

REACH Only Representative Services Standard Process Summary

ChemADVISOR's Only Representative Services are administered according to the following standard process:

1. The client appoints ChemADVISOR Europe sprl, hereafter referred to as ChemADVISOR, as the Only Representative for contracted substances imported into the European Union in quantities greater than one metric tonne per annum (average per annum import over a three year period for phase-in substances). The official assignment from non-EU entity must be received electronically.
2. ChemADVISOR submits a preregistration for designated phase-in substances. For non-phase-in substances ChemADVISOR submits an "inquiry prior to registration."
3. The client will employ ChemADVISOR for the purposes of SIEF communication or designate a third party or itself as the third party for SIEF communication.
4. Upon the request of the client, ChemADVISOR will provide a compliance audit and data gap analysis to determine what data is needed for the purposes of Registration.
 - a. ChemADVISOR's compliance audit will include analysis against contracted substances against REACH provisions to determine the following:
 - i. Requirements related to Safety Data Sheets and other documents covered by Title IV on supply chain communication;
 - ii. Possible Substances of Very High Concern;
 - iii. Information requirements according to Annexes VI – X;
 - iv. Notification requirements for the Classification and Labelling Inventory.
 - b. ChemADVISOR will offer a data gap analysis to include the following general points (to view a more detailed outline of this service please refer to our standard process sheet):
 - i. ChemADVISOR creates a spreadsheet detailing data owned and available to the client for the purposes of registration.
 - ii. ChemADVISOR rates the data according to standard Klimisch reliability ratings.
 - iii. Missing, or incomplete, endpoints are identified.
5. Upon the request of the client, ChemADVISOR will draft designated elements of the Registration Dossier for contracted substances. Final approval of dossier content is subject to the client's approval. ChemADVISOR offers dossier assistance with the following services in IUCLID5:
 - a. Substance set-up across categories and templates
 - b. Data entry for the substance dataset
 - c. Elements of the Chemical Safety Report
 - d. Dossier creation

6. ChemADVISOR will submit in a timely matter all Registrations for contracted substances.
7. ChemADVISOR will submit any updates necessary to maintain compliance. Upon receipt of updated information ChemADVISOR will process all updates in a timely manner.
8. Standard deliverables:
 - a. ChemADVISOR will act as the legal entity responsible for REACH compliance for contracted substances in the European Union (EU) for a non-EU manufacturer.
 - b. Acting as the legal entity for a substance falling under a REACH registration requirement, ChemADVISOR will submit and maintain dossiers of contracted substances for entities without a European base for the following:
 - i. Preregistration or inquiry prior to registration
 - ii. Registration
 - iii. PPORD notification
 - iv. Notification of substances in articles
9. Deliverables upon the request of the client:
 - a. Compliance audit and data gap analysis
 - b. Management and coordination of SIEF activities
 - c. Data entry in the building of substance datasets
 - d. Technical support services related to Registration Dossier or substance dataset creation, including:
 - i. Drafting REACH-compliant Safety Data Sheets
 - ii. Translation of study reports into endpoint study records
 - iii. Classification and Labelling assistance
 - iv. Drafting of a Chemical Safety Report
 - v. Literature search and data adaptation analysis

Important Notes:

1. The client retains responsibility for the final content of the dossier.
2. Registration fees are to be paid in advance of the submission of the Registration Dossier by the client to ChemADVISOR.
3. Fees related to test data purchased for the purposes of building a Registration Dossier are to be paid by the client.
4. Services “upon the request of the client,” including substance dataset write-ups, are subject to an hourly consulting rate.
5. SIEF consulting services are subject to a consulting rate plus any travel expenses incurred in the administration of SIEF-related activities.