

**Capacity building on compliance with  
chemicals legislation with emphasis on  
REACH/CLP linked to Industrial  
Emission Directive – Technical aspects**

***REACH  
ENFORCEMENT IN BULGARIA***

***ECRAN-TAIEX, 60146***

***SKOPJE,***

***THE FORMER YUGOSLAV REPUBLIC OF  
MACEDONIA***

***1 – 3 SEPTEMBER 2015***

**Outline**

- Legal framework
- Competent/enforcement authorities
- Administrative capacity and resources
- Organisational structure and competencies
- Enforcement strategy
- Documents and tools


## 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

OBOC

Екологична оценка

Комплексни разрешителни

Екологична отговорност

EMAS

Екомаркировката на ЕС

Съобщения

Полезни връзки

**ПРЕВАНТИВНА ДЕЙНОСТ | ХИМИЧНИ ВЕЩЕСТВА | НАЦИОНАЛНО ИНФОРМАЦИО**

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



- да осигурява информация относно **основените задължения на компаниите**, произтичащи от:
  - **Регламент REACH** относно регистрацията, оценката, разрешаването и ограничаването;
  - **Регламент CLP** за класифицирането, етикетването и опаковането на вещества и смеси;
  - **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 предоставят и **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 "И" относно прилагането на REACH и CLP.


Ако не сте открили интересувашата Ви информация:

**ЗАДАЙТЕ СВОЯ ВЪПРОС ТУК!**

*Важно!* Информацията, осигурявана от Националното информационно бюро по химикали е **но 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: \*

Организация

Тип: \*

Изберете от списъка...

Име на фирма: \*

Адрес на регистрация: \*

Размер на предприятието: \*

Изберете от списъка...

Код по НКИД: \*

Изберете от списъка...

Запитване

Ключова тема: \*

Изберете от списъка...

Въпрос: \*

Изпрати

Изчисти

**Важно!** Информацията, осигурявана от Националното информационно бюро по химикали, е

## 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 stuff:** 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,

## BG enforcement activities, 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: intermediated, 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*

**Thank you!**



**PARVOLETA LULEVA**  
*HEAD OF UNIT*  
*HAZARDOUS CHEMICALS DEPARTMENT*  
*PREVENTIVE ACTIVITIES DIRECTORATE*

*MINISTRY OF ENVIRONMENT AND WATER,*  
*BULGARIA*

[WWW.MOEW.GOVERNMENT.BG](http://WWW.MOEW.GOVERNMENT.BG)