CHEMICALS

Risk assessment of chemicals including

<u>Mechanisms for assessment, classification and labeling of chemicals, including initiatives for harmonized classification and labeling of chemicals"</u>

The Global harmonized system for classification and labeling (GHS) was adopted in 2002 from the United Nations Economic and Social Council (ECOSOC) and revised in 2005 and 2007. GHS aims to improve communication regarding dangers for workers, users and responsible persons for emergency safety, as well as in the transport sector through harmonized labels and where appropriate – with safety data sheets. The criteria of the Global Harmonized System for placing on the market and the use of chemical substances have been introduced in the legislation by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures (CLP), which will replace the existing system. The new rules are coming into force for the substances on 1.12.2010 (1.12.2012 for the substances, placed on the market before 1.12.2010) and for mixtures on 1.06.2015 (1.06.2017 for mixtures, placed on the market before 1.06.2015).

In terms of national legislation, the criteria for classification, packaging and labeling of chemical substances have been introduced by the **Law of protection from harmful impact of the chemical substances and preparations (LPHICSP),** Chapter 2. Pursuant to its provisions, any person who markets chemicals must classify them on the basis of their physicochemical, toxicological and ecotoxicological properties, and pack and label them according to requirements in the event that the substance is classified in one or more risk categories.

Regulation (EC) 1907/2006 of the European Parliament and the Council of December 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (**REACH**) introduces the requirement for companies producing or importing chemicals in quantities above one ton per year, to **register** those substances in the new Chemicals Agency in Helsinki. Registration is a requirement for industry to collect and generate a specific set of data on the properties of substances. This information is used to assess the dangers and risks that this substance may represent and to control these risks. The main objective of this system is to achieve a high level of protection of human health and environment by strengthening the role and responsibility of industry to provide reliable information on substances and to ensure safe use in the conditions of free movement of chemicals in the internal European market. REACH will facilitate further evaluation of **substances** for which there is reason to suspect might, pose a risk to humans and environment, as provisioning a system for **authorization** of substances of particular concern, such as substances that cause cancer, infertility, genetic mutations, generic defects, and also substances that are persistent and accumulative in the human body and in the environment.

"Initiatives to assess the toxicity of substances, risk and danger assessment and participation in various international and regional initiatives; strategies for assessing exposure, environmental monitoring and improving the procedures for using toxicological and ecotoxicological data for predicting and evaluating the effect of chemicals on human health and the environment".

Requirements for toxicological and ecotoxicological evaluation of chemicals on human health and the environment have been introduced in **LPHICSP** and regulations thereto. Biocidal products are marketed and used after authorization by the Minister of Health. The draft permit is considered at the Expert's Council on Biocides, based on toxicological expert opinion, prepared by the Ministry of Health (MoH) and ecotoxicological expert opinion, prepared by the Ministry of Environment and Water (MEW).

Plant protection products (PPP) are placed on the market after issuing a certificate for marketing, prepared by the Minister of Agriculture and Food (MAF). The draft of the certificate is accepted by the Committee for authorization of plant protection products on the basis of:

- expert ecotoxicological evaluation prepared by MEW;
- expert toxicological evaluation prepared by the Ministry of Health (MH);
- report for physical and chemical properties, analytical methods, residues and efficacy of PPP, prepared by MAF.

"Exchange of information and cooperation, ensuring data quality, implementation of criteria for assessment and activities in relation to risk reduction"

Regulation (EC) 1907/2006 of the European Parliament and the Council of December 18, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) introduced a procedure of registration for a period of 11 years for approximately 30.000 chemical substances that are current-use, a process that will allow the missing information about the dangers caused by substances to be collected , and at the same time enable the appropriate risk management measures to be identified.. The industry will be commited to collecting the necessary data for the substances and identifying measures to control risk.

"Effective management of toxic substances:

Policy, undertaking measures for exlusion of chemicals, which poses hard controlled risk for human health and environment, such as ozone depleting substances"

In the Law on Protection from the Harmful Impact of Chemical Substances and Preparations (LPHICS) measures for the implementation of Regulation (EC) 689/2008 of the European Parliament and of the Council concerning the export and import of

dangerous chemicals and Regulation 850 /2004 of the European Parliament and of the Council on persistent organic pollutants **have been listed.**

In line with a requirement of the Regulation (EC) 689/2008, the exporters of dangerous chemicals, which are used and put on the market are banned or firmly restricted in the EU (such as plant protection products, biocides or industrial chemicals for professional or mass uses) and are obliged to notify of the first year's export, giving information about the dangers and risks of these substances. In addition, the export of certain dangerous chemicals is realized only after receiving the explicit consent for import of the competent authorities of those countries, which accept import. This consent may contain additional conditions and dates.

Persistent organic pollutants (POPs) are not produced in Bulgaria. The import of POPs is prohibited in Bulgaria as follows:

Preparation	Years of prohibition
Aldrin	1969
Dieldrin	1969
Endrin	1969
Mirex	Never have been imported
Toxaphene	1985
Hexachlorobenzene	Never have been imported
Heptachlor	1991
Chlordane	Never have been imported
DDT	1969

Annually awarded funds from the Enterprise for Management of Environmental Protection Activities (EMEPA), are granted to municipal projects for safe storage in repaired or newly renovated centralized warehouses or permanent storage in BB – cubes or disposal abroad of obsolete pesticides.

Bulgaria does not produce substances that deplete the ozone layer. Therefore, the criteria for performance of obligations under the Montreal Protocol is only about their import, export and use.

In 1996 the import of chlorofluorocarbons (CFC) was prohibited, and since 2007 the use of recycled or reclaimed CFC for maintenance of existing refrigeration and air conditioning has been prohibited. The use of partially halogenated chlorofluorocarbons (HCFC) is authorized, in accordance with the timetable for phased termination of their use.

Since its accession to the European Union in 2007, Bulgaria has implemented the requirements of Regulation (EC) № 2037/2000 on substances that deplete the ozone layer. Measures for the implementation of the Regulation are established as amended in 2006 by the Clean Air Act (promulgated SG. 99/8.12.2006) and amendments to the

Decree № 254/1999 for management and control of substances that deplete the ozone layer (amended and supplemented by Decree №.28/06.02.2007).

Regulation (EC) № 2037/2000 provides for terminatation of the marketing and use of ozone depleting substances (ODS) for a short time, including the HCFC, than those set forth in the Montreal Protocol and its amendments. The European Commission (EC) has introduced an electronic licensing of imports and exports of ODS; permits are issued by the Commission after the approval of the Member States. Each year before September, the European Commission publishes notices in the Official Journal to potential users, importers and exporters in the European Community.

„Policies and frameworks for the prevention of accidents, preparedness and response"

In the Environment Protection Act, Chapter VII "Preventing and reducing the industrial pollution" and in the Regulation for prevention of major accidents involving dangerous substances and limiting their consequences, measures have been introduced limiting their consequences for human life and health and for the environment. Under these regulations, any operator of a new or existing establishment and / or installation in which certain quantities of dangerous chemicals are used and / or stored, shall be classified as an establishment and / or installation with low risk potential or establishment and/or installation with high risk potential about which the Minister of Environment and Water is to be informed..

The Minister of Environment and Water issues a permit under Art. 104, para. 1 of the Environmental Protection Act (EPA). The permit may set conditions concerning the construction and operation of the establishment and / or instalation.

Documents necessary for authorization of an establishment with **low risk potential:**

- •Notification for classification of establishment and / or installation and
- •Report on the policy to prevent major accidents (RPPMA).

RPPMAcomprises information on: general objectives and policies regarding the safe operation of the establishment and / or installation, measures to be taken by the operator to reduce the risk of major accidents; management system for safety measures.

Documents necessary for authorization of an establishment with **high risk potential:**

- •notification for classification of establishment and / or installation
- •Safety report (SR).

The SR contains: report on policy for preventing major accidents; information about the environment in the area of establishment and / or installation; installations, processes and activities in the establishment; risk assessment of major accidents and the measures and

means to prevent and / or limit their consequences; information about the organization created to comply with the rules and regulations for fire safety - risk assessment of fire, measures and means to prevent and / or reduce and mitigate the fires, documents on the status of automatic fire and the fire appliances and equipments.

• Emergency plan for the establishment and / or installation, containing specific individuals and actions to be taken in case of emergency situation.