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Research Article

On preparation to the enactment of the TR EAEU 041/2017 "On safety of chemicals" as a step towards globalisation and development of digital economics

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ABSTRACT
Annotation: The steps which are required for the practical use of the Technical Regulation of the Eurasian Economic Union "On safety of chemicals" (TR EAEU 041/2017) are examined. The importance of the procedure of inventorying chemical substances is underlined, and the practical aspects of its realisation are laid out. A connection is found between the Register of chemical substances and mixtures of the EAEU (a result of inventorying) and the strategic developments of the Russian Federation, as well as Sustainable Development Goals.
Clean-up and prevention of the negative impacts of anthropic activity is quickly becoming the main vector of development of the modern global economics. The ever-increasing environmental damage, growing extraction and usage of natural resources demand a different perspective of the way processes of manufacturing goods and providing services is organised.

Keywords: Eurasian Economic Union, technical regulation of the EAEU 041/2017, safe management of chemicals, conformity assessment, environmental protection, sustainable management of chemicals

INTRODUCTION

Developed economies establish and regularly follow necessary and voluntary requirements for products, set up procedure of its conformity assessment in order to ensure its quality, as well as prevent manufacturing and circulation of products which may pose danger to humans and environment.
Russian Federation is a member country of the Eurasian Economic Union (EAEU), which also consists of Armenia, Belarus, Kazakhstan and Uzbekistan. Technical regulation and standardisation are the most important instrument of realisation of industrial policy and integration of the member countries [1]. Technical regulation of products is a system of general principles in the areas of development, usage and satisfaction of the obligatory requirements for the products, rules and procedures of its transportation, storage, marketing and utilisation, as well as legal settlement of the matters related to conformity assessment.
Acceptance of the unified principles of technical regulation of products allows to create an integrated economic zone through lifting technical barriers between the Union's member countries, as well as to protect the Union's market from unsafe products, improve quality and competitiveness of the circulating products. Such principles are [2]:
- establishment of integral obligatory requirements for products in Technical Regulations;
- implementation and compliance with the requirements of the Technical Regulations in the EAEU member countries regardless of types and/or specifics of business deals.
There are various authorised bodies within the Eurasian Economic Commission dedicated to the issues of technical regulation, such as: department of technical regulation and accreditation; consultative committee on technical regulation and implementation of sanitary, veterinary and phytosanitary measures; department of sanitary, veterinary and phytosanitary measures; subcommittees on separate types of activities. The consultative bodies also include representatives of industry and business, which allows to make more coordinate and effective decisions.
The system of technical regulations is based on national standards and implementation of the Technical Regulations. In 2012 the conformity assessment of the multitude of product groups (such as personal protection equipment, packaging materials, light industry products, perfume and cosmetics, goods for kids, toys, etc)

is performed within the framework of the EAEU legislation requirements.

Technical Regulations can be conventionally divided into "horizontal" and "vertical" ones:

- a "horizontal" Technical Regulation establishes requirements which can be applied to all kinds of a product type regulated therein;
- a "vertical" Technical Regulation establishes requirements only for certain kinds/groups of products.

As of now chemicals in the EAEU are only regulated partially via several "vertical" Technical Regulations. Such regulations are, for example, the Technical Regulation of the Customs' Union 028/2012 "On safety of explosives and products on their basis", the Technical Regulation of the Customs' Union 030/2012 "On requirements for lubricants, oils and special fluids". A number of already accepted "vertical" Technical Regulation has not yet been enforces (i.e., TR EAEU 039/2016 "On requirements for mineral fertilizers"), some "vertical" Technical Regulations are yet to be developed (i.e., for regulation of household chemicals).

The general principles of regulation of chemicals are established by the approved by the Decision of the Council of the Eurasian Economic Commission (EEC) No. 19 of 3rd of March, 2017 "horizontal" TR EAEU 041/2017 "On safety of chemicals". Originally the TR was supposed to be enacted on the 2nd of June, 2021, which required the formalisation of the so-called "second level documents" – the orders of formation and keeping the Register of chemical substances and mixtures of the EAEU, the order of notification of new chemical substances [3]. But these documents are still in the process of coordination, which means that the timelines of implementing the TR 041/2018 may be delayed.

The second level documents are a very important constituent of the system of chemicals' technical regulation, since the proper functioning of elements and procedures outlined in the Technical Regulation itself is impossible without them. Regardless of the difficulties in coordinating the second level documents the work required for the enactment of the Technical Regulation is ongoing.

According to the provisions of the TR EAEU 041/2017, the procedure of chemicals' conformity assessment with the requirements of the TR is state registration. Two forms of registration are outlines: informative (the simplified form) and permissive (the stricter form). One of the key elements which determine whether it's possible to register a chemical using the simplified procedure is the Register of chemical substances and mixtures of the EAEU (hereinafter – the Register). If all substances which are present in the product in concentrations above 0,1% can be found in the Register, and if the concentration of the so-called restricted substances is not above the limits established in the Annex 4 to the TR, then the chemical can be registered using the simplified procedure.

If the product contains substances which are not present in the Register (so-called new substances), and/or concentration of the restricted substances is above the limits, the procedure of registration complexifies – the permissive form of registration requires more documents and, therefore, more time for the authorised bodies in order to check these documents. But the main difficulty of registering chemicals which contain new substances is the process of including these new substances into the Register – the procedure of notification.

The procedure of notification of new substances is described in detail in a dedicated second level document. The main difficulty of the process is in the requirement for the documents to be provided for notification to contain the results of a whole complex of tests on determination of various properties of the new substance (bioaccumulation, carcinogenicity, mutagenicity, toxicity), and these tests can take months and even years. This is why it's extremely important to form the most possibly extensive Register of "existing" substances, thus bringing the necessity of the procedure of notification to minimum.

The formation of the Register is done in stages, and the first stage was the procedure of inventorying – collection of data on substances present in the chemicals provided by manufacturers and importers thereof. On 7th of November, 2019 the Ministry of Industry and Trade of the Russian Federation organised the process of inventorying of chemical substances which are being circulated on the territory of the Russian Federation using the platform of the State Industry Information System (GISP).

The procedure of inventorying was organized in the form of creating a data submission window within the GISP. To get access to the window an organisation had to sign up to the GISP (this action is allowed only for organisations legally registered and located in the Russian Federation). The simple interface of the submission window allowed intuitive interaction, and the link to the instruction on the procedure of working in the GISP and on the procedure of inventorying was integrated therein.

The inventorying was performed via submissions to which a filled template with the information on chemical substances was attached. The amount of submissions from one organisation was not

limited, which allowed to gradually collect the necessary information. Then the submission was reviewed by the authorized body with the following possible results:
- fully accepted (all substances of the submission are included into the national Register of chemical substances);
- partially accepted (some substances of the submission are accepted, and in order to process the remaining substances more information is required);
- wrong file format (the template attached to the submission is corrupted or filled entirely in a foreign language).
The results of inventorying will be used to form the national Register of chemical substances which will be subsequently incorporated into the Register of chemical substances and mixtures of the EAEU.
The deadline of inventorying was delayed due to the COVID-19 pandemic and the first stage of inventorying ended on the 1st of August, 2020. Up until the late October the industry and importer enterprises had an opportunity to provide missing information of substances which were already submitted before but for any reason not included into the national Register. Then, upon the publishing of the EAEU Register, and until the moment of the enactment of the TR and during the efficacy of the delayed norm a different form of inventorying will be accessible. It will require the provision of documents which prove that the substance was circulating within the territory of the EAEU before the date of the enactment of the TR EAEU 041/2017. Afterwards, if the chemical substance is missing from the Register, it will have to undergo the procedure of notification.
Inventorying of chemical substances is a voluntary procedure, and the company has a right to submit the data on chemical substances to be included into the Register, therefore stating that these substances "exist and are in circulation" within the EAEU's customs area. During the stage of inventorying the minimal information on substances is required, there is no state fee and no requirement to provide any proving documents whatsoever.
The authorized body which were to organise the procedure of inventorying was determined by a tender – it was won by the CIS Center (Association "Non-commercial Partnership Coordination and Information Center of the CIS Member States"). The CIS Center faced the necessity to develop the complex procedure of collecting data on chemical substances, taking into account the fact that people with various skillsets can participate in the inventorying – some would be experts which can classify chemical substances in accordance with the requirements of the interstate standard (GOST) 32419 and 32424, and some would be less experienced, not knowing, for instance, what a EC number is. Different skillsets of the inventorying participants, wide scope of substances which are submitted by different branches of industry, difficulties of checking data on rare and confidential substances – this is not even an extensive list of problems faced by the CIS Center' experts responsible for processing data on results of inventorying.
Still it has to be noted that the developed template of data submission for inventorying, as well as the instructions on filling the templates and information research [4], turned out to be sufficiently universal and extensive. The template for inventorying is made in a convenient and popular Excel format using macros which does not require any special skills to work with [5].
Though on paper the procedure of collecting data under the framework of inventorying looks easy, in fact it was a complex task. The principle of optional data provision on polymers, the format of representing substances with complex and/or changing composition (UVCB substances) – these are just examples of question the answers to which can be found in the documents provided by the authorized body, but which still frequently occurred among the participants of inventorying.
Even the process of identification of some substances can cause difficulties, not to mention the problem of providing information on such substances for inventorying. For instance, among the data which can be provided for inventorying there are a few identification numbers:
- CAS registry number, which is given to a substance by the Chemical Abstracts Service – a part of American Chemical Society;
- EC registration number (EINECS/ELINCS/NLP), which is given to a substance by the European Chemicals Agency.
In various databases of chemical substances these numbers for a given substances can be wrongly matched.
The optionality of inventorying polymers also caused difficulties. For the purposes of conformity assessment, a principle of polymer identification via its monomers was accepted – with the obvious intent to avoid the registration of massive amounts of polymers. At the same time, identification of some polymers is complicated because of the specifics of their manufacturing process and requirements of the Technical Regulation 041/2017.
Let's look at a specific example of the polyvinyl alcohol (PVA). It seems logical to identify PVA as a

polymer of vinyl alcohol, and submit vinyl alcohol alone for inventorying. But, unlike the vast majority of polymers which are obtained by monomer polymerisation (polyethylene is derived from ethylene, etc.), PVA cannot be obtained by the polymerisation of vinyl alcohol, and it is manufactured from another polymer – polyvinyl acetate. In this case it is necessary to remember the requirement of the TR 041/2017 on additive and impurities in concentrations above 0,1% for registration – that is, to inventory vinyl acetate as well.

It is necessary to mark the coordinated and operative work of the authorized body during the process of inventorying, which has organized a hotline in order to support the industry and importer enterprises.

The preliminary results of inventorying in the form of the preliminary Register, publicly available in the GISP [6], speak for themselves. The preliminary Register contains data on more than 50 thousand chemical substances. For comparison, the largest Russian-language database of chemical substances – the Federal Register of Potentially Hazardous Chemical and Biological Substances – contains almost five times less substances, a little over 11 thousand [7]. The scale of the preliminary results allows to make an assumption that the authorized body and the industry and importers representatives have made a colossal work, the results thereof can be used for more than just inventorying and preparation to the enactment of the TR 041/2017 themselves.

Among the second level documents there is a list of officially approved data sources on chemical substances. It includes the following resources, for instance:

- European Chemical Agency (ECHA) database (https://www.echa.europa.eu/);
- OECD global portal of information on properties of chemical substances eChemPortal (https://www.echemportal.org/echemportal/index.action);
- the US National Center for Biotechnology Information's database PubChem (https://pubchem.ncbi.nlm.nih.gov/);
- on-line information of the aforementioned Federal Register of Potentially Hazardous Chemical and Biological Substances (http://www.rpohv.ru/online/).

Judging by the approved sources of information and the preliminary results of inventorying it can be said that the largest Russian-language database of chemical substances can be formed using the results of inventorying in the Russian Federation (and, subsequently, the other EAEU member countries).

It needs to be noted that apart from achieving practical goals – the work on conformity assessment under the framework of the TR 041/2017 – the creation of a Russian-language database of chemical substances is a step forward in both the strategic development of the Russian Federation (i.e. the Russian national project "Digital Economics"), as well as Sustainable Development Goals (i.e. SDG 9.1 "Develop quality, reliable, sustainable and resilient infrastructure, including regional and transborder infrastructure, to support economic development and human well-being, with a focus on affordable and equitable access for all").

To sum it up, the successfully completed procedure of inventorying was highly effective, giving a high start to the process of implementing the new EAEU Technical Regulation 041/2017. The results of inventorying will allow to not only improve the internal system of chemicals management, but also become a step towards globalization and development of digital economics. The actual implementation of the TR 041/2017 assists the harmonization of the national chemical management systems, lifting trade barriers in export-import operations, preserving the decent level of ensuring safety of human beings, animals and the environment.

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