

## REACH Compliance Workshop at the BfR

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More efforts in increasing the quality of registrations under the European REACH regulation are necessary in order to achieve a higher compliance of the registration dossiers. This is one of the outcomes of the workshop 'REACH Compliance – A workshop on data quality in registrations dossiers' which took place at the German Federal Institute for Risk Assessment (BfR) in Berlin, on the 23/24 of August 2018. REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals. According to REACH, chemical substances are only allowed to be marketed in the EU, when they have been registered and when the registrants deliver required information to ensure a safe use for workers, consumers and the environment.

The workshop based on the results of a project which assessed more than 3,800 registration dossiers for substances that were produced or imported into the EU at tonnages of at least 100 tons per year (tpa). The REACH Compliance project is a joint project of the BfR and the German Environment Agency (UBA). It investigates the availability of human health and environmental data in the REACH registrations of chemicals regarding their compliance with the requirements on toxicological and eco-toxicological information as laid down in REACH.

More about the workshop:

[https://www.bfr.bund.de/en/event/reach\\_compliance\\_a\\_workshop\\_on\\_data\\_quality\\_in\\_registration\\_dossiers-205356.html](https://www.bfr.bund.de/en/event/reach_compliance_a_workshop_on_data_quality_in_registration_dossiers-205356.html)

According to the European chemicals regulation REACH, substances with import or production quantities of 1 tpa and more have to be registered at the European Chemicals Agency ECHA. Since 2010, the principle of 'no data, no market' applies. To register a chemical, a certain set of data on the substance has to be collected, generated and compiled by the producer or importer. The registrants have to demonstrate a safe use of the substance for workers, consumers and the environment throughout the whole life-cycle – from the production to its use and finally to its disposal as waste.

The information requested on a substance to be registered depends on the volume of production or import. For substances at high tonnages the registration requires a variety of data on physico-chemical, toxicological and eco-toxicological properties. In particular long term studies predicting chronic effects on humans and the environment are extensive and costly. To avoid unnecessary testing in vertebrates, data sharing is binding under REACH. As a basic principle the registrants have to fulfil the information requirements. Following certain rules as laid down in the regulation, alternative methods may be used or justifications can be given to use alternative data or to waive the requirement.

Within the REACH Compliance project, the information given in the registration on 3,800 substances at 100 tpa and more were assessed with regard to the endpoints of highest significance for human health and environment. By checking the available information on selected toxicological and eco-toxicological endpoints in this high number of dossiers, the project provides a representative outcome on the quality of registration dossiers.

The project, ongoing since 2014, found that – related to the endpoints assessed and considering that the evaluation work has not been fully completed at the date of the workshop – the current average rate of “compliance” was 31 % for substances registered at 1000 tpa and more and 44 % for substances at tonnages between 100 and 1000 tpa. The option to deviate from standard testing requirements and to provide justifications for such deviations was commonly used by registrants – for the assessed endpoints on average of about 70 % (range 50-93 %). However, alternative data (e. g. using read-across to other substances) or justifications for data waiving or adaptations were often not sufficient. For example, 32 % of the dossiers for substances at tonnage levels of 1000 tpa and more were found to be “non-compliant” with REACH requirements on average over the assessed endpoints. The average rate of “non-compliance” was at 19 % for substances at 100-1000 tpa. It should be noted that the evaluation methodology did not allow deciding for all dossiers whether they were in compliance with the REACH requirements: Therefore for both tonnage bands, averaged over the assessed endpoints about 37 % of the dossiers remained without conclusion.

The outcome of the project indicates that increased efforts by industry and authorities are needed to achieve a higher rate of compliance for the chemical dossiers.

At the workshop, ECHA introduced its new strategies on dossier quality after the registration date for substances at volumes between 1 and 100 tpa has passed on 31 May 2018. With support from the project’s results, the dossier evaluation can become more efficient. Procedures on dossier evaluation will be optimised, e. g., by allowing a combined substance evaluation with regards to the identified concerns on risks for man and the environment. Measures to encourage the updating and improving of dossiers, including the Chemical Safety Report, are under consideration.

The BfR workshop was intended to inform on the dossier quality of the majority of the registrations on high tonnage substances and to facilitate a dialogue between industry and regulators on how the dossier quality can be improved.

The project was commissioned by the Federal Environment Agency as part of the Environmental Research Plan – FKZ 3715674220 and 3716674220 – and financed by federal funds.

#### **More information on REACH at the BfR website**

Programme and presentations of the workshop:

[https://www.bfr.bund.de/en/event/reach\\_compliance\\_\\_\\_a\\_workshop\\_on\\_data\\_quality\\_in\\_registration\\_dossiers-205356.html](https://www.bfr.bund.de/en/event/reach_compliance___a_workshop_on_data_quality_in_registration_dossiers-205356.html)

A-Z Index, REACH:

[https://www.bfr.bund.de/en/a-z\\_index/reach-202838.html](https://www.bfr.bund.de/en/a-z_index/reach-202838.html)

REACH – Communication on Consumer Health Protection:

[https://www.bfr.bund.de/cm/350/reach\\_communication\\_on\\_consumer\\_health\\_protection.pdf](https://www.bfr.bund.de/cm/350/reach_communication_on_consumer_health_protection.pdf)

#### **About the BfR**

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It

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*This text version is a translation of the original German text which is the only legally binding version.*