Mind the Gap –
Data Availability in REACH Registrations

BfR-Workshop, 2 March 2015, Berlin

Imprint

BfR Abstracts

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2 Session 1: Welcome & Introduction

2.1 Introduction

Jörg Lebsanft
Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB), Bonn, Germany

In the year 2001, the White Paper on a ‘Strategy for a future chemicals policy’ reported that there was a general lack of knowledge about the properties of existing chemicals. This information deficit triggered a political debate resulting in the development of a new legislative framework, the REACH Regulation. 14 years after the publication of the White Paper, all chemicals produced or imported in quantities above 100 tons per year have been registered and the European Chemicals Agency ECHA has checked compliance of many registration dossiers. However, available resources only allow for an in-depth examination of a small percentage of dossiers. According to the REACH-Regulation, ECHA has to examine at least 5 % of the dossiers for each tonnage band. The 5 % target has already been met for substances above 1000 tons per year. The question therefore arises, whether the required information about the properties is now available. The German project analyses data availability for substances above 1000 tons per year with respect to the most relevant information on intrinsic properties. First results are presented in this workshop.

2.2 ECHA's New Strategy to Ensure Data Quality in REACH Registrations

Leena Ylä-Mononen
Director of Evaluation, European Chemicals Agency (ECHA), Helsinki, Finland

Improved quality of the information in the REACH registration dossiers is the first of four strategic objectives of ECHA to enable the safe manufacture and use of chemicals. High quality information means scientifically sound, understandable and reliable. ECHA had by the end of 2013 concluded compliance checks for over 1.000 registration dossiers submitted for the first REACH registration deadline. 69 % of these mostly non-randomly selected dossiers were found to be non-compliant on one or more of the endpoints checked. The outcome of the 2014 compliance check work is similar, as reported in the annual evaluation report published in February.

To maximise the impact on the safe use of chemicals, ECHA has changed the strategy how it checks the compliance of registration dossiers. The ECHA Management Board endorsed a new compliance check strategy in September 2014 and it is now implemented from 2015 onwards. The main focus is to check information on those substances that matter most for the protection of people and the environment. This means high-tonnage registrations with information deficiencies in critical human health or environment endpoints and with high potential for significant exposure. Most dossiers will be chosen for compliance check because of these concerns but some dossiers will still be picked up randomly so that no registrant can be certain that their dossier will not be selected.

Another aim of the new strategy is to eventually identify substances of concern and coordinate different REACH and CLP measures to address these concerns effectively. This is related to ECHA's second strategic aim to mobilise EU authorities to use the REACH registration data intelligently to identify and address chemicals of concern. Using a common screening technique, ECHA and the national authorities are selecting priority substances for compliance checks, substance evaluation and risk management measures.

According to the new strategy, besides compliance checks also other measures are used to improve the information quality on chemicals. ECHA provides help through its guidance, IT-tools, webinars and website. Furthermore, now ECHA is also publishing a list of planned compliance checks, which allows concerned registrants to verify that their dossier is up to date before ECHA starts the formal process. ECHA may also contact registrants directly to encourage dossier updates on specific dossier parts as was already done for substance identity and intermediate use. The annual ECHA Evaluation report gives concrete recommendations to registrants on how to update their dossiers to overcome commonly found shortcomings. Another important source of learning is compliance check decisions, which are all published on ECHA's website. The online dissemination of information for registered substances will also be summarised in understandable formats. ECHA will also increase the amount of available information from each dossier and enable interested parties to see which parts of dossiers have been updated.

In ECHA's view it is essential that industry takes full ownership of its registration dossiers and regularly and proactively improves their content and quality. However, an active role of all different actors, including Member States authorities, is important. ECHA will only achieve its key strategic objective with the active contribution of all stakeholders who believe in the success of REACH: the full knowledge on and safe use of chemicals.

2.3 KnowSEC – A Web-System for Managing Data on Substances

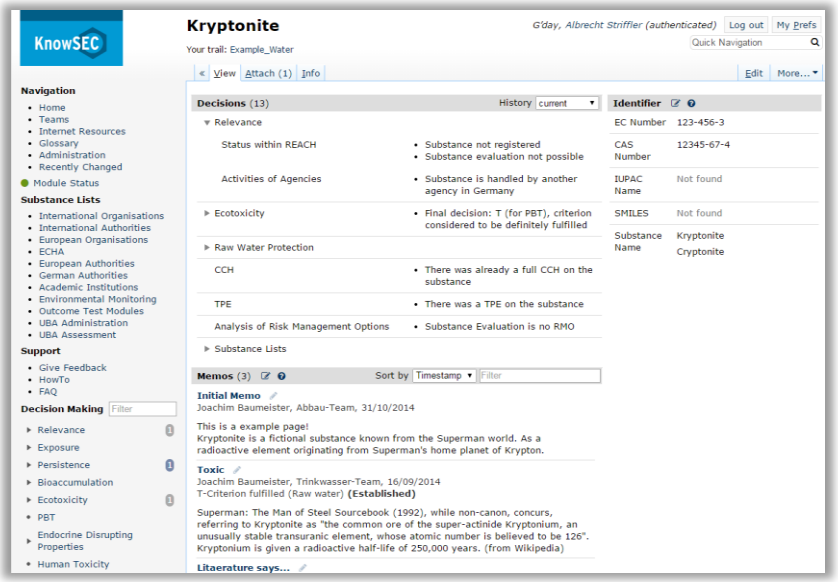
Albrecht Striffler, Joachim Baumeister
denkbares GmbH, Würzburg, Germany

REACH requires the industry to register used substances together with naming the potential hazards and risks. The Federal Environment Agency of Germany (UBA) works on substances within task-oriented teams. Registered chemicals are prioritized and then evaluated with respect to their concern for man and the environment.

A defined number of criteria are considered for the substance evaluation, for instance exposure, persistence, bioaccumulation, and toxicity.

The evaluation and risk management of chemicals is a complex and time-consuming process incorporating teams also from other agencies. The distributed location of the teams further aggravates the work on the chemicals. In summary, it is very elaborate to comment the current overall state of a chemical‘s risk assessment.

To assist with these complex tasks, the Federal Environment Agency of Germany in collaboration with the denkbares GmbH created the web-based system KnowSEC, in productive use in the agency since 2012.



KnowSEC provides intuitive interfaces for the documentation of information and decisions on substances in a centralized manner. Knowledge-based systems were developed by subject-matter experts and provide integrated decision support. The decision modules offer automated guidelines for the assessment of domains like persistence, bioaccumulation, toxicity, exposure, and mobility of chemicals. Authorized experts can add and modify the documentation but also the decision support directly from within the system. Users can view the available information on selected substances in real time. KnowSEC can define personalized overviews and analysis pages that are updated in real time.

In this talk, Albrecht Striffler describes the most important aspects of KnowSEC and its potentials. Furthermore, we discuss how KnowSEC helped with the evaluation of the compliance for a large number of REACH registration dossiers.

3 Session 2: The Project

3.1 Availability of Health and Environmental Data for High Tonnage Chemicals under REACH: Introduction to the Project

Andrea Springer, Dana Sittner, Henning Herrmann
Federal Institute for Risk Assessment, Berlin, Germany

For the registration of chemicals produced at volumes equal and above 1000 tpa, according to REACH a complete set of information is required. In particular, this includes data on sub-chronic/long-term toxicity and developmental/reproductive toxicity. The examination of the data availability for these chemicals is therefore of high priority to identify areas for further action, e.g. to fill possible data gaps. Within the scope of a German project the Federal Institute for Risk Assessment (BfR) and the Environmental Agency (UBA) developed a systematic web-based classification scheme in order to assess the availability of the data required. The (eco-) toxicological data of lead and individual dossiers of high tonnage chemicals were checked in a standardized manner for compliance with the appropriate REACH Annexes VII–XI. The reviewed endpoints comprised repeated dose toxicity, developmental/reproductive toxicity and genetic toxicity as well as environmental endpoints such as degradation, accumulation, aquatic toxicity and environmental exposure. As a result, endpoints were categorized into three domains, indicating ‘compliance’ or ‘non-compliance’ according to the developed classification scheme which is based on the REACH information requirements. Alternatively, endpoints were classified as ‘complex’ due to adaptations/waiving of standard requirements or other endpoint specific reasons that were not assessable within the remit of the project. Furthermore, dossiers were assigned to these categories based on the endpoint decisions. The project revealed that the majority of dossiers (58 %) contain ‘non-compliant’ data in at least one of the regarded endpoints, whereas only one dossier was classified as ‘compliant’ according to the REACH information requirements. The remaining ‘complex’ dossiers accounted for 42 % of all dossiers checked. The frequency distribution of the endpoint decisions throughout the dossiers is explained and a first overview of the results is given. Overall, the project has achieved a broad overview of the proportion of REACH data compliance for high tonnage chemicals and has detected some data gaps. Further activity should focus on aspects such as the ‘complex’ dossiers.

3.2 Availability of Health and Environmental Data for High Tonnage Chemicals under REACH: Results from the Human Health Endpoints

Dana Sittner, Andrea Springer, Henning Herrmann
Federal Institute for Risk Assessment, Berlin, Germany

The project aimed at analysing the data availability and quality of REACH registrations for phase-in substances with a production volume of equal or more than 1000 tons per year. In total, 1932 dossiers were checked with regard to the data availability for selected environmental and human health endpoints which are particularly relevant for high tonnage substances. These comprise for human health repeated dose toxicity, genetic toxicity, and toxicity to reproduction. The standard information requirements for the three endpoints at this tonnage level are specified in Annex VII to X of the REACH Regulation. The requirements include comprehensive testing, including the performance of higher-tier studies and/or different study types. To analyse if the requirements were fulfilled, each endpoint was assessed with a standardised screening approach and allocated to one of four categories. Either the data provided for the endpoint complied with the requirements of the developed approach (‘compliant’) or they did not (‘non-compliant’). The submission of a testing proposal formed the third category. A fourth group gathered those dossiers which cannot be assessed without an in-depth analysis (‘complex’ cases). This was the predominant category applying to 46–73 % of all dossiers for human health endpoints. 5–24 % of all cases were assigned to the category ‘compliant’, while 11–28 % of the dossiers did not fulfil the requirements. The talk focuses on the analysis of endpoint-specific reasons for the decisions ‘non-compliant’ and ‘complex’. Moreover, some overall aspects are addressed as well. Results from a more detailed analysis of a small number of randomly selected ‘complex’ cases complement the presentation.

3.3 Availability of Health and Environmental Data for High Tonnage Chemicals under REACH: Results from the Environmental Endpoints

Henning Herrmann, Andrea Springer, Dana Sittner
Federal Institute for Risk Assessment, Berlin, Germany

This part of the project on data availability and data quality for high tonnage chemicals in REACH registrations focuses on endpoints which are of major concern for environmental risk assessment: degradation (biotic and abiotic), bioaccumulation, aquatic toxicity and environmental exposure. For 1932 dossiers the respective endpoint study records were evaluated with regard to their conformity with the REACH information requirements. A standardised screening procedure based on decision trees was used to assign each endpoint to one out of four decision categories. The endpoints either comply (‘compliant’) or do not comply (‘not-compliant’) with standardised information requirements. The compliance remains undecided (‘complex’), if an in-depth analysis is required, e.g. due to deviations from the standard information or a ‘testing proposal’ is suggested instead.

The environmental results showed that the distribution of decision categories varied considerably among the endpoints. The percentages of the decision categories ‘compliant’ and ‘non-compliant’ ranged from 4–45 % and 3–15 %, respectively. This indicates for example that 4 % of the dossiers were ‘compliant’ for the endpoint aquatic toxicity. However, the majority of the endpoints could not finally be assigned to one of these categories and remained undecided, with percentages ranging between 43–82 %. ‘Testing proposals’ were of minor importance (< 1 %) for the assessed environmental endpoints.

Selected results will provide some insight into the main crosscutting issues for the environmental endpoints as well as for some endpoint-specific characteristics. The main underlying reasons for the decision categories ‘compliant, ‘non-compliant’ and ‘complex’ will be summarised for environmental endpoints. Furthermore, general concerns identified during the project will be outlined highlighting the potentials to improve the overall data quality in REACH registration dossiers.

4 Session 3: REACH Registrations – Challenges to Address Data Requirements

4.1 Quality of Scientific Data in REACH Dossiers

Ellen Ingre-Khans and Christina Rudén
Stockholm University, Stockholm, Sweden

Background
The REACH regulation requires industry to provide information on the properties of substances they produce or import at or above one tonne per year, as well as to assess the hazard and potential risks associated with the substance. The industry is, thus, responsible for ensuring safe use of their chemicals. The quality of the data and the methods used for data selection and evaluation form the baseline of the hazard and risk assessment. In this ongoing study we scrutinize how scientific data are used for hazard and risk assessment within the REACH registration process.

Aim
The aim of the study is to investigate how data are selected and evaluated for risk assessment purposes in REACH registrations, and to discuss the transparency of the process. In particular we will investigate the following aspects:

- Are all the relevant and reliable data included in the dossier?
- Are the data used for the hazard assessment publicly available?
- How have DNELs been derived?
- How are assessment factors determined and applied?
- Have the guidelines provided by ECHA been adhered to when reporting study summaries and deriving DNELs?

The initial phase of this study focuses on toxicological data on repeated dose toxicity as it is a mandatory endpoint for substances manufactured or imported in quantities at or above 100 tonnes per year.

Method
For the purpose of the study 30 registration dossiers were selected. The selected substances were registered in the first phase of REACH registration with the registration deadline 1st of December 2010 and selected with help from the BfR project on REACH compliance. From each of the 30 dossiers relevant information was extracted from the registration dossier and compiled into a Microsoft Access database. The database format facilitates a quantitative analysis also of qualitative information.

Results
Some preliminary findings will be presented.

4.2 The Perspective from a Lead Registrant

Edgar Leibold
BASF SE, Product Safety, Ludwigshafen, Germany

With BASF SE as example, the resources and efforts are shown to achieve the REACH requirements on a company level particularly when being lead registrant. An excellent communication network inside the company and with external stakeholders is essential for fulfilling the REACH registration requirements and getting REACH dossiers prepared. REACH Tier 1 was a challenge for industry in many aspects. Experiences and lessons learnt from Tier 1 were used to improve REACH Tier 2 workflows and processes.

Once a substance is registered under REACH, there is a continuous pressure for updating the dossiers due to business or regulatory reasons. The high number of dossier updates and the high number decision letters received from ECHA clearly demonstrate that REACH is effectively working.

4.3 The Perspective from an NGO

Tony Musu
European Trade Union Confederation (ETUC), Brussels, Belgium

ECHA uses dossier evaluation firstly to examine testing proposals submitted by registrants in case of missing data, and secondly to check whether the dossiers actually contain the information required for registration. The latter, known as a 'compliance check' is done on only 5 % of dossiers and can be used as an indicator of the quality of data provided by the industry. Apparently, however, 61 % of the dossiers examined in 2013 were significantly deficient in quality. This includes, for example, inadequate or incomplete information on substance identity, its intrinsic dangers, uses and/or estimated exposure levels. This therefore makes it impossible to ensure that the risks for the substances concerned are properly identified and controlled in order to protect workers and the public at large. What this means is that workers who use these chemicals are being provided through manufacturers' safety data sheets with risk management measures and conditions of use that are in practice not fit for purpose.

This is why in just such cases ECHA calls for additional information from registrants, who must produce it within a specified period. Unfortunately, the Agency's powers stop there and if additional data are not supplied, only the—chronically understaffed—national policing and enforcement authorities have power to take action against offenders. The quality of data provided by industry is recognised as a problem by ECHA, which has made it a key strategic objective of its work programme for the years ahead. Recently, ECHA has adopted a new strategy to improve the quality of information provided by companies. Arguably, the proposed solutions are not far-reaching enough. The European Trade Union Confederation thinks ECHA is using too much carrot (soft measures) and not enough stick to get registrants to up the quality of their registration dossiers.

The ETUC suggests several measures to improve the quality of data in REACH dossiers. First, the outright withdrawal of the registration number (and therefore the right to be on the European market) for a virtually empty or very poor quality dossier. Second, an increase in the number of dossiers checked for compliance. Third, the transparency of compliance check outcomes should be raised by making publicly available the names of compliant and non-compliant companies (fame & shame system) Fourth, as Member States have an important role to play in ensuring compliance with the data requirements, the enforcement actions also need to be increased.

4.4 Outlook

Agnes Schulte, Uta Herbst
Federal Institute for Risk Assessment, Berlin, Germany

The REACH Regulation requires a set of standard information for all substances registered at production levels of or above 1000 tpa. Data gaps in registrations mean that potential hazards of substances may not be identified and potential risks could not or insufficiently be characterised. Safe use of chemicals cannot be demonstrated by the responsible registrants for those substances that have major data gaps.

The project ‘Data Availability in REACH Registrations’ screened registration data on seven human health and environmental endpoints. It identified data gaps in a high percentage of registration dossiers on chemicals at a production volume of more than 1000 tpa. Standard information as laid down in the REACH Annexes VII to X is the legally binding minimum requirement that is essential to ensure the safe use of chemicals. The registration dossiers identified as ‘non-compliant’ to REACH Annexes require all stakeholders to take actions towards an improvement of the data quality of the registrations. A number of commonly observed shortcomings were identified and efforts are needed to make the registrants aware that substantial improvements of their dossiers are required in order to increase confidence in the according safety and risk assessments.

ECHA aims to improve data quality in REACH registrations by measures following their recent compliance check strategy and is currently preparing to consider the outcome of the project for their screening activities. This will in turn support the Member States’ activities to identify potentially dangerous substances and take measures to protect the human health and environment.

The project outcome will be used by the German Competent Authorities to identify substances of high concern due to the lack of appropriate data and to prioritize substances for immediate and long-term actions under REACH and CLP. Other measures to improve data quality in registration dossiers have to be considered.

In a follow-up project dossiers will be considered which were categorized as “complex” cases due to use of data deviating from the standard requirements, the justification of which was not assessed within this project.

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