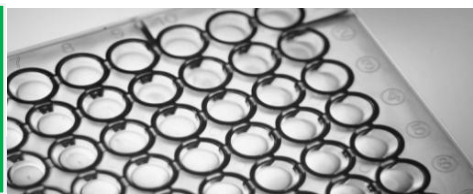


# REACH Inquiry – New Chemical Notification in Europe



**CIRS**  
CHEMICAL INSPECTION  
& REGULATION SERVICE

**‘EU REACH regulation has replaced the old framework of notification of new substances (NONS) with a New Chemical Registration – Inquiry Process’.**

New chemical registrations require an *inquiry dossier* to be submitted to ECHA. This concerns companies who would like to put a new substance on EU market for the first time (>1t/y) and companies who decide to register an existing substance without pre-registration.



## REACH Registration Process: Inquiry + Registration

- Inquiry dossier must be firstly submitted to ECHA to see what data is required, what data is available and if there are other potential registrants;
- Potential registrant negotiates the cost of data with previous registrant or other potential registrants and reaches data sharing agreement (via letter of access);
- Potential registrant collects the rest of data required (usually by GLP testing), prepares registration dossier and submits it to ECHA;

## Inquiry Dossier

- the identity of the company;
- the identity of the substance (Name, EC, CAS, analytical data, etc);
- which information requirements would require new studies involving vertebrate animals to be carried out ;
- which information requirements would require other new studies to be carried out.

## Registration Dossier (consists of two parts)

### 1. Technical Dossier

- Identity of manufacturer/importer;
- Identity, volume and identified uses of substance;
- Classification and labelling ;
- Study report and robust study summaries according to Annex VII to X (physicochemical, toxicological, ecotoxicological properties, etc);
- Testing proposal;
- Statement whether tests have been carried out on vertebrate animals;

### 2. Chemical Safety Report (> 10 ton per year)

- Human hazard assessment, physicochemical properties assessment, environmental hazard assessment and PBT/vPvB assessment;
- Exposure Scenario is required if classified as dangerous or PBT/vPvB;
- operational conditions and risk management measures for each use;
- exposure estimation;

(The total reach registration cost depends on the tonnage band and the hazard properties of the substance).

## CIRS provides a one-stop range of registration services including:

- Inquiry dossier preparation and submission;
- Data gap analysis, literature search, GLP testing, QSAR and read-cross, testing proposal;
- Data cost negotiation and purchase of letter of access;
- Full IUCLD 5 registration dossier preparation including technical dossier and chemical safety report
- Safety data sheets

For more please consult: [morgan@cirs-reach.com](mailto:morgan@cirs-reach.com)