GUIDANCE ON TEST TYPES STATED ON GLP COMPLIANCE STATEMENTS

This guidance has been issued to provide general guidance as to what types of studies may fall within the individual test types stated on the GLP compliance statements of facilities within the UK GLP Compliance programme.

Analytical and/or Clinical Chemistry	Clinical chemistry includes the analysis of plasma, serum, urine and whole blood to determine clinical parameters such as specific protein concentrations, electrolyte concentrations coagulation times and cell counts. These tests would usually be associated with animal toxicology studies. Analytical chemistry would include: formulation analysis, stability/homogeneity studies, the analysis of crops for pesticide residues and bioanalysis (including proof of exposure, PK and TK evaluation) performed as part of a mammalian toxicology study. Biological based analytical techniques such as ELISA, RIA etc will also be covered by this category.
Ecosystems	This would include all field studies that do not fall within either the "Environmental Fate" or "Residue Studies" category e.g. mesocosm studies, effects on natural invertebrate populations. It would also include some laboratory based studies that use "Microcosms" – mixed populations designed to mimic natural ecosystems.
Environmental Fate	Studies that determine the likely distribution of the test item within environmental compartments and its rate of degradation. Most commonly this would be biodegradation (in soil, sediment and sewage sludge), soil metabolism, plant metabolism studies, sludge sorption isotherm etc. and fish bioaccumulation studies.
Environmental Toxicity	Studies that determine the toxic effects of the test item on aquatic and terrestrial organisms. This includes aquatic ecotoxicology studies (fish, daphnia, algae etc.) and the terrestrial equivalents (earthworm, bees, beneficial arthropods etc.). Marine toxicology (fish, invertebrates and bacteria/algae). Non target plant studies (phytotoxicity and vegetative vigour) would also fall here. These would all tend to be laboratory based or non-field studies.
Mutagenicity	All in-vivo and in-vitro genetic toxicology studies (Ames, chromosome aberration, micronucleus etc.).
Phys.Chem Testing	Determination of physico-chemical properties (e.g. density, pH, surface tension, flash point etc.) and characteristic spectra. Conduct of storage stability testing.

Residue Studies	This classification is used for facilities that conduct residue field trials, or complete pesticide residue studies – i.e. both the field phase and the corresponding residue analysis. It also includes residue studies in livestock species and honey.
Toxicology	All mammalian toxicology studies from single dose range finder studies to carcinogenicity and reproductive toxicology studies. It also includes safety pharmacology and target animal safety testing of veterinary medicines in livestock and domestic pet species.
Other - details to be given on the Statement of GLP Compliance	Where a facility conducts a very specific test type that would not be accurately described using the test types listed above a specific test type may be stated. For example, if a facility conducts only safety pharmacology, a categorisation of "Toxicology" could be misleading and the statement would say only "safety pharmacology". Similarly, facilities conducting only histopathology will have this detailed on their statement. Where a facility conducts complete studies for which these activities are implicit, individual activities are not stated on compliance statements. For example, histology and statistics would not be listed on the statement of a facility conducting toxicology studies that include these activities.