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GEORGIAN NATIONAL CENTER FOR DISEASE
CONTROL AND PUBLIC HEALTH

Establishment of National Register and
Biocides Sound Management System in Georgia

Project report

Establishment of Key Elements of Sound Chemicals Management Systems in Selected
Countries in Eastern Europe, Caucasus and Central Asia (Georgia, Belarus, Kazakhstan)



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Globally Harmonized System of Classification and Labelling of Chemicals

List of Acronyms and Abbreviations

DCFTA – Deep and Comprehensive Free Trade Area

EaP– Eastern Partnership

EC – European Commission

ENPI – European Neighbourhood and Partnership Instrument

EU – European Union

MEPA-Ministry of Environmental Protection and Agriculture of Georgia

CLP - The Classification, Labelling and Packaging Regulation

MoH -Ministry of Internally Displaced Persons from Occupied Territories, Labour, Health and Social Affairs of Georgia

NGO – Non-Governmental Organization

NCDC- National Center for Disease Control and Public Health of Georgia

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

UNECE – 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

WHO – World Health Organization

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

Introduction

Chemical production is increasing worldwide and poses risks to ecosystems and human health. Population and wildlife are exposed to mixtures of chemicals from medicinal and biocidal products and through contaminated water, food, air and soil. Health adverse effects include cancer, decreased fertility, allergies, diabetes, depression, dementia, stress, respiratory, cardiovascular and skin diseases. Environmental effects include the degradation and loss of function of ecosystems and their services. The diversity and quantity of synthetic chemicals in use has increased rapidly globally, chemical production has expanded 50-fold since 1950¹, and it is set to triple again by 2050 compared to 2010, mainly outside Europe².

Setting-up a system enabling sound management of chemicals (SMC) is a priority for both countries - having Association Agreements with the European Union (EU) and countries that are parties of the Eurasian Economic Union (EEU). Advanced policies and proper legislation, availability of systems for information collection and sharing, as well as adequate human and technical resources are essential for making progress in preventing the negative impacts of chemicals on human health and the environment. Despite existing specificity of the approaches to chemicals management in different countries (national legislation, infrastructure, etc.), the basic elements including chemicals registration, as well as availability and access to information on chemicals, are common and unique requirement.

In the framework of a project „Development of operational and legislative system for collection and sharing information on hazardous chemicals in Georgia“ 2015-2017³ (funded through the Advisory Assistance Program of the German Environment Agency (UBA)), WHO organized meeting in Georgia, Tbilisi on 28-29 March 2017, where all participating countries reported limited capacities (technical, human and financial), and lack of expertise at the national level necessary for implementation of the existing legislation on chemicals and for developing new legal acts. The need for support from donors and international organizations has been emphasized.

In response to the countries' request, a project “Establishment of national systems for a sound management of chemicals in selected countries in Eastern Europe, Caucasus and Central Asia” has been developed. It aims to set the main elements of SMC systems by drafting legislative acts and strengthening technical infrastructure, as well as building up national capacities for SMC.

Implementation of the project will contribute to the European Environment and Health Process and to the implementation of commitments at regional (Ostrava Declaration) and global (SDGs, SAICM, MEAs) levels.

¹ Trasande, L., et al., 2016, 'Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis', *Andrology* 4(4), pp. 565-572.

² OECD, 2012, Fig. 6.13, Environmental outlook to 2050: The Consequences of Inaction
<http://dx.doi.org/10.1787/9789264122246-en>

³ Report on the project “Development of legislative and operational framework for collection and sharing of information on hazardous chemicals in Georgia”
<https://www.ncdc.ge/Pages/User/News.aspx?ID=bdd35a23-5323-4a12-993e-ba6670d01dd0>

Chapter 1. Background

Human ingenuity has produced well over 100 000 new chemicals — substances which have never before been part of the terrestrial environment.

For most of these chemicals, however, we simply do not know how they pass through the environment, whether they are accumulated, dispersed or transformed, and how they affect living organisms and human health at different concentrations.

People are exposed to a complex mixture of chemicals on their daily basis. The chemical burden of human body results from combined daily chemical exposures, as well as exposure from persistent chemicals, that entered the body in the past and accumulated in the tissues. Substances include synthetic chemicals, such as industrial chemicals, pharmaceuticals, pesticides and biocides, chemical pollutants unintentionally emitted from industrial processes and combustion, and chemicals that occur naturally in the environment.

The volume and diversity of chemicals produced and consumed grew substantially over the past century and continues to increase (CEFIC, 2018). Of the 314 million tons of chemicals consumed in the EU in 2018, 71 % were classified as hazardous to health (Eurostat, 2020e). In terms of diversity, 22 920 unique substances had been registered under the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation (EU, 2006b) by July 2020⁴.

While chemicals contribute significantly to national economies and are an indispensable component of everyday life, sound management is essential to avoid risks to human health and the environment. Reliable information on chemicals at international and regional levels is required to inform national decision-making and thus minimize the negative effects of chemicals on humans and the environment. The Strategic Approach to International Chemicals Management (SAICM) states that “knowledge and information are basic needs for decision-making for the sound management of chemicals, including products and articles containing chemicals”^{5, 6}

Lack of clear, accessible, timely, appropriate information for sound management of chemicals in order to minimize their negative effects on human health and the environment has been recognized by many countries and in the WHO European Region⁷. Registration of chemicals and relevant national inventories allow the identification and prioritization of chemicals of concern, preparation of monitoring and risk assessment strategies and prevention of illegal traffic and stimulate capacity-

⁴ EEA Environment and Health, 2020.

file:///C:/Users/NANAGA~1/AppData/Local/Temp/Healthy%20Environment_TH-AL-20-005-EN-N.pdf

⁵ National chemicals registers and inventories: benefits and approaches to development

https://www.euro.who.int/_data/assets/pdf_file/0018/361701/9789289052948-eng.pdf

⁶ Overarching policy strategy. Geneva: Strategic Approach to International Chemicals Management; 2017

<http://www.saicm.org/Resources/Publications/tabid/5507/language/en-GB/Default.aspx>

⁷ Overall orientation and guidance for achieving the 2020 goal of sound management of chemicals. In: Fourth session of the International Conference on Chemicals Management (ICCM4). Geneva: Strategic Approach to International Chemicals Management; 2015 (http://old.saicm.org/index.php?option=com_content&view=article&id=525&Itemid=700)

building. Collection of information on hazardous chemicals can also facilitate the adoption of appropriate decisions related to chemicals management. For example, in a chemical emergency, poison information centres should have an access to a relevant database⁸ for more effective response.

1.1 EU chemical policies

The SAICM⁹ is a global policy framework with the overall goal of achieving sound management of chemicals, so that, by 2020, chemicals are produced and used such as to minimize significant adverse impacts on human health and the environment. Information considered important and that countries may wish to take into account when preparing a national database or inventory includes:

- the toxicology of priority chemicals (carcinogenicity, immunotoxicity, endocrine disruption and ecotoxicology);
- hazards and risks;
- reporting on health and environmental risk assessments;
- exposure and susceptibility to exposure;
- exposure pathways;
- information (e.g. on hazards) on chemicals produced in large volumes;
- information on chemicals that are priorities but not necessarily produced in large volumes, e.g. significant exposure; and
- guidance on chemical safety for preparing SAICM implementation plans.

In addition to SAICM documents, the SAICM Secretariat and the United Nations Institute for Training and Research prepared guidance for SAICM implementation plans¹⁰, in collaboration with the Inter-Organization Programme for the Sound Management of Chemicals, in 2009. This outlines various possible activities and provides practical suggestions for preparing a SAICM implementation plan. It recommends an integrated approach to chemicals management, including integrated information exchange, which provides, for example, an opportunity to streamline national information exchange and dissemination under international agreements, improved information exchange within and among parties and increased awareness by the general public.

The EU has a large body of policies regulating chemicals.

In 2006 and 2008, the European Union adopted new regulations to ensure appropriate risk management of hazardous substances and mixtures, and the collection of information is still being centralized and harmonized. National registers of hazardous substances and mixtures have been set up, however, for areas that are not regulated by European Union legislation and for national purposes.

⁸ Health-sector involvement in chemicals management at the national level: review of current practice. Copenhagen: WHO Regional Office for Europe; 2014 <http://www.euro.who.int/en/publications/key-publications>

⁹ Overarching policy strategy. Geneva: Strategic Approach to International Chemicals Management; 2017 <http://www.saicm.org/Resources/Publications/tabid/5507/language/en-GB/Default.aspx>,

¹⁰ Guidance for developing SAICM implementation plans. Geneva: Strategic Approach to International Chemicals Management; 2009 (<http://cwm.unitar.org/publications/publications/inp.aspx>)

Directive 67/548/EEC ON DANGEROUS SUBSTANCES¹¹ forms the basis of all subsequent chemical control directives, with the exception of e.g. finished pharmaceuticals, direct food additives, radioactive substances and ammunition. The key aim of the Directive was to oblige suppliers of chemicals to submit a list of the substances they manufactured or imported, with detailed chemical identity.

REACH- The Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (EU, 2006b) is the key horizontal legislation that aims to protect human health and the environment. The REACH¹² Regulation obliges companies to provide information on the properties and hazards of the chemicals that they manufacture and market in the EU in registration dossiers, as well as manage the associated risks. The regulation also calls for the progressive substitution of the most hazardous chemicals, when economically and technically suitable alternatives have been identified. This is done by enforcing restrictions on their uses or by authorizing the chemical uses for defined purposes.

The Classification, Labelling and Packaging (CLP) Regulation¹³ (EU, 2008b) protects human health and the environment by putting in place rules for the classification, labelling and packaging of chemicals and ensuring that information about hazards is communicated down the supply chain. Regarding chemical products, the EU has a comprehensive legislation to regulate chemicals in detergents, biocides, plant protection products and pharmaceuticals. Policies limit the use and presence of hazardous chemicals in consumer products, to ensure consumer safety and protect the environment from diffuse emissions, including personal care products, cosmetics, textiles, electronic equipment and food contact materials. Limits are also in place for chemicals in food and drinking water.

¹¹ The Directive on Dangerous Substances. Brussels: European Commission; 2014 (http://ec.europa.eu/environment/archives/dansub/consolidated_en.htm)

¹² The main objective of REACH is to ensure a high level of protection for human health and the environment, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). Brussels: European Union; 2006 (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>)

¹³ CLP operationalizes the United Nations Globally Harmonized System (GHS) of Classification and Labelling of Chemicals. The regulation obliges all manufacturers, importers and users to classify all their substances and mixtures before placing them on the market; thus, the obligation to classify lies with industry.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance). Off J Eur Union 2008;L353/1 (<http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32008R1272>)

Directive 528/2012/EU on Biocides-The biocidal products regulation¹⁴ provides for approval of all active substances and authorization of the use of biocidal products. The regulation was adopted on 22 May 2012 and was applicable from 1 September 2013, with a transitional period for certain provisions. As in the previous biocides directive (98/8/EC), use of a biocidal product had either to be authorized or, in the case of low-risk substances, to be registered. Consequently, Member States have collected information on these products. In line with regulation 528/2012/EU, the ECHA¹⁵ keeps a register of biocidal products.

Guidance for collecting and sharing information in the European Union¹⁶ Guidance has been published on the information requirements of REACH with regard to the properties of substances, exposure, use and risk management in the context of chemical safety assessment and on chemical safety assessment as one of a series of guidance documents to assist all stakeholders in fulfilling their obligations under the REACH regulation. The guidance covers:

- the collection of information on the intrinsic properties of substances to be registered;
- assessment of this information against the requirements of REACH;
- identification of data gaps; and
- generation of additional information to fill the data gaps.

The guidance is also designed to assist industry in conducting chemical safety assessments and preparing chemical safety reports, as required. A chemical safety report may be required as part of a registration dossier, an authorization application or downstream user obligations. The guidance also sets out the basic principles for preparing a risk assessment, which may be required to support a proposal for restriction, to include substances in the authorization regime or as part of a substance evaluation.

The specific information requirements include:

- the properties of substances: physical-chemical data; human data, including epidemiological data; the results of testing in vitro and in vivo; data obtained with quantitative models of structure–activity relations; grouping of substances; comparisons with other substances; the weight of evidence and any other data that might be useful in identifying the hazardous properties of a substance;
- assessment of the reliability, relevance, adequacy and completeness of all the information on the physical -chemical properties, environmental fate, toxicity and ecotoxicity of the substance; and
- use and exposure, e.g. the manufacture (if within the European Union), use, handling and disposal of the substance or of articles containing the substance (i.e. throughout its lifecycle), and the nature of the exposure, i.e. routes, frequency and duration.

¹⁴ 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 Text with EEA relevance. Brussels: European Union; 2012 (<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012R0528>)

¹⁵ ECHA European Chemical Agency <https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr>

¹⁶ Guidance on information requirements and chemical safety assessment. Helsinki: European Chemicals Agency; 2016 (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>)

1.2 Health impacts of chemicals

The human health impacts of chemicals are considerable. The World Health Organization estimates that 2.7 % of the total disease burden and 1.7 % of total deaths were attributed to chemicals globally in 2016 (WHO, 2018c). The scope of this estimation was confined to a small number of chemicals for which causality is well described.

Exposure to hazardous chemicals is known to be associated with a wide range of serious health impacts, including chronic diseases, neurological disorders and developmental effects in unborn children (Prüss-Ustün et al., 2011). In terms of translating health costs into economic terms, an assessment of the economic costs of adverse effects on human health from exposure to several hazardous chemicals, estimated costs greater than 2.5 % of global GDP (Grandjean and Bellanger, 2017)¹⁷.



Picture 1. Sources of chemicals and exposure router for humans

The EU has the most comprehensive and advanced chemicals legislation in the world, spearheaded by the REACH Regulation. Under REACH, the understanding of which substances are produced and used in the EU and the associated risks has improved dramatically. Efforts are under way to prioritize substances of potential concern and evaluate the potential risks, with the aim of identifying those substances that should be subject to controls (ECHA, 2018a).

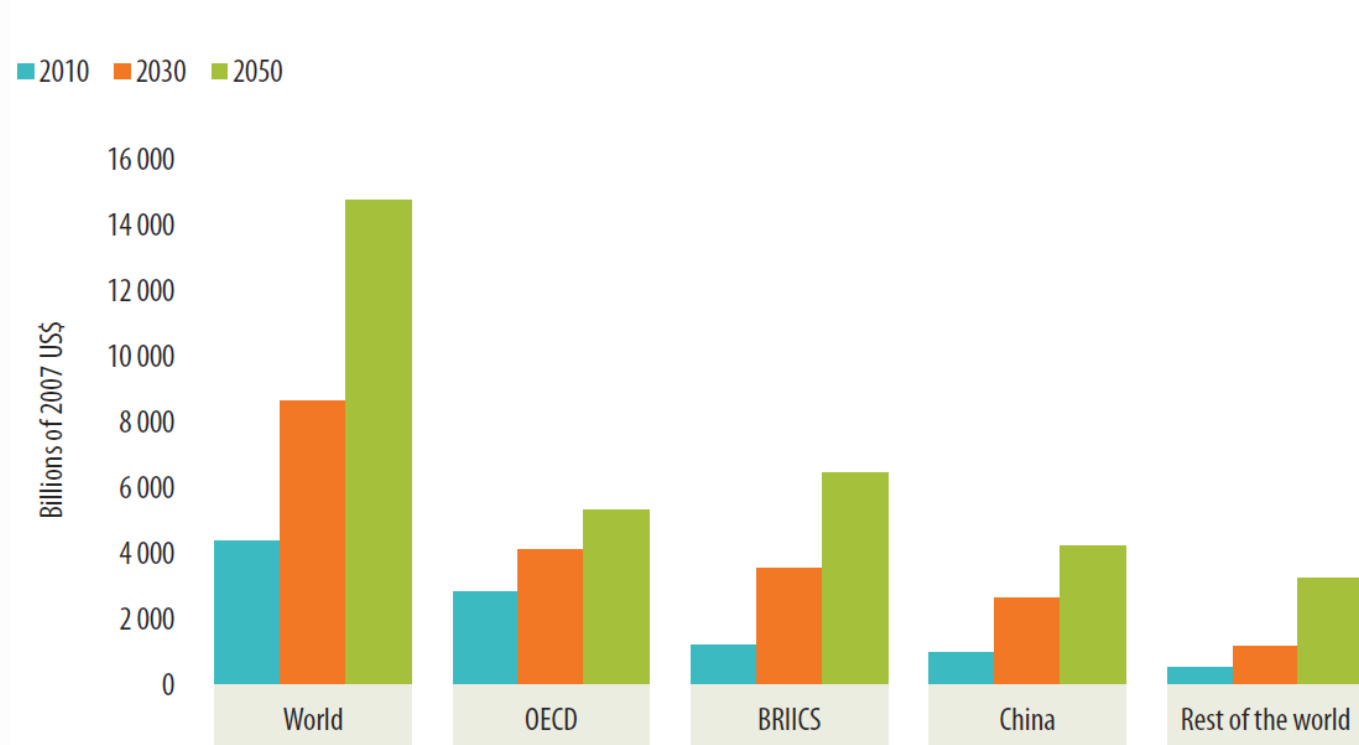
¹⁷ Grandjean and Bellanger, 2017 **Calculation of the disease burden associated with environmental chemical exposures: Application of toxicological information in health economic estimation.**

Exposure to various chemicals occurs every day and through multiple routes such as ingestion, inhalation, skin contact and via the umbilical cord to the unborn child. Many chemicals are harmless or even beneficial; others are a threat to our health and to the environment.

Chemicals production continues to increase and, with it, the potential for chemical exposure.

As shown in Figure 1 the fastest growth in chemical production is projected to be in non-OECD countries¹⁸.

Figure 1. Projected chemicals production (sales) by region, “Baseline” scenario, 2010–2050



Source: *OECD Environmental Outlook to 2050: The Consequences of Inaction*, (Chapter 6: Health and Environment) (OECD, 2012, doi: <http://dx.doi.org/10.1787/9789264122246-en>).

1.3 Benefits of a chemicals register

Compiling data on chemicals requires considerable human and financial resources. Therefore, all available national and international sources of information and databases should be used, either as the basis or as an adjunct. European Union register and databases consist of information submitted by companies, and evaluation can be considered. A national chemicals management database is commonly a inventory for all or only for hazardous (depending on national legislation) chemicals present in a country and their characteristics, in whatever form. It can therefore be used to:

- manage chemicals according to their properties and quantity so that they do not harm human health or the environment;
- prepare reports for decision-makers, the public and other groups;
- prioritize chemicals and assess their risks to health;

¹⁸ THE PUBLIC HEALTH IMPACT OF CHEMICALS: KNOWN AND UNKNOWN

file:///C:/Users/NANAGA~1/AppData/Local/Temp/WHO_FWC_PHE_EPE_16.01_eng.pdf

- trace and assess the probable impact of chemicals on human health and the environment, and take action as appropriate;
- evaluate the socioeconomic impact of planned regulatory measures, such as authorization, restriction or prohibition;
- raise awareness in all sectors of society, including industry, workers and the public;
- facilitate the exchange of information on chemicals in national commerce among stakeholders;
- facilitate and encourage partnerships among all sectors of society;
- facilitate and support the enhancement and enforcement of national chemicals management legislation; and
- facilitate regular updating of the national chemicals management profile.

Information exchange systems, including national registers or databases, facilitate access to information by various institutional actors and user groups for developing legal, technical, individual and institutional capacity for controlling chemicals, reducing risks and promoting sound chemicals management, as stated in the United Nations Institute for Training and Research „information exchange guidance note”¹⁹.

Information exchange systems help to ensure that the people involved in the numerous aspects of national chemicals management and safety get the information they need at the right time, at the right place and in a form that is suitable to their needs.

Information collected through a national chemicals register is used to inform decision-makers, the public and other groups about the chemicals that are on the market, make recommendations (also for individuals) and monitor the movement of hazardous chemicals.

A number of sources suggest the types of information that may be necessary to assess the health risks, environmental risks and hazards of chemicals.

The WHO Human Health Risk Assessment Toolkit: Chemical Hazards²⁰ is designed for public health and environmental professionals, regulators, industry managers and other decision-makers. The categories of information required may include:

- hazard identification (chemical identity, hazardous properties);
- hazard characterization and identification of guidance or guideline values; and
- exposure assessment.

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.

In view of abovementioned concerns, National road map „TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA” has been developed in Georgia, in order to conduct risk assessment on

¹⁹ Information exchange for sound chemicals management: guidance note. Geneva: United Nations Institute for Training and Research; 2001 <http://cwm.unitar.org/publications/publications/inp.aspx>

²⁰ WHO human health risk assessment toolkit: chemical hazards. Geneva: World Health Organization, International Programme on Chemical Safety; 2010 (http://www.who.int/ipcs/methods/harmonization/areas/ra_toolkit/en/)

human health, to identify the information necessary to complete an assessment, with electronic links to international resources, from which the user can obtain information and methods for conducting a human health risk assessment.

Chapter 2. Methodology

To address chemical information needs, WHO Regional Office for Europe, in cooperation with relevant Georgian national authorities, started implementation of the project „Development of Operational and Legislative System for Collection and Sharing of Information on Hazardous Chemicals in Georgia“ (2015-2017), funded through the Advisory Assistance Program of the Federal Environmental Agency (UBA) and the World Health Organization European Center for Environment and Health in Bonn, Germany. In the framework of the Project, WHO organized a meeting during March 28-29, 2017 in Tbilisi Georgia, where participating countries reported limited capacities (technical, human and financial), and lack of expertise at the national level needed for implementation of the existing legislation on chemicals and for development of new legal acts. The need for support from donors and international organizations was emphasized.

In response to the countries' request, the Project (2nd stage) “Establishment of National Systems for Sound Management of Chemicals in Selected Countries in Eastern Europe, Caucasus and Central Asia (Belarus, Georgia, and Kazakhstan)” has been developed. The project was focused on Biocides in Georgia and industrial chemicals in Belarus and Kazakhstan. Project contributed to the European Environment and Health Process and to the implementation of commitments at regional (Ostrava Declaration) and global (SDGs, SAICM, MEAs) levels.

Within the context of the Project, Georgia established National Register and Registration System of Biocides and set up technical basis for on-line collection and sharing of information on biocides. Work is in progress for harmonization of the REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning making available on the market and use of biocidal products.

The project implementation was lead 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 Environmental Protection and Agriculture of Georgia.

Taking into account all mentioned above, the overall goal of the project was to develop national capacities for management of risks from priority groups of chemicals and to establish essential elements of national system of chemicals management, including registers of chemicals in selected countries in Eastern Europe, Caucasus, and Central Asia (Belarus, Georgia, and Kazakhstan).

2.1 The project implementation team

The project has been implemented by NCDC /MEPA team with the support from experts from the Federal Environment Agency UBA of Germany, WHO ECEH. In each country (Georgia, Belarus and Kazakhstan), project coordinators have been appointed. In Georgia the project was coordinated by Dr.

Nana Gabriadze (NCDC) and Dr. Ana Berejiani (MEPA). The national project implementation team consisted from the leading national experts and IT Group members.

To ensure successful implementation of the project and achievement of its objectives a number of actions were taken: establishment of national expert's team, involvement of highly qualified international experts, organization of workshops involving Georgian, Belarusian and Kazakh representatives, organization of stakeholder's consultations and discussions with participating countries IT Groups. Summary of main activities of the project are provided below.

2.2 Main steps of the project implementation

2.2.1 Two-days' project inception workshop in Tbilisi, Georgia, on 17-19 July 2018.

The meeting was attended by national experts from Belarus, Georgia and Kazakhstan, international experts, representatives of industry and non-governmental organizations. The meeting was opened by the Director General of NCDC, Georgia, Prof Amiran Gamkrelidze. Welcoming participants, he stressed that the project was built on a success of previous project implemented in Georgia with financial support from Advisory Assistant Programme (UBA, Germany) and technical assistance from WHO Regional Office for Europe. Economic development is important for Georgia but public health and healthy environment is a top priority. Harmonization of chemical safety protection regulations are included in the Association Agreement between Georgia and the European Union, thus NEHAP has been developed and submitted to government for consideration; Health and Environment Ministries are jointly implementing the Twinning project GE22 which is supported by the Governments of Italy, Poland and the United Kingdom.

Dr. Zaza Bokhua, the First Deputy Minister of Internally Displaced Persons from Occupied Territories, Labor, Health and Social Affairs of Georgia on behalf of the Minister Dr. David Sergeenko greeted participants and shared concern about growing incidence of non-communicable diseases in Georgia, that can be also caused by exposure to hazardous chemicals. Understanding the harm that chemicals can pose to human health led to inclusion of actions related to toxic chemicals management in the national development strategy for 2015-2019.

The Deputy Minister of Health, Chief Sanitary Doctor of the Republic of Belarus Dr Nataliya Zhukova shared the opinion on importance of chemical safety for promotion of public health. In Belarus, the national strategy included many elements of chemical safety such as registration of chemicals, collection of information, strengthening of legislation. Recently adopted Regulation "On Chemical Safety" in Eurasian Economic Cooperation countries provided a great opportunity to accelerate actions towards sound chemicals management. In Belarus, the Ministry of Health is a responsible Agency for the implementation of the Regulation.

Dr. Zaure Akhmetova, speaking on behalf of the Ministry of Health of Kazakhstan, noted that in her country, as in many other countries globally, around 80% of NCD are linked to environmental and social factors. To consolidate efforts for improving the situation, the government of Kazakhstan took a decision on creating the National Public Health Centre. Ministry of Health of Kazakhstan believed that the project would create a basis for implementing sound management of chemicals in the country.

All speakers expressed their gratitude towards WHO Regional Office for Europe and the German Government for fruitful collaboration and supporting the countries in the way towards improving environmental health and chemical safety.

The representative of the World Health Organization in Georgia, Dr. Marian Ivanusa stressed that environmental health is one of the five priorities of the Organization claimed by the WHO Director General Dr. Tedros Adhanom Ghebreyesus. It is of paramount importance to address specific needs of vulnerable population and to pay special attention to exposure to chemical mixtures given that it happens with us every day.

Representing themselves the meeting participants expressed their interest in the project and gratitude NCDC, Georgia for hosting the meeting. Dr. Zhukova was elected a meeting chair.

The meeting participants adopted the agenda. Through the plenary sessions, panel and group work discussions, the meeting participants addressed a number of topics starting from the origin of the project to the best practice of chemicals management, as well as opportunities and challenges for its implementation in participating countries.



Picture 2. Opening ceremony of the two-day' project inception workshop which was organized in Tbilisi, Georgia, on 17-19 July 2018. (Marijan Ivanusa-WHO CO, Dr. Nataliya Zhukova - Deputy Minister of Health, Chief Sanitary Doctor of the Republic of Belarus, Dr. Zaza Bokhua - First Deputy Minister of Health -MoH of Georgia, Prof. Amiran Gamkrelidze - Director General of the NCDC, Ms. Irma Khonelidze - Deputy Director General of the NCDC.

The project is funded by Federal Environment Protection Agency, Germany (UBA) through its Advisory Assistant Program (AAP) for Environmental Protection in the countries of Central and Eastern Europe, the Caucasus, Central Asia and other countries neighboring the European Union. The AAP promotes exchange and transfer of knowledge, enforcement of environmental administration, raising environmental standards, sharing instruments and raising awareness on environment protection to contribute to strengthening of cross-boundary and bilateral cooperation, political effectiveness of actions, and implementing of the EU standards of the environment quality. The AAP topical areas cover water and air quality management, climate and energy, radiation, recycling and other environmental technologies, chemical safety, public participation, education and capacity

building. Many project were implemented in the countries, for example e-waste management (Belarus and Kazakhstan), forests and wetlands protection (Georgia).



Picture 3. Prof. Paata Imnadze- Deputy Director General of the NCDC, Johann F. Moltmann-UBA, Irina Zastenskaya-WHO ECEH

In the AAP framework UBA is working directly with partner countries or through an implementing organization, for example WHO. The current project was built on achievement of the project on collection of information funded by the AAP in 2015-2017 and strong political commitment of all three countries to improve management of chemicals.

2.2.2 Software for online registration of chemicals//biocides has been developed and tested.

Within the context of the Project, Georgia established National Register and Registration System of Biocides and set up technical basis for on-line collection and sharing of information on biocides. Work is in progress for harmonization of national legislation with the REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning making available on the market and use of biocidal products.

NCDC IT Team developed national register enabling identification of producer/user, collection of information on chemicals and their mixtures and grouping and analyzing of data.

Single registry for biocidal products has been developed in Georgia and confidentiality of information is highly protected. Additionally, manual for NCDC staff and business operators was prepared. Chemical Register is an electronic system where both the biocidal product and active substances are registered at one place. It enables to upload all the necessary documents, pay the registration fees, review the registration documents by the relevant authorities, conduct laboratory research, make a decision and prepare all the relevant certificates and documents electronically. Chemical Registry is cross country project which is defined to be implemented in Georgia, Belarus and Kazakhstan.

However, some other countries are involved in development process and the program can be shared and implemented in other countries as well. The program is multilanguage and is available in Georgian, Russian and English languages.

According to the Agreement with WHO, the source code will be transferred to participant countries, where all the necessary server resources are already allocated and ready for system launch. Business processes and even fields would be modified according to the country needs.

In Georgia Chemical registry was launched on 15th of September, 2020 countrywide. Testing period is defined to be till 31th of December. Until 1st of March companies are obliged to check-in all the old registered products into the electronic system. Registry will be connected to the Revenue Service and the data provided by companies will be synchronized in real time, which will allow Revenue Service to send information to companies during registration process and automatically fill in the relevant fields. Registration of a substance in the electronic system is done by the company itself, which can be a manufacturer, importer and distributor. Registration of the organization in the electronic system is required only once, and then only the desired substance is authorized or re-authorized. Both Georgian and foreign companies can register the chemical in the system through its Georgian representative office. Electronic system carries out national authorization of the biocidal product on the territory of Georgia, as well as re-authorization, which is necessary within 10 years. Both operations are regulated by an administrative act by which the competent authority in Georgia - the National Center for Disease Control - allows the availability and use of a biocidal product or group of biocidal products (family) on the market in Georgia. Through the Chemical Registry, company registers desired biocidal product and active substances in the system, uploads licenses and other necessary documents and pays the amount related to authorization and laboratory tests electronically. In addition to the company, the authorities review documents and publish decisions in the same system. Registration process involves several confirmation stages, such as confirmation from National Center for Disease Control and Public Health (NCDC) administrative, financial department and Lugar laboratory. In case of any inaccuracies during registration process, communication between the company and the authorities is carried out through the system. After final decision is made, there is an opportunity to issue the e-certificate. The system has an integrated analytical module that allows the regulator to set up and run any type of analytics on biocidal products.

Chemical Registry is connected to the electronic laboratory management system through the LIMS service, which enables the exchange of laboratory research answers between the two systems and the provision of relevant answers to the company. To have the whole picture and involve old data for analytics, system is adapted to register old products, imported, manufactured or distributed in Georgia till now. During project timeframe several workshops and meeting were organized, in different countries, not only face to face, but also virtual.

During 09-12th of April, 2019 in Astana, Kazakhstan training-meeting “Key elements of national systems for sound chemicals management: training for government representatives” using IOMC Toolbox for decision-making was organized, where electronic system was demonstrated and several crucial topics were discussed.

Training for National Coordinators and IT -engineers was organized in Tbilisi, Georgia during 28-31th of October 2019, where not only participant countries, but National Institute of Health- ISS experts from Italy (Guido Mellomo) participated.

Alongside with these meetings and trainings, several virtual meetings were held, where electronic system development details were discussed, business processes, country specific requirements, validations and etc. Last call was organized by WHO and recent challenges have been discussed, also discussion was about system handover to participant countries, source code transfer, server resources allocation and its following actions.

Additionally following organizational orders have been developed:

1. Order # 06-162 /O 11.08.2020 of NCDC Director General on the regulation of organizational issues related to the operation of the E-Register of Biocides (disinfectants, disinsectants, deratizations);
2. Order # 06-162 /O 15.09.2020 of NCDC Director General on protection of confidentiality for accession to the E-Register of Biocides;

In the framework of the project draft Decree "Technical Regulation concerning the making available on the market and use of biocidal products" has been prepared according to European REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Georgian version and Explanatory Note have been prepared, the first draft version adapted, agreed with the Legal Department and sent to different Ministries and Agencies for remarks and comments by October 20th.

The Working Group (WG) consisting of nominees from various agencies will be set up to review the Technical Regulation. WG will summarize the comments and remarks from state agencies and consolidated draft will be introduced to Government of Georgia, the general public, non-governmental organizations, entrepreneurs and etc. For this stage, we have received the nomination of the Revenue Service in the working group.

2.2.3 Screening review: report « Screening assessment of chemicals management in Georgia»

Screening review "Screening assessment of chemicals management in Georgia" and the road map "TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA" were published. The Review was prepared by a group of national experts representing stakeholders from different governmental agencies, industry and civil society. The Review is available at: www.ncdc.ge

2.2.4 A multi-country and multi-stakeholders two-days' workshop «Legal and information frameworks for sound chemicals management» in Minsk, Belarus on 29-31 October 2018.

Two-days workshop was organized on 29-31 October 2018 in Minsk, Belarus and was hosted by the implementing institution in Belarus, Scientific-practical Centre of Hygiene. National experts from 5 countries, international experts, the donor representative and WHO staff participated in the workshop. In total, there were 65 participants. 6 participants from Georgia, Project coordinator, representative of the Ministry of Environmental Protection and Agriculture of Georgia and NCDC IT team.

The IT-team from NCDC (Georgia) presented engine for the development of national registers including identification of producer/user, collection of information on chemicals and their mixtures,

grouping and analysis of the information. The issue of confidentiality and protection of confidential information has been raised. All participation countries have a legislation on information protection in place and the register adaptation at national level will be done to correspond to the national legislative requirement related to protection of confidential information.

A proposal to prepare a manual for the register owners and for registrants has been done as well as to prepare a document describing what agencies will be responsible for the chemical information collection, how information will be analyzed and circulated, who will have an access to data and how the access will be organized, how confidential information will be protected.

The following actions and timeframe were agreed:

- IT- team of Georgia to share the current version of engine shortly after the meeting and continue working at the engine and share it together with a manual for the register owners till the end of 2018;
- The countries provide the feedback to the draft engine till the end of November 2018;
- The national coordinators and national experts in consultation with a person responsible for the register adaptation at the national level, conclude what information should be collected through the register and share it with the IT-team leader till the end of March 2019;
- The software should be adopted in the countries till September 2019 with testing registration (at least 5 registrants and at least 5 chemical products) in November 2019;
- It-team will decide about needs for IT-team meeting if the national team will face problems with the software adaptation and face-to-face meeting is the only option to solve them.
- The document describing the register and its functioning will be prepared as soon as the national competent institutions for registration will be identified and the registers are adopted at the national level.

The discussion with the national coordinators focused on:

- Reporting requirements
- Screening assessments
- Identification of topic for the next training.

2.2.5 National road map „TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA” has been developed.

Within the context of the Project, Georgia established National Register and Registration System of Biocides and set up technical basis for on-line collection and sharing of information on biocides. Work is in progress for harmonization with the REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning making available on the market and use of biocidal products.

Currently, according to the Law “On Health Protection of Georgia” the registration is mandatory only for substances for disinfection, deratization and disinsection. The registration is carried out by the National Centre for Disease Control and Public Health of Georgia. The list of the registered disinfectants is available on the NCDC web-site: www.ncdc.ge. Due to the upcoming obligations under the new technical regulation on Biocides and the number of suppliers subject to these obligations, increasing number of obligations in the agenda is expected also for the NCDC. For this reason, it is more than necessary to strengthen the staff’s capacity and knowledge, and ensure operational

preparedness of analytical laboratories in the context of introduction of new obligations for Biocides Management, such as: classification of substances and mixtures, testing of their physical and chemical, toxicological and ecotoxicological properties for the purposes of authorization and subsequent management of risks to health and the environment.

This Roadmap “TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA”²¹ has been developed according to WHO recommendation and comprises sets of issues and actions contributing to the introduction and step by step implementation of EU biocidal regulation with the involvement of all stakeholders in Georgia. (Annex 1)

Scope of the Roadmap

“The Roadmap towards Sound Management of Biocides in Georgia “(further – Roadmap) consists of actions, that need to be fulfilled by all stakeholders (state entities, policymakers, funding bodies, NGOs, chemical industry, academia and commercial entities) in order to achieve the overarching objectives of the Strategic Approach to International Chemicals Management (SAICM) and prevent negative impact of production and use of chemicals on human health and the environment. This Roadmap particularly focuses on management of biocides (disinfectants).

Methodology Used for Development of the Roadmap. The Road map towards Sound Chemicals Management was developed in consonance with WHO Chemical Roadmap²² and the Workbook²³. The Roadmap considers key actions into four areas: risk reduction; knowledge and evidence; institutional capacity; and, leadership and coordination, as defined in the WHO Roadmap, which was adopted at Seventieth World Health Assembly to enhance health sector engagement in the strategic approach to international chemicals management towards the 2020 goal and beyond. To make the Roadmap as impactful and user-friendly as possible, it was distributed among experts from the government and industry. The feedback from all other stakeholders was positive. Roadmap "TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA. 7 published copies were sent to the World Health Organization European Center for Environment and Health in Bonn, Germany. (Annex 1).

²¹ Roadmap “TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA”

²² WHO Chemicals Road Map and Workbook <https://www.who.int/ipcs/roadmap/en/>

²³ WHO Chemicals road map and Workbook
<https://apps.who.int/iris/bitstream/handle/10665/273136/9789241513630-eng.pdf?ua=1>



2.2.6 Training for government representatives in Nur-Sultan, Kazakhstan on 9-12th of April 2019 regarding national systems for sound chemicals management and using IOMC Toolbox for decision-making.



Picture 4. National coordinators of the project Dr. Nana Gabriadze - Georgia, Dr. Iryna Iluykova - Belarus, Dr. Nasima Zhunusova - Kazakhstan.

This training was a joint event, organized in the framework of two projects: “Establishment of key elements of national systems for a sound chemicals management in selected countries in Eastern Europe, Caucasus and Central Asia”, funded by the German Federal Environment Agency, and “IOMC Toolbox for decision making in chemicals management - Phase III: from design to action”, funded by the European Commission.

Training was attended by 7 participants from Georgia. Leading international experts covered several topics of chemicals management, including:

- Management of chemicals through the life-cycle;
- Implementation of the Globally Harmonized System for Classification and Labelling of Chemicals and their Mixtures at national level;
- Chemical risk assessment;
- Regulation of biocides in the European Union and non-agricultural pest control; and
- Inspections to control legislation enforcement (REACH, biocides) at national level.

An experience acquired during the training will contribute:

- to strengthening national capacities for the implementation of sound management of chemicals;
- support the implementation of SAICM and contribute to the achievement of the SDGs;
- also facilitate in developing road map and;
- Will be taken into account while implementing commitments under the Ostrava Declaration on Environment and Health.



Picture 5. Participants from Georgia - Ms. Makrine Babluani - MEPA, Dr. Nana Gabriadze – NCDC, Ms. Lali Ebanoidze – NCDC, Ms. Nino Jibgashvili - NCDC, Ms. Nino Dedabrishvili – NCDC, Ms Nato Dolidze.

Presentations used during abovementioned trainings will be used at upcoming seminar - National follow-up trainings for industry and governmental institutions.

2.2.7 WHO/UBA-Training workshop "Health and environment risk and impact assessment in the national system for sound chemicals management"- in Minsk, Belarus during 11-13th of November 2019

WHO / UBA-Training workshop "Health and environment risk and impact assessment in the national system for sound chemicals management" was undertaken during 11-13th of November, 2019 in Minsk, Belarus, where 3 experts from Georgia participated. More than 30 representatives of governments from five countries, industry and NGOs received knowledge on REACH and EU legislation on chemicals,

best practice of information collection and sharing, as well as on national programs and road maps planning. Leading international experts covered several topics of chemicals management, including:

- Assessment of risks from combined exposure to multiple chemicals;
- Health impact assessment (HIA) in the context of EIA;
- Assessment of impact on human health and burden of diseases;
- Human biomonitoring
- Benefits and limitations, HBM position in REACH, HBM4EU
- Bioaccumulative and non-accumulative substances, biomarkers of exposure and susceptibility
- Road maps towards sound chemicals management

The meeting was informative and useful. Those presentations will be used in the planned training, which will be held in November 2020 for the representatives of the different Ministries.

2.2.8 National follow up trainings

National follow up training was organized in Georgia on 15th of Dec 2020 (First, we planned to organize the national follow up training on 30th of Sep, but later it was postponed due to COVID-19).

Topic of trainings include:

Strategic Approach to International Chemicals Management (SAICM) and prevention of negative impact of production and use of chemicals on human health and the environment, impact assessment, risk assessment. Regulation of chemicals through the life-cycle, legislation (good practice and national), and GHS. The training was attended by 17 representatives of National government and industry, stakeholders working in chemical safety area. The training feedback was very positive, though provoking and useful. We plan to conduct additional trainings after the removal of Covid-19 Lockdown. The training presentations are available in the (Annex 2)

2.2.9 Development of programs for continuous education on chemicals management

1. "Biocidal product-types and their descriptions according to Biocide Directive".
2. "Classification, packaging and labelling of the Biocidal Products".

Development of National post-graduate training programs. Trainings will be continuous for professional long-term education (e.g. for Bachelors of the public health faculty at the University of Georgia (an agreement has already been reached)).

2.2.10 Creation of help desk

Help desk has been established to support governmental authorities and private sector. Organizational legislation has been developed.

In September 2016, in the framework of the project, study visit to Germany was organized for Georgian coordinators from Health and Environmental Sectors. During the study visit, Georgian Experts visited several German Regulatory Agencies: Dessau -UBA, Berlin BfR (Poison centers & product documentation), Dortmund (B.A.U.A., databases in the realm of B.A.U.A./BfC (e.g. ECHA) and WHO/EHEC).

The firsthand experience and knowledge shared by colleagues from the Federal Institute for Occupational Safety and Health (BAuA) in Dortmund was of special importance, as good practices and lessons learned from a host country assisted us in successfully tackling challenges regarding chemical safety in Georgia. One of the most important issue shared by our colleagues was so-called “Help Desk Operation System”, which offers free consulting for entrepreneurs on chemicals and biocides.

Taking into account theoretical and practical knowledge acquired during study visit, National Center for Disease Control & Public Health of Georgia established “Help-desk”, with aim to provide relevant information and guidelines to business operators and support them in fulfilling obligations under national legislation on Biocides. Newly developed “Help Desk” is managed by one person (She attended training in Nur-sultan), functions from Monday to Friday, from 10:00 to 17:00 and provides free consultation in the area of safe production and application of Biocides. Technical Assistance is provided by the IT Department. (Working Hot Line: 116 001, and Email : pr.ncdc@ncdc.ge)

Simultaneously we started individual and group trainings about registration of biocidal products and operation of register with support of “Help-Desk” for business operators (Local producers and importers). We are strictly limited in terms of gatherings due to Covid19 pandemic, therefore since 15th of August 2020, we have organized training courses for 37 companies, e.g 2 or 3 entrepreneurs per day. Also I would like to mention that trainings are still ongoing continuously.

As for setting up trainings for state agencies - we have individually consulted with customs/revenue service and all relevant stakeholders online, because as I mentioned before we have to follow rules around gatherings. Additionally, I would like to mention, that in April of the current year we were planning to run training course, which was postponed until 30th of November 2020, where we will make presentations including materials from Astana training.

The European Biocides Directive and Explanatory Note have been prepared, the final version of which were sent to the Ministries for review and comments by October 20th .

An order draft has been prepared in Georgian, regarding the establishment and functioning of the register from 15th of September 2020. Also, Provision on Biocidal Products Information "Help desk" for functioning has been developed and officially will be approved under separate order.

2.2.11 Functioning of the “Help Desk” during the COVID-19 outbreak

The National Center for Disease Control and Public Health (NCDC) has played an important role in Georgia's response against COVID-19. Responsibilities of the Center, among others, involve readiness and response measures. These include real-time epidemiological surveillance, management of new coronavirus laboratory diagnostics, supervision of compliance with standards, epidemiological surveillance over identified and suspected cases, contact tracing, isolation recommendations, and monitoring.

The functioning of the Help Desk was especially important during this period. Particularly, during the coronavirus outbreak most countries were closed, disinfectants were in short supply, and imports were

suspended. With support of Help Desk, small businesses were informed about the production of hands and surfaces disinfectants in accordance with WHO methodological recommendations²⁴.

NCDC has played an important role in Georgia's response against COVID-19 nationwide. Entrepreneurs submitted the required documentation in accordance with the law and registered hand and surface disinfectants, which removed the deficit and made available hand and surface treatment products on the consumer market, namely:

From February 2020 to September more than 554 industry representatives using the "Help Desk" consultations. and registered 173 disinfectants.

During two months (August-September 2020) more than 42 companies were informed and trained on on-line registration of biocides using capacities of the Help-Desk.

2.2.12 Legal act on biocides management

Draft Decree of biocides Regulation in Georgian has been prepared in correspondence with the EU Biocides Regulation, where GHS is one of main elements. But, due to GHS isn't enforced yet for chemicals in general in GEO, some delay with classification and labelling of biocidal products according to GHS can be predicted. Working group of representatives from Ministries and Agencies involved (environment, custom, economy and sustainable development, finance, health and labor) was created by NCDC to discuss and reach an agreement on the draft before submitting it for approval to the Cabinet of Ministries.

Assessment of how costly it will be for countries, to support maintenance of chemical registers functionality and operability, is very important for predicting the long-term sustainability of registers. Relevant expenses for Georgia were calculated.

2.2.13 Legal basis for on-line registration of chemicals and ensuring GHS implementation

Georgia actively worked on creating a legal basis for on-line registration of chemicals and for biocides and notable progress has been achieved. That means that government of GEO took a responsibility to implement REACH-like chemical regulation (the TR "On Safety of chemical products") including transition to GHS. In the project framework the main focus was on sublegislative acts that allow sustainable operation of on-line registration of chemicals and functioning of the chemical registry.

In Georgia technical rules for on-line operation of chemical registry were developed. The rules include the follows: purpose of the registry; requirement for appointment of a responsible organization; steps for creation of the registry and its day-to-day operation.

An order has been prepared and approved in Georgian, regarding the establishment and functioning of the register from 15th of September 2020, additionally following organizational orders have been developed:

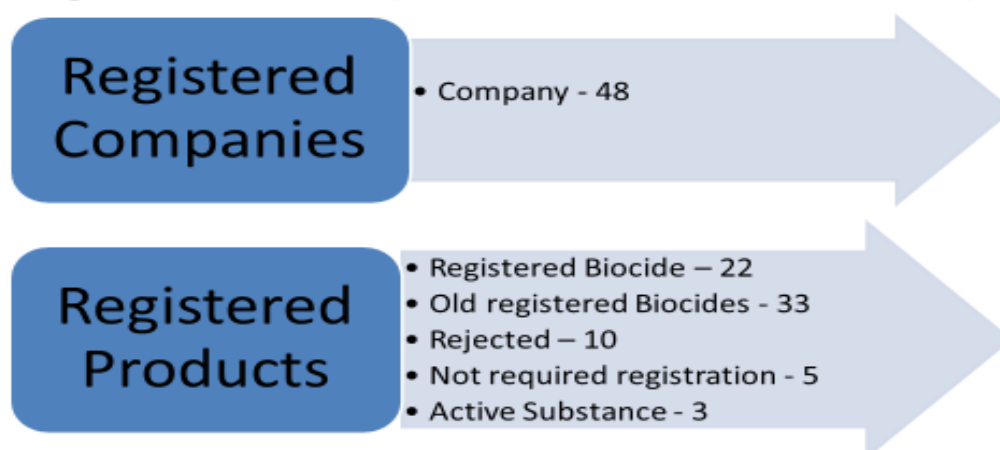
²⁴ Guide to local production: WHO-recommended handrub formulations

<https://www.who.int/publications/i/item/guide-to-local-production-who-recommended-handrub-formulations>

- 1. Order # 06-162 /O 11.08.2020 of NCDC Director General on the regulation of organizational issues related to the operation of the E-Register of Biocides (disinfectants, disinsectants, rodenticides);
- 2. Order # 06-162 /O 15.09.2020 of NCDC Director General on protection of confidentiality for accession to the E-Register of Biocides.

Also, Provision on "Help desk" functioning has been developed and officially will be approved under separate order.

Registered Data (21.09.2020- 15.01.2021)



2.2.14 Meeting of National Coordinators and IT engineers in the framework of the project" in Tbilisi on 28-30th of October 2019

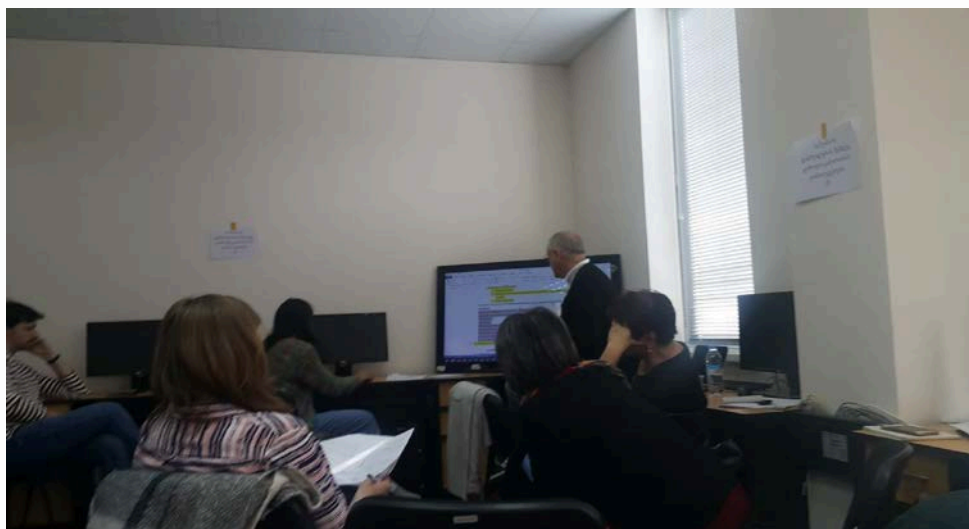
"Meeting of National Coordinators and IT engineers in the framework of the project", organized by NCDC, was held in Tbilisi, Conference Hall of NCDC on 28-30th of October 2019. The meeting of National Coordinators and IT engineers was also attended by expert Mr. Guido Mellomo from National Institute of Health- ISS, Italy. Interesting and informative presentations were made during the meeting.



Picture 6. "Meeting of National Coordinators and IT engineers in the framework of the project" in Tbilisi on 28-30th of October 2019.

The IT-team from NCDC (Georgia) presented engine for the development of national registers including identification of producer/user, collection of information on chemicals and their mixtures, grouping and analysis of the information.

The issue of confidentiality and protection of confidential information has been raised. All participating countries have a legislation on information protection in place and the register adaptation at national level will be done to correspond to the national legislative requirement related to protection of confidential information.



Picture 7. Discussion at the Meeting of National Coordinators and IT engineers.

Chemical Registry Electronic System

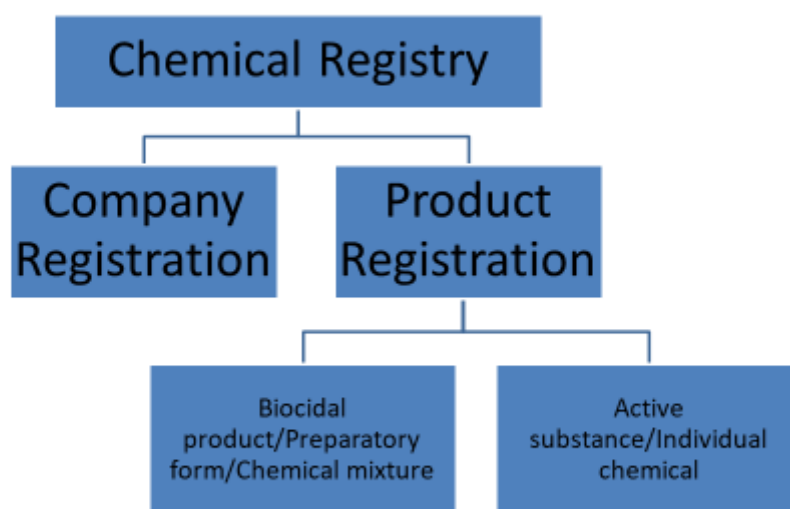


Figure 2. Stages of the Biocides registration in the electronic system.

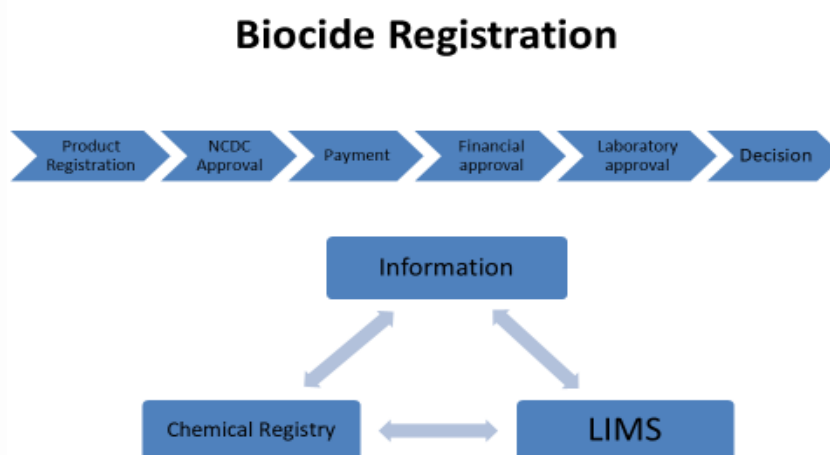


Figure 3. Stages of the Biocides registration in the electronic system.

Pilot testing of the software in all participating countries. (Webex meeting) October 7th, 2020, Tbilisi, Georgia

The Webex meeting for project coordinators and IT engineers was held on October 7th, 2020, which was attended by representatives of all participating countries coordinated by Dr. Irina Zastenskaya. During the meeting, a participant from Kazakhstan demonstrated how pilot system works. The comments made by other countries were also taken into account and all the questions were answered by Mr. Alexander Turdziladze, Head of the IT Group. He noted that the online system has been introduced in Georgia and from 15th of September all biocides are duly registered. From 1st of January 2021 no paper forms will be available, the country will use only electronic system for biocide registration. Businesses are obliged to register in the system until 1st of March 2021 and upload comprehensive information, including background of the company.

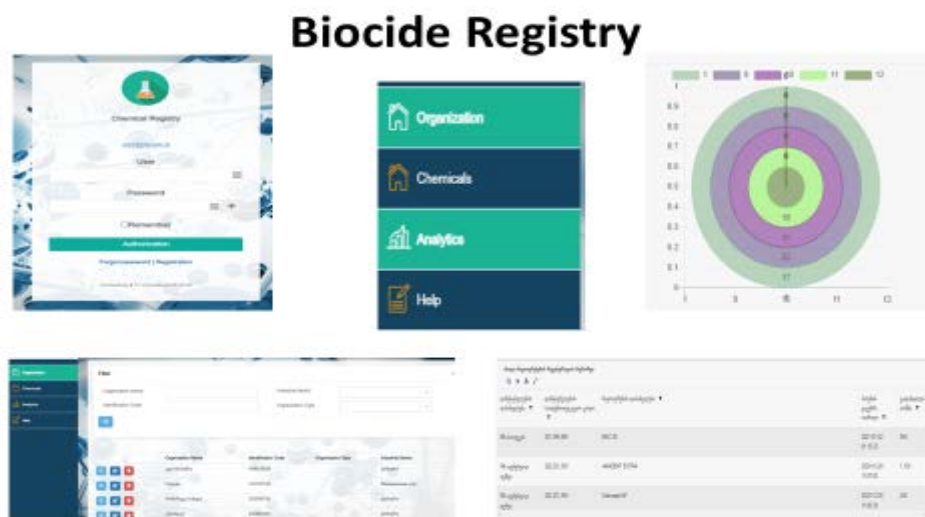


Figure 4. Stages of the Biocides registration in the electronic electronic system.

The IT-team from NCDC (Georgia) presented engine for the development of national registers including identification of producer/user, collection of information on chemicals and their mixtures, grouping and analysis of the information. The issue of confidentiality and protection of confidential information has been raised. All participation countries have a legislation on information protection in place and the register adaptation at national level will be done to correspond to the national legislative requirement related to protection of confidential information.

2.2.15 Final workshop in the framework of a project “Establishment of key elements of national systems for sound chemicals management in selected countries in Eastern Europe, Caucasus and Central Asia (Belarus, Georgia and Kazakhstan) (Virtual meeting) on 19-20 January, 2021.

Final workshop in the framework of a project “Establishment of key elements of national systems for sound chemicals management in selected countries in Eastern Europe, Caucasus and Central Asia (Belarus, Georgia and Kazakhstan) was held on 19-20 January, 2021.

The final workshop of the project has been organized to share lessons learned and experience gained through implementation process at national and regional levels, and to plan next steps. Meeting was attended by National experts from the countries implementing the project(10 from Georgia) , as well as national focal points for the WHO Global Chemicals and Health Network from other countries of Central and Eastern Europe, the Caucasus, and central Asia.

During the workshop the project outcomes, as well as challenges faced during implementation were presented and discussed; the IT team and Project National Coordinator from Georgia provided information about instruments and tools available to assist countries in establishing sound chemicals management systems. Also identified needs for further actions to improve chemicals management.

2.2.16 Additional meeting with the representatives of the Ministry of Environmental Protection and Agriculture of Georgia (MEPA) and independent experts on January 25, 2021.

MEPA nominated members and experts participated in all stages of the project implementation and international meetings. Their remarks and recommendations were taken into account during the working process.

On January 25, 2021, an additional zoom meeting was held with MEPA, where IT-team from NCDC (Georgia) presented engine for the development of national registers, including identification of producer / user, collection of information on chemicals and their mixtures, grouping and analysis of the information.

Participants noted that the current structure of biocidal register is acceptable for MEPA. Such a functioning sectoral register (biocides) will greatly help and become the basis for the development of hazardous chemicals register taking into account an experience shared by our colleagues from Kazakhstan and Belarus. At this stage, MEPA is actively working on a new law - "On the management of hazardous chemicals", which will be in full compliance with the European legislation. All the questions and issues raised during the meeting, were fully answered by Mr. Alexander Turdziladze, Head of the IT Group.

2.2.17 Second Virtual Meeting the Global Chemicals and Health Network

On 26.12.2020 was held second virtual meeting of the Global Chemicals and Health Network - "National case studies on implementing the WHO Chemicals Road Map" organized by World Health Organization Headquarters (WHO HQ). The Roadmap towards Sound Chemicals Management was developed in consonance with WHO Chemical Roadmap and the Workbook.

The Roadmap and case study was prepared by a group of national experts and stakeholders and is available on Official Website of NCDC – www.ncdc.ge.

ROADMAP TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA

CASE STUDY
Develop a road map towards sound management of biocides in Georgia

The road map has been developed in the framework of the project "Establishment of key elements of national systems for sound management of chemicals in selected countries Eastern Europe, Caucasus and Central Asia" (funded by the German Federal Environment Ministry's Advisory Assistant Programme (AAP), in cooperation with the German Environment Agency).

Goals and Objectives

- Objectives:** To raise awareness about sound management of biocides
- To assess the current situation with biocides management
- To develop national road maps for setting-up a system for sound management of biocides
- To strengthen national capacities of all stakeholders to ensure sustainable operability and functioning of national information systems for biocides

Target audience: governmental bodies, industry, NGOs

Activities: screening review of current situation, development of a Road map towards sound management of biocides, creation of national on-line system for collection of information on biocides (biocides register).

Project Overview

Context

The project focused on biocides management which is under the Ministry of Labor, Health and Social Affairs mandate in Georgia. Disinfectants and other biocidal products are widely used in the country, over 450 disinfectants and 100 disinfectants are on the market in Georgia. 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 chemical safety area, including legislation on biocides management.

The implementing organization, the National Center for Disease Control and Public Health, initiated the national activities related to biocides and has an advanced experience in coordination of this area, including with the private-sector. Development and implementation of sound biocides management requires strengthening capacities in all stakeholders: governmental bodies (health, environment, custom, regional development, justice, etc.), industry, and the public. Development of a road map on biocides management based on critical assessment of gaps and needs is needed to plan activities in this area in short- and long-term perspectives.

Approach

The Road Map consists of actions, that need to be fulfilled to contribute to achieving of the overarching objective of the Strategic Approach to International Chemicals Management. It was developed in consonance with WHO Chemical Road map and the Workbook. The roadmap considers key actions into four areas: risk reduction; knowledge and evidence; institutional capacity; and, leadership and coordination, as defined in the WHO Roadmap, which was adopted at Seventieth World Health Assembly to enhance health sector engagement in the strategic approach to international chemicals management towards the 2020 goal and beyond.

Chemicals Road Map

Thbilisi 2020

World Health Organization

On the meeting, presentation was done about lessons learned while implementing project „Establishing national systems for a chemicals management”, main achievements and tasks ahead „ - Creating a system and technical basis for on-line registration of biocides in Georgia”

The Roadmap and case study is available on Official Website of NCDC-WWW.NCDC.Ge and WHO²⁵

Chapter 3 Conclusions and steps ahead

3.1 Conclusion

Excellent quality of partnership between UBA, WHO and beneficiary country was a determining factor for successful implementation of the project. Capacity development of NCDC is a driving force for harmonization of EU Legislation according AA with EU.

Improvement of registration and authorization service quality at the national level is an essential component of the NCDC policy. This project has enabled implementation of screening assessment in order to achieve the overarching objectives of the Strategic Approach to International Chemicals Management (SAICM) and prevent negative impact of production and use of chemicals (Biocides) on human health and the environment, which is defined in the roadmap- “The Roadmap towards Sound Management of Biocides in Georgia”.

One of the keys to successful conclusion of the project is to establish an extended IT team for developing Biocides registration portal in Georgia; Help Desk is operating, Georgian Draft Decree of EU Biocides Directive with explanatory note has been prepared and distributed with all stakeholders for their remarks.

It’s noteworthy, that the assessment report and Roadmap has provided a comprehensive list of prioritized recommendations for the future collaboration in the framework of the Advisory Assistance Program.

The success and final outcomes would not have been possible without UBA and WHO ECEH continuing and wide-ranging support in the implementation of the project.

Due to COVID 19, it was impossible to organize a final workshop in face-to face mode. However, all activities were performed within the project timeframe.

During trainings and workshops participants and decision makers increased their knowledge on European Chemical Safety Legislation. Problems have been analyzed and possible solutions identified. The project has been a rich experience not only for the national experts, but also for those responsible for the management of hazardous chemicals.

3.2 The Next steps

²⁵ Case study: development of a road map towards sound management of biocides in Georgia

<https://www.who.int/publications/i/item/9789240017665?fbclid=IwAR10SwOapHw1GwG3LPXqv5GJNjm7FdJaYADqLVQJda0R8rzUM3YyahUfSrg>

Needs for further actions to improve chemicals management in Georgia was discussed at the final workshop of the project. Environmental health gains more and more priority in Georgia. For 2018-2022 NCDC has 5 strategic directions, one of which is Environmental Health; moreover, Environmental Health Department was established last year as a structural unit of the NCDC.

As a result of an enhanced efforts of the Government, Ministry of Health, NCDC and other involved parties, National Environment and Health Action Plan (NEHAP-2) was adopted by the Government of Georgia on 29.12.2018, elaboration of which was also greatly supported by the EU funded Twinning program “Institutional Strengthening of Environmental Health System of Georgia”.

The Four Strategic tasks set in the NEHAP-2 include prevention of diseases caused by exposure to chemicals. The results of the project are on the priority agenda of the National Government.

It should be noted that Georgia is a signatory to the EU AA and should fulfill taken obligations to perform harmonization of its legislation with that of European Union and introduce internationally recognized environmental approaches and recommendations.

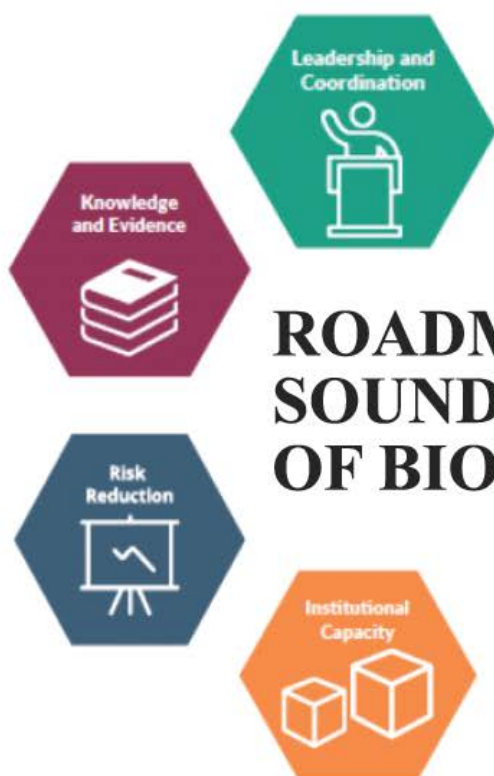
The results of the project can be used for awareness raising at national level and advocacy for a better implementation of international agreements. The project findings will serve as the evidence basis for creating an improved legislative/normative framework related to Chemicals. The existing hygienic norms and technical regulations need to be revised taking into consideration the WHO Guidelines and relevant European Directives.

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

During recent meeting with MEPA, representatives noted that the current structure of biocidal register is acceptable for MEPA. Such a functioning sectoral register (biocides) will greatly help and become the basis for the development of hazardous chemicals register taking into account an experience shared by our colleagues from Kazakhstan and Belarus.

Despite of successful implementation of the project, which was achieved with the support of the German Federal Environment Agency and WHO experts, we consider important to continue further cooperation in the project implementation process in order to:

- Development of national portfolios for implementation of the Ostrava Declaration commitments;
- Implementation of the National Environment and Health Action Plan NEHAP-2. Strategic objective 4;
- Implementation of legislation relating to Biocides in Georgia (Technical Regulation concerning the making available on the market and use of biocidal products);
- Establishment of Poison (control) Centre, as well as measures of further train employees of key institutions;
- Implementation of National road map - "TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA“.



ROADMAP TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA

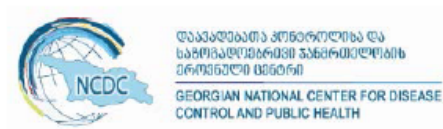
Tbilisi 2020

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ESTABLISHMENT OF KEY ELEMENTS OF SOUND CHEMICALS MANAGEMENT SYSTEMS IN SELECTED COUNTRIES IN ESTERN EUROPE, CAUCASUS, AND CENTRAL ASIA (2018-2021)

The project was funded by the Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety (BMUB) under the Advisory Assistance Programme for Environmental Protection in Central and Eastern European countries, the Caucasus and Central Asia, as well as other countries neighboring with the European Union. The project was implemented with the assistance of the Federal Environmental Agency (UBA).



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Introduction

The National Center for Disease Control and Public Health of Georgia successfully implemented the Project „Development of Operational and Legislative System for Collection and Sharing of Information on Hazardous Chemicals in Georgia“ (2015-2017), funded through the Advisory Assistance Programme of the Federal Environmental Agency (UBA) and the World Health Organization European Center for Environment and Health in Bonn, Germany. In the framework of the Project WHO organised a meeting during March 28-29, 2017 in Tbilisi Georgia, where participating countries reported limited capacities (technical, human and financial), and lack of expertise at the national level needed for implementation of the existing legislation on chemicals and for development of new legal acts. The need for support from donors and international organisations was emphasised.

In response to the countries' request, the Project (2nd stage) “Establishment of National Systems for Sound Management of Chemicals in Selected Countries in Eastern Europe, Caucasus and Central Asia (Belarus, Georgia, and Kazakhstan)” has been developed. Implementation of the Project contributed to the European Environment and Health Process and to the implementation of commitments at regional (Ostrava Declaration) and global (SDGs, SAICM, MEAs) levels.

Within the context of the Project, Georgia established National Register and Registration System of Biocides and set up technical basis for on-line collection and sharing of information on biocides. Work is in progress for harmonization with the REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning making available on the market and use of biocidal products.

Currently, according to the Law “On Health Protection of Georgia” the registration is mandatory only for substances for disinfection, deratization and disinsection. The registration is carried out by the National Centre for Disease Control and Public Health of Georgia. The list of the registered disinfectants is available on the NCDC web-site: www.ncdc.ge.

Due to the upcoming obligations under the new technical regulation on Biocides and the number of suppliers subject to these obligations, increase number of obligations in the agenda is expected also for the NCDC. For this reason, it is more than necessary to strengthen the staff's capacity and knowledge, and ensure operational preparedness of analytical laboratories in the context of introduction of new obligations for Biocides Management, such as: classification of substances and mixtures, testing of their physical and chemical, toxicological and ecotoxicological properties for the purposes of authorization and subsequent management of risks to health and the environment.

This Roadmap “TOWARDS SOUND MANAGEMENT OF BIOCIDES IN GEORGIA” has been developed according to WHO recommendation and comprises sets of issues and actions contributing to the introduction and step by step implementation of EU biocidal regulation with the involvement of all stakeholders in Georgia.

Scope of the Roadmap

“The Roadmap towards Sound Management of Biocides in Georgia “(further – Roadmap) consists of actions, that need to be fulfilled by all stakeholders (state entities, policymakers, funding bodies, NGOs, chemical industry, academia and commercial entities) in order to achieve the overarching objectives of the Strategic Approach to International Chemicals Management (SAICM) and prevent negative impact of production and use of chemicals on human health and the environment. This Roadmap particularly focuses on management of biocides (disinfectants).

Methodology Used for Development of the Roadmap

The Roadmap towards Sound Chemicals Management was developed in consonance with WHO Chemical Roadmap and the Workbook.

The Roadmap considers key actions into four areas: risk reduction; knowledge and evidence; institutional capacity; and, leadership and coordination, as defined in the WHO Roadmap, which was adopted at Seventieth World Health Assembly to enhance health sector engagement in the strategic approach to international chemicals management towards the 2020 goal and beyond. To make the Roadmap as impactful and user-friendly as possible, it was distributed among experts from the government and industry. The feedback from all other stakeholders was positive.

Stakeholder’s views and comments have been incorporated into this roadmap and served as an important step to form the final version of the roadmap.

Actions needed to be taken were identified through the screening-review of management of chemicals and biocides in Georgia. The Review was prepared by a group of national experts representing stakeholders from different governmental agencies, industry and civil society. The Review is available at: www.ncdc.ge



Risk Reduction

Objective: To minimize and prevent risks for human health and the environment from production and use of biocides

- Adopt the Draft Law on Biocides Regulation, harmonized/approximated, as much as possible, with REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning making available on the market and use of biocidal products including the following essential elements¹:
 - Definitions and classification of types of biocidal products;
 - Approval of active substances (in accordance with the EU list);
 - General principles concerning the authorization of biocidal products;
 - Data protection and data sharing;
 - Information and communication;
 - Classification, packaging and labelling of biocidal products and safety data sheets;
 - Poison control;
 - Competent authority;
 - Penalties;
 - Laboratory control.
- Set a system for authorization of biocidal products (locally produced and imported);
- Develop risk assessment guidance as a basis for decision-making on minimization/prevention of negative health impacts from biocidal products on human health and the environment;
- Conduct early assessment and reviewing of various sources of data to identify the impact of hazardous chemicals contained in biocidal products;
- Implement legislation, procedures, and programs to identify and eliminate or control workplace hazards and achieve health safety during working with biocidal products;
- Set a system for inspection of safety at workplaces in terms of production and use of biocidal products;
- Ensure that risk reduction measures are planned and implemented for all workplaces where biocidal products are produced and used, including availability of proper PPE;
- Develop recommendations on safe use of biocidal products by households;
- Develop requirements for safe management of wastes of biocidal products and their containers;
- Set a system for consultation with industry on topics related to biocides management including safety of biocidal products;
- Review toxic and physical properties of biocidal products on the national market, containing chemical substances according to SDS for any handling, storage, or disposal procedures, as well as

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0528&from=EN>

for any dangerous interactions or incompatibilities with other chemicals and materials in the process;

- Ensure assessment of safer alternatives and their risks for human health and environment, taking into account the life cycle of active substances and biocidal products and promoting the use of these alternatives;
- Promote identification and adaptation of the best testing methods for assessment of safety and efficacy of biocides, early detection of non-communicable and occupational diseases potentially caused by biocides. Initiate legislative amendments requiring mandatory reporting of all non-communicable and occupational diseases including allergies, potentially related to exposure to biocides;
- Establish Register of Biocides and ensure its proper functioning;
- Develop guidelines for prevention and management of intoxications caused by biocidal products;
- Establish operations and surveillance system of poisoning, including by biocidal products (toxicoepidemiology);
- Consider revision of legislation and tax system to support use of safer alternatives.



Knowledge and Evidence

Objective: To ensure availability of information on biocidal products, their safety and efficacy, best practice and protective measures for all stakeholders' groups such as decision- and policy-makers, workers, employers, health-care and public health professional, and the public.

- Set a system for collection and sharing of information on biocidal products on the market;
- Ensure access to international and the EU databases on biocides and hazardous chemicals in biocidal products;
- Create a web-page to disseminate information on hazardous chemicals in biocidal products in national language;
- Make available the list of active substances registered in the EU;
- Post brochures and flayers for awareness-raising, conduct campaign to help the public recognize risks of biocides for human health and prevent it;
- Publicize good practices on safe use of biocides;
- Develop and implement awareness-raising campaigns for health care workers, employers and employees on risks of biocides & good practices for their safe use;
- Collect evidence on acute and chronic effects on health due to improper management of biocidal products;
- Develop and implement projects with the support of WHO, ECEH, UNEP;
- Share knowledge with industry and the public on biocides and their effects on human health and the environment including via training workshops & webinars for different stakeholders;
- Develop mechanisms to collect and manage health data and information necessary for reporting progress on production and use of biocides, their safety and efficacy;
- Create a platform for receiving information, interactive websites and/or discussion forums for specific issues related to the impact of biocidal products on health;
- Engage with Georgian consumers/producers to build their knowledge and skills to eliminate or reduce hazardous exposures to biocides;
- Disseminate & communicate health promotion materials about chemical risks, which may be developed while using biocidal products;
- Establish and use indicators for measuring progress.



Institutional Capacity

Objective: To ensure that institutional capacities are adequate and allow safe management of biocidal products through their life-cycle in terms of policy, expertise, human, technical, financial and other resources

- Identify national institution authorized for management of biocides and strengthen its capacities;
- Set a national register of biocidal products;
- Establish the poison control center according to the WHO guidance on poison control centers;
- Establish a help-desk for supporting of the industry and the public in biocides management and, in particular, in authorization of biocidal products;
- Ensure availability of expertise for classification and labelling of chemicals and their mixtures according to GHS, health and the environment risk assessment of biocides, assessment of safer alternatives;
- Identify gaps and elaborate national policy and regulatory frameworks to address the health impacts of biocidal products throughout the life cycle;
- Establish monitoring of production, transport, use and release of all types of biocidal products and waste, and promote regional and international cooperation with a view to enhancing compliance with the existing regulations and preventing illegal traffic;
- Develop and implement training programs on biocides for the industry, the public, workers and employers, as well as health professionals;
- Develop tools, guidance, technical regulations to support comprehensive implementation of biocides regulation;
- Disseminate educational materials for the targeted audiences (medical professionals and healthcare workers, the public) on specific topics of safe use of biocidal products (e.g. assessment and monitoring of health risks, gathering of evidence, diagnosing and treatment of health disorders, chemical safety awareness, and labelling);
- Introduce curricula in medical schools and other academic institutions to address the health impacts of biocidal chemicals, with an emphasis on toxicology and occupational and public health;
- Strengthen analytical capacities for assessment of safety and efficacy of biocides;
- Ensure continuity of financial support for sound management of biocides.



Leadership and Coordination

Objective: To create condition for the health sector to perform its leading role in sound management of biocides in cooperation and coordination with other governmental agencies, industry and the public.

- Consider creation of multi-stakeholder platform in the authorized governmental body or institution to ensure participation of all stakeholders in decision-making process on biocides management;
- Identify mandate of governmental agencies in biocides management;
- Appoint a contact person in the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia for the issues related to chemicals and health including implementation of this Roadmap, and establishment of national chemicals and health network, implementation of the Strategic Approach to International Chemicals Management (SAICM);
- Organize briefing sessions on impact of hazardous chemicals, occurring in biocides, to human health for politicians and senior officials at the national, regional and international levels;
- Implement the strategy for strengthening of engagement of the health sector in implementation of the Strategic Approach;
- Ensure capacities of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs for representation of Georgia on conferences and meetings on biocides and chemical management in general;
- Develop and strengthen, as appropriate, multi-sectoral cooperation at the national, regional and international levels in order to minimize and prevent significant adverse impacts of chemicals and waste on health, inter alia, within the health sector itself.

CASE STUDY

Development of a road map towards sound management of biocides in Georgia

Georgia

The Road Map has been developed within the framework of the project “Establishment of key elements of national systems for sound management of chemicals in selected countries of Eastern Europe, the Caucasus and Central Asia” (funded by the German Federal Environment Ministry’s Advisory Assistant Programme [AAP], in cooperation with the German Environment Agency).

Goals and Objectives

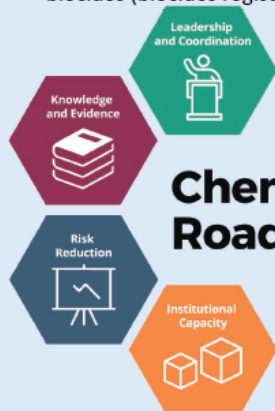
The goal of this project was to strengthen the sound management of biocides.

The objectives were to:

- raise awareness about the sound management of biocides;
- assess the current situation in regards to biocides management;
- develop a National Road Map for setting up a system for sound management of biocides; and
- strengthen national capacities of all stakeholders to ensure sustainable operability and functioning of national information systems for biocides.

Target audience: Governmental bodies, industry, nongovernmental organizations (NGOs).

Activities: Screening review of current situation; development of a road map towards sound management of biocides; creation of a national online system for collection of information on biocides (biocides register).



Chemicals Road Map

Project Overview

Context

The project focused on biocides management, which is under the mandate of the Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs in Georgia. Disinfectants and other biocidal products are widely used in the country – over 950 disinfectants are on the market in Georgia. In July 2013 the European Union and Georgia completed the negotiation of an Association Agreement and agreed on a number of measures necessary to be taken in the area of chemical safety, including legislation on biocides management.

The implementing organization, the National Center for Disease Control and Public Health, initiated the national activities related to biocides and has advanced experience in coordination of this area, including with the private sector. Development and implementation of sound biocides management requires strengthening capacities in all stakeholders, including governmental bodies (health, environment, customs, regional development, justice, etc.), industry and the public. Development of a road map on biocides management based on critical assessment of gaps and needs is needed to plan activities in this area taking both short- and long-term perspectives.

Approach

The Road Map consists of actions that need to be fulfilled to contribute to achieving the overarching objective of the Strategic Approach to International Chemicals Management (SAICM). It was developed in consonance with the WHO Chemicals Road Map and the corresponding Workbook.

The Road Map on biocides management considers key actions in four areas – risk reduction, knowledge and evidence, institutional capacity, and leadership and coordination – as defined in the WHO Road Map, which was approved at the Seventieth World Health Assembly, to enhance health sector engagement in the SAICM towards the 2020 goal and beyond.



World Health Organization

Results

All activities in the project framework were coordinated by intersectoral and multi-stakeholder working groups, which served as a basis for further cooperation for sound management of biocides.

A screening analysis of the situation focused on biocides management has been prepared to identify gaps and needs for biocides management. Aspects analysed included the legislative framework, institutional infrastructure, information system, risk assessment, monitoring, control and health surveillance, risk reduction, risk communication, research and innovation, and participation in international agreements. The situational analysis can be found on the project website: <https://www.ncdc.ge>.

A road map towards sound management of biocides was developed and agreed upon in consultation with all stakeholders. The document is available at: <https://www.ncdc.ge/Files/roadmap1.pdf>.

A number of trainings to create initial capacities for management of biocides (registration, classification and labelling, health impact assessment) were organized at regional and national levels, including for industry experts.

A help desk was created in the leading institution to guide industry efforts towards sound management of biocides.

Lessons Learned

Ideally, the biocides road map should be incorporated into the road map to sound chemicals management; however, Georgia's experience demonstrates that road maps to sound management of priority chemical groups contribute significantly to management of chemicals in general.

The involvement of all stakeholders is critical to ensuring the success of the road map implementation.

Initial capacity-building is needed and should inform discussion of a road map, as justified by the experience in Georgia; this increases understanding of the planned actions and capacities required.

Recommendations

The WHO Chemicals Road Map and Workbook are recommended to be considered as a methodological support for national road maps development.

All actions – starting from identification of gaps and needs to acceptance of the Road Map on biocides management – should be conducted with the involvement of all stakeholders.

The case study was authored by National Center for Disease Control & Public Health of Georgia. The named authors alone are responsible for the views expressed in this publication.



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This case study is one of a series of case studies coordinated by WHO to illustrate the implementation of the WHO Chemicals Road Map.



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