



BioCentrum

REACH SERVICES

REACH (Registration, Evaluation, Authorization

of Chemicals) is a novel system regarding the testing of chemicals which are used within the EU member states. It is based on the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006. It's most important aims are to improve protection of human health and the environment from the risks of chemicals and to maintain the competitiveness of EU industry. According to this no registration means no marketing authorization and, as a consequence, no turnover of chemicals.

To meet the industry needs for professional analytical services and consulting covering REACH directive, **BioCentrum** offers:

Spectral and chromatographic analysis

The REACH directive obligates both the manufacturers of chemicals and their importers to establish the composition of each substance, degree of its purity, the nature and percentage of impurities and any additives, together with delivering spectral and chromatography data which support the findings described above. In addition, the analytical methods should be described in such a detail to allow for their reproduction.

In fact, it is a complex analytical task which requires employing advanced chromatographic and spectroscopic techniques. In the case of organic chemicals, the analytical task is realized by performing high performance liquid chromatography (HPLC) or gas chromatography in combination with spectral techniques such as mass spectrometry (MS), nuclear magnetic resonance spectrometry (NMR) together with infra-red spectrometry (IR) and ultra-violet and visible spectrometry (UV-VIS). When inorganic substances are under investigation, X-ray diffraction and/or fluorescence and atomic spectroscopy (absorption and emission).

BioCentrum employs highly qualified specialists with hand-on experience in analytical method development based on analytical techniques described above. In addition, according to REACH directive, we offer broad support in terms of the reporting of experimental data interpretation and detailed description of analytical methods applied.

Genotoxicity tests

Genotoxicity tests are one of the main constituents of the evaluation of the safety of chemicals. BioCentrum delivers services aimed at genotoxicity (mutagenicity) evaluation in accordance with REACH directive, which are performed both on bacteria and eukaryotic cells.

AMES TEST (BACTERIAL REVERSE MUTATION TEST)

*The bacterial reverse mutation test uses amino-acid requiring strains of *Salmonella typhimurium* and *Escherichia coli* to detect point mutations such as substitution, addition or deletion of one or a few DNA base pairs. Ames test is commonly employed as an initial screen for genetic toxicity activity and point mutation-inducing activity of compounds and products of either cosmetic, pharmaceutical, biotechnology or industry companies. The principle of this assay is that it detects mutations which revert mutations present in the test strains and restore the functional capability of the bacteria to synthesize an essential amino acid. The revertant bacteria are detected by their ability to grow in the absence of the amino acid required by the parent test strain.*

For early genotoxicity assessment BioCentrum offers high-throughput, pre-validated and precise Ames test with the use of optimized reagents and protocol. On the customer's request compounds may be screened in parallel for genetic toxicity with the use of Micronucleus assay and for cytotoxicity. Test is performed according to OECD TG 471 guideline.

MICRONUCLEUS (MN) ASSAY

Micronucleus (MN) formation is a hallmark of genetic toxicity, and the micronucleus assay (MNA) is an important component of genetic toxicology studies. Micronuclei arise from acentric chromosomes and lagging whole chromosomes. Chromosome mutations of both structure and number are implicated in many human diseases. There is substantial evidence that chromosome mutations and related events in oncogenes and tumor suppressor genes of somatic cells are involved in induction and/or progression of some cancers in humans and experimental animals.

*The best known, reliable and repeatable genotoxicity assay that is an important component of genetic toxicology screening programs using eukaryotic cells is Micronucleus assay (MNA). The purpose of the *in vitro* MN assay is to detect those agents that modify chromosome structure and segregation in such a way as to lead to induction of micronuclei in interphase cells.*

Biocentrum offers service of genotoxicity analysis in CHO-K1 cell line using standard Micronucleus method with the use of proper negative and positive controls both with and without metabolic activation. Offered MN assay is a perfect completion of prokaryotic cell – based Ames genotoxicity assay. Test is performed according to OECD TG 487 guideline.