

Chemical substances: tests, good laboratory practice (repeal. Directive 87/18/EEC). Codification

2002/0231(COD) - 26/09/2002 - Legislative proposal

PURPOSE : to present a proposal for a Directive on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (Codification). **CONTENT** : Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. In the context of the people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen. This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain shattered, so that they must be sought partly in the original instrument and partly later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify current rules. For this reason a codification of rules that have frequently been amended is also essential if Community law is to be clear and transparent. The purpose of this proposal is to undertake the codification of Council Directive 87/18/EEC of 18 December 1986, on the harmonisation of laws, regulations and administrative provisions relating to the principles of good laboratory practice and the verification of their applications for tests on chemical substances. The new Directive will supersede the various Directives incorporated in it; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.