

8.0 rLLNA Data Quality

8.1 Adherence to National and International GLP Guidelines

The extent to which the LLNA studies complied with GLP guidelines is based on the information provided in published and submitted reports. Based on the available information, the following papers and data submissions were identified as originating from studies that followed GLP guidelines or used data obtained according to GLP guidelines: H.W. Vohr/BGIA, P. Ungeheuer/EFfCI, E. Debruyne/Bayer CropScience SA, P. Botham/ECPA, M.J. Olson/GSK, and D. Germolec/NIEHS.

8.2 Data Quality Audits

Formal assessments of data quality, such as quality assurance audits, generally involve a systematic and critical comparison of the data provided in a study report to the laboratory records generated for a study.

Much of the data published by Gerberick et al. (2005) was conducted following GLP guidelines or were conducted in GLP-compliant facilities. Therefore, it was previously inferred that data audits were conducted on the data (ICCVAM 1999).

A formal assessment of the quality of the remainder of the LLNA data included in this BRD was not feasible. The published data on the LLNA were limited to tested concentrations and calculated SI and EC3 values. Auditing the reported values would require obtaining the original individual animal data for each LLNA experiment, which were not obtained. However, the conduct of many of the studies according to GLP guidelines implies that an independent quality assurance audit was conducted.

8.3 Impact of Deviations from GLP Guidelines

The impact of deviations from GLP guidelines cannot be evaluated for the data reviewed in this BRD, because no information on data quality audits was obtained.

8.4 Availability of Laboratory Notebooks or Other Records

The original records were not obtained for the studies included in this evaluation. Data were available for several of the substances included in the ICCVAM 1999 evaluation, thus some of the raw data for these substances were available for review.