

CHEMICALS

Assessment of chemical risks

Chemicals are a factual presence in modern economies and societies but can pose risks for the environment and human health if not carefully managed, and all stakeholders are involved in the sound management of them. Romania is committed to the goal set by the World Summit of Sustainable Development in Johannesburg in 2002 that, chemicals should be used and produced in a way that minimize significant adverse effects on the environment and human health. The diversity and potential consequences of using chemicals make sound chemicals management a key cross-cutting issue for sustainable development. Romania, as EU member had set as priority the implementation of UE legislation in the field of chemicals.

Mechanisms for systematic evaluation, classification, and labelling of chemicals

Before joining the UE the institution responsible for chemicals was the National Agency for Dangerous Substances and Preparations and some activities have been developed regarding restricting the use, manufacture and placing on the market of dangerous chemicals, such as POPs, chemicals in paints, chemicals in electronic and electrical equipments based on national legislative frame which had mirrored the UE legislation. (Government Decision No. 347/2003, Government Decision No .992/2005, Government Decision No. 735/2006).

Romania became the member of the European Union on 1 January 2007 and aiming to have an efficient structure for chemicals management and reduced number of agencies, the National Agency for Dangerous Substances and Preparations was undertaken by National Environmental Protection Agency and National Environmental Guard.

The following EU legislation was implemented for the environment and health protection with regard to the evaluation, classification and labelling of chemicals:

- The Council of the European Union Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
- European Union Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

The requirements have been implemented in the national legislation.

The “*REACH Age*” defined by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization 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) provides several measures regarding evaluation of chemicals, substances and mixtures.

Our REACH and CLP Competent Authorities have been appointed from environmental protection authorities, human health authority, and consumer protection authority. Application of this regulation required the competent authorities to perform tasks specified in the regulation, enforcement provisions and penalties applicable for infringement in order to assure a high level of protection to human and environment. Our REACH and CLP experts are participating into the works of special committees of European Agency in the procedures of classification, evaluation, authorization, restriction of chemicals.

During the period 2010 - 2015, in Romania, as UE Member State, provisions of Directives and Regulation mentioned above will apply.

In 2015 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 will be the only reglementation regarding classification, labelling and packaging of substances and mixtures in UE.

Taking into consideration the fact that CLP Regulation is linked to REACH regulation the helpdesk activities are performed through a national Helpdesk and a dedicated web site in the structure of NEPA.

At national level there are procedures referring to authorization of biocides, fertilizers and pesticides for placing on the internal market. The Commissions are based on collaboration of agriculture, environment and health authorities.

The National Commission for homologation of plant protection products is functioning at agriculture authority, and in 2008 issued 104 certifications for products into national procedure implementing Directive 91/414 regarding placing on the market of plant protection products. The Inter-ministerial Commission for authorization of fertilizers is functioning at agriculture authority.

The National Commission for biocide products is functioning at health authority, and issued 244 certificates for year 2008, in conformity with Directive 98/8 regarding placing on the market of biocides

Participation in international and regional initiatives

The cooperation with OECD has a special place in Romanian activities, our experts participated as observers in the work of working groups for evaluation of substances and good laboratory practices.

Romania ratified the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade in 2003, approved by Law no.91/2003, and was deeply involved in the activities as Vice-President at The fourth meeting of the Conference of the Parties to the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

In 2008, in the area of import export of restricted chemicals new provisions are applying through Regulation EC no.689 of European Parliament and of the Council of 17 June 2008 concerning the export and import of dangerous chemicals.

In 2008 Romanian DNA issued 2 export authorizations and 2 import authorizations under the PIC Procedure. Also the PIC inventory of importers and exporters was updated.

Exported substances were 361.47 kg and imported preparations 33,108 tone, with 20.098 active substance (diazinon) under *Regulation EC no, 689/2008, general trend for restricted substances being to diminish the circulation on the market.*

Romania ratified the Stockholm Convention on Persistent Organic Pollutants by Law no 261/2004, and made sustained efforts for the implementation of the obligations assumed through ratification. In this sense the first step was the development of the National Implementation Plan for Stockholm Convention with GEF and UNIDO support. Romania submitted the National Implementation Plan to the Secretariat in April 2006. The National Implementation Plan was adopted by the Governmental Decision no 1497/2008.

At national level, with UNIDO support, some activities were organized such as Workshop on “POPs destruction technologies and decision support tools for their assessment and selection”, held in Mahmudia, Tulcea County, in 2006 and the ongoing project “Disposal of PCBs wastes in Romania”, which started in 2007, taking into consideration the fact that The National Implementation Plan (NIP) for the Stockholm Convention for Romania identified the polychlorinated biphenyl (PCB) issues as one of the top priorities requiring immediate attention and action. Through TAIEX and Twinning Project systems some activities were developed with the aim to share information related to the various implementation issues such as: reporting requirements, national implementation plans, methodologies of the inventories elaboration, modalities of disposal and recovery of the waste consisting of, containing or contaminated by POPs, measures to reduce, minimise or eliminate the production, use and release of persistent organic pollutants, effect of POPs over the human health and environment.

At regional level, in 2009, Romania, with UNIDO support, officially launched the “Regional BAT and BEP Forum for Central and Eastern Europe, Caucasus, and Central

Asia (CEECCA) to Promote Strategies to Reduce or Eliminate Unintentionally Produced POPs from Industry”. For 2 years period Romania has the Chairmanship of the Forum being assisted by two Co-chairs, Armenia and Sweden.

The Forum is focused on providing technical assistance to developing countries and countries with economies in transition in order to fully enable implementing the BAT/BEP related provisions, mentioned in the Article 5 of the Stockholm Convention on persistent organic pollutants.

The scope of the activities foreseen within the Plan of Action of the Forum is to strengthen the capacities of the CEECCA countries to enable facilitation of transfer of environmentally sound technologies including or taking into account the increased use of local and traditional knowledge and techniques in the industrial sector in the region.

Since 2007, when Romania became a Member State to the European Union also the provisions of Regulation (EC) no 850/2004 on persistent organic pollutants were applied at national level. In order to create the infrastructure for the implementation of Regulation provisions was adopted the Governmental Decision no 561/2008 on establishment of measures for the implementation of Regulation (EC) no 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/CEE.

Romania also ratified the Convention on Long-range Transboundary Air Pollution (CLRTAP) by Law no 8/1991 and the Protocol on persistent organic pollutants by Law no 271/2003. As Party of CLRTAP, Romania reports every two years to the Secretariat on the strategies and policies for the abatement of air pollution. Romania ratified Vienna Convention for the Protection of the Ozone Layer, adopted in 1985 in Vienna, The Montreal Protocol that Deplete the Ozone Layer adopted in Montreal in 1987 and its Amendments adopted in London (1993), Copenhagen (in 2001), Montreal (in 2001) and Beijing (in 2004). This emphasizes the Romanian Government’s strong commitment to take the necessary measures to protect the ozone layer.

Romania is also applying the provisions of Convention ILO 170 on Safety at work place through the competent authority for labour.

Strategies for exposure assessment and environmental monitoring and improvement in procedures for using toxicological and epidemiological data to predict and estimate the effects of chemicals on human health and the environment are shortly presented bellow.

The Annual report on Environment on Romania with specific data on dangerous substances which uses implies a risk to environment is located on NEPA web site.

NEPA is responsible for Detergents monitoring at national level and has made an inventory regarding placing on the market of detergents under Regulation EC no.648

2004 on detergents. An inventory realized in 2007, showed a number of 80 importers, manufacturer or users and 8.5 tonnes of detergents.

Improvement in procedures for using toxicological and epidemiological data to predict and estimate the effects of chemicals on human health and the environment is based on implementing the Directives and Regulation and cooperation between health and environment authorities.

Information exchange and cooperation, data-quality assurance, application of assessment criteria, and linkages to risk management activities

Information on health and safety of chemicals in support of risk reduction and decision making are available on the ministries web sites (PRTR, legislation, reports, studies, guidance and codes), cleaner production information (facilities to be close). A new instrument for information on chemicals provided for industry is National HELPDESK on REACH and CLP Regulations as previous mentioned.

During 2008 a lot of meetings with industry were taken place, such as workshops and conferences having as subject the preregistration procedures under REACH.

The Aarhus Convention (Directive 2003/4/EC of the European Parliament and the Council of 28 January 2003 on public access to environmental information) states in Article 7 (1) that each Contracting Party shall develop an integrated register of pollutants emitted and transferred to Community (European PRTR) as a publicly accessible electronic database.

At European Community level was launched the European E-PRTR register website that contains also the data reported by Romania in 2007. Link can be accessed at <http://prtr.ec.europa.eu> .

Romania is applying the provisions of Regulation (EC) no. 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC adopted at 18 January 2006, called EPRTR Regulation and established the national Register which is located on NEPA website: www.anpm.ro.

Sound management of toxic chemicals

Progress within the larger framework of Strategic Approach to International Chemicals Management (SAICM)

During ICCM 1 in Dubai, in 2006 and all period nowadays, Romania acted and is continuing its activities for implementing Strategic Approach objectives, acting as vice president of ICCM1 and as Regional focal point for CEE region in the intersessional period to ICCM2.

We are committed to implement those activities as specified on Global plan of action and the Overarching Policy Strategy, and pledged to work in partnership with all stakeholders to achieve chemical safety, to achieve the Johannesburg Plan of Implementation 2020 goal and the objectives set forth in the Strategic Approach, and in so doing to assist in fighting poverty, protecting vulnerable groups, and advancing public health and human security.

Romania is reviewing the National Chemicals Management Profiles, as first step towards developing and implementing SAICM National Implementation Plan.

All activities are developed through an inter-ministerial coordination and cooperation mechanism with an effective national stakeholder's participation.

Besides having financial contribution to ICCM 2 organization, Romania is trying to support activities to enable initial capacity building and implementation in developing countries, least developed countries, Small Island Developing States and countries with economies in transition being contributor to Quick Start Programme (QSP) in response to the ICCM invitation to Governments to contribute to the QSP.

Reporting Questionnaire for Romania at ICCM 2 is available on web site www.saicm.org

We are interested to contribute to the development of the emerging policy issues stated by ICCM2 especially on Chemicals in products, nonmaterial, and lead in paints.

Risk reduction, particularly taking in to account the life cycle of the chemicals in EU is governed by the REACH regulation.

Romania follows the EU procedures. During the restriction (Annex XV restriction) and authorization procedure the assessment of the identified restriction and other risk management options and the assessment of effects on human health and the environment are developed.

Substance evaluation aims to clarify any grounds for considering that a substance constitutes a risk to human health or the environment. The general substance evaluation process, the compilation of the Community rolling action plan (Article 44) and the allocation of substances between the Member States (Article 45 procedure) are the steps to risk reduction.

For the performance of a substance evaluation the Agency relies on MS-CAs. Substance evaluation is not a standalone process. Information obtained from the evaluation process should be considered for identification of substances of very high concern (Article 59(3)), restriction (Article 69(4)) and harmonised classification and labelling (Article 115(1)) procedures. In certain cases it may however be more appropriate to use the information for risk management procedures under other Community legislation

Additionally, regarding asbestos uses since 2007 it was banned the trade and use of it.

Policy measures to phase out chemicals that pose unreasonable and unmanageable risk to human health and human environment.

Until 1st of January 2008, Romania was classified as Art. 5 Party, developing country, in accordance with the Montreal Protocol, after this date Romania changed her status. Due to the accession to the European Union Romania was reclassified as Art. 2 party, developed country. As a developing country Romania had the possibility to access money for the implementation of ODS (ozone depleting substances) phase-out project from the Multilateral Fund for the Implementation of Montreal Protocol.

In order to align to the requirements of the Montreal Protocol and its amendments and the EU legislation Romania up-dated the Country Programme in 2003, this was needed to:

- Assess feed-back gained to date on the implementation of the National Action Plan for the phase out of Ozone Depleting Substances (ODS), elaborated in 1995
- Identify what additional measures might be needed to ensure the phase out of the remaining ODS consumption in Romania, and with priority for the period 2003 - 2006
- Up-date the National Action Plan to reflect the latest Amendments to the Montreal Protocol;
- Update information pertaining to ODS importers, exporters, producers and users in Romania
- To obtain financial assistance from Multilateral Fund for the implementation of Montreal Protocol

Based on the information obtained the following projects have been identified by the Country Programme Update, approved by a Governmental Decision no. 58/2004 as the National ODS Phase-out Management Plan, as being necessary element in achieving phase out of the remaining use of ODS in Romania, projects which were approved in the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol.

These projects had as a final target the total phase-out of ozone depleting substances.

The list of projects approved in the period 2004 – 2007 (having as implementing Agency UNIDO) is the following:

1. National CFCs Phase-out Plan (implemented by UNIDO and SEI Sweden)
 - Technical Assistance Halon Management Plan;
 - ODS s Phase-out in the Production Sector;
 - Conversion of the CTC production capacity to other chlorinated solvents at Oltchim Ramnicu Valcea;
 - Conversion of the production capacity to phase out CTC as a by-product at Chimcomplex Onesti;
 - Closing-up of CFC production capacity from BICAPA Tarnaveni;

- Closing-up of the MeBr production capacity from Sinteza - Oradea Company;
- 2. Regional demonstration project chiller conversion from CFC to ecological refrigerant (Radio House - beneficiary).

At 1st January 2010, Romania fulfilled all the Montreal Protocol requirements related to the Phase-out of ODSs and now is applying the EU Regulation 1005/2009.

Every year Romania sends reports to the Ozone Secretariat based on the Art. 7 of the Montreal protocol and also to the European Commission based on the Regulation 1005/2009. Our experts are participating to the EC coordination meetings and also to the Open-Ended Working Group and Meeting of the Parties/Conference of Parties.

In 2008 and 2009 Romania was member of the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol, representing the Art. 2 countries, donor's countries, from the Eastern Europe and Central Asia Region.

Romania join at **framework for prevention of accidents, preparedness and response** according to the Government Decision no. 804/2007 transposing **Council Directive 96/82/EC on the control of major accident hazards involving dangerous substances (Seveso II)**.

This involves identification and notification of establishments with dangerous activity, internal and external emergency plans, informing the public and dissemination of information related to safety including public consultations, evaluation of the consequences of major-accidents; and control of the safety management system in view of prevention of hazards and protection of people, land-use planning, inspections etc.

Romania has ratified **the Convention on the Transboundary Effects of Industrial Accidents** in 2003 and is **Party of the UNECE Convention** and actively participates in its implementation.

Starting with 2005, before accession period, Romania became active in the negotiation process regarding the European strategy for the **metallic mercury management**.

As a starting point Romania began collecting information in order to have a database on import, export, storage and metallic mercury production or devices that contain metallic mercury. After that, as an obligation from the strategy, Romania reported annually this national data.

Romania was active at the negotiations for the EU Regulation 1102/2008. This Regulation has to establish a legally binding instrument and ban the exports for metallic mercury from EU and, also, safe storage of this for the environment and human health.

At the national level were organized workshops and bilateral meetings (Romanian – German) having as principal task to fulfil the EU obligation at the national level. Also, in collaboration with the EC was organized a TAIEX regarding the management of metallic mercury.

At the national level we are studying the opportunity to store the metallic mercury in our own salt mines or, store it in other UE state.

We are studying also, from the financial point of view, the retrofitting process for the installation that still use metallic mercury in their processes. Having that in mind, we will start a program for collecting and recycling the devices that contain metallic mercury.

The inventories for mercury and nickel (quantities and articles that contain these metals or some compounds), quantities of nickel and his compounds, used/imported between 2005 and 2007 can be found in the Annual Report for environment that is on the National Agency for Environment website www.anpm.ro.

The overdependence on the use of agricultural chemicals is reduce by

- Applying the concept of Ecological agriculture through National Strategy for Ecological Agriculture under agriculture authority;
- Romania is implementing the Regulation EC no.1107/2009 on placing on the market of plant protection products and repelling Directives 79/117/EEC and 91/414/EEC, and principle stated by Thematic Strategy on sustainable use of pesticides.

As financial mechanism, the Environment Fund (EF) is established under the European principles ‘polluter pays’ and ‘producer responsibility’ for implementing environmental legislation, harmonized with the *acquis communautaire*.

This Fund is managed by the Environmental Fund Administration (AFM), a public institution, which is coordinated by the Ministry of Environment and Forests. The Environment Fund Administration give financial support for priority environmental projects, helping on the one hand local authorities to implement the National Development Plan priorities and directives of the European Union, for increasing the investment potential, environmental rehabilitation and quality of life in communities and health protection, and on the other hand helping the economic operators to fulfil the obligations contained in compliance programs.

The Environment Fund’s incomes are public incomes and consist of taxes and contributions, based on the polluter pays principle for the production, import and use of hazardous substances collecting fees amounting to 2% of the value of hazardous substances produced and used.

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National Authorities should imply a lot of resources, financial and human, in order to fulfil comply with the Regulations. Lots of our human resources have left the institutions. In order to comply with the provisions set in the procedures for evaluation there is a special need for environmental and human health research institutes to be involved.