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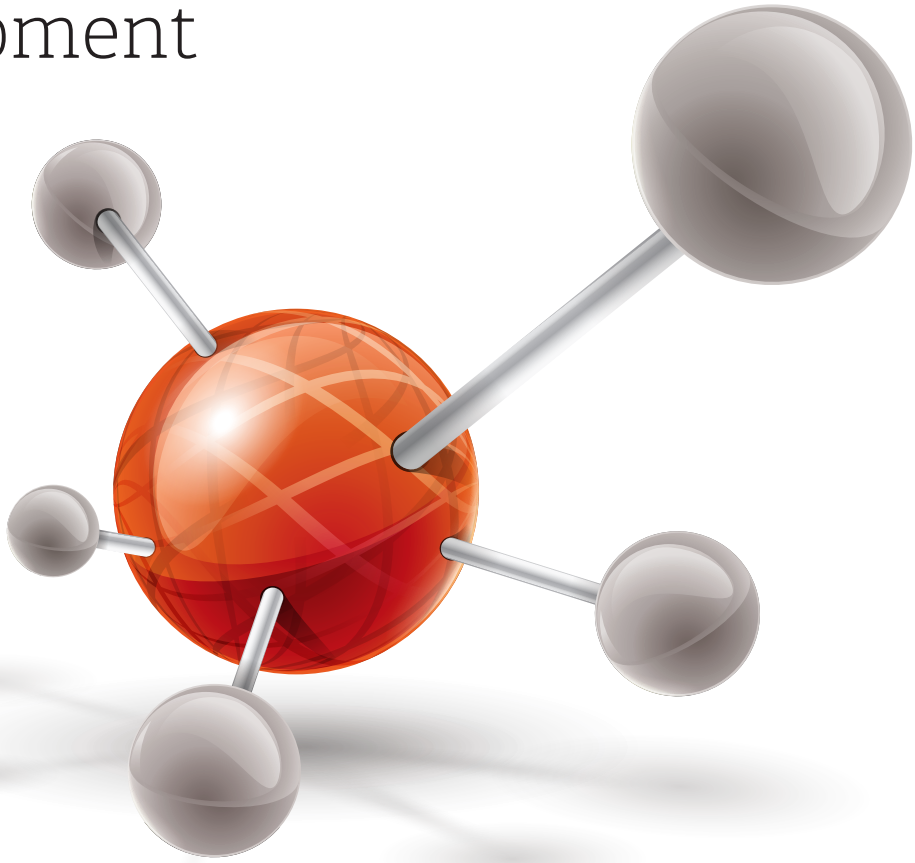
National chemicals registers and inventories: benefits and approaches to development



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National chemicals registers and inventories: benefits and approaches to development

ABSTRACT

The aim of this publication is to describe approaches for setting up national chemicals registers and how they improve sound chemicals management. The requirements and recommendations of international organizations can direct discussions at national level on setting up a chemicals register and on the complementary roles of international and national activities. Examples of national registers and inventories, including information on how they were set up and their scope and maintenance, are also given for use by those planning such activities. The publication has been developed in the framework of the project "Development of legislative and operational framework for collection and sharing of information on hazardous chemicals in Georgia" executed by the WHO Regional Office for Europe (2015–2017).

KEYWORDS

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Contents

Abbreviations and acronyms

CAS	Chemical Abstracts Service
CLP	classification, labelling and packaging
CORS	Chemicals Office of the Republic of Slovenia
DDT	dichloro-diphenyl-trichloroethane
ECHA	European Chemicals Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
IHR	International Health Regulations
ILO	International Labour Organization
IPCS	International Programme on Chemical Safety
ISK	Information System on Chemicals (Slovenia)
IT	information technology
KEMI	Swedish Chemicals Agency
OECD	Organisation for Economic Co-operation and Development
PBDE	polybrominated diphenyl ethers
POP	persistent organic pollutant
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SAICM	Strategic Approach to International Chemicals Management
SDS	safety data sheet
SEPA	Swedish Environmental Protection Agency
UNECE	United Nations Economic Commission for Europe
US EPA	Environmental Protection Agency in the United States of America

Introduction

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" *(1)*.

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 Region *(2)*. 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-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 can access a relevant database *(3)* for a more effective response.

Initially, the overview of existing practices of setting up national registers has been prepared to facilitate making a decision on a design and operational framework of the national chemical register in Georgia. This publication has been prepared in response to a big interest of other countries developing their national chemicals registers in this information. Also, wider distribution of information on international experience collected in the framework of the project in Georgia increases the outcome and the impact of the AAP-project.

The purpose of this publication is to describe the benefits of a national chemicals register, to provide brief explanations of international and regional requirements or recommendations for the collection and sharing of data (including those from existing databases) on hazardous chemicals and related issues (e.g. accidents, transport and illegal traffic) and to share information on good practice in national systems for the registration of chemicals. The sources include conventions, guidelines, guidance materials, other international and regional documents, selected legislation and experience from countries. Recommendations and check-lists for setting up a register of hazardous chemicals are provided as initial guidance.

The list of sources and examples is not exhaustive but represents selected international and regional tools and sources to assist countries in compiling information, designing national systems for information collection (including inventories and databases) and international reporting. The links to the sources cited and relevant databases are listed in annexes 1 and 2; chemicals subject to international conventions and other relevant information are listed in annexes 3–6.

1. Types of information required on chemicals

Collection of information on chemicals has been on the chemical safety agenda since 1972, when the United Nations Conference on the Human Environment endorsed the Stockholm Declaration on the Human Environment *(4)*, which states that the information on chemicals and the data required internationally include physical and toxicological properties, production and use, effects on human health and the environment, exposure, standards, laws and regulations, and emergency procedures. In response to this request and the need for information on chemicals in general, the International Programme on Chemical Safety (IPCS) was created in 1980 as a joint programme of WHO, the International Labour Organization (ILO) and the United Nations Environment Programme *(5)*. IPCS publications (INCHEM) are a valuable source of information on chemicals of important public health concern *(6)*. In 2006, the international community adopted the Strategic Approach to International Chemicals Management (SAICM), which requires the collection and sharing of information that is "available, accessible, user friendly, adequate and appropriate to the needs of all stakeholders" *(7)*. It is also recognized that sound chemicals management is playing important role in the implementation of sustainable development goals in terms of protection of human health and the environment.

Many sources of international requirements and recommendations for information collection and exchange are available to assist countries in compiling information on chemicals, designing national systems for collecting relevant information (including regular collection, such as chemicals inventories and databases) and reporting to international bodies as a co-benefit (e.g. for international conventions). Alignment or implementation of the requirements at national level requires consultation among all relevant stakeholders.

The following principles may be considered in setting up a database.

- Before deciding how chemicals should be controlled, those that should be controlled should be identified.
- Such decisions require organized information about the chemicals produced, imported and used in a country and about the risks associated with their marketing and use.
- Legislation should oblige producers, importers and other stakeholders to submit adequate information on chemicals to the appropriate government body and authorize the government to collect additional information, including confidential commercial information, as appropriate.
- Laws should also provide for the communication of information on safe handling and use to all people, including workers, farmers and consumers, who may come into contact with potentially harmful chemicals at any stage of their life cycle.

Several types of information or data should be collected at national level in order to facilitate sound chemicals management, including:

- chemical properties (and risks and hazards);
- the type and volume of chemicals produced, used, transported and stored (and the users);
- hazardous activities and installations;
- pollution of environmental media (air, water, ground), drinking-water, food, consumer products (by monitoring);
- toxic wastes (volume, location); and
- poisonings (statistics, first aid, poison control).

1.1 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. Most European Union registers and databases consist of information submitted by companies, and evaluation can be considered.

A national chemicals management database is commonly an inventory of all or only of 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 (Box 1);
- prepare reports for decision-makers, the public and other groups (Box 2);
- prioritize chemicals and assess their risks to health (Box 3);
- 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 authorisation, 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.

1.2 INFORMATION EXCHANGE FOR SOUND CHEMICALS MANAGEMENT

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" *(9)*:

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.

According to this guidance, the following types of information may be of value for exchanges among national stakeholders for sound chemicals management:

- factory licensing records;
- monitoring data (e.g. levels of chemicals in air, water, soil, food);
- data from research on chemicals;
- pesticide registration data;
- import, export and manufacturing statistics;
- industrial emissions (estimates and data) and other monitoring data;
- trade in chemicals (including imports and exports);
- sales data (e.g. pesticides sold in shops or wholesale to farmers);
- international and national toxicological data, including human health and environmental effects;
- emergency response data; and
- inventories of stockpiled, unused, undistributed and stored chemicals.

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.

1.3 INFORMATION FOR PRIORITIZING CHEMICALS OF CONCERN AND ASSESSING THE RISKS THEY POSE TO HUMAN HEALTH AND THE ENVIRONMENT

A number of sources suggest the types of information that may be necessary to assess the health risks, environmental risks and hazards of chemicals. Box 3 shows an example of the use of existing data on chemicals to assess the risks to the population.

1.3.1 Assessment of risks to human health

In order to determine the risks of chemicals to human health, specific information must be identified, acquired and used to assess the hazards, exposure and corresponding health risks at local and/or national level. The WHO Human Health Risk Assessment Toolkit: Chemical Hazards *(10)* 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.

Box 1. Making a decision to restrict a chemical in consumer products based on the information available from national chemicals registers: the case of methanol in Poland and Slovenia

Growing numbers of cases of methanol poisoning due to either accidental or intentional consumption of methanol-containing products have been registered in some countries in the European Union since 2011. An analysis of regulations on methanol in consumer products and risk reduction measures was therefore undertaken to decide on methanol restriction. To determine the effect of the proposed restriction, data were obtained on:

- companies that might be producing and/or placing such chemical products on the market;
- relevant chemical products and their concentrations of methanol; and
- the total quantity of such chemical products.

National registers provided the necessary information, including: number of products on the market containing methanol, from basic parameters such as the CAS No.; the methanol content of each product; the companies, safety data sheets (SDS); and the quantities of the products imported or on the market in the past few years.

Different approaches were proposed in Poland and in Slovenia on the basis of the information obtained, and an analysis was conducted that included the number of poisoning cases (18 in 2011 and 43 in 2012 in Poland and one in both 2011 and 2012 in Slovenia), communication with the relevant industry and data on health benefits (from European Union dossiers and additional national data).

In Poland, the Government decided to include additional classification, labelling and packaging (CLP) requirements. They concluded that:

- the special rules on packaging defined in Annex II, part 3, section 3.1.1.3 of the CLP directive apply to methanol; and
- packaging of whatever capacity supplied to the general public must have a child-resistant fastening if the concentration of methanol in the substance or mixture is ≥ 3.0%.

In Slovenia, the national chemical authorities were provided with data for a discussion of the country position at the level of the European Union, which could be to:

- reject the proposed restriction because of disproportionality for Slovenian industry;
- propose certain changes to the proposal (e.g. limit the restriction above a certain concentration); or
- agree with the proposal.

The final decision has not yet been made.

Sources: Dr Andrzej Kalski, Bureau for Chemical Substances, Poland, personal communication; Dr Alojz Grabner, Chemical Office, Slovenia, personal communication; June 2017.

Box 2. The main statistical products for analysing information from the national chemicals register in Sweden

In Sweden, the Swedish Chemicals Agency (KEMI) not only uses the register for supervision but is also responsible for publishing statistics on chemicals, alone or in cooperation with Statistics Sweden.

The main statistical products are:

- flow analysis of chemical substances to determine, for example, whether turpentine is manufactured in Sweden; which products contain acetic acid; whether nonylphenolethoxylate is used in many consumer products;
- quantities of pesticides (active substances) sold, on the basis of information provided by authorized holders of pesticides, which were published by the Swedish Environmental Protection Agency until 1979 and by the Swedish Chemicals Agency from 1985;
- overview tables listing for instance how many dishwasher detergents were sold to consumers during one year and the chemicals used most commonly in the metal-working industry; and
- statistics in brief, which present diagrams and graphs of developments in the production and use of substances and product groups of interest, showing how chemicals are used and trends over time.

Source: Ulf Rick, retired from Swedish Chemicals Agency, Sweden, personal communication; June 2017.

Road maps can be prepared for a human health risk assessment and 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.

1.3.2 Assessment of risks in emergency situations

The International Health Regulations (2005) (IHR) *(11)* is an international legal instrument that is binding for 196 countries. They help the international community to prevent and respond to acute public health risks that could cross borders and threaten the world. The IHR entered into force on 15 June 2007. It requires countries to notify WHO of all types of events that possibly constitute a public health event of international concern. The main requirements are notification of events and the creation of necessary core capacity *(13)* to ensure that a country is properly prepared to respond to a chemical emergency situation by rapid risk assessment *(12),* including the use of relevant databases.

Several sources of notification and alert can be used for chemical events, both within and outside the health sector. Within the health sector, poisons centres, hospital emergency departments, primary health care facilities and toxicology laboratories can carry out surveillance of poisoning and outbreaks of possible or known chemical etiology *(14).* Non-health sector sources include:

Box 3. Prioritization of chemicals for assessment of population risks

Under the Canadian Environmental Act (CEPA), assessment of the risks to the Canadian population posed by polybrominated diphenylethers (PBDEs) was prioritized based on consideration of information included in the Domestic Substances List. The general population was potentially exposed to PBDEs by direct contact with products containing these substances or in the environment by use and disposal of these products.

The ranking of PBDEs during categorization of all substances on the Domestic Substances List provided a semi-quantitative measure of exposure to these substances, as a basis to consider its priority for assessment. Therefore, through national registries, potential exposure was determined from:

- the number of companies producing and/or using PBDEs;
- the volume of production; and
- the sum of "expert ranked uses" (derived from expert consideration of use codes for substances submitted in the compilation of the Domestic Substances registry).

This information led to the conclusions that:

- four of the congeners (tetra-, penta-, hexa- and heptabromodiphenylether) present the "lowest potential for exposure" of the general population; and
- three of the congeners (octa-, nona- and decabromodiphenylether) present "intermediate potential for exposure" of the general population.

PBDEs were also nominated for assessment under CEPA. A screening level assessment of potential human health risks associated with estimated exposure based on reported concentrations of PBDEs in water, ambient and indoor air, human breast milk, various foods and dust, standard reference values for intake and the available toxicological information led to the conclusion that additional more detailed assessment of the health risk of PBDEs (as a Priority Substance) was a low priority, because of the narrow margin between the most conservative estimated critical values for exposure and lowest reported effect levels relevant to assessment of human health, taking into account associated uncertainties.

Source: WHO *(8)*.

- agencies for consumer protection and food safety, which could provide alerts about chemically unsafe consumer products and foods;
- environmental agencies, which could signal unusually high levels of chemicals in (routine) monitoring of environmental media, such as surface water, air and soil, or a chemical release;
- first responders who alert the authorities to an event;
- plant operators that notify a chemical release at their facility;
- the public, which may signal an overt release, such as an explosion, a chemical plume, contaminated drinking-water, dirty surface water or dead wildlife; and
- the media and websites.

The IHR requirements for core capacity for surveillance and response include the responsibility of Member States to develop national (and, when possible, a sub-national) *risk assessment capacity*, which is recognized as an integral part of prevention, surveillance and response *(12)*. Risk assessment is the systematic collection, assessment and documentation of information for assigning a level of risk to an event, including hazard, exposure and context assessment and risk characterization. The structure and location of this capacity, which may be a dedicated team or embedded in an existing prevention, surveillance and response system, depends on the country.

The IPCS programme in the field of the prevention and management of poisoning builds capacity in countries and promotes the establishment and strengthening of poisons centres within the IPCS INTOX Programme. Other activities include the provision of information on chemicals and information management tools. Poison centres are responsible for collecting and sharing information on chemicals and their acute health hazards.

1.3.3 Hazard assessment

A number of international organizations are involved in collecting and disseminating information on chemical hazards from existing scientific assessments, including ILO, the Organisation for Economic Co-operation and Development (OECD) and WHO.

The OECD Council decision on new chemicals *(15)* forms a basis for a meaningful first assessment of the potential hazard of a chemical. The recommended minimum pre-marketing data include:

- chemical identification;
- production, use and disposal;
- recommended precautions and emergency measures;
- analytical methods;
- physical and chemical characteristics;
- acute toxicity;
- toxicity after repeated doses;
- mutagenicity;
- ecotoxicity; and
- degradation and accumulation.

A "screening information data set" consists of the minimum data required for an initial hazard assessment of chemicals. It has been agreed upon by OECD for assessments that cover the full range of end-points *(15)*. For targeted assessments, the data collected should be the same as for targeted screening and non-screening end-points. The data set is organized under five headings *(16)*:

- information on the substance,
- physical and chemical properties;
- environmental fate;
- environmental toxicity; and
- mammalian toxicity.

For international classification and labelling, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) *(17)* allows classification of chemicals by type of hazard and proposes harmonized elements for hazard communication, including labels and safety data sheets (SDS). Its aim is to ensure that information on the physical hazards and toxicity of chemicals is available for the protection of human health and the environment during handling, transport and use of these chemicals. The system also provides a basis for harmonizing rules and regulations on chemicals at national, regional and global levels – an important means for facilitating trade.

The system provides harmonized criteria for classifying substances and mixtures according to the following groups of hazards.

Physical harzards are:

- explosives
- flammable gases
- aerosols
- oxidizing gases
- gases under pressure
- flammable liquids
- flammable solids
- self-reactive substances and mixtures
- pyrophoric liquids
- pyrophoric solids
- self-heating substances and mixtures
- substances and mixtures which, in contact with water, emit flammable gases
- oxidizing liquids
- oxidizing solids
- organic peroxides
- corrosive to metals
- desensitized explosives.

Health hazards comprise:

- acute toxicity
- skin corrosion or irritation
- serious eye damage or irritation
- respiratory or skin sensitization
- germ-cell mutagenicity
- carcinogenicity
- reproductive toxicity
- specific target organ toxicity – a single exposure
- specific target organ toxicity – repeated exposure
- aspiration hazard.

Environment hazards:

- hazardous to the aquatic environment
- hazardous to the ozone layer.

References to available information on chemical hazards can be found in Annex 2.

1.3.4 Assessment and prevention of risks in work places

The purpose of **ILO Convention 170** *(18)* and **Recommendation 177** *(19)* on safety in the use of chemicals at work, adopted by the International Labour Conference at its 77th session in 1990, is to protect workers against the risks associated with the use of chemicals during their work. It applies to all branches of economic activity in which chemicals are used. In addition, it states that all chemicals should be labelled to indicate their identity and that hazardous chemicals should be marked so as to provide essential information on their classification, their hazards and the safety precautions to be observed. It also requires that SDS for hazardous chemicals be available. Chemical suppliers are responsible for ensuring that chemicals have been classified, marked and labelled and include SDS.

Chemicals subject to this Convention are those that have:

- toxic properties, including both acute and chronic health effects, in all parts of the body;
- chemical or physical characteristics that include flammability, explosion, oxidization and dangerous reactivity;
- corrosive and irritant properties;
- allergenic and sensitizing effects;
- carcinogenic effects;
- teratogenic or mutagenic effects; and
- effects on the reproductive system.

Basic information on the hazards of chemicals is also available from ILO/WHO international chemical safety cards *(20)*, a joint initiative of WHO and ILO to disseminate the appropriate information on hazards of chemicals in the workplace in an understandable manner. To date, about 1700 cards are available. They are a good source of information on hazards for a chemicals database, including:

- the identity of the chemical;
- physical data;
- chemical properties;
- acute health hazards;
- short- and long-term health effects;
- fire and explosion hazards and preventive measures;
- first aid and firefighting;
- regulatory information;
- classification and labelling;
- environmental data; and
- spillage, disposal and safe storage.

1.4 INFORMATION REQUIRED BY INTERNATIONAL AND REGIONAL CHEMICALS CONVENTIONS AND INITIATIVES

A number of international and regional chemicals conventions and initiatives have information requirements, often for reporting to the convention. Countries may wish to use national inventories, registers and databases to prepare such reports, as they provide information on the production, use, stocks and releases of specific chemicals under these conventions.

1.4.1 Multilateral environmental agreements

The **Basel Convention** on the Control of Transboundary Movements of Hazardous Wastes and their Disposal *(21)* is a global treaty that entered into force on 5 May 1992. It includes requirements for notice, consent and tracking of the movement of wastes across national boundaries. Among the obligations under the Convention, Parties are required to notify any transboundary movement of wastes that are regulated under the Convention (Article 6 on transboundary movement between Parties) and to transmit information about wastes to the Conference of the Parties annually (Article 13 on transmission of information). For wastes to be classified as hazardous, information is required not only on their composition but also on their hazard in wastes.

Relevant information in national databases that can be used for national reporting under the Basel Convention is:

- characteristics of wastes;
- classification as per Annex 5 of this publication (Annex III of the Basel Convention) according to hazardous characteristic, H number and United Nations class; and
- accidents that occur during transboundary movement and disposal of hazardous and other wastes.

The **Stockholm Convention** on Persistent Organic Pollutants (POPs) *(22)* is a global treaty that entered into force on 17 May 2004. Its aim is to eliminate or restrict the production and use of POPs.

Parties to the Stockholm Convention are obliged to report certain data on POPs to the Conference of the Parties and to collect data by monitoring POPs. Information that can be compiled in national databases that would assist national reporting to the Stockholm Convention includes:[1]

- volume of polychlorinated biphenyls (kg/year), local destruction, import and export;
- volume (kg) of POPs produced, exported and imported per year (for import and export, countries of origin and destination, respectively);
- volumes of dichloro-diphenyl-trichloroethane (DDT) produced and used;
- volume of pentachlorobenzene (kg/year);
- volume of hexachlorobenzene (kg/year);
- volume, location and condition of POP stockpiles (kg);

1 These information categories refer to POPs regulated under the Stockholm Convention, as per Annex 5 of this publication.

- existence of products and articles in use containing POPs and type of chemical; and
- existence of contaminated sites and type of chemical.

The Convention Secretariat has prepared an electronic reporting system *(23)* that can provide further details on collecting this information.

The **Rotterdam Convention** on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade *(24)* is a multilateral treaty adopted on 24 February 2004. It promotes shared responsibility for the importation of hazardous chemicals. As stated in Article 3 of the Convention, the Convention covers: banned or severely restricted chemicals and severely hazardous pesticide formulations. The Convention encourages countries to consider creation of a national chemicals register or inventory.

Parties under the Convention are obliged to prepare an export notification to the importing Party whenever a chemical that is banned or severely restricted by a Party is exported from its territory (Article 12 on Export Notification). Information that could be collected in a national database for this use is:[2] the name of the banned or severely restricted chemical and a summary of the following information:

- common name;
- chemical name according to an internationally recognized nomenclature (for example, International Union of Pure and Applied Chemistry), when such nomenclature exists;
- trade names and names of preparations;
- code numbers: CAS number, harmonized system customs code and other numbers;
- hazard classification, when the chemical is subject to classification requirements;
- use or uses of the chemical; and
- physico–chemical, toxicological and ecotoxicological properties.

When more than one such chemical is included in a mixture or preparation, the information shall be provided for each chemical.

At the request of the 3rd meeting of the Conference of the Parties to the Rotterdam Convention, the Convention Secretariat prepared a standard form for export notification, which can be consulted for further details *(25)*.

Other documents have been prepared by organizations to assist countries in implementing the Rotterdam Convention, such as a guidance document prepared originally for a joint pilot project between the Secretariat of the Rotterdam Convention and the United Nations Institute for Training and Research *(26)*. It outlines the obligations of Parties to the Rotterdam Convention (including those related to information collection and exchange) and provides guidance on the legal and administrative aspects that should be in place in order to comply with those obligations.

The **Minamata Convention** on Mercury *(27)* is a global treaty designed to protect human health and the environment from the effects of mercury by controlling anthropogenic emissions and

2 These information categories refer to the chemicals subject to the Rotterdam Convention, as per Annex 3 of this publication.

releases of mercury into the environment It was finalized on 19 January 2013 and will enter into force on 16 August 2017.

The Conference of the Parties of the Minamata Convention will decide at its first meeting[3] the timing and format of reporting by Parties. In the context of national chemical product registers, the reporting requirements will probably include information on manufacturing processes in which mercury or mercury compounds are used and artisanal and small-scale gold mining with mercury. National inventories and databases could include information on these items for national reporting under the Convention.

The **SAICM** *(1)* 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 plans *(28)*, 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.

SAICM participants adopted overall orientation and guidance for achieving the 2020 goal of sound management of chemicals at fourth session of International Conference on Chemicals Management in 2015. Eleven basic elements and six core activity areas have been recognized as critical at national and regional levels for attainment of sound chemicals and waste management. One of the 11 basic elements is collection of and systems for the transparent sharing of relevant data and information among all relevant stakeholders by a life-cycle approach, such as use of the GHS. One of the six priority actions is increasing the accessibility of relevant information and making it understandable to all levels of society.

3 The first meeting of the Conference of the Parties is scheduled on 24–29 September 2017.

1.5 INFORMATION REQUIRED FOR PREPAREDNESS FOR AND RESPONSE TO EMERGENCY SITUATIONS

Several international agreements regulate countries' activities for the prevention of and response to chemicals emergencies, including the IHR *(10)* and ILO and United Nations Economic Commission for Europe (UNECE) conventions.

1.5.1 Prevention of Major Industrial Accidents Convention C174 and Recommendation R177 (ILO)

The purpose of this Convention *(29)* is to prevent major accidents involving hazardous substances and limit the consequences of such accidents in major hazardous installations. The Convention requires competent national authorities to establish a system for identifying major hazardous installations on the basis of hazardous substances and the threshold quantities.

Recommendation R177 *(30)*, written to facilitate implementation of the Chemicals Convention (1990) *(18)*, set requirements and criteria for classification, labelling and packaging of chemicals and for SDS. These requirements were revised in the GHS. The basic requirements for the provision of reliable information for workers, which are enforced by the Convention and the Recommendations, state that workers and their representatives should have the right to "obtain chemical SDS and other information from the employer so as to enable them to take adequate precautions, in co-operation with their employer, to protect workers against risks from the use of hazardous chemicals at work".

1.5.2 Industrial Accidents Convention (UNECE)

The Convention on the Transboundary Effects of Industrial Accidents *(31)* was adopted on 17 March 1992, signed by 26 UNECE member countries and the European Union, and entered into force on 19 April 2000. The aim of the Convention is to protect human beings and the environment against industrial accidents by preventing such accidents as far as possible, by reducing their frequency and severity and by mitigating their effects. It promotes active international cooperation between the Contracting Parties, before, during and after an industrial accident.

The scope of the Convention includes activities in which hazardous substances are present in quantities higher than the thresholds listed in Annex I, which defines the qualifying criteria for hazardous substances, hazard categories, named hazardous substances and threshold quantities which are capable of transboundary effects.

Annex 1[4] to the Convention lists the following categories:

4 Annex 1 to the Convention has been amended to align it with the Globally Harmonized System of Classification and Labelling of Chemicals. Therefore, the categories listed above will change in the next edition of the Annex.

- flammable;
- highly flammable;
- extremely flammable;
- toxic;
- very toxic;
- oxidizing;
- explosive; and
- dangerous for the environment ("toxic to aquatic organisms" and "very toxic to aquatic organisms").

It also names substances that can cause an emergency situation, including:

- ammonium nitrate;
- potassium nitrate;
- chlorine;
- ethylene oxide;
- hydrogen;
- toluene diisocyanate;
- sulfur trioxide;
- lead alkyls;
- phosgene;
- methyl isocyanate;
- liquefied extremely inflammable gases (including liquefied petroleum gas) and natural gas; and
- petroleum products: gasolines and naphthas; kerosenes (including jet fuels); gas oils (including diesel fuels, home heating oils and gas–oil blending streams).

A full list of substances regulated under the Convention is given in Annex 6 to this publication.

1.6 RESPONSIBILITY OF GOVERNMENTS AND INDUSTRY TO INFORM THE PUBLIC ABOUT CHEMICAL THREATS

1.6.1 Aarhus Convention (UNECE)

The UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention) *(32)* was adopted on 25 June 1998. It puts environmental democracy into practice by giving people the rights to access information easily, participate in environmental decision-making and seek justice if their rights are violated.

The Aarhus Convention includes provisions to ensure that public authorities (i) make environmental information available to the public, (ii) have updated environmental information that is relevant to their functions and (iii) establish mandatory systems for an adequate flow of information to public authorities about proposed and existing activities that may significantly affect the environment.

Provisions applicable to chemical databases and inventories are:

- that each Party shall, in response to a request for environmental information, make such information available to the public in the form requested, unless it is reasonable for the public authority to make it available in another form (in which case it may be made available in that form) or if the information is already publicly available in another form (Article 4 on Access to Environmental Information);

- that each Party shall ensure that:
  - public authorities have updated environmental information that is relevant to their function;
  - mandatory systems are established to ensure an adequate flow of information to public authorities about proposed and existing activities that may significantly affect the environment; and
  - in the event of an imminent threat to human health or the environment, due to human activities or natural causes, all information that could enable the public to take measures to prevent or mitigate harm arising from the threat and is held by a public authority is disseminated immediately and without delay to members of the public who may be affected (Article 5 on Collection and Dissemination of Environmental Information); and

- that each Party shall ensure that environmental information progressively becomes available in electronic databases that are readily accessible by the public through public telecommunications networks.

It further states that each Party shall take steps to establish progressively, taking into account international processes where appropriate, a coherent, nationwide system of pollution inventories or registers in a structured, computerized, publicly accessible database compiled by standardized reporting. Such a system may include inputs, releases and transfers of a specified range of substances and products (Article 5 on collection and dissemination of environmental information).

1.7 INFORMATION NECESSARY TO PREVENT ILLEGAL TRAFFIC

The information required on the transport of chemicals and illegal traffic is included in several instruments, some of which are summarized below. Preventing illegal international traffic is one of the objectives of SAICM, which is to "promote information sharing and to strengthen the capacity of developing countries and countries with economies in transition at the national and regional levels for the prevention and control of illegal international traffic".

1.7.1 United Nations Regulations on the Transport of Dangerous Goods

Recommendations on the transport of dangerous goods are presented as "model regulations" *(33)*. They present a basic scheme for uniform national and international regulation of the various modes of transport, yet they remain flexible enough to accommodate any special requirements.

The Regulations provide a framework for classifying and defining classes of dangerous goods, listing the principal dangerous goods, general packaging requirements, testing procedures, marking, labelling or placarding, and transport documents.

A list of over 3000 dangerous goods is maintained. When a new or amended classification of a substance is proposed, the following information is required:

- substance identity
- physical properties
- flammability
- chemical properties
- harmful biological effects
- supplementary information.

The **Harmonized Commodity Description and Coding System** *(34)*, generally referred to as the "harmonized system", is a multipurpose international nomenclature for products. It comprises 5000 commodity groups, each identified by a six-digit code. Contracting Parties are required to apply the codes and "make publicly available its import and export trade statistics in conformity with the six-digit codes".

Section VI of the Code (2012 edition) covers chemical products, including:

- inorganic chemicals;
- organic chemicals;
- pharmaceutical products;
- fertilizers;
- tanning or dyeing extracts; tannins and their derivatives; dyes, pigments and other colouring matter; paints and varnishes; putty and other mastics; inks;
- essential oils and resinoids; perfumery, cosmetic or toilet preparations;
- soap, organic surface-active agents, washing preparations, lubricating preparations, artificial waxes, prepared waxes, polishing or scouring preparations, candles and similar articles, modelling pastes, "dental waxes" and dental preparations with a basis of plaster;
- albuminoidal substances; modified starches; glues; enzymes;
- explosives; pyrotechnic products; matches; pyrophoric alloys; certain combustible preparations;
- photographic and cinematographic goods; and
- miscellaneous chemical products.

The World Customs Organization Policy Commission endorsed five risk areas for customs enforcement, including health and safety, intellectual property rights (e.g. fake or counterfeit pharmaceuticals, substandard items such as tainted foodstuffs) and the environment (e.g. illegal cross-border trafficking of hazardous and toxic waste, ozone-depleting substances). The World Customs Organization has also published a correlation table of products with harmonized system codes and those covered by the Basel, Rotterdam and Stockholm conventions.

2. Check-lists for setting-up a register of hazardous chemicals

A country's approach to creating a national register depends on its information requirements, national legislation and its capacity; however, many common characteristics should be considered at the planning stage. The questions to be asked when determining the legal and practical basis for a register of hazardous products are the following.

- What are the objectives of creating the register? For what purposes will it be used?
- What kind of information and precise data will meet the objectives?
- Who will be responsible for generating the data and for the database? Will the authorities who create the register or industry be responsible for submitting information?
- Is it sufficient to collect existing information or should new information be generated and collected? Are there sufficient resources to generate new information?
- Where will the register be based? Which authority is most suitable for managing and maintaining the register?
- What will be the administrative and financial burden of creating the register? Will it be cost–efficient in relation to the objectives?
- Are the necessary resources available? Who should bear the costs?
- If an electronic database with on-line submission is foreseen, which option is most suitable, cost–efficient and user–friendly: further development and revision of an existing system or creation of a new system? A test phase and improvement of the electronic system might be required.
- Who should have access to the information? Who would use or interpret the information appropriately?
- Should the public have access to the register? If so, partially or completely? What information should be considered confidential?
- How can confidential treatment of sensitive information be ensured?
- If industry is to submit information, should an authority monitor the appropriateness of the information? If so, which would be the most competent body? Does it have the necessary resources? Monitoring information may improve compliance by industry.
- If industry is obliged to submit information, is there a trained enforcement authority to enforce compliance?
- Are the details of all obligations covered by appropriate, legally determined definitions? Is the terminology harmonized with that of international legislation?

The recommendations below may be helpful in creating a register.

- State unambiguous obligations, and clearly identify the entities that are obligated. Build trust, demonstrate fair treatment and ensure appropriate confidentiality in the handling of information. Consider that foreign companies also have obligations under other regimes.

- If one objective is to support a (future) poison information centre (or another body in an emergency), ensure direct, easy, permanent access for faster intervention.

- It is recommended that business and industry be responsible for submitting information and for data quality. The approval of submitted information will be challenging and resource-consuming, because of the large number of mixtures available on the market. Furthermore, approval of information transfers the responsibility for data quality from industry to the public administration. The quality of data should nevertheless be monitored, at least randomly, and enforced by the authorities.

- It is highly recommended that business and industry be obliged to submit information directly to the database in electronic form. Submissions in paper format take up space and require administrative capacity to load data from SDS into a searchable database and archive them.

- The SDS contain useful information about substances and mixtures, which is usually sufficient for emergency services. To ensure that a database is searchable effectively and rapidly, some information, such as trade name, composition and classification, should be introduced directly into the database and linked to an electronic version of the SDS.

- The right balance should be found between the volume of required information to be added to the system in searchable form and the ease of users, who may wish to notify hundreds of substances or mixtures. The kind of data that will be submitted should be foreseen. A mechanism for making many similar submissions might be added.

- The system should be easy to operate and intuitive (user-friendly). To address questions about using the system, a good user manual should be written, with clear answers to frequently asked questions. Support can be offered in the form of guidelines, a "help desk" and training of companies and entities that are obliged to report. Training videos could be produced. Without such support, the queries may overwhelm the capacity of the authority or result in submission of incorrect information.

- If possible, actions such as restoring a blocked account or changing a password should be automatic.

- In order to avoid errors (e.g. typographical) and misuse of the system, automated methods can be introduced to verify submitted information, such as a "completely automated public Turing test to tell computers and humans apart" (CAPTCHA) code or inclusion and verification of a tax number (or other identification number) of a company, which can be doubled-checked by the system. Drop-down menus and options should be used as often as possible to facilitate comparison and assessment of information, searches and preparation of statistics.

- Users of registers often want access to all the data, although this may be problematic. The implications of establishing a data reporting system or of major changes should be evaluated for all stakeholders, and the result should suit all parties. Some compromises will have to be made between the data needs of the final user, the sensitivity of certain data, the workload and information technology (IT) support provided by the government authority, and the administrative burden for companies. Finding such a compromise may be difficult, and some interaction or meetings should be organized between the authorities, company representatives, poison centre representatives and other possible users of data, at which the data to be reported can be confirmed and agreed upon by all.

- Areas for further improvement are likely be identified once the database becomes operative. It is advisable to include the requirements for maintenance and improvement (e.g. number of hours) in the budget or to ensure a budget for further improvement.

- If the database on substances and mixtures is to be set up by government authorities, it is advisable to base data collection on existing open (public) sources in order to save resources. The data should nevertheless be complemented by information on chemicals placed on the market, by notifications from companies, supported by information from customs authorities.

The following questions provide a further check-list of issues to be resolved.

- Who should notify or report?
  - Refer to the agreed terminology of manufacturers, producers, users, downstream users, importers, distributors, national and foreign companies and legal entities. Are there any exemptions? (e.g. users of low-risk chemicals, like schools and research institutes, are not obliged to report.)

- What should the subject of notification or reporting be?
  - Consider the information required on substances or mixtures, hazardous substances or mixtures, products containing certain substances or mixtures, substances or mixtures in certain products and/or uses of hazardous chemicals.
  - Consider what classes of hazardous substances qualify for notification or reporting: e.g. all substances and mixtures, only physical and/or human and/or environmental hazards.
  - Consider any exemptions, e.g. for substances and mixtures that are covered by other specific or detailed legislation (such as pesticides), for which stricter rules should be applied (such as radioactive substances) or for which the associated risks are known and considered negligible (e.g. certain ores, substances used in small volumes).

- What precise information should be notified or reported?
  - Consider requesting identifying information about the legal reporting entity; ensure that only authorized people can submit a notification on behalf of a company.
  - Consider requesting identifying information on the subject of notification, such as the name, CAS number and customs code.
  - Consider requesting the properties of the subject of notification that are necessary for the register, such as classification, tonnage manufactured, imported and used, application or use, information on storage, SDS, information on hazards, first aid measures in case of an accident, labelling, exact chemical composition of mixtures.

- When should a notification or report be submitted?
  - Consider a baseline date by which existing manufacture, import or use should be notified or reported (e.g. within one year of the entry into force of relevant legislation or by the end of the first commercial year after entry into force).
  - Consider when a first notification should be submitted for new manufacture, import or use (e.g. at the start of production, importation or use or at the end of every year); whether and when to update the information (when relevant new information becomes available or at the end of every year); and whether the information should be reviewed regularly.

- Should there be a fee for notification or reporting?
  - Consider the costs of maintaining the system and the services provided and also those of companies for the notification. Calculate any fee proportionately.
  - Consider when the fee should be paid (e.g. at the time of an update).
  - Consider whether the fee could be reduced, e.g. according to the size of company, the volume or hazard of the substance or mixture or the number of notifications submitted.

- How should a notification or report be submitted?
  - Electronic submission (directly into the system) is strongly preferred, but consider access to the system by all obligated companies. Consider alternatives such as email, a CD or paper.
  - Consider the availability of the system to foreign companies; English (or other) language versions may be necessary. Consider alternatives such as email, a CD or paper.
  - Consider systems that allow immediate verification of the information submitted and drop-down menus, which may improve compliance.
  - Consider how to verify submissions, e.g. by authentication, email verification, registration numbers, digital signatures.

- Should the information submitted be systematically verified, validated or randomly controlled?
  - Depending on the information requested, consider verifying it, e.g. classification or SDS.
  - Consider the resource required for verification; if all information is approved by an authority, it is ultimately responsible for its correctness.
  - Consider random controls for enforcing the submission of appropriate data.
  - Consider steps to reduce submission of inappropriate data, e.g. telephone calls or letters to companies or hard measures such as enforcement.

- How can compliance be enforced?
  - Consider the selection of enforcement authorities and the resources required. Consider training requirements.
  - Consider a system of sanctions and penalties and also alternative methods such as “name and shame”, publication of lists of compliant and reliable companies and fee reductions for compliant companies.

- How should the register be set up? What should the database look like?
  - Consider whether all the information submitted may, can or must be included in the database.
  - Consider who will have access to the register and what information they require.
  - Consider what information should be searchable, search functions and coupling of information.

- Who should have access to the register?
  - Consider who will have access to the database, taking into account the objectives and main purposes of setting up the register.
  - Consider the availability of information, e.g. permanently on line or through an administrator (telephone or email contact).

- Consider the confidentiality of certain information and an exact list of confidential information. Refer to international or regional (e.g. European Union) standards.
- Consider allowing access to part of the database for certain groups, e.g. the general public, researchers and poison control centres.

- How can confidential treatment of relevant information be assured?
  - Consider both physical and on-line access to the database.
  - Consider treating hard copies and encryption of messaging.
  - Consider restricted access, with different levels for different stakeholders. Monitor and document access types and history.
  - Consider involving specialists.

Questions specific to each country should be addressed carefully during planning and creating a national register.

3. Key European Union legislation related to chemicals management

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.

3.1 DIRECTIVE 67/548/EEC ON DANGEROUS SUBSTANCES

Directive 67/548/EEC *(35)* 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. The final list was known as the European Inventory of Existing Chemical Substances. Since the Directive on registration, evaluation, authorization and restriction of chemicals (REACH) entered into force in 2007, information on "new substances" is replaced by the provision of data in the context of registration (cf. 3.3).

3.2 DIRECTIVE 99/45/EC ON DANGEROUS PREPARATIONS

Directive 88/379/EEC *(36)* on the approximation of laws, regulations and administrative provisions of Member States relating to the classification, labelling and packaging of dangerous preparations provided that Member States shall appoint bodies responsible for receiving information on dangerous preparations placed on the market, including their chemical composition. This provision is continued in Directive 99/45/EC *(37)*, which replaced Directive 88/379/EEC. Directive 99/45/EC states that "the authorities of the Member States may request information on the composition of the preparation and any other pertinent information from any person responsible for placing the preparation on the market." The Directive also gives Member States the authority to "appoint the bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physical-chemical effects." This later provision, with its more exact formulation, narrowed the area of application; however, it also gave Member States the possibility to regulate substances and mixtures hazardous to the environment. No detailed provision for implementation or methods was introduced, again leaving the responsibility to Member State.

The preambles of both directives state that countries must ensure the protection of the general public and, in particular, people who come into contact with dangerous preparations in the course

of their work or in the pursuit of a hobby; they must also protect consumers and the environment. These principles and provisions have been adapted in national laws by several Member States while setting up a national register of dangerous substances and preparations, although the scope, the information collected and the methods used in national registries differ, as these issues are not identified in the directives but were left to the discretion of Member States.

3.3 DIRECTIVE 1907/2006/EC ON REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS (REACH)

In 2001, the European Commission adopted a "white paper" on the strategy for a future Community Policy for Chemicals. The original legislative proposal of the Commission was adopted in autumn 2003 and negotiations began on the draft. The European Parliament and the Council found a negotiated agreement on the final version of REACH *(38)* in early December 2006, and the regulation was adopted at the Environment Council on 18 December 2006.

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. As stated by the Environment Commissioner at the time, Margot Wallström *(39)*,

> **This is one of the most important initiatives the Commission has taken in the context of sustainable development. We have decided on a step-by-step approach to phase out and substitute the most dangerous substances – the ones that cause cancer, accumulate in our bodies and in our environment and affect our ability to reproduce. This decision is crucial for future generations.**

The legislation entered into force on 1 June 2007. It was considered the most ambitious chemicals legislation anywhere in the world, combining ambition for the strongest protection of health and the environment with enhancing the competitiveness of European industry.

The day-to-day management of REACH is maintained by the European Chemicals Agency (ECHA) *(40)*, which was established in Helsinki, Finland.

REACH requires registration of all chemical substances on their own, in a mixture or in an article, manufactured or imported in the European Union in a volume of at least in 1 tonne/year. "Phase-in" substances (those that are already in use) were or will be registered in three stages, in 2008, 2010 and 2018, depending on tonnage manufactured or imported and their inherent properties. New substances must be registered before manufacture or import. Registration requires the collection or generation of information on the potential hazards of the substances to allow risk assessment. On this basis, appropriate risk management measures are identified and adopted to ensure safe use of the chemical.

The Regulation expressly states that industry is responsible for ensuring that a substance is safe for humans and the environment. Consequently, industry must generate the data required for registration. The basic data requirements, adjusted to the tonnage to be registered, are listed in relevant annexes of REACH. They state that animal testing shall be kept to a strict minimum, and

the use of alternative testing methods is encouraged; measures to promote this principle are included in REACH.

In order to ease the administrative and financial burden on both industry and government authorities and to align and improve the quality of data, companies that manufacture and/or import the same substance are required to cooperate in generating the necessary data and, as a main rule, should submit a joint registration – the principle of "one substance – one registration". Industry is responsible for identifying the measures necessary to manage the risks. REACH provides for the preparation of a chemical safety assessment, a chemical safety report, exposure scenarios, the supply of SDS and communication of all information relevant for ensuring safe use in the supply chain and in certain cases for workers and consumers. All the documentation must be updated by industry when relevant new information, e.g. on use volumes, becomes available.

REACH specifies cases in which SDS are to be supplied and the exact content of the document (in annex II, amended by Commission Regulation 453/2010/EU and later by Commission Regulation EU 2015/830), when it must be updated and when the new version is to be supplied, as well as the language and format of the SDS.

It is for European Union authorities, the ECHA and Member States' Competent Authorities to adopt and enforce regulatory risk management measures when the hazard and risk of a substance justify it. As part of this regulatory process, ECHA and Member States evaluate registered substances, focusing on those that are suspected of posing a risk to health or the environment. The risk management measures foreseen by REACH are identification of a substance of very high concern (SVHC), authorization of a substance of very high concern and restriction of substances that pose an unacceptable risk to humans or the environment. The regulatory processes are well defined and include consultation with involved parties and the general public in order to ensure transparency, the collection of all relevant information and taking account of all relevant scientific and technical information. Article 33 of the REACH stipulates the right for consumers to request data from industry and suppliers on the content of SVHC in articles (above 0.1 % weight).

Substances that are carcinogenic, mutagenic or toxic to reproduction (category 1A or 1B), persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), or substances that raise equivalent concern, such as endocrine disrupters, may be identified case by case. Substances of very high concern are eventually subjected to authorization; until then, in order to promote their safe use, special reporting requirements are foreseen. REACH authorization provides for safe use conditions and promotes substitution of hazardous substances with safer alternatives. If a substance is subject to authorization, it may be used after the specified date only if the concerned companies submit an application with detailed documentation. Use of such substances by a company is authorized by the European Commission on the basis of the ECHA opinion. All applications for authorization must include an analysis of alternatives and a substitution plan if a suitable alternative exists.

When the risk posed by a substance or a use is deemed unacceptable, REACH provides for restriction. Restricted substances and conditions for restrictions are listed in an annex of REACH. Restriction may consist either of a total ban on a substance (it shall not be manufactured, imported or used) or a partial ban on its use (e.g. certain uses or use above a certain percentage of weight are forbidden). For substances of very high concern, identification, authorization and

restriction are applied with no limit on the volume of the substances. REACH regulation is directly applicable in all European Union Member States.

3.4 DIRECTIVE 1272/2008/EC ON CLASSIFICATION, LABELLING AND PACKAGING

The regulation on CLP of substances and mixtures *(41)* amended and later repealed directives 67/548/EEC and 1999/45/EC on the CLP of substances and mixtures,[5] respectively. CLP operationalizes the United Nations **Globally Harmonized System** (GHS) of Classification and Labelling of Chemicals (see section 2.3). 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. In order to determine the appropriate classification, companies must identify, examine and assess all relevant data and information; new tests may be performed if necessary, taking into account the rules of REACH to generate new information. Substances and mixtures must be classified with no limit on tonnage, and all physico-chemical, toxicological and ecotoxicological end-points must be classified. CLP provides for harmonized classification of substances of particular concern. Harmonized classification, as a main principle, must be implemented by all manufacturers, importers and users; the end-points for a substance that does not have a harmonized classification must be analysed by the company. Proposals for harmonized classification may be submitted to ECHA by both Member States' authorities and companies. The strict procedure for harmonized classification is described in the regulation. If a company has information that may change the harmonized classification of a company, it can submit it to Member States' authorities in which the substance is sold on the market.

Substances and mixtures must be labelled according to their classification, and the labels must contain all the elements specified in the legislation. Labelling is considered a means for hazard communication. Dangerous substances and mixtures must be packaged in such a way that the content does not accidentally enter the environment. For certain substances and mixtures, child-resistant fastenings and tactile warnings of danger must be applied.

The classification and labelling of all substances registered under REACH and any other hazardous substances placed on the market must be notified to ECHA. The obligation to notify lies with the manufacturer, importer or group of manufacturers or importers that place the substance on the market. For every substance, ECHA creates an entry containing information from all notifiers. Notifiers and registrants are required make every effort to agree on an entry, indicating the absence of diverging or contradictory information on a substance. ECHA thus establishes and maintains a classification and labelling inventory of substances registered or placed on the market in the European Union.

The CLP regulation also requires the appointment of Member State authorities who will receive information from importers and users that place mixtures on the market, which is relevant for identifying preventive and curative measures in the event of a health emergency. The obligation

5 The CLP regulation introduced the term "mixture" to replace "preparation". In this publication, the two words are considered to be synonyms.

relates to mixtures that are classified as hazardous on the basis of their health and physical effects. The regulation requires that the information include the chemical composition of mixtures, including the chemical identity of substances in the mixtures, for which a request for use of an alternative name has been accepted by ECHA. The appointed bodies must ensure the confidentiality of any such information, which may be used only to decide on preventive and curative measures, in particular in emergencies, or to undertake statistical analyses to support adoption of better risk management measures. Several Member States implemented the requirements of Article 45 through their national systems, as they were considered to fulfil the requirements.

In line with the CLP regulation, the European Commission and Member States are working to harmonize the information to be requested and the format of submission. These requirements will be included in the CLP regulation as an annex. The aim is harmonize the information provided to poison centres in all European Union Member States. Negotiations resulted in the new annex *(42)*.

The CLP regulation is directly applicable in all European Union Member States, so that no national legislation can contain the same or differing rules with the same scope (e.g. different definitions of hazardous substances or mixtures). Nevertheless, Member States may have a national register with a scope that is different from that under the European Union regulation.

3.5 DIRECTIVE 528/2012/EU ON BIOCIDES

The biocidal products regulation *(43)* 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 ECHA keeps a register of biocidal products. Registers of biocides are not covered in this publication.

3.6 GUIDANCE FOR COLLECTING AND SHARING INFORMATION IN THE EUROPEAN UNION

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 *(44)* 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: physico-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 physico-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 life-cycle), and the nature of the exposure, i.e. routes, frequency and duration.

4. Chemical products registration in some countries in the European Union

The main aim of all registers is to collect the information necessary to protect human health and the environment from adverse effects of chemicals. Most were created according to the requirements of national or regional legislation, although information can also be collected voluntarily. The registers have common characteristics because they have similar objectives and requirements, whereas the specificity of national legislation may also be reflected in the content of registers and the approach to collecting and sharing of information.

4.1 HUNGARY

In preparation for its accession to the European Union, Hungary harmonized its national legislation with the "acquis communitaire" of the European Union, which are the legal acts (regulations, directives, decisions) and court decisions that constitute European Union law. Hungary has thus adapted the main principles of chemical safety, most importantly in national Act XXV of 2000 on chemical safety *(45)*, which provides for the submission of information on hazardous chemicals (substances and mixtures and their uses) and for the management of and access to a database on such chemicals. Decree no. 44 of the Minister of Health on implementation of the Act laid down further rules on the database, in particular on the information to be submitted.

The main purpose of establishing and maintaining a register, as stated in the Act, is to facilitate access to data on dangerous substances and mixtures to be used in medical emergencies. The database is also useful for deciding on Hungary's position on risk management under REACH and CLP and is considered to comply with the requirements of Article 45 of the CLP regulation. The database can be used as a general source of information on chemicals and also facilitates enforcement of REACH.

4.1.1 Scope of the register

Companies (legal and private persons) that manufacture or place a hazardous substance or mixture on the market in Hungary shall notify their substance or mixture, unless the same substance or mixture has been previously notified. All substances and mixtures that are classified as hazardous by the CLP are subject to notification, except for the following: medicines, drugs, cosmetics, waste, radioactive substances, food and feeding stuff, pesticides and substances and mixtures for which similar requirements of notification or authorization exist. Substances and mixtures that are exclusively used for research and development or experimental production (but not industrial test production) and are under controlled conditions are exempt from the obligation to notify.

Notification should be made at the latest by the time of manufacture or placement on the market. Notified hazardous substances are added to the Hungarian register of hazardous substances and mixtures in the register of hazardous products. The registers are based on the names of the substances and products, so that the identity of a product (mixtures) is based on its name. An administration fee is charged for notification (currently about 30€). Changes to notifications, such as ceased manufacture or placement on the market, should also be notified. Notification of changes is free of charge; however, a change to the name of a notified substance or mixture is considered a new notification.

Professional and industrial activities involving any hazardous substance or mixture should also be notified to the local authorities. The information is collected in the same database as notifications of substances and mixtures.

Violation of the provisions is penalized by a fine of up to approximately 32 000€.

4.1.2 Institutional infrastructure and responsible bodies

The main activities associated with notification of hazardous substances and mixtures manufactured or marketed in Hungary were the responsibility of the National Institute of Chemical Safety and now of its successor, the National Public Health Centre. These bodies act for the office of the Chief Medical Officer, which provides the IT (software, maintenance, development) for the register. The Toxicological Information Service is responsible for providing toxicological information in emergencies and therefore also uses the register.

The system is operated by one IT person, who is the user administrator, and provides a help-desk service. The content of the register is administered by three people and a supervisor, and one and a half posts are dedicated to financial administration and invoicing.

4.1.3 Types of information collected and structure of the database and register

The legislation requires companies that notify substances to submit the following information: a notification sheet, SDS prepared in line with European Union regulation 453/2010/EU and a draft label in line with the CLP regulation. Notification of mixtures is completed by a notification sheet and SDS.

The notification sheet for a dangerous substance contains: the name, the CAS or European Community number, contact details (name, address, telephone and fax numbers) of the notifier, identification code of the activity with the substance, certification of payment of the fee and the date of notification. The notification sheet for a dangerous mixture contains: the name, contact details (name, address, telephone and fax numbers) of the notifier, identification code of notification of the activity with the mixture, certification of payment of the fee and the date of notification.

Notifications of changes should reference the number of the original notification, the name of the substance or mixture, contact details and identification code of notifier, statement of ceased manufacture or presence on the market, if relevant, and date of notification.

Notifiers may request deletion of falsely notified items (e.g. due to wrong classification), but only if they were the original notifiers.

Administrators at the National Public Health Centre assess whether all the required information has been submitted and whether the SDS and label meet the legislative criteria. If all the necessary information is not submitted (e.g. no certification of payment or a deficient label or SDS), the missing information will be requested. If the administrator notes apparent mistakes in the data submitted (e.g. wrong classification in SDS or missing elements on the label), he or she informs both the notifier and the national enforcement authorities; in these cases, however, the notification may be considered complete. Once the notification has been processed, it is saved in the database and allocated an identification number. The notifier then receives confirmation of notification.

The register of dangerous substances and the product register of dangerous mixtures are based on the information notified. The content of the dangerous substances register is also determined by the regulation: it shall contain the chemical name of the substance, the CAS and European Community number (if available), a hazard symbol or hazard codes (i.e. classification), the risk (R)- or hazard (H)-phrase codes of the substance and the codes of the precautionary (P)-phrases. Currently, the register also contains the notification code and the index number (or REACH registration number) of each substance. The database allows access to a toxicological information service for all data submitted, i.e. the full SDS and the draft label, if relevant.

4.1.4 Submitting information

At the time the register was established, information was submitted on paper; since 2012, however, only electronic submissions are accepted from Hungarian companies. Unfortunately, the system has only a Hungarian version, and foreign companies that place substances or products on the Hungarian market and do not have a Hungarian representative may still submit information on paper. Notifications on paper (including old notifications) are loaded onto the system by the administrators of the register and colleagues at the National Public Health Centre.

The system operates as part of the Government information system, but the subsystem is dedicated to the notification of hazardous substances, mixtures and activities. The system is strongly protected by firewalls.

Companies must register in the system with a user identification and a password. At first registration, the data to be provided are the contact details of the notifying person and notifying company, in particular the tax number, which is double-checked by the system, the name of the company and the city in which the company is based (from a drop-down list). The notifier also selects the sub-system to which it requires access from a drop-down list and the access rights being requested. Submissions are verified by a Completely Automated Public Turing Test To Tell Computers and Humans Apart (CAPTCHA) code. Confirmation and approval of the request (with the user identification and password) are sent within a few days to the email address of the notifier. Once a company is registered, several people can be added as notifiers, or the same person can notify on behalf of several companies. The next time they log in, notifiers can register with their user identification and password and, if relevant, select the company on behalf of which

they are acting. Access rights can also be amended later, and additional companies or notifiers may be added.

Once a notifier enters the system, he or she can update the data on the company and then select the desired action: notification of a dangerous substance, notification of a dangerous mixture or notification of an activity with a dangerous substance or mixture. For notification of a substance or mixture, the notification sheet can be filled in electronically: data on the company are filled in automatically, and mandatory fields are marked. Once the notification sheet is completed, the SDS can be submitted in one of two ways: by filling in an electronic format on line, facilitated by drop-down menus, or by attaching the pdf version of the SDS. Exposure scenarios and draft labels, if relevant, should also be attached, with certification of payment of the administration fee, which is a mandatory element of notifications.

The system also provides for communication between the authority and a company. The administrator can inform the company in a free-text field if further information or data are necessary or if the submitted documents are incorrect. This field is also accessible to national enforcement authorities, who can monitor any corrections.

4.1.5 Access to the database, information sharing and confidentiality

Only the administrators of the registers (IT and technical experts), the toxicological information service and local enforcement authorities have direct access to the full information in the databases, with different access rights. In particular, local enforcement authorities may not add to, amend or delete any data from the databases, while technical experts at the National Public Health Centre have full access rights. The system is being amended to allow emergency and toxicological units in hospitals read-only access to some of the information in the database. Access is always based on registration, and access rights are given by the IT (user) administrator on the basis of requests to and authorization by the office of the Chief Medical Officer.

As the Toxicological Information Service operates emergency services continuously, it requires continuous access to all the information in the databases. The Service can be contacted by the general public as well as by health service providers (e.g. hospitals, ambulance, general practitioners and firefighters) in an emergency and will receive advice on first aid, toxicological information and e.g. physico-chemical properties. Calls to the Toxicological Information Service in an emergency are free of charge, and it also has a toll-free number. The Service also provides free information to authorities on request. Toxicological information on substances and mixtures may be requested by anyone in the form of an expert's opinion, which will be provided for an administration fee (about 15€). Only public information is provided. The confidentiality of data is established by the European Union and national legislation (the SDS are not confidential).

The register of dangerous substances is publicly available, so that companies can determine whether their substance has been notified. The product register and the database of mixtures, however, cannot be accessed by companies. If they wish to know whether their mixture has been notified, they must submit a query to the National Public Health Centre, for an administrative fee of about 15€.

4.2 ITALY

At the end of 1990s, Italy decided to apply the principle introduced by the Dangerous Preparations Directive of the European Community (at that time, Directive 88/379/EEC, later modified by Directive 99/45/EC) and in 2000 created a centralized national database at the National Health Institute (Istituto Superiore di Sanità), as the appointed body, of dangerous preparation and specific information about their chemical composition. The European legislation was implemented by national legislative decree n. 65 on 14 March 2003, which describes all the steps required for the creation of the national database of information on dangerous mixtures.

The main purpose of the register was to ensure immediate access by national poison centres to the full chemical composition of a preparation in a case of accidental poisoning, in order to give appropriate first aid measures. The poison information database (*Archive Preparati Pericolosi*) *(46)* makes product formulation notified by manufacturers and distributors available for consultation and treatment of an emergency health response to poisoning. Other objectives were to provide a new instrument for the central and regional bodies responsible for protecting public health (including in workplaces), reporting and monitoring and evaluating national alerts.

The setting up of a national database as a suitable enforcement tool is in line with REACH and is useful and necessary for ensuring REACH implementation. In addition, it fulfils the requirements of Article 45 of the CLP regulation.

4.2.1 Scope of the register

Registration in the database is mandatory in Italy for all classified dangerous preparations (except for those classified as dangerous for the environment only), as it is in the scope of the directive on dangerous preparations and the CLP. The system also applies to detergents; therefore, the database contains information about these substances, regardless of whether they are classified as dangerous.

The legislation requires people responsible for placing a dangerous mixture on the market to send information on the mixture, including its composition, to the Istituto Superiore di Sanità. Registration in the database is mandatory for companies trading in dangerous mixtures, independently of their use. Companies are also invited to send information voluntarily on: mixtures covered by Legislative Decree n. 65/2003 but which are not dangerous, on preparations containing dangerous substances below the limit for CLP classification and on mixtures not covered by the Decree.

One exemption from mandatory registration in the Dangerous Preparations Archive is samples (generally weighing < 1 kg) sent to a professional user to test the product before purchase. They are exempted because the quantity is small, the length of use is short, and they are used exclusively by professionals.

The following companies have to submit a registration to the database:

- producers (even those who produce elsewhere in the European Union and market in Italy directly without traders);

- importers from third countries (even those who import from elsewhere in the European Union and market in Italy directly without traders); and
- traders of preparations produced in the European Union who change the label for the Italian market (e.g. include their name).

Registration in the database must be uploaded within 30 days from the first introduction of the product onto the Italian market.

The aim is to acquire information about preparations that are or can reasonably be assumed to be still in use. Even if a preparation is no longer marketed by a company, it will be used for a certain time; a product sold to the public may remain in shops, on shelves or in the domestic environment for a long time. If a preparation is not marketed in Italy for at least 5 years, declaration is no longer necessary. No fee is charged for registering in the databases; however, a penalty up to 30 000€ is applied for not fulfilling the requirements provided for by the legislation.

4.2.2 Institutional infrastructure and responsible bodies

To ensure that the register is functional, the necessary human and technical resources must be considered. The competence required for maintaining the register in Italy includes: technical (available at all times) and IT assistants, a scientific assistant, a person responsible for the activity and an administrative assistant. Additional IT and scientific support is often required. The Istituto Superiore di Sanità handles about 500 requests a year for technical support and 400 requests a year for IT support by email or telephone.

4.2.3 Types of information collected and structure of the database and register

Producers, importers or traders of dangerous preparations (mixtures) that are obliged by the legislation to notify must provide the following information for each preparation:

- the name or names or trademarks of the preparation;
- the name and address, telephone and fax numbers and, if available, email address of the person responsible for placing the preparation on the Italian market;
- the complete qualitative and quantitative composition of the preparation;
- the physico-chemical properties of the preparation;
- the field(s) of application and use;
- classification and labelling (mandatory since introduction of CLP); and
- the type of packaging.

The most important information for registering products is the full chemical composition. As this information is clearly covered by confidentiality rules, the database is not open to the public.

Additional information is required when the composition or presence on the market of the preparation is changed. A distinction is made between dangerous and non-dangerous components. For every dangerous component, the following information should be specified: the chemical name (a list of classified substances is available in the system), the CAS or European Community number (if available), the exact percentage of the component (optional or mandatory)

and the range of concentrations (values to choose from are given in the system). A substance must be reported if it is classified as very toxic, toxic, carcinogenic (categories 1 and 2), mutagenic (categories 1 and 2), toxic for reproduction (categories 1 and 2) and present at > 0.1% by weight or as corrosive, harmful, sensitizing, irritating and present at ≥ 1%. For substances classified by physical risk (e.g. flammability, explosiveness), the limit is fixed at 1%. For non-dangerous ingredients, the chemical group name can be given rather than the exact name, showing, however, significant functional groups (indications are available in the program). For the indication of volume, the same criteria are applied as for dangerous substances. The limit beyond which such substances must be reported is established at 5%.

The composition of a registered product can be amended under the same trade name. The system gives guidance on such cases. Information on packaging is requested if it is necessary to identify the product type in the absence of the commercial name.

If the company responsible for placing a dangerous preparation on the Italian market does not know its exact composition, every effort will be made to obtain the necessary information from the Italian or community supplier. Alternatively, the company can link the declaration made by the supplier to the dangerous preparations archive, if the preparation is marketed in Italy. This opportunity is generally useful for a producer or distributor that has a "preparation component" as the raw material in its formulation. A distributor (who will not modify the composition) can link the declaration to the supplier's declaration, while the producer of a mixture (who will use several substances) can link the declaration to that of the supplier only partially.

A preparation that is no longer marketed should not be deleted from the archive, but the information on it must be updated. In particular, the "Marketing cessation date" will be entered in the section "Preparation sheet".

The database operates 24 hours a day, 7 days a week. By mid-2016, about 5000 companies were registered in the database; most were Italian (about 4000), 750 were in the European Union, and 40 were in countries outside the European Union. About 1 500 000 records of preparations are stored in the database, for about 30 000 detergents, 1 300 000 dangerous mixtures and 200 000 non-dangerous mixtures.

4.2.4 Submitting information

A completely IT-based system was set up in 2000, based on a client–server platform managed by a dedicated webpage (www.preparatipericolosi.iss.it) and is still in place. The project is national but is also applicable to foreign companies selling their products in Italy, and various languages can be used. Companies can send information through the Internet.

On the main web page, a company must first register in the database with its tax identification number. After registering, the company can use the code provided to access the forms for each preparation and provide the required information by filling in the forms on line. The program guarantees maximum automation to avoid errors by manual insertion. The program therefore offers drop-down lists to select information, such as a direct link to the ECHA database for classified substances, type of use, physical state and non-dangerous components.

If the user gives the name of a chemical group, it must be one of those in the "ingredient list". Non-dangerous substances present at > 5% must be registered; their generic names can be used.

If the mixture is produced outside the European Union:

- the importer can submit a declaration of the composition based on the information provided by the supplier, although this may be difficult to obtain;
- the non-European Union manufacturer submits the declaration, and the importer links the national declaration to that of the supplier using the "company code" and the "preparation code" of the supplier; or
- the importer declares only partial composition of the preparation by extracting the information from the SDS.

A user guide is available to assist suppliers in making declarations. If registered users have a technical problem with the database or Internet connection they can send an email and attach the notification as an attachment. They will receive an email to confirm reception from the Technical Secretariat.

4.2.5 Access to the database, information sharing and confidentiality

The main users of the database are authorized poison centres, which can find the information in the archive IT tool. On-line access is granted only to poison centres certified by the Ministry of Health as having the capacity for confidential treatment of the information accessed. Currently, nine national poison centres have been granted direct on-line access, with an estimated frequency of access of seven times a day.

Other levels of access have been granted for enforcement. Qualified, authorized inspectors are allowed to consult the system only for inspection, to determine whether and when the product was registered as fulfilling the requirements of national legislation.

Requests for information received from central and regional bodies are usually checked by the Istituto Superiore di Sanità case by case. Activities related to the rapid alert system for non-food products are also monitored.

The Istituto Superiore di Sanità sends a report to the Ministry of Health at least once a year about use of the database by the poison centres and any problems, such as anomalous epidemiological data, to activate supervision by the Ministry of Health. If the Istituto Superiore di Sanità identifies several requests for information on a certain product, it will immediately inform the person responsible for placing it on the Italian market and the Ministry of Health.

4.3 POLAND

The Polish register of hazardous mixtures was initiated shortly after appointment of a central Government authority on substances and mixtures (Inspector for Chemical Substances).
The inspector is supervised by the Minister of Health and is assisted by the Bureau for Chemical

Substances, which was established in 2001, when Polish legislation was harmonized with the "acquis communautaire". It has since been the competent Polish authority for chemicals legislation such as REACH and CLP. The legal basis for the Bureau and its obligation to report dangerous or hazardous mixtures was the Act of 11 January 2001 on Chemical Substances and Preparations *(47)*, which was replaced by the Act of 25 February 2011 on Chemical Substances and their Mixtures *(48)*.

Before Polish accession to the European Union and before the REACH and CLP regulations entered into force, Polish authorities collected three types of information about chemicals. The first was on "new" substances, i.e. any substance not listed in the European Inventory of Existing Chemical Substances (the list closed in 1983), and notification was necessary. The second was on dangerous preparations. In these cases, the first entity in the supply chain within Poland was obliged to notify the Inspector on the placing on the market of a dangerous preparation and to submit SDS. The Bureau stored information on the composition of mixtures, the contacts of the entity that placed the preparation on the market and the properties, classification and safety phrases of the mixtures. The third type of information collected was on precursors of category 2 drugs, as laid down in the regulations concerning the prevention of drug abuse.

Since 2011, notification of dangerous or hazardous mixtures has been submitted according to Article 15 of the Act of 25 February 2011 on chemical substances and their mixtures, Since 30 June 2015, notifications must be submitted exclusively through an electronic system, Electronic Declaration of Information on Mixtures (ELDIOM; http://eldiom.chemikalia.gov.pl). The system includes an English language module. .

Currently, the register of dangerous and hazardous mixtures serves a medical purpose by preventing risks posed by these mixtures for medical treatment, particularly in an emergency, or for conducting a statistical analysis to identify areas that require better risk control. The register provides an overview of the mixtures available on the Polish market, the substances used in the mixtures and the sectors in which the mixtures or substances are used. These data can also be used to make an initial evaluation of the socio-economic impact of a planned regulatory measure, such as restriction or authorization of substances under REACH, to identify users of substances that may have to be authorized or restricted and to invite interested parties to participate in a public consultation.

The IT system, known as the Electronic Declaration of Information on Mixtures, allows Bureau employees to conduct surveys and to collect the replies from entities.

4.3.1 Scope of the register

According to Article 15 of the Act of 25 February 2011 on chemical substances and their mixtures *(47)*, every natural or legal person that manufactures a dangerous mixture in Poland and places it on the market and every natural or legal person that brings such a mixture into Poland shall notify those that are classified as dangerous according to the CLP to the Inspector. This information is submitted at the latest on the date on which the mixture is placed on the market or entered Poland. The information is submitted electronically.

4.3.2 Institutional infrastructure and responsible bodies

The register is maintained by the Bureau.

The administrator of the system is responsible for collecting information and sharing it, including with the poison control centre, and for overall maintenance of the system. He or she also checks the submitted notifications for technical compliance and signals any problem or whether further clarification or correction is necessary. The administrator does not verify the quality of the submitted data. He or she has full access to all submitted data, can analyse them and produces a report on the database or creates and sends a survey to the system to collect opinions.

The Sanitary Inspectorate is responsible for deciding whether an entity that is obliged to submit information about a dangerous mixture did so correctly. A unique notification number is used for this purpose, and the user can generate a report that includes the notification numbers of mixtures to prove that they submitted the information to the Inspector. In case of doubt, enforcement authorities can ask the Bureau whether the entity submitted the necessary information. The Sanitary Inspectorate does not have direct access to the ELDIOM system.

Two staff members in the IT department support the technical operation of the register and the development of the system. An external IT company is contracted by the Bureau to correct any errors.

Additional work was required to set up the register and to enter the notifications submitted before the electronic system become operative and obligatory.

4.3.3 Types of information collected and structure of the database and register

The notification sheet is for dangerous or hazardous mixtures manufactured in or imported to Poland. The notification includes:

- the first and last names and address of the place at which the activities of the business are conducted or the business name and address of the registered office, as well as the telephone number and electronic address of the entity submitting the information;
- the trade name of the mixture;
- the application of the mixture;
- information on substances contained in the mixture, with enough information for identification in accordance with Article 18(2) of the CLP regulation and the concentrations of the substances in the mixture in accordance with section 3.2 of Annex II of REACH;[6]
- classification of the mixture in accordance with the provisions of CLP (previously with national legislation harmonized with the Dangerous Preparations Directive[7]); and

6 According to this provision, information may not be required from some components, and only ranges of the concentrations of the listed components may be given.

7 Since 1 June 2015, all mixtures placed on the market must be classified in line with CLP; however, mixtures placed on the market before that date will not have to be relabelled until 1 June 2017.

- the SDS for the mixture; if there are no SDS (as there is no obligation to compile or deliver SDS), the information required in sections 2 and 3 of Annex II of REACH.

If any of the above information is changed, the entity or person that placed a mixture on the market is obliged to submit revised information to the Inspector within 14 days of the date of its updating.

This information, which is beyond that required to compile the SDS for a mixture, stipulated in Annex II of REACH, is confidential and may be used only for medical purposes to prevent risks posed by these mixtures, to provide medical treatment, particularly in the event of an emergency, or to conduct a statistical analysis to identify areas that might require alteration for improved risk control.

IF the Inspector decides that the information provided is inadequate to conclude that the mixture constitutes an unacceptable risk to human health or to the environment, he or she may request disclosure of the detailed chemical composition of the mixture (regardless of provision 3.2 of Annex II of REACH).

4.3.4 Submitting information

Since the provision of 20 March 2015 amending the Act on chemical substances and their mixtures entered into force on 30 June 2015, the only means of submitting information on dangerous or hazardous mixtures to the Inspector, in accordance with Article 15, is through the "electronic declaration of information on mixtures" (http://eldiom.chemikalia.gov.pl). This makes it possible to collect more searchable information; electronic versions of data sheets in PDF format can be attached to each notification. The system contains an English language module.

The system verifies whether the same entity has several accounts by checking the unique tax identification number. An account created in the previous system can be recovered. The user whose data were entered during registration of the entity account becomes the administrator of the account. Only one administrator of a particular entity can log into the system. The administrator of an entity can, however, register other users. They can also reset the passwords of employees of their entity.

The main difficulty during development of the new database was to find the right balance between the number of requests to add information to the system in searchable form and the ease of users, who might have hundreds of mixtures to notify. The system is based on a combination of tabs and functions that are readily available by clicking on buttons.

In order to submit a new notification sheet, the user must log onto the system, select "mixtures – notification" and complete the notification as follows.

- Enter data (trade name, European article number, other codes and names, if applicable, whether the mixture is a detergent, biocide and/or contains nano substances, authorization number for biocidal products and whether the mixture is produced or imported into Poland).
- Attach the SDS.

- Enter information on the composition of the mixture (consecutively, populating the appropriate field with the beginning of the name by entering either the CAS or the EC number and selecting a substance from the list. If the component is not specified in the database, the user can enter its name, CAS and EC numbers (if known), its contents and units. This information should be checked by the Bureau staff. The three options for indicating the concentrations of components of a mixture are "exactly", "about" and "from–to" with the units; the system arranges the components in order from the highest to the lowest concentrations.
- Classify the mixture on the basis of physical, human health and environmental hazards according to CLP, which has been mandatory since 31 May 2015. The classification is entered by selecting a hazard class and the appropriate phrase from the list offered by the system. Provide information about the sector of use or application and the product category of the notified mixture by selecting entries from the menu or providing information in a free-text field.
- Provide any additional information considered relevant by the user.
- Verify and submit the data.

At each step, the user can save the notification sheet as a working version and continue later. The options "continue" and "go back" are provided.

All submissions are marked as new and sent to the Bureau's mail box. Notifications of substances that are not recorded in the database are marked as "warnings" and saved separately. A unique notification number is generated, which is displayed during viewing of the notification. An email message confirming receipt of the notification by the Bureau is sent to the entity.

Notifications are checked in closed sessions during verification by Bureau employee. If verification is successful, the notification is closed and sent to the "mixtures" archive, and the notifying entity receives a confirmatory email.

4.3.5 Access to the database, information sharing and confidentiality

The system administrator has full access to all the submitted data and can analyse them and produce a report on the database. An enforcement authority that wishes to verify whether an entity has submitted all the required information should contact the Bureau.

The poison control centre may access information in electronic declarations of information on mixtures to prevent any risks posed by the mixtures and to provide medical treatment, particularly in the event of an emergency. The general public does not have access to data on individual companies.

4.4 SLOVENIA

A new chemicals act was adopted in 1999 during Slovenia's accession to the European Union, which covered not only European Union provisions for chemical safety but also national provisions, including a registration procedure for companies handling dangerous chemicals and establishment of a Chemicals Product Register for industrial chemicals and biocides. The Act

(49) provides the basic requirements for reporting on chemical products, a provision for non-compliance and establishes the Chemicals Office of the Republic of Slovenia (CORS). The Minister issued detailed rules for reporting data on chemicals based on the Act *(50)*.

The Act forms the basis for making decisions on measures and actions to protect human health and the environment from the harmful effects of chemicals. The most important decisions in the past few years have been prohibitions and restrictions on specific chemicals and chemical groups, such as bisphenol A in thermal paper, ammonium salts in isolation materials, carcinogenic and mutagenic chemicals and tributyltin compounds. The first step in decision-making is evaluation of the current status. Data in the Chemical Products Register provide rapid answers to questions about:

- whether a certain chemical product is present in the country;
- how many producers or importers are involved;
- the kind of products in which a chemical is used;
- the final users of a chemical product;
- the annual amounts on the market; and
- the influence a new prohibition or restriction would have on producers, importers, the economy in general and chemical safety.

Other purposes of collecting data on chemicals are for preparation of strategic documents, action plans, new or amended legislation and for inspections, projects, studies, educational activities and communication with companies and the general public.

The Information System on Chemicals (ISK) was established in 2002 as a server–client application to provide ready access to data on products on the market for users at various ministries and institutions (i.e. the poison centre) working in chemical safety. The system allows easy, fast processing of data on chemicals.

In the first few years after introduction of the register, during checking of the reports received, it was found that the majority of the SDS were not of adequate quality. CORS therefore asked companies to improve the quality of SDS. All registered companies were required to have an "adviser for chemicals", a person with the appropriate training who was given a two-day course on chemical legislation. With other education and training activities, CORS raised awareness on chemical safety to an acceptable level.

4.4.1 Scope of the register

A company that is required to report is any legal entity in Slovenia that produces or imports chemicals classified as dangerous on the basis of their physical and chemical properties and their risk to human health and the environment. Data must be reported upon first delivery of the chemical to a third party or first import of the chemical into Slovenia at the latest. Raw materials for medicines, oil and oil derivatives and other organic chemicals used for engine fuel or heating, ores and chemicals classified as dangerous on the basis of their physical or chemical properties that are made or imported at an annual amount < 100 kg are exempt from reporting. The annual amounts of chemicals with certain hazard statement codes must be reported by 31 March of the

current year for the previous year; for less harmful chemicals, companies must report data on annual amounts only on request from CORS, if necessary.

Reporting is done electronically and is free of charge. The administrative burden of reporting, with regard to time and costs, is an important aspect of the collection of data. An evaluation by the Ministry for Public Administration in 2010 for reducing the administrative burden resulted in some changes; however, the total cost of data reporting to companies is estimated to be about 100 000 €/year. Over 1000 companies are obliged to report. As registered companies are obliged to have an adviser for chemicals, a number of organizations offer reporting services. As a consequence, the chemical product reports of 60% of companies are prepared and reported by contracted organizations, which also results in a higher quality of data received.

4.4.2 Institutional infrastructure and responsible bodies

According to the Chemicals Act, the Ministry of Health through CORS is responsible for registering companies involved in the production, trade, storage or use of dangerous chemicals in the Biocidal Products Register and the Chemical Products Register. All three registers are included in the ISK database.

CORS prepares all the necessary legislation for data collection and reporting, which is formally adopted by the Minister of Health, and operates the ISK applications. In preparing new legislation or important changes in ISK application, CORS contacts the Ministry of the Environment, the Environment Agency, the Ljubljana University Medical Centre and the Poison Centre, as they are the most frequent users of data, as well as Chamber of Commerce, which represents companies.

The CORS electronic system is part of the common electronic network of the Government administration, which is strongly protected against open web.

At CORS, two people are responsible for the Chemical Products Register. Their average total workload is 4 h/day and covers:

- processing new and modified reports (about 50 reports per day);
- administration of ISK users (total of about 500 users);
- coordination and daily maintenance of ISK with the Ministry for Public Administration and contract IT organizations; and
- development and upgrading of ISK with the Ministry for Public Administration and the contract maintenance organization.

Daily support for interruption of operations, hidden mistakes and user problems and development and upgrading (e.g. new functionalities, adaptations to structural changes) of ISK are carried out by a contract IT organization, by four people on a part-time basis, at a cost of about 15 000€/year. The ISK application with the Oracle database runs on a server at the Ministry for Public Administration and is maintained by their staff, free of charge.

Information on the composition, annual amounts and names of chemicals used in production is treated as confidential. ISK has four levels of security measures:

- at the database level: encryption;
- at the application level: authentication, encryption of data transfer;
- for reading and printing: access rights and rules; and
- for exchanging data: rules.

4.4.3 Types of information collected and structure of the database and register

The Chemical Products Register in Slovenia is structured into three levels with three databases, which are linked. Level 1 is companies, level 2 is chemical product reports, and level 3 is reports of annual amounts.

At company level, the data collected are:

- the CORS number, date of registration and status (active, not active);
- company name, business registration number and decision number;
- contact details (address, telephone, fax, email);
- area of work (production, trade, storage, use, reporting);
- notes; and
- electronic data file (attached if necessary).

For chemical product reports, the data collected are:

- product identification (report number; active, not active, to be confirmed), date of registration, date of erasure, trade name of the product, technical name, other names, synonyms);
- product category (substance or mixture, European Nomenclature of Economic Activities trade sector code, REACH product category, customs tariff code, source (produced, imported from the European Union or from elsewhere), general consumer use (yes / no));
- classification of the mixture and label elements (hazard class and category, hazard pictograms, signal word, hazard statement);
- product identifiers of the mixture components (substances) (chemical name, CAS number, European Community number, index number, hazard statements, concentration in weight %); and
- SDC electronic data file (doc, pdf, tif),

For reports of annual amounts:

- year;
- date of report;
- status (completed / not completed);
- chemical product report number;
- chemical product name; and
- annual amounts in tonnes produced, imported, put on the market and exported.

4.4.4 Submitting information

Originally, chemical product reports were received in paper format and entered manually into the ISK database; two to three staff were required to process the reports. Between 2008 and 2012, CORS introduced a new approach, as the global economic crisis resulted in a significant decrease in the CORS budget, and the Government policy was to reduce the number of employees (CORS has lost one quarter of its staff) and to reduce the administrative burden on companies (fewer reports and, if possible, in electronic form). Stabilization of the general situation 10 years after adoption of the Chemicals Act and adaption of all European Union chemical legislation also called for a new approach.

In 2011, ISK was upgraded to a web application, with qualified digital certificate authentication, and it expanded, with electronic reporting of data for chemical products reports and annual amounts of chemical and biocidal products. With this change, the administrative burden and workload of companies and of CORS were significantly (50%) reduced.

After 2012, an electronic system replaced printed forms for receiving chemical products reports, and companies (producers, importers or their contractors) can connect to ISK with qualified digital certificate authentication. During registration of new users, data are read from the certificate and compared with the data in the company register. New users must conform to the general terms for ISK use. The CORS ISK administrator gives final confirmation by issuing a password at the first log-in. Digital certificates can be obtained from the Slovenian certification authorities. Chemical products reports are entered manually, and annual amounts can be imported as Excel files. Companies can see all the data on their registered chemical products. The benefits of electronic data reporting are that it is less time-consuming, does not require paper work, is less expensive, is available continuously and provides an overview of all the data on registered chemicals by company.

4.4.5 Access to the database, information sharing and confidentiality

ISK offers access to chemical databases for users at various ministries and other institutions (poison centre) working on chemicals safety. It ensures easy, fast processing of chemicals data, such as filtering reports by one or more parameters and 19 predefined statistical reports. Unlimited filtration and extraction of data is granted for the majority of parameters, and data can be exported into Excel files for further processing.

Article 35 of the Chemicals Act states that data from the Chemical Products Register may be used only for the protection of human health and the environment by authorized agencies and institutions. The internal users with direct access to ISK are CORS, including Chemical Inspection; and the external users are the Poison Centre at Ljubljana University Medical Centre, the Slovenian Environmental Agency and the Financial Administration (customs) of the Ministry of Finance. About 200 requests for access have been made each year for the past two years, of which 100 were made by Chemicals Inspection, 60 by the Poison Centre and 40 by other users. Requests by CORS staff responsible for ISK and for preparing extensive reports in response to internal and external requests are included. Five such requests were received in one year. Users with direct access to ISK can connect through a qualified digital certificate, and the system of access is the same for reporting companies. External user organizations, however, must sign a written “Agreement for

ISK usage" with CORS, which defines access rights, data usage and handling and security aspects in detail.

Local communities have no direct access to ISK, although they require data for preparing long-term protection and rescue plans in case of accidents.

4.5 SWEDEN

Concern about the potential harmful effects of chemicals grew in Sweden in the 1960s and 1970s. In 1973, Parliament approved a new law on health and environmentally hazardous goods, and the Product Control Board under the Ministry of the Environment was founded to control pesticides and other potentially hazardous chemicals. As little was known about such chemicals, it became clear that a database should be created to collect information on their characteristics and uses. It was decided to use modern electronic techniques to compile and store the data.

The Swedish Environmental Protection Agency (SEPA) and the Swedish Work Environment Authority were the obvious choices to create the register, and the Poison Information Centre was also considered; however, as several state and regional authorities would use the compiled data, it was important that one authority should not claim supremacy over the register. From the beginning, therefore, the register was located under the Products Control Board, on which the appointed members are the directors of various interested state authorities; the Board had no personnel. The decisions taken were prepared by the Product Control Bureau, organized by the SEPA.

Between 1978 and 1985, the register had no formal legal basis but was considered a routine task of the authority. In 1985, the new Law on Chemical Products came into force. Under this Law, a new authority, the Swedish Chemicals Inspectorate, was established and given responsibility for the Products Register. This Law and the implementing ordinance established the legal foundation for the register, which is still under the same authority, although it has changed its name to the Swedish Chemicals Agency (KEMI). The relevant provisions for the register are laid down in the Environmental Code of Sweden, the Law on Chemical Products and the Ordinance on Chemical Products and Biotechnical Organisms. Although Sweden joined the European Union in 1995, the legal basis of the register did not change, as this was not an area for European Union regulation; however, the CLP labeling system is now used in the Products Register.

The main purposes of the register are to facilitate supervision of chemical products and to create a database of information to increase understanding of the chemicals in the country. Annual updates of the register indicate trends in the chemical substances being used.

4.5.1 Scope of the register

The Environmental Code of Sweden *(51)* obliges reporting by producers of a chemical product, whether they actually synthesize the chemical or just blend it, and importers who either import the chemical for their own use or sell it to customers in Sweden. Thus, the same chemical product may be reported by one or more companies. A third category of companies responsible for reporting are those that put their brand names on a product without either manufacturing or importing it.

To ensure a clear definition of the chemicals that are to be registered, the Swedish chemicals registration system is based on the customs tariff codes, which are known to all importers. The definitions of products considered to be chemicals (i.e. chemical products) were taken from the complete list of codes, and the tariff codes of chemicals that must be registered are listed in an addendum to the Ordinance (2008:245) on chemical products and biotechnical organisms *(52, 53)*.[8] The Swedish experience shows that this approach works well. For practical reasons, it was decided that only chemicals produced or imported in volumes > 100 kg/year should be reported. Although there was some discussion about whether hazardous products such as poisons should be reported when produced or imported in any quantity, it was decided that this would not be required.

Certain chemicals, such as cosmetics, medicals, food and beverages and tobacco that are regulated by other laws also do not have to be reported. A distinction is also made for polymers. A granulated polymer must be reported but not a granulated polymer that is in a form in which it is no longer considered a chemical product but goods.

A report can be made at any time, but reporting companies are requested to update their information no later than 28 February each year. At that time, all new products in the previous year must be reported, and new information, such as the volume or changes in the formulation of previously reported products, is given.

The costs of national supervision of chemicals are paid by the companies manufacturing or marketing the chemicals in Sweden. The register is therefore used to calculate the charge for each reporting company, which depends on the number of products and the total tonnage reported by the company. (There is no fee for reporting, but a chemical fee is calculated on the basis of the reports.)

Companies that manufacture notifiable chemical products in Sweden or import or transfer such into Sweden must report such activity to KEMI. The activity report *(55)* must be submitted to the Products Register no later than the start of the activity. On the basis of this report and the registration, a "company register" is set up, which is publicly available and searchable on the KEMI website (http://webapps.kemi.se/foretagsregistret/). This database contains no information on registered products.

KEMI also keeps a list of more than 130 000 chemical substances with CAS numbers and related names, which is a combination of shortlists of CAS numbers originally created by the Environmental Protection Agency in the United States of America and the European Community. These inventories were bought by the Swedish Products Register, instead of creating a national chemical inventory and adding substances when they were reported. A substance is this defined as either a unique chemical entity or a natural mixture such as "fatty acids, tallow" or "gasoline" and defined by a unique CAS number. This combined substance register is publicly available and searchable on the KEMI website.

8 Available only in Swedish. The English definitions of the codes are listed in reference 54.

4.5.2 Institutional infrastructure and responsible bodies

KEMI is responsible for supervising chemical products in Sweden. The Agency, including the Products Register, is funded by fees paid by the reporting companies. The financing covers updating information, programming and answering questions from authorities and others, including interested citizens. The other state authorities involved are SEPA, the Swedish Work Environment Authority, the Swedish Civil Contingencies Agency and the Swedish Poisons Information Centre. Although mainly state authorities use the information, 23 regional authorities and 290 local authorities may also request information from the Register in order to supervise chemicals.

Six to eight chemists familiar with chemical nomenclature are employed to manage the register, with three to four administrative personnel. Consultants will be employed for large changes in the data system.

4.5.3 Types of information collected and structure of the database and register

The information to be reported to the Products Register is:

- name and address of reporting company;
- name or designation of the chemical product;
- whether the product is manufactured in Sweden, imported into Sweden or being renamed;
- customs tariff code of the product;
- indication of the use of the product (function code);
- where the product is used (branch code);
- whether the product will be sold to private customers;
- tonnage of the product the previous year;
- labelling of the product, if any; and
- chemical composition of the product: CAS number of each component, if available, or chemical name of each component if the CAS number is not available; the exact percentage weight for each component and any component that is a preservative.

Substances that are not classified and not considered hazardous to health or the environment that occur at < 5% in the product and impurities in raw materials that occur at < 1% need not be reported.

The product register can be searched by KEMI personnel by company, product name, function code, branch code, customs tariff code, labelling, CAS number or chemical name, individually or in combinations. It is easy to register by using the codes, which can be entered by typing a number four to ten digits long. Code systems are arranged by chemical function and branch. Codes created by the revenue authority are used for companies and substances, and companies can type the CAS number and add the complete chemical name to the composition scheme.

4.5.4 Submitting information

Initially, all reports were made on paper, with one for each product, and this reporting form is still available on the Internet *(56)*. Later, technical developments made it possible to send reports by email. For the past five years, all reporting is done directly into the data system (see KEMI website).

4.5.5 Access to the database, information sharing and confidentiality

There is no direct access to the Products Register from outside KEMI. KEMI personnel provide information to other authorities and to interested citizens; and, as mentioned above, SEPA, the Swedish Work Environment Authority, the Swedish Civil Contingencies Agency and the Swedish Poison Information Centre can use the information in the register, as can 23 regional authorities and 290 local authorities. The company register and the substance register are available for free on the KEMI website.

In Sweden, the principle of openness is established by law, so that information stored by any authority is openly available, except under the law on secrecy. Thus, information that could hurt a private company's economic interests cannot be published. Any question put to the Products Register must be answered, but the answer must comply with the secrecy law.

5. Chemical products registration in a non-European Union country: Russian Federation

In 1992, the Russian Federation aligned itself with the worldwide trend to create state registries of information about chemicals in use and their hazardous properties and decided to monitor the chemicals used and produced in order to plan preventive measures to protect human health and the environment. The initiative to create a register was that of the head of the State Sanitary and Epidemiological Service. In the former Soviet Union and later in the Russian Federation, this Service was part of the Ministry of Health and was responsible for advocating for chemical safety, monitoring chemicals in the environment and consumer products and exposure and occupational and environmental risk assessment.

According to Act No. 869 of 12 November 1992 on state registration of potentially hazardous chemical and biological substances, registration of chemicals has been required. In compliance with paragraph 4 of the Act, the Russian Registry of Potentially Hazardous Chemical and Biological Substances *(57)* was set up within the State Sanitary and Epidemiological Service.

In 1999, state registration of potentially hazardous chemicals was legislated by Article 43 of Federal law No. 52-FZ *(58)* of 30 March 1999 on the sanitary and epidemiological well-being of the population and further by Act No. 609 of 20 July 2013 on maintaining a Federal registry (inventory) of potentially hazardous chemical and biological substances *(59)*.

On 1 July 2010, with the entry into force of the Customs Union agreement on sanitary measures adopted on 11 December 2009, state registration was introduced. Under the agreement, however, an insignificant proportion of the chemical and petrochemical products used in Member States were subject to registration.

The Russian register provides toxicological information on chemical and petrochemical products for the purposes of state registration, in compliance with the requirements of the Customs Union, and provides entries for the database. It operates within the Federal Service for Surveillance of Consumer Rights and Human Well-being *(Rospotrebnadzor)*.

5.1 SCOPE OF THE REGISTER

According to Russian legislation, state registration is required for all potentially hazardous chemicals and biological substances of natural and man-made origin produced in the Russian Federation or imported for use by enterprises and other economic entities. This obligation is applied to companies regardless of their form of ownership or location in the country.

All chemicals that are dangerous for human health during their production, use, transport and household use must be registered before they are placed on the Customs Union market. The same

rules are applicable for chemical mixtures and products. New substances that are ingredients in mixtures are also subject to registration.

In accordance with the decision of the Customs Union Commission *(60)*, the applicant for a certificate of product registration should be the manufacturer (producer) or the supplier (importer).

The registration fee is about 5000 rubles (70€). Applications for certification of products must be submitted on paper.

5.2 INSTITUTIONAL INFRASTRUCTURE AND RESPONSIBLE BODIES

In accordance with Act No. 609 of 20 July 2013, the Federal budgetary health institution *Rospotrebnadzor* is responsible for maintaining the register. State registration certificates are issued by the registry, and decisions on registration are based on expert evaluations organized and conducted by the registry. Information on registered chemicals is published in the *Toxicological Bulletin* issued by the registry.

The staff of the registry are physicians in preventive medicine, chemists, biologists, IT specialists and a translator.

5.3 TYPES OF INFORMATION COLLECTED AND STRUCTURE OF THE DATABASE AND THE REGISTER

Applicants for state registration must submit the following information and documents:

- the application;
- copies of documents in compliance with which products are manufactured (standards, specifications, regulations, technological guidelines, formulations, information on ingredients) attested as correct by the manufacturer; for products that are produced outside the Customs Union territory, SDS in Russian and in English;
- copies of product labels (packaging) attested as correct by the applicant; and
- expert evaluations of the toxicity and hazard of the chemical product.

The applicant is responsibility for the authenticity of documents submitted for examination.

The following information on substances is entered into the register:

- identification of substance, including common name, chemical name according to internationally recognized nomenclature (for example, International Union of Pure and Applied Chemistry), if such nomenclature exists, trade names, names of compounds, code numbers, CAS numbers, the codes of the Harmonized System of Commodity Description and Coding System *(34)* and others;
- type of use of the substance;

- assessment of hazard to human health and the environment, taking into account the physical, toxicological and ecotoxicological properties of the substance;
- hygienic and other standards and limits for the substances in environmental media, including living areas; and
- measures to prevent harmful effects of the substances on human health and the environment, including waste management.

Information cards on potentially hazardous chemicals and biological substances prepared by registry staff are the main sources of information for decisions on registration. On the basis of these cards, the registry created an automated information retrieval system on hazardous substances, which is the basis of the register. The system allows the collection and analysis of information on substances in compliance with the recommendations of the OECD, including an assessment of the hazardous properties of substances. Open domestic and foreign information sources are used to complete the Information cards and the database entries, including literature references (scientific monographs, articles, reports, reference books, regulatory documents and databases). A wide range of sources are used for the evaluation of chemicals and for their registration: the United Nations Environment Programme, ILO, OECD, IPCS, the European Chemicals Bureau, the Environmental Protection Agency in the USA (US EPA) and other international and national structures, such as those listed in Annex 2.

5.4 SUBMITTING INFORMATION

Applications for state registration must be submitted on paper. Other requirements to be met in submitting an application are available on the registry's website (www.rpohv.ru).

5.5 ACCESS TO THE DATABASE, INFORMATION SHARING AND CONFIDENTIALITY

The website of the registry (www.rpohv.ru) provides free access to the information, including IUPAC chemical name, synonyms, trade names, structural formula, reference numbers assigned by the registry, CAS, RTECS and the European Union, uses, aggregate state, product form, first-aid measures, clinical picture of acute poisoning, main target body organs and systems, dermal and ocular irritation and first aid in case of poisoning.

In accordance with the legislation, data on the effects of chemicals on human health and the environment are not considered confidential. Confidentiality issues are specified in contracts made between the registry and its customers.

Complete information on chemicals is available in the automated information retrieval system database on hazardous substances. Currently, the two databases contain information on more than 10 600 substances. Both the register and the retrieval system are also available electronically. Access to the retrieval system database is free for Federal authorities, while other users are charged a fee. A demonstration version of the database is available on the website (www.rpohv.ru).

6. Comparative analysis of national data collection

All the national systems analysed in this paper were established to collect information on chemicals in order to protect health and the environment, either by indicating treatment in an emergency or for adopting appropriate risk management measures.

The Member States of the European Union follow the principles laid down in European legislation to harmonize their policy and legislation with that of the Community and the Union. Although these countries apply the European Union regulations REACH and CLP, these regulations have not yet harmonized the collection of data for national purposes. REACH provides for registration of all substances manufactured or imported into the European Union at a volume > 1 tonne/year, with registration requiring the provision of all physico–chemical, toxicological and ecotoxicological data necessary for assessing the hazards and risks associated with the substance and for adoption of appropriate risk management measures. This information does not, however, provide a picture of the hazards or risks in a particular country or support in emergency situations and does not address mixtures. CLP provides in Article 45 for the collection of information on hazardous mixtures classified according to their physico–chemical and toxicological properties, but the collection of information is not yet harmonized; furthermore, the Article does not cover substances and mixtures with hazardous ecotoxicological characteristics. Thus, currently, registers of hazardous products (mixtures) are based on national approaches and may therefore differ among European Union Member States. Nonetheless, the definitions of most terms (e.g. manufacturer, importer, placement on the market, substance, mixture, hazardous mixture) that may be used in reporting obligations and in the classification of substances and mixtures are harmonized in European Union Member States.

In the six countries used as examples above, the collection of information on chemicals has been ensured by high-level legislation, mainly national acts and their implementing legislation. This may increase awareness and better compliance by obligated entities. The laws define the obligation: who should submit or notify, on what kind of chemical, when and the exact information to be submitted. Further details, such as access to the database, fees or penalties in case of non-compliance, may also be addressed in relevant legislation.

According to European Union policies, European Union Member States require companies that manufacture produce, import or place a chemical product on the market to submit relevant information to the appointed national bodies; i.e. the responsibility for providing sound data lies with industry. In most countries, the obligation is associated with placement on the market, and chemicals that are manufactured or produced for use by a company might not have to be notified. The system in the Russian Federation, however, is different. Companies that wish to place a chemical on the market must submit an application to the authority; the necessary information is collected from both these applications and other resources, especially scientific databases.

The scope of the obligation to notify applies mainly to chemicals, in most cases mixtures, classified as hazardous. In some countries, information is also collected not only on hazardous substances but also on non-hazardous mixtures (although notification of such data may be voluntary).

The countries used as examples appointed a national authority or body to which information is to be submitted. Some of these authorities were established for the specific purpose and related tasks and are usually within the central health or environment administration. They have designated personnel for performing tasks related to the operation of the registries, which are established on the basis of the notifications. While the number of staff depends on the administrative capacity of the country, usually at least five to eight people work on related tasks. The appointed bodies may cooperate with other relevant national bodies and authorities, such as national poison information centres or similar bodies and national enforcement authorities.

The greatest difference between the countries is in the type of information required and collected. The European Union Member States must avoid overlap with the information requirements under REACH and ensure that notification does not constitute a disproportionate administrative burden for companies. The information most commonly required for hazardous mixtures is: identification of the mixture, classification, details of composition (identification, percentages and classification of components), use or application, labelling information and SDS. In some countries, information on the volumes placed on the market or on packaging to enable identification is also required.

All European Union Member States now have established IT systems for notification and processing of data into databases. The systems are often linked to other national databases, enabling verification of data on the submitting company (e.g. tax number) or the chemical (e.g. CAS number). This ensures that only real, existing companies or entities register in the system, with valid data. Data can be submitted after registration and log-in to the system. The fields provided correspond to data requirements under national laws, and, whenever possible, drop-down menus are available, which ensures that the data submitted are correct, comparable and searchable. Most systems are automated to accept only complete submissions. IT personnel are essential for maintaining the systems.

Although confidentiality of data is a very important issue in all countries, access to parts of the databases is allowed, with different access rights. Confidentiality is based on national and European Union legislation, as articles 118 and 119 of REACH also address access to data. Certain information, such as a list of registered substances, toxicological information and SDS, is usually publicly available, either on line or provided by the appointed body upon request. Information such as the detailed composition of a preparation is, however, considered confidential. Information is usually provided to or accessible by other authorities, especially poison information centres, which must have direct, continuous access to relevant data, including confidential data. To maintain the confidentiality of some data, physical and IT protection of databases should be a core issue in all countries that maintain a chemical products register. In some countries, the legislation explicitly states that confidential data may be used only to support use of curative measures in emergency situations or anonymously, mainly for statistical analysis.

7. Challenges and opportunities presented by a national chemicals register

The challenges and benefits of systems depend on the information collected and how older systems have been incorporated into the new databases. Most countries appreciate that chemicals databases facilitate the preparation of statistics and support national decisions on and the necessity of risk management measures. Electronic data submission has considerably decreased the administrative burden for both industry and the authorities, and electronic databases allow easy, rapid access to data in all situations. Search functions are considered another benefit of the systems.

Countries reported certain organizational and technical challenges in setting up and maintaining a national register of chemical products:

- lack of a staff at the initiation of registers;
- finding the right balance between data needs and the administrative burden of ensuring the correctness of submitted data (quality check), in particular according to administrative capacity;
- ensuring correct, complete data on composition, as formulators and importers of mixtures might not know the exact composition; and
- the administrative burden of digitalizing data submitted on paper and providing support to submitters.

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UNITED NATIONS INSTITUTE FOR TRAINING AND RESEARCH

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- National reporting. Guidance. Châtelaine: Secretariat of the Basel Convention; undated (http://www.basel.int/Countries/NationalReporting/Guidance/tabid/1498/Default.aspx, accessed 18 January 2018).
- Notification and movement documents. Châtelaine: Secretariat of the Basel Convention; undated (http://www.basel.int/Procedures/NotificationMovementDocuments/tabid/1327/Default.aspx, accessed 18 January 2018).
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Rotterdam

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Annex 2. Databases

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- OECD substitution and alternatives assessment toolbox. Paris: Organisation for Economic Co-operation and Development; undated (http://www.oecdsaatoolbox.org/, accessed 18 January 2018) (compilation of resources, including a tool selector, case studies and a compilation of regulations and restrictions).
- PRTRnet. Geneva: United Nations Economic Commission for Europe; undated (http://prtr.net/en/links/, accessed 18 January 2018) (links to all registers of pollutant release and transfer worldwide).

EUROPEAN UNION

- Registered substances. Helsinki: European Chemicals Agency; undated (http://echa.europa.eu/information-on-chemicals/registered-substances, accessed 18 January 2018) (includes the REACH registered substances list and pre-registered substances list).
- EC inventory. Helsinki: European Chemicals Agency; 2008 (http://echa.europa.eu/information-on-chemicals/ec-inventory, accessed 18 January 2018) (includes the European inventory of existing commercial chemical substances, the European list of notified chemical substances and no-longer polymers).
- ECICS consultation. Brussels: Taxation and Customs Union; 2018 (http://ec.europa.eu/taxation_customs/dds2/ecics/chemicalsubstance_consultation.jsp?Lang=en, accessed 18 January 2018) (a tool managed by the European Commission Directorate General for Taxation and Customs Union that provides clear information on chemicals and combined nomenclature).
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US ENVIRONMENTAL PROTECTION AGENCY

- TSCA chemical substance inventory. Washington DC: United States Environmental Protection Agency; 2017 (http://www2.epa.gov/tsca-inventory, accessed 18 January 2018) (list of all chemical substances manufactured, processed or imported in the USA; plays a central role in regulation of most industrial chemicals in the USA).

- Envirofacts. Washington DC: United States Environmental Protection Agency; 2017 (http://www3.epa.gov/enviro/, accessed 18 January 2018) (allows selection of data from US EPA databases at a single point of access).
- Ecotox knowledgebase. Washington DC: United States Environmental Protection Agency; 2018 (http://cfpub.epa.gov/ecotox/, accessed 18 January 2018) (provides data on toxicity to aquatic life, terrestrial plants and wildlife).
- Chemical data access tool. Washington DC: United States Environmental Protection Agency; 2017 (http://java.epa.gov/oppt_chemical_search/, accessed 18 January 2018) (designed to increase public access to chemical information; includes health and safety data regulated under the Toxic Substances Control Act).
- Integrated risk information system. Washington DC: United States Environmental Protection Agency; 2017 (http://www2.epa.gov/iris, accessed 18 January 2018) (includes assessments of health hazards and toxicity of chemicals).

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- PubChem. Bethesda (MD): National Center for Biotechnology Information; undated (http://pubchem.ncbi.nlm.nih.gov/, accessed 18 January 2018) (three linked databases, on substances, compounds and bioassays).
- Chemexper.com. Brussels: ChemExper; undated (http://www.chemexper.com/), accessed 18 January 2018) (lists chemicals with their physical characteristics; information can be added and retrieved by users).
- Compendium of pesticide common names. Alan Wood; undated (http://www.alanwood.net/pesticides/, accessed 18 January 2018) (ISO-approved standard names and other institutional names of chemical pesticides).
- Common chemistry. Columbus (OH): Chemical Abstracts Service; 2017 (http://commonchemistry.org/, accessed 18 January 2018) (contains about 8000 chemicals, with their CAS registry numbers).
- MatWeb, your source for materials information. Blacksburg (VA): MatWeb LLC; undated (http://www.matweb.com/index.aspx, accessed 18 January 2018) (a searchable database of the properties of materials, from polymers to metals and fibres).
- OSHA occupational chemical database. Washington DC: Occupational Health and Safety Administration; undated (https://www.osha.gov/chemicaldata/, accessed 18 January 2018). (reports on chemicals, with physical properties, exposure guidelines, NIOSH pocket guide and emergency response information).
- TOXMAP environmental health maps. Bethesda (MD): US Department of Health and Human Services; 2017 (http://toxmap.nlm.nih.gov/toxmap/, accessed 18 January 2018) (a geographical information system developed by the US Department of Health and Human Services for consultation of information in the toxics release inventory).
- Brown JA. Haz-map®: information on hazardous chemicals and occupational diseases. Bethesda (MD): US Department of Health and Human Services; 2017 (http://hazmap.nlm.nih.gov/), accessed 18 January 2018) (an occupational health database listing adverse effects of workplace exposures to chemicals).
- International toxicity estimates for risk (ITER). Bethesda (MD): US Department of Health and Human Services; undated (http://toxnet.nlm.nih.gov/newtoxnet/iter.htm, accessed 18 January 2018) (provides comparative charts of international risk assessment information).

- CAMEO chemicals. Database of hazardous chemicals. Silver Spring (MD): National Oceanic and Atmospheric Administration; undated (http://cameochemicals.noaa.gov/, accessed 18 January 2018) (a database on hazardous material incident response and planning, including datasheets with response-related information, recommendations and a prediction tool).
- RISCTOX: a comprehensive database on toxic and hazardous substances. Brussels: European Trade Union Institute; undated (http://www.etui.org/Topics/Health-Safety/Chemicals-and-REACH/RISCTOX-database), accessed 18 January 2018) (database of hazardous substances, with concise information on health and environmental risks due to chemicals contained in products).

Annex 3. Chemicals subject to the prior informed consent procedure of the Rotterdam Convention

Of the 46 chemicals listed in Annex III of the Convention, 32 are pesticides (including three severely hazardous pesticide formulations), and 14 are industrial chemicals.

Chemical	Relevant CAS number(s)	Category
2,4,5-T and its salts and esters	93-76-5*	Pesticide
Alachlor	15972-60-8	Pesticide
Aldicarb	116-06-3	Pesticide
Aldrin	309-00-2	Pesticide
Azinphos-methyl	86-50-0	Pesticide
Binapacry	485-31-4	Pesticide
Captafol	2425-06-1	Pesticide
Chlordane	57-74-9	Pesticide
Chlordimeform	6164-98-3	Pesticide
Chlorobenzilate	510-15-6	Pesticide
DDT	50-29-3	Pesticide
Dieldrin	60-57-1	Pesticide
Dinitro-ortho-cresol and its salts (including ammonium salt, potassium salt and sodium salts)	534-52-1 2980-64-5 5787-96-2 2312-76-7	Pesticide
Dinoseb and its salts and esters	88-85-7*	Pesticide
1,2-dibromoethane	106-93-4	Pesticide
Endosulfan	115-29-7	Pesticide
Ethylene dichloride	107-06-2	Pesticide
Ethylene oxide	75-21-8	Pesticide
Fluoroacetamide	640-19-7	Pesticide
Hexachlorocyclohexane (mixed isomers)	608-73-1	Pesticide
Heptachlor	76-44-8	Pesticide
Hexachlorobenzene	118-74-1	Pesticide
Lindane	58-89-9	Pesticide
Mercury compounds, including inorganic mercury compounds, alkyl mercury compounds and alkyloxyalkyl and aryl mercury compounds		Pesticide

Chemical	Relevant CAS number(s)	Category
Monocrotophos	6923-22-4	Pesticide
Parathion	56-38-2	Pesticide
Pentachlorophenol and its salts and esters	87-86-5*	Pesticide
Toxaphene	8001-35-2	Pesticide
All tributyltin compounds including:		Pesticide
– Tributyltin oxide	56-35-9	
– Tributyltin fluoride	1983-10-4	
– Tributyltin methacrylate	2155-70-6 4	
– Tributyltin benzoate	342-36-3	
– Tributyltin chloride	1461-22-9	
– Tributyltin linoleate	24124-25-2	
– Tributyltin naphthenate	85409-17-2	
Dustable powder formulations containing a combination of:		Severely hazardous pesticide formulation
– Benomyl ≥ 7%	17804-35-2	
– Carbofuran ≥ 1%	1563-66-2	
– Thiram ≥ 15%	137-26-8	
Methamidophos (soluble liquid formulations of substance > 600 g active ingredient/L)	10265-92-6	Severely hazardous pesticide formulation
Phosphamidon (soluble liquid formulations of substance > 1000 g active ingredient/L)	13171-21-6 (mixture, (E) & (Z) isomers) 23783-98-4 ((Z)- isomer) 297-99-4 ((E)- isomer)	Severely hazardous pesticide formulation
Methyl-parathion (emulsifiable concentrates ≥ 19.5% active ingredient and dusts ≥ 1.5% active ingredient)	298-00-0	Severely hazardous pesticide formulation
Asbestos:		
– Actinolite	77536-66-4	Industrial
– Anthophyllite	77536-67-5	Industrial
– Amosite	12172-73-5	Industrial
– Crocidolite	12001-28-4	Industrial
– Tremolite	77536-68-6	Industrial
Commercial octabromodiphenyl ethers including:		Industrial
– Hexabromodiphenyl ether	36483-60-0	
– Heptabromodiphenyl ether	68928-80-3	

Chemical	Relevant CAS number(s)	Category
Commercial pentabromodiphenyl ethers including:		Industrial
–Tetrabromodiphenyl ether	40088-47-9	
– Pentabromodiphenyl ether	32534-81-9	
Perfluorooctane sulfonic acid, perfluorooctane sulfonates, perfluorooctane sulfonamides and perfluorooctane sulfonyls including:		Industrial
– Perfluorooctane sulfonic acid	1763-23-1	
– Potassium perfluorooctane sulfonate	2795-39-3	
– Lithium perfluorooctane sulfonate	29457-72-5	
– Ammonium perfluorooctane sulfonate	29081-56-9	
– Diethanolammonium perfluorooctane sulfonate	70225-14-8	
– Tetraethylammonium perfluorooctane sulfonate	56773-42-3	
– Didecyldimethylammonium perfluorooctane sulfonate	251099-16-8	
– N-Ethylperfluorooctane sulfonamide	4151-50-2	
– N-Methylperfluorooctane sulfonamide	31506-32-8	
– N-Ethyl-N-(2-hydroxyethyl) perfluorooctane sulfonamide	1691-99-2	
– N-(2-hydroxyethyl)- N-methylperfluorooctane sulfonamide	24448-09-7	
– Perfluorooctane sulfonyl fluoride	307-35-7	
Polybrominated biphenyls	36355-01-8 (hexa-) 27858-07-7 (octa-) 13654-09-6 (deca-)	Industrial
Polychlorinated biphenyls	1336-36-3	Industrial
Polychlorinated terphenyls	61788-33-8	Industrial
Tetraethyl lead	78-00-2	Industrial
Tetramethyl lead	75-74-1	Industrial
Tris (2,3-dibromopropyl) phosphate	126-72-7	Industrial

Annex 4. Wastes, hazardous characteristics and disposal operations subject to the Basel Convention

Categories of wastes to be controlled (as per Annex I of the Basel Convention)

Waste streams	
Y1	Clinical wastes from medical care in hospitals, medical centers and clinics
Y2	Wastes from the production and preparation of pharmaceutical products
Y3	Waste pharmaceuticals, drugs and medicines
Y4	Wastes from the production, formulation and use of biocides and phytopharmaceuticals
Y5	Wastes from the manufacture, formulation and use of wood preserving chemicals
Y6	Wastes from the production, formulation and use of organic solvents
Y7	Wastes from heat treatment and tempering operations containing cyanides
Y8	Waste mineral oils unfit for their originally intended use
Y9	Waste oils/water, hydrocarbons/water mixtures, emulsions
Y10	Waste substances and articles containing or contaminated with polychlorinated biphenyls and/or polychlorinated terphenyls and/or polybrominated biphenyls
Y11	Waste tarry residues arising from refining, distillation and any pyrolytic treatment
Y12	Wastes from production, formulation and use of inks, dyes, pigments, paints, lacquers, varnish
Y13	Wastes from production, formulation and use of resins, latex, plasticizers, glues/adhesives
Y14	Waste chemical substances arising from research and development or teaching activities that are not identified and/or are new and whose effects on humans and/or the environment are not known
Y15	Wastes of an explosive nature not subject to other legislation
Y16	Wastes from production, formulation and use of photographic chemicals and processing materials
Y17	Wastes resulting from surface treatment of metals and plastics
Y18	Residues arising from industrial waste disposal operations

Categories of wastes to be controlled (as per Annex I of the Basel Convention)

Wastes that have as constituents	
Y19	Metal carbonyls
Y20	Beryllium; beryllium compounds
Y21	Hexavalent chromium compounds
Y22	Copper compounds
Y23	Zinc compounds
Y24	Arsenic; arsenic compounds
Y25	Selenium; selenium compounds
Y26	Cadmium; cadmium compounds
Y27	Antimony; antimony compounds
Y28	Tellurium; tellurium compounds
Y29	Mercury; mercury compounds
Y30	Thallium; thallium compounds
Y31	Lead; lead compounds
Y32	Inorganic fluorine compounds excluding calcium fluoride
Y33	Inorganic cyanides
Y34	Acidic solutions or acids in solid form
Y35	Basic solutions or bases in solid form
Y36	Asbestos (dust and fibres)
Y37	Organic phosphorus compounds
Y38	Organic cyanides
Y39	Phenols; phenol compounds including chlorophenols
Y40	Ethers
Y41	Halogenated organic solvents
Y42	Organic solvents excluding halogenated solvents
Y43	Any congenor of polychlorinated dibenzo-furan
Y44	Any congenor of polychlorinated dibenzo-p-dioxin
Y45	Organohalogen compounds other than substances referred to in this Annex (e.g. Y39, Y41, Y42, Y43, Y44)

Categories of wastes that require special consideration (as per Annex II of the Basel Convention)

Y46	Wastes collected from households
Y47	Residues arising from the incineration of household wastes

List of hazardous characteristics (as per Annex III of the Basel Convention)

Class*	Code	Characteristics
1	H1	Explosive. An explosive substance or waste is a solid or liquid substance or waste (or mixture of substances or wastes) that is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings.
3	H3	Flammable liquids. The word "flammable" has the same meaning as "inflammable". Flammable liquids are liquids, or mixtures of liquids, or liquids containing solids in solution or suspension (for example, paints, varnishes, lacquers, but not including substances or wastes otherwise classified on account of their dangerous characteristics) which give off a flammable vapour at temperatures of not more than 60.5 °C, closed-cup test, or not more than 65.6 °C, open-cup test. (As the results of open-cup tests and of closed-cup tests are not strictly comparable, and even individual results by the same test are often variable, regulations varying from the above figures to make allowance for such differences would be within the spirit of this definition.)
4.1	H4.1	Flammable solids. Solids, or waste solids, other than those classed as explosives, which under conditions encountered in transport are readily combustible or may cause or contribute to fire through friction.
4.2	H4.2	Substances or wastes liable to spontaneous combustion. Substances or wastes that are liable to spontaneous heating under normal conditions, encountered in transport or to heating on contact with air and being then liable to catch fire.
4.3	H4.3	Substances or wastes that, in contact with water, emit flammable gases. Substances or wastes that, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.
5.1	H5.1	Oxidizing. Substances or wastes that, while in themselves not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other materials.
5.2	H5.2	Organic peroxides. Organic substances or wastes that contain the bivalent -o-o-structure, are thermally unstable substances that may undergo exothermic self-accelerating decomposition.
6.1	H6.1	Poisonous (acute). Substances or wastes liable either to cause death or serious injury or to harm human health if swallowed or inhaled or by skin contact.
6.2	H6.2	Infectious substances. Substances or wastes containing viable microorganisms or their toxins, which are known or suspected to cause disease in animals or humans.
8	H8	Corrosives. Substances or wastes that, by chemical action, will cause severe damage when in contact with living tissue or, in the case of leakage, will materially damage, or even destroy, other goods or the means of transport; they may also cause other hazards.
9	H10	Liberation of toxic gases in contact with air or water. Substances or wastes that, by interaction with air or water, are liable to give off toxic gases in dangerous quantities.
9	H11	Toxic (delayed or chronic). Substances or wastes that, if inhaled or ingested or if they penetrate the skin, may have delayed or chronic effects, including carcinogenicity.

List of hazardous characteristics (as per Annex III of the Basel Convention)

Class*	Code	Characteristics
9	H12	Exotoxic. Substances or wastes that, if released, present or may present immediate or delayed adverse impacts to the environment by means of bioaccumulation and/or toxic effects upon biotic systems.
9	H13	Capable, by any means, after disposal, of yielding another material, e.g. leachate, which has any of the characteristics listed above.

* Hazard classification system of the United Nations Recommendations on the Transport of Dangerous Goods (ST/SG/AC.10/1Rev.5). New York: United Nations; 1988.

List of disposal operations (as per Annex IV of the Basel Convention)

Section A. Operations that do not allow resource recovery, recycling, reclamation, direct re-use or alternative uses	
D1	Deposit into or onto land (e.g. landfill)
D2	Land treatment (e.g. biodegradation of liquid or sludgy discards in soils)
D3	Deep injection (e.g. injection of pumpable discards into wells, salt domes of naturally occurring repositories)
D4	Surface impoundment (e.g. placement of liquid or sludge discards into pits, ponds or lagoons)
D5	Specially engineered landfill (e.g. placement into lined discrete cells that are capped and isolated from one another and the environment)
D6	Release into a water body except seas or oceans
D7	Release into seas or oceans, including sea-bed insertion
D8	Biological treatment not specified elsewhere in this Annex that results in final compounds or mixtures thT are discarded by means of any of the operations listed in Section A
D9	Physico-chemical treatment not specified elsewhere in this Annex that results in final compounds or mixtures that are discarded by means of any of the operations listed in Section A (e.g. evaporation, drying, calcination, neutralization, precipitation)
D10	Incineration on land
D11	Incineration at sea
D12	Permanent storage (e.g. emplacement of containers in a mine)
D13	Blending or mixing before submission to any of the operations listed in Section A
D14	Repackaging before submission to any of the operations listed in Section A
D15	Storage pending any of the operations listed in Section A

List of disposal operations (as per Annex IV of the Basel Convention)

Section B. Operations that allow resource recovery, recycling, reclamation, direct re-use or alternative uses	
R1	Use as a fuel (other than in direct incineration) or other means to generate energy
R2	Solvent reclamation or regeneration
R3	Recycling or reclamation of organic substances that are not used as solvents
R4	Recycling or reclamation of metals and metal compounds
R5	Recycling or reclamation of other inorganic materials
R6	Regeneration of acids or bases
R7	Recovery of components used for pollution abatement
R8	Recovery of components from catalysts
R9	Used oil re-refining or other re-uses of previously used oil
R10	Land treatment resulting in benefit to agriculture or ecological improvement
R11	Uses of residual materials obtained from any of the operations numbered R1–R10
R12	Exchange of wastes for submission to any of the operations numbered R1–R11
R13	Accumulation of material intended for any operation in Section B

Annex 5. Persistent organic pollutants subject to the Stockholm Convention

More details can be found in the text of the Convention and its amendments: Convention text. Châtelaine: Secretariat of the Stockholm Convention Clearing-house; undated (http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx, accessed 18 January 2018).

List of persistent organic pollutants (POPs) subject to elimination of production and use as per Annex A of the Stockholm Convention

Chemical	CAS number	Activity	Specific exemption
Aldrin	309-00-2	Production	None
		Use	Local ectoparasiticide Insecticide
α- Hexachlorocyclohexane	319-84-6	Production	None
		Use	None
β-Hexachlorocyclohexane	319-85-7	Production	None
		Use	None
Chlordane	57-74-9	Production	As allowed for the Parties listed in the Register
		Use	Local ectoparasiticide Insecticide Termiticide Termiticide in buildings and dams Termiticide on roads
Chlordecone	143-50-0	Production	None
		Use	None
Dieldrin	60-57-1	Production	None
		Use	In agricultural operations
Endrin	72-20-8	Production	None
		Use	None
Heptachlor	76-44-8	Production	None
		Use	Termiticide in structures of houses Termiticide (subterranean) Wood treatment In use in underground cable boxes

List of persistent organic pollutants (POPs) subject to elimination of production and use as per Annex A of the Stockholm Convention

Chemical	CAS number	Activity	Specific exemption
Hexabromobiphenyl	36355-01-8	Production Use	None None
Hexabromocyclododecane	25637-99-4; 3194-55-6; 134237-50-6; 134237-51-7; and 134237-52-8	Production Use	As allowed for the Parties listed in the Register in accordance with the provisions of Part VII of Annex A of the Convention Expanded polyestyrene and extruded polysterene in buildings in accordance with the provisions of Part IV of Annex A of the Convention.
Hexabromodiphenyl ether and heptabromodiphenyl ether		Production Use	None Articles in accordance with the provisions of Part IV of Annex A of the Convention
Hexachlorobenzene	118-74-1	Production Use	As allowed for the Parties listed in the Register Intermediate solvent in pesticide Closed system site limited intermediate
Lindane	58-89-9	Production Use	None Human health pharmaceutical for control of head lice and scabies as second-line treatment
Mirex	2385-85-5	Production Use	As allowed for the Parties listed in the Register Termiticide
Pentachlorobenzene	608-93-5	Production Use	None None
Polychlorinated biphenyls		Production Use	None Articles in accordance with the provisions of Part V of Annex A of the Convention
Technical endosulfan and its related isomers	115-29-7; 959-98-8; 33213-65-9	Production Use	As allowed for the Parties listed in the Register Crop–pest complexes as listed in accordance with the provisions of Part VI of Annex A of the Convention
Tetrabromodiphenyl ether and pentabromodiphenyl ether	5436-43-1; 60348-60-9	Production Use	None Articles containing these chemicals for recycling in accordance with the provisions in Part IV of Annex A of the Convention
Toxaphene	8001-35-2	Production Use	None None

List of POPs subject to restriction (as per Annex B of the Stockholm Convention)

Chemical	CAS number	Activity	Specific exemption
DDT	50-29-3	Production	*Acceptable purpose:* Disease vector control use in accordance with Part II of Annex B of the Convention *Specific exemption:* Intermediate in production of dicofol Intermediate
		Use	*Acceptable purpose:* Disease vector control in accordance with Part II of Annex B of the Convention *Specific exemption:* Production of dicofol Intermediate
Perfluorooctane sulfonic acid its salts and perfluorooctane sulfonyl fluoride	1763-23-1; 307-35-7	Production	*Acceptable purpose:* In accordance with Part III of Annex B of the Convention, production of other chemicals to be used solely for the uses below Production for uses listed below *Specific exemption:* As allowed for Parties listed in the Register
		Use	*Acceptable purpose:* In accordance with Part III of Annex B of the Convention for the following acceptable purposes or as an intermediate in the production of chemicals with the following acceptable purposes: ■ Photo-imaging ■ Photo-resist and anti-reflective coatings for semi-conductors ■ Etching agent for compound semiconductors and ceramic filters ■ Aviation hydraulic fluids ■ Metal plating (hard metal plating), only in closed-loop systems ■ Certain medical devices (such as ethylene tetrafluoroethylene copolymer (ETFE) layers and radio-opaque ETFE production, in-vitro diagnostic medical devices, and CCD colour filters) ■ Fire-fighting foam ■ Insect baits for control of leaf-cutting ants of *Atta* spp. and *Acromyrmex* spp.

List of POPs subject to restriction (as per Annex B of the Stockholm Convention)

Chemical	CAS number	Activity	Specific exemption
			Specific exemptions: For the following specific uses or as an intermediate in the production of chemicals with the following specific uses: ■ Photo masks in the semiconductor and liquid crystal display industries ■ Metal plating (hard metal plating) ■ Metal plating (decorative plating) ■ Electric and electronic parts for some colour printers and colour copy machines ■ Insecticides for control of imported red fire ants and termites ■ Chemically driven oil production ■ Carpets ■ Leather and apparel ■ Textiles and upholstery ■ Paper and packaging ■ Coatings and coating additives ■ Rubber and plastics

List of POPs produced unintentionally (as per Annex C of the Stockholm Convention)

Chemical	CAS number
Hexachlorobenzene	118-74-1
Pentachlorobenzene	608-93-5
Polychlorinated biphenyls	
Polychlorinated dibenzo-p-dioxins and dibenzofurans	

Annex 6. Chemicals subject to the United Nations Economic Commission for Europe Convention on the Transboundary Effects of Industrial Accidents

Ammonium nitrate
Potassium nitrate
Arsenic pentoxide, arsenic (V) acid and/or salts
Arsenic trioxide, arsenious (III) acid and/or salts
Bromine
Chlorine
Nickel compounds in inhalable powder form: nickel monoxide, nickel dioxide, nickel sulfide, trinickel disulfide, dinickel trioxide
Ethyleneimine
Fluorine
Formaldehyde (concentration ≥ 90%)
Hydrogen
Hydrogen chloride (liquefied gas)
Lead alkyls
Liquefied flammable gases, category 1 or 2 (including liquefied petroleum gas) and natural gas
Acetylene
Ethylene oxide
Propylene oxide
Methanol
4,4'-Methylene bis (2-chloraniline) and/or salts, in powder form
Methyl isocyanate
Oxygen
Toluene diisocyanate (2,4-toluene diisocyanate and 2,6-toluene diisocyanate)
Carbonyl dichloride (phosgene)
Arsine (arsenic trihydride)
Phosphine (phosphorus trihydride)
Sulfur dichloride
Sulfur trioxide
Polychlorodibenzofurans and polychlorodibenzodioxins (including tetrachlorodibenzodioxin (TCDD)), calculated in TCDD equivalents

The following carcinogens or mixtures containing the following carcinogens at concentrations > 5% by weight:

- 4-Aminobiphenyl and/or its salts
- Benzotrichloride

- Benzidine and/or salts
- Bis(chloromethyl) ether
- Chloromethyl methyl ether
- 1,2-Dibromoethane
- Diethyl sulfate
- Dimethyl sulfate
- Dimethylcarbamoyl chloride
- 1,2-Dibromo-3-chloropropane
- 1,2-Dimethylhydrazine
- Dimethylnitrosamine
- Hexamethylphosphorictriamide
- Hydrazine
- 2-Naphthylamine and/or salts
- 4-Nitrodiphenyl
- 1,3-Propanesultone

Petroleum products and alternative fuels:

- Gasolines and naphthas
- Kerosenes (including jet fuels)
- Gas oils (including diesel fuels, home heating oils and gas oil blending streams)
- Heavy fuel oils
- Alternative fuels serving the same purposes and with similar properties as regards flammability and environmental hazards as the four previous products

Anhydrous ammonia
Boron trifluoride
Hydrogen sulfide
Piperidine
Bis(2-dimethylaminoethyl) (methyl)amine
3-(2-Ethylhexyloxy)propylamine
Mixtures of sodium hypochlorite classified as aquatic acute category 1 (H400) containing > 5% active chlorine and not classified under any of the other hazard categories
Propylamine
tert-Butyl acrylate
2-Methyl-3-butenenitrile
Tetrahydro-3,5-dimethyl-1,3,5,-thiadiazine-2-thione
Methyl acrylate
3-Methylpyridine
Bromo-3-chloropropane

The WHO Regional Office for Europe

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