

Chemical control regulation in the EAEU

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THE EURASIAN ECONOMIC Union (EAEU), an economic union of states in central and northern Asia and Eastern Europe, was created between 2014 and 2016. It comprises Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan, with an integrated single market of 180 million people and a GDP of over \$5 trillion.

The EAEU encourages the free movement of goods and services, and provides for common policies in the macroeconomic sphere, transport, industry and agriculture, energy, trade and investment, customs, technical regulation, competition and anti-trust regulation. Provisions for a single currency and greater integration are envisioned in the future.

Russian regulation is the basis of chemical regulation in the EAEU. '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 President Putin on 4 December 2003, No. Pr-2194, defines ensuring chemical safety as both a priority issue and of strategic importance in Russia.

The policy is based on improving and strengthening the relevant institutions and the legal framework. Its aim is to create a comprehensive system, providing for classification, volume forecasting, prevention and the elimination of chemical and biological threats, and managing emergencies resulting from chemical and biological factors.

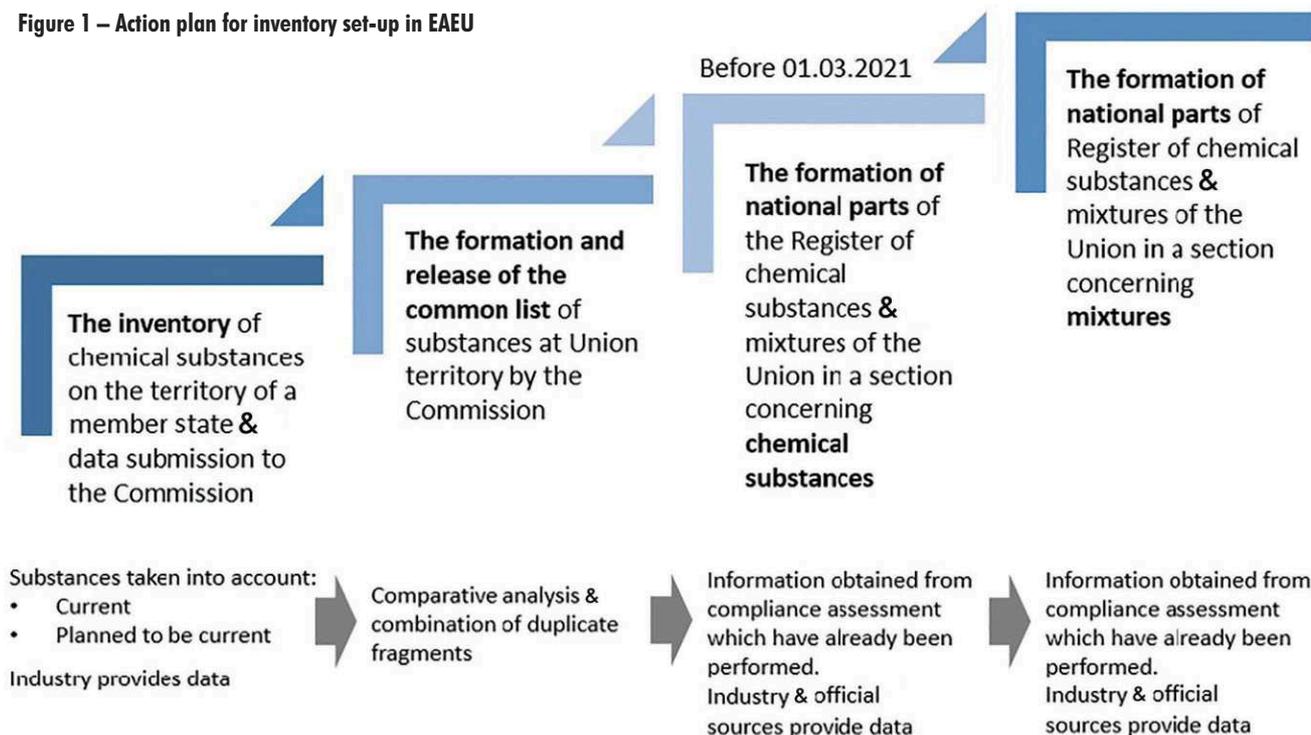
Former legislation & new developments

Russia implemented a registration system in 1992, which was amended several times. Several laws and decrees deal with the safe use of chemicals and hazard communication.

Mandatory state registration of potentially hazardous chemical and biological substances was implemented in order to prevent adverse effects on human health and the environment. This was applicable to all chemical substances on their own or in mixtures, as well as to biological compounds produced or imported into Russia. The production, import and use of unregistered substances were prohibited.

By the end of 2019, about 3,400 substances had been registered in

Figure 1 – Action plan for inventory set-up in EAEU



Source – CIS Coordination Centre

➔ Russia. About 15,000 substances had been evaluated under Soviet regulations up to 1992. These were considered as registered too. Thus, the split into ‘old’ and ‘new’ substances was comparable with the pre-REACH chemicals legislation in the EU.

In most cases, the registrations were performed by FBEPH, the Russian Register of Potentially Hazardous Chemical & Biological Substances. FBEPH was a federal body empowered by Rospotrebnadzor, the ‘Federal Service for Surveillance on Consumer Rights Protection & Human Well-being’.

The FBEPH issued a database of over 10,000 ‘hazardous substances’, which contained information about registered chemical compounds. It included data on physical and chemical properties; toxicity and hazard to humans and the environment; and hygiene and environmental standards. The register had sub-registers, including those of:

- Certificates of state registration
- Products that underwent state registration before 1 July 2010
- Sanitary-epidemiological conclusions

On 7 October 2016, Russia approved a new chemical law, namely the Technical Regulation (TR) on the Safety of Chemical Products, which will enter into force at the end of 2021 or early 2022, replacing former legislation. As with REACH, responsibility for evaluating intrinsic properties, hazard, risk and exposure assessment, as well as the creation of safety data sheets (SDSs), will pass to the manufacturer and importer.

While existing substances – those already listed – only need to be notified, new substances or chemical products will have to be registered as soon as they exceed the threshold of 0.1% in a formulation. This is mandatory, irrespective of tonnage bands.

These requirements basically correspond to REACH Annex VIII. Similar to the REACH chemical safety report (CSR), it is necessary to provide information about physical-chemical properties, study results on toxicity and ecotoxicity, persistence and bioaccumulation potential, and risk assessment considering exposure.

Substance inventory

A timed action plan has been implemented for the formation of

a chemical substances inventory in the Commonwealth of Independent States (CIS). The aim is to prepare the industry for the entry into force of several technical regulations of the EAEU ‘On the Safety of Chemical Products’.

TR EAEU 041/2017 refers to the inventory compilation under the TR on Safety of Chemicals Products, also known as ‘Eurasia REACH’. This consists of 14 chapters and seven annexes. Its purpose is to set out mandatory requirements for chemicals placed on the Eurasian market to ensure their safe use.

The inventory is the first step in the creation of a register and inventory of chemical substances and mixtures of the EAEU. The action plan was approved on 29 January 2019 and adopted by Russia on 16 March 2019. Figure 1 shows the action plan for setting it up.

All chemical substances a company places or plans to manufacture in or import into the Russian or EAEU market, including those within a mixture manufactured or imported, are subject to inventory listing. Chemical products, their main component and all impurities and supplements present in a concentration of >0.1wt% should

Figure 2 – Comparison of data & information requirements, in inventory submission v. new substance notification

Inventory submission	New substance notification
1. Substance identification & use information	1. Substance identification & use information
2. Classification	2. Producer/importer information
3. Producer/importer information	3. Substance identification analysis (Spectra & chromatograms)
	4. Test reports
	5. Chemical safety report
	- Data on production
	- Hazard classification & labelling
	- Recommendations on safe use
	- Physical & chemical properties
	- Effects on human health (acute & chronic)
	- Environmental effects (acute & chronic)

Note: Estimated cost – \$250,000 over two years

be considered. For mixtures, all components at a concentration of >0.1wt% should be considered.

Substances excluded from the inventory submission process are listed in Annex 1 of TR EAEU 041/20179. These comprise:

- Chemical products intended for use in scientific R&D and/or obtained from it
- Minerals in their natural state of occurrence, and the following products, if not chemically changed: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied gas, gas condensate, process gas & its components, dehydrated, desalted & stabilised oil, associated petroleum gas, coal & coke
- Medical products & preparations for veterinary use
- Perfumes & cosmetics
- Chemical products serving as a source of ionising radiation (including wastes from such products), due to the presence of radiation
- Food products, including biologically active supplements & food additives, & finished animal feed
- Products in articles which, during treatment in the customs territory of the EAEU, do not change their chemical composition & which are not

subject to decomposition or oxidation processes, & which do not form dusts, vapours & aerosols containing chemicals that are hazardous to the life & health of humans, animals or plants, the environment or property

- Wastes from the production & consumption of chemical products, if they are to be recycled
- Chemical products that are subject to the procedure of customs transit through the territory of the EAEU

Industry participation

Inventory reporting is a voluntary procedure in which a company has the right to submit data on chemical substances for inclusion in the list, thereby declaring them as existing in the customs territory of the Union. The list will be the basis for the formation of the Register of Chemical Substances & Mixtures of the EAEU.

After TR EAEU 041/2017 comes into force, all chemical substances not in the inventory will be considered 'new' for the customs territory of the union. Before any chemical product containing these can be placed on the EAEU market, the respective company must undergo a registration procedure for these new substances.

The registration process requires a comprehensive dossier to be submitted, including all hazardous properties and analysis of risks to human health and the environment by submitting a CSR. At the inventory stage, by contrast, the legislation requests only minimum information on the chemical substances, somewhat comparable to the EU REACH pre-registration process.

Submitting information to the inventory and the reporting procedure are free of charge and do not require any documented proof that the substances were already on the market. Companies that did not participate in inventory submission and which realise that their substances are not included in it after the entry into force (and therefore are identified as new chemicals), can submit data to the register before 2 June 2023 without conducting a registration procedure.

However, documentation needs to be provided that confirms the circulation of a chemical substance on the EAEU market before the effective date of TR EAEU 041/2017. Confirming documents may include supply agreements, purchase and sale documentation, consignment notes, information on the presence of a chemical substance in the national lists of chemicals of an EAEU member state, etc.

After the entry into force of the legislation and the deadline of 2 June 2023, all 'new' chemicals need to be notified, even as part of a mixture. Figure 2 compares the information requirements of inventory reporting versus a new substance registration.

Data submission process

In Russia, data can be submitted only by a Russian legal entity. A foreign company without a legal entity there can appoint a Russian representative for data submission. Unlike EU REACH, the representative is not required to have knowledge in the practical handling of the substances. The Russian importer or customer can act as a representative for

➔ inventory data submission, as well as a third-party representative (e.g. service provider).

To submit information on substances at the inventory stage, it is necessary to complete a template and submit it electronically to the Ministry of Industry & Trade. The submitter needs to send an information letter on official company letterhead, signed by the managing director, with contact details of the responsible person in the company for the submission procedure.

The subject of the letter should clearly identify the 'Inventory of Chemicals' and needs to be sent to the Ministry of Industry & Trade at: Moscow, Presnenskaya Naberezhnaya, 10, Bld. 2 (Tower 2). The preliminary start date for accepting completed templates from industry was 10 August 2019. The deadline, originally 1 January 2020, has been extended to 1 May 2020.

For inventory reporting, all information about chemical substances is requested, without reference to the final product or mixture and the percentage in the composition. Thus, notifiers need to provide a list of all the chemical substances in a single list. They do not need to duplicate the information if several mixtures contain the same substance.

It is important to note that the presence of a substance in the existing list does not necessarily exclude the need to submit data (or to complete the required information in the template) at the inventory stage, since the basis for the inventory will be data provided by industry.

Further information on requirements relating to polymers and monomers, and for substances of unknown or variable composition, complex reaction products or biological materials (UVCB), as well as on volumes, classification and hazard classification, and other issues is also available.

To ensure confidentiality, the information on production or import volumes and the applicant's identity will not be made publicly available. The compiled inventory list of chemical substances will be anonymised. Compositions of mixtures do not need to be submitted.

The submission template is password-protected to preserve the uniform settings for further automatic processing of the submitted data. To solve any problems arising with the template, a detailed description and a screenshot of the error should be reported.

In addition, because the template was compiled for a Russian user, problems may arise on software running on non-Russian operating systems. Unfortunately, at the moment, this issue can be resolved only through the use of Russian software.

Conclusion

The global trend towards tightening chemical regulations is also happening in Russia and the EAEU. 'Eurasia REACH' has copied some important elements of EU REACH, in particular regarding classification and labelling, SDSs and hazard, exposure and risk assessments. Hence, it is expected that this regulation will significantly

improve the handling of hazardous substances in the EAEU.

A new chemical inventory is currently being compiled in Russia. If a substance is successfully notified to this, it will be included to a consolidated EAEU inventory at a later stage. If a substance is not on this, it may still be possible to include it until 2023, if documented proof can be provided that the substance was on the EAEU market in the past.

Submitting information on polymers is optional because they are excluded from the notification process. In this regard, it is important to note, that a regulatory definition of a polymer is not yet available. Thus, as a precautionary measure, it might be advisable to submit polymers to the inventory in parallel with their monomers.

Finally, new substance registrations in EAEU are expected to be similar to EU REACH registrations, probably including joint registration and only representative concepts. An advantage for companies in the chemical industry will be that safety studies that have already been carried out for existing chemical control legislation, such as EU REACH, can be used again for registration purposes in the EAEU.

On the other hand, it is expected that SMEs are going to face major challenges in the future business with Russia and the EAEU due to the language barrier, such as submission of registrations and inventory notifications in Cyrillic. They will require extensive support from local experts. ●

Members of the EAEU



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