

REACH

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Soluciones integrales para adaptarse
al Reglamento REACH

una sociedad de

INERCO  y feiQue



Our values

feiQue



- **Defence of the interests of Industry and** their customers.
- Deep knowledge of **REACH and CLP**, Spanish model business organization in matters of REACH.
- **Relationships with key REACH agents** in Europe: European Agency, business organizations, administrations, industries.
- Fluid relationship with associations and its industries.

INERCO



- **Expert company in REACH and CLP**, with services covering all phases and disciplines.
- **Engineering leader** with more than 25 years working with Industry.
- **Technical capacity** (300 Professional).
- Knowledge of industrial reality, independence and solvency.

WHY REACH INTEGRA?



- **Comprehensive consultancy**, tailored to the needs and requirements of each company.
- **Continuous advising** in all matters involving REACH, CLP and parallel legislation throughout the compliance cycle..
- A **team of experienced Professionals** in all REACH and CLP phases.
- **Dialogue ability** at all levels: Supply chain, ECHA, Lead registrants, Consortia, SIEF, competent authorities, labs, etc.
- **Only representatives** (Members of Only Representative Organization).
- Guarantee absolute **confidentiality**.

REACH INTEGRA SERVICES

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I. Planning, implementation and training on REACH and CLP

II. REACH and SDS Regulations:

1. Individual registration
2. Complete registration and SIEF and Consortium management.
3. Safety data sheets.
4. Downstream users.
5. SVHC substances. Use authorization.

III. Only representative

IV. CLP Regulation.

V. International Regulatory Analysis

SERVICIOS DE REACH INTEGRAL

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- I. Planificación, implantación y formación en REACH y CLP
- II. Reglamentos REACH y 453/2010 (FDS):
 1. Registro individual.
 2. Registro completo y Gestión de SIEF y Consorcios.
 3. Fichas de datos de seguridad.
 4. Usuarios intermedios.
 5. Sustancias SVHC. Autorización de usos.
- III. Representante exclusivo (Only representative)
- IV. Reglamento CLP (R.D. 363/1995 y R.D. 255/2003).
- V. Análisis regulatorio internacional
- VI. Biocidas (pdte revisión servicios)

I. PLANNING, IMPLEMENTATION AND TRAINING ON REACH AND CLP

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- Planning

- Identification of obligations.
- Planning of actions.
- Registration and authorization strategies.
- Justification analysis for exemption from registration.

- Technical consultancy

- REACH and CLP consulting, as well as parallel legislation.
- REACH-IT account and ECHA communications management.
- Supply chain communications management.
- Legal advice.

I. PLANNING, IMPLEMENTATION AND TRAINING ON REACH AND CLP

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- Implementation

- REACH, CLP and SDS legislation Compliance Audits.
- Development of procedures for the implementation of REACH and CLP management systems.
- Inspections and chemical safety audits preparation(Andalusia).

- Training

- In-company and trainings.

- Technical support to business associations

- Assistance for internal meetings and training sessions for members.
- Helpdesk and document development.

II. REACH AND SDS REGULATIONS



1. Individual registration

- **Late pre-registration** (phase-in substances).
- **Development and submission of the Inquiry dossier to ECHA** (non-phase-in substances).
- **Development and submission of the individual registration dossier to ECHA.**
 - Registration – general case.
 - Registration of on-site isolated intermediate substances.
 - Registration of transported isolated intermediate substances.
- **Representative**
 - Representation in substance information exchange forums (SIEF) and Consortia.
 - Third part representative (TPR) in SIEF.
 - Manage participation in the Joint submission and consortia, acquiring letter of access, SIEF Agreement, ...

II. REACH AND SDS REGULATIONS

1. Individual registration

- On-site and transported isolated intermediate substances

- Analysis of strict control conditions of strict control for intermediates.
- Development of testing procedures for strictly controlled conditions.

- Substance identification

- Identification of substances, advice on the structural characterization and determination of the quantitative composition.
- Management of laboratories, outsourcing and monitoring of characterization studies.

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II. REACH AND SDS REGULATIONS



2. Complete registration and SIEF and Consortium management.

- Complete registration

- Development of common dossier(IUCLID 5).
- Data gap analysis, test proposal and classification and labeling.
- Technical-economic evaluation of studies.
- Collection of bibliographic information and information generation (read-across, group category, QSAR -Episuite, OECD Toolbox- etc.).
- Use mapping and generic exposure scenarios (ES) for workers, consumers and environment (ECETOC TRA, ART, EUSES, ...) and refined (Consexpo, ART, STOFFEN MANAGER, ...).
- Development of chemical safety report (CSR), hazard assessment (D(M)NEL/PNEC) and risk characterization (CHESAR, ECETOC TRA).

II. REACH AND SDS REGULATIONS

2. Complete registration and SIEF and Consortium management.

- SIEF and Consortium management

- Lead registrant and facilitator.
- Financial management of the consortium and cost sharing management in the consortium and SIEF.
- Consortium administrative management and agreement development.
- Legal advice.
- SIEF management and letter of access development.
- Confidentiality agreements.

- Laboratory management

- Management of budgeting, outsourcing and monitoring of studies on physicochemical properties and (eco)toxicology. Effects.



II. REACH AND SDS REGULATIONS

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3. Safety data sheets (SDS)

- Audits of suppliers and own SDS.
- Procedures of SDS review.
- SDS preparation and adequacy of substances and mixtures, as well as blend generic families.
- Collection of information to complete the SDS.
- Development of communication sheets of Article 32 information.
- Development of ES.
- Management of SDS and ES translations.

4. Downstream users

- Management of communications with suppliers and customers.
- Analysis of exposure scenarios application.
- CSR and ES (own and customers use) preparation.

II. REACH AND SDS REGULATIONS

5. SVHC substances. Use authorization.

- **SVHC substances in articles:**

- Identification of SVHC substance uses.
- Analysis and identification of SVHC substances in articles.
- Notification of SVHC in articles.

- **Substance use authorization (Annex XIV).**

- Analysis of the adequacy of the authorization.
- Notification to ECHA of the submission of application for authorization and informative meeting with ECHA.
- Development of specific CSR, use mapping and refined ES.
- Analysis of alternatives and substitution plans.

- Socioeconomic analysis.

- Development with IUCLID 5 and submission of



III. ONLY REPRESENTATIVE



- Designation as only representative (OR).
- Development of representative agreement.
- Only representative change.
- REACH and CLP guidance.
- Legal entity in Europe maintenance.
- Development of late pre-registrations, registration dossiers, Inquiry dossier presentation, authorization, ...
- SIEF and Consortia participation.
- Management of the communication to importers.
- Management of pre-registrations and registrations before ECHA.
- Financial management of letters of access and ECHA taxes.
- SDS and updated export list maintenance.

IV. CLP REGULATION



- Determination of classification and labeling of substances and mixtures.
- Classification and labeling notification (development and submission to ECHA).
- Technical assistance in activities in the REACH-IT platform for harmonized classification and labeling.
- Development of harmonized classification and labeling modification proposal.
- Labels design.

V. INTERNATIONAL REGULATORY ANALYSIS

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- Analysis of obligations for export to new markets.
- USA: Register in FDA.
- Turkey:
 - Registration before the Inventory and Control of Chemicals Registration No. 27402.
 - Local Representation Management in Turkey.
- France: Annual Statement of nanomaterials under Decree No. 2012- 232 (L. 523-4 of the France Code of Environment).

VI. BIOCIDAS (Plaguicidas no agrícolas)

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- Análisis de obligaciones derivadas del R.D. 3349/1983, R.D. 1054/2002 y Reglamento Nº CE 522/2012.

Elaboración de la documentación para la inscripción en el Registro oficial de plaguicidas (R.D. 3349/1983) de la DGSP. (Según la disposición transitoria del R.D. 1054/2002).

Comunicación a la DGSP de la información definida en la disposición transitoria segunda del R. 1054/2002.

- Elaboración de la documentación para la inscripción en el Registro Oficial de Biocidas (R.D. 1054/2012) de la DGSP.
- Inscripción en el Registro oficial de establecimiento y servicios biocidas de cada comunidad.

OFICINAS

SEVILLA

Parque Tecnológico de la Cartuja
C/ Tomás Alba Edison, 2
41092 Sevilla

TARRAGONA

Avenida de Roma, 7 – 2ª planta
43005 Tarragona

MADRID

C/ Jorge Juan, 50 Bajo Izqda
28004 Madrid

PERÚ

Calle Julio Verne 114 - 118 Urbanización Bartolomé Herrera
San Miguel (Lima)

COLOMBIA

Carrera 47A No. 91-92 La Castellana.
Bogotá



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EXPERIENCIA DE REACH INTEGRAL EN REACH Y CLP

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- Identificar las obligaciones y establecer un Plan de Acción específico para la implantación y cumplimiento de REACH, CLP, Biocidas, etc. si fuese necesario.
- Gestionar la información sobre las sustancias, mezclas y artículos en la cadena de suministro, tanto de proveedores como de clientes de cualquier sector industrial (Químico, Siderúrgico, Metalúrgico, Petroquímico, Minero, Aeronáutico, Cementero, Alimentación, etc.).
- Capacitar y formar a las empresas y sus técnicos sobre los Reglamentos REACH y CLP.
- Realizar las auditorías REACH, CLP y Biocidas, etc. de las actividades realizadas.
- Realizar el cumplimiento legal: Prerregistro de las sustancias en fase transitoria, elaboración de expedientes de registro y envío a la Agencia Europea de Sustancias y mezclas químicas (en adelante la Agencia), notificación de sustancias contenidas en artículos, Registro de establecimientos biocidas, etc.

EXPERIENCIA DE REACH INTEGRAL EN REACH Y CLP

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- Gestionar consorcios de empresas y foros de intercambio de información sobre sustancias de empresas europeas para el registro y autorización de sustancias.
- Gestionar de forma integral la solicitud de autorización de las sustancias incluidas en el Anexo XIV para los usos de la empresa cliente y/o en su cadena de suministro.
- Realizar el dossier de registro del líder de registro incluyendo la elaboración de dossier común, el análisis técnico-económico de los estudios sobre propiedades fisicoquímicas y efectos (eco)toxicológicos.
- Las fichas de datos de seguridad de sustancias y mezclas y desarrollo de las condiciones de uso incluyendo las medidas de gestión de los riesgos.
- Desarrollo y evaluación de las condiciones de control estricto de las sustancias intermedias.
- Asesorar a asociaciones sectoriales de empresas y sus asociados.

EXPERIENCIA DE REACH INTEGRAL EN REACH Y CLP

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- Definir la clasificación y etiquetado de las sustancias y mezclas, elaborar evaluaciones de riesgos de sustancias y mezclas (usando herramientas de nivel 1 y 2), los escenarios de exposición y el informe sobre la seguridad química.
- Actuar como Representante Exclusivo ante la Agencia con respecto al Reglamento REACH.
- Asesorar en los asuntos técnico-legales, a través de bufetes de abogados expertos en REACH y CLP con los que INERCO mantiene acuerdos de colaboración.
- Definir las técnicas de caracterización de las sustancias inorgánicas y orgánicas: XRD, XRF, AAS, RMN (líquida y sólida), IR, UV-Vis, GC, GC-MS, HPLC, IC, etc.
- Gestionar y monitorizar los estudios de identificación y caracterización de sustancias y los análisis de sus propiedades fisicoquímicas y efectos (eco)toxicológicos.