

STEP-BY-STEP IMPLEMENTATION OF A NATIONAL REGISTER OF CHEMICALS IN GEORGIA



Report on the project

“Development of legislative and operational framework
for collection and sharing of information on hazardous
chemicals in Georgia”



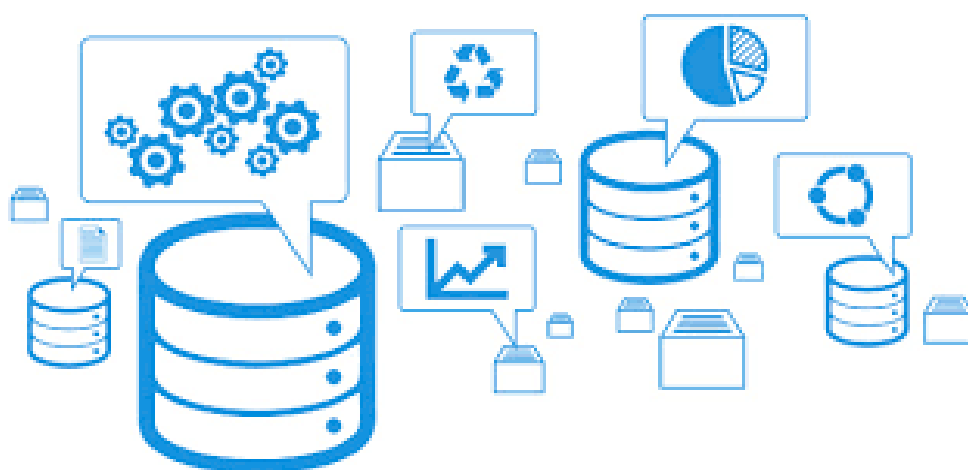
Tbilisi 2017



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Tbilisi 2017



Federal Ministry for the
Environment, Nature Conservation,
Building and Nuclear Safety

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Nana Gabriadze, Project National Coordinator

List of Acronyms and Abbreviations

CSF –Civil Society Forum

CSO – Civil Society Organization

DCFTA – Deep and Comprehensive Free Trade Area EaP– Eastern Partnership

EC – European Commission

ENPI – European Neighbourhood and Partnership Instrument EU – European Union

FAO – Food and Agriculture Organization of the United Nations GEF – Global Environment Facility

GEL – Georgian National Currency - *Lari*

GHG – Greenhouse Gas

MENRP – Ministry of Environment and Natural Resources Protection of Georgia (*since 2013 up to now and earlier in 1996-2003*), *formerly known as*:

MEPNR – Ministry of Environment Protection and Natural Resources of Georgia (*in 2004-2010*) and

MEP – Ministry of Environment Protection of Georgia (*in 2011-2012 and before in 1992-1995*)

NGO – Non-Governmental Organization

OECD – Organization for Economic Co-operation and Development POPs – Persistent Organic Pollutants

PRTR – Pollutant Release and Transfer Register

REACH – Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals

SAICM – Strategic Approach to International Chemicals Management SEIS – Shared Environmental Information System

SMC – Sound Management of Chemicals SMEs – Small and medium sized enterprises

UBA - German Federal Environmental Agency

UN ECE – United Nations Economic Commission for Europe UNDP – United Nations Development Programme

UNEP – United Nations Environment Programme

UNIDO – United Nations Industrial Development Organization USAID – United States Agency for International Development USD – United States Dollar

WB – World Bank

WHO – World Health Organization

WHO ECEH -World Health Organization, the European Center for Environment and Health

Introduction

While chemicals are a significant contributor to national economies and an indispensable component of everyday life, the sound management of chemicals is essential to avoid significant risks for human health and environment. Sound chemicals management can be achieved by implementing measures aiming at regulation of hazardous chemical substances in a coherent and coordinated way. It includes all (natural and synthetic) chemicals at the stages of their life-cycle including extraction, synthesis, industrial production, transportation and utilization of wastes. Accessibility of reliable information on chemicals both on international and national level is crucial to support informed decision making to minimize negative impact of chemicals on humans and the environment.

Setting chemicals registration system and development of national chemical registers will provide significant input to identification and prioritization of chemicals of concern, development of monitoring and risk assessment strategies, prevention of illegal traffic of chemicals, and will stimulate capacity building at national level.

Since 2003, fundamental changes were made and reforms have been carried out in Georgia. The realities with regard to institutional structure of executive branch and civil society development have changed. In view of a large-scale fight against corruption, the old system of control and surveillance was denied. In 2005-2007, a radical reform with full abolition of the State Sanitary Surveillance System was implemented. In 2007, the Georgian “Sanitary Code” was declared invalid in pursuance of the Law of Georgia on Public Health. Surveillance, controlling and permissive powers within the competence of the Sanitary Surveillance Service were completely withdrawn without establishing alternative structures and therefore they were no longer reflected in the new legislation.

After 2003, in correlation to the general liberalization of legislation, the laws pertaining to the production, use and disposal of hazardous chemicals were also liberalized. This led to a negative influence on developments in the area of human health and environment.

Liberalization of legislation in the field of hazardous chemicals in Georgia was carried out through a very simplistic approach, and in many cases, the only action was abolishing certain laws, for example, the Law on Hazardous Chemicals.

In 2009, a multi-sectoral assessment of chemicals management in Georgia, conducted in the framework of development of a Chemical Profile of Georgia, revealed gaps in chemicals management and resulted in the identification of national priorities towards chemical safety. Collection and sharing of information on hazardous chemicals has been recognized as one of main priorities.

In July 2013, the EU and Georgia signed an Association Agreement, which includes a number of measures necessary to be taken in the chemical safety area. In particular, it included the harmonization of classification and labelling of chemicals with the EU requirements.

According to the earlier and latest national assessments related to the implementation of sound management of chemicals (SMC) in Georgia [Chemical Profile of Georgia (2009), UN ECE (2010), National PRTR in Georgia (2010-2012), Hazardous Chemicals Inventory Report (2013)], revealed that availability of information chemicals and chemical products is the main shortcoming at the national level that need to be addressed urgently to ensure implementation of SMC.

According to the National Chemical, Biological, Radiological and Nuclear (CBRN) Threat Reduction Strategy (Governmental Decree #164, 14.02.2014) and CBRN action plan for 2015-2020, *“the shortfalls in legislation of the chemical security field must be highlighted among existing challenges”*.

To support the Georgian Government in identification of information gaps and needs for the implementation of SMC and , the WHO Regional Office for Europe, in cooperation with the National Centre for Disease Control and Public Health of Georgia and the Ministry of Environment and Natural Resources Protection of Georgia implemented the project “Development of legislative and operational framework for collection and sharing of information on hazardous chemicals in Georgia” funded by the German Federal Environment Agency through Advisory Assistance Program.

Chapter 1. Background

At present, the chemical industry offers a wide range of chemicals to all sectors of economy. Along with tremendous benefits that the use of chemicals brings, their inappropriate use may cause environmental pollution and health-related problems, such as: acute poisoning; oncological, respiratory, cardiovascular and autoimmune diseases; reproductive disorders; congenital anomalies; and other defects.

Human beings are exposed to toxic chemical substances in the workplace, when using consumer products, consuming food and water, breathing the air, having contact with chemicals contained in waste and soil, etc.



According to the data published by World Health Organization (WHO)¹, the range of chemicals affecting human health is wide and growing. Chemical production and consumption in the WHO European Region has the highest figures in the world: 11 of the top 30 major chemical-producing countries are European, generating chemical sales of € 533 billion. These include *hazardous chemicals, such as heavy metals and some persistent and non-persistent organic pollutants - for which toxicity to human is well-established - as well as emerging chemicals, all of which cause public health concern.*

Globally, 1.3 million lives and 43 million disability-adjusted life-years (DALYs) were lost in 2012, as a result of exposure to selected chemicals, the health effects of which are well estimated. In Europe, mercury pollution exacts a toll of € 5.1 billion/year, while a broader estimate of childhood medical and physiological conditions, resulting from chemical hazards, suggests the costs in the order of € 71 billion/year. A recent analysis estimated the cost of the burden of disease attributable to endocrine-disrupting chemicals (EOCs) at € 163 billion/year.

Therefore, the world community is striving for sustainable development, in terms of which the present generations' needs are met without prejudice to future generations of people. In this regard, safe use of chemicals is an essential component of sustainable development.

As already noted, in 2009, based on a multi-sectoral assessment of chemicals management in Georgia, conducted in the framework of development of a Chemical Profile of Georgia, information collection and sharing has been recognized as a "bottleneck" for the implementation of SMC in Georgia. Improvement of the information system is becoming more critical including due to responsibilities of Georgia under the Association Agreement with the EU signed in 2013.

To address chemical information needs, WHO Regional Office for Europe, in cooperation with relevant Georgian national authorities, started implementation of the project "Development of legislative and operational framework for collection and sharing of information on hazardous chemicals in Georgia" funded by the German Federal Environment Agency through its Advisory Assistance Program in 2015.

Taking into account all mentioned above, **the overall goal of the project was** to develop legislative and operational framework for collection and sharing of information on hazardous chemicals as well as to develop a model of register/inventory and to test its applicability in relation to the stakeholders' needs.

It was expected that the project would input to: strengthening the inter-agency cooperation and raising awareness on collection and sharing of information and its importance for the implementation of SMC; identification of national priorities for information collection and legislative gaps; improved knowledge on approaches to registration/notification of chemicals and their mixtures in the EU and non-EU

¹ Fact sheet 5, Chemical Safety : <http://www.euro.who.int/Safety.pdf?ua=1>

countries; better understanding of benefits and challenges of creating a national chemical register and information collection system; gathering information on priority/most hazardous chemicals; designing the national register model and its operational framework; development of proposals for strengthening the national legislation given activities and timeframe in the EU-Georgia Agreement; sharing the lessons learned between stakeholders and experts from the countries planning/developing their national registers.

Implementation of the project would provide multiple benefits in the long-term perspective such as implementation of GHS, development of registration system comparable with the main EU chemical policy (REACH).

In the frame of the Association Agreement between Georgia and the EU the SEIS – Shared Environmental Information System- for all stakeholders should be developed. The inventory will be included in the system. Overall, it would provide support to the implementation of SMC in Georgia.

The project outputs included: Situational analysis of collection and sharing of information on hazardous chemicals and stakeholder's information needs for the implementation of sound chemicals management in Georgia; overview of existing practices for creation of a register/inventory of hazardous chemicals in Georgia; overview of international requirements and recommendations for collection and sharing of information on hazardous chemicals and related issues; model and operational framework of the national register; proposals for amendments to the legislation and for the development of new legal acts.

Chapter 2. Methodology

The project implementation was leadership by the National Center for Disease Control and Public Health of Georgia with support from the Ministry of Health and Social Affairs and the Ministry of Natural Resources and Environment Protection of Georgia.

To ensure successful implementation of the project and achievement of its objective a number of actions was taken: creation of a national expert's team, involvement of experienced international experts, organization of experts missions and a study tour, organization of stakeholders consultations and discussions with international experts during workshops. Summary of main actions in the project framework is provided below.

2.1 The project implementation team

The project has been implemented by the national expert team with the support of experts from the Federal Environment Agency UBA of Germany, WHO ECEH, Hungary and Slovenia in 2015-2017. The project has been coordinated by two coordinators from NCDC and MENRP, namely, by Dr. Nana Gabriadze and Ms. Irma Gurguliani. The national project implementation team consisted from the leading national experts in certain areas such as toxicology, environment protection, environmental health, occupational health, jurisprudence. Mr Alverd Charkseliani, Prof. Inga Gvineria, Prof. Abashidze Ketevan, Mr Irakli Legashvili, Mr Alexander Turdziladze, Ms Khatuna Chikviladze and Mr Malkhaz Dzeladze made an invaluable input in the project implementation being members of the national expert team. Information about national experience in other countries what have advanced experience in chemicals management has been provided by topical experts from Italy, Hungary, Poland, Russian Federation, Slovenia and Sweden.

The complexity of the project, as a pioneering activity related to the collection of information on chemicals in the Georgian market, has been noted by representatives of the Government, national experts and representatives of different institutions. The reasons for that are: lack of expertise in chemical safety area at the national level; on-going changes of the public health and environment protection

infrastructure; gaps in the national legislation, including the legislative framework for chemicals management; and, strong focus on liberalization of economic activities.

2.2 Basic information for the project implementation

Main documents that were analyzed to develop proposals for core elements of Georgian system of chemicals and chemical products registration and identification of priority chemicals for the Georgian register of chemicals are as follows:

- the European Union legislation including REACH (1907/2006/EC) ;
- CLP (1272/2008/EC); Biocides Regulation 528/2012;
- International legally binding and voluntary agreement in chemicals safety area; analysis of these documents contributed to understanding of expected contribution from establishing a register to the country reporting on the implementation of „chemicals “conventions, as well as to provide information on available international recommendations has been compiled by the international experts;
- experience of setting registers in Hungary, Italy, Poland, Russian Federation, Slovenia and Sweden in terms of general objectives of collecting information on chemicals; national approaches to chemicals and chemical mixtures notification; historical background, legal basis and purpose of creating of registers; their scope of the registers; institutional infrastructure and responsible actors; type of information collected and structure of register; technical modalities to submit information; access to database, sharing information and confidentiality; challenges and benefits of establishing of the national registers.

2.3 Ensuring multi-stakeholders approach to the project implementation

To ensure all stakeholders' involvement, the project multi-sectoral steering group has been formed. The group included: National Statistics Office of Georgia, Ministry of Internal Affairs, Consumer Protection Federation of Georgia, Land Transport Agency, Ministry of Economy and Sustainable Development of Georgia, Ministry of Agriculture, Ministry of Labour, Health & Social Affairs Of Georgia, Revenue Service of Georgia, NGO Green Movement of Georgia, Toxicology Poisoning Center of Georgia, Labor Medicine and Ecology Research Institute, Emergency Management Agency of MIA of Georgia, Tbilisi State medical University, United Water Supply Company of Georgia, National Food Agency, and Petre Melikishvili Institute of Physical and Organic Chemistry.

A number of meeting with involvement of interested stakeholders were organized to provide an arena for opened discussion of the project implementation, development of a system for registration of chemicals, identification of most applicable ways for improvement of collection and sharing information on chemicals. More detailed information about the consultation is provided below.

2.4 Main steps of the project implementation

1. Situational analysis of collection and sharing information on hazardous chemicals and stakeholder's information

needs for implementation of sound chemicals management in Georgia The project started from assessment of current situation with collection and sharing information on hazardous chemicals aiming to identification of gaps and stakeholders needs in chemical information as well as identification of priorities in setting a national register. The information gaps and needs identified by the national experts were discussed and concluded at the first multi- stakeholders' workshop meeting on 29-30 October 2015.

2. Development of a model and operational framework of a national chemical register

Based on the national assessment and deep analysis of existing experience, the model and demo electronic software were developed by the national expert team, in close cooperation with international experts, through face-to face consultations (two experts missions in September 2016 and March 2017), discussion with relevant stakeholders at the national level including two meetings: multi-stakeholders' workshop

meeting on 22-23 June 2016 and an international workshop “Towards creation of a system for collection and sharing of information on hazardous chemicals: experience of Georgia” on 28-29 March 2017. A study tour to Germany for the national project coordinators for health and environment sectors has been organized and financed by UBA, Germany for sharing experience on collection and sharing information on chemicals in Germany.

3. Development of proposals for legislative framework for setting a national register of chemicals

Proposal for creating of legislative basis to ensure sustainability of the chemical register has been prepared by the national experts in consultation with the international project support team including international, WHO and the donor experts.

4. Next steps in setting of a national chemical register in Georgia

The next steps (till 2020) were discussed and agreed by governmental and non- governmental; actors at the international meeting (28-29 March 2017, Tbilisi, Georgia).

2.5 Workshops and stakeholders meetings conducted in the framework of the project

Several workshops were organized in the project framework for certain purposes, commonly to discuss and agree with all relevant stakeholders the proposals of the national and international project implementation team.

Needs for information on hazardous chemicals to ensure implementation of sound chemical management in Georgia: multi-stakeholders’ workshop (29-30 October 2015)



Picture 1. The national experts meeting prior to the multi-stakeholders meeting (28.10.2015)

The workshop was the first stakeholders meeting in the project framework with the main objective to launch the project and discuss gaps and needs of information to direct the project implementation and its further steps.

The following tasks were considered in organizing of the workshop:

to introduce the project “Development of legislative and operational framework for collection and sharing information on hazardous chemicals in Georgia”;

- to share information on recommendations and requirements of international and regional organizations on the collection and sharing information on chemicals;
- to map and summarise needs of different stakeholders for information on hazardous chemicals in Georgia; and
- to get an overview of gaps in legislation hindering collection and sharing of information.



Picture 2. Working groups discussion to identify priorities of stakeholders in collection and sharing information on chemicals (First multi-stakeholders' workshop meeting on 29-30 October 2015).

Experts' meeting for the implementation of the tasks 3, 4 and 5 of the project at the national level (22-23 June 2016)

An extraordinary experts' meeting was organized to direct the national experts in designing of a model and operational framework of a national chemical register. Governmental experts as well as experts from local enterprises, importers of chemical substances and biocides attended the meeting.

This informal meeting was organized with the purpose to discuss the current status of the implementation of the project, to update on existing information, to introduce international expert's analysis and to plan next steps.

Summary of international experience of setting of national registers has been provided during the meeting for further consideration of the national experts.



Picture 3. Informal meeting on 22-23 June 2016, Johann F. Moltmann-UBA, Irina Zastenskaya-WHO ECEH

National experts' meeting on 9 September 2016

The meeting was organized to analyse information on the existing practices and to decide on the register model most applicable for Georgia, was attended by the members of the national expert team, representatives of the Revenue Service and the head inspector of the Customs Department. The discussion focused on reaching an agreed

opinion register model the most applicable and corresponding to the Georgian needs and to create a register which would include three databases: on chemical substances; on hazardous chemical substances and mixtures; and on biocides. Georgian experience in the registration of biocides and pesticides paved a path for setting a chemical register.

National multi-stakeholder workshop for introduction and discussing the inventory model and operational framework of a register of hazardous chemicals in Georgia (31 October 2016)

The workshop objective was to discuss proposed design and operational framework of a national register of hazardous chemicals and their mixtures and to agree the register content and requirements with all relevant stakeholders and interested parties – governmental bodies, industry and other business, non-governmental organization – taking into account identified needs of information on hazardous chemicals and their mixtures. The meeting was attended by 46 participants, 2 international experts from the WHO and UBA.

International workshop “Towards creation of a system for collection and sharing of information on hazardous chemicals: experience of Georgia” on 28-29 March 2017

The international workshop was organized in the framework of the project to provide an arena for open multilateral discussion on establishing a national information system, sharing experience and lessons learned between experts from Georgia and other countries, which have created their chemical registers. In addition to national experts and other stakeholders, the meeting was attended by experts from countries planning improvement or creation of their national chemical registers: Albania, Azerbaijan, Belarus, Bosnia and Hercegovina, Moldova, and Ukraine.

National and international experts, governmental and non-governmental stakeholders and industry representatives discussed the following topics:

- Requirements and recommendations for collection and sharing of information at international level;
- Existing experience in collection and sharing of information on hazardous chemicals in the countries;
- Step-by-step approach applied by Georgia to modelling of the national chemical register, its operational and legislative framework;
- Lessons learned from the project implementation;
- Next steps to ensure sustainability of information exchange in Georgia and other countries.



Picture 4. International workshop on 28-29 March 2017 at NCDC



Picture 5. International workshop on 28-29 March 2017 at NCDC



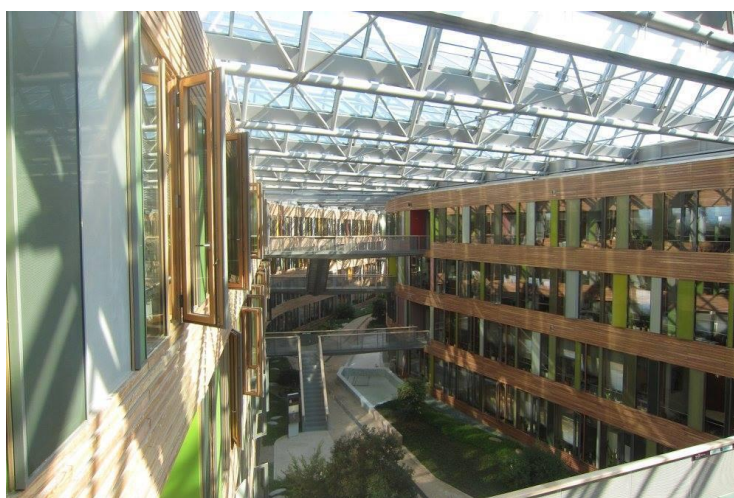
Picture 6. Open multilateral discussion on establishing a national information system, sharing experience and lessons learned between experts from Georgia and other countries



Picture 7. Open multilateral discussion on establishing a national information system, sharing experience and lessons learned between experts from Georgia and other countries

2.6 Study visit of the Georgian experts to Germany and international experts mission to Georgia

A study visit of the project national coordinators carried out in Germany, in September 2016, with a view to sharing experience, was of utmost importance. During the study visit, Georgian Experts visited several German Regulatory Agencies Dessau -UBA, Berlin BfR (Poison centres & product documentation), Dortmund (B.A.U.A., databases in the realm of B.A.U.A./BfC (e.g. ECHA) and WHO/EHEC in Bonn to discuss the relevant international databases, and EU-LIFE Proposal "Consumer Information Rights". During the visits, presentations focused on how the process of collection and sharing of information on hazardous chemicals is organized. Discussions held were interesting, informative and useful and all the questions were answered.



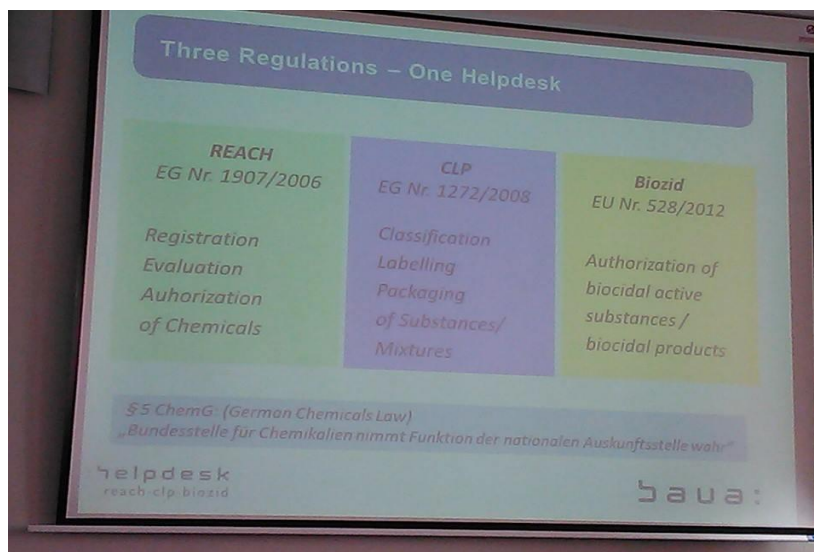
Picture 8. Dessau, UBA

In Germany, collection and organization of information and data on hazardous chemicals entails considerable information resources, both human and financial. Knowledge gained regarding the German experience was shared with a team of national experts. It includes ways of using data registries for the following:

- Assessment of chemical effects on human health, other living systems and the environment;
- Identification of pathways of human and environmental exposure, including the levels of chemicals in environmental media;
- Distributing and ensuring availability of information;
- Assessment of the existing national and international regulatory mechanisms and measures;
- Response to emergency situations such as spills or poisonings, and
- Waste disposal and gathering information on wastes.

Through the presentations, the project national coordinators familiarized themselves with CLP and REACH procedures, documentation, ways of collection and sharing of data, further analysis and use, role of the Poisoning Information Centres in public awareness and high level of human health protection, which will be the basis for our further cooperation. The experience shared by colleagues from the Federal Institute for Occupational Safety and Health (BAuA) in Dortmund was of special importance since we learned how requirements for collection and sharing of information on chemicals were introduced in stages. We also learned of the assistance provided by the state and of a so-called "Help Desk" offering free

consulting and familiarizing entrepreneurs with the requirements, as well as with the ways of delivering and sharing information on chemicals.



Picture 9. “Help Desk” offering free consulting and familiarizing entrepreneurs with the requirements (BAuA in Dortmund).

First international experts mission (19-23 September 2016)

The project has achieved great success in terms of raising awareness of all stakeholders, and the assistance provided by international consultants from Slovenia and Hungary was especially valuable. Two international experts from the National Chemical Bureau of Slovenia (Mr Alojz Grabner, Director, Republic of Slovenia Ministry of Health, Chemicals office of the Republic of Slovenia) and the National Institute of Public Health of Hungary (Dr.Ms Szilvia Deim, National Public Health Center of Hungary, National Directorate of Chemical Safety) worked with the national experts team on 19-23 September 2017 and on 13-14 March 2017; the missions were organized by the international project coordinator upon requests of the national project coordinators from both the MoH and the MoE; the mission objectives were to assist the national team and build national capacities for the register modelling and the legislation strengthening; the mission terms of reference was developed by the international project coordinator based on the analysis of the project implementation and main gaps in the national capacity; final workshop with the national experts (23 September 2016, NCDC, Tbilisi) resulted in the development of the first draft of the register model and operational framework. During the visit, several organizations were visited to continue discussion with high-level representatives of the interested organizations, including the Ministry of Environment and Natural Resources Protection of Georgia.

The main purpose of the expert mission held on 13-14 March 2017, was to assist the Georgian team of national experts in the next stage of development of proposals for filling

gaps in the national legislation regulating collection and sharing of information on hazardous chemicals. National legislation should be reviewed and improved taking into account previous national and international commitments such as development and implementation of a regulation on classification, labelling and packaging chemicals (probably in 2020-2021).

National experts suggested using the existing Law on Public Health as an entry point for creating a legislative base for registration of chemicals: the Law includes articles requiring collection of information on hazardous substances. Responsible Ministries should cooperate with NCDC, Georgia to ensure progress in the legal framework.

Terminology and definitions such as registration, authorization, and restriction are different in the Georgian and EU legislation. Special discussion is necessary to reach consistency and avoid misunderstanding.

In addition to the legislative framework, sophisticated electronic software and trained staff are necessary to set up and maintain a chemical register. The Advisory assistance Program of German Federal Environment Agency and Special Programme of UNEP were introduced as potential sources of funding of further actions at national and regional level.

The plenary discussion continued in three working groups discussing next steps that can be taken on a national and regional scale to facilitate collection and sharing of information on hazardous chemicals.

Second international experts mission (13-14 March 2017)

The main purpose of the mission was to assist the Georgian team of national experts in the next stage of development of proposals for filling gaps in the national legislation regulating collection and sharing information on hazardous chemicals.

The mission consisted of the following tasks:

- To study existing information on the national legislation regulating collection and sharing information on hazardous chemicals;
- To study the proposals prepared by the national experts for a discussion of the legislation improvement;
- To share expertise, knowledge and experience during the discussion with the national experts' team;
- To assist and support the national experts team in the development of proposals for filling gaps in the national legislation (existing and planned to be developed).

The mission resulted in clarifying of the scope of the database and the purpose it should serve as well as defining the contents the database, i.e. the chemicals it should include, and the level of information.

All actions in the project framework described above led to successful implementation of the project and achievement of its objectives.

Chapter 3. Performance-achievement of the expected outcomes of the project

3.1 Situational analysis of collection and sharing of information on hazardous chemicals: overview of main gaps and needs -First National Situational Analysis



The first step in the project framework was an analytical overview of a situation concerning collection and sharing of information on chemicals in Georgia with specific objectives as follows:

- to analyze existing legislation requirements to industry/research institutions/non- governmental organizations in generation and sharing of information;
- to describe existing practice of involvement of research institutions, non- governmental organizations and industry in generation and sharing of information on hazardous chemicals;
- to identify gaps and needs in relation to information necessary for fulfillment of their role in sound chemicals management.

Situational analysis of the legislative requirements related to information on chemicals, existing practices of registration of chemical substances, and potential needs for information has been organized in four different areas: 1) health-related information aspects; 2) information related to environment protection; 3) information related to prevention of illegal traffic of hazardous chemicals; 4) information needs of NGOs, Academia, industry.

The analysis of the existing situation was the first step of the project implementation and was conducted by topical national experts. The following areas were addressed in the assessment:

- Existing legislation requirements to industry/research institutions/nongovernmental organizations in generation and sharing of information;
- Existing practice of involvement of research institutions, non-governmental organizations and industry in generation and sharing of information on hazardous chemicals;
- Identification of gaps and needs for information necessary for fulfillment of their role in sound chemicals management.

The main findings of the national situational analysis are summarized below.

Chemicals turnover in Georgia

Despite of Georgia has not developed chemical industry, there are many types of chemicals which are produced, used and imported in Georgia including:

- industrial chemicals (chemical compounds and mixtures, used in industry), including: copper concentrate, manganese ore, ferromanganese, silicomanganese, crude oil, ammonium nitrate, ammonium sulfate, sodium cyanide, nitric acid. Paints and varnishes, as well as soaps, detergents, scouring pastes and powders, are also produced in Georgia.
- pesticides; pesticides are not produced in Georgia, while the volume of imported pesticides, as of the past few years, made the average of 1800-2000 tons annually. Different-purpose pesticides are imported, including: fungicides, insecticides, herbicides, rodenticides, seed disinfectants. They belong to different
- chemical classes: inorganic copper compounds; carbamates, thio- and dithiocarbamic acid derivatives; organophosphates and organochlorines; urea, guanidine derivatives; synthetic pyrethroids; anticoagulants.
- other agricultural chemicals; as for mineral fertilizers, the country produces nitrogen fertilizers (ammonium nitrate), whereas calcium and phosphorus fertilizers are imported;
- other chemical goods; 106 types (HS code 2707-3824) of various chemical agents (including those, classified as hazardous chemicals), are imported in Georgia, including:

- consumer/household-purpose agents (detergents, adhesives, solvents, varnishes and paints);
- materials containing amphibole and chrysotile asbestos - used in construction, industry, energy, for paper production, in textile manufacturing, aviation, automotive industry;
- disinfectants;

Besides, there are also chemical residues that have the chemical weapon status.

Chemicals that are regulated by legally binding agreements also are on the domestic market.

Georgia obligations at international level: the EU-Georgia Association Agreement and “chemical” conventions

In July 2013 the EU and Georgia completed the negotiation of an Association Agreement, and agreed a number of measures necessary to be taken in the relevant areas – chemicals, environment protection, consumer product safety, workers health and safety and management of emergency situation. According to the Agreement, Georgia undertakes to gradually approximate its legislation to the following EU legislation and international instruments with stipulated timeframe. A number of EU Directives requires collection and sharing information with public. In chemical safety area, it is expected that Regulation (EC) No 689/2008 of the European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals and Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, will be adopted in Georgia. Georgia is a party of a number of international agreements in chemical safety area including Basel, Stockholm, Rotterdam and Minamata conventions and International Health Regulation. All conventions require reporting based on national monitoring and surveillance. In addition to getting knowledge on chemicals to protect human health and the environment, to adopt EU legislation, fulfilment of the country international responsibilities is also driving force to create appropriate information collection and sharing system. Moreover, Georgia is a member of Aarhus Convention and in accordance of the Convention requirements all interested parties have an opportunity to request and receive the information on chemicals and wastes. Development of a system for collection of information on chemical products and creation of a register will contribute significantly to the improvement of reporting in the framework of the Conventions.

Thus, information on hazardous chemicals is critical for the implementation of monitoring and evaluation systems, planning health and the environment protection measures, fulfilment of international agreements.

Existing political commitments

Some political commitments to improve collection and sharing information on chemicals are already on place. The government decree #164/ 2014, adopted the National Strategy for Reduction of Chemical, Biological, Radiological and Nuclear Threats. Under this decree, the national strategy, 2015-2019 action plan has been elaborated for its implementation. The priority issues in the action plan are those, related to the problems associated with collection and dissemination of chemical safety data: the analysis of the existing legislative framework and initiation of amendments; creation of an institutional framework; elaboration of a draft law on hazardous chemicals; creation of the national register of hazardous chemicals and its regular updating; strengthening capacity for monitor chemical contamination of drinking water, foodstuffs and environment; improvement of public readiness in case of chemical and biological accidents; in the chemical, biological, radiological and nuclear (CBRN) hazards sphere, development of the information resources with the aim to disseminate best practices and raise public awareness; creation of a web- portal. Several implemented activities aimed at creation of legislative and operational framework for collection and sharing information on hazardous chemicals are in line with national priorities and planned activities at the national level.

Legal arrangements

Georgia has developed legislation system which is currently adapted to the EU requirements. Analysis of existing requirements, opportunities and limits for its enforcement is necessary to identify main gaps and develop recommendations on collection and sharing information on hazardous chemicals to ensure sustainability of the information system. Environment-related legislation of Georgia includes the following legal acts: Constitution, Environment protection laws, international agreements (conventions), By-law regulations, President decrees, Governmental decrees, Ministerial orders etc.

Wide range of legal acts regulate chemicals management in Georgia such as the Georgian Constitution, the Laws "On Environmental Protection", Product Safety and Free Circulation Code, "On the Health Care", "On Public Health", "On Soil Protection"; "On Protection of Plants from Harmful Organisms" "On Water"; "On Transit and Import of Waste in the Territory of the Republic of Georgia"; "On Pesticides and Agrochemicals"; Code on Safety of Foodstuffs and Animal Feed, Veterinary and Plant Protection"; "On Air Protection"; "On Food and Tobacco"; "On Export and Import Control of Armaments, Military Equipment and Dual-Use Goods"; "On Harm Caused by Hazardous Chemicals"; "On Conservation and Soil Fertility Restoration Circumstances"; "On Licenses and Permits"; "On Environmental Impact Permit"; "National Pollutant Release and Transfer Register"; "On Protection of the Population and Territory from Natural and Man-made Emergency Situations", etc.

Based on the analysis of existing legislation the national experts concluded that:

- There are requirement for sharing information on chemicals pollution of air and water, wastes management, environment impact assessment reports; import and export of chemicals, licenses for activities characterized by increased danger for human's life or health, chemical safety passports;
- There are requirement for provision of information on chemical pollution for public;
- There is no requirement for reporting on chemicals production in the national legislation on statistical data collection;
- No chemicals registration system is required by the national legislation;
- No requirements to create unified database of chemical safety datasheets to provide basic information on chemical properties;
- The lists of hazardous chemicals and wastes, the transboundary movement of which should either be restricted or prohibited, do not formally exist;
- There are significant gaps in the legislation enforcement;
- The issue of availability of information on a national language is an important issue for consideration.

Existing experience in creating of databases

In case of full enforcement of the existing legislation the following data should be available:

- EIA reports;
- Monitoring data on air and waters pollution;
- Wastes generation and composition data;
- Database of licenses of activities characterized by increased danger for human's life or health;
- Custom Declarations;
- Chemical safety datasheets;
- Safety passports and safety declarations;
- Registered disinfectants;
- Registered pesticides and other agrochemicals.

There is the national experience in creating databases that should be considered when developing a national register of hazardous chemicals.

In accordance with the requirements of the FAO "International Code of Conduct on the Distribution and Use of Pesticides» and the EEC 91/114 directive, Georgia maintains the state catalogue of pesticides

permitted for use in Georgia, which is annually amended and supplemented. Pesticides and Agrochemicals Division of the National Food Agency is responsible for the catalogue updating. The catalogue is also available in the digital format: http://nfa.gov.ge/?sec_id=130&lang_id=GEO . The catalogue includes: trade name of pesticide; its formulation; data on active substances; state registration number; range of use and treatment standard; name of crop and treated object; application methods; hygienic standards - maximum daily human exposure, MAC – in soil, water, air of working environment, atmosphere; maximum residue limits in foodstuffs. The catalogue provides data on 254 active substances and 682 formulations. http://nfa.gov.ge/?sec_id=130&lang_id=GEO

The Ministry of Labor, Health and Social Affairs provides registration of disinfectants, disinfectants and extermination agents. The list of registered preparations includes 530 items. The data are published on the web-site of the National Centre for Disease Control and Public Health:

http://ncdc.ge/AttachedFiles/8.01.2016_495d7f8b-c0c0-4623-a1fe-523c7dc83a15.pdf

In medical statistics, the acute poisonings are presented along with injuries of different etiology and have been observed as:

- thermal and chemical burns;
- poisoning by drugs, medicaments and biological substances, predominantly the impact of toxic substances of non-medical purposes, as well as the effect of other extraneous unspecified reasons.

Poisoning-related information is submitted from the regional public health centers to the National Center for Disease Control; after their processing, the statistical data are published on the website: <http://ncdc.ge/ka-GE/Statistics>; <http://ncdc.ge/ka-GE/DiseaseStatistics/StatisticalYearbook>.

It should be noted that information on chemicals is collected through national monitoring systems including monitoring of chemicals in ambient air, ground and drinking water, wastes and soil, and food.

Information on chemical hazards is available from chemical safety datasheets which are on a progress at national level and in the national language. There are two possibilities to create nation-wide chemical safety datasheets: in the Ministry of Labour, Health and Social protection gathering information from enterprises and in the Research Institute of Professional Medicine and Ecology based on preparation of safety datasheets using internationally available information on chemical hazards. Both approaches don't contradict each other and can contribute to collection of information on chemical hazards. However, despite the fact that specific technical regulations²⁰ for personal protection from chemical substances/products to provide it to workers in the context of prevention of occupational diseases are not adopted yet – all relevant requirements under the Labor Code have direct legal applicable force. There is a lack of enforcement due to the fact that there is no specialized enforcement and monitoring body for safe and healthy working environment within the Ministry of Labor, Health and Social Protection (responsible agency for enforcement of the Labor Code).

Geostat collect information on chemicals import and export as well as environmental pollution information.

However, more detailed information on chemicals is required to ensure its use for risk assessment for human health and the environment, monitoring of poisonings and chronic diseases caused by chemicals, planning of risk reduction measures.

National capacities that can be involved in setting of a national register of hazardous chemicals

In Georgia, there are basic capacities necessary for collection and sharing information on chemicals that requires further development and strengthening.

Health sector. The National Center for Disease Control was established at the Ministry of Labor, Health and Social Affairs as the leading institution in environmental health area. Competences of the Centre in the chemicals management field: disease monitoring and maintenance of medical statistics, recording and proper systematization of the cases of human poisoning with hazardous substances. Besides, based on information on pollution of the environment, food and drinking water, the Centre shall assess health risks and conduct epidemiological studies. Despite of the structures within the competence of the Sanitary Surveillance Service, empowered to exercise supervision, control and issuance of permits, were annulled in 2007, and an alternative structure was not set up, Georgia has developed public health system.

Environment sector. In sphere of chemicals management the leading coordinating state institution is the Ministry of Environment and Natural Resources Protection of Georgia which is the competent authority of Stockholm, Basel, Rotterdam, Minamata, Orhus, Ozone and other Conventions in Georgia. The mentioned Ministry is also competent authority for SAICM and Global Environmental Foundation (GEF) in Georgia. Ministry of Environment also coordinates implementation of National Implementation Plan of POPs, and performs state policy in the sphere of wastes and chemical agents management according to national legislation, what is expressed in realization of international cooperation in sphere of chemicals management; development of national legislation; national planning; state ecological expertise; issue of licenses and permissions; state monitoring and control; development of national strategic projects etc.

Research sector. Currently, existing main research institutions, keeping and generating information on hazardous chemicals according to their research and scientific needs, are: Sanitation, Hygiene and Medical Ecology Institute; Research Institute of Professional Medicine and Ecology; Agricultural University; Institute of Biochemistry and Biotechnology; Institute of Soil Science, Agrochemistry and Melioration; Institute of Plant Protection; Veterinary Medicine Institute; Caucasus Institute of Mineral Materials; Institute of Physics and Organic Chemistry; Medical Polymers Research Institute; Georgian Technical State University; Georgian Institute of Water Management; Institute of Hydrogeology and Engineering Geology; Institute of Hydrometeorology; Centre of Enterprise and Natural Resources.

Despite of the above institutional changes, in recent years there were a lot of examples of academic institutions successful involvement in the field chemicals in Georgia. Namely, number of state functions and activities in the field of management of chemicals were performed by contracting research institutes. For example:

- Precondition of the state registration of pesticides and agrochemicals is expertise of these substances (and of the results of expert examination). For this purpose types of expert examination is carried out: biological, hygiene-toxicological, environmental, ichtyo-toxicological and veterinary-sanitarian (documentary, laboratory and field examinations).

- Ecological expertise of activities which require preparation of EIA study and obtaining of environmental impact permit is carried out by the Ministry of Environment and Natural Resources Protection by employing independent experts of the relevant fields mainly from research institutes.

Ongoing activities cover some other important engagements in research and data gathering as well:

Sanitation, Hygiene and Medical Ecology Institute starting from 2015 has translated international chemical safety cards into Georgian language by the in the frame of governmentally funded program in the area of occupational health.

Despite the fact that currently there are shortcomings in collection and especially in sharing (e.g. results of scientific studies are not available on-line) of information on hazardous chemical substances for research (academic) purposes, there is a substantial interest and need in contribution to development of information sharing systems and in having access to integrated and/or specialized data bases on hazardous chemicals - based on particular scientific profile (e.g., information that is necessary for scientific research, methods for detection, results of epistudies and risks assessment, toxicological data etc).

A number of national NGOs are actively involved in both collection and sharing of information. Recent examples of both NGO engagements through NGO driven projects are shown below:

- Chemicals Profile of Georgia (2009) / NGO - Center for Strategic Research and Development of Georgia
- PRTR Project (2009-2012) / NGO – CENN
- SAICM Project (2012-2013) / NGO - Greens Movement of Georgia/Friends of the Earth- Georgia.

There are many other examples of recent successful involvement and cooperation in the field of chemicals not mentioned in the overview. At the same time, NGOs, because of their role and civil society related responsibilities, have definite interest in this area, particularly in contribution and having access to hazardous chemicals data bases. With the above regard it has to be especially noted NGOs role in EIA procedures, public information and participation in environmental decision-making. E.g, under existing procedures, project developers which require EIA must organize public discussions and public hearing of the preliminary EIA report with concerned parties, with a focus on the local population and NGOs. In this process NGOs require wide range of data (including on hazardous chemicals) to properly comment on EIA report and therefore to submit to project developers and environmental authorities their recommendations for improvement. Therefore, NGOs need to have access to integrated and/or specialized national and international data bases on hazardous chemicals.

Thus, it should be stressed that involvement of research institutions and NGOs in creation of the national chemicals register will strongly benefit its functionality and usefulness due to taking into account research sector and NGO needs as well as input in the register creation.

Main information gaps

Based on the situation analysis the main information gaps identified. They are summarized below:

- information on production, use and storage of hazardous chemicals and products (types of substances, volumes); E.g, Georgian National Investment Agency commissioned market research on chemical products to be further used in development of Georgia's chemical industry. Market research was conducted by consulting company KMPG [KMPG, 2015] for the following main groups of chemical products: Essential Oils; Hydrocarbons Alcohols Acids and Aromatics; Industrial Gases; Lubricating Preparations Mineral Fertilizer and Nitrogen Compounds; Agrochemical Products (Pesticides, incl. Herbicides, Fungicides, Insecticides, Rodenticides and other plant protection products); Paints Varnish and Other Coatings; Perfumery and Cosmetics; Pigments and other Coloring Matter; Polishing Materials; Soap and Washing and Cleaning Preparations. During the market research no data was available regarding the production and consumption of the above products in Georgia. For estimating the consumption of the products in Georgia several assumptions were made, among them most important was method of calculation – “the net import (import minus export) of a product was considered as consumed during the year”.

- information on production and placement, including temporary placement/storage (location, type, volume and placement/storage conditions) of the hazardous and other wastes (waste type and volume). In 2015 Georgia adopted legislation on wastes management harmonized with the EU legislation. Ministry of Environment is developing a system for collection of information on wastes and creation of the national database.

- list (register) of industrial facilities that use, produce and storage hazardous chemicals; Various agencies possess the aforesaid data, but they are either not systematized and their use is unfeasible (for example, registers of hazardous facilities in the technical surveillance inspections), or they are outdated – has not been updated (at the Emergency Situations Management Department);

- information necessary for assessment of chemicals risks for human health and the environment is insufficient

- data on chemical contamination of food and drinking water – such measurements are performed by the National Service for Food Safety, Veterinary and Plant Protection Agency; however they are not performed regularly. Information is available upon request.
- data on the effects of exposure to chemicals on human health – the NCDC collects statistical information (<http://ncdc.ge/ka-GE/Statistics>) of reported cases of poisoning. However, due to the lack of technical means of identification of etiological factors, this information is not comprehensive;
- data on monitoring of the environment pollution with chemicals; the National Environmental Agency is gradually improve the monitoring system, but the number and periodicity of measurements, as well as access to the collected information –are not satisfactory, it is available only upon request;
- no data on chemical hazards, their classification and labelling are available in the national language;
- Existing information not always is available online;
- There is lack of unified stream of information, coordination and cooperation among various state agencies. No mechanism is foreseen for the mandatory exchange of information among the Customs Department and the Ministry of Environmental Protection or the Ministry of Healthcare, which is vital for preventing illegal traffic in hazardous chemicals and wastes. It seems that each state agency is tackling various aspects of the issue within its own competence (f.e. Land Transport Agency, Government, etc).

Outcomes of multistakeholder consultation on information gaps and needs

In order to discuss stakeholder's needs for information a round-table "Needs of stakeholders for information on hazardous chemicals in Georgia and gaps in legislation limiting collection and sharing of information" was organized on 29-30 October 2015 in Tbilisi. Representatives of governmental agencies, non-governmental organizations and research sector discussed what kind of information and for what purposes is necessary for ensuring implementation of sound chemicals management in Georgia.

The discussion focused on availability of information of presence of hazardous chemicals and chemical products in Georgia; their volume; information on enterprises what use, produce and storage hazardous chemicals; data on chemicals import-export; information on hazardous and non-hazardous properties of chemicals; chemicals and chemical products classification and labelling; environmental, foodstuff and drinking water monitoring data; monitoring of wastes generation and management; laboratory capacities and human resources to collect information required for assessment of chemical risks for humans and the environment; diagnostic, treatment and surveillance of chemical acute and chronic effects and creation of poison control center regarding WHO recommendations; safety at workplaces; legislation requirements and gaps in legal system for chemicals management; information necessary for ensuring preparedness and response to chemical emergencies; creation of a relevant infrastructure.

Prioritizing information needs the meeting concluded that the following information collection should be addressed as a priority:

- Information on chemicals that are used, produced, storage, their volume and owners
- Information on chemical properties
- Information on hazardous activities, its location;
- Information on poisonings and toxicological glossary

It was also concluded that the main purposes of collection and sharing information on chemicals and chemical products are:

- to insure healthy and safe environment and working environment and to protect human health from negative chemicals impact as well as workers' health;
- to be prepared to emergency situations and meet relevant post emergency requirements;
- to classify and label chemicals according to international practice especially for exported chemicals;
- to generate and have access to information on less or non-hazardous chemicals to be used

in technological process with elimination of health and environment risks.

On a whole there is interest and need in contribution to development of information sharing systems and in having access to integrated and/or specialised data bases.

Recommendations on the register considerations

Recommendations on the register consideration were the main outcomes of the national situational analysis and analysis of stakeholders needs of information on chemicals:

- International experience in collection information on hazardous chemicals in the context of priorities identified at the stakeholders consultations should be analysed in order to decide on the national register and registration system development;
- One of the major recommendations is urgent need for the state to streamline harmonize both various pieces of the Georgian legislation with each other, as well the Georgian legislation with international standards. Such action would address most information needs and serve as the reasonable starting point for addressing all legislative gaps and information needs.
- The list with classifications of the prohibited hazardous chemicals and wastes, as well as restricted chemicals and wastes should be drawn up and made available via unified, up-to-date, technically sound and user-friendly electronic state database. Similar database should be drawn up for the chemical properties.
- Detailed rules should be drawn up and implemented to ensure that the databases are regularly updated and the Customs Department, the Ministries of Healthcare and Environmental Protection have full access to the registry.
- The classification and labeling according to UN GHS/CLP should be considered when developing the national legislation system;
- The information should be translated into the user-friendly electronic and hard copy manuals for the customs officers, for them to prevent illegal traffic in practice.
- The permanent exchange of information among all relevant Georgian state authorities should be established relating to the information about permit, declaration, approval certificate templates; prohibited and restricted chemicals and wastes; chemicals and chemical products hazards; etc.
- To consider establishment of infrastructure to ensure the register functionality;
- Formation of poisoning information&consulting center (Poisoning Control Center):
- information and advisory support to healthcare institutions regarding modern methods of diagnosis and treatment of acute poisoning, complications; in critical situations - provision of relevant specialized assistance in accordance with the modern standards. Provision of medical networks (ambulatory, outpatient's, municipal and regional hospitals), as well as the population, with information on composition of chemical products, used in household chemicals, agriculture and industry; threats of harmful effects; poisoning prevention, diagnosis and remedial measures;
- Ensure scale of the register (consider formulation).
- These consideration were focused when the model and operational framework of the national register of hazardous chemicals has been discussed and created.

3.2 Development of a model of register/inventory of chemicals and operational framework

Structure of the model of a register/inventory of hazardous chemicals developed in Georgia was based on an overview of international practices of registration/notification/inventory of hazardous chemicals, taking into consideration the economic development requirements, legislative framework and existing human and institutional capacity in the country.

The model of a register was developed in accordance with the definitions under the following EU

Directives: REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products, REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration/notification, Evaluation, Authorization and Restriction of Chemicals (REACH).



Structure of the model of register/inventory of hazardous chemicals

Procedure for REGISTRATION/NOTIFICATION OF COMPANY/LEGAL ENTITY (REGISTRANT) is as follows:

If a company/legal entity manufacturing, importing, exporting, re-exporting for the first time a dangerous substance or dangerous mixtures in the amount of 1 ton (needs to be agreed among key stakeholders) or more per year, shall notify of higher tonnages first or use for manufacturing/production purpose .

All substances and mixtures that are classified hazardous according to the CLP are subject to registration/notification at any quantity. Consequently, companies that manufacture or import chemical substances and place a hazardous substance or mixture on the market shall register their substances and/or mixtures with the relevant governmental institution. This information is submitted through data transmission in the form of an electronic document in the system.

First, the company has to register in the database through the main webpage. For registration/notification purposes the VAT number of the company is required. The system is bilingual and offers Georgian and English versions. Registration/notification will be available 24 hours 7 days in a week.

The entire procedure comprises 4 steps:

STEP 1 - LEGAL ENTITY/COMPANY REGISTRATION/NOTIFICATION

The registrant has to indicate its legal status: legal entity or company, after following data needs to be provided: contact details of the notifying person, data/contact details of the notifying company, in particular the tax-number, which is double-checked by the system, name of the company; city where the company and its branch(s) is/are based (can be selected from a drop down list).

STEP 2 - CHEMICALS REGISTRATION/NOTIFICATION

As a second step, the company has to provide theCOMPANY/LEGAL ENTITY PROFILE, LOG IN

STEP 3 - REGISTRATION/NOTIFICATION OF CHEMICALS

The obligation to register lies with the manufacturer, importer, exporter, re-exporter or group of manufacturers, importers, exporters, re-exporters who place the dangerous chemicals (substance or /and mixture) on the market. Governmental institution/agency

/central body (eg. MoE, MoA, MoH, MoD), which must be informed in regards of registration/notification has to be determined in accordance with the legislation.

The registrant also needs to select the sub-system from the drop down menu which it requires the access to, and the access-rights he/she requests. Confirmation and approval of request (together with the User ID and password) are sent within a few days to the E-mail address of the notifying person.

STEP 4 - REQUESTED INFO FOR REGISTRATION/NOTIFICATION OF

- **dangerous substance**
- **dangerous mixtures**

In this case, information has to be updated regularly, every time when new information becomes available.

PRODUCT (BIOCIDES) REGISTRATION/NOTIFICATION

Before placing a biocidal product on the Georgian market, for a particular type of product **the registrant/notifier** will need to ensure that the active substance is either approved or under review in that Product Type. The status of the active substance can be checked through the NCDC webpage.

The biocidal product type should be selected from the drop down list (from the main group of the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) (EU) 528/2012)(BPR)). **APPROVAL FROM CENTRAL BODIES (NCDC):** authorization or restriction

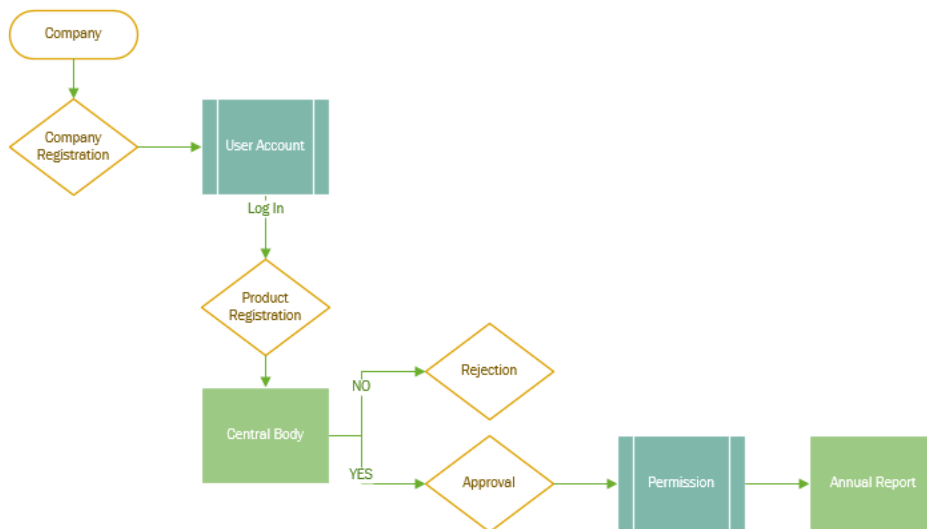
Once the authorisation is granted that the product may be placed on the market in Georgia, it should be done so in a manner consistent with the conditions and restrictions associated with the authorisation.

Where an application does not meet the required standards, an authorisation will not be issued. The applicant may have the opportunity to modify/update their application in order to make it acceptable. NCDC will have open lines of dialogue with applicants to facilitate the process.

In addition, companies have to submit an annual report covering the following data:

- Year
- Date of report
- Status (completed / not completed, where it was used) o Chemical product report number
- Chemical product name
- Annual amounts in tons for production, import, placing on the market and export o Rest of chemicals (quantity, storage location)
 - It should be emphasized that this procedure foresees to protect customers from harmful effect of chemicals and relevant information will be available to them via the website, an SMS service or application,
 - Product check in markets (checks of barcodes)
 - Information from the website (information about the product, organization, producer, warning labels, signal words)
 - First aid measures in case of chemical poisoning
 - Contact details of appropriate medical facilities (poisoning centers, labs) o Reporting new cases
 - Reporting poisoning cases

REGISTRATION / NOTIFICATION SCHEME



It should be noted that exchange of information flows via the system among the following authorities/actors will be ensured:

Information from the Revenue Service (organization, manufacture, distribution); Information from the Customs Service (import);

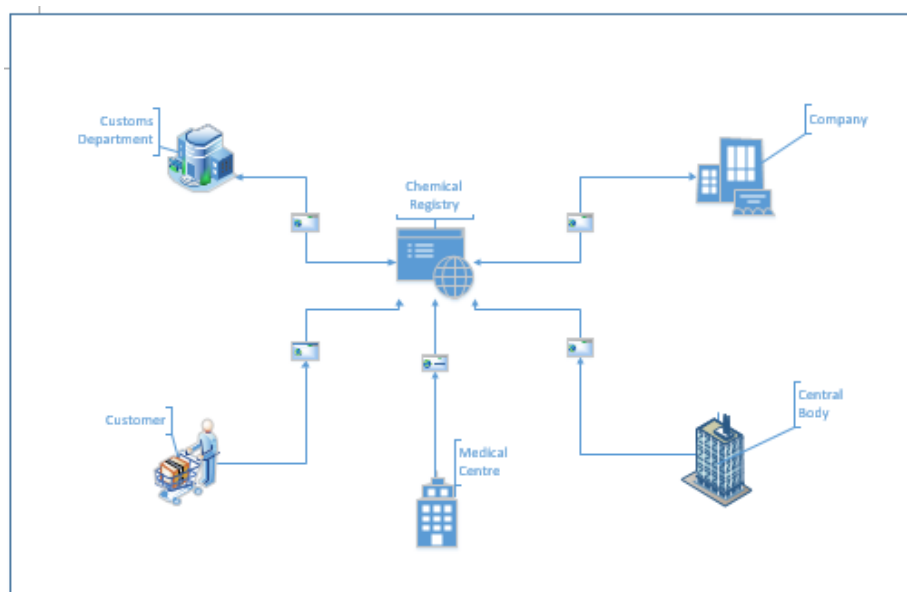
Information exchange with organizations (manufactured, imported products); Information exchange with customers (information retrieval from the website, reporting new cases);

Information exchange with central bodies (registered organizations, registered products, restricted products, and monitoring, rules and regulations);

Scheme for Information Flows

The appointed bodies (designated according to the Law) have to ensure the confidentiality of information about chemical composition of mixtures, including chemical identity of substances in the mixtures.

Confidential information may only be used to decide on preventive and curative measures, in particular in case of emergencies, and/or to undertake statistical analysis to support the adoption of improved risk management measures.



Once the notification sheet is filled, there are two ways to submit the safety data sheet: either to fill in an electronic format on-line, which is facilitated by drop down menus, or by attaching the pdf-version of the SDS.

Exposure scenarios and draft labels, if relevant, need to be attached too, as well as a certification of payment of administration fee, which is a mandatory element of notifications. The system also provides communication between the authority and the company: the administrator informs the company via this field in case further information/data is necessary, or if the administrator considers that the submitted documents/information are not correct. This field is also accessible for national enforcement authorities. If possible, therefore, the program offers drop down lists to select relevant information (e.g. direct link to ECHA database for classified substances, type of use, physical state, family of non dangerous components etc.).

Hazard Communication Standard (HCS) requires chemical manufacturers, distributors, or importers to provide Safety Data Sheets (SDSs) (formerly known as Material Safety Data Sheets or MSDSs) to communicate the hazards of hazardous chemical products. Safety Data Sheets are the main communication tool between suppliers and users of substances and mixtures.

The information presented in the register will be updated yearly, taking into consideration annual reports from the companies.

The template of Safety Data Sheets elaborated in the framework of the model of register meets relevant international requirements.

It is well worth mentioning that the experience gained and results achieved within the project proved to be very interesting for the countries which face similar problems in the area of collection and sharing of information on hazardous chemicals.

3.3 Proposals for strengthening of the national legislation for ensuring sustainability of information collection and sharing

To ensure sustainability of chemicals registration in Georgia the proposals for legislation framework were developed based on the analysis of existing legal acts, legislation strengthening in the framework of the Agreement with EU and a discussion with experts and stakeholders' representatives during relevant workshops.

Objective of the Legal Concept Note was to give brief analyses of the national legislation in compliance with the already agreed draft National Chemicals Registry design and its operational framework and to create a list of legislative acts that should be considered for amendments and/or if relevant legislation exists to propose what kind of sub-legislative acts were required.

During the last decade, several measures were taken in Georgia to establish a system for chemicals management and to protect population from negative impacts of chemicals. The major law that sets comprehensive system for chemicals Notification and admission to the market is the Georgian Law on **Pesticides and Agrichemicals (25/11/1998)** and related sub- laws. This legal act regulates issues related to the design, production, Notification, labelling, packaging, sale, storage, transportation, use, elimination, disposal, information exchange, advertisement and export-import. Major sub-laws stipulated from the Law on Pesticides and Agrichemicals and serve for effective implementation of the mentioned law. Responsible governmental institution is the Ministry of Agriculture and its Food safety Agency.

The Law 29/11/2013 Law on the Control of Military and Dual-Use Goods and related sub- laws setting a regulatory regime for import-export and transit of chemicals used solely for military defense purposes or both for military and civil applications, competent authority is the Ministry of Defense.

From 2014 entered in force **No 428/31/12/2013 Government Decree on the Technical Regulation for Labelling of the hazardous chemicals** laying down the rule on labelling and packaging of chemicals. In 2016 was adopted **The Government Decree No 263/13/06 on the Approval of the Rule of Export-Import**

of Certain Hazardous Chemicals and Pesticides and Prior Informed Consent (PIC), which setting a regulatory regime for the management of certain hazardous chemicals and pesticides in accordance with requirements of the Rotterdam Convention on PIC and the Stockholm Convention on Persistent Organic Pollutants, designating competent authorities engaged in the regulation of international trade with chemicals and defining their competencies in order to better protect human health and environment and, promote safe use of certain hazardous chemicals and pesticides. Ministry of Environment and Natural Resources Protection is the designated competent In case of hazardous chemicals authorities and the Ministry of Agriculture is the designated competent authority for Pesticides.

One of the factors hampering the hazardous chemicals management process is a lack of information resources – either their absence or insufficient quality or reliability. Improvement of the information system is becoming more critical due to Georgia responsibilities under Association Agreement with EU (signed in 2014). Chemicals Management covered in Section VI of the AA Agreement: Cooperation in other areas, Chapter 3: Environmental Protection, Article 302: "Cooperation shall aim at preserving, protecting, improving, and rehabilitating the quality of the environment, protecting human health, sustainable utilization of natural resources and promoting measures at international level to deal with regional or global environmental problems, including in the areas of: chemical management."

With the above regard Advisory Assistance Program "Development of legislative and operational framework for collection and sharing information on hazardous chemicals on Georgia" funded by the German Federal Environment Agency has been implemented by WHO Regional Office for Europe, in cooperation with the National Centre for Disease Control and Public Health of Georgia and the Ministry of Environment and Natural Resources Protection of Georgia.

Within the scope of the above Programme detailed Chemicals Registry structure, content and steps for registration of chemicals was developed in 2017 by the group of national technical experts with involvement of international consultants from Slovenia and Hungary. Draft Chemicals Registry was discussed and agreed with relevant governmental agencies and other stakeholders. By the end of this process concept note on development of the Georgian National Legislation to implement Draft Chemicals Registry was elaborated. Legal concept not was also discussed and agreed with key stakeholders.

Objective of the Legal Concept Note was to give brief analyses of the national legislation in compliance with the already agreed draft National Chemicals Registry design and its operational framework and to create a list of legislative acts that should be considered for amendments and/or if relevant legislation exists to propose what kind of sub-legislative acts were required.

After review and discussions with international experts and national stakeholders at stakeholders meeting on 13-14 March, 2017 (Tbilisi, Georgia, NCDC Conference Hall) further next steps were agreed were agreed to be implemented:

- drafting of texts of amendments to existing legislation to ensure registration of hazardous chemicals including legislative acts in the area of human health protection, occupational safety, transboundary traffic of hazardous chemicals, environment protection, preparedness and response to emergency situations or development of respective new draft legal acts
- preparation of proposals on further steps for creation of legislative framework to ensure sustainability of collection and sharing information on chemicals

Furthermore, presentation of information on legislative platform for collection and sharing information on chemicals registry was presented during the International Workshop on 28-29 March 2017 (Tbilisi, Georgia).

All Legal options for establishment of chemicals registration system were considered in light of the "Draft Structure of the Chemicals Registry" of 2017.

As a result of the above process the legal option bellow was found appropriate to serve as entry point for establishment of chemicals registration system in Georgia:

- Law on Public Health of 2007 (Article 24 - Chemical safety) to be used to introduce registration system for chemical substances and their mixtures
- Subsequent detailed sub-law to be established and approved by the government in a form of technical regulations – including operational technical details concerning chemicals data base and registration system.

Short explanation of approach

Amendment to the Law on Public Health of 2007 (e.g, with introduction of new version of existing Article 24 allows to integrate much more legally important provisions on chemical substances (definition of chemicals subject to registration, scope of introduced registration system, etc.) to be further detailed in subsequent technical regulations under the Law on Public Health of 2007 (Annex 2).

It has to be especially noted that according to Georgian law general principles the government (Cabinet of Ministers or individual governmental agencies) is prohibited from writing regulations (sub-laws), which are either inconsistent with or not explicitly required by the law. While it is impractical and inadvisable to include numerical standards in the law itself, the law should include some detailed descriptive guidance for how appropriate technical requirements should be established.

According to the present legal proposal, Article 24 of the Law on Public Health of 2007 is modified and new version of this article is instead.

The above amendment in a form of modification aims at creation of Chemicals Registry as a national system of registration of chemicals for the purposes of:

- aiding in the protection of the people and the environment by finding out the risks to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals
 - providing information, and making recommendations for decision-making on chemicals
 - if appropriate, giving effect to Georgia's obligations under international agreements relating to the regulation of chemicals
 - collecting statistics in relation to the chemicals; being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals.

The amendment defines, that the Chemicals Registry will be maintained as electronic database.

According to the amendment, manufacturers, importers and downstream users will be bound by obligation to register chemicals into Chemicals Registry.

The following chemical substances on their own, in mixtures or in articles will not be manufactured in Georgia or placed on the market unless they have been registered into the Chemicals Registry:

- Biocides – from July 1, 2018
- Hazardous substances – from July 1, 2018
- Industrial chemicals – from July 1, 2020

As currently Georgia does not have legally binding list of hazardous substances, the amendment defines that for the purposes of registration into the Chemicals Registry, hazardous substances mean substances listed in Table 3.1 (List of harmonised classification and labelling of hazardous substances) of Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

Most important provision of the amendment stipulates that the Chemicals Registry will gradually integrate data and information on the other chemicals (rather than biocides, hazardous substances and industrial chemicals), namely:

- Pesticides and agrochemicals – from January 1, 2022;
- Wastes within the scope of Waste Management Code of Georgia – from January 1, 2023;

- Radioactive substances and wastes – from January 1, 2023;
- (Food and feeding stuffs – from January 1, 2024;
- Pharmaceuticals (medicinal products) for human or veterinary use;
- Cosmetic products – from January 1, 2025;
- Military and dual-use products – from January 1, 2026.

Based on gradual integration the Chemicals Registry will become the fully integrated Chemicals Registry after 2016.

The amendment defines competent authority for chemicals registration - the National Centre for Disease Control and Public Health of Georgia that is assigned to carry out the obligations related to the management of the Chemicals Register.

Details on chemicals registration, namely: structure, operational and notification and registration rules and procedures, as well as detailed lists of substances (including their quantitative description) subject to registration into the Chemicals Registry will be determined in detail under the Technical Regulation on the Chemicals Registry. This Regulation will be adopted by the Government of Georgia upon the proposal provided by the Ministry of Labour, Health and Social Protection of Georgia not later than July 1, 2018.

Thus July 1, 2018 is a target date to put the Chemicals Registry and chemicals registration into practice.

In addition to the Technical Regulation on the Chemicals Registry, the Government of Georgia is prescribed to adopt also:

- Technical Regulation on Biocides not later than end of 2018 – to be subject to harmonization with the standards under the Regulation (EC) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;

and

- Technical Regulation on Classification, Labelling and Packaging of Substances and Mixtures not later than July 1, 2022 – to be subject to harmonization with the standards under the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

To cover the subject integrally, the amendment also sets the date for development and adoption of framework legislation on chemicals safety and management not later than January 1, 2022. This framework law has to be prepared in collaborative manner jointly by the Ministry of Labour, Health and Social Protection and the Ministry of Environment and Natural resources Protection.

Final provision of the amendment is related to the penalties for non-compliance. According to the amendment the Government of Georgia has to draft and not later than July 1, 2018 submit to the Parliament of Georgia appropriate legal amendments on penalties applicable for infringement of the provisions concerning chemicals registration. Thus, the amendment coincides putting into the practice of the Chemicals Registry with enactment of related penalties for non-compliance – both from July 1, 2018 – given that the present amendment is approved in the second half of 2017.

Chapter 4. Conclusions and steps ahead

4.1 Conclusions

Through the national assessment of existing situation, the needs of stakeholders were identified and paved the path for further development of a national model of chemical register, its operational framework and proposals for legal bases.

The proposal for the register model, its demo-version and operational framework have been developed by national experts in cooperation with the international project manager and international experts.

The Concept Note on Georgian Chemicals Registry has been finalized based on the multi- stakeholders' meeting outcomes and has been shared with different Ministries for comments and notes.

The first national toxicological glossary has been created by national experts based on the WHO and IFCS joint publication „Glossary of Terms on Chemical Safety“ and has been published in the national language. In addition, over 40 Material Safety Data Sheets (MSDS) are prepared in the national language. Information available on chemicals in Georgia has been collected.



Additional activities related to the information management were initiated in the process of the project implementation, namely:

During the discussion held on the national information needs by stakeholders' representatives (29-30 October 2015), the lack of legal management of chemicals regulated by the Stockholm and Rotterdam Conventions was revealed. By now, upon the nomination of the Ministry of Environment and Natural Resources Protection of Georgia, the Georgian Government Approved Resolution #263 of 13 June 2016 on PIC-procedure and adopted the list of prohibited or severely restricted hazardous chemicals and pesticides in Georgia.

In addition, as the meeting follow-up, several regulations were developed by the experts of the N. Makhviladze S/R Institute of Labour Medicine and Ecology, in coordination with NCDC in accordance with Art. 4 of the Council Directive 98/24/EC of 7 April 1998 and the Georgia-EU Association Agreement on the protection of health and safety of workers from the risks related to chemical agents at work. The documents developed are as follows:

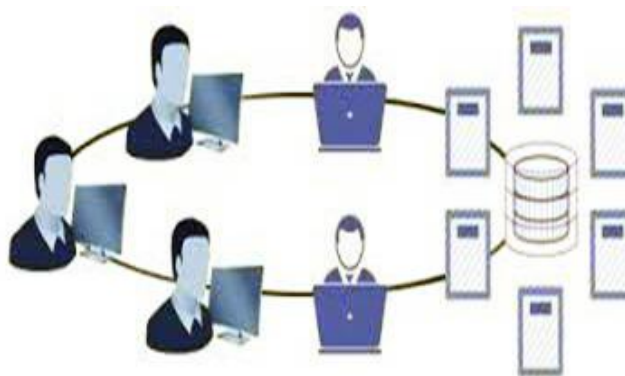
1. Technical Regalement on Occupational Exposure Limits for Chemicals;
2. Classification of Chemicals. General Requirements;
3. SDS. General Requirements;
4. Labeling of Chemicals. General Requirements.

In the framework of the project, participants and decision makers increased their knowledge of European Legislation about chemical safety area. Problems have been analyzed and possible solutions identified. Now it is very important that the national experts are motivated. The project should continue and create appropriate opportunities. On the one hand, they are ready to improve the real situation. On the other hand, national experts remind the authorities of their obligation and of considering requirements under the EU AA, whereby the Government of Georgia began an irreversible process.

The project has been a rich experience not only for the national experts, but also for those responsible for the management of hazardous chemicals. Involvement of the Regional Public Health Centers in workshops held in the framework of the project is well worth a special emphasis. Once again, this is clear proof of problems arising on the local level in terms of protecting population health from the effect of chemicals, of their information awareness concerning the presence of chemicals on site, their storage, sale, warehousing, various sources of contamination etc.

4.2 The next steps

The results of the project are on the priority agenda of the National Government. Georgia is a signatory to the EU AA and should fulfill taken obligations to perform harmonization of its legislation with the legislation of the European Union and to introduce internationally recognized environmental approaches, regulations and recommendations. The results of the project can be used for awareness raising at national level and advocacy for a better implementation of international agreements.



The project findings will serve as the evidence basis for creating an improved legislative/normative framework related to Chemicals. The existing hygienic norms and technical regulations need to be revised taking into consideration the WHO Guidelines and relevant European Directives.

For the purposes to insure chemical safety of the country the Unified National Database of Chemicals – Electronic Registry (UNDC-ER) shall be created.

The next steps towards creating of the national chemical register in Georgia were discussed at the final meeting in the project framework Towards creation of a system for collection and sharing of information on hazardous chemicals: experience of Georgia (Tbilisi, Georgia, 28-29 March 2017).

The meeting participants decided that setting the national chemical register in Georgia is beneficial for SMC through:

- Better management of chemicals - knowledge about what is on a market and how to manage existing chemicals soundly;
 - Availability of data on quantities and storage to assess risks for human health and the environment;
 - Availability of data on first aid and safety measures during chemical emergencies;
 - Continue collection of information about chemicals that are a subject to relevant Conventions;
 - Different sectors can use the database (software can easily be adopted to needs and it is operational almost instantly);
 - Data in the database could be opened to all with limited access, given confidentiality of data and other relevant issues;
 - Database is important for risk managers – risk assessment and risk communications; for inspectors
- in the case of accident, routine control and planning preventive actions.

Electronic reporting system should be considered at the planning stage due to many advantages it provides:

- Electronic database starts working immediately unlike paper files which take a lot of time for evaluating and a lot of space for storage; timely updating of information and confidentiality of data is questionable if hard copies are submitted;
- It is much easier to share the information by providing access to interested stakeholders as well as public, given confidentiality and other legislative requirements on information sharing;
- Software can be easily adopted to the chemical legislation requirements (for example, reject registration of prohibited chemicals) and eliminated language barriers;
- Software is web based that provide an opportunity to enter data from anywhere as long as you have internet connections and even use a phone if needed;
- Having such an electronic system in place gives opportunity to create different reports using different variables (trader, chemical, hazard etc).

Discussion of the next steps resulted in the following proposals:

The national experts proposed step-by-step approach for implementation of the registration system

starting with registration of any amount of biocides and highly hazardous chemicals in the amount exceeded 100 kg. Information should be provided by producers, users and importers. The list of chemicals, Annex VI of the CLP regulation, which includes 4500 substances will be applied to identify highly hazardous chemicals. All industrial chemicals will be a subject for registration to 2020.


As mentioned, national legislation should be review and improved taking into account previous national and international commitments such as development and implementation of a regulation on classification, labelling and packaging chemicals (probably in 2020-2021). National experience in registration of pesticides and disinfestations should be taken into account.

The national experts suggested using existing Law on Public Health as an entry point for creating legislative basis for registration of chemicals: the Law include article requiring collection of information on hazardous substances. Responsible ministries should cooperate with NCDC, Georgia to ensure progress in the legal framework development.


Terminology and definitions such as registration, authorization, restriction are different in the Georgian and EU legislation. Special discussion is necessary to reach consistency and avoid misunderstanding at later stages of information system implementation.

In addition to legislative framework, sophisticated electronic software and trained staff is necessary to set up and maintain a chemical register. The electronic software (demoversion) was developed and demonstrated to the workshop participants. The Advisory Assistance Program of the German Federal Environment Agency and the Special Programme of UNEP were introduced as potential sources of funding of further actions at national and regional level.

Demonstration software for the national chemical register in Georgia


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News

Chemicals Agency withdraws the authorisations of plant protection products with glyphosate and POE-tallowamine


10/4/2016 The Swedish Chemicals Agency withdraws the authorisations of eleven plant protection products containing glyphosate and the co-formulant POE-tallowamine.

Chemicals Agency reviews the authorisations of plant protection products with the co-formulant POE-tallowamine

9/6/2016 The European Commission has decided that the co-formulant POE-tallowamine shall no longer be included in plant protection products containing the active substance glyphosate.


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Warning labels

Hazardous chemical products must be labelled with danger symbols and text containing information about the hazard. Information about how to protect oneself and handle the product in a safe way must also be stated. The companies manufacturing, importing or selling the product are responsible for ensuring that it is labelled correctly.


[Find out more](#)



Registered substances

Outline an app feature/benefit here. You can change the icon above to any of the 500+ FontAwesome icons available.


[Find out more](#)



Restricted substances

Outline an app feature/benefit here. You can change the icon above to any of the 500+ FontAwesome icons available.

[Find out more](#)



Poison centers

Contact details of medical facilities in chemical poisoning cases.

[Find out more](#)

Rules and regulations



REACH Regulations (EU) No 907/2006 concerns the registration and restriction of chemical substances. It also contains requirements addressed to the users of chemicals.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemical Agency [European Chemical Agency](#) last consolidated on 14 July 2016

Commission Regulation (EU) 2016/ 266 of 7 December 2015 amending Regulation (EC) No 440/2008 ([Test methods](#))

Commission Regulation (EU) 848/2012 of 19 September 2012 [amending Annex XVII](#)

Links to information on REACH on the ECHA web pages The European Chemicals Agency (ECHA) assists companies in complying with the legislation, promotes the safe use of chemicals, provides information on chemicals, and addresses chemicals that are of concern. All the links below take you to ECHA

Databases

Restricted Substances Database

This database contains information on whether the restrictions placed on a substance or group of substances are in compliance with the provisions set out in Swedish Government regulations or are in compliance with those set out in the Swedish Chemicals Agency regulations.

[Go to the Restricted Substances Database.](#)

Classification and Labelling Register (including substances in Annex VI to CLP)

This database contains classification and labelling information on notified and registered substances received from manufacturers and importers. It also includes the list of harmonised classifications (Tables 3.1 and 3.2 of Annex VI to the CLP Regulation) and the names of harmonised substances translated into all EU languages.

[Go to ECHA's Classification and Labelling Inventory](#)

Pesticides Register

The Pesticides Register contains information on more than 3,000 authorised and previously authorised pesticide products in Sweden. The register is only in Swedish, but you can easily find user classes, registration numbers, specific conditions and dates of validity and expiry. [Go to the Pesticides Register.](#)

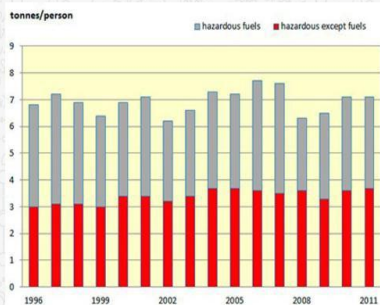
The priority guide PRIO

A web-based tool intended for taking preventive action in reducing the risk posed by chemicals to human health and the environment.

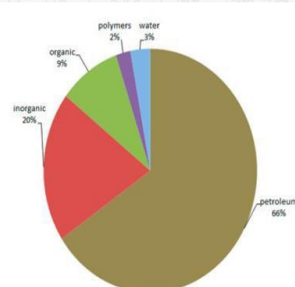
[Go to PRIO](#)

Statistics in brief

Amount of chemical products hazardous to health per person per annum



Breakdown between different groups of substances



Publications



Welcome to Chemicals Registry

User (Personal Id/E-Mail)


Password

☐ Remember Me

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Register

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LAW OF GEORGIA

ON AMENDMENT TO THE LAW OF GEORGIA ON PUBLIC HEALTH (DRAFT)

Sec. 1. The Law of Georgia On Public Health (Official Gazette of Georgia - LHG, Vol. 26, 2007, Cl. 244) is hereby amended as follows:

Article 24 shall be modified to read as follows:

“ARTICLE 24. CHEMICAL SAFETY**1. Definitions.**

For the purposes of this Law:

- a. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- b. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- c. manufacturing: means production or extraction of substances in the natural state;
- d. manufacturer: means any natural or legal person established within Georgia who manufactures a substance within Georgia;
- e. import: means the physical introduction into the customs territory of Georgia;
- f. importer: means any natural or legal person established within Georgia who is responsible for import;
- g. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
- h. downstream user: means any natural or legal person established within Georgia, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer shall be regarded as a downstream user;
- i. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

2. Chemicals Registry and Registration of Chemicals.

- a. In order to insure chemical safety of the country the Chemicals Registry shall be created;
- b. The Chemicals Registry serves as a national system of registration of chemicals for the purposes of:
 - (i) aiding in the protection of the people and the environment by finding out the risks to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals; and
 - (ii) providing information, and making recommendations for decision-making on chemicals; and

(iii) if appropriate, giving effect to Georgia's obligations under international agreements relating to the regulation of chemicals; and

(iv) collecting statistics in relation to the chemicals; being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals.

c. The Chemicals Registry shall be maintained as electronic database;

d. Manufacturers, importers and downstream users shall be bound by obligation to register chemicals into Chemicals Registry;

e. The following chemical substances on their own, in mixtures or in articles shall not be manufactured in Georgia or placed on the market unless they have been registered into the Chemicals Registry:

(i) Biocides – from July 1, 2018;

(ii) Hazardous substances – from July 1, 2018 (for the purposes of registration into the Chemicals Registry, hazardous substances shall be interpreted within the meaning of listed in Table 3.1 /List of harmonised classification and labelling of hazardous substances/ of Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures);

(iii) Industrial chemicals – from July 1, 2020.

f. The Chemicals Registry shall gradually integrate data and information on the following chemicals:

(i) Pesticides and agrochemicals – from January 1, 2022;

(ii) Wastes within the scope of Waste Management Code of Georgia – from January 1, 2023;

(iii) Radioactive substances and wastes – from January 1, 2023;

(iv) Food and feeding stuffs – from January 1, 2024;

(v) Pharmaceuticals (medicinal products) for human or veterinary use;

(vi) Cosmetic products – from January 1, 2025;

(vii) Military and dual-use products – from January 1, 2026.

g. The National Centre for Disease Control and Public Health of Georgia shall be assigned to carry out the obligations related to the management of the Chemicals Register;

h. Structure, operational and notification and registration rules and procedures, as well as detailed lists of substances (including their quantitative description) subject to registration into the Chemicals Registry shall be determined in detail under the Technical Regulation on the Chemicals Registry to be adopted by the Government of Georgia. Upon the proposal provided by the Ministry of Labour, Health and Social Protection of Georgia, the Government of Georgia shall adopt the above Technical Regulation not later than July 1, 2018;

i. In addition to the Technical Regulation on the Chemicals Registry, the Government of Georgia shall adopt:

(i) Technical Regulation on Biocides not later than July 1, 2018. This Technical Regulation shall be subject to harmonization, where appropriate, with the standards under the Regulation (EC) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products;

(ii) Technical Regulation on Classification, Labelling and Packaging of Substances and Mixtures not later than July 1, 2022. This Technical Regulation shall be subject to harmonization, where appropriate, with the standards under the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

3. Framework for Chemicals Safety and Management.

a. For the purposes to establish the framework legislation on chemicals safety and management, the Government of Georgia shall prepare and submit to the Parliament of Georgia Framework Draft Law on Chemicals Management not later than January 1, 2022;

b. Framework Draft Law on Chemicals Management shall be prepared upon the proposal jointly provided by the Ministry of Labour, Health and Social Protection of Georgia and the Ministry of Environment and Natural resources Protection of Georgia.

4. Penalties for non-compliance.

The Government of Georgia shall draft and not later than July 1, 2018 submit to the Parliament of Georgia appropriate legal amendments on penalties applicable for infringement of the provisions laid down in this Article concerning chemicals registration and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.”.

Sec.2. The amendment made by Sec.1 shall enter into force following to official publication.

Promulgation by the President of Georgia - /Signature/

Done at, thisth day of 201....

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