Global Data Sharing: Requirements from Chemical Regulation

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In this article on the increasing importance of global data sharing, we focus on the development of international chemical control legislations. Many countries and regions around the world have recently implemented chemical control legislations, which are often harmonized with EU-REACH. Therefore, it has not only become possible, but even necessary to organize data sharing, which is already performed within REACH consortia and Letter of Access management, also on a global level. We examine the opportunities and risks of global data sharing. Additionally, we look at how global data sharing will look like and how it is performed in practice. There are important advantages of global data sharing such as reducing costs and reduced animal testing as well as avoiding conflicting data. However, there is a high demand for efficient administration and strong cooperation amongst all stakeholders.

I. Introduction

Twelve years ago, the European Chemicals Legislation REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) came into force with the Regulation (EC) No. 1907/2006.¹ In order to improve the protection of humans and the environment, any chemical substance produced in or imported into the European Union in quantities of at least one ton per year must be registered with the European Chemicals Agency ECHA in Helsinki. For this

purpose, the submission of a registration dossier is required. To be able to evaluate the potential risk of a chemical, the registration dossier, graded according to tonnage bands, must contain a large number of data and study results. ECHA tries to cope with this enormous amount of data according to the principle ‘one substance, one registration’.² All registrants of the same substance are required to join the same registration (Joint Submission) and thus access the same data. The sharing of data and related costs is specifically regulated in the REACH Data Sharing Regulation of 5th January 2016.³ In particular, this regulation takes into account the need for transparency and fairness when sharing data and costs between the parties involved. In practice, the REACH data sharing process is visible by the Letter of Access (LoA) procedure and the establishment of SIEFs. **NOTE 4 NICHT GEFUNDEN** and Consortia and demonstrates, that the chemical industry has implemented well-functioning systems in this respect.

In recent years, REACH has served many countries worldwide as a model and impetus to enact their own chemical legislation. The spectrum ranges from inventory lists to comprehensive chemical control regulations. Probably the most advanced and best-known example besides EU-REACH is the so-called Korean-REACH (K-REACH), which was adopted by the South Korean government in 2013.⁵ It entered into force in 2015 and was revised and complemented

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1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [...].

2 Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data-sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Art 3.

3 Commission Implementing Regulation (EU) 2016/9.

5 Act on the Registration and Evaluation, etc of Chemical Substances, Enforcement date 01 January 2015, Act No 11789, 22 May, 2013 Cf. Dieter Drohmann, ‘REACH in Südkorea (K-REACH) – Folge des globalen Wandels im Chemikalienmanagement’ (2015) *StoffR* 4, 136–140.

in 2017. In many respects, such as pre-registration, dossier submission, Only Representative function and consortia management, it is similar to the European REACH Regulation – not least the name indicates the similarity.

Other Asian countries have also implemented chemical control laws. In Taiwan, for example, the so-called ‘Taiwan-REACH’⁶ is in force since 2015, and in Thailand substances must be listed in the Thai Existing Chemical Inventory (TECI)⁷. There is a worldwide trend towards the introduction or revision of standards in chemicals management. In 2016, for example, the implementation of the Frank R. Lautenberg Chemical Safety for the 21st Century Act revised the U.S. Chemicals Legislation TSCA.⁸

In Turkey, KKDIK⁹ came into force in 2017 and new chemical regulations are to apply in Russia¹⁰ in 2021. There are also efforts in South America to establish uniform standards for the safe handling of chemicals. The regulatory framework in Brazil is the most advanced in Latin America. At the beginning of 2016, the National Commission for Chemical Safety presented a draft for a comprehensive chemical legislation to the National Congress.¹¹ Argentina is currently planning to implement a comprehensive chemical regulation, too. The country has finalised a draft bill for regulating industrial chemicals that would see a national inventory of substances established, after which their risk would be evaluated. Importers or producers of all such chemicals would have three years to register them.¹²

With regard to the development of global chemical regulations, all of which raise high data requirements, the question comes up to what extent the approach of global data sharing can simplify the implementation of the individual legislation.

II. Opportunities and Risks of Global Data Sharing

When a company sells a chemical substance to countries, which are subject to certain chemical requirements, it may be obliged to register or notify this substance in each country - under different conditions, but always with the requirement to provide substance-related information and data. So far, EU REACH registrations have generated enormous amounts of data – consequently, it is obvious to make this data available for registrations in other countries

as well or to use information from other countries vice versa.

If one examines the approach of global data sharing in terms of its benefits, the most important fact is that by exchanging study results it can be avoided that the same studies are conducted repeatedly. This can drastically reduce animal testing, in line with EU animal welfare legislation¹³ and REACH. In any case, REACH requires vertebrate animal testing to be kept to a minimum.¹⁴ From the authors' point of view, global data sharing should therefore be in the focus of animal welfare NGOs and should be promoted.

Another important aspect of data sharing is that by carrying out each study only one time and share the costs, duplication of efforts and unnecessary costs can be avoided. Obviously, it is always cheaper to acquire data access rights and share the costs with other registrants than to commission a study and pay for it alone. Further, the time line until studies can be conducted or completed and until the final study reports are available should not be neglected and can become the determining factor for a registration. Data sharing can therefore ensure that registrations can

- 6 Toxic Chemical Substances Control Act (TCSCA) und Occupational Safety and Health Act (OSHA); Dominik Kirf and Dieter Drohmann, ‘Taiwan REACH – Einblicke in die taiwanesischen Chemikalienregulierung. Taiwans Beitrag zur ständigen Reform des asiatischen Chemikalienmanagements’ (2016) StoffR 4, 213–218.
- 7 TECI = Thailand Existing Chemicals Inventory. Dominik Kirf and Dieter Drohmann, ‘Chemikalienrecht in Thailand. Folgen des Weltgipfels für nachhaltige Entwicklung’ (2016) StoffR 5, 263–267.
- 8 TSCA = Toxic Substances Control Act; Kerstin Berg, Dominik Kirf, Dieter Drohmann, ‘Folgen der TSCA-Reform in den USA. Ein Einblick in den Frank R. Lautenberg Chemical Safety for the 21st Century Act’ (2016) StoffR 6, 317–320.
- 9 KKDIK = Kimyasalların Kaydı, Değerlendirilmesi, İzni Ve Kısıtlaması Hakkında Yönetmelik (Registration, Evaluation, Authorization and Restriction of Chemicals); Dominik Kirf and Dieter Drohmann, ‘Stand der chemikalienrechtlichen Regelungen in der Türkei. Konsequenz der EU-Beitrittsverhandlungen und des globalen Umbruchs im Chemikalienrecht’ (2016) StoffR 2, 89–92.
- 10 Technical regulation on the safety of chemical products. Dieter Drohmann and Natalia Jansen-Bouriatchenko, ‘Russland verabschiedet neues Chemikalienrecht. Mehr Sicherheit im Umgang mit chemischen Produkten’ (2017) StoffR 4, 179–182.
- 11 Regulação de Substâncias Químicas Industriais; Dominik Kirf, Dieter Drohmann and Doris Peters, ‘Chemikalienrecht in Südamerika unter besonderer Berücksichtigung Brasiliens. Der Markt des Südens – vom wirtschaftlichen Hoffnungsträger zum Sorgenkind’ (2017) StoffR 1, 16–22.
- 12 ChemicalWatch News (*Chemical Watch* 7 June 2019) <<https://chemicalwatch.com/>> accessed 8 June 2019.
- 13 Art 13 AEUV <<https://dejure.org/gesetze/AEUV/13.html>> accessed 6 June 2019.
- 14 Regulation (EC) No 1907/2006, Title III: Data Sharing and Avoidance of Unnecessary testing, Ch 1, Art 25 (1).

be carried out more quickly. From a business point of view, it is always appreciated to introduce new substances to the market as fast as possible (time-to-market). All these aspects, which have already been identified as benefits of data sharing under REACH, are equally relevant to global data sharing approaches.

There is another decisive factor when considering data sharing, which is conflicting data. In case certain studies on a substance are carried out multiple times by different laboratories and maybe even in different countries, this may lead to different study results. However, different study effects would not only result in additional work, since substance information in the registration dossiers and chemical safety reports would have to be adjusted, but could also, in a worst-case scenario, challenge the classification and labelling of a substance. Conflicting data could lead to different hazard classifications in different chemical inventories. This scenario can be avoided by global data sharing, because in international chemical legislation based on the same data, the resulting classifications of substances should be the same or at least similar.

It is therefore reasonable to adopt the approach of global data sharing. For implementation, however, it must be kept in mind that, despite many advantages, there are also disadvantages. For example, a certain loss of control for the study owner is associated with global data sharing. If access rights to information are resold and distributed worldwide, it is difficult to control who ultimately has access to the study results. In addition, globally applicable legal conditions would first have to be created, regulating data sharing and establishing binding ownership relations. The associated administrative effort should of course not exceed the benefits.

So much for theory - but how can global data sharing look like in practice? Due to the establishment of K-REACH, there are already efforts to promote the exchange of data between the EU and Korea, enabling both regions to benefit from each other.

III. Global Data Sharing in Practice

According to REACH, companies who actually intend to register a substance and need to generate new data, typically form a consortium for one or more substances or groups of substances. The management of data sharing among the co-registrants is of-

ten provided through the consortia and their consortium managers. This also includes calculating the costs of a Letter of Access for co-registrants. The calculation includes the costs of the required studies, the costs of dossier preparation and administration. By signing the Joint Submission Agreement, the co-registrant agrees to contribute to the total costs of the registration among other things. After payment of the Letter of Access fees, the co-registrant receives a Letter of Access document (LoA), certifying that he has the right to access the data. The LoA primarily documents the purpose for which the co-registrant may use the data. In practice, cost reductions of approx. 30-40 % have been established for the use of data for 'REACH only'. This means that the co-registrant bears approx. 60-70 % of the data costs for a registration under REACH.

With the implementation of K-REACH, however, there is a need for more extensive use of the data. For this reason, many consortia and data owners see the need to extend data access to certain regions or even directly to global use. In this case, no deductions are made for the LoA fees; the proportionate data costs are 100 % included in the calculation. This model could also be applied to other country-specific chemicals legislations. Some consortia offer graduated LoA fees:

- REACH only (60 % cost sharing)
- REACH +1 (80 %)
- Global Access (100 %)

There are also more requests for data sharing from K-REACH registrants who have not registered under REACH. If the data is only required for K-REACH, a calculation model with a cost sharing of 30-50 % is frequently used. This model is intended to roughly reflect the share of the Korean market in the global market. Based on the experience of twelve years of REACH, there are mature contracts that have to be adapted to country-specific requirements. However, it should be noted that there is currently no obligation to share data between REACH and K-REACH or other chemicals legislations.

It is a challenge how global data access can be implemented more efficiently in the future. For example, the database system IUCLID is not used under K-REACH. This means that the dossiers created in the EU cannot be transferred directly for K-REACH purposes. However, most data owners are very reluctant to provide the study reports. The only option left is to provide the study summaries (RSS, Robust Study

Summaries) in order to carry out the dossier preparation in Korea. The Korean authority is entitled though to request study reports. Hence, the submission of the study reports to the authority can only take place via the data owner or consortium manager. The preparation of the RSS as well as the increased administrative effort causes in turn costs, which must be considered in the calculation of the LoA fees.

IV. Conclusion

With regard to the development of global chemicals legislations, global data sharing is a resulting requirement, makes sense and is becoming more and more urgent for the following considerations:

- Reduction of animal testing;
- Reduction of study costs;
- Avoidance of conflicting data.

It is necessary to map and outline the conditions for global data sharing in the corresponding consortium agreements as detailed as possible. This is already common practice in numerous REACH consortia; data sharing models that go beyond REACH are

used. The issue of global data sharing is quite complex and leaves a number of open questions. For example, it must be clarified how the income from selling data access globally or from selling data access to related legislations such as biocides or pesticides shall be distributed amongst data owners and co-registrants.

The experience of twelve years of consortia management under REACH has shown that data sharing only under REACH is already a challenge. Global data sharing increases the need for efficiency, coordination and expertise. In addition, there are cultural differences that need to be considered. Data costs in the EU are not negotiable because they represent real costs to be shared transparently and fairly. This contradicts, for example, Asian conventions of negotiation.

The ongoing global development of chemical legislation and the resulting requirements for global data sharing demand a compromise between reasonable administrative efforts and a pragmatic approach in order to fully utilize the benefits of global data sharing. This calls for close cooperation of all stakeholders.