

## Russia's accession to the OECD: features of chemicals legislative harmonization

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Comprehensive understanding of negative impact on environment and human health, to which the effect of chemicals as a result of their applications actually in all types of industry lead, was forming gradually and at outrance: destroyed ecosystems, heavy increase of various disturbances of human health and mortal diseases furthered recognition of the necessity of international control of chemicals.

Global approach on control of chemicals was formed in 2006 in the frameworks of the conference arranged by the UN ecological program (UNEP) together with WHO, ILO, FAO, UNDP, UNIDO, UNITAR, World Bank, and OECD. On February 6, 2005, during the I session of the International conference on chemicals management (ICCM) in Dubai, over 100 states of the world approved the Strategic approach to international chemicals management (SAICM) in the frameworks of which rational management of chemicals is proposed, that will allow to minimize the material adverse effect of chemical on human health and environment by 2020.

It should be noted that since 1978 OECD has been implementing the Program on chemicals management, and a special authority – Chemicals committee – was formed for its implementation. The program mainly focuses on human health and environment protection from the point of view of chemical safety; prevention of non-tariff barriers in trade; assistance of harmonization of chemicals management systems among the member states and non-member states.

The operations conducted allowed to implement efficient tools, due to which primary goals of the OECD in the field of chemical management are achieved.

Thus, testing, appraisal, systematic study of existing and new chemicals, including nanoscale materials are performed; emission and contamination transfer registers among members and non-members of the Organization are established; operations on prevention of chemical breakdowns are conducted; minimization of contamination with especially hazardous chemicals (mercury, leads, PCBs) of the environment is secured; information interaction,

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including in relation to export of prohibited or strictly restricted chemicals is implemented, etc. Also in the frameworks of the program OECD is actively promoting achievement of goals and challenges, set in the frameworks of the SAICM.

Thus, OECD activity, aimed at security of chemicals of the OECD, has been performed quite long ago and successfully enough, which is conditioned, among other things, by its close attention to environment protection from the very beginning of operation of this international organization.

One of the primary achievements of the OECD in the sphere of international regulation of chemicals turnover is implementation of the system of mutual recognition of information, received at testing of chemicals (hereinafter - MAD system).

In the 90s OECD came to a conclusion that testing of chemicals is a labour intensive and expensive process, repeated testing of chemicals and their testing in several states leads to additional costs. As a result in 1981 the OECD made a decision, according to which information on safety of chemicals, received in the member state of the OECD considering the Guidelines of testing and principles of the good laboratory practice (GLP), developed by the OECD, may be accepted in other member states of the organization. MAD system is based on high requirements to chemicals testing<sup>1</sup>, it represents a basis of information of risk assessment for the human health and environment. Moreover, the system promotes reduction of the number of animals used at testing, and saves time and financial costs, as it excludes necessity of repetition of the conducted tests in other OECD states. Thus, according to the OECD estimates, due to MAD system, its participants save over 153 million euro per year<sup>2</sup>. In opinion of the OECD General Secretary Angel Gurría: “The states, participating in the MAD system, are sure that chemical safety tests, received in other countries, are of high quality. This reduces the necessity of test repetition, saves costs and eliminates potential non-tariff trade barriers”<sup>3</sup>.

All OECD member states are adherent to this system. Since 1997 the MAD system has been open for the OECD member states, as a result of which information received in these member states are accepted in the OECD states for estimation purposes.

Singapore is the first non-member state – participant of the MAD system – from 2010. Later South Africa joined this system, then India did. In 2013 Malaysia joined it. Also Argentina and Brazil are participants of the MAD system<sup>4</sup>. Thailand is a preliminary adherer of the system. The specified status is conditioned by the special order

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<sup>1</sup> OECD standards for testing methods (recommendations of the OECD on testing) and data quality (OECD Principles of good laboratory practice) should be used

<sup>2</sup> URL: <http://www.oecd.org/env/ehs/47813784.pdf>, <http://www.oecd.org/env/48943696.pdf> (date of application 10.04.2014)

<sup>3</sup> URL: <http://www.oecd.org/env/ehs/malaysia-joins-oecd-agreement-on-mutual-acceptance-of-chemical-safety-data.htm> (date of application 10.04.2014)

<sup>4</sup> Full compliance only in relation to industrial chemicals, pesticides and biocides

of implementation of the MAD system in non-member states: first non-member state performs its preliminary compliance in the frameworks of which testing of chemicals is conducted with application of the OECD standards for the testing methods (OECD testing recommendations) and data quality (OECD principles of good laboratory practice). Simultaneously, activities in the OECD states, aimed at adaptation of control programs of compliance with the GDP for the purpose of its harmonization by the used approach in other member states, are conducted. Today a non-member state accepts information on chemicals from the OECD states and other MAD system adherers. Later a group of experts from the OECD states estimate the control program of compliance with the principles of GLP of non-member states, and in accordance with the inspection results, OECD council may invite a preliminary adherer to become a competent participant of the MAD system, having equal rights and liabilities with the members.<sup>5</sup>

It shall be noted that one of the conditions of Russia's accession to the OECD is the availability of laboratories in the country, operating under the GLP principles and mutual recognition of chemical testing results among the member states of the OECD and non-member states, adherent to the MAD system, from the moment of accession. Committee on chemicals will present its official opinion to the OECD council in relation to the readiness and capacity of the Russian Federation to undertake liabilities, related to the membership. This committee is one of the primary committees of the OECD, which positive opinion is mandatory so Russia could obtain the status of a member of the Organization.

Today the work on implementation of OECD requirements in this sphere is conducted in Russia. National program on realization of principles of the OECD GLP in the activity of the Russian testing centers (laboratories)<sup>6</sup> is adopted. The aim of the program is creation of conditions for mutual recognition of testing results, performed in accordance with the specified principles by Russian and OECD countries.

The specified is relevant because provision of mutual recognition of testing results (implementation of the MAD system) is possible only at implementation of the good laboratory practice in the state, as well as confirmation of its compliance with the requirements of the Organization in accordance with the established procedure.

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<sup>5</sup> Recommendations of the OECD council on adherence of non-member states to the documents of the OECD council on mutual recognition of information on assessment of chemicals C(81)30FINAL, C(89)87 FINAL

<sup>6</sup> National program of implementation of OECD GLP in the activity of Russian testing centers (laboratories) in the field of non-clinic laboratory testing of the objects contained in pesticides, cosmetics, medicines for medical use, medicines for veterinary use, food and feed supplements, as well as chemicals of industrial purpose. Approved by the Decision of the Government of the RF dated December 28, 2012 No 2603-p. The program establishes the procedures on its implementation, as well as the Approximate structure of the department program of implementation of GLP principles in the activity of Russian testing centers (laboratories)



As of today, OECD guidelines on testing and principles of GLP are not implemented in Russia in a mandatory manner. Principles of GLP are implemented as interstate standards, introduced in 2010 and 2013<sup>7</sup>. Experience of the European Union, which demonstrates mandatory order of compliance with the GLP principles at conduction of chemical testing, should be noted. Thus, since 1987 the OECD principles have been included into the standard base of the European Union. For example, national requirements of GLP, besides USA, are established in Great Britain, Japan, France, Spain, Italy, Switzerland, South Korea and other EU countries.

Also there is no establishment at the legislative level of mandatory order of mutual recognition of the results of value estimation of certain types of chemical products, if this estimation resulted in accordance with the OECD guidelines on testing and OECD principles of GLP

There is a project of the Federal law “On introduction of changes in certain legal acts of the Russian Federation due to application of principles of good laboratory practice” which provides introduction of change into the group of federal laws<sup>8</sup>, but the order of recognition of application of other OECD member state about the fact that testing results are received in accordance with the GLP principles, if such other state was acting in accordance with the OECD principles, is actually not regulated in this project. The specified among other things is conditioned by the provisions of the Agreement of the Governments of the member states of the Eurasian Economic Community dated January 25, 2008 “On conduction of the agreed policy in the sphere of technical regulation, sanitary and phytosanitary measures” in the frameworks of which it was established that all states accessed to the appropriate international agreements (article 9 of the Agreement).

The specified impedes the complete implementation of the MAD system in Russia. Alongside with this, Decision of CCS dated March 2, 2011 No 564 approved the project of Regulations of good laboratory practice of the Customs Union and a decision to hold intrastate procedures on agreement of the document was made. Alongside in the frameworks of this document the issue refers to the recognition of testing results at the unified customs territory, performed in the laboratories in accordance with the GLP principles, but in relation to the substances contained in the medicines. Today,

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<sup>7</sup> The list is approved by the order of the Government of the RF dated November 08, 2013 under No 2067-p. Includes: GOST 31879-2012 “Principles of good laboratory practice (GLP). Guidelines on monitoring of compliance with GLP principles.”; GOST 31880-2012 “Principles of good laboratory practice (GLP). Guidelines on conduction of inspection of testing centers and examination audits”; GOST 31900-2012 “Principles of good laboratory practice (GLP). Guidelines on preparation of reports on testing centers inspections”. GOST R 53434 – 2009 “Principles of good laboratory practice”, developed on the basis of the Guidelines of the OECD council No 1, enforced on March 01, 2010; other documents came into effect on January 01, 2013.

<sup>8</sup> FL “On circulation of medicines”, FL “On safe handling of pesticides and agrichemicals”, FL “On technical control”, etc.

activities are conducted in the frameworks of the ECE between partners for CU and EEA aimed at achievements of agreements on provision of performance of liabilities by Russia on recognition of laboratory testing results, performed in accordance with the principles of GLP of the OECD after accession to this international organization. In case of positive result the specified will allow Russia to perform its liabilities in full both in the frameworks of regional integration and OECD.

Before adoption of the federal law regulating relations on recognition and further assessment of compliance of laboratories (centers) with the specified principles, the specified recognition and assessment are performed upon the initiative of laboratories (centers) in a voluntary order by Rosakkreditatsiya<sup>9</sup>. Considering the fact that the unity of applicable approaches and methods due to application of OECD documents in the GLP sphere (there are about 150 of them) is the basis of the Program of principles of GLP, assessment of this approach, namely, implementation of laboratory control in relation to their compliance with the GLP principles, will be considered by the OECD in the frameworks of assessment of national GLP programs, including at approval of the decision by the Committee on chemicals concerning the readiness of Russia to comply with the OECD standards. Russia should consider the specified at development of the draft law.

Considering the information reviewed we may come to conclusion about current process of implementation of OECD standards into the Russian legislation in the sphere of turnover of chemicals, which further will allow to provide mutual recognition of results of assessment of properties of certain types of chemicals in an international scale.

For the purpose of exclusion of impediments of Russia's accession to the OECD, it is necessary to adopt available draft laws for the full-rate implementation of the MAD system into the national legal system, under the guidance of the primary documents of the OECD in the sphere of regulation of chemicals, including considering solution of this issue between the partners of the Customs Union and Eurasian Economic Community. In this relation it is reasonable to determine the order of implementation of GLP principles in Russia (mandatory and voluntary), considering international practice and confirm compliance of the applied GLP principles with the OECD requirements in accordance with the procedure, established in the frameworks of the Organization.

Considering potential membership as well as for the purpose of comprehensive interaction on issues of the MAD system implementation into the legal system, Russia should establish interaction with the Committee on chemicals and its auxiliary authorities in the frameworks of special interaction forms of the OECD with non-member states. Considering the ongoing integration process of Russia into the international system of

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<sup>9</sup> Order of the Government of the RF dated 17.12.2013 No 1172 "On recognition and assessment of compliance of testing laboratories (centers) with the principles of GLP of the OECD"// Corpus of legislative acts of the RF", 23.12.2013 No 51 article 6880



chemicals turnover, it is important to provide development of new and more detailed national programs, aimed at conduction of emergency prevention procedures, related to emission release and elimination of their consequences; programs aimed at reduction of impact of leads on the environment; programs on systematic examination of existing chemicals considering appropriate guidelines and principles of the OECD (e.g. Guidelines for preparation of reviews on chemicals) for the purpose of harmonization of national legislation with the OECD standards in the field of regulation of chemicals. Achievement of specified tasks will further approval of the policy conducted in Russia in this sphere by the Committee on chemicals, which will positively influence the general assessment of the OECD council concerning readiness of Russia to become a member of the organization.

Also the specified will allow bringing of national legislation in compliance with the international standards, due to which Russia will be able to expand international partner relations in the field of chemicals turnover as a legally competent member, that correlates with the priority directions of the foreign economic activity of Russia, including those, marked in the Strategy 2020<sup>10</sup>.

### **BIBLIOGRAPHY:**

Order of the Government of the RF dated 17.11.2008 No 1612-r "On the concept of long-term social and economic development of the Russian Federation for the period till 2020" //Corpus of legislative acts of the RF dated 24.11.2008 No 47, page 5489

Order of the Government of the RF dated 17.12.2013 No 1172 "On recognition and estimation of compliance of testing laboratories (centers) with the principles of good laboratory practice complying with the principles of OECD GLP"// Corpus of legislative acts of the RF dated 22.12.2013 No 51, page 6880

Decision No 564 of the Commission of the Customs Union "On the draft Regulations on GLP of the Customs Union". Adopted in Moscow on 02.03.2011, document was not published. Access from the reference and legal system "Consultant-plus".

Agreement of governments of the member states of the Eurasian Economic Community dated 25.01.2008 "On conduction of the agreed policy in the field of technical control, sanitary and phytosanitary measures"// Bulletin of international agreements No 8, August 2012.

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<sup>10</sup> According to the order of the Government of the RF dated 17.11.2008 No 1662-p "On the concept of long-term social and economic development of the Russian Federation for the period till 2020" strengthening of relations with rapidly developing countries of Asia, including by means of increase of the Russian export of chemical industry, relates to the priority directions of foreign economic activity of Russia. As it was noted in the study, such Asian states as Malaysia, Singapore, Thailand, India, etc. are adherent to the MAD system.

Decision of the Government of the RF dated December 28, 2012 No 2603-r “On approval of the National program of implementation of principles of GLP of the Organization of Economic Cooperation and Development in the activity of Russian testing centers (laboratories) in the field of non-clinical laboratory tests of objects contained in pesticides, cosmetics, medicine for medical application, medicines for veterinary application, food and feed supplements, as well as chemicals for industrial purposes // Corpus of legislative acts of the Russian Federation dated 14.01.2013 No 2, page 134.

Order of the Government of the Russian Federation dated November 8, 2013 No 2067 “On approval of the list of documents in the field of standardization, compliance with the requirements of which by testing laboratories (centers) at conduction of lab tests, provides compliance of the specified testing laboratories (centers) with the principles of GLP of the OECD”// Corpus of legislative acts of the RF dated 18.11.2013 No 46, page 5960

Recommendations of the OECD council related to the adherence of the member states to the documents of the OECD council on mutual recognition of information on estimation of chemicals. S(81)30FINAL, C(89)87 FINAL.

URL: <http://www.oecd.org/env/ehs/47813784.pdf> (date of application 10.04.2014)

URL: <http://www.oecd.org/env/48943696.pdf> (date of application 10.04.2014)

URL: <http://www.oecd.org/env/ehs/malaysia-joins-oecd-agreement-on-mutual-acceptance-of-chemical-safety-data.htm> (date of application 10.04.2014)

