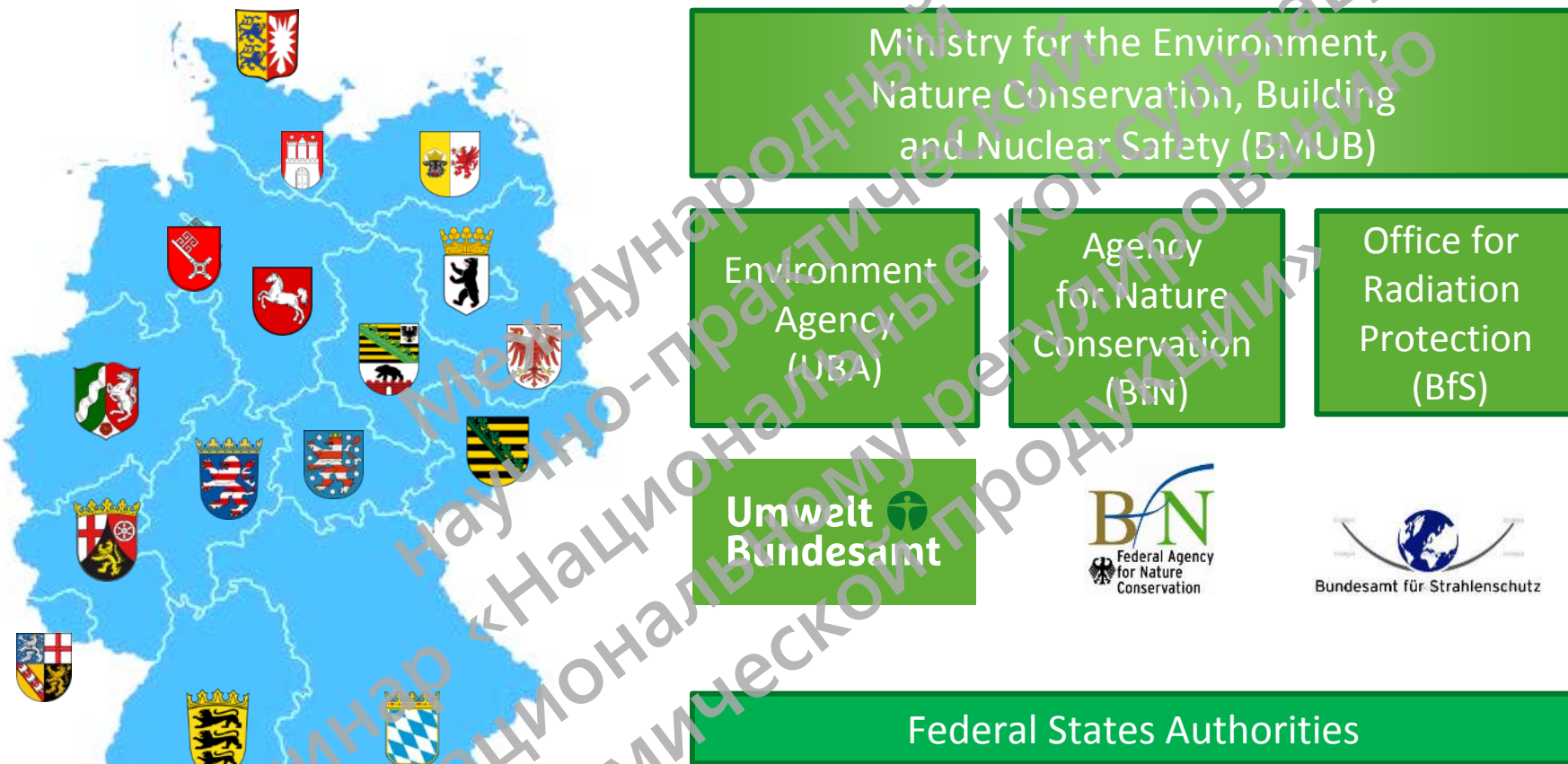


- **UBA**

**Немецкий федеральный ведомство по защите окружающей среды**

Международный  
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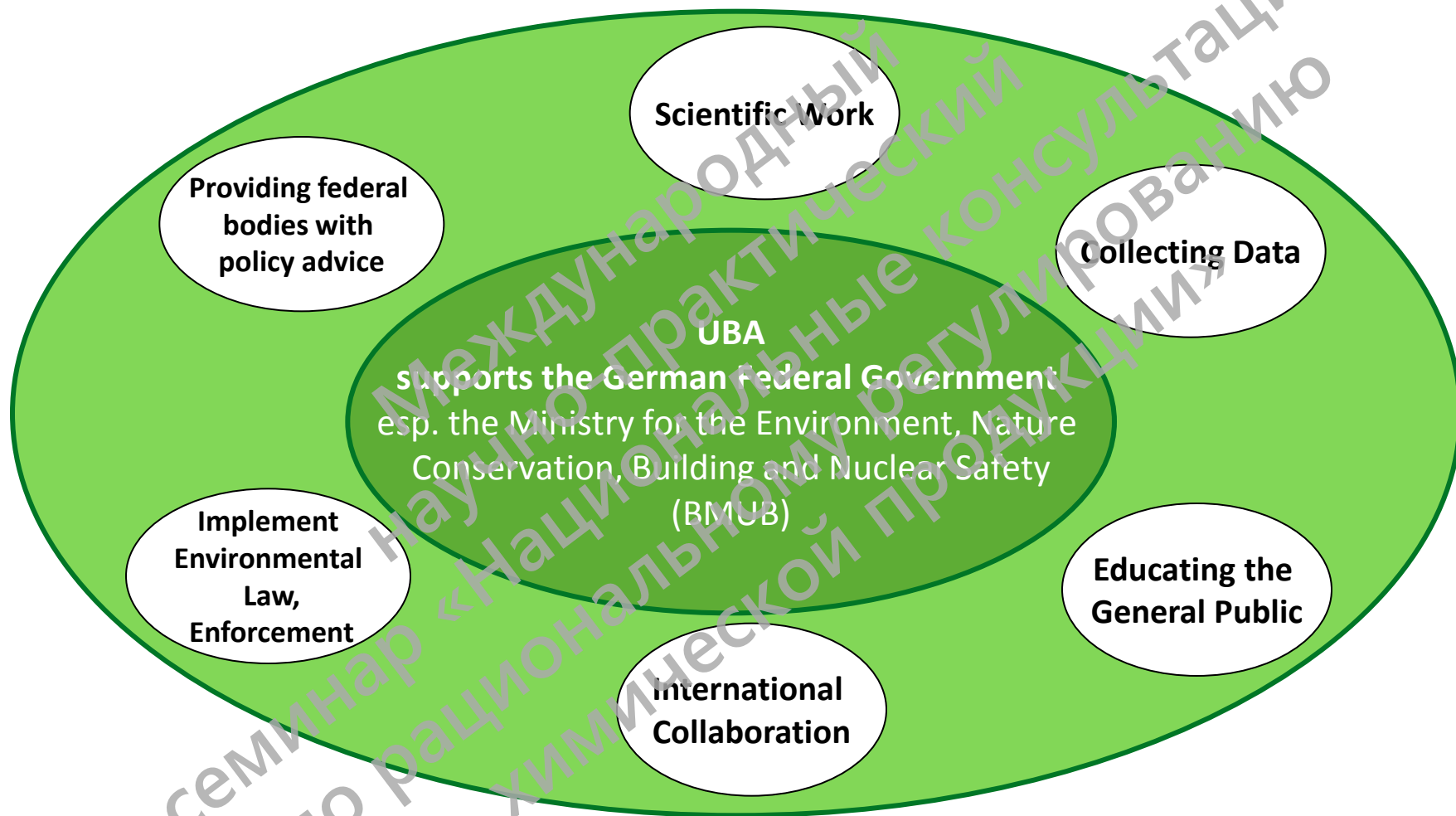
## Environmental Management in Germany







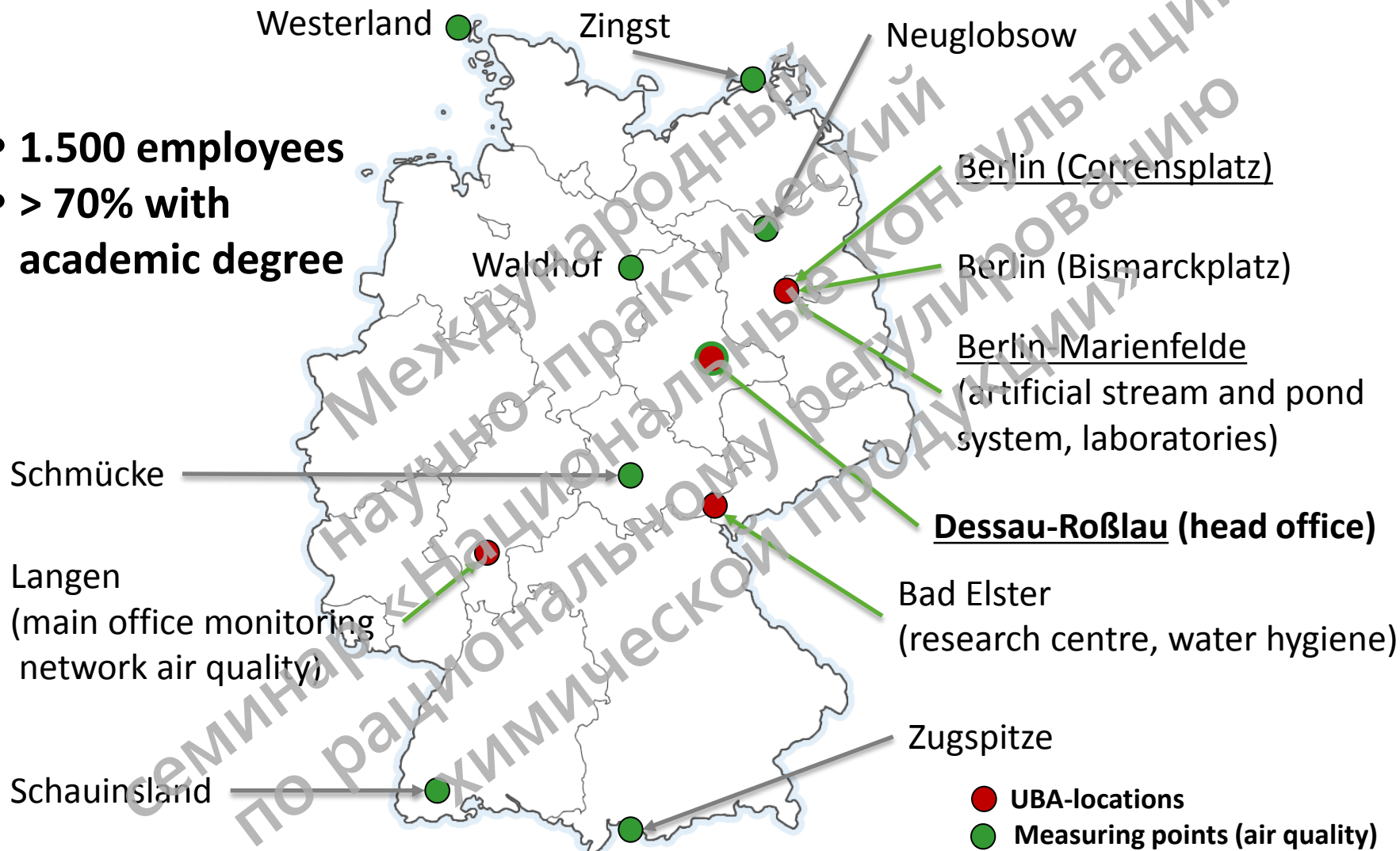
## German Environment Agency - Tasks





## German Environment Agency - Locations

- **1.500 employees**
- **> 70% with academic degree**



## German Environment Agency - Organisation

**Mission** of the German Environment Agency: “Für Mensch und Umwelt”

“Для людей и для окружающей среды”, “For our environment”

**Main Task:** To ensure that citizens have a healthy environment where they are protected against air, water and other pollutants

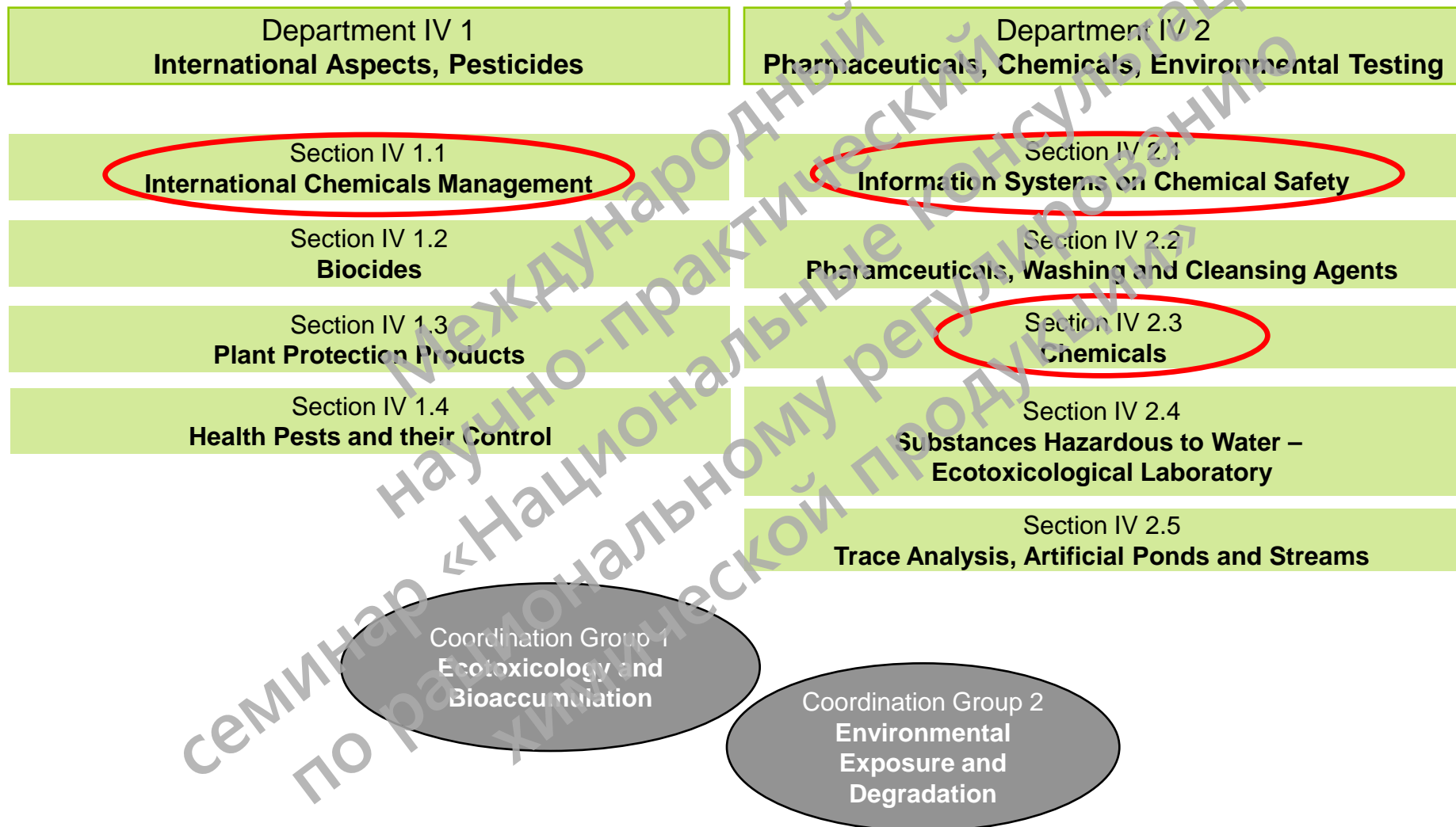
**President**  
Mrs M. Krautzberger

**Vice President**  
Mr T. Holzmann

Central Division Z	Division I	Division II Mrs Lilian Busse	Division III Mrs B. Rechenberg	Division IV Mrs Jutta Klasen	Division E
Budget, Organisation, Human Resources	Environmental Planning and Sustainable Strategies	Environmental Health and Protection of Ecosystems	Sustainable Production and Products, Waste Management	Chemical Safety	German Emissions Trading Authority (DEHSt)



## Devision IV - Chemical Safety



- **Reach - Directive**

**Предписание закона ЕС относительно  
химических веществ**

Международный  
научно-практический  
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химической продукции»



## REACH-Regulation (EC) No. 1907 / 2006



**R**EGISTRATION,

РЕГИСТРАЦИЯ,



**E**VALUATION,

ОЦЕНКА,



**A**UTHORISATION

РАЗРЕШЕНИЕ

(AND RESTRICTION) OF

(И ОГРАНИЧЕНИЕ)



**CH**EMICALS

ХИМИЧЕСКИХ ВЕЩЕСТВ



## REACH – Main Instruments

- **Registration** needs to assess all available information, hazards and risks
- With a registration, companies prove the safe use for the whole life-cycle of a substance (→ Chemical Safety Report CSR)
- **Evaluation** is the task of the Member State Competent Authorities (MSCA) to verify the quality of registrations and assessment
- At least 5% of all registered dossiers are compulsory checked for compliance by the European Chemicals Agency (ECHA)
- Member States select certain substances for substance evaluation (SEv), and nominate them for the Community Rolling Action Plan (CoRAP)
- **Authorisation** and **Restriction** are legal instruments to minimise risks

## REACH Regulation article 1 – Aims of the regulation

### HEALTH & ENVIRONMENT

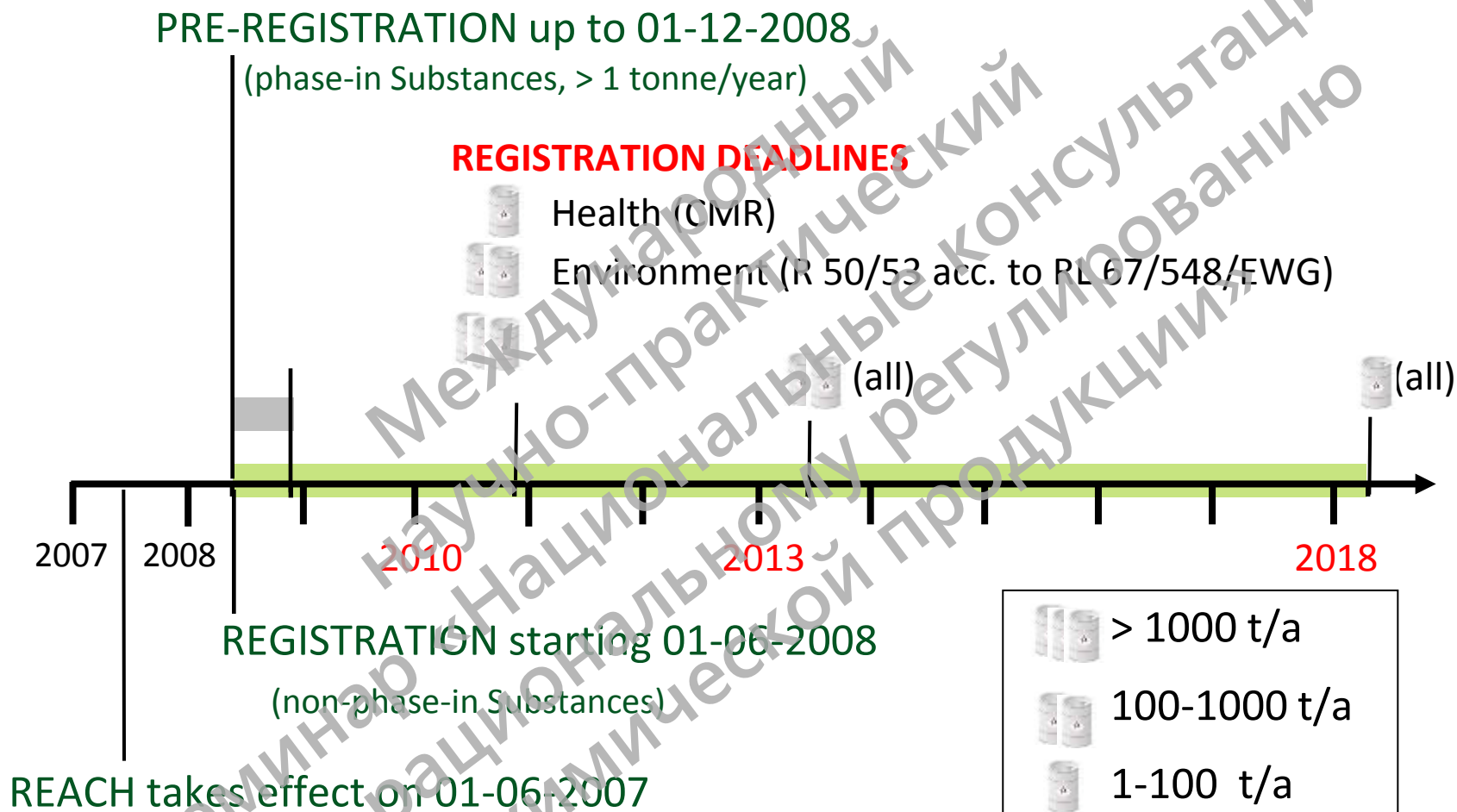


### INDUSTRY & PROFESSIONAL



- Ensure a high level of protection of human health and the environment
- Progressively substitute **Substances of Very High Concern (SVHC)** with suitable safer substances
- **Responsibility to demonstrate safe use lies with the industry**
- Ensure the free circulation of substances on the EU market
- Enhance competitiveness and innovation of the industry
- Achieve sustainable development for the chemicals sector
- Promote the development of alternative methods for the assessment of hazards of substances

## Registration of Chemicals under REACH



Phase-in Substances: either in the market before 1981 or listed in the No-Longer-Polymer-List (definition of Polymers was narrowed);  
Non-phase-in Substances: all others (e.g. substances placed in the market after 1981);

## What does REGISTRATION mean under REACH ?

- The owner of a chemical (Registrant) **notifies** his wish to place a chemical on the European market to the EU Chemicals Agency (ECHA).
- The Registrant provides a **dossier with data** on identification, uses, properties, health and environmental behaviour (→ IUCLID 6).
- The dossier provides the proof for **safe use**.
- The extent of data is **dependent on the yearly tonnage** and certain risk indicators.
- 5 % of all registrations are checked for data **compliance**.
- All substances are screened for **hazardous properties** and possible further regulatory measures.

**Registration under REACH is something different than ...**

***Registration for pesticides, biocides, and pharmaceuticals (~ Authorisation)***

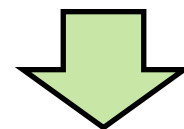


## Regulatory Options

- Chemical Safety Assessment
- Identification as substance of very high concern (**SVHC**)
- **Authorisation**
- **Restriction**
- Classification and Labelling
- Industrial Emission Directive (IED)
- Product Regulations (e.g. for toys)
- EU Water Framework Directive (WFD)
- Workers Protection Legislation
- Restriction of Hazardous Substances Directive (RoHS)
- International (Environmental Agreements, e.g. POP-Convention)

**Risk or Concern?**

**What is the most suitable measure?**



**Regulatory Measures**

## Identification of Substances of Very High Concern (SVHC)

Substances of  
very high concern  
SVHC

... meeting the criteria as CMR category 1A or 1B,

... are **persistent, bioaccumulative** and **toxic** in accordance with the criteria set out in Annex XIII (PBT-Substances),

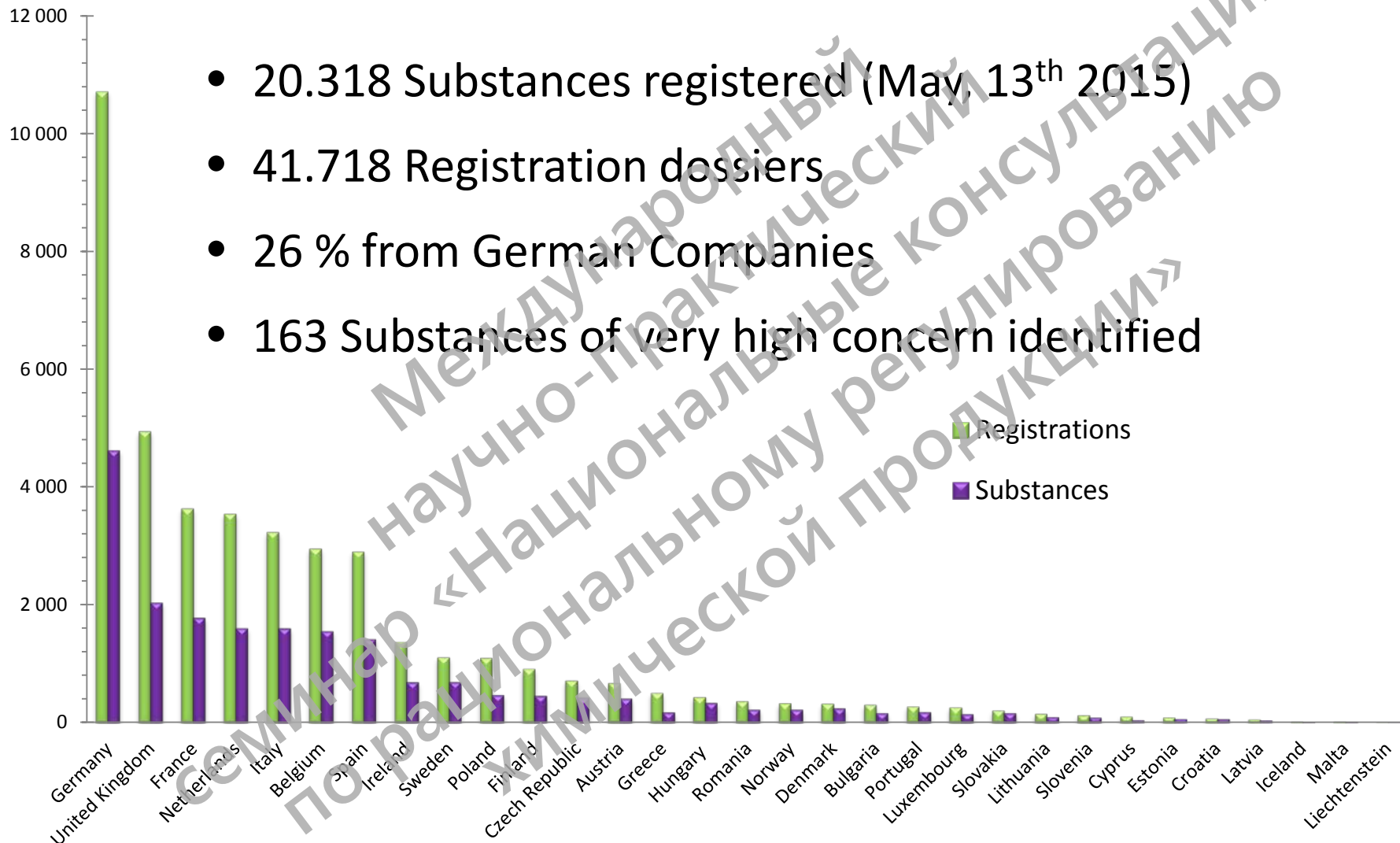
... are **very persistent** and **very bioaccumulative** in accordance with the criteria set out in Annex XIII (vPvB-Substances),

... having endocrine disrupting or PBT or vPvB properties (but not fulfilling the criteria) for which there is scientific evidence of probable serious effects to human health or the environment **which give rise to an equivalent level of concern.**

***Article 57 a) – f) of the REACH Regulation***

## REACH Regulation – Information on chemicals

- 20.318 Substances registered (May, 13<sup>th</sup> 2015)
- 41.718 Registration dossiers
- 26 % from German Companies
- 163 Substances of very high concern identified



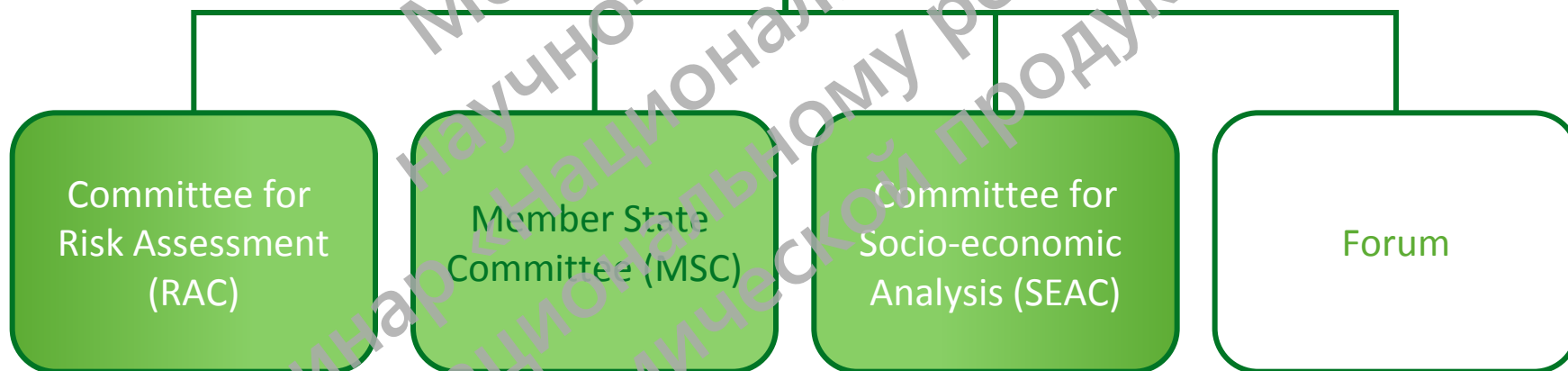
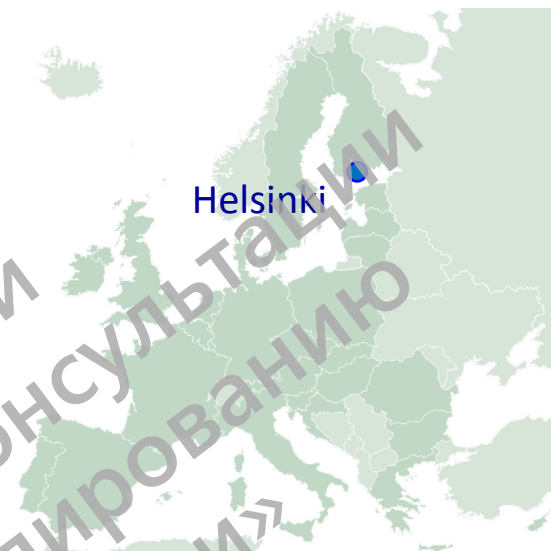


## REACH-stakeholders

Companies	<ul style="list-style-type: none"><li>• Registration of substances</li><li>• Responsible for safe use</li><li>• Communication in the supply chain</li><li>• Application for authorisation</li></ul>
EU-Commission  ECHA European Chemicals Agency	<ul style="list-style-type: none"><li>• Decision-making</li><li>• Center for Registration</li><li>• Review and Evaluation of Registration Dossiers</li><li>• Screening for SVHC</li></ul>
National Authorities	<ul style="list-style-type: none"><li>• Substance Evaluation</li><li>• Screening and Identification of substances of very high concern (SVHC)</li><li>• Proposals for restriction</li><li>• Nominates Members for MSC, RAC, SEAC, and FORUM</li></ul>
Local Authorities	<ul style="list-style-type: none"><li>• REACH enforcement</li></ul>

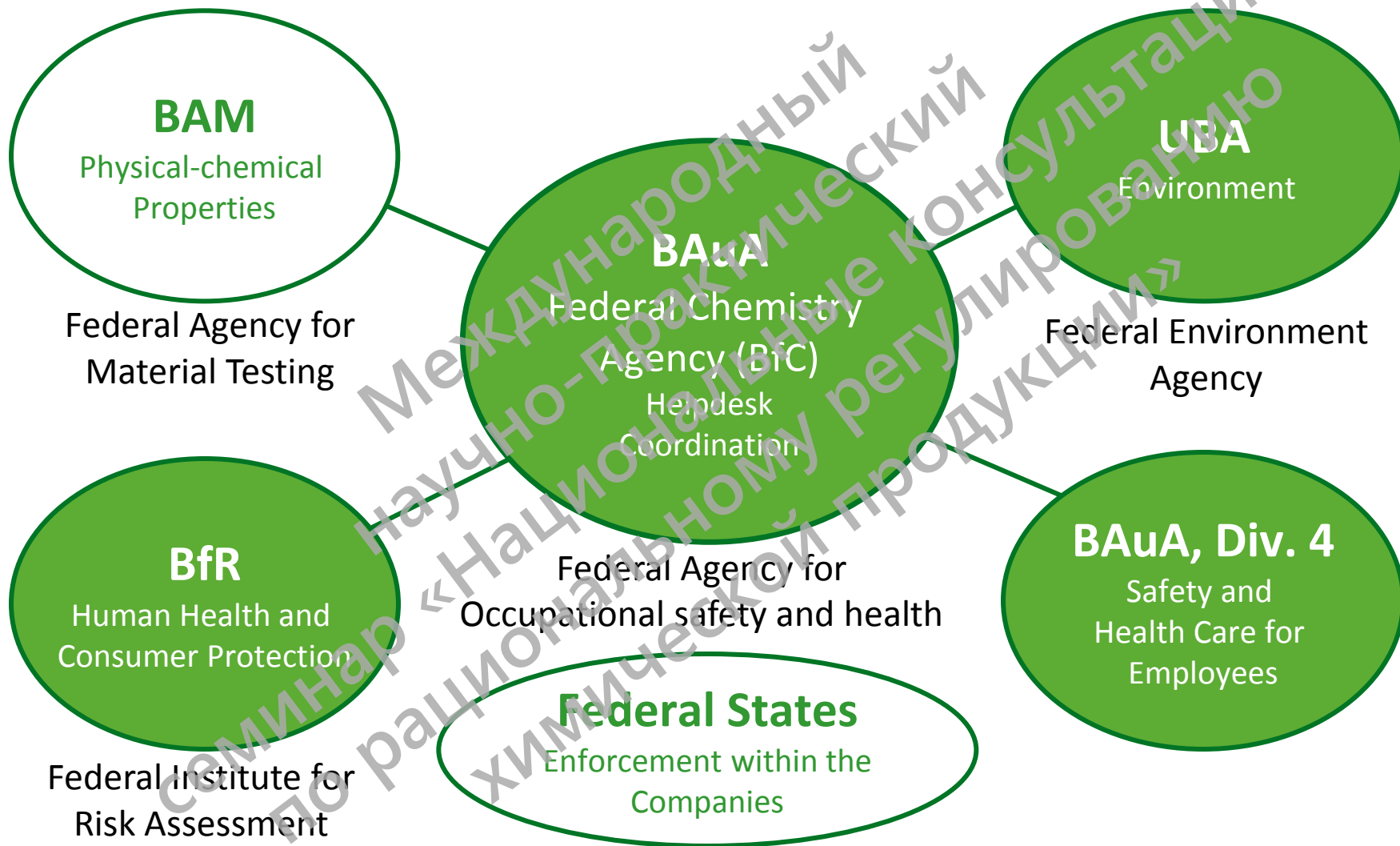


## REACH-stakeholders





## REACH-stakeholders in Germany





## REACH Regulation - Key activities UBA

- Screening, assessment and identification of substances for which regulatory activities are necessary
- Preparing regulatory activities (e.g. Annex-XV-dossiers)
- Substance evaluation - environment
- Developing assessment methodologies and guidelines, e.g.
  - PBT-assessment
  - Development of criteria for endocrine disruption
  - Use of (Q)SAR and read across
  - Ecotoxicological assessment
  - Analysing environmental releases and exposure
- Providing information for the public



## REACH Regulation – Data sources for daily work

- Use of data from Registration dossiers, stored with ECHA
- Use of national and international data bases

**KnowSEC**

G'day, [Nannett Aust](#) (authenticated) [Log out](#) [My Prefs](#)

### Substance Lists of International Organisations

Your trail: Substance Lists of..., Substance Lists of..., Substance Lists of..., SL [Quick Navigation](#)

ICPR 2007 Reine..., Substance Lists of..., SL NORMAN EU Netwo...,  
Dokumentation UFOP..., SL UFOPAN Compla..., Substance Lists fo..., Substance Lists fo...

[View](#) [Attach](#) [Info](#) [Edit Mode](#) [Edit](#) [More...](#) [«](#)

#### Navigation

- Home
- Teams
- Internet Resources
- Glossary
- Administration
- Recently Changed

#### Substance Lists

- International Organisations
- International Authorities
- European Organisations
- ECHA
- European Authorities
- German Authorities
- Academic Institutions
- Environmental Monitoring
- Outcome Test Modules
- Compliance Checks
- EPA Administration
- USA Assessments

#### Support

- HowTo
- FAQ

#### Decision Making

No substance selected

#### OECD "Cooperative Chemicals Assessment Programme"

- OECD HPV Chemicals (List of High Production Volume Chemicals) (2879)
- OECD SIAM Chemicals (List of chemicals with a full SIDS (Screening International Data Set) Assessment in the SIDS Initial Assessment Meeting (SIAM)) (314)
- OECD LPV Chemicals (List of Low Production Volume Chemicals) (24)
- OECD Lists of PFOS, PFAS, PFOA, PFCA, related compounds and chemicals that may degrade to PFCA (ENV/JM/MONO/2006/15) (992)

#### World Health Organisation

- WHO IPCS Chemicals (List of Chemicals of the International Programme on Chemical Safety) (153)
- WHO IARC Group 1, 2A or 2B Carcinogenic to humans, Monographs and risk assessment reports on cancerogenic risk (159)
- WHO IARC Group 3 or 4 Not classifiable to carcinogenicity to humans, Monographs and risk assessment reports on cancerogenic risk (182)

#### Stockholm Convention on Persistent Organic Pollutants (POPs)

- Stockholm Convention on Persistent Organic Pollutants (POPs) (21)
- European Community Implementation Plan on Persistent Organic Pollutants (POPs) (24)

#### Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

- Rotterdam Convention PIC (44)

#### Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal

- Basel Convention (9)

#### Global Automotive Stakeholders Group

- Global Automotive Declarable Substance List (GADSL) (247)

- **Other EU Regulations**

**Дальнейшие регламенты ЕС**

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## Biocide directive



### Biocidal Products Regulation

The Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product.

- › Understanding BPR
- › Legislation
- › Case Law
- › Upcoming deadlines

<https://echa.europa.eu/regulations/biocidal-products-regulation>

### Processes



Companies can apply for the approval or the inclusion in Annex I of an active substance by submitting a dossier to ECHA.

- › Approval of active substances



After the approval of an active substance, companies wishing to place biocidal products on the market have to apply for product authorisation at national or Union level.

- › Authorisation of biocidal products

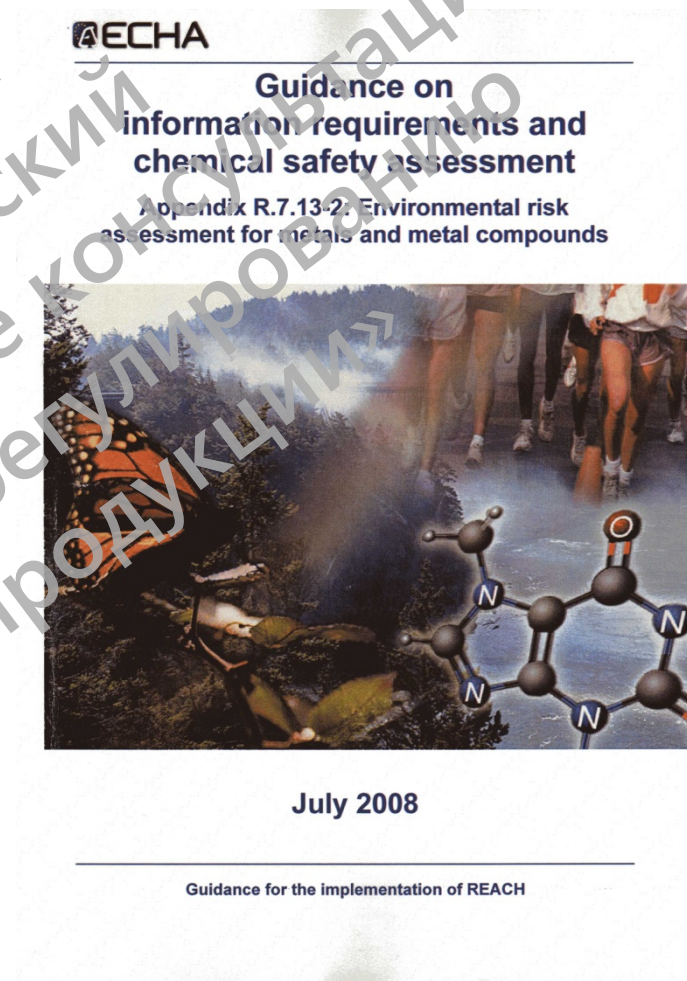




## Regulation for Metals under REACH

### R 7.13-2 Environmental risk assessment for metals and metal compounds

- For metals as single ions and in salts
- For pure metallic forms, alloys and corrosion products
- Not valid for organic metallic compounds
- Special metal properties are considered
- Chapter for exposure- and effect assessment
- Chapter for risk assessment (PEC / PNEC)
- Templates for: assessment of e.g. Cu, Zn, Ni



- **Summary**  
**Резюме**

Международный  
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химической продукции»

# Предписание закона ЕС относительно химических веществ REACH (EG 1907/2006)



## • Цели REACH

- высокий уровень защиты человеческого здоровья и окружающей среды
- принцип предотвращения опасности
- замещение опасных химических веществ и сокращение их использования



## Предписание закона ЕС относительно химических веществ REACH (EG 1907/2006)



- **Новая роль предприятий**

- оценка степени риска для человеческого здоровья и окружающей среды
- идентификация свойств опасных химических веществ
- информация о безопасности должна передаваться на предприятия которые перерабатывают произведенный продукт



## Предписание закона ЕС относительно химических веществ REACH (EG 1907/2006)



- Новая роль государственных органов & ЕСНА (Европейское химическое агентство)

- Поддержка предприятий инструкциями, инструментарием и методами.
- Идентификация химических веществ, использование которых необходимо регулировать
- Инициирование и организация необходимых мероприятий



## ECHA -Homepage

An agency of the European Union

News and Events | Press | Contact | English (en)

**ECHA**  
EUROPEAN CHEMICALS AGENCY

Search the ECHA Website

Advanced search >

About Us | Regulations | Addressing Chemicals of Concern | Information on Chemicals | Chemicals in our Life | Support

ECHA > Homepage

**REACH 2018**

08/05/2017 - News item  
**Got a question about registration? Enrol to the REACH 2018 Spring School**

ECHA organises an intensive REACH 2018 week from 15 to 19 May. Each day, you will be able to ask questions directly to our experts – linked to the topic of the day's webinar. The whole registration process will be covered, including a new webinar on getting your chemical safety assessment done.

**Search for Chemicals** Advanced search

☐ I have read and I accept the legal notice

**REACH 2018**  
REGISTER YOUR CHEMICALS BY 31 MAY 2018

**News**

03/05/2017 - News item  
**Try out IUCLID Cloud online**

You can now get familiar with the ECHA Cloud Services by trying out the new IUCLID Cloud Trial. It allows you to work with IUCLID online without having to install the application.

28/04/2017 - News item  
**Chemical products with old labels off the shelves by 1 June 2017**

Are you selling products containing hazardous chemicals? Companies must classify, label and package their hazardous chemicals appropriately before placing them on the market.

28/04/2017 - News alert  
**Six opinions adopted by the Biocidal Products Committee**

The Biocidal Products Committee (BPC) has adopted opinions supporting the approval of two active substances for use in biocidal products used as disinfectants for human and veterinary hygiene.

27/04/2017 - News alert  
**List of active substances in the Review Programme updated**

The list of biocidal active substances to be evaluated by Member States has been updated. Substances no longer supported in the Review Programme must be phased out by 4 November 2017.

25/04/2017 - Press release  
**All known substances of very high concern being tackled**

With three years to go before the target of having all relevant currently known substances of very high concern on the Candidate List, progress is on track. All substances for which there is sufficient information on the hazard properties have already been addressed. The focus now is on getting more data on other substances of potential concern, to enable the Agency and the Member States

**CLP 2017: ACT NOW!**

- > REACH-IT
- > IUCLID
- > CHES
- > R4B
- > SPC Editor
- > ePIC
- > ECHA Cloud Services
- > QSAR Toolbox

<https://echa.europa.eu/en/home>



## Принимать домашние сообщения

- Люди подвергаются воздействию химических веществ различными путями: во время работы, через потребительские товары, через окружающую среду и т. д.
- В зависимости от цели необходимы разные данные: Безопасное рабочее место, устойчивые и здоровые потребительские товары, экологически безопасная промышленность, чистые реки и т. д.
- UBA играет важную роль в области охраны окружающей среды и здоровья на национальном и международном уровнях
- UBA готов оказать поддержку наращиванию потенциала Беларуси, например, Проектов сотрудничества, обмена персоналом.



**Благодарю за внимание!**  
**Thank you for your attention!**

**Dr. Stefan Kacan**

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[www.umweltbundesamt.de/en](http://www.umweltbundesamt.de/en)