

## Annex II: Study design and sections released

Generic structure of the regulatory study reports conducted under Good Laboratory Practices (GLP) with the indication on the raw data to be released.

Report structure and sections <sup>17</sup>	Confidentiality assessment
Study Title	Disclosed. Only Article 63(2) and personal data will not be disclosed
Introductory and administrative pages. GLP statements	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment.
Table of content	Disclosed. Only Article 63(2) and personal data will not be disclosed
Summary	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as a sanitised summary and the EU study assessment are already published.
Introduction/Background	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as a sanitised summary and the EU study assessment are already published.
Material, experimental conditions, methods	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as these are guideline studies, for which the methodology is available and the relevant methodological details and deviations are included in the sanitised summary and the EU study assessment already published.
Other administrative GLP sections (e.g. archives)	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment.
Results/Discussion/Conclusions	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment as the section presents the views of the study authors, not EFSA views. The EU study assessment is already published.
Tables with aggregated data	Disclosed. Only Article 63(2) and personal data will not be disclosed
Figures with aggregated data	Disclosed. Only Article 63(2) and personal data will not be disclosed
Appendices/Annexes with raw data	Disclosed. Only Article 63(2) and personal data will not be disclosed
Certificates/Statements and other administrative appendices	Not disclosed in order to protect the economic investment of the study owners. Not relevant for an independent scrutiny of the EFSA assessment.

<sup>17</sup> Note: The Table of Content and the section titles may have different structures and subtitles in the different studies.