

FOCUS ANALYTICS

NEWSLETTER OF RD&I ANALYTICS

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REACH & More - Regulatory aspects of product development

Every successful new development from RD&I eventually reaches the point of approval. However, product registration is not possible without analysis. We develop precise and reliable substance information for your products, on the basis of which authorities issue approvals and registrations. The RD&I Analytics of Evonik, with its expert Dr. Hans-Bernhard Mekelburger, has been advising and supporting you in this area for more than 20 years, even beyond the requirements of REACH.



Innovations in the chemical industry go hand in hand with the development of new substances and mixtures, which form the basis for new products and applications. Before a product is launched, the regulatory requirements must be determined in cooperation with product safety. Depending on the target application, it is necessary to determine which substance data is expected by the respective authorities.

RD&I Analytics has been supporting researchers, developers, and product safety experts for decades in selecting and implementing the appropriate analysis strategy, including documentation that complies with official requirements.

Dr. Hans-Bernhard Mekelburger (Project Manager Analytics for Regulatory Issues) having many years of experience in this field, coordinates the targeted and quality-assured implementation of the requirements. This is because the topics and issues are diverse. There are very different areas of law (including chemicals, biocides, food, pesticides, pharmaceuticals) for which very different requirements exist. In addition, different countries and regions (e.g., EU, USA, Korea, China) have their own requirements.

Getting started

The investigation begins with the characterization of substances and products, i.e., simply: Tell me what the material consists of and how much of each substance it contains (identity and composition). It has been shown that even this seemingly simple question can prove to be a major challenge: Are components in a mixture in equilibrium with each other? Are solvents part of the substance or can they be disregarded? Often, the search for traces of certain harmful impurities is also expected. Especially with

fine-grained solids, morphology is an important issue (keyword: "nanoparticles").



REACH-Regulation

Regulation (EC) No. 1907/2006 (REACH Regulation) is an EU chemicals regulation that came into force in 2007. REACH stands for Registration, Evaluation, Authorization, and Restriction of Chemicals. Through REACH, the previous chemicals legislation has been fundamentally harmonized and simplified. Since its entry into force, the regulation has been continuously updated and adapted.

Step-by-step approach using the REACH Regulation as an example

In the first step, the "sameness" is examined by analyzing the identity and composition: Has this substance (with the same composition) already been registered under REACH? Or is it a new substance? For typical organic substances, there is a standard set of analysis methods; for inorganic substances, an

individual package must be selected in each case.

In addition, in some cases, a decision must be made as to whether solvents can be removed (not part of the substance to be registered) or whether this leads to changes in the substance.

Thanks to the extensive portfolio of methods available at RD&I Analytics of Evonik, we can also characterize very special substances and mixtures. We combine the results of the different methods to form an overall picture.

REACH investigation into "sameness": Analysis of identity and composition

Identity

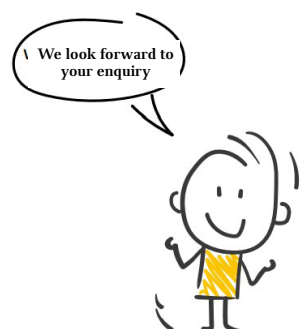
- IR spectroscopy (Raman spectroscopy)
- UV/Vis spectroscopy
- NMR spectroscopy
- Mass spectrometry (e.g., GC-MS, LC-MS)
- X-ray diffraction (XRD)
- ICP-OES spectrum

Composition

- GC analysis
- HPLC (high performance liquid chromatography) analysis
- Titration, gravimetric determinations
- Elemental analysis CHNOS
- ICP-OES, ICP-MS, and AAS analysis

Impurities

- X-ray fluorescence analysis (XRF)
Overview analysis (semi-quantitative)
- ICP-MS screening (semi-quantitative)



The next step is to determine physical and chemical endpoints. Under the REACH Regulation, the scope of the required parameters depends on the annual tonnage of the product. Here, too, substance-specific properties such as reactivity and solubility must often be taken into account before the test is carried out.

REACH registration: Physical-chemical endpoints

- Melting and boiling point
- Density
- Vapor pressure
- Surface tension
- Water solubility
- Partition coefficient (Log K_{ow})
- Flash point
- Granulometry (for solids)
- Dissociation constant
- Viscosity (at 20 and 40 °C)

Further safety-related endpoints can be determined at the Safety Testing Center in Hanau



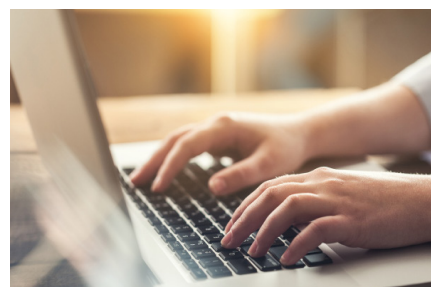
In the final step of the entire analysis package, special formal requirements apply to these topics, which particularly concern the type of report and the scope of the documentation.

Reporting / Documentation

- Front page of the report with substance data and list of endpoints
- Separate attachment for each endpoint (analytical parameter)



- Detailed test report in English incl. analytical parameters as well as spectra and chromatograms, if applicable
- Draft report which can be checked by the sponsor
- Final report



As simple as possible for you

In order to be able to directly implement the special requirements for analytics for regulatory issues ("REACH orders") directly, we have established clear responsibilities in RD&I Analytics. Inquiries and orders should be directed to the project manager, Dr. Mekelburger. He will handle your orders and clarify the required test methods with the indivi-

dual laboratories. This ensures that the wide range of options available at all RD&I Analytics locations (Darmstadt, Essen, Hanau, Marl) can be optimally utilized to characterize your product or mixture. Early involvement of colleagues from Product Safety ensures that the scope of the required data and suitable and understandable wording are

included in the test report. The practical handling (including sample shipment and order creation) is then coordinated by order management in Hanau.

CONCLUSION

Investigations for regulatory issues are not standard analyses but require substance-specific processing with comprehensive and coordinated documentation.

The coordinated handling of these orders by our project manager with detailed prior coordination is more effective and thus leads to faster and more cost-effective implementation of the project.



Do you have any questions?

Please feel free to contact us!

This will allow us to clarify details and prepare a customized offer for you.

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OUTLOOK

To date, polymers have been exempt from the REACH Regulation. As part of a planned revision, however, polymers are also to become partially "REACH-compliant" (Polymer REACH).

The criteria for PRR (Polymers Requiring Registration) and the requirements are still being discussed. The timetable for implementation is also still very vague.

The analytics department is represented in committees and can act quickly in your best interests.