

# *Bulgarian experience: harmonisation of chemicals legislation with the EU acquis*

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# Content

- \* Pre- and post-EU accession process and lessons learned*
- \* National measures for implementation and enforcement of the EU Regulations on chemicals*
- \* Duties and tasks of the Member states*

# Pre-EU accession process

## Key objectives:

- ❖ Approximation of the national legislation to the EU acquis- transposition phase, progress monitoring and reporting
- ❖ Strengthening of the administrative capacity and distribution of competences in the field of chemicals
- ❖ Implementation and enforcement of the harmonised chemicals legislation

## Challenges:

- New legislation to replace the old chemicals system was underway at that time (Council and Parliament negotiations on REACH)- observer status
- Complex implementation of the Conventions and EU Regulations (e.g. PIC)
- Lack of practical experience in the old legislation and smooth transition to the new chemicals system (REACH)
- Shortage in the staff during the accession process (Ministry of Health)

# Legal framework before accession

**Law on Protection Against Harmful Impact of Chemical Substances and Preparations, adopted on 20. 01. 2000 (SG 10/2000, as amended in SG 91/2002, 86/2003, 114/2003)**

**Transposes the main provisions of the Community legislation on chemicals in the scope of Environment and Free movement of goods, and sets out legal framework for the implementation of the *acquis communautaire* on chemicals (EU Regulations)**

# Legal framework before accession

## Sub-law enactments:

- Ordinance on classification, packaging and labeling of chemical substances and preparations:

Directive **67/548/EEC**, as amended by **92/32/EEC** on classification, packaging and labeling of dangerous substances and Directive **99/45/EEC** on classification, packaging and labeling of preparations and the relevant provisions of Directive **91/155/EEC** on the Safety Data Sheets. The European Inventory of Existing Commercial Substances (**EINECS**), the European List of Notified Chemical Substances (**ELINCS**), the List of the Chemicals, Classified as Dangerous (**ANNEX I**) are annexed to the Regulation.

# Legal framework before accession

## - Ordinance on the notification of new chemical substances

Transposes the relevant provisions of Directive **67/548/EEC**, as amended by Directive **92/32/EEC** on classification, packaging and labeling of dangerous substances and introduces the requirements for registration of the new chemical substances.

## - Ordinance on risk assessment to men and the environment of new chemical substances

Sets up legal basis for the implementation of the relevant provisions of Directive **93/67/EEC**, laying down the principles of the risk assessment to men and the environment of new chemical substances, notified according to the provisions of Directive **67/548/EEC**.

# Legal framework before accession

- **Ordinance on risk assessment to men and the environment of new chemical substances**

Sets up legal basis for the implementation of the relevant provisions of Directive **93/67/EEC**, laying down the principles of the risk assessment to men and the environment of new chemical substances, notified according to the provisions of Directive **67/548/EEC**

- **Ordinance on bans and restrictions for marketing and use of certain dangerous substances and preparations**

Transposes the provisions of Directive **76/769/EEC** on restrictions on the marketing and use of certain dangerous substances and preparations.

# Legal framework before accession

## - Ordinance on the import and export of certain dangerous substances and preparations on the Bulgarian territory

Creates a legal basis for implementation of the relevant provisions of Regulation EC 304/2003, which replaces Regulation EC 2455/92 on the export and import of certain dangerous chemicals. The regulation introduces the requirements of the PIC procedure for certain hazardous chemicals and pesticides in the international trade.

## - Ordinance on placing on the market of detergents

Transposes the requirements of Directives 73/404/EEC, 73/405/EEC, 82/242/EEC relating to detergents, methods of testing the biodegradability of anionic and non-ionic surfactants.



# Institutional set-up

## - Ministry of Environment and Water

(notification and risk assessment of new substances, import and export of dangerous substances)

## - Ministry of Health

(CLP, biocides, bans and restrictions on the marketing and use)

- 15 Regional Inspectorates of Environment and Water under the MoEW;

- 28 Regional Inspectorates on Protection and Control of Public Health under the Ministry of Health;

# Legal setup and trends nowadays

- Centralised implementation- EU regulations on chemicals
- Comprehensive fitness checks
- Improved interface of the chemicals, products and waste legislation
- Improved interlinks of the chemicals and OSH and ENV legislation
- New EU strategy for chemicals for sustainability and non-toxic environment
- Targeted revision of the EU legislation, including REACH and CLP

Bulgarian experience in  
implementation and enforcement of  
the chemicals legislation

# National measures for implementation of REACH and CLP (1)

## **Competent authorities and implementing bodies:**

- **Minister of Environment and Water-** designated as a national **competent authority** to perform the tasks allotted to it in **REACH** and **CLP**
- **Hazardous Chemicals Department** (2002)– organisation and coordination of all activities for implementation and enforcement of REACH and CLP
- **Expert Committee for SEV and RMM** (2015) - appointed by the MoEW to perform the tasks on substance evaluation, identification of SVHC, restriction or harmonisation of classification and labelling of hazardous substances under REACH and CLP, and where appropriate, elaboration of national measures to control the risk(s) to human health and/or the environment arising from certain substances of a very high concern for human health and/or the environment

# National measures for implementation and enforcement of REACH and CLP (2)

- **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

# National measures for implementation and enforcement of REACH and CLP (3)

***Titles VII and VIII “Enforcement and administrative provisions” of the Chemicals Act lay down:***

- Powers and responsibilities of the national enforcement authorities (NEAs);
- 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*** (Memorandum of Understanding on market surveillance of chemicals);

# National measures for implementation and enforcement of REACH and CLP (4)

- (16) Regional Inspectorates of Environment and Water
- (28) Regional Health Inspectorates
- (28) Regional Labour Inspectorates

## **CLP**

- Regional Health Inspectorates
- Regional Inspectorates of Environment and Water

# Tasks and responsibilities of the national enforcement authorities (1)

## *Distribution of the tasks among the NEAs:*

- ***Regional Inspectorates of Environment and Water:*** registration, data sharing, communication in the supply chain (focused on the 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;



# Tasks and responsibilities of the national enforcement authorities (2)

## ***Cooperation and coordination among the CA and NEAs on REACH and CLP:***

- ✓ Standing Committee for implementation of REACH under the MoEW, Order of the MoEW of 2009
- ✓ REACH Enforcement Instructions, MoEW Order, 2009
- ✓ National Ordinance for Implementation of the REACH Restrictions, EiF 2012 (notified in TRIS)
- ✓ Draft REACH and CLP Enforcement Strategy is under consultation in the WG (MoEW/MH/MLSA), 2012

# Tasks of the national competent authority (1)

- to establish and make it operational a ***national helpdesk on REACH and CLP*** for providing advice and assistance to the industry, esp. SMEs for performing their obligations under the chemicals legislation
- 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 national competent authority (2)

- \* to select substances from CoRAP (incl. such of national concern) for **substance evaluation** and formulate and further propose appropriate **RMM(s) (SVHC Roadmap)**;
- \* to **cooperate** with and contribute to the work of other MSs in their activities under REACH and CLP;
- \* to **communicate** information on risks arising from the chemicals to the public;
- \* to provide **assistance to the NEAs** 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 (1)

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

- **Number of the staff:** 7 personnel
- **Professional background:** chemistry, chemical engineering, biotechnology, biochemistry and molecular biology.
- **Other tasks:** PIC, POPs, Detergents, Mercury, Seveso, RoHS, Biocides (ENV properties), International Chemicals (PIC, POPs, SAICM, Mercury and TEIA), participation in a number of working groups/expert committees for preparation and implementation of the national legislation related to chemicals (e.g. EIA, WFD, air protection, hazardous waste, explosives etc.)

## Administrative capacity for performing the tasks under REACH and CLP (2)

- **Ministry of Health (Public Health Directorate) (Biocides, NEA, BG REACH Standing C'ttee)**
- **National Centre for Public Health Protection and Analysis (Department of Toxicology) under the MH (RAC, NC on TMR)**
- **Ministry of Economy (SEAC, REACH C'ttee, BG REACH Standing C'ttee)**
- **Executive Agency “General Labour Inspectorate” under the Ministry of Labour and Social Affairs (NEA, BG REACH Standing C'ttee)**
- **National Customs Agency**

# Activities on substance evaluation and RMM (1)

- to set out ***Rules of Procedure for the SEV Expert Committee*** based on the updated ECHA's SEV working procedures, templates and guidance documents (State Gazette, No. 83 of 2014)
- to establish the ***SEV EC*** and make it operational, as well as ensure its ***continuous and consistent*** work on SEV, RMOAs and subsequent RMM proposals (external experts in clinical toxicology, carcinogenicity, mutagenicity, ecotoxicology, QSAR, read-across, exposure assessment, etc.)
- to establish a **pool of (external) experts** with specific expertise for the purposes of SEV/RMOA-related to provide proper training for the ***SEV EC, including on experience and lessons learnt*** from the first rounds of SEVs (2012-2014)

# Activities on substance evaluation and RMM proposals (2)

- **Data gathering:** national environmental, epidemiological and (bio)monitoring data for identification of substances of (national) concern
- **Support and training** by ECHA and exchange of view and experience with the MSCAs is needed and welcome
- **Reserved budget** for financing the work of the external experts in the long term
- **Estimated capacity for substance evaluation/RMM:** one substance (per year) as from 2016; 2-3 substances for manual screening; 1-2 substances for RMOAs under the SVHC Roadmap
- **Manual screening** and selection of substances from CoRAP 2016-2018
- Participation in RIME meetings and SVHS Roadmap activities;
- Nomination of new experts in the Risk Assessment Committee (RAC) of ECHA, etc.

# Overview of the MSCA tasks on SEV under REACH

- \* Manual screening of potential candidates for CoRAP (optional)
- \* Selection of priority substances from CoRAP for SEV in accordance with agreed hazard and risk-based selection criteria
- \* Substance evaluation against initially, and where appropriate, additionally identified concern(s)
- \* Drafting proposal for requesting further testing of the substance
- \* Consultation with the registrant, ECHA and other MSCAs
- \* MSC consultation and agreement seeking on the final DD
- \* Follow-up SEV
- \* Follow-up RMM, if necessary and appropriate.





**Thank you for listening!**

**Questions?**

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