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Comparison of hazard concept

In the EU the term hazardous substance is legally defined by the classification and labelling regulation (Regulation number 1272/2008) and clear methods and criteria exist to determine whether or not a substance is hazardous (and needs to be classified and labelled). In the Russian Federation no legal definition of „hazardous substance“ exists – all substances are considered as potentially hazardous. Nevertheless, substances and mixtures which undergo an assessment under the Russian system are assigned to so called danger classes, which are defined by substance properties such as acute toxicity, sensitisation or aquatic toxicity. In the near future the adoption of the GHS classification and labelling system is expected in the Russian Federation.

The understanding of the concept of a „hazardous substance“ in the context of environmental protection has evolved in the EU over the last 20 years. The concept not only includes the aquatic toxicity but also properties such as bioaccumulation and persistence. It also considers severe health effect, such as carcinogenicity, as relevant because of potential bioaccumulation of substances in the food chain. In the Russian Federation, the general understanding of a hazardous substance is that it is toxic to human health. Properties like the aquatic toxicity of bioaccumulation, even if known as critical parameters, are not normally brought forward as priority issue.

With the introduction of REACH, in the EU a new registration system was established covering the manufacture, import and use of substances as such, in mixtures and in articles on the EU market. Some substance are exempted from REACH, as detailed legislation already exists (e.g. pharmaceuticals), some are exempted from specific requirements. Each manufacturer and importer is to register separately and is responsible for the completeness and quality of the information submitted and conclusions drawn on safe manufacture and handling.

In the Russian Federation, substances also have to be registered if imported or manufactured. Production, import and use of unregistered substances are prohibited. For the registration, the manufacture and importer is to provide information to an accredited institution that is entitled to carry out respective scientific assessments to prepare the registration. The institutional setup and actual performance of the registration system confirms the focus on the protection of human health.
Since 1992 approximately 3 400 substances have been registered, but the situation seems to be similar with pre-REACH new/existing substances system in EU - about 15 000 substances have been investigated prior to 1992, and those are considered as being registered as well. Specific registration schemes under different Ministries and subordinated bodies exist for pharmaceuticals, pesticides and other plant protection products, agricultural and forestry growth regulators.

The testing requirements for a registration under REACH depend on the registered tonnage, the dangerous properties and, for the higher volume substances, on considerations regarding potential exposures. In the Russian Federation, the degree of testing needed depends mainly on the potential hazard class, i.e. the existing or obtained during testing knowledge on hazards. Basic information is always required in both systems.

In managing risks from hazardous substances, priority setting has been an essential exercise in the EU during the past years, due to the high number of different substances on the market. Therefore, a system for prioritizing substances for taking action has been developed: in many environmental and chemicals legislation, substances are screened with regard to the relevant substance properties (in the context of environmental protection persistence, bioaccumulation, aquatic toxicity, CMR and endocrine disruption). In a second step the potential levels of exposures are estimated and assessed, mostly based on the produced amounts and the types of uses (industrial and professional processes) and applications (final products).

In the Russian Federation priority setting on chemical risks (and also at more general level) has not been observed as important issue or routine exercises at the level of legislation making or implementation. However, the degree of danger in terms of the severity of a potential health hazard is considered while setting limit values and assigning danger class for a substance.

In the EU, priority setting and decision taking on chemicals is a multi-step and multi-stakeholder process, involving an assessment of pro´s and con´s as well as the effectiveness of different measures including an assessment of societal risks and benefits. At the end, different legal and economic instruments are used to implement the risk management measure at EU (or national) level that has been found appropriate.

In contrast to this, in the Russian Federation decisions on the prohibition or setting of limit values is taken at central level. Stakeholder consultations or assessments of different options for legislation are not normally applied. The most frequent measure is the setting of limit values (workers protection, environment, ad also consumer-related, e.g. drinking water norms), which are then further used in permitting and other downstream legislation. The bans-restriction system is not commonly used, although the substance assessment methodology allows assigning limit values for most problematic substances (which equals as prohibition on use). However, class 1 and 2 substances are prohibited to be used in consumer products in general.

Regarding the scientific logics of the assessment of hazards and derivation of limit values, the two systems in the EU and Russia are comparable: at an abstract level, testing results are used to derive the concentrations or doses below which no effects are observed (EU: NOEC, in Russian methodology referred as 0-effect concentrations or LIM values). Based on these and using different factors to take account for extrapolation of study results to real life and other uncertainties, threshold values are

derived. These are then translated into legally binding limit values[1]. These values may then be used to derive emission limit values, e.g. in the permitting process of installations or to define permissible contents of substances in product.

In the EU the focus of chemicals management has changed from regulating only big installations to a lifecycle approach, taking account of the fact that a high share of emissions actually occurs during the use of hazardous substances in smaller installations or professional uses. Furthermore, the use of end-products, mixtures as well as articles, has got more and more attention as a core emission source of hazardous substances.

Whereas the use of mixtures in installations is in the focus of environmental permitting in the Russian federation, emissions from mixtures and articles in consumer uses do not seem to play a role in the assessments for substance registrations or the general priority setting in chemicals risk management. How the use of substances in mixtures and articles is specifically regulated, e.g. via existing standards (GOSTs) and hygienic certificates is yet to be further assessed before respective conclusions can be drawn.

[1] In the EU_ workers - occupational exposure limit values (OELs); consumers - acceptable daily intakes or exposures; environment - environmental quality standards (EQS). In the Russian Federation, maximum allowable concentrations (MAC or MCP) or doses are defined. Although Russian authorities consider their MPC to be stricter than EQS in the western European countries, the actual comparison of the values does not give any systematic trend.

Comparison of permitting (some extracts from HES II project report 8-2)

General principles: Setting environmental objectives

The role of the permitting system and the functions required of it must be considered in the context of the overall environmental regulatory system. The overall system is generally seen as a cycle that starts with policy planning and the setting of environmental standards and objectives, together with establishment of legislation and regulations in order to give them legal effect. It is the legal framework that gives force to the interacting activities of permitting, compliance control and promotion, and enforcement. Assessment of the success of the system in achieving its objectives may then be fed back to the appropriate part of the system by way of a commitment to continuous improvement of the overall system (see Figure 1). Therefore, permitting is only one element of the environmental regulatory system, and reaching environmental objectives requires attention to all elements and to the way they interact with each other.

The EU policy areas are grouped in the following environmental themes [source: http://ec.europa.eu/environment/newprg/strategies_en.htm] :

- Air
- Biotechnology
- Chemicals
- Civil protection and environmental accidents
- Climate change
- Environmental economics
- Enlargement and neighbouring countries
- Health
- Industry and technology
- International issues
- Land use
- Nature and biodiversity
- Noise
- Soil
- Sustainable development
- Waste
- Water

Priority policy-making areas for a certain period are set out in an environmental action programme framework. The Sixth Environment Action Programme of the European Community 2002-2012 sets following Thematic Strategies:

- Air
- Waste prevention and recycling
- Marine Environment
- Soil
- Pesticides
- Natural resources
- Urban Environment

The Thematic Strategies will be reviewed in 2010

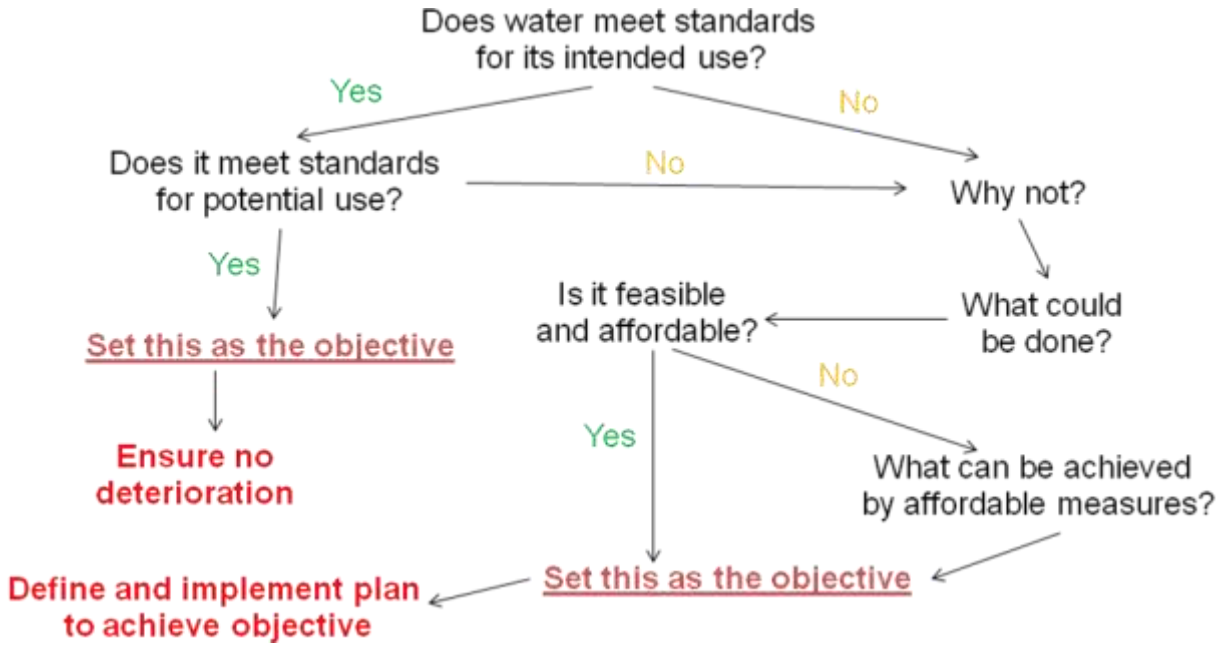
The Thematic Strategies are a modernisation of EU environment policy-making, taking a broader, strategic approach. The Thematic Strategies build on the existing EU legal/regulatory framework and include new knowledge on threats to human health and the environment. They focus on an integrated approach (the effects of decisions in one policy area which has consequences on the others) and on implementation issues.

The Thematic Strategies can be seen as key elements of the Commission's **Better Regulation Strategy** (see Chapter 2.2): they are all accompanied by a thorough impact assessment, assessing the economic, social and environmental impacts of different policy options, extensive stakeholder consultations were held and they aim, where possible, at simplifying the existing regulatory framework.

As confirmed by the Russian experts, there is no similar system of setting objectives. Long term strategic objectives are set usually by President decree, also the Russian Federation has adopted Strategy for Sustainable Development. But action plans how to achieve those are not set since 2000.

However, if Russia wishes to bring its legislation closer into line with EU, the harmonisation process cannot be limited to the technical standards elaborated in EU Directives and guidance documents, e.g. BREFs, but within the wider EU policy objectives and goals.

Figure 1 Decision tree for setting environmental objectives (water as an example)



Purpose of regulatory framework

The European Union has, over the years, developed a sophisticated body of legislation which continues to deliver **economic development**, **environmental protection** and **improvement of social standards**, notably through the completion of the internal market. As progress towards these objectives is being achieved, it has also become clear that the way in which we regulate has considerable impact on whether we meet these objectives efficiently. [source: http://ec.europa.eu/governance/better_regulation/index_en.htm]

In the context of the renewed Lisbon Strategy, refocused on growth and jobs, the Commission has launched a comprehensive strategy on better regulation to ensure that the regulatory framework in the EU contributes to achieving **growth and jobs**, while continuing to take into account the **social and environmental objectives** and the benefits for citizens and national administrations. The EU's Better Regulation policy aims at simplifying and improving existing regulation, to better design new regulation and to reinforce the respect and the effectiveness of the rules, all this in line with the EU proportionality principle.

The Better Regulation strategy is based on three key action lines:

- Promoting the design and application of better regulation tools at the EU level, notably simplification, reduction of administrative burdens and impact assessment.

- Working more closely with Member States to ensure that better regulation principles are applied consistently throughout the EU by all regulators.
- Reinforcing the constructive dialogue between stakeholders and all regulators at the EU and national levels.

Despite the Better Regulation strategy, dialogue between Competent Authority and applicant, and also resulting certain flexibility of the system, have been one of the key principles of the EU permitting system for years.

In the Russian Federation there is mostly no dialogue between permitting authorities and enterprises (but there are some positive examples from regions); moreover the dialogue is not considered necessary by authorities – it has been even expressed that authorites and enterprises are „at the different sides of a barricade". Such legislative and permitting approach has lead to the situation, where most stakeholders admit that it is not possible to fulfil requirements in the legislation, and resulting permitting conditions. At the same time, high standing persons are expressing needs to srentghten penalties for violations, i.e. industry alone seems to be responsible for all miseries ...

Comparison of general principles

Issue	EU	Russia
Defining strategies, setting environmental objectives and action programmes	Regular practice on 17 themes related to environment. For 5 to 10 year periods priority themes are defined and relevant action programmes elaborated	There is no comparable system of prioritisation and defining actions, especially regarding setting objectives and action programmes.
Legal system should contribute to achieving growth and jobs, while taking into account social and environmental objectives	In permitting dialogue between Competent Authority and applicant has been established, enterprises are seen as partners; still permit shall not be issued if environmental objectives established as quality standards are not achieved.	No dialogue, rigid permitting system. Permit conditions can often not be fulfilled and system is considered solely to be a „money making machine". If environmental objectives are not achieved temporary permit is issued, but associated action plans are rarely accomplished.