

# **ECRAN Regional Workshop on Compliance with REACH/CLP Regulations**

## *REACH/CLP IMPLEMENTATION AND ENFORCEMENT IN BULGARIA*

*14 – 15 OCTOBER 2015  
IZMIR, TURKEY*

### Outline

- *Legal framework*
- *Competent/enforcement authorities*
- *Administrative capacity and resources*
- *Organisational structure and competencies*
- *Enforcement strategy*
- *Documents and tools*
- *Recent FORUM developments*
- *Interlinks with other legislation*

## Legal framework

- **Law on protection against harmful impact of chemical substances and mixtures (Bulgarian Chemicals Act)** (SG/10 of 2000, latest amend. SG/84 of 2012, ongoing amendments),
- **Council of Ministers' Decree for implementation of REACH restrictions** of manufacture, placing on the market or use of certain hazardous substances,
- Ministerial Order No. 250 of 8.04.2009 for adoption of **Strategy and Guidance for REACH Enforcement in Bulgaria** (currently under development)

## Measures for implementation and enforcement of REACH and CLP

### **Chapter V “Measures for Implementation of REACH and CLP”, Chemicals Act**

- **Minister of Environment and Water-** designated as a national **competent authority** to perform the tasks allotted to it in **REACH (2007)** and **CLP (2010)**
- **Expert Committee on Substance Evaluation (2015)-** appointed by the MoEW to perform the tasks on substance evaluation, proposals for identification of substances of a very high concern (SVHC) for authorisation, restrictions or harmonisation of classification and labelling of hazardous substances under REACH and CLP
- **National REACH (2007) and CLP (2010) Helpdesk (Hazardous Chemicals Department)-** advice and assistance to industry, esp. SMEs for performing their obligations



Стратегически документи

Законодателство

Химични вещества

ОВОС

Екологична оценка

Комплексни разрешителни

Екологична отговорност

EMAS

Екомаркировката на ЕС

Съобщения

Полezni връзки

[ПРЕВАНТИВНА ДЕЙНОСТ](#) | [ХИМИЧНИ ВЕЩЕСТВА](#) | [НАЦИОНАЛНО ИНФОРМАЦИ](#)

**Националното информационно бюро по химикали е създадено с цел:**

- да осигурява информация относно **основните задължения на компаниите**, произтичащи от:
  - **Регламент REACH** относно регистрацията, оценката, разрешаването и ограничаването;
  - **Регламент CLP** за класифицирането, етикетването и опаковането на вещества и
  - **Директива SEVESO** за контрол на риска от големи аварии;
- да подпомага компаниите при определяне на **специфичната им роля по** отношение на химикали /вносители, производители, разпространители, потребители по веригата/ и техните отговорности и задължения;
- освен информация относно правните аспекти, експертите от информационното бюро ще отговарят на **прилагането и налагането** на Регламент REACH и CLP на национално ниво.

Често най-бързият начин да намерите отговор на своя въпрос е да проверите в секция "История на въпросите" относно прилагането на REACH и CLP.

Ако не сте открили интересуващата Ви информация:

[ЗАДАЙТЕ СВОЯ ВЪПРОС ТУК!](#)

OneStat.com

**Важно!** Информацията, осигурявана от Националното информационно бюро по химикали е само за информационни цели и не е законово обвързваща. Бюрото не е отговорно за това как индустрията изпълнява горепосочените правни актове.

  СТРУКТУРНИ ФОНДОВЕ  Портал на МС за обществени консултации

## Задаване на въпрос

REACH
CLP
SEVESO

Забележка: Полетата, маркирани със звездичка (\*), са задължителни!

**Контакт**

Лице за контакт: \*

Роля във веригата на доставки: \*

Изберете от списъка...

Адрес за кореспонденция: \*

Електронна поща: \*

Телефон: \*

**Запитване**

Ключова тема: \*

Изберете от списъка...

Въпрос: \*

**Организация**

Тип: \*

Изберете от списъка...

Име на фирма: \*

Адрес на регистрация: \*

Размер на предприятието: \*

Изберете от списъка...

Код по НКИД: \*

Изберете от списъка...

[Изпрати](#) [Изчисти](#)

**Важно!** Информацията, осигурявана от Националното информационно бюро по химикали, е само за информационни цели и не е законово обвързваща. Бюрото не е отговорно за това как индустрията изпълнява горепосочените правни актове.

## Bodies for implementation and enforcement of REACH and CLP



### **Chapter V, Chemicals Act**

- **The Multiprofile Hospital for Active Treatment and Emergency Medicine, “N. I. Pirogov”** under the Ministry of Health is designated (2008) as a **National Poison Centre** under **CLP Art. 45** and responsible for receiving information of the use of hazardous mixtures related to **emergency health response** and formulating preventative and curative measures
- **Executive Agency “Bulgarian Accreditation Service”** is appointed as a **GLP conformity assessment body** for the purposes of REACH and CLP

## Enforcement of REACH and CLP



### **Chapters VII and VIII “Enforcement and Administrative Provisions”, Chemicals Act**

- Powers and responsibilities of the national enforcement authorities (NEAs);
- ‘Effective, proportionate and dissuasive’ penalties for non-compliance of REACH and CLP;
- Cooperation with Customs in relation to the import and placing on the market of hazardous chemicals subject to **authorisation** or **restriction** (final draft of a joint Memorandum of Understanding on market surveillance of chemicals has recently been developed and now under ongoing inter-service consultations);

## Tasks of the REACH enforcement authorities

- **Regional Inspectorates of Environment and Water:** registration, data sharing, communication in the supply chain (focused on production and formulation of chemicals at industrial sites), DUs' duties, authorisation, restrictions (substances of ENV concern);
- **Regional Health Inspectorates:** communication in the supply chain (focused on retailers and distributors placing chemicals on the market), restrictions (substances of HH concern);
- **Executive Agency "General Labour Inspectorate":** access to information for workers, safety and health at workplace involving hazardous chemicals (in particular SVHCs), exposure control at working environment;

## Division of tasks under REACH

In general, enforcement responsibility is determined by the type of REACH duty to be enforced:

- **REGISTRATION RELATED DUTIES**

Environmental Inspectorates (due to the leading role of MoEW as REACH Competent Authority)

- **SUPPLY-CHAIN RELATED DUTIES**

Human Health Inspectorates (until retail sale)

- **PRODUCTION AND USE RELATED DUTIES**

Environmental Inspectorates (safe storage) and Labour Inspectorates (health and safety at work)

## REACH/CLP authorities (1)

- **Ministry of Environment and Water (MoEW)**, acting with the **Hazardous Chemicals Department**, has the policy lead in developing by-law legislation and strategy for implementation and enforcement in the field of chemicals management, incl. REACH
- **16 Regional Inspectorates of Environment and Water (RIEW).**

## REACH/CLP authorities (2)

### **Other authorities involved:**

- **Ministry of Health:**
  - **28 Regional Health Inspectorates,**
  - National Center of Public Health and Analyses,
  - National Toxicological Center,
- **Executive Agency, General Labor Inspectorate** under the Ministry of Labour and Social Affairs (*REACH only*)
  - **28 Regional Labour Directorates**
- **Ministry of Economy;**
- Customs Agency, Commission for Consumer Protection, National Revenue Service and National Statistical Institute.

## Tasks of the competent authority



- to establish and make operational a ***national helpdesk on REACH and CLP***
- to introduce appropriate national ***measures for effective and efficient implementation and enforcement*** of REACH and CLP
- to ***organise and coordinate the national activities*** for REACH and CLP ***implementation***
- to ensure ***proper representation*** in the ***ECHA's Management Board, Committees and the Forum*** and in the REACH Committee

## Tasks of the competent authority (2)



- to select substances (incl. of national concern) from Community Rolling Action Plan for ***substance evaluation*** and formulate and propose appropriate ***RMM(s) (SVHC Roadmap)***;
- to ***cooperate*** with and contribute to the work of other member states in their activities under REACH and CLP;
- to ***communicate*** information on risks arising from the chemicals to the public;
- to provide ***assistance to the national enforcement authorities*** in carrying out their enforcement tasks-participation in national and EU enforcement projects;
- to ***report*** on the implementation and enforcement of the these regulations in the country;

## Administrative capacity for performing the tasks under REACH and CLP

### **MoEW (Hazardous Chemicals Department (2001), Preventive Activities Directorate):**

- **Number of the staff:** 10
- **Professional background:** chemistry, chemical engineering, biotechnology, biochemistry and molecular biology.
- **Number of REACH and CLP experts:** 6 (NHD, REACH&CLP HelpNet, Caracal, REACH Committee, Member State Committee, Forum, Management Board of ECHA)
- **Other tasks:** PIC, POPs, Detergents, Mercury, Seveso, RoHS, Biocides (ENV properties), International Chemicals (PIC, POPs, SAICM, Mercury and Convention on transboundary effects of industrial accidents), participation in a number of working groups/expert committees for preparation and implementation of the national chemicals related legislation, etc.

## Cooperation and coordination

- **Intergovernmental Standing Committee under the MoEW** for implementation and enforcement of REACH- provide advice on policy issues, discuss emerging issues, identify priority substances for evaluation and risk management measures, set out priorities and co-ordinate enforcement activities (mandate to be extended to CLP), Ministerial Order, 2009
- Cooperation with **Customs Authorities** on the import/export of hazardous substances subject to **authorisation** or **restriction**, as well as **registration** duties on imported substances
- **Memorandum of Understanding** for continued and more defined cooperation between REACH NEAs and Customs,

## Coordination and cooperation (2)



- Regular meetings of the regional inspectorates
- Exchange of knowledge and sharing practical experience on enforcement aiming at harmonised and coordinated approach for enforcement
- Participation in trainings of trainers organised by the Forum of ECHA and carrying out follow up trainings for the NEAs
- Carrying out joint inspections, where possible, to reduce the administrative burden address all issues related to the chemical safety

## Enforcement strategy



### **Promoting compliance by:**

- education, help and advice
- range of proactive and reactive interventions backed up by formal enforcement where appropriate
- focus on enforcement of those duties in REACH needed to **effective operation of REACH**

### **Main objectives:**

- Better management and control of chemicals at national level;
- Improve the level of protection of consumers, workers and the environment from exposure to hazardous chemicals;
- Put dutyholders into compliance with the regulation while distinguishing between deliberate and accidental breach.

## Enforcement approach

- **Active enforcement:**
  - Annual inspection plans,
  - Risk based approach for selection of dutyholders and chemicals for targeted enforcement,
  - Topic specific campaigns on (pre-)registration (charcoal, individual submissions, intermediates), SDSs and communication in the supply chain, safe storage of chemicals, restrictions (asbestos in cars, chromium VI in cement, nickel in jewellery, azocolourants in textile and clothes), etc.
  - EU wide and national coordinated enforcement projects.
- **Reactive enforcement:**
  - Information provided by competitors, consumers or other NEAs (e.g. RAPEX notifications, information on imports by Customs)
  - Upon request by ECHA, European Commission or other NEAs MSs;

## Enforcement tools

- Written Advice,
- Official inspection records,
- Administrative interventions,
- Written orders imposing:
  - fines/penalties,
- prohibition for use or placing on the market or withdrawal from the market.

## Enforcement tools (2)



- Inspectors often, in cooperation with the national Helpdesk, provide advice to the companies while their main task remain the enforcement of the legislation.
- Verbal or written recommendations and instructions, especially when no contraventions, or only minor deficiencies are found

## Enforcement documents



- Minimum Criteria for REACH and CLP inspections (Forum, ECHA, 2011),
- Strategies for enforcement of REACH and CLP (Forum, ECHA, 2011),
- Strategy and guidance for REACH enforcement in Bulgaria (MoEW, 2009, under revision),
- General instructions for planning and reporting environmental inspections in Bulgaria,
- Topic specific checklists and guidance documents for REACH inspections,

## Enforcement activities in Bulgaria, 2008-2015



- ‘No data, no market’ enforcement
- Inspection campaigns centred around certain hazardous substances
- EU co-ordinated projects:
  - REACH-EN-FORCE-1* – pre-registration
  - REACH-EN-FORCE-2* – information in the supply chain (SDS and downstream users)
  - REACH-EN-FORCE-3* – registration and only representatives (prolonged in 2014, follow-up actions in the supply chain outside the country)
  - REACH-EN-FORCE-4* – restrictions
- Pilot projects: intermediates, authorisation, child resistant fastenings, etc.
- Reactively driven enforcement issues

## Future activities



Controls of registrations/notifications/authorisation decisions/restrictions,

Participation in the relevant campaigns of the FORUM (REACH-EN-FORCE and pilot projects), continue current targeted and organise new campaigns

Organise training seminars and inform companies on the new responsibilities under REACH and CLP

Promote cooperation with the customs and labour authorities

## Recent FORUM developments – ongoing projects



**1<sup>st</sup> Pilot project** on authorisation of **Musk xylene (5-tert-butyl-2,4,6-trinitro-m-xylene)** and **MDA (4,4'-Diaminodiphenylmethane)** (running phase from 2014 until end of 2015); SD- 21/08/2014

- Continuation of the operational phase (started on 1 January and running until 30 June)
- Participation of 18 countries, 426 inspections planned
- Trainings done in all countries except some with a limited number of inspectors

**2<sup>nd</sup> Pilot project** on substances with a sunset date in 2015 (started in March 2015); the main objective is to build enforcement experience and practices involved in controlling authorisation related obligations;

## Training of enforcement trainers 2015



- **Classification and labelling of mixtures**
- **24-25 September 2015**, ECHA
- Back-to-back one-day **workshop** with participation of both the FORUM and HelpNet members
- Objectives: to prepare and deliver training for trainers in the MSs on **classification and labelling of mixtures** for the purposes of enforcement

## REF-4 Enforcement of REACH Annex XVII Restrictions



### List of restrictions entries proposed for the scope of REF-4:

- **Benzene** (entry 5) in glues for consumers and professionals
- **Asbestos fibres** (entry 6), fibres in articles
- **Cadmium** (entry 23) in plastic materials / packaging, brazing fillers and jewellery
- **Nickel** (entry 27) in jewellery, zippers and buttons
- **Chloroform** (entry 32) in glues for consumers and professionals
- **Azocolourants and Azodyes** (entry 43) in textile and leather articles
- **Diphenylether, octabromoderivative C<sub>12</sub>H<sub>2</sub>Br<sub>8</sub>O** (entry 45), substances and mixtures

## REF-4 Enforcement of REACH Annex XVII Restrictions (2)



- **Chromium VI** (entry 47) in cement and leather articles
- **Toluene** (entry 48) in adhesives and spray paints
- **Trichlorobenzene** (entry 49), substances and mixtures
- **Polycyclic aromatic hydrocarbons (PAH)** (entry 50) in consumer articles
- **Phthalates** (entries 51, 52) in toys and childcare articles
- **Lead** (entry 63) in jewellery

## Topics for REF-5

- **Top 1 - Extended SDS / RMM** – Project combining suggestions from different submitters: consistency of the SDSs with CSRs and supply of extended SDS. Risk Management Measures and Operational Conditions.

## ECHA tools to support control of extended SDS

- **Exposure Scenarios (ES)** are communicated in the supply chain for registered substances for which a CSA including exposure assessment has been carried out
  - 5 years after first registration deadline, the ES remain a **challenge for supply chain communication**:
    - Lack of harmonised format
    - Length and complexity (but also missing uses!)
    - Unrealistic/Inappropriate conditions compared to on-site practices
- *Challenge for enforcement authorities too!*

## Initiatives to improve



ECHA and Stakeholders decided to work together to address challenges:

- **CSR/ES Roadmap**

- A joint action plan towards 2018
- Implementation plans provide details!

<http://echa.europa.eu/csr-es-roadmap>

- **Exchange Network on Exposure Scenarios (ENES)**

- Meets twice a year to identify good practices
- Successful 8th meeting held in May!

<http://echa.europa.eu/enes>

## Focus areas



- **Harmonisation of formats**

- Publication of templates for ES for communication
- Illustrative example of ES

- **Facilitating the electronic transmission**

- ES Communication package = Catalogue of standard phrases + XML format

- **Streamlining the content**

- Include a Table of Content between SDS main body and ES annex based on Structured Short Titles
  - quick overview of ES: e.g. Life cycle stages covered

## Enforcement aspects



Facilitating the verification of:

- ✓ Use coverage
- ✓ Compliance with ES conditions
- ✓ Consistency between registration - supply chain communication
- ✓ Promotion of good practices and advice
- ✓ Feedback 'from the field': practical difficulties with the implementation, additional areas where support is needed, etc.
- ✓ Promoting quality of eSDS. Being key link between REACH and other legislations.

## Interlinks with other legislation



Ongoing processes for improving the interlinks and synergy with other pieces of legislation ():

- **Seveso III** (chemicals hazards in classification of upper- and lower-tier establishments, safety measures for major accidents prevention) and **Environmental Impact Assessment** (EIA) and **Strategic Environmental Assessment** (SEA, land-use planning)
- **Industrial Emissions Directive** (IPPC permits)
- **Water Framework Directive** (Priority Substances)
- **Waste Framework Directive** (Waste Classification, End-of-Waste Criteria)
- **Work safety legislation** (chemical agents, carcinogens and mutagens at work), etc.

**Thank you!**



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