

QUALITY REQUIREMENTS WHEN TESTING FOR PHYSICAL HAZARDS

REACH and CLP require GLP¹ only for new ecotoxicological or toxicological tests and analyses.

There are no requirements in REACH for a quality system for testing for physical hazards.

CLP is however more specific in its article 8-5:

*“Where new tests for physical hazards are carried out for the purposes of this Regulation, they shall be carried out, **at the latest from 1 January 2014**, in compliance with a relevant recognised quality system or by laboratories complying with a relevant recognised standard”.*

As many companies need to generate physical data to fulfill the requirements of article 8-2 of CLP which entails extensive physical testing for both substances and mixtures (*“For the purposes of determining whether a substance or a mixture entails any of the physical hazards referred to in Part 2 of Annex I, the manufacturer, importer or downstream user shall perform the tests required in that Part, unless there is adequate and reliable information already available”*).

In ECHA’s “Guidance on the Application of the CLP criteria (para. 2.1.5, page 73), the provisions of article 8-5 are further detailed:

“Even though the quality requirement does not become immediately effective, it is highly recommended to do so if reasonably possibly. In general, the following alternative strategies can be pursued:

- 1. Compliance with the principles of good laboratory practice (GLP) (as formerly required by the DSD²)*
- 2. Application of EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” as a relevant recognised standard.*
- 3. Other internationally recognised standards of comparable scope.*

Any testing organisation that carries out physical hazard tests for classification purposes can therefore choose how to fulfill the quality requirements of CLP.”

Option 3 being probably a general opening clause with no practical relevance as we do not know any other internationally recognized standard of comparable scope, in practice, it may be expected that option 2, which means that the testing facilities need to be accredited, will be the preferred solution.

¹ Good Laboratory Practice

² Dangerous Substances Directive

