Overview of REACH INTEGRA
Regulatory services

2021

una sociedad de
INERCO y feiQue

Our values

- **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.

- **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 REACH and CLP services

I. **Planning, implementation and training on REACH and CLP**

II. **REACH and SDS Regulations:**

1. Individual registration and substance characterization
2. Full registration and Consortium management.
3. Extended Safety data sheets.
4. Management of physicochemical and (eco)toxicological test
5. SVHC substances. Use authorization.

III. **Only representative services**

IV. **CLP Regulation**

V. **PCN notification**

vi. **REACH and CLP audits**

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Planning, implementation and training on REACH and CLP

- **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.

  Analysis of strict control conditions of strict control for intermediates
- **Training**
  - In-company and trainings.
- **Technical support to business associations**
  - Assistance for internal meetings and training sessions for members.
  - Helpdesk and document development.

REACH AND SDS REGULATIONS

Individual registration

- **Development and submission of the Inquiry dossier to ECHA**
- **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, ...

REACH AND SDS REGULATIONS

Complete registration and SIEF and Consortium management

Complete registration

- Development of common dossier (IUCLID 6).
- 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).

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.
- SIEF management and letter of access development.
- Confidentiality agreements.

- Laboratory management

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

REACH AND SDS REGULATIONS

Safety data sheets (SDS)

- Audits of suppliers and own SDS.
- Procedures of SDS review.
- SDS preparation and adequacy of substances and mixtures.
- Collection of information to complete the SDS.
- Development of communication sheets of Article 32 information.
- Development of ES and scaling.
- Management of SDS and SDS translations.

Downstream users

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

REACH AND SDS REGULATIONS

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.
  - SCIP Notification
- **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 and submission of application for authorization.
  - Management of participants in the authorization.

Only representative services

- 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.

CLP services

- 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.
- PCN Notification

BPR services and national regulation

I. **Planning, implementation and training on BPR**

II. **National and Union authorization of biocidal products**

IUCLID dossier, SPC and Draft risk assessment of biocidal products

III. **Same biocides**

IV. **Article 95 communication to List of substances and suppliers**

V. **Technical equivalence, level I and II**

vi. **National authorization according to R.D. 363/1995**

VII. **Management tests of physical, chemical and technical properties**

VIII. **Management of physicochemical and (eco)toxicological test**

THANK YOU!