The Russian system of chemicals management

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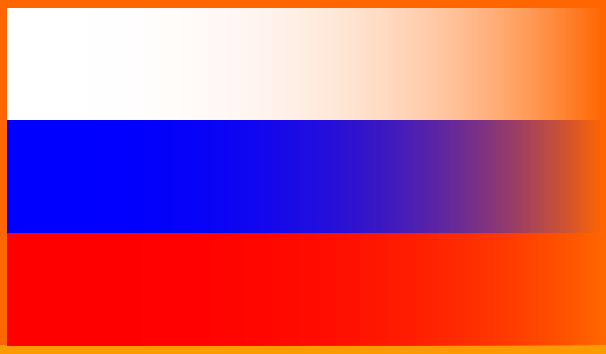

Baltic Environmental Forum
BEF GROUP

Federal Ministry for the Environment, Nature Conservation and Nuclear Safety

Umwelt Bundes Amt
for our Environment

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CURRENT UNDERSTANDING

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Contents

List of Abbreviations

BAT	Best available techniques
BCF	Biological Concentration Factor
BOD	Biological oxygen demand
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency (United States)
EU	European Union
FSEH	Federal State-owned Establishment of Public Health
GHS	Globally Harmonized System
GLP	Good Laboratory Practice
GN	Hygenic norm/regulation
GOST	State standard (Gosudarstvennyy standard)
MAC	see PDS and PDK
MPC	Maximum permissible concentration
MU	Methodological Guidelines
OBUV	Tentatively safe levels of exposure (Orientirovochno bezopasnyy uroven' vozdeystviya)
ODU	Tentative allowed level (Orientirovochno dopustimyy uroven)
OECD	Organisation for Economic Co-operation and Development
PDK	Maximum allowed concentration (Predelno dopustimaya koncentraciya)
PDS	Maximum allowed concentration (Predelno dopustimye sbrosy)
RosPotreb-Nadzor	Federal Service for the protection of consumer rights and well-being of humans (Federal-naya sluzhba po nadzoru v sfere sashchity prav potrebiteley i blagopoluchiya cheloveka)
RRPHCBS	Russian Register of Potentially Hazardous Chemical and Biological Substances
SanPin	Sanitary-epidemiological rules and norms (Sanitarnye pravila, normy I gigienicheskie nor-mativy)
SDS	Safety Data Sheets
TR	Technicheskiy reglament
TU	Technical Conditions
VNIRO	Russian Federal Research Institute of Fisheries and Oceanography
WHO	World Health Organization

Editorial

Hazardous substances are a serious threat for human health and the environment and particularly when reaching water bodies or seas, their management is mostly not anymore subject to responsibility of one state alone. While inside the European Union, many processes are on-going to streamline the activities in the member states for the protection of the environment from the dangers of hazardous substances, the cooperation with non-member states, with different legislation on hazardous substances, as well as own interests causes additional challenges for a joint protection of a shared water body. A particularly vulnerable sea is the Baltic Sea — with a unique eco-system but vulnerable to pollution due to its special geographic and hydro-morphological conditions being connected to the ocean only through the extremely narrow Danish belts which hinder the water exchange — surrounded by eight member states of the EU and the Russian Federation taking part in implementation of agreed EU environmental regulations.

Russian classification of hazards of chemicals substances differs largely from the EU, especially with regard to environmental hazards which are not addressed by Russian regulation. There is a lack of knowledge among the Russian scientific community and other stakeholders about the environmental concerns as for instances laid down in the EU Water Framework Directive and as background motivation for selecting certain substances under REACH. However, also vice versa there is a lack of knowledge at EU stakeholders about the current Russian hazardous substance regulatory frame and related practices to reduce and/or control hazardous substances uses and emissions.

Efficient control and management of hazardous substances, however, can only be achieved, if both sides speak the same language. As this document will show, there are many seeming similarities between the European Union and the Russian Federation, however, the background and the details are different, and over the past decades European Union policy makers have gone many steps further, e.g. acting preventively and not to wait until scientific evidence proves the danger of a certain substance, just to mention one crucial point. Although, there are clear signs, as we will see further on, that the current legal framework in Russia in the process of fundamental revision, it will certainly still remain in force for some years, and therefore in the following chapters, the current legal background and its procedures of management of hazardous substances and ensuring chemical safety will be explained for audience from the European Union, who seek for cooperation with Russian stakeholders from public administrations and business. The European in mind of the authors are respresentative of competent authorities of EU members, as well as European institutions seeking for cooperation on reduction of certain hazardous substances (e.g. to the Baltic Sea environment), business partners from trade and industry in need of understanding the Russian hazard classification system.

The document would like to provide background information for the EU reader to enable them to understand the conceptual thinking behind the current Russian system of chemicals saftety. It is not meant to be a gap analysis of the Russian system in comparison the

European system and it does aim at proposing concrete changes for the new regulatory framework.

The document will at certain points pay special attention to the St. Petersburg and the surrounding Leningrad region, as some regional variations occur in a large country like the Russian Federation. Recalling, that this document has been prepared in the light of finding a common way to reduce the pollution from hazardous substances in the Baltic Sea, this region in Russia consequently is of particular concern.

The remainder of this introductory chapter will set the frame and provide information about the different legal acts governing chemicals safety, chapter 2 will provide information about the responsibilities, the scope, and the procedure for registration of chemical substances. Chapter 3 is dealing with the different necessary assessments of substances, and its procedures, while chapter 4 is documenting the current practices concerning the classification of substances. Chapter 5 is then providing additional information about Pollution prevention and control measures. The final Chapter 6 summarizes once more the findings and lists the main conclusions that can be drawn, in comparison to European legislation, procedures, and practices.

This document was prepared in the frame of an international project, “Capacity building on hazardous substance management in North West Russia”, financially supported by the German Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety and the German Federal Environment Agency.

We hope you find it useful

Heidrun Fammler

Baltic Environmental Forum Group

1. Introduction

Ensuring chemical safety is considered as a priority issue in the Russian Federation of strategic importance, as defined in «The foundations of the state policy for ensuring chemical and biological safety of the Russian Federation for the period up to 2010 and longer terms», approved by the President of the Russian Federation Vladimir Putin on December 4, 2003. No Pr-2194. The policy is based on improving and strengthening of the relevant institutions and the legal framework. The aim is to create a comprehensive system providing for classification, forecasting, prevention, and elimination of chemical and biological threats, as well as the management of emergencies resulting from chemical and biological factors. One of the major tasks in the improvement of the legal framework is the harmonization of legislation of the Russian Federation in ensuring chemical and biological safety with the provisions of international law, international treaties and agreements, of which the Russian Federation is a part of.

The changes, however, are progressing slowly, and so far there is no common legal framework on chemicals management issues. Up to now, the system on safe handling of substances and mixtures in Russia is governed by several laws and regulations that determine:

- Approaches to hazard classification;Registration of substances;
- Hygienic registration of mixtures and other products;
- Rules of communicating hazard information to authorities and the general public
- Rules related to the availability of hazard information (labelling and safety data sheets)
- Maximum concentration limit values in the environment (MPCs);
- Limited distribution in the territory of Russian Federation of certain groups of substances.

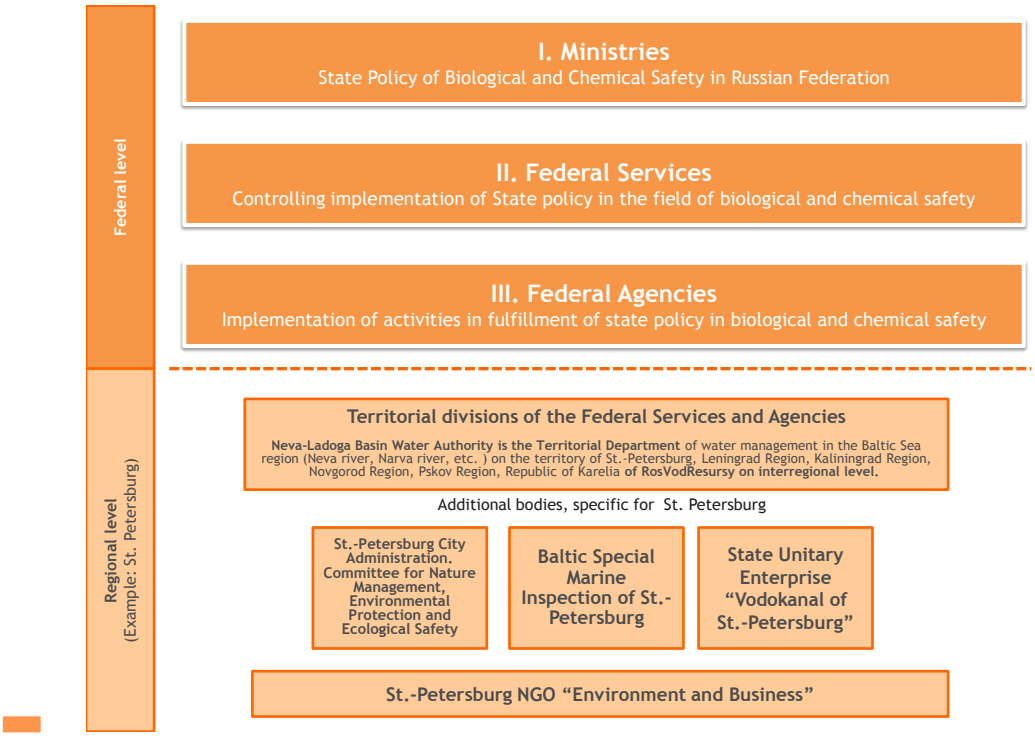
The foundations of the system are defined by the following legal acts:

- **"Federal law of March 30 1999 No. 52-FZ "On sanitary and epidemiological welfare of population"** — deals with state registration of potentially hazardous chemicals and biological substances, setting requirements on specific products, radioactive substances, industrial and household wastes as well as specific types of products imported into the Russian Federation which are potentially hazardous for human health.
- **"Federal Law of July 21 1997 No. 116-FZ "Industrial Safety of High-Risk Industrial Facilities"** is the only higher-level legal act dedicated solely to chemical safety issues and concerns the declaration and appraisal of industrial safety at industrial enterprises handling hazardous chemical substances (manufacturing, storage, use and transportation) starting from certain amounts.
- **"Federal Law of January 10 2002 No. 7-FZ "On Environmental Protection"** stipulating protection of the environment in manufacturing and use of chemicals as pollutants - limits and regulations of allowable emissions and discharge of chemicals, maximum concentration limit values, environment pollution fee.

- **"Labour Code of the Russian Federation" of December 30 2001 No 197-FZ** stipulating restrictions on industrial use of hazardous or dangerous substances, materials or products having no developed methods and metrological control procedures, and with respect to which toxicological (sanitary and hygienic, medical biological) tests were not performed; occupational safety rules in using new substances etc.
- **Federal law "On protection of consumer rights" of February 7, 1992 No. 2300-1** stipulates requirements on the safety of consumer goods and services to human life and health, property and the natural environment in case of normal handling.
- **Federal Law of July 19, 1997 No. 109-FZ "On Safe Handling of Pesticides and Agrochemicals"**
- **Federal Law of December 20 2004 No, 166-FZ "On Fisheries and preserving aquatic biological resources"** stipulates in Article 47 setting of a methodology for the elaboration of the quality norms (MCPs) of fishery waters and also the basisi for the establishment of these MCPs.

In addition, details of the present system are given by national standards (GOST) and hygienic rules (SanPiNs). The Federal Act "On Technical Regulation", entering into force in 2003, requires revision of the current standards system, e.g. replacement by 'tekhnicheskiy reglamenty'[1] (TRs) by 1 July, 2010. The adoption of TRs has been very slow, therefore in January 2010 changes were adopted in the law allowing the consideration of foreign (particularly EU and Customs Alliance, i.e. Byelorussia and Kazakhstan)

Figure 1: Schematic institutional setup on Federal and Regional level (example St. Petersburg)



1 '*Tekhnicheskiy reglament*' is a legally biding document which can be best described as a regulation combined with technical guidelines. (plural: *tekhnicheskie reglamenty*)

regulations at the request of manufacturers.[2] It is expected that in 2010 the first TR on chemicals management are adopted, enforcing classification accroding to the Globally Harmonized System (GHS) and safety passports (i.e. Safety Data Sheets, SDS).

A multitude of organizations is involved in chemicals safety and management of hazardous susbtances on Federal, regional, and local levels. A full list with responsibilities can be found in Annex V of this document. Figure 1 illustrates the responsibilities schematically and examplifies the case for St. Petersburg and the Leningrad region.

For the purposes of this document, only a small number of Ministries, and Federal Services are of primary concern. These will be addressed in detail in the following sections. Nevertheless it is important to keep in mind, that there are many other players involved, This signifcantly contributes to the complexity of the topic in Russia.

Apart from using printed and electronically available information sources, this report has been compiled based on past experience, discussions at the Baltic Sea Day 2009 and in expert meetings in Tallinn in May 2009 and in Riga in November 2009 [1]. The main aspects of the systems in place in the Russian Federation can be briefly summarized as follows:

- The current system of substance registration is complex, involves several assessment steps and is focused towards the prevention of damage to human health.
- The aim of the registration is to ensure that negative effects are identified, dangerousness is defined by hazard classes and communicated respectively. Furthermore, MCPs are developed based on toxicological (and ecotoxicological considerations in case of fishery waters).
- The setting of MPCs is carried out by different institutions for human health and the fishery waters. There seems to be lack of cooperation between the authorities, perhaps caused by the previously unclear legal position of fishery MPCs, which was finally solved in the end of 2009.
- The extent of testing depends on available knowledge and also partly on risks (information on production and uses) and testing methods and endpoints can be regarded as similar to the EU. The following endpoints are considered and tests are performed accordingly:

  Human health

  - Carcinogenicity, mutagenicity, reprotoxicity;
  - Acute toxicity and chronic toxicity, including different effects on organs, nervous system etc.;
  - Skin irritation and corrosiveness;
  - Eye damage and eye irritation;
  - Sensitisation (skin and respiratory tract);

2 http://www.business-help.ru/news.php?id=89

Environmental hazardousness

- Acute aquatic toxicity and chronic aquatic toxicity (long term testing)
- Biodegradability (persistence)
- Accumulation potential (BCF (Biological Concentration Factor) by testing accumulation in animals)

- The implementation of classification and labeling of GHS will contribute further to an alignment of parameters to describe hazards of chemicals.
- Mixtures are subject to hygienic assessment, which could be based solely estimating the hazards by the composition of the product, but preferably a simplified testing approach for the mixture is used.
- Chemicals as well as safety data sheets are registered and certified for marketing and use by authorities.

2. Registration of substances

In accordance with the Russian Federation Law No 52-FZ of 30/03/1999 on “Sanitary and Epidemiological Well-being of the Population” (Art. 43 concerning state registration of substances and products) and with the Government’s Decree about “State Registration of Potentially Hazardous Chemical and Biological Substances” No 869 of 12/11/1992, in the Russian Federation a mandatory state registration of potentially hazardous chemical and biological substances has been implemented in order to prevent adverse effects on human health and the environment.

State registration is applied to all individual chemical and biological compounds produced and/or imported into Russia including those used as ingredients in the composition of end products. Substances having in their composition by-products produced in the course of manufacturing or use are to be registered like individual substances[3]. Production, import and use of unregistered substances is prohibited.

Since 1992 approximately 3,400 substances have been registered and are contained in a respective registration database. However, about 15,000 substances have been investigated prior to 1992, and those are considered as being registered as well [1].

2.1 Current institutional setup

The Federal State-owned Establishment of Public Health (FSEH) — Russian Register of Potentially Hazardous Chemical and Biological Substances (RRPHCBS) is entrusted by Rospotrebnadzor with the preparation of documents necessary for the state registration of chemical and biological substances. The institution is a National Correspondent of the UNEP Chemicals programme.

3 Legislation is not further specifying the meaning of this clause, i.e. does it requires registration of impurities or unintentionally produced substances.

The FSEH “RRPHCBS” is accredited:

- to conduct studies on toxicity and hazard assessment of substances;
- to provide comprehensive information about properties of substances, regulation systems for safe handling of chemicals on the territory of the Russian Federation;
- to develop safety passports (i.e. Safety Data Sheets);
- to develop and maintain a database on substances handled on the territory of the Russian Federation (database - Hazardous Substances). [2]

2.2. Scope of registration

Since 1992 substances which are imported or produced in the Russian Federation have to be registered. In general, all substances are considered as „potentially hazardous substances“, and therefore are subject to registration. Excluded are pharmaceutical substances, pesticides and other plant protection products, agricultural, and forestry growth regulators, there are, however, separate registration regimes (legislation) applying instead. The registration and control of these substances falls under the authority of the responsible ministries (e.g. Ministry of Agriculture). Substances used for the production of weapons or warfare agents are also exempted [1].

Each substance needs to be registered only once and the registration costs have to be borne by the first registrant only [1]. The substance is registered for a certain term, usually for 3 years. Upon expiry of the certification term the registration procedure should be repeated. The renewal of the certification is justified based on scientific arguments, i.e. if new data is available, this should be taken into account in MPCs and they may need revision.

Information on whether or not a substance is already registered can be obtained from the database or requested from the registering authority. On its homepage, the RRPHCBS lists recently registered substances (currently 509 entries) and substances, of which the registration has expired (currently 635 entries) [2].

The database “Hazardous Substances” contains information about chemical compounds which have passed state registration. It includes data about physical and chemical propertie, toxicity and hazards to humans and the environment, and hygienic and environmental standards. It is available online at the RRPHCBS homepage, but its access is available for registered users for a fee (annual charges of a license are 20,000 Roubles or around 500 Euros). Since 28 October, 2009 the database is registered as a National Database with registration the number 2009620521. The database was down for maintainance purposes in late 2009/ early 2010 [2]. An example of the registry information is provided here in Annex I.

2.3. The registration procedure

The procedure of the state registration of a substances includes:

- the examination of documents submitted by applicants by the RRPHCBS, including results of investigations, toxicological, hygienic and other assessments;
- the preparation of documents on the properties of substances under question and subject to state registration by the RRPHCBS;
- the issuing of state registration certificates by the Federal Service for Surveillance on Consumer Rights Protection and Human Well-being (RosPotrebNadzor). [2]

Companies having to register a substance have to provide information on its identity (name, molecular structure etc.) and other information for the preparation of documents (see Chapter 3.1). In principle, the system has similar features with EU registration scheme: an organisation which wants to market a chemical substance will contract an accredited organisation to carry out the assessment on a paid basis. Once the assessment is done, the applicant presents the dossier to the RRPHCBS to prepare the registration documentation.

The assessment and compilation of the respective documentation can be done by any accredited institution having access to accredited laboratories. The results of the assessment contain information on hazardous properties of a substance (test results from literature as well as from newly performed studies, classification of substance into different hazard classes) and measures to ensure safe handling together with proposed environmental quality standards[4] (MPCs). The data collection and assessment of a substance takes between 1 and 2 years [1].[5]

The information about the assessment of the substances is forwarded by the applicant to the organisation in charge of the actual substance registration. This may include the conclusion that, based on the available information, no hygienic norm is necessary to ensure safe handling. For a substance which shall also to be produced in Russia, the dossier must also include all technical documentation related to the production processes, e.g. standards, technical conditions, reglamenty, technological instructions, product specifications, etc. And that all necessary approvals or permits are obtained.

4 The full procedure of assigning a MPC is not fully described in legislation: if the registrant proposes the MPCs in the documentation, should the MPC be assigned in the legislation by the competent authorities before or after the registration occurs. With hygienic norms it is not a major issue, as the authority confirming MPC and registration is the same.

5 Remark: Fishery water MPCs are assigned by an authority not belonging to the RosPotrebNadzor or the structures of the Ministry of Health. In principle, the registration procedure should ensure assignment of all types of MPCs, but still it is quite common that a substance is registered and MPCs for human health are assigned, but no ecotoxicological MCP (value for fishery water) are assigned. At the same time, Article 47-2 of the Federal Law "On Fisheries and preserving aquatic biological resources" states that it is prohibited to discharge substances not having fishery MPC assigned to fishery waters. But in environmental permitting practice each water body is considered as fishery one. In practice, the opposite is also possible: a fishery MPC is assigned, but the substance is not registered and/or no human health related MPC assigned.

For substances to be imported, the dossier must include copies of documents confirming their safety for human health, issued by authorities of the country of origin (MSDS)[6]. Moreover, the necessary label on the packaging (or confirmed design of it) must be presented in both cases.

The fee for review and preparation of the documents in RRPHCBS ranges from 28,792 to 38,486 Roubles (approximately 730-980 Euros), depending on the speed of the service (30 to 2 days). Also a fee of 1,500 Roubles (about 40 Euros) is charged for the registration in RosPotrebNadzor. In total, the review and registration fee is quite marginal compared to the assessment costs [1].

After registration the information on substance properties is published in the substance data base. As in the European Union, data on the amounts which are produced or imported are subject to confidentiality.

After haveing been successfully certified, the substance can be used in industrial production. Nevertheless, new substances[7] are subject to a clinical-hygienic probation period over one year. In the case that observations indicate damage to human health or the environment are caused by such substances, it is immediately reported and MPCs are amended correspondingly [1]. It is worthwhile to mention that if test results and product assessments indicate high risks, a temporary registration for two years is given and manufacturing or use of the substance is not prohibited (unless competent institutions have refused to assign MPCs due to extremely high risks).

6 As defined in the Governmental Decree.

7 There is no legal definition of „new substance“, but according to the information received in expert workshops, substances placed on the market after 1992 should be considered as new ones.

3. Substance assessment

Assessment of hazardousness of substances involves the following two main steps:

1. The data collection on the hazards of a substance, and
2. the comparison of data with criteria to decide, whether an environmental quality standard (MPC) is needed. There are official methodological guidelines available to decide, and if the criteria are met to establish MPC, this can be done by applying an “express method”, a temporary norm can be established, or it can be decided that a full scale assessment is required.

The assessment can be performed by any accredited organisation having access to accredited laboratories. Assessments are performed separately for toxicological properties (hygienic assessment described in Chapter 3.1) and for ecotoxicological properties (as described in Chapter 3.2).

After a substance assessment is completed, the dossier is given to competent authorities for evaluation and establishing MPCs:

- for hygienic assessments, RosPotrebNadzpor is in charge
- For fishery water assessments, the Federal Fishery Agency with approval of the Ministry of Natural Resources and Ecology is responsible.

3.1. Toxicological assessment

The assessment of toxicological properties of substances for registration is done according to the provisions of the Hygienic Regulation GN 1.1701-98 “Hygienic criteria for rating the necessity for setting up MPCs and TSELs/ODU of harmful substances in the occupational air, the ambient air of residential areas and the water of water bodies hygienic norms”, adopted in 1998. The substance assessment focuses on the hazardous properties of substances from the viewpoint of human health.

The scope of the assessment depends on the substance’s physico-chemical properties, the level of toxicity to humans and other organisms, the production volume, the amount of people potentially being exposed, economic priority or importance8, presence/concentrations in different environmental compartments, stability and other parameters which may have relevance for defining impacts on human health. There are four stages involved in making decision:

8 If there is economic pressure to use the substance, it is assessed if it is possible to assign MPC by express methods or to assign a temporary norm.

1. Collection and processing information to decide upon setting hygienic norms and the need to conduct further investigations (see Chapter 3.1.1);
2. Comparison of information with the criteria and checking if the assignment of hygienic norms is triggered (Chapter 3.1.2);
3. Defining an investigation plan to be able to define temporary hygienic norms with express methods (see Chapter 3.1.3);
4. Defining hygienic norms in accordance with the full methodology (Chapter 3.1.4).

In Chapter 3.1.5 stability issues as a part of hygienic assessment are reviewed.

3.1.1. Deciding need for setting hygienic norms

The following data are required about a substance to decide on the needs to establish hygienic norms:

- purpose of use;
- production volume, amount used and emitted (emissions to air and discharge to water bodies); both considering the specific installation and the national level;
- type of substance (форма выпуска);
- chemical structure and molecular mass;
- physico-chemical parameters: state (at 20 °C, atmospheric pressure), boiling and melting point, vapour pressure (упругость паров) at 20 °C, density, solubility in water, fat and other media, pH, potential for odours and colouring, reactivity, stability, fate in different environmental compartments;
- toxicological parameters: acute toxicity (LD_{50} for oral and skin exposure, LC_{50} for inhalation), cumulative effects, skin and eye irritation, skin resorption;
- for sensibilisation, reprotoxic, mutagenic and cancerogenic effects specific methodological guidelines are available regarding when investigations should be performed and to what extent/for which exposure routes. Most of these methods were adopted in 1975-1986 and are listed in Annex II.

If data are already available (provided by registrant, available in literature or databases on substance properties, including foreign ones), they are used in the assessment. If information is missing, respective studies are conducted.

3.1.2. Criteria not to establish hygienic norms

If available information about a substance reveals that there is no need to establish hygienic norms, it is possible to stop the assessment procedure. The Hygienic Regulation GN 1.1701-98 defines in Chapter 2 a set of criteria to consider establishing hygienic norms necessary. Taking into account the scope of the current document, only criteria for water are reviewed (not for workplace and ambient air).

For water bodies used for extracting drinking, bathing and household water, the following cases are defined that would not require setting of hygienic norms:

- unstable substances (stability class IV – see Chapter 3.1.5), which decompose to substances having hygienic norms established;
- if substance appears as an impurity in mixtures with stable composition, not being main component in the mixture, and having less hazardous properties than those components recommended to be subject to controlling their discharge to water bodies;
- substances of hazard class IV[9], which may enter into environment only with industrial discharges and if they concentration in normal technological discharge is not exceeding 0,001 mg/l, and not triggering change of organoleptic properties of water;

For extremely hazardous substances, belonging to hormones, cytostatic substances, allergens, and certain groups of antibiotics, which discharge to water bodies is prohibited, also no MPC is established. The issue could be considered as a basis to ban substances regarded as too dangerous for the Russian market. But this decision is not formalised and depends on the opinion of the assessor of the substance.

3.1.3. Defining temporary hygienic norms / using express methods

The Hygienic Regulation GN 1.1701-98 defines in Chapter 3 cases, when hygienic norms, including temporary ones[10], can be established with express methods[11]. Taking into account the scope of the current document, cases for workplace air and ambient air are not reviewed.

Hygienic norms for water bodies used for extracting drinking, bathing and household water can be defined by express methods as follows:

- MPCs for a substance discharged into a water body are defined using a sequential scheme of justification for the norm and the hazard classification. A decision not to define an MPC can only be taken after conducting the first range of investigations (c.f. previous chapter).
- For substances which are solely used in pilot technological processes (для веществ, внедрение которых находится на стадии производственных испыта-

9 Low hazard substances. Definition of hazard classes is given in Table 6 in Chapter 4.2

10 Temporary norms are expressed as “approximate allowed safe level (ODU)”, they are valid until results of full-scale testing become available and MPC is adopted. The ODUs can be only used for control of construction or reconstruction activities of technological lines and wastewater treatment facilities, but not in environmental permitting under normal operational conditions of an installation.

11 There is no definition of „express method“, but it might be considered as screening methods for presence of certain effect.

ний) a temporary hygienic norm could be established with an approximate allowed safe level (ODU) established by calculations and express toxicity test methods.

- It is allowed to use new formulas to calculate the estimation of the toxicity,[12] not approved by the Ministry of Healtcare of the Russian Federation. These may be used only if they are scientifically justified and based on representative cases.
- For a substance suspected to be carcinogenic,[13] the establishment of hygienic norms as express method is allowed and performed as follows:
  - If the substance is a member of a structural row, and MPCs are assigned for a number of substances in that row, then, extrapolation can be performed based on an appropriate method, considering the parameters of closest structural analogues;
  - If the new substance has structural similarity (presence of groups associated to trigger carcinogenic effects) with substances classified as carcinogenic, and which are also classified as mutagenic, justification of the hygienic norm is based on short-term tests quantifying the mutagenic effect(s) as specified in relevant methodological guidelines;
  - If there is no data on mutagenic properties for a substance or its analogues, the substance shall be tested for the presence of cytogenetic effects in mammals; in case the effects are present, relevant methodological guidelines are followed.
  - If there are no cytogenetic effects and the substance has a structural similarity with weak carcinogens, the justification of norms is conducted according to common toxicological or other specific characteristics of these substances.
- For a new substance suspected to be mutagenic, having structural similarity (presence of groups associated to trigger mutagenic effects) with substances having mutagenic effects, and having cytogenetic effects in mammals, a temporary hygienic norm is established according to the relevant methodological guidelines.
- For inorganic substances, for which the toxicity is mostly dependant on the same element, and for organic substances having similar chemical structures, effects and levels of hazardousness, it is recommended to establish an hygienic norm for a whole group of substances.

In case, that there is no justification to avoid the establishment of a hygienic norm or to perform an express assessment, the full assessment shall be performed.

12 It is not explained in the methodology, but similarity to QSAR formulas could be assumed.

13 Based on structural similarity with substances being already classified.

3.1.4. Assessment of toxicological properties

The full assessment of toxicological properties of the substance comprises various endpoints, which are comparable to those assessed for classification purposes, e.g. under the GHS regulation. If data is already available (provided by registrant, available in literature or databases on substance properties) it is used in the assessment. If information is missing, respective studies are conducted. Methodological guidelines used to determine toxic properties of substances are listed here in Annex II.

One of the main purposes of the assessment is to establish maximum permitted concentrations (MPC) of a substance for various environmental compartments (air, water, soil)[14]. Taking into account the scope of this document the methodological guideline on setting hygienic norms for water bodies used for bathing and extracting drinking, and household water (MU 2.1.5.720-98, replacing earlier version from 1975) is reviewed more in detail.

Maximum permissible concentration for household, cultural, and general water use (MPC_w). The MPC_w is a concentration of a harmful substance in the water, below which no direct or indirect adverse effects on human health should occur (if continuously being exposed over the lifetime), or on the health of the next generations, and which should not worsen hygienic conditions of the water use.

The development of an MPC for a substance consists of 6 stages (presented in Table 1). At each stage it is carefully assessed, which further investigations are necessary. There are several calculation methods available at each stage to estimate toxicity parameters and thoroughly plan the next stages of the assessment. Stages 2-4 can be used both for the substance and its degradation products (degradation products are chemically identified in stage 3).

Table 1: Stages of development of hygienic MPC for water bodies used for extracting drinking, bathing and household water

No.	Stage	Investigations performed
1	Preliminary decision	Literature and database research on substance properties, potential biological and pharmacological effects. Studying the production process and/or the use of the substance. Preliminary calculation of hygienic parameters according to physico-chemical parameters, MPC assigned for other media and in other countries, including 'read-across' data of similar substances.
2	Express estimation	Estimation of a substance impact on organoleptic properties of water and sanitary conditions of water bodies. Investigation of potential for degradation. **Stability category is assigned.** Testing acute toxicity parameters, including finding species, sex and age specific differences in sensitivity to a substance. Calculation parameters of chronic toxicity according to DL_{50} (average lethal dose), TL_{50}.(average time of lethality) and combined mathematical models. **Assigning hazard class for a substance.**

14 They are not ecotoxicological endpoints, but assigned from perspective of human health

No.	Stage	Investigations performed
3	Express experiments	Testing sub-acute toxicity parameters. Investigation of effects on reproductive organs based on functional parameters, screening tests for embryotoxic and mutagenic effects. Estimation of skin resorption action. Estimating chronic toxicity parameters and assessment of hazard class for a substance. Identification of degradation products.
4	Testing chronic toxicity	Chronic toxicity tests to investigate general toxicity effects. Evaluation of mutagenic effects and effects on reproductive organs. Evaluation of hazardousness of degradation products. Calculation of safety coefficients, extrapolation of animal test data for humans.
5	Specific investigations	In-depth investigations of cancerogenic, atherosclerotic and allergic effects. Additional investigations of reprotoxic and mutagenic effects. **Justification of MPC for bathing, household and drinking water.**
6	Epidemiological studies	Link between public health and using water containing the substance and/or its degradation products.

Stage 1: Toxicity parameters calculated are average lethal dose DL_{50}, lowest observed chronic effect dose or concentration (LD_{chr} / LC_{chr}), maximum no observed chronic effect dose ($NOED_{chr}$) or maximum no observed effect concentration ($NOECD_{c}$).

Based on received information at Stage 1, the following decisions are made:

- If there is a possibility that the substance can enter water bodies from production, storage, transportation or use, including industrial, agricultural or household use, or released from articles, equipment or reagents, or due to any other factors, including accidents MPC_{w} is developed for the substance.
- If reliable foreign information is available to recommend a value for the MPC, the assessment be concuded at Stage 2 or Stage 3 by proposing that value.
- If literature research reveals that the substance is extremely hazardous (e.g. belonging to narcotics, hormones, having strong carcinogenic, mutagenic effects, etc.), the recommendation is given to prohibit the discharge of the substance with wastewater[15].

Stage 2: At first, the potential to cause organoleptic changes of water ($LC_{org.}$) and to change the sanitary regime of the water body (LC_{san}) are established in any case (no read-across data used or actual hazardousness considered). Stability and fate of the substance in the natural water environment, to heating and in typical water treatment processes (chlorine, ozone- and UV-treatment) is evaluated by applying organoleptic, analytical and biological testing methods. A stability class of the substance according to hygienic criteria is established (see Chapter 3.1.5). In case the substance appears to be unstable (class 3 or 4), further assessment is done in parallel for the substance and its major degradation products.

15 It means discharge from production sites. Use of extremely hazardous substances in consumer goods is prohibited.

The following parameters of acute effects are tested: average lethal dose DL_{50} and average time of lethality TL_{50} in case of oral exposure. If there are data available about the substance's ability to penetrate skin, also acute skin exposure tests are performed. It is also recommended to find out the dose causing effects in case of single exposures (Lim_{ac}).

These parameters together with physico-chemical parameters, biological constants, (Q) SAR relationships and combined mathematical models are used to estimate the relevant parameters for chronic toxicity tests. Also the calculated chronic toxicity parameters from Stage 1 are used. The calculation of trigger doses for skin resorption effects are performed, if considered necessary. Based on the calculated lowest observed chronic effect concentration LC_{chr} and the established $LC_{org.}$ and LC_{san} the substance is assigned to one of the four hazard classes.

Investigations can be finished at this stage in case:

- The substance belongs to a well-investigated structural row of substances having a similar mode of action and estimation methods for chronic toxicity parameters are based on representative data from several substances of the row already having norms established.
- According to the calculated lowest observed chronic effect concentration LC_{chr} and established $LC_{org.}$ and LC_{san} the substance belongs to hazard class 4.
- There is reliable information available that the substance causes no long-term effects.
- The substance is easily hydrolysed within 24 hours and the degradation products already have norms established.

Thus the MPC for hazard class 4 substances and temporary norms (ODU) for class 3-4 substances can be assigned at this stage. In all other cases species, sex and age specific differences in sensitivity to a substance in acute toxicity tests are established and Stage 3 is performed.

Stage 3: Sub-acute toxicity investigations involve testing on:

- General toxicity: studying specific and integrated parameters, while applying every day exposure for the substance to be tested, including releavant metabolites or degradation products. Furthermore, dermal tests are performed for substances showing similar or higher toxicity by skin resorption than via oral exposure as examined already in previous stages.
- Main long-term effects:
  - Impairment of reproduction: investigated at the end of sub-acute testing according to functional parameters;
  - Embryotoxic effect: tested in case the effect is to be effected according to literature data or properties of structural analogues;
  - Mutagenic effect: tested on laboratory animals, e.g. with micronucleus test;
  - Cumulative properties;
  - Substance take-up into organs and tissues, excretion of the substance and/or its metabolites;

The main purpose of sub-acute experiments is to define the lowest observed sub-acute effect doses for the tested endpoints ($ПД_{пэк}$). The results will be used for estimating the lowest observed chronic effect doses ($ПД_{хр}$) and the maximum no observed chronic effect doses (МНД) based on dose- effect relationships. Also the ratios of average lethal dose DL_{50} to the lowest observed sub-acute effect doses $ПД_{пэк}$ are calculated for classification purposes.

In case the general toxicity $ПД_{пэк}$ is at least 10 times lower than $ПД_{пэк}$ for long-term effect, no chronic tests for long-term effects at further stages need to be performed.

During stage 3 the degradation products of substance are chemically identified, if it has been observed in the previous stages that their effects on water quality may be worse than those of the substance itself. It is decided if additional testing of the degradation products is necessary to to better justify hygienic norms of the substance.

MPCs for hazard class 3-4 substances belonging to well-investigated structural rows and temporary norms (ODU) for class 2 substances can be assigned with a 3-stage assessment.

Stage 4: Chronic toxicity tests are considered necessary if at previous stages the substance was classified as hazard class 1 or 2 or if long-term effects were observed. Furthermore, chronic tests may be performed for class 3 substances, if a better justification of hygienic norms is needed.

The duration of chronic tests is 3 months or longer if effects on growth over time are to be observed. Tests are performed with laboratory animals exposed to the substance (or its degradation products) every day. Both LOEC and NOEC are experimentally found. In addition to general toxicity tests investigations of skin resorption, mutagenic and gonatoxic effects are performed.

A 4-stage testing is sufficient to justify MPCs for most of substances belonging to hazard class 1-3, if safety coefficients for extrapolation of animal test data for humans are applied (see Table 5).

Stage 5 is necessary for extremely toxic and highly accumulative substances and in the case that the information about the nature of toxic effects are insufficient. Also, if substances of hazard class 1 have carcinogenic and atherosclerotic effects as well as for investigating specific biological effects, like e.g. allergic reactions, long-term neurotoxic effects, embryotoxic and teratogenic effects. The stage includes life-long tests, developmental studies (1^{st} and 2^{nd} generation), etc.

Stage 6 relies on epidemiologic evidence and is applied if it is possible to identify effects of the substance from the variety of other factors, and/or calculate concentration-risk relationships. The results can be used for correction of the MPC, establishing stricter hygienic requirements and monitoring schedule for wastewater discharge.

3.1.5. Stability in water

The methodological guidelines on setting hygienic norms for water bodies which are used for extracting drinking, bathing and household water (MU 2.1.5.720-98) involve the investigation of the stability of a substance and its degradation in water. Although their primary purpose is the justification of the hygienic MPC, the results can serve as a basis for choosing the most suitable wastewater treatment method.

The stability/degradation investigation involves the following steps:

- Theoretical assessment, taking into account the physico-chemical properties, the technological documentation and the material safety data sheets regarding storage conditions and time and recommended methods for wastewater treatment.
- Preliminary qualitative assessment of biodegradability in natural self-purification processes, or in biological wastewater treatment facilities based on the dynamics of the biological oxygen demand (BOD) measurements.
- If the dynamics of the BOD measurements reveal that the substance may degrade, further investigations in a modelled water body are performed. These investigations involve aerobic biodegradation tests (performed in standardised conditions according to GOST R 50595-3).
- Degradation of the substance is tested with destruction factors normally applied in water treatment processes (chlorine, ozone- and UV-treatment) and food processing (boiling). Stability and degradation is evaluated by applying organoleptic, physico-chemical analytical and biological methods.

Substances are classified according to stability to 4 classes – see Table 2. $T_{1/2}$ is half-period of degradation.

Table 2: Stability classes of substances in hygienic assessment

Stability class	$T_{1/2}$ of natural self-purification	Destruction in UV, heat, etc treatment	Biodegradability (active sludge)		Relevance to the results of hygienic assessment
			Induction time of active sludge	$T_{1/2}$ of degradation	
1. Extremely stable	> 15 days	< 40%	> 25 days	> 4.33 hours	MPC has safety factor 10 and hazard class 1 unit stricter
2. Stable	1-15 days	40-80%	3-25 days	1.5-4.33 hours	MCP has safety factor 3
3. Less stable	1-24 hours	81-95%	2-10 days	0.22-1.5 hours	Degradation products are also given MCP
4. Unstable	< 60 minutes	> 95%	< 3 days	< 0.22 hours	

3.2. Assessment of ecotoxicological properties

Hygienic assessments of substances involve certain aspects relevant to assess ecotoxicological properties. At least among the physico-chemical characteristics to be presented for the assessment the water solubility and the octanol/water partitioning coefficient (Log_{Kow}) are included and different stability aspects, like biodegradation, are investigated and considered.

There is another set of MPCs applicable to waters used for fishery purposes.[16] The respective methodology[17] was elaborated by the Russian Federal Research Institute of Fisheries and Oceanography (VNIRO). In principle, it should be assigned when there is reason to assume that a substance reaches fishery waters.

Setting fishery quality standards for a substance involves the following aspects [3]:

- assessment of effects on the chemical conditions of a water body (dissolved oxygen, oxidisability by Kubel method, BOD_5 and BOD_{20}, change of balance of nitrogen ions: ammonium, nitrites and nitrates);
- assessment of effects on fish feedstock (algae, zooplankton, bentos) and on microorganisms;
- assessment of effects on fish growth and development (eggs, juveniles and adults);
- assessment of effects on commercial quality (e.g. taste);
- evaluation of stability as a pollutant.

An overview of test-species used and tested parameters is presented in Table 3.

If these methods are equivalent with EU/OECD methods, e.g. does bacterial microflora corresponds to “sewage sludge” and the test performed with respective OECD respiration test with activated sludge, needs further detailed comparison of test methods.

Based on assessment results substances are divided into 4 hazard classes (see Chapter 4.2 for the background of classification system):

1. Extremely hazardous with MPC_{fw} < 0,1 µg/l: substance should not be discharged (not detected);
2. Hazardous (toxic, but stable): MPC_{fw} assigned
3. Toxic (stable and not accumulating): MPC_{fw} assigned
4. Hygienic MPC_w is relied upon. [3]

16 Perechen’ rybokhozyaystvennykh normativov: predel’no dopustimykh koncentracii (PDK) i orientirovochno bezopasnykh urovney vozdeystviya (OBUV) vrednych vesheshv dkya vody vodnykh ob”ektov, imeyushchikh pybokhozyastvennoe znachenie. Moskva: VNIRO 1999. *[List of Fishery regulations: Maximum Allowed Concentrations (PDK) and Tentatively Safe Levels of Exposure (OBUV) of hazardous substances to water bodies of water with fish industry. Moscow: VNIRO 1999.]*

17 Metodicheskie ukazaniya po ustanovleniyu ekologo-pybokhozyaystvennykh normativov (PDK i OBUV) zagryaznyayushchikh veshchestv dlya vody vodnykh ob”ektov, imeyushchikh rybokhozyastvennoe znachenie. Moskva VNIRO 1999. [*Guidance on the establishment of ecological fisheries management regulations (PDK and OBUV) of pollutants to water of water bodies of relevance for the fish industry. Moscow VNIRO 1999.*]

Table 3: Species used and parameters tested while setting MPC_{fw} [4]

Species		Parameters to test	
		Main	Supporting
Decomposers	Bacterial microflora	Number of cells. Respiration (by BOD). Concentration of oxygen, ammonium-, nitrite- and nitrate ions	-
Producers	Algae	Overall number of cells, pH of media, concentration of oxygen, ratio of living and dead cells	Biomass. Content of pigments. Rate of photosynthesis
	Macrophytes	Survival, growth of the stem, shoots, roots	Rate of photosynthesis
Zooplankton	Ciliates	Survival, reproduction	Behaviour
	Crustaceans	Survival, fertility, number and age structure of model population	Morphological changes
Zoobentos	Shellfish	Survival, fertility, feeding, weight	Behaviour, morpho-logical changes, oxygen consumption
	Chironomidae	Survival at different stages and duration of stages. Morphological anomalities. Fertility	Behaviour, weight, conditions of larvae and adults
Fish	Embryogenesis	Survival of embryos. Hatching and state of prelarvae	Development anomalies. Biochemical deviations
	Adults	Survival, body weight, anatomical and clinical hanges, feeding, frequency ofd breathing, meat organolpetic properties, cumulativity	Behaviour, biochemical changes

Due to administrative reforms there was change in structures responsible for setting standards for fishery waters (in the meanwhile, the Ministry of Agriculture was responsible, in July 2008 the Federal Fishery Agency was excluded from the Ministry's jurisdiction and fell directly under the control of the Government), and also legal confusion. The methodology to set the MPC_{fw}, including its test methods, was legally (re-)inforced with the Decree of Federal Fishery Agency No. 695 04.08.2009 (registered as an official methodological guideline No. 14702 by the Ministry of Justice in 03.09.2009).

3.3. Assignment of norms (MPCs) for chemical substances

Based on the result of the assessments maximum permitted concentrations of chemical substances for various media are calculated. The NOEC is divided by respective safety coefficients. A general matrix is presented in Table 4.

Table 4: Base information related to the derivation of MPCs [1]

MPC value	Test data (species)	Type of test	Used for
Fisheries water	Most sensitive aquatic organism	Chronic aquatic toxicity Biodegradation, accumulation	Emission limit values to water
Surface water	As above	As above	Emission limit values to water
Atmospheric air	Most sensitive mammal	Chronic, inhalation	Emission limit values for ambient air
Soil	Sediment organisms	Accumulation, biodegradation	Control of soil emissions
Workplace air	Most sensitive mammal	Chronic toxicity, inhalation	Occupational exposure limit values
Food	Most sensitive mammal	Chronic toxicity, ingestion Accumulation	Control of food stuffs

Further, the calculation of an hygienic MPC for water bodies is illustrated. In this case from LD_{chr} the NOED is calculated, which is further transferred to NOEC by taking into account the average weight of a human (60 kg) and a daily water consumption used for drinking and cooking food (3 litres). Thus

$$NOEC = 20 * NOED$$

The safety factors applied are presented in Table 5.

Table 5: Safety factors applied while assigning MPCs

Hazard class	Cumulation safety factor		Long-term effects safety factor		
	DL_{50} / LC	K_3 from general toxicity	Z_{sp}	K_3 from gonadic effects	K_3 from embryogenic effects
Extremly hazardous	$> 10^5$	10	1	10	10
Highly hazardous	10^5-10^3	5	0,1-1,0	5	
Moderately hazardous	10^3-10^2	3	0,01-0,1	3	
Low hazard substance	$< 10^2$	3	0,01	3	

The NOED is then compared with threshold concentrations of organoleptic changes (LC_{org}) and changing sanitary regimes of a water body (LC_{san}). The lowest of them is taken as MCP (or ODU) with indicating the relevant hazard category (i.e. MCP_{tox}, MCP_{org} or MCP_{san}). If the substance appears not to be degradable, the safety factors indicated in Table 5 are applied, i.e. the MCP for extremely stable substances is reduced by 10 and for stable substances by 3.

Fishery water MPCs are elaborated for substances to be discharged in water or if there is the risk that the substance reaches fishery waters. There should be a request from an applicant in order to initiate the elaboration of the MPC for a specific substance.

There is no need to elaborate MPCs for inert and biologically inactive substances[18] like graphite type natural minerals, glass, etc., if sufficient evidence can be provided that they do not contain water-soluble toxic impurities.[19]

3.4. Summary: test methods and data analysis

The test methods of toxicological (for hygienic assessment of water bodies) and eco-toxicological parameters have repeatedly been stated to be similar with EU ones. Also laboratories performing testing have to be accredited (so far according to ISO 17025, GLP system is being still introduced in Russia). Still, the testing results might be difficult to compare (details given in Russian methodological guidelines were not compared with OECD testing guidelines).

If different species are used to test or data from different animals is already available, the lowest results are selected:

1. From the chronic studies conducted on human health properties as well as aquatic toxicity and bioaccumulation, the LC_{50} and LC_0 are determined. The LC_0 value for a specific effect is also called $Lim_{sp.eff.}$ and can be compared to the NOEL used in European chemicals assessment. The Lim value determines the concentration or dose below which the specific effect cannot be observed.
2. The lowest[20] minimal risk levels are then multiplied with specific coefficients to derive so called „maximum permissible concentrations“ (MPCs). MPCs are derived for fisheries waters and bathing waters, for workplace air and environmental air, for food and for soil. (see Chapter 3.4).

18 Biologically inactive substance has $LC_{50} \geq 1\,000$ mg/l for 96 h test. If there is no literature data, test is performed with zooplankton organisms by the laboratory elaborating the MPC.
19 Test performed by accredited laboratories
20 The Lim values for the different specific effects tested are compared and the lowest concentration or dose is taken to derive the MPC. If an MPC for workplace air is derived, the respective test for selecting the Lim value would have to be an inhalation study.

Endocrine disruption is not assessed according to the standard procedure. However, if there are indications of a hormone-like mode of action and/or respective epidemiologic evidence, testing could be carried out.

Applied coefficients: The coefficients to calculate the MPC values depend on the hazardousness of a substance. The more hazardous a substance is (for a specific property), the larger becomes the coefficient to multiply the Lim value with for deriving the MPC value.

The following information is the result of the chemical assessment

- LC_0 and LC_{50} values for specific human health effects based on chronic testing
- LC_0 and LC_{50} values for acute toxic human health effects, also called $Lim_{sp.eff.}$
- Effects on skin and eyes
- LC_0 and LC_{50} for acute and chronic aquatic toxicity as well as bioaccumulation Q potential
- Data on the biodegradability of substance
- MPC values
- Danger classes for different effects based on the MPC values

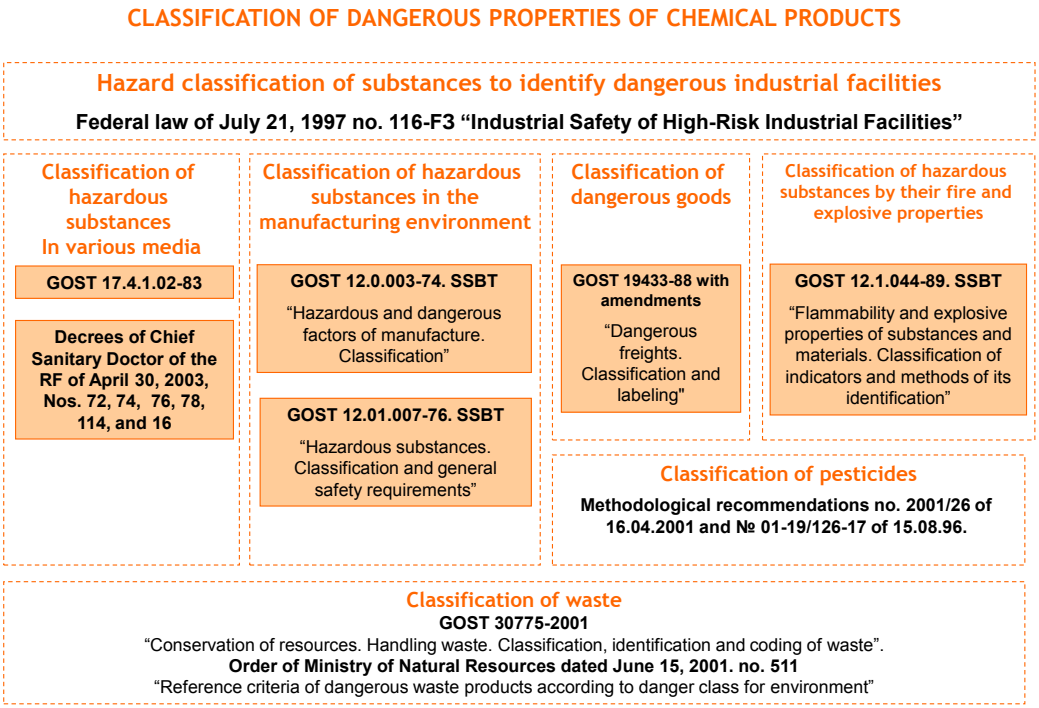
It is an interesting observation that although the substance assessment methodologies reviewed above consider persistence in the environment, the handbook on pesticides [5] is providing persistency data, but referring to the United States Environmental Protection Agency (EPA) relevant classification and WHO recommendations. There is no reference to a Russian system.

4. Classification and hazard communication

4.1. Classification framework

In general, each legal framework has its own classification system of chemicals, i.e. no common classification system and respective criteria currently exist in Russia. The different frameworks are presented in Figure 1. Endpoints to consider in each framework and criteria for classification, i.e. assigning class of danger for each endpoint, are mostly defined by national standards (GOSTs) and methodological guidelines.

Figure 2: Different classification systems of dangerous properties of chemicals



In 2010 it is expected that the Russian Federation will adopt the Federal Law "TR on Chemicals Safety", which will introduce the GHS classification principles both for substancees and mixtures. The classification of mixtures will be performed with calculation methods provided in Annex III of the 'reglament'[21] (Article 7-3). According to Article 18 the new classification system will come into force 24 months after the official publication of the adopted law.

Article 7-4 stipulates that the classification of substances is either based on existing data in the national registry of hazardous substances or by testing, if no data is available. According to Article 7-6 of the draft law it is possible to accept classification not performed in the Russian Federation (if it is foreseen by international agreements). Currentyl, it is still unclear, whether the GHS classification is taken over, or if it is translated into the Russian classification system in an adapted, but corresponding form.

Article 8 specifies that the national registry relies on data found in international registries or lists, and data as well as test results provided by competent national authorities. Details about composing the list will be given by a Governmental Regulation; according to Article 17-2 the regulation should be adopted by the date of enforcing the law, i.e. 12 months after official publication of the adopted law[22]. The National registrty of hazardous substances is approved by Government of the Russian Federation. It is still unclear, if the old registry remains in place, and if each change in the registry needs approval from the government.

It is worthwhile to mention that currently the GHS classification is carried out by the industry only for substances which are exported and where the importing country requires the classification.

4.2. Classes of danger

In Russia, the classes of danger serve for classification purposes. They can be regarded as similar to the EU classification system as they have defined criteria and cut-off values to determine the class of danger. The main systematic difference is that the MPC values are used for the determination of the danger class, which includes the use of a coefficient, whereas in the EU system, primary data from testing are used.

The danger classes are used to regulate substances in a generic way (not using lists or specific properties): Different legislation makes reference to "substances belonging to a certain danger class". For example, substances in the danger classes I or II (regardless for which property) are not to be used in mixtures for consumers.

The criteria for falling into a class (cut-off values) are defined usually by national standards (GOSTs) and are specific for an endpoint and exposure route. Hence, if a substance could fulfil the criteria of Class I for acute toxicity and of Class III for chronic toxicity, for

21 Chapter 4 of the Annex specifies the assessment of physical parameters of mixtures, including cases when testing can be avoided

22 There is a 24 month transition period for implementing the classification, but certain elements shall be in place already within a year.

the final classification, the lowest danger class is selected. In the case of mixtures, the most toxic substance in the mixture is to be identified and its LC_{50} or LD_{50} value is derived for the determination of the hazard class.

The GOST 12.1.007-76 is defining hazard classes for the purpose of classification of hazardous substances and general safety requirements based on health effects. Substances are divided into four danger classes. The danger class I is the most hazardous and the danger class IV means that there are almost no hazards at all. The rating is the following:

- Class I – extremely hazardous;
- Class II – highly hazardous;
- Class III – moderately hazardous;
- Class IV – low hazard.

The parameters considered while defining the danger class are presented in Table 6.

For pesticides 5 classes of danger are used. Combined classification according to health and environmental effects in provided in Table 7.[23]

Table 6: Matrix to determine the class of danger according to health effects (GOST 12.1.007-76)

Parameter	Class of danger			
	I	II	III	IV
Workplace air limit value, mg/m^3	< 0,1	0,1-1,0	1,0-10,0	> 10
Oral LD_{50}, mg/kg	< 15	15-150	151-5 000	> 5 000
Skin LD_{50}, mg/kg	< 100	100-500	501-2 500	> 2 500
Inhalation LC_{50}, mg/m^3	< 500	500-5 000	5 001-50 000	> 5 000
Coefficient of intoxication by inhalation (KVIO) *	> 300	300-30	29-3	< 3
Zone of acute effects **	< 6,0	6,0-18,0	18,1-54,0	> 54,0
Zone of chronic effects ***	> 10+	10,0-5,0	4,9-2,5	< 2,5

* Coefficient of intoxication by inhalation (KVIO): maximum possible concentration of the substance in air at 20 °C divided by LC_{50} for mice.

** Zone of acute effects: LC_{50} of the substance divided by LOEC (lowest observed effect concentration) at the level of organism as a whole, exceeding the level of normal adaptational physiological reactions.

23 There is GOST 17.1.3.04-76 (re-issued in 2004) dealing with classification of pesticides. It is using different classification schemes according to certain effects: toxic effects on warm-blood animals are classified, in reversed order compared to hygienic and fishery norms: hazard class 1 is least dangerous, hazard class 4 extremely dangerous; classification for groundwater uses letters: A – practically not hazardous, D – hazardous, being persistent or almost persistent; there is no classification of pesticides for surface water, only division of pesticides by name to hazard classes 2,3, A-D given. Handbook is referring to other GOSTs. See also Annex IV

*** Zone of chronic effects: LOEC (lowest observed effect concentration) at the level of organism as a whole, exceeding the level of normal adaptational physiological reactions divided by the minimum concentration causing negative effect in chronic tests of the endpoints (exposure 4 hours, 5 days per week in duration not less than 4 months).

Table 7: Matrix to determine the class of danger for pesticides [5] (based on GOST 12.1.005-76)

Parameter	Class of danger				
	I	II	III	IV	V
LD_{50}, mg/kg	< 50	50-200	200-1 000	1 000- 5 000	> 5 000
Work zone air limit value, mg/m^3	< 0,1	0,1-1,0	1,0-10,0	10-30	> 30
Ambient air limit value, mg/m^3	0,005	0,0055-0,04	0,05 - 0,45	0,5-0,95	> 1,0
Water limit value, mg/l	< 0,0009	0,001-0,009	0,01-0,09	0,1-0,9	> 1,0
Fishery water limit value, mg/l	Not detected, 0,0009	0,001-0,009	0,01-0,09	0,1-0,9	> 1,0

Another set of classes of danger is used to determine the risk class of an installation or factory. The substance or mixture with the lowest danger class determines the danger class of the installation. The system is defined by Federal law of July 21, 1997. no. 116-FZ "Industrial Safety of High-Risk Industrial Facilities". High-risk industrial facilities are facilities using hazardous substances or mixtures for the production, processing, formation, storage, transportation, removal or any other use. In fact, this system considers different types of hazards (physic-chemical, toxicological and eco-toxicological endpoints):

- **Flammable gases** – gases that become flammable under normal atmospheric pressure and in contact with air. Boiling temperature at normal atmospheric pressure is 20 °C or lower;
- **Oxidizing substances** – substances supporting burning, inducing inflammation / promoting inflammation of other substances resulting from redox exothermic reaction;
- **Flammable substances** - liquids, gases, dusts, capable of self-ignition, as well as igniting from a fire source, capable to burn independently after its removal;
- **Explosive substances** – substances, which under certain outside influence are capable of instant self-propagated chemical transformation accompanied with emission of heat and formation of gases;
- **Toxic substances** – substances causing death of living organisms and having following characteristics: oral LD_{50} from 15 mg/kg to 200 mg/kg; skin LD_{50} from 50 mg/kg up to 400 mg/kg; inhalation LC_{50} from 0,5 mg/l to 2 mg/l;
- **Highly toxic substances** – substances causing death of living organisms and having following characteristics: oral LD_{50} max. 15 mg/kg; skin LD_{50} max. 50 mg/kg; inhalation LC_{50} max. 0,5 mg/l;
- **Substances dangerous for aquatic environment** – substances having the following indicators of toxicity in aquatic environment: LC_{50} max 10 mg/l (fish, 96 h); EC_{50} max. 10 mg/l (daphnia, 48 h); EC_{50} max. 10 mg/l (algae, 72 h).

4.3. Registration and classification of mixtures

According to the Federal Law of March 30, 1999 No. 52-F3 “On sanitary and epidemiological welfare of the population” the specific types of products for which registration is obligatory, are materials, equipment, appliances and other technical facilities for purification of water, intended for use in water supply systems for industrial and household needs, disinfecting, disinsection and deratization chemicals used in household, medical treatment and prophylactic institutions and other facilities to ensure safety and health of people Household chemicals.

The Government Regulation of April 4, 2001 N. 262 “On state registration for specific types of products posing potential threats to human health, as well as specific types of products imported in the territory of Russian Federation for the first time” further specifies the above list.

The registration of mixtures (products) is performed by regional departments of RosPotrebNadzor. Chemical products which are subject to registration must have a sanitary-technical assessment of the production, the use and the disposal. Based on this assessment, the Public Health Protection Service issues a hygienic certificate for a product.

The assessment procedure performed for a mixture is based on its components is similar to the substance registration:

- Literature search: hygienic norms, data on homological rows of organic substances, norms of other countries, toxicological parameters, predicted or calculated concentrations for the substances in the mixture as well as the mixture as such
- The need for further assessment depends on the purpose of the assessment, e.g. if a mixture with known ingredients and known toxicity is assessed in order to establish a new purpose of use– no tests are carried out.
- If there is suspicion that a mixture contains unevealed components or additive / synergetic toxicological effects could be presumed – tests are conducted to obtain data.

The stage of testing is relatively simple (express techniques are applied to test mixtures) and is taking into account the economic feasibility (including amount of product produced): certain limit tests are carried out, e.g. test on integrated toxicity with *daphnia*.

A risk based approach is implemented in elaborating the testing plan for a product: the extent of testing depends on the knowledge about the properties of its components. If a 1st class substance is used in a mixture as raw material during industrial production, the conditions of the whole mixture shall be classified as 1st class of hazardousness. No calculation method is applied as Russian toxicologists consider that a living organism’s response to exposure from that mixture would not be linear, and the concentration of the substances would not allow predicting the effects. Indeed, normally it is confirmed that effects from exposure to mixtures substantially differ from effects of the most hazardous component.

If there is suspicion that special health effects can occur (carcinogens, etc.) and the product has large production volumes, further specific tests are carried out, e.g. Ames test on mutagenicity or tests on carcinogenic properties, etc.

The assessment of the product is based on Technical Conditions (TU)[24] of the product (composed by the producer). While setting up the testing plan, the conditions of its use are estimated. If release to environment occurs, also an environmental assessment is conducted, but the primary goal of the assessment is the protection of human health. Usually producers choose components for their products in that way, that expensive testing programmes can be avoided

Testing also includes studies on certain properties, e.g. for synthetic washing agents tests of stability/biodegradability, foam forming are performed beside toxicological assessment.

4.4. Labelling

Uniform requirements for labelling did not exist until 1 January, 2009. The following standards were used for different product categories:

- GOST 19433-88 “Dangerous goods. Classification and marking””
- GOST 14192-96 “Marking of cargoes”;
- GOST 9980.4-2002 “Paint material. Marking”;
- GOST 1510-84 “Petroleum and petroleum products. Marking, packing, transportation and storage”;
- GOST 3885-73 “Reagents and super pure substances. Regulations of acceptance, sampling, packing, marking, transportation and storage”;
- GOST 14189-81 “Pesticides. Rules, for acceptance, method of sampling, packing, marking, handling and storage”;
- GOST 14839.20-77 “Commercial explosives. Packing, marking, transportation and storage”

An example of a Russian product label for a paint product according to GOST 9980.4-2002 is given in Figure 2. In Figure 3 is presented labelling example of transport container for paint and varnish product according to requirements GOST 19433-88 and GOST 14192-96.

The labels of chemical products for consumers, falling into the classes III and IV contain instructions for safe use of the substance / mixture. Pictograms are not used on consumer labels. Some producers were using EU product labelling pictograms in parallel with Russian labelling. Also in case of imported products from the EU the original labelling was kept together with the Russian one, although information may be misleading or contradicting.

Transport classification and labelling of substances and mixtures for shipments outside Russia is done in accordance with the rules of the international transport classification and labelling system.

In 2007 the national standard GOST 31340-2007, which enforced common product labelling according to the GHS system since 01.01.2009 was adopted.

24 It is the description of the main elements of production process, the composition of the product, and the description of how the product is used.

Figure 3: Label of a paint product according to GOST 9980.4-2002

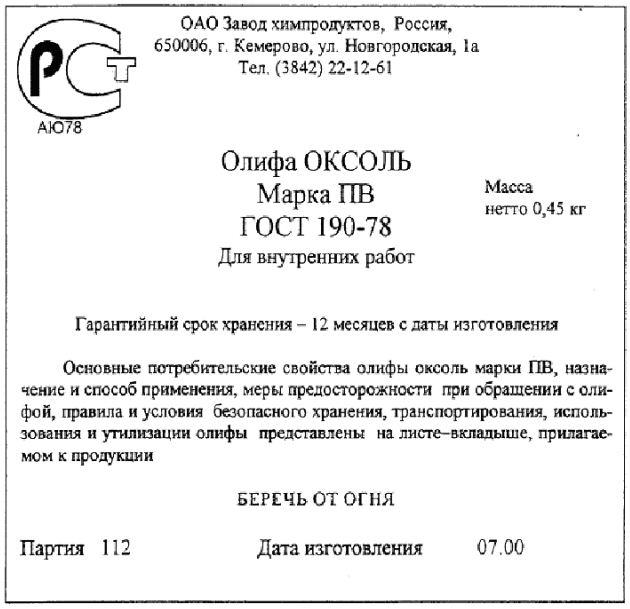
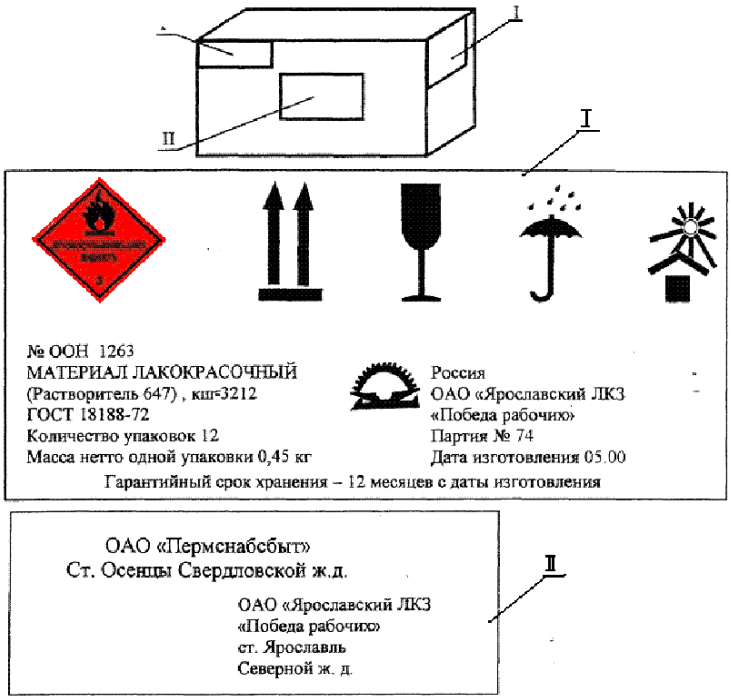


Figure 4: Example of transport cartoon label for a paint product



The future Federal Law, the "Tekhnicheskiy Reglament on Chemicals Safety", will further ensure the implementation of the GHS labelling principles. The new provisions will come into force 24 months after the official publication of the adopted law. Article 11-2 stipulates that labels of products marketed in Russia shall be in Russian language. Other languages may be also present on the label, but the content shall be identical.

4.5. Safety data sheets

Currently there is no clear legally binding requirement to provide safety data sheet in Russia. Still, safety data sheets (safety passports) have been developed in Russia since 1993:

- 1993 – GOST R 50587-93. Substance (Material) Safety Passport. Basic principles.
- 1995 – Adoption of standard of Common wealth of Independent States on SDS: GOST 30333-95 "Substance (Material) Safety Passport. Basic principles. Information on material safety at manufacturing, utilization, storage, transportation and disposal handling"

Safety Data Sheets according to GOST 30333-95 consist of a title page and of 16 sections containing details about the dangers of a chemical. Further, they contain information about measures providing its safe handling (corresponding to requirements ISO 11014.01, however, the exact content differed from previous and current EU practice). The GOST 30333 required that the SDS is presented for examination and registration to the Information and Analytical Centre for Safety of Substances and Materials of RosStandard. A registered SDS is comes with a stamp and a signature on the title page (see Figure 5).

By 2005 more than 13,500 Russian SDS were registered. The legal status of the system and the actual use in practise was unclear — SDS are apparently not used as a hazard communication tool, but entity placing a mixture or substance on the market or the producer of substance or mixture develops it only to fulfil legal requirements. If users request an SDS its supply is charged. It is even reported that some SDS were 30-40 pages in length.

Further, while registering a SDS, the Information and Analytical Center may give recommendations to improve the content of SDS, but producer is not obliged to follow them. It has lead to situation that registry contains several totally different SDS for the same product manufactured by different producers.

In 2007 GOST 30333 was revised. Since 01.01.2009 the content of SDSs provided in Russia should be in full accordance with UN Recommendation ST/SG/AC.10/30 "Globally Harmonized System of Classification and Labelling of Chemicals" and EC Regulation No. 1907/2006 concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

According to GOST 30333-2007 the SDS is an obligatory part of the technical documentation of a chemical product (substance, mixture, material, industrial waste[25]) and should ensure providing the correct information for safe professional handling, as well as for safe household use[26]. The SDS must be provided free of charge. Before producers or importers distribute an SDS, it shall be registered according to a procedure defined by the competent organisation The competent organisation is assigning an expiry date (5 years from date of issue), but in case of availability of new information the SDS shall be revised earlier. After registration a revised version of the SDS is to be distributed to all clients having bought the product within 12 months from date of revision of SDS.

Figure 5: Example of Russian SDS cover page

ПАСПОРТ БЕЗОПАСНОСТИ ХИМИЧЕСКОЙ ПРОДУКЦИИ
(Safety Data Sheet)

Внесен в Регистр

РПБ № 00204872.21.20888 от «06» мая 2009 г.
Действителен до «06» мая 2014 г.

Ростехрегулирование
Информационно-аналитический центр «Безопасность веществ и материалов» ФГУП «СТАНДАРТИНФОРМ»
Руководитель

НАИМЕНОВАНИЕ:

техническое (по НД)	Кальций хлористый технический
химическое (по IUPAC)	Кальций дихлорид (гидрат)
торговое	Кальций хлористый технический гидратированный и кальцинированный высшего и первого сортов
синонимы	Нет

Код ОКП: 215221 0000
Код ТН ВЭД: 2822720000 0

Сведения о регистрации продукции
Свидетельство о государственной регистрации в РПОХБВ АТ-000468 от 10.05.1995 г.; АТ-000555 от 20.07.1995 г.

Условное обозначение и наименование основного нормативного, технического или информационного документа на продукцию (ГОСТ, ТУ, ОСТ, СТО, (M)SDS и т.д.)
ГОСТ 450-77 Кальций хлористый технический. Технические условия.

ХАРАКТЕРИСТИКА ОПАСНОСТИ:
Сигнальное слово: Осторожно
Краткая (словесная): Умеренно опасное вещество по степени воздействия на организм. Вызывает раздражение кожных покровов, слизистых оболочек глаз и дыхательных путей. Может загрязнять водоемы и почву.
Подробная: в 16-ти прилагаемых разделах паспорта безопасности.

ОСНОВНЫЕ ОПАСНЫЕ КОМПОНЕНТЫ	ПДК р.з, мг/м³	Класс опасности	№ CAS	№ ЕС (если имеется)
Кальций дихлорид	2	3	10043-52-4	233-140-8
Кальций хлорид гидрат			10035-04-8	

ЗАЯВИТЕЛЬ: ОАО «Сода» (наименование организации), Стерлитамак (город)
Тип заявителя: производитель, поставщик, продавец, экспортер, импортер (ненужное зачеркнуть)
Код ОКПО: 00204872 Телефон экстренной связи: (3473) 29-78-63
Руководитель организации-заявителя: _____ (подпись) / С.А. Лобастов / расшифровка
м.п.

The future Federal Law “Tekhnicheskiy Reglament on Chemicals Safety”, will further strengthen the position for providing SDS according to the GHS/EC principles. Articles 12-8 and 12-9 are specifying procedures for registration of SDSs. Each registered SDS will have a unique identification number. The scope of the required documentation for

25 As you see, industrial wastes are considered in chemicals safety regulations. It seems to apply for hazardous wastes. Classification of wastes is performed by accredited organisations, one of them being the Russian Register of Potentially Hazardous Chemical and Biological Substances.

26 Consumer can request the SDS.

the registration of an SDS is similar to the substance/product registration by RosPotrebNadzor, in addition, there is the need to provide the certificate of substance/product registration, if registration is required by law. The procedure for registration of the SDS shall be accomplished within 30 days from receiving the application. Article 12-11 specifies cases when an application can be rejected, including lack of required documentation, problems with classification, and lack of compliance of the SDS content with the requirements. Validity of a registered SDS will be 10 years. Conditions for review of SDS are similar as given GOST 30333-2007.

The SDS will be used as a basis for notification of chemical products actually handled in the Russian Federation. According to Article 14-3 of the draft Federal Law "Tekhnicheskiy Reglament on Chemicals Safety" registry shall contain following data about a product:

- registration number of SDS;
- name and designation of the product;
- producer (supplier, importer) of the product;
- amounts released to the market;
- hazardous substances contained in the product provided that these substances influence hazardous properties and hazard class of the product;
- investigations (tests) performed, if any; toxicity and ecotoxicity parameters;
- classification and labelling of the product.

All this information, except amount released to the market and test performed shall be available in public database.

5. Pollution prevention and control measures

It is a common point of view that potential pollutants are not specifically regulated in the Russian Federation when we compare the EU approach of restrictions-prohibition of use, BAT requirement on substitution of hazardous substances used in production processes to less hazardous, principles of water discharge permitting.

Although the measures are not directly comparable, there are some similar elements in place (at least foreseen by legislation).

5.1. Prohibited substances

As referred to in Chapter 2, production, import and use of unregistered substances is prohibited in the Russian Federation. Also, according to the health and environmental legislation the same applies for substances not having MPCs (or temporary norms, ODUs) assigned. While comparing the number of substances used in the EU (ca 108,000 substances in ELINCS/EINECS list) and in the Russian Federation (~18,500 substances considered to have registration), it may be assumed that the registration requirement is not strictly followed.

Pesticides have separate a registration system and it was said to be better functioning [6]. Pesticides allowed for use should be included in National catalog (GosHimKomissija MinSelHozProda of RF, 1998) and in the "List of pesticides and agricultural chemicals allowed for use on the territory of the Russian Federation"[27]. Those substances which do not appear in the list should be considered as prohibited. As some pesticides used previously, during Soviet times, are not in the lists, there might be a lot of obsolete stocks, and therefore still considered in environmental norms / regulations. [5]

Moreover, a specific framework is established for **ozone depleting substances**. Import and export of ozone depleting substances is subject to licensing. In general, import and export, and production of substances in Annex 1 and Annex 2 to relevant governmental regulation[28] is prohibited, certain exemptions are possible. The regulating legal framework is based on the Federal Law on Regulation of Foreign Trade Activities, Federal Law on Ecological Assessment, Governmental Regulation 24.05.1995 No 526 on priority measures to fulfil the Vienna Convention and Montreal Protocol.

27 cited as annexes to Plant Protection Journal. List is published annually.

28 Resolution of the Government Russian Federation No. 563 of 05.08.1996 «On the Regulation of import into the Russian Federation and export from the Russian Federation of ozone-depleting substances and products containing them», as amended. RF Government Decree of 27.12.1996 No. 1560 from 15.11.1997 No. 1423, from 22.02.2000 No. 148, from 30.11.2001 No. 830, from 29.03.2005 No. 166, from 27.08.2005 No. 539)

Another measure is controlling the import of substances. Customs regulations[29] require the declaration of narcotic and psychotropic substances and their precursors, very potent and very toxic substances, chemicals which could be used for production of chemical weapons. In practice it means that import is allowed only in specific cases, including requirement to have special license or permit.

5.2. Prioritisation of pollutants

In general, the legal framework applied in the Russian Federation is not setting priorities according to amounts released (e.g. if in Estonia the annual release of a substance has to exceed 0,001 tonnes to be mentioned in a permit application and in reporting, in Russia it is required to report each gram – actually no threshold limits are assigned) or toxicity (every substance having an MCP should be controlled, e.g. in monitoring programmes).

Since 1997, at least, a risk based approach was recognised among public health protection authorities, when it was concluded that the list of substances subject to compulsory control in surface water bodies used for drinking water supply according to hygienic rule SanPiN 2.1.4.559-96 is not universal for all regions and water bodies. It is impossible to control all substances having MPCs or ODUs assigned (approximately 2,000), and also it is not necessary to protect public health [7]. Instead substances should be selected for regional or water-body based monitoring programmes according to following priorities:

1. Toxicity and hazardousness of the substance (substances of hazard class I and II having potential to cause long-term effects; carcinogenic, mutagenic and reprotoxic substances);
2. Amount in discharges, rate of exceeding assigned MPCs according to monitoring data;
3. Ability of a substances to be retained at drinking water treatment plants;
4. Stability and potential for degradation.

While including substances of hazard class I and II into monitoring programmes, it is recommended to assess if the predicted doses from discharges, etc. have actual relevance for public health [7]. This statement is somewhat in contradiction with the requirement that it is prohibited to discharge substances assigned to hazard class I (extremely hazardous substances).

Certain prioritisation is possible through a pollution charges system. Rates of specific substances that are the most wide-spread are calculated with regard to their relative hazard thereof (the value reciprocal to the maximum permissible concentration, MPC). The rates of fees for air emissions of pollutants by fixed sources are provided for 225

29 The list of products subject to obligatory declaration in written form as they move individuals through the customs border of Russia for the personal use of hand baggage, accompanied and unaccompanied baggage (given in the Letter of RF Federal Customs Service from May 3, 2006 N 01-06/15085)

substances, discharges of polluting substances into surface or ground waters (in rubles per 1 ton) –143 ingredients.[30] The stricter the MPC, the higher the pollution charge rate.

Regional priorities may be set by operators of municipal sewage system operators. Discharge to municipal sewage system is not subject to wastewater discharge permits, but is regulated by contract between operator of the sewage system and client (similar to EU countries). To ensure safety and compliance with wastewater discharge permit issued for the operator, the contract refers to general conditions[31]. These can contain a list of priority contaminants (up to 50 substances and product/group of substances), but they may differ by regions depending on the environmental and/or climatic conditions). [1]

List of substances and relevant limit values for the St. Petersburg region are provided in Table 8.

Table 8: List of hazardous substances having strict discharge limits to St. Petersburg sewage system

Substance	Limit concentration in discharge, mg/l
2,4,6-Trichlorophenol	0,004
Dichloromethane	0,02
Dichloroethane	0,02
Pentachlorophenol	0,001
PCB, PCT	0,0001
Tetrachloroethylene	0,02
Trichloroethylene	0,02
Triethylamine	2
Chloroform (trichloromethane)	0,1
Carbon tetrachloride (tetrachloromethane)	0,002
Benz(a)pyrene	0,0001

In Annex IV a brief classification overview for selected hazardous substances according to different classification schemes (ambient air, water, pesticides) is provided.

30 Regulation of the Russian Government No. 344 of 06/12/2003 “On Standard Fees for Air Emissions by Fixed and Mobile Sources, Emissions of Pollutants into Surface and Ground Water Bodies, Production and Household Waste Disposal”.(revised in 2005).

31 In St. Petersburg: Order of the Committee on Urban Governance Administration of St. Petersburg from 25.11.1996 No. 201 (as amended on 26.08.2005). «On approval of admission of pollutants in wastewater discharged into the sewage system by subscribers in St. Petersburg

6. Summary and conclusions

The Russian Federation has taken the political decision to consider ensuring of chemicals safety as one of the top priorities. The policy is based on improving and strengthening of the relevant institutions and the legal framework, including harmonisation of legislation with the provisions of international law, international treaties and agreements, of which the Russian Federation is a part of. At the same time the changes are progressing slowly. Already in 2004, drafting of a common legal framework on chemicals management issues was a good starting point, including preparations for GHS implementation. However, in 2010 the first TR on chemicals management is expected to be adopted, enforcing classification and labelling according GHS. It also includes a provision for substance registration and safety data sheets.

Requirements for the registration of substances are in place since 1992. Approximately 3,400 substances have been registered. However, about 15,000 substances have been investigated prior to 1992, and those are considered being registered as well. Thus, the situation in the Russian Federation could be considered similar to the EU pre-REACH circumstances with having “old” and “new” substances.

In principle, the registration system in the Russian Federation has similar features with EU registration scheme: an organisation which wants to market a chemical substance will contract an accredited organisation to carry out the substance assessment on a paid basis. Once the assessment is done, the applicant presents the dossier to the competent authority to prepare the registration documentation.

The results of the assessment contain information on hazardous properties of a substance (test results from literature as well as from newly performed studies, classification of substance into different hazard classes) and measures to ensure safe handling together with proposed environmental quality standards (MPCs).

Assessments are performed separately and by different institutions for toxicological properties (hygienic assessment) and for ecotoxicological properties in the aquatic environment (fishery water assessment). Thus there are two types of environmental quality standards for water and different competent authorities for establishing them:

- for hygienic assessments, RosPotrebNadzpor is in charge;
- for fishery water assessments, the Federal Fishery Agency with approval of the Ministry of Natural Resources and Ecology is responsible.

The full procedure of assigning a MPC is not fully described in legislation: if the registrant proposes the MPCs in the documentation, should the MPC be assigned in the legislation by the competent authorities before or after the registration occurs. With hygienic norms it is not a major issue, as the authority confirming MPC and registration is the same. But still it is quite common that a substance is registered and MPCs for human health are assigned, but no MCP for fishery water is assigned. The opposite is also possible: a fishery

MPC is assigned, but the substance is not registered and/or no human health related MPC assigned. Hopefully the situation is improved in the near future as the methodology to set the fishery water MPC, including its test methods, was legally (re-)enforced in September 2009.

It is worthwhile to mention that if test results and product assessments indicate high risks, a temporary registration for two years is given and manufacturing or use of the substance is not prohibited, unless competent institutions have refused to assign MPCs. For extremely hazardous substances, belonging to hormones, cytostatic substances, allergens, and certain groups of antibiotics, for which discharge to water bodies is prohibited, also no MPC is established. The issue could be considered as a basis to ban substances regarded as too dangerous for the Russian market. But this decision is not formalised and depends on the opinion of the assessor of the substance.

If there is economic pressure to use the substance, it is assessed if it is possible to assign MPC by express methods or to assign a temporary norm.

Regarding classification, the current situation is quite complicated — each legal framework related to certain aspects of chemicals management has its own classification system of chemicals, i.e. no common classification system and respective criteria currently exist in Russia. The GHS classification system for substances and mixtures will come into force 24 months after the official publication of the new TR, i.e. as currently expected, not earlier than 2nd half of 2012.

In 2007, the national standard GOST 31340-2007 was adopted, which enforced common product labelling according to the GHS system as of 1 January, 2009

The requirement to provide a safety passport (i.e safety data sheet) for chemical products has been in place since 1993 in the Russian Federation. Since 1 January, .2009 the content of SDS provided in Russia should be in full accordance with GHS and REACH. Before producers or importers distribute an SDS, it shall be registered by the competent organization. It is intended by the adoption of the new TR that the SDS will be used as a basis for notification of chemical products actually handled in the Russian Federation.

Regarding prioritization of substances according to the hazardous properties and amount released, it is not defined in the legislation. There are some regional attempts to establish priority lists.

In general, the legal framework applied in the Russian Federation is not setting priorities according to amounts released. Due to missing legislative demands and the historical background, where chemicals safety equals protection of human health only, there is a lack of awareness among professional stakeholders and the public regarding hazardous substances for the aquatic environment.

While comparing the chemicals management system in the Russian Federation with the EU principles, the following overall conclusions can be drawn:

- The current system fails to assign the responsibility for the safety of products to enterprises as the certification places the responsibility on the authorities.
- Actual enforcement of the legal requirements is problematic, e.g. substances not having sanitary or fishery water MCP assigned are actually marketed; although assigned MCPs are in some cases even stricter than EU ones, it is common that temporary emission limit values are used systematically by the waste water discharge permitting system, which in fact overrule and allow exceeding of previously assigned MCPs
- In Russia, no common classification system exists, each chemicals management framework has its own set of classification criteria.
- The results of the hazard assessment have not been transparently communicated in the past. This is expected to change with the implementation of GHS.
- The system appears compatible to the EU system, however the translation of conclusions from the assessments requires a more scientific assessment of the test methods and parameters used for the evaluation.
- It is still unclear, how efficiently the Russian system deals with articles: the hygienic product certification involves them, but is the use of articles, which could also lead to emissions of hazardous substances, actually controlled?

Annex I. Example of substance registration database entry

Распечатка полной информации по веществу

Регистрационный номер: ВТ 000042 Страница: 1

СТРУКТУРНАЯ ФОРМУЛА:

ХИМИЧЕСКОЕ НАЗВАНИЕ ВЕЩЕСТВА ПО IUPAC: Бензол

СИНОНИМЫ: Циклогексатриен, фенилгидрид

ТОРГОВЫЕ НАЗВАНИЯ:
Бензол

МОЛЕКУЛЯРНАЯ (БРУТТО) ФОРМУЛА C6H6

МОЛЕКУЛЯРНАЯ (АТОМНАЯ) МАССА 78,12

РЕГИСТРАЦИОННЫЕ НОМЕРА:
№ РПОХВ: ВТ 000042
CAS: 71-43-2 RTECS: CY1400000 ELINECS /EINECS/: 2007537

ДАТА РЕГИСТРАЦИИ: 28.04.94 Характер регистрации: постоянно

НТД: ГОСТ 9572-77

ОРГАНИЗАЦИИ ПРОИЗВОДИТЕЛИ / ИМПОРТЕРЫ И ОБЪЕМЫ ПРОИЗВОДСТВА / ИМПОРТА:
1. АООТ "Рязанский нефтеперерабатывающий завод"(Рязанская обл.)
391016, г.Рязань, пос.Никуличи. Факс: (0912) 72-00-84. Телефон: (0912) 72-05-61.

ОБЛАСТЬ ПРИМЕНЕНИЯ:Химическая промышленность

ОРГАНИЗАЦИИ, ПРОВОДИВШИЕ ТОКСИКОЛОГО-ГИГИЕНИЧЕСКУЮ ОЦЕНКУ, ИХ АДРЕСА:

СТЕПЕНЬ ЧИСТОТЫ ВЕЩЕСТВА 98,5 %

ПРИМЕСИ:
толуол 0,5 %
ксилол 1,0 %

---------- 1. ФИЗИКО-ХИМИЧЕСКИЕ ПОКАЗАТЕЛИ ----------

1.1. АГРЕГАТНОЕ СОСТОЯНИЕ: жидкое

1.2. ТЕМПЕРАТУРА КИПЕНИЯ: 80,1 град. С
1.3. ТЕМПЕРАТУРА ПЛАВЛЕНИЯ: 5,5 град. С

1.4. ПЛОТНОСТЬ: 0,879 (г/куб.см)

1.5. РАСТВОРИМОСТЬ
растворимо в жирах: (мг/л)

1.6. СМЕШИВАЕМОСТЬ (ВЕЩЕСТВО-ВОДА) 20 град. С: 91,9

1.8. ЗАПАХ: Выраженный

1.9. РЕАКЦИОННАЯ СПОСОБНОСТЬ: Хлорируется, окисляется, нитруется

1.10. ФОРМА ВЫПУСКА: Жидкость

---------- 2. УСЛОВИЯ ХРАНЕНИЯ И ИСПОЛЬЗОВАНИЕ ----------

2.1. ОСОБЫЕ МЕРЫ ПРЕДОСТОРОЖНОСТИ ПРИ ТРАНСПОРТИРОВАНИИ, ХРАНЕНИИ И ОБРАЩЕНИИ:
Хранить в герметичной таре в вентилируемом помещении вдали от открытого огня на складе ЛВЖ

2.2. НЕСОВМЕСТИМОСТЬ С ВЕЩЕСТВАМИ:Окислители, кислоты, щелочи

2.3. ОПАСНЫЕ ПРОДУКТЫ РАЗЛОЖЕНИЯ:---

2.4. СРЕДСТВА ИНДИВИДУАЛЬНОЙ ЗАЩИТЫ:
респираторы ; защитные очки ; перчатки ; другие

2.5. МЕРЫ ПРИ РАЗЛИВЕ И РАССЫПАНИИ:Собрать и передать на утилизацию

2.6. УТИЛИЗАЦИЯ:Сжигание

---------- 3. ОПАСНОСТЬ ВОСПЛАМЕНЕНИЯ И ГОРЕНИЯ ----------

ПОЖАРОВЗРЫВООПАСНОСТЬ: Да

3.1. ТЕМПЕРАТУРА ВСПЫШКИ: -11,1 град.С

ТЕМПЕРАТУРА ВОСПЛАМЕНЕНИЯ: град. С

ТЕМПЕРАТУРА САМОВОСПЛАМЕНЕНИЯ: 560 град. С

3.2. ТЕМПЕРАТУРНЫЕ ПРЕДЕЛЫ РАСПРОСТРАНЕНИЯ ПЛАМЕНИ: -15-(+13) град. С

3.3. КОНЦЕНТРАЦИОННЫЕ ПРЕДЕЛЫ РАСПРОСТРАНЕНИЯ ПЛАМЕНИ: 1,43-8,0 % объем.

3.4. ВОЗМОЖНОСТЬ ТЕРМОДЕСТРУКЦИИ: Да

ОБРАЗУЮЩИЕСЯ ПРОДУКТЫ:Оксиды углерода

3.5. СРЕДСТВА ПОЖАРОТУШЕНИЯ:пена ; порошок

3.6. ОСОБЫЕ МЕРЫ ПРОТИВОПОЖАРНОЙ БЕЗОПАСНОСТИ:

---------- 4. ТОКСИЧНОСТЬ ----------

4.1. ОСТРАЯ ТОКСИЧНОСТЬ:

тип DL	Значение (мг/кг)	Путь поступления	Вид животного
DL50	1175 - 6400	в/ж	крысы
DL50	4700 - 5000	в/ж	мыши
DL50	299	в/б	мыши

Минимальная смертель- ная доза для человека при поступлении через рот - 50 мг/кг.

тип CL	Значение (мг/куб.м)	Время экспозиции (ч)	Вид животного
CL50	65000	4	крысы
CL50	24000 - 45000	2	мыши

Мин.смерт. концентра- ция для человека при вдыхании в течение 5 мин 60000 мг/м3.

4.2. КУМУЛЯТИВНОСТЬ: Слабая
Метод Lim et al., 1/10 DL50, в/ж, крысы. Ccum 6,9. Ежедневное введение в/ж крысам доз 1/10, 1/20, 1/50 DL50 в течение 30 дней не вызывало гибели животных.

4.3. КЛИНИЧЕСКАЯ КАРТИНА ОСТРОГО ОТРАВЛЕНИЯ:При вдыхании - возбуждение, сменяющееся сонливостью, головная боль, головокружение, одышка, тошнота, рвота, нарушение координации движений, непрерывный тремор, постепенно (см.доп.лист) ослабевающий и сменяющийся судорогами, позже наступает неподвижность; при попадании через рот - рвота, боль в горле, по ходу пищевода, в животе.

4.4. НАИБОЛЕЕ ПОРАЖАЕМЫЕ ОРГАНЫ И СИСТЕМЫ:Центральная и периферическая нервная система, желудочно-кишечный тракт, печень, почки, система крови

4.5. ДОЗЫ (КОНЦЕНТРАЦИИ), ОБЛАДАЮЩИЕ МИНИМАЛЬНЫМ ТОКСИЧЕСКИМ ДЕЙСТВИЕМ (ПОРОГИ ДЕЙСТВИЯ, ИХ РАЗМЕРНОСТЬ, ПУТЬ ВВЕДЕНИЯ, ВРЕМЯ ЭКСПОЗИЦИИ, ВИД ЖИВОТНЫХ.):

	Тип:	Значение:	Размерность:	Путь введения:	Время эксп.:	Вид животного:
1.	ПДхр	0,25	мг/кг	в/ж	6 мес.	крысы
	(по изменению в центральной нервной системе и органах кроветворения)					
2.	ПДостр	0,32	мг/кг	в/ж	однократно	крысы

(по увеличению количества тромбоцитов и снижению лимфоцитов в периферической крови)
3. ПКхр 0,6 мг/м3 инг. 3 мес. крысы
(по изменению иммунологических показателей)
4. Limac 1100 мг/м3 инг. 4 ч крысы
(по изменению морфологического состава крови)
5. ПКзап 2,8 мг/м3 инг.
человек
6. ППКээг 1,5 мг/м3 инг.
(по влиянию на биоэлектрическую активность коры головного мозга)
7. ПКреф 300 - 1000 мг/м3 инг. 40 мин. кролики
(по изменению сгибательного рефлекса)

4.6. РАЗДРАЖАЮЩЕЕ ДЕЙСТВИЕ: На кожу: Да ; На глаза: Да
кожа:
15 мг нативного вещества, выстриженный участок боковой поверхности спины кроликов, 24 ч - слабое раздражающее действие.

кожа:
500 мг нативного вещества, выстриженный участок боковой поверхности спины кроликов, 24 ч - умеренное раздражающее действие.

глаза:
2 мг нативного вещества, однократно, кролики - сильное раздражающее действие
4.7. КОЖНО-РЕЗОРБТИВНОЕ ДЕЙСТВИЕ: Да
Lim ac - 1840 мг/кг, н/к, "хвостовой метод", однократно, крысы.
Lim ch - 64 мг/кг, н/к, "хвостовой метод", 4 мес., крысы (по изменению функционального состояния нервной системы и морфологического состава периферической крови).
4.8. СЕНСИБИЛИЗИРУЮЩЕЕ ДЕЙСТВИЕ: Да
При длительной ингаляции и поступлении в желудок морских свинок и белых крыс отмечено аллергическое действие.
4.9. ЭМБРИОТРОПНОЕ ДЕЙСТВИЕ: Да
Бензол проникает через плаценту.

670 мг/м3, инг., круглосуточно в течение 15 дней до спаривания и в течение всей беременности, крысы-самки - снижение рождаемости (индекса фертильности).

ECmin 56,6 мг/м3, инг., круглосуточно, 1-21 день беременности, крысы-самки - снижение рождаемости (индекса фертильности).

4.10. ГОНАДОТРОПНОЕ ДЕЙСТВИЕ: Да
64 мг/кг, н/к, "хвостовой метод", 4 мес., крысы - изменение структуры гонад.
56 мг/м3, инг., 4 мес., крысы - снижение количества нуклеиновых кислот в мужских и женских гонадах.
5 мг/кг, в/б, мыши-самцы, однократно - увеличение предимплантационной гибели
4.11. ТЕРАТОГЕННОЕ ДЕЙСТВИЕ: Да
56 мг/м3, инг., 4 мес., крысы - у потомства сдвиги в система кроветворения, в функциональном состоянии ЦНС, снижение количества нуклеиновых кислот в мужских и

женских гонадах.
16,3 мг/м3, инг., 6-15 день беременности, мыши - опухоли лимфатической системы (включая селезенку и костный мозг), воздействие на кровь.

4.12. МУТАГЕННОЕ ДЕЙСТВИЕ: Да
Бензол не мутагенен для бактерий, дрожжей, дрозофилы, клеток культуры лимфомы мышей, а также клеток млекопитающих in vivo. Вызывает хромосомные аномалии в клетках млекопитающих in vitro и у мышей и крыс in vivo.
В производственных условиях индуцирует хромосомные аномалии у людей.

Цитогенетический анализ:
1 ммоль/л, 72 ч, лейкоциты человека

Изменение сестринского хроматидного обмена:
0,2 ммоль/л, лимфоциты человека

Незапланированный синтез ДНК:
1 ммоль/л, клетки печени крыс

Доминантные летальные мутации:
1 мг/кг, однократно, в/ж, половые и соматические клетки мышей

Доминантные летальные мутации:
0,2 мг/кг, 12 дней, п/к, половые и соматические клетки крыс

4.13. КАНЦЕРОГЕННОЕ ДЕЙСТВИЕ: человек: Да
Контакт человека с бензолом может вызывать нарушения гемопоэтической системы, в том числе панцитопению. Связь между воздействием бензола и развитием острых миелоидных лейкозов подтверждена эпидемиологическими исследованиями.
В исследованиях, проведенных на 233 предприятиях Китая с обследованием 28460 рабочих, подвергавшихся воздействию бензола, отмечено в 23 случаях - острая лейкемия, в 7 - хроническая лейкемия. Смертность от лейкемии составила 14 на 100 тыс. человека в год. среди людей, подвергавшихся воздействию бензола; в контрольной группе - 2 на 100 тыс. человек в год.
Смертность от лейкемии у рабочих резинового производства органического синтеза контактирующих с бензолом, составила 701 на 100 тыс. человек в год. Концентрации были от 10 до 1000 мг/м3, но в основном укладывались 50-500 мг/м3.
По материалам МАИР доказательства канцерогенности для человека достаточные.
Отнесен в группу 1 (безусловно канцероген для человека):

ECmin 200 мг/м3, инг., 78 недель, человек - лейкемия, тромбоцитопения (канцероген по критериям RTECS).
ECmin 32,5 мг/м3, инг., по 8 ч в течение 10 лет, человек - лейкемия (канцероген по критериям RTECS).
EDmin 200 мг/кг (суммарно 52 г/кг), в/ж, 52 недели, человек - опухоли эндокринной системы, лейкемия (канцероген по критериям RTECS).

КАНЦЕРОГЕННОЕ ДЕЙСТВИЕ: животные: Умеренное

Пероральное введение бензола крысам и мышам мужских и женских особей индуцировало образование опухолей в различных органах. При ингаляционном воздействии у самцов мышей наблюдали анемию, лимфопению, гиперплазию костного мозга и увеличение частоты лимфоидных опухолей.

670 мг/кг, в/ж, 19 недель, - развитие лейкемии.
20 мг/м3, инг., мыши - развитие злокачественных новообразований.
EDmin 31,7 мг/кг (суммарно 2 г), в/ж, 2 года, мыши - опухоли эндокринной системы, лимфогранулематоз.
EDmin 4,9 г/кг (суммарно 1200 г/кг), н/к, 49 недель, мыши - опухоли кожи.

Доказательства канцерогенности для животных достаточные.

Оценка МАИР: группа 1

---------- 5. ГИГИЕНИЧЕСКИЕ НОРМАТИВЫ. ----------

ПДК м.р. (атм. возд.) [мг/м.куб.]:	0,3	; рез.
ПДК с.с. (атм. возд.) [мг/м.куб.]:	0,1	; рез.
ПДК м.р. (раб. зона) [мг/м.куб.]:	15 ; К,+	; пары
ПДК с.с. (раб. зона) [мг/м.куб.]:	5	; пары
ПДУ кожа [мг/см.кв.]: 0,05	; К	; 4 класс опасности
МДУ (пища) [мг/кг]:		
ПДК (вода) [мг/л]: 0,01	; К	; с.-т.
ПДК (почва) [мг/кг]: 0,3		; воздушно- миграционный

ПРИМЕЧАНИЯ, ДОПОЛНЕНИЯ, РАСШИФРОВКА ИСПОЛЬЗОВАННЫХ СИМВОЛОВ:
К - канцерогены
+ требуется специальная защита кожи и глаз

6. КЛАССЫ ОПАСНОСТИ (ПО ПДК):
АТМ. ВОЗДУХ: 2 ; РАБ. ЗОНА: 2 ; ВОДА: 1

---------- 7. МЕТОД ОПРЕДЕЛЕНИЯ ----------

7.1. МЕТОД ОПРЕДЕЛЕНИЯ. ПРИНЦИП, ЧУВСТВИТЕЛЬНОСТЬ, НТД НА МЕТОД:
Раб.зона - газожидкостная хроматография,0,7-10 мг/м3.Методические указания по измерению концентраций вредных веществ в воздухе рабочей зоны.-М.,1981.-
Вып.XVII.-№2328-81.-С.89. Атм.в. - газохроматографический, 0,5 мг/м3. Муравьева С.И. и др. Справочник по контролю вредных веществ в воздухе.-М., Химия, 1988.-(см.доп.лист) С.264.
Вода - фотометрический, 0,1 мг/л.Новиков Ю.В. и др. Методы исследования качества воды водоемов.-М., Медицина.-С.273.
Почва - газохроматографический, 0,01 мг/кг. Руководство по санитарно-химическому исследованию почв.-М., 1993.

8. ПЕРВАЯ ПОМОЩЬ ПРИ ОТРАВЛЕНИИ.
При вдыхании - свежий воздух, покой. тепло. При ослаблении или остановке дыхания - искусственное дыхание методом "изо рта в рот". При попадании через рот - обильное

питье воды, активированный уголь, сульфат натрия (1ст.ложка на стакан воды). При попадании на кожу и в глаза - смыть проточ- ной водой. (см.доп.лист)
Обратиться за медицинской помощью.

---------- 9. ЭКОЛОГИЧЕСКАЯ БЕЗОПАСНОСТЬ. ----------

9.1. СТАБИЛЬНОСТЬ В АБИОТИЧЕСКИХ УСЛОВИЯХ:
t 1/2 = 5,3 сут / 7 - 1 сут. - стабильно /

9.2. ТРАНСФОРМАЦИЯ В ОКРУЖАЮЩЕЙ СРЕДЕ: трансформируется
ПРОДУКТЫ ТРАНСФОРМАЦИИ:

9.3. БИОЛОГИЧЕСКАЯ ДИССИМИЛЯЦИЯ: 10 - 20 % (трудная) ; БД=(БПК5/ХПК)*100% : 16,3
9.4. БПК полное: 1,15 [мгО/дм куб.] ; БПК5: 0,55 [мгО/дм куб.]
9.5. ХПК: 3,07 [мгО/дм куб.]

9.6. ОСТРАЯ ТОКСИЧНОСТЬ ДЛЯ РЫБ.

	Тип	Значение (мг/л)	Вид рыб	Время экспозиции (ч)
1.	CL50	5,8	Morone saxatilis	96
2.	CL50	9,2	Salmo gairdneri (Форель радужная)	96
3.	CL50	34,4	Carassius auratus (Карась серебряный)	96

9.7. ОСТРАЯ ТОКСИЧНОСТЬ ДЛЯ ДАФНИЙ МАГНА [CL50 (мг/л), вид, время экспозиции (ч.)]:
CL50 10 4

9.8. ТОКСИЧЕСКОЕ ВОЗДЕЙСТВИЕ НА ВОДОРОСЛИ (В КУЛЬТУРЕ) [CL50 (мг/л), вид, время экспозиции (ч.)]:
EC(ингибирование роста)>1400 Scenedesmus quadricauda (Зеленые) CL50 525
Chlorella vulgaris (Хлорелла) 48

9.9. ТОКСИЧЕСКОЕ ДЕЙСТВИЕ НА ПОЧВЕННЫХ БЕСПОЗВОНОЧНЫХ [CL50 (мг/л), вид, время экспозиции (ч.)]:

9.10. ВЫЯВЛЕННЫЕ ЭФФЕКТЫ НА МОДЕЛЬНЫЕ ЭКОСИСТЕМЫ:
EC (ингибирование роста) 96 мг/л Pseudomonas putida 16 ч

---------- ЭКОЛОГИЧЕСКИЕ НОРМАТИВЫ. ----------

ПДК для рыбохозяйственных водоемов: 0,5 ,токс., 4 класс опасности

ПДК растения (мг/м куб.):
ПДК древесные породы (мг/м куб.):
ПДК в биосфере (мг/м куб.):
ДОК корма для с/х животных (молочный скот, яйценоские птицы) (мг/кг):
ДОК корма для с/х животных (откормочные животные и птицы) (мг/кг):

ФРАЗЫ И КОДЫ РИСКА.
R: 45-11-23/24/25-48
R11 - Очень огнеопасно (легко воспламеняется)
R45 - Может вызвать заболевание раком
R48 - Опасность серьезного ущерба для здоровья при продолжительном воздействии
R23/24/25 - Токсично при вдыхании, контакте с кожей и попадании в желудочно-кишечный тракт

S: S:53-16-29-44
S53 - Не подвергайтесь воздействию - перед использованием изучите инструкцию по безопасному обращению с веществами
S16 - Беречь от огня - не курить
S29 - Не выбрасывать остатки в канализацию
S44 - При ухудшении самочувствия обратиться к врачу. При себе иметь по возможности этикетку используемого вещества

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10. ДОПОЛНИТЕЛЬНЫЕ СВЕДЕНИЯ:
Внесены изменения в информационную карту 12 апреля 2004 г. Пороговая концентрация по влиянию на органолептические свойства воды по запаху: ПКорг.зап. 5 мг/л. В концентрациях 5-25 мг/л вещество не нарушает процессы самоочищения водоемов. Биодеградация в (см.доп.лист) биотических условиях t1/2 16-28 дней в грунтовых и речных водах.
Максимальная концентрация, которая при постоянном воздействии в течение длительного времени, не вызывает нарушения биохимических процессов воды водоемов: МКб 25 мг/л.
Аварийная карточка: №314. Номер ООН: 1114.

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11. ИСТОЧНИКИ ИНФОРМАЦИИ:
НОРМАТИВНЫЕ ДОКУМЕНТЫ:
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2. ПДК вредных веществ в воздухе рабочей зоны. Постановление Главного государственного санитарного врача Российской Федерации от 30.04.2003, №76. ГН 2.2.5.1313-03, утв. 27.04.2003 г.-М., РПОХВ Минздрава России, 2003.
3. ПДК загрязняющих веществ в атмосферном воздухе населенных мест. Постановление Главного государственного санитарного врача Российской Федерации от 30.05.2003, №114. ГН 2.1.6.1338-03, утв. 21 мая 2003 г.-М., РПОХВ Минздрава России, 2003.
4. ПДК химических веществ в воде водных объектов хозяйственно-питьевого и культурно-бытового водопользования. Постановление Главного государственного санитарного врача Российской Федерации от 30.04.2003, №78. ГН 2.1.5.1315-03, утв. 27.04.2003 г.-М., РПОХВ Минздрава России, 2003.
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7. Перечень рыбохозяйственных нормативов: предельно допустимых концентраций (ПДК) и ориентировочно безопасных уровней воздействия (ОБУВ) вредных веществ для воды водных объектов, имеющих рыбохозяйственное значение. Государственный комитет Российской Федерации по рыболовству, утв. 28 апреля 1999, №96.-М., ВНИРО, 1999.

БАЗОВЫЕ ИСТОЧНИКИ ИНФОРМАЦИИ:

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2. Вредные химические вещества. Углеводороды. Галогенпроизводные углеводородов. Спр. п/р В.А.Филова и др. - Л., Химия, 1990.-, С.115-137.

3. Единая транспортная номенклатура опасных грузов.-М., В/О "Мортехинформреклама", 1989.-, Ч.1.-С.16; Ч.2,3.-С.44.

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Inflammable "F"


Toxic "T"

Annex II. Testing guidelines for substances: toxicological endpoints

- Temporary Methodical Guidelines for Establishing Maximum Permissible Concentrations of Air Pollutants in Residential Areas. No. 4681-88, approved by the Ministry of Health of the USSR on 15.06.88.
  (Временные методические указания по обоснованию ПДК загрязняющих веществ в атмосферном воздухе населенных мест. N 4681-88, утв. Минздравом СССР 15.06.88.)
- Study of Methodical Guidelines for Establishing Sanitary Standards With Regard to Harmful Substances in Working Place Air. No. 2163-80, approved by the Ministry of Health of the USSR on 04.04.80.
  (Методические указания к постановке исследований для обоснования санитарных стандартов вредных веществ в воздухе рабочей зоны. N 2163-80, утв. Минздравом СССР 04.04.80.)
- Methodical Guidelines on Elaboration and Scientific Justification Regarding Maximum Permissible Concentrations of Harmful Substances in Water Basins. No. 1296-75, approved by the Ministry of Health of the USSR on 15.04.75.
  (Методические указания по разработке и научному обоснованию ПДК вредных веществ в воде водоемов. N 1296-75, утв. Минздравом СССР 15.04.75.)
- Methodical Recommendations for Studying Carcinogenic Properties of Chemical Substances and Biological Products in Chronic Animal Testing. No. 2453-81, approved by the Ministry of Health of the USSR on 09.10.81.
  (*Методические рекомендации по исследованию канцерогенных свойств химических веществ и биологических продуктов в хронических опытах на животных. N 2453-81, утв. Минздравом СССР 09.10.81.)*
- Methodical Recommendations for Experimental Justification of Hygienic Standards for Carcinogenic Chemical Substances. No. 3864-85, approved by the Ministry of Health of the USSR on 08.05.85.
  (Методические рекомендации по экспериментальному обоснованию гигиенических регламентов химических канцерогенных веществ. N 3864-85, утв. Минздравом СССР 08.05.85.)
- Methodical Guidelines for Studying the Mutagenic Activity of Chemical Substances When Establishing Their Maximum Permissible Concentration in Water. No. 41110-86, approved by the USSR Ministry of Health on 12.06.86.
  (*Методические указания по изучению мутагенной активности химических веществ при обосновании их ПДК в воде. N 41110-86, утв. Минздравом СССР 12.06.86.)*

- The Methodical Guidelines: “Requirements for Conducting Experimental Studies Regarding Maximum Permissible Concentration of Industrial Chemical Allergens in Atmospheric and Workplace Air.” No. 1.1.578-96, approved by Goskomsanepidnadzor of Russia on 21.10.96. (State Committee for Sanitary and Epidemiological Surveillance)
  (*Методические указания “Требования к постановке экспериментальных исследований по обоснованию предельно допустимых концентраций промышленных химических аллергенов в воздухе рабочей зоны и атмосферы”. N 1.1.578-96, утв. Госкомсанэпиднадзором России 21.10.96.)*
- Methodical Guidelines for Applying Calculation and Experimental Express Methods With Regard to Hygienic Standards for Chemical Compounds in Water Basins. No. 1943-78, approved by the Ministry of Health of the USSR on 08.12.78
  (*Методические указания по применению расчетных и экспресс-экспериментальных методов при гигиеническом нормировании химических соединений в воде водных объектов. N 1943-78, утв. Минздравом СССР 08.12.78.)*
- Methodic Guidelines on Setting Approximate Safe Exposure Levels for Air Pollutants in Residential Areas. No. 2630-82, approved by the Ministry of Health of the USSR on 25.11.82.
  (*Методические указания по установлению ориентировочных безопасных уровней воздействия (ОБУВ) загрязняющих веществ в атмосферном воздухе населенных мест. N 2630-82, утв. Минздравом СССР 25.11.82.)*
- Methodic Guidelines on Setting Approximate Safe Exposure Levels for Harmful Substances in Working Place Air. No. 4000-85, approved by the Ministry of Health of the USSR on 04.11.85.
  (*Методические указания по установлению ориентировочных безопасных уровней воздействия вредных веществ в воздухе рабочей зоны. N 4000-85, утв. Минздравом СССР 04.11.85.)*

Annex III. Comparison of EU and Russian regulation systems for selected substances

1. General remarks

EQS / MPC values for inland surface water bodies are compared (in Russia there are $MPC_{fishery}$ values usually assigned for sea water too)

EQS origin from DIRECTIVE 2008/105/EC, if not otherwise stated

EQS origin from DIRECTIVE 2008/105/EC, if not otherwise stated

Hygienic norms are taken from ГН 2.1.5.1315-03 (enforced from 15.06.2003), if not otherwise stated.

Remarks about registration are not systematically added

2. Highlighing codes used:

Emphasized:	HELCOM / EU substances discussed in COHIBA project
	(please note that for octaBDE, PFOS/PFOA, HBCDD, SCCP/MCCP Russian MPC for water environment were not detected, i.e. they are not included in the table). Also for octylphenol and nonylphenol matches were not found, but their ethoxylates are regulated.
Grey	not exact match, but suspected to be relevant

3. Hazard classes

Class 1:	extremly hazardous; discharge of class 1 substances to a water body used for drinking water extraction and recreational and general use is prohibited according to hygienic norms
Class 2:	highly hazardous
Class 3:	moderately hazardous
Class 4:	low-hazard substance

4. Abbreviations used

EQS	environmental quality standard
MPC	MPC – maximum permitted concentration; similar to EQS, but due to differences, e.g. in averaging periods, terms are not equivalent;
AA	annual average
MAC	maximum allowed concentration
Priority HS	priority hazardous substance
WFD I	Water Framework Directive List I substance
WFD II	Water Framework Directive List II substance
IPPC	substance to be considered in IPPC permitting (no specific water priority)

ELV	emission limit value to St. Petersburg sewage system
Est	MAC according to Estonian legislation
sea	MPC is assigned only for sea water
org	organoleptic norm (smell, taste, foaming)
san	general sanitary norm

Substance	EU regulation		Russian regulations			
	EQS, µg/l	Priorities	$MPC_{fishery}$, µg/l hazard class	$MPC_{hygienic}$, µg/l hazard class	Pollution charge rate, RUB/t	Remarks (e.g. registration)
METALS						
Arsenic	Est: 50	WFD II	50 (III)	10 (I)	5,510	
Cadmium	0.08-0.25 0.45-1.5	priority HS	5 (II)	5 (II)	55,096	
Cobalt (Co^{2+})	-	WFD II	10 (III)	100 (II)	27,548	
Copper (Cu^{2+})	Est: 15	HELCOMW-FD II	1 (III)	1* (III)	275,481	
Chromium, total	Est: 10	WFD II	70 (Cr^{3+} , III)	50 (II) 500 (Cr^{3+})	3,935 (Cr^{3+})	
Chromium (Cr^{6+})	-	HELCOM	20 (III)	-	13,774	
Iron	-	-	100 (IV)	300 (III)	2,755	
Lead	AA 7.2	HELCOMW-FD II	6 (II)	10 (II)	45,913	
Manganese (Mn^{2+})	-	-	10 (IV)	100 (III)	27,548	
Mercury (Hg^{2+})	AA 0.05 MAC 0.07	priority HS	Not allowed (0,01), (I)	0.5 (I)	27,548,091	
Molybdenum		WFD II	1 (II)	70* (III)	229,568	
Nickel	AA 20	HELCOMW-FD II	10 (III)	20 (II)	27,548	
Tin (all salts)	Est: 3	WFD II	112 (IV)	-	2,460	
Vanadium	-	WFD II	1 (III)	0.1 (III)	275,481	

Substance	EU regulation		Russian regulations			
	EQS, µg/l	Priorities	$MPC_{fishery}$, µg/l hazard class	$MPC_{hygienic}$, µg/l hazard class	Pollution charge rate, RUB/t	Remarks (e.g. registration)
Wolfram (W^{6+})	-	-	0.8 (III)	50 (II)	344,352	
Zinc	Est: 50	HELCOM WFD II	10 (III)	1,000 (III)	27,548	
OTHER INORGANICS						
Cyanides	Est: 100	IPPC	50 (III)	70* (II)	5,510	
Sulphides	-	-	5 (III)	50* (smell) (IV)	55,096	
ORGANICS						
Benzene	AA 10 MAC 50	WFD II	500 (IV)	1* (I) 10 (in 2003) 500 (in 1998, class II)	552	
Decabromodiphenyl ether	-	HELCOM	10,000 (sea, cl. IV)	-	-	
Dibutyl pthalate	-	HELCOM	1 (II)	200* (III)	-	
1,2-dichloroethane	AA 10	WFD I	-	3* (I)	2,755	ELV: 20 µg/l
Dichloromethane	AA 20	WFD II	9,400 (IV)	20 (I)	-	ELV: 20 µg/l
Di-(2-etylhexyl)-pthalate		HELCOM	-	8* (I)	-	
Nonylphenol	AA 0.3 MAC 2	Priority HS	300 (III)	100 (org. foam cl. IV)	918	(ОП 7[1])
Nonylphenol ethoxylates	-	HELCOM	10-250 (IV)	100-300 (org. foam cl. IV)	-	Neonol AF 9-4, 9-6, 9-10, 9-12 [2]
Octylphenol	AA 0.1	HELCOM	-	-	-	
Octylphenol ethoxylate	-	HELCOM	250 (IV) 100 (sea)	-	-	Neonol AF 14
PCB		WFD II, review priority HS	Not allowed (0.01), (I)	0.5* (3 and 5 chloro congeners, cl. I)	-	ELV: 0.1 µg/l

Substance	EU regulation		Russian regulations			
	EQS, µg/l	Priorities	$MPC_{fishery}$, µg/l hazard class	$MPC_{hygienic}$, µg/l hazard class	Pollution charge rate, RUB/t	Remarks (e.g. registration)
Pentabromo-diphenyl ether	AA 0.0005	Priority HS	Discharge prohibited[3]	-	-	
Phenol	Est: 1	WFD II	1 (III)	1 (smell) (IV)	275,481	
Tetrachloro-ethylene	AA 10	WFD I	160 (III)	5* (I)	-	ELV: 20 µg/l
Tetrachloro-methane (carbon tetrachloride)	AA 12	WFD I	Not allowed (0,014), cl. I	2 (I)	-	ELV: 2 µg/l
Tetraethyl lead	-	-	-	not allowed (cl. I)	27,548,091	
Tributyltin compounds	AA 0.0002 MAC 0.0015	Priority HS	Not allowed (0.01), cl. II	0.1 (I)[4] 20 (II)[5]	-	
Trichlorobenzenes	AA 0.4	WFD I	1 (II)	30 (smell), (III)	-	
Trichloroethylene	AA 10	WFD I	10 (IV)	5* (I)	-	ELV: 20 µg/l
Trichloromethane (chloroform)	AA 2.5	WFD I	5 (I)	60* (I)	-	ELV: 100 µg/l
Triphenyltin compounds		HELCOM	Not allowed (0,01), cl. I	-	-	
PAH AND DIOXINS						
Benz(a)pyrene	AA 0.05 MAC 0.1	Priority HS	-	0.01* (I)	-	ELV: 0.1 µg/l
2,3,7,8-TCDD		review priority HS	-	0.1* pg/l (I)	-	
PESTICIDES **						
Alachlor	AA 0.3 MAC 0.7	WFD II	1	0.1	-	
Atrazine	AA 0.6 MAC 2	WFD II	5 (III)	2	55,096	
Chlorpyrifos	AA 0.03 MAC 0.1	WFD II	0.01 (I)	2	27,548 091	
Deltametrin	-	-	0.0002 (I)	6	1,377,404 560	

Substance	EU regulation		Russian regulations			
	EQS, µg/l	Priorities	$MPC_{fishery}$, µg/l hazard class	$MPC_{hygienic}$, µg/l hazard class	Pollution charge rate, RUB/t	Remarks (e.g. registration)
Diuron	AA 0.03 MAC 0.1	WFD II	2	200-1,000 (IV)	-	
DDT	AA 0.025	WFD I	Not allowed (0.01), cl. I	2-100 (II)	27,548,091	
Endosulphan	AA 0.005 MAC 0.01	priority HS	0.023 (I)	not allowed	11,977,431	
Hexachloro-benzene	AA 0.01 MAC 0.05	priority HS	-	1** (I)	-	
Hexachloro-butadiene	AA 0.1 MAC 0.6	priority HS	-	0.6** (I)	-	
Hexachloro-cyclohex-ane	AA 0.02 MAC 0.04	priority HS	0.01 (I)	20 org (IV) 100 san (III)	-	
Isoproturon	AA 0.3 MAC 1	WFD II	-	90	-	
Malathion	-	HELCOMW-FD II	0.01 (I)	50 (IV)	27,548,091	
Permethrine	-	-	0.017 (I)	50-70	16,204,759	
Pentachlorophenol	AA 0.4 MAC 1	WFD I	0.5 (II)	1 / 9* (I)	-	ELV: 1 µg/l
Simazine	AA 1 MAC 4	WFD II	2.4 (III)	not allowed	-	
Toxaphene	-	HELCOMW-FD II	-	-	27,548,091	
Trifluralin	AA 0.03	WFD II	0.3 (III)	20 (IV)	918,270	

* As set in 2007 by GN 2.1.5.2280-07

** MPC values for pesticides are taken from „RosHydroMet. Handbook on monitoring of pesticides in the environment. Part II. 2008“ [5], except for hygienic MCP marked with **“, they origin from GN 2.1.5.2280-07

1 ОП 7 (and also ОП 10) is a mixture of polyethyleneglycol ethers of mono- and dialkylphenols, used as a surfactant (e.g. contained in fungicides)

2 Fishery norms are assigned also for following products: Prevocel NCE - 10/16: ethoxylated and propoxylated isononylphenol (99,5 %) 0,05 µg/l (haz. class 4), no hygienic norm assigned; Prevocel NG-12: contains 80 % of the ethoxylated and propoxylated isononylphenol: 500 µg/ml, hygienic norm assigned for NY-12: 100 µg/ml (due to foaming, class 4); corrosion inhibitors containing nonylphenol ethoxylates: СНПХ-6301А: contains Neonol AF 25 %, СНПХ-6302Б: Neonol AF 9-12 , etc. (no hygienic norms assigned)

3 Not considered hazardous, discharge prohibited due to forming bottom layer (named as pentabromodiphenyloxide)

4 Tributyl [(2-methyl-oxypropyl-2-enyl)oxy]tin

5 Tributyltin chloride (tributylchlorotin)

Annex IV. Classification of selected substances according to different Russian schemes

1. **Dioxins** (PCDD), **furans** (PCDF) & dioxin-like polychlorinated biphenyls – **I hazard class** (ambient air)

2a. **Tributyltin** compounds (TBT) – **II hazard class** (recreational water)
2b. Triphenyltin compounds (TPhT) – could not be dentified

3a. Pentabromodiphenyl ether (pentaBDE) – could not be dentified
3b. Octabromodiphenyl ether (octaBDE) – could not be dentified
3c. Decabromodiphenyl ether (decaBDE) – could not be dentified

4a. **Perfluorooctane sulfonate** (PFOS) – **IV hazard class** for atmospheric air
4b. Perfluorooctanoic acid (PFOA) – could not be dentified

5. **Hexabromocyclododecane** (HBCDD) – **IVth hazard class** (air)

6a. **Nonylphenols** (NP) – **III rd hazard class**
6b. Nonylphenol ethoxylates (NPE) –could not be dentified

7a. **Octylphenols** (OP) – **IIIrd hazard class** and **IVth hazard class** for fishery water
7b. **Octylphenol ethoxylates** (OPE) – **IV hazard class** (fishery water). “The forth hazardous class includes substances whose impact is **affecting ecological conditions** in a water body (eutrofication, mineralisation etc.). IIIrd hazard class and IVth hazard class for marine water bodies.

8a. **Short-chain chlorinated paraffins** (SCCP or chloroalkanes, C10-13) - .). **IIIrd and IVth** hazard class.
8b. Medium-chain chlorinated paraffins (MCCP or chloroalkanes, C14-17) – could not be dentified

9. **Endosulfan** – **IV hazard class** – **very hazardous** (for water bodies according to pesticide classification) as well as Class D - hazardous, non-degradable or hardly degradable. Use of endosulfanis prohibited in all subareas of sanitary protection zones.

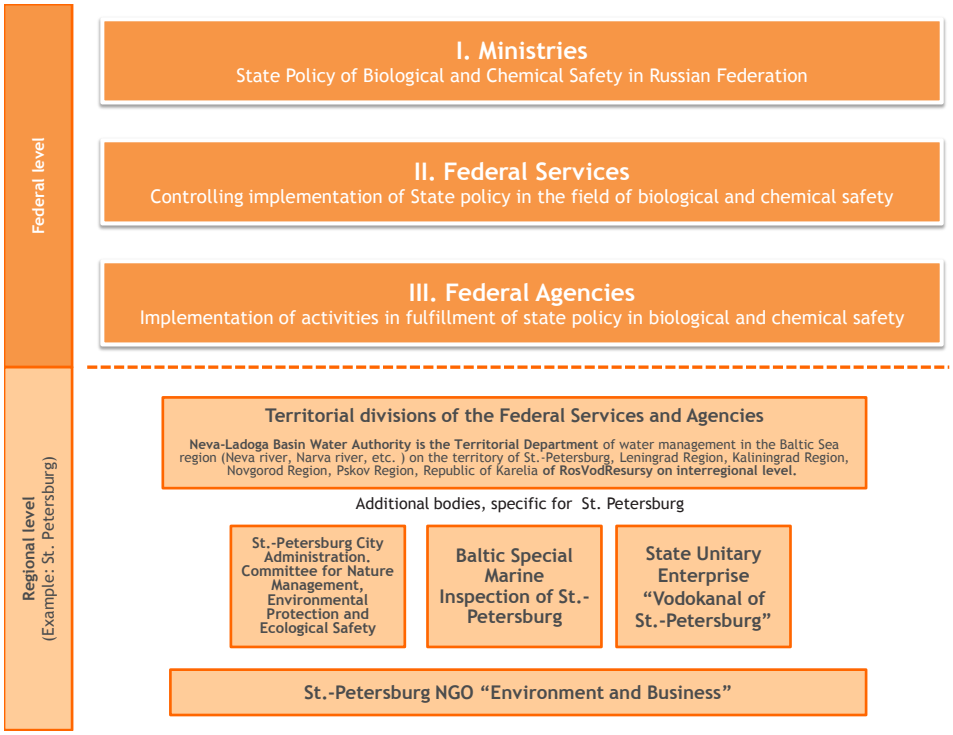
10. **Mercury** (Hg) – **I class** (drinking & recreational water)

11. **Cadmium** (Cd) – **II class** (drinking & recreational water)

Annex V: Institutions currently in charge of hazardous substances and chemicals management

The following section lists all institutions, which could be identified to be currently involved in the management of hazardous substances, as well as in charge of chemicals and biological safety

Schematic institutional setup on Federal and Regional level (example St. Petersburg)



Further explanations can be found on the following pages. Included in this text are organizations of experts which have been consulted during the preparation of this document. See also Reference [1].

A. Federal level

I. Ministries – State Policy of Biological and Chemical Safety in Russian Federation

1. Ministry of Health Protection and Social Development

http://www.minzdravsoc.ru

- Ensuring biological and chemical safety of population in the Russian Federation
- Exercising normative regulation in sanitary and epidemiological welfare of population
- Development and confirmation of Hygienic Regulations, MPC for air and MPC for cultural and household water bodies

2. Ministry of Agriculture

http://www.mcx.ru

- Exercising normative regulation in veterinary and phytosanitary welfare
- Protection of animals and plants in agricultural farms from hazardous substances and chemicals management in agriculture

3. Ministry of Defense

http://www.mil.ru

- Protection of Armed Forces of the Russian Federation from hazardous substances and chemicals

4. Ministry of Emergency (Civil Defense)

http://www.mchs.gov.ru

- Implementing environmental monitoring system in significant sites, evaluation and forecasting of possible pollution areas by hazardous substances in civil defense cases (jointly with RosPotrebNadzor and RosSelhozNadzor)

5. Ministry of Industry and Trade – initiated the Draft Chemical Regulation that had been submitted to the Parliament (currently suspended from adoption)

http://www.minprom.gov.ru

- Fulfillment of requirements of the Convention about biological weapon prohibition and the Convention about chemical weapon prohibition
- Implementation of activities regarding significant biological and chemical sites for reducing their negative impact from technological processes, products and waste products on public health and environment (as well as with RosTechNadzor and Ministry of Emergency)

The Russian Union of Chemists (Russian Chemists Union on the web-page) – Association of chemical industries is in close contact with the Ministry and took part in developing the Draft Chemical Safety Regulation (Draft Technical Regulation on Chemical Safety). They organize workshops and train industries on the topic of REACH requirements, implications on Russian exporters, and registration of chemicals.

- http://www.ruschemunion.ru

6. Ministry of Natural Resources and Environment

- http://www.mnr.gov.ru
  - > Development of Technical Regulations defining the requirements for chemical safety on technical installations
  - > Development of methodologies and rules for setting of MPC and normative permissible discharge/emission (NPD/NPE)

7. Ministry of Foreign Affairs

- http://www.mid.ru
  - > Ensuring biological and chemical safety in the Russian Federation at international level
  - > Co-ordinating Russia's obligations under international treaties

8. Ministry of Internal Affairs

- http://www.mvd.ru
  - > Protection of extra significant state-owned sites using operating with hazardous substance and chemicals

9. Ministry of Transport

- http://www.mintrans.ru
  - > Ensuring safety on all types of transportation used for hazardous biological and chemical cargo

10. Ministry of Economic Development

- http://www.economy.gov.ru
  - > Endorsement of Target Program projects regarding biological and chemical safety in the Russian Federation (jointly with Ministry of Education and Science)

11. Ministry of Education and Science

- http://www.mon.gov.ru
  - > Coordination of scientific and research activities that may contribute to biological and chemical safety in the Russian Federation

II. Federal Services – Controlling implementation of State policy in the field of biological and chemical safety

1. Federal Service for Surveillance in Protection of Consumer Rights and Human Welfare (RosPotrebNadzor)

http://www.rospotrebnadzor.ru

- Supervision over State policy implementation in connection with public health protection and ensuring sanitary and epidemiological welfare of population
- Development and implementation of National Standards and Technical Regulations determining the requirements to biological and chemical safety on technical sites

1.1 Federal State Institution for Health Protection (FGUZ) "Russian Register of Potentially Hazardous Chemical and Biological Substances (RRPHCBS)"

http://www.rpohv.ru

- Conduction of studies on toxicity and hazard assessment of chemical and biological substances
- Providing comprehensive information about properties of substances, regulation systems for safe handling of chemicals on the RF territory
- Development of safety passports (i.e. Safety Data Sheets)
- Development and maintenance of a database on chemicals handled on the territory of Russian Federation (database "Hazardous Substances")

1.2 FGUZ "The Centre for Hygiene and Epidemiology (CHE)"

- Conduction of sanitary and epidemiological evaluation; research, tests, toxicological, hygienic and other assessments.

2. Federal Service for Veterinary and Phytosanitary Surveillance (RosSelhozNadzor)

http://fsvps.ru

- State control for safe handling of pesticides and agrochemicals
- State control for protection of agricultural lands from their pollution by hazardous chemical substances

3. Federal Service for Technical and Export Control (FSTEC)

http://www.fstec.ru

- Development of draft specifications on biological and chemical products that require export control
- Ensuring conduction of export control

4. Federal Service for Safety (FSS)

http://www.gan.ru

- Creating database on biological and chemical safety of Russian Federation including information about transnational terrorist threats (jointly with Ministry of Civil Defense and Ministry for Internal Affairs)

5. Federal Service for Environmental, Technological and Nuclear Surveillance (RosTechNadzor)

http://www.fsetan.ru

- Control and surveillance on safety of industrial sites using hazardous chemicals
- Registration of hazardous industrial site and administrating the state register for such sites

5.1 Centre for Laboratory Analysis and Technical Instrumentation (CLATI)

http://www.clati.ru

- Development of passport for hazardous waste products

6. Federal Service for Nature Management Surveillance (RosPrirodNadzor)

http://www.rpn.gov.ru

- Control and surveillance of use of fauna, forests, water resources and ensuring biological and chemical safety in the Russian Federation

7. Federal Service for Hydrometeorology and Environmental Monitoring (RosHydroMet)

http://www.meteorf.ru

- Monitoring of environment, air and water
- Urgent messaging of information about environment pollution including chemical contamination

8. Federal Intelligence Service (FIS)

http://fsb.ru

- Ensuring protection of the Russian Federation against external biological and chemical threats

III. Federal Agencies – Implementation of activities in fulfillment of state policy in biological and chemical safety

1. Federal Medical and Biological Agency (FMBA) under the Ministry of Health Protection and Social Development

http://www.fmbaros.ru

- Monitoring of hazardous natural pathogens and chemical substances as well as diseases caused by them
- Ensuring protection of population from hazardous biological agents and chemical substances

1.1 Small State Enterprise (MGP) "Regional Toxicological and Hygienic Information Centre " (TOXI) [Expert: V. Smirnov]

On one hand it belongs to the ministerial subdivision within the Ministry of Health, on the other hand, not inside of the governmental structure which allows expressing independent views and come up with critical assessment of governmental initiatives. It does function in a close interaction with ministerial divisions both at the federal and regional (agency) levels, however capable of developing strategy documents and research on innovative solutions (IT models). TOXI has its own accredited laboratory for radioactivity and chemical tests. It has a regional status, therefore may cover larger area than only St.Petersburg

- **Calculation methods for a feasibility of MPC of chemical substance for various environmental media**
- **Assessment of combined effect of chemical substance on the environment and human health**
- **Impact assessment of chemical substance loss by transit**
- **Development and implementation of accountability mechanisms of chemical substance by transport**
- **Development of integrated environmental and hygienic regulation of chemical substance circle**
- **Development of methods for environmental impact and human health assessment**
- **Development of information monitoring systems of potentially hazardous substances, waste and dangerous goods transport**
- **Evaluation of technological methods for the control of hazardous substance handling**
- **Sanitary-hygienic expertise:**
- **Sanitary hygienic examination of production, protection and treatment plants, agricultural lands;**
- **Sanitary hygienic expertise with issuing certificates transmitting and antenna-feeder devices**

2. Federal Agency on Science and Innovations (RosNauka)

http://www.fasi.gov.ru

> Organization and ensuring implementation of research, technical and innovation projects for improved biological and chemical safety in the Russian Federation

3. Federal Agency on Technical Regulation and Metrology (RosTechRegulirovanie)

http://www.gost.ru

> Examination and preparation of technical reviews of draft federal target programs in connection with negative impacts of hazardous biological agents and chemical substances on humans and environment

4. Federal Agency of Water Resources (RosVodResursy)

http://voda.mnr.gov.ru

> Activities on water resources protection for biological and chemical safety

5. Federal Agency of Forestry (RosLesHoz)

http://www.rosleshoz.gov.ru/

> Monitoring of forests

6. Federal Agency of Fishering (RosRybolovstvo)

http://www.fishcom.ru/

> Development and issuing MPC values for fishery water bodies

Federal services and federal agencies like RosPotrebNadzor, RosTechNadzor, RosPrirodNadzor, RosVodResursy etc. have their representations (called Territorial Departments) in each subject of the Russian Federation on regional (local) level. St.-Petersburg is a separate subject of the Russian Federation and has regional status like Moscow, Karelia.

Saint-Petersburg is also an administrative centre of the North-West Federal District, which is a unit of presidential power delegation. North-West Federal District has a seat of the Plenipotentiary Representative of the President of the Russian Federation whose function is to represent the RF President within the NWFD and ensure implementation of constitutional authority of the head of the state within the District. This division does not interfere with the distribution of the functions listed above.

For the ministerial divisions the following division applies:

Federal level (consisting of 83 Federal Subjects – see further here

http://en.wikipedia.org/wiki/Federal_subjects_of_Russia

B. REGIONAL (Subject of the Russian Federation) LEVEL

St.-Petersburg

I. State governing bodies, state unitary establishments

1. Territorial Departments of Federal Services and Federal Agencies

1.1 Neva-Ladoga Basin Water Authority is Territorial Department of RosVodResursy on interregional level.

http://voda.mnr.gov.ru

- State water management in the Baltic Sea region (Neva river, Narva river, etc.) on the territory of St.-Petersburg, Leningrad Region, Kaliningrad Region, Novgorod Region, Pskov Region, Republic of Karelia

2. St.-Petersburg City Administration. Committee for Nature Management, Environmental Protection and Ecological Safety

http://gov.spb.ru

- State and regional environmental control for air, water resources, soil, industrial waste (incl. hazardous and radioactive wastes) on the territory of St.-Petersburg (for the sites outside of federal jurisdiction)
- State environmental examination (ecological expertise) on the territory of St.-Petersburg
- Development of Ecological Passport of St.-Petersburg

Currently this Committee co-ordinates development of the Concept and further on, Programme of chemical and biological safety for Saint-Petersburg. This activity is executed in compliance with the Federal Target Programme on chemical and biological safety. It sets legal obligations upon each subject of the Russian Federation (regional level) to develop such target programme by each subject of the RF.

Berezin is the focal person in co-coordinating the working group that jointly reviews results of the contracted work (currently Concept, further on the Programme).

3. Baltic Special Marine Inspection of St.-Petersburg

- State control of compliance with transport legislation and environmental requirements on sea shipping and other waterways

4. State Unitary Enterprise “Vodokanal of St.-Petersburg”

http://www.vodokanal.spb.ru

- Implementation of projects regarding reduction of water pollution (biogens: N, P) discharge to Baltic Sea to comply with the HELCOM requirements
- Endorsement of projects of normative permissible discharges (NPD) to municipal sewage system for enterprises of St.-Petersburg
- Restriction of discharge into sewers of certain chemicals (partly following HELCOM recommendations) in concentrations above the established MPCs (PDKs).

II. Nongovernmental organizations (NGO)

1. St.-Petersburg NGO “Environment and Business”

http://www.helcom.ru

- Collection, analysis and systematization of information regarding environmental status of the Russian area of the Baltic Sea under the Helsinki Convention. Prepares reports on Russia’s compliance with its HELCOM obligations for submission to HELCOM Secretariat;
- Collection, analysis and reporting for Russia as a leading party on compliance of the HELCOM parties with HELCOM Recommendation 23/7 on Reduction of discharges and emissions from the metal surface treatment;
- Taking part in preparation of HELCOM JCP for Russia
- Implementation of programs, projects following HELCOM resolutions
- Implementation of BALTHAZAR (reduction hazardous and agricultural wastes on Baltic sea) project from Russian side

References

In the following, frequently recurring references are listed. Those references not listed here are marked in footnotes at the relevant places in the text. All websites and online documents were last accessed on 01 March, 2010.

[1] Information given by Russian expert at meetings in May (Tallinn) and November (Riga) 2009 The consulted experts include the following persons:

Igor Berezin: Head of the department. Emergency Response Co-ordination department, Saint-Petersburg Committee for Nature use, environmental protec-tion and ecological safety. Mr. Berezin is in charge of developing regional programme within chemical, biological and radiation safety in the area of Saint-Petersburg.

Igor Kukushkin: Executive Director, Russian Union of Chemists, Member of the Intergovernmental Council of the CIS on standardisation and metrology (WG on REACH and GHS implementation in the CIS countries).The Union represents industrial organisations of the Russian chemical sector. It has been assigned the role of National co-ordinator for the development of Chemical Safety Concept and is a member of the “Responsible Care Initiative”. The Union is the leader within REACH educational services and already has provided about 30 workshops. A Co-ordination and Information Centre assisting CIS companies in the issues of products chemical safety has been established with participation of the Russian Union of Chemists and two research institutions.

Viacheslav Smirnov: Director, Regional Toxicological Information Centre “TOXI”, PhD Med., UNIDO expert. Mr. Smirnov is professionally working with toxicology and environmental protection.

Alexander Startsev: Director General, UNIDO North –Western International Cleaner Production Centre, expert of the Public Council of RosPrirodNadzor. Besides managing the North-West CPC has other roles at a political level within chemical safety issues assisting Deputy Chairman of the Environmental Committee of the State Duma of RF. He is an expert of the Top-level Environmental Council in Saint-Petersburg and represents Ministry of natural resources at the Public Council of RosPrirodNadzor.

[2] Web-page of Russian Register of Potentially Hazardous Chemical and Biological Substances (http://rpohv.ru/lang/en/)

[3] XuMuK.ru. Article 6.2 „Control of pollutants in water bodies“ (in Russian). http://www.xumuk.ru/ecochem/18.html

[4] O. F. Filenko: Biologicheskie metody v kontrole kachestva okruzhayushey sredy. Ekologicheskie sistemy i pribory No. 6. 2007 g. [Biological methods for controlling the quality of the environment. Ecologcial systems and equipment No. 6/2007]. www.ecoguild.ru/docs/2007-06-18-20.doc

[5] RosHydroMet. Handbook on monitoring of pesticides in the environment. Part II. 2008 (in Russian)

[6] Results of BACCON Rus 1 project, October 2004 - December 2005. More information available from the Baltic Environmetal Forum Latvia, Riga. http://www.bef.lv.

[7] Informacionnoe pis'mo Departamenta Gossanepidnadzora Minzdrava RF ot 7 avgusta 1997 g. N i/109-111 "O spiske prioritetnykh veshchestv, soderzhashchikhsya v okruzhayushej srede i ikh vliyanie na zdrov'e naseleniya" [*Informational letter of the Department Gossanepidnadzor of the Ministry of Health of thr Russian Federation of 7 August, 1997. N i/109-111 "About the list of pirority substances occurring in the environment and their influence on the health of the population"*]

[8] Results of HES II Project (2007-2009). Report 10-5. http://www.ippc-russia.org

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Baltic Environmental Forum Latvia
Doma laukums 1-53
LV-1050 Riga
www.bef.lv

Baltic Environmental Forum Germany
Osterstraße 58
D-20259 Hamburg
www.bef-de.org

Baltic Environmental Forum Estonia
Liimi 1
EE-10621
www.bef.ee

Center for Transboundary Cooperation – St. Petersburg
Kozhevennaja linia 34-411
199106 Saint Petersburg
www.ctcsbp.ru

For more information, there is an electronic glossary of terms related to hazardous substance management in the European Union and Russia. It was prepared with the aim to fill a gap in the common understanding of both systems of Russia and the EU by comparing the related terms to each other. This comparison is available in Russian and English.

http://hs.befgroup.net/.