



#APPLICATION SERVICES

# REGISTRATION, EVALUATION AND AUTHORISATION (REA)



TRASY S  
INTERNATIONAL

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# OPTIMISING THE EFFECTIVENESS OF THE B2B COMMUNICATION AND THE MANAGEMENT OF COMPLEX DOSSIERS

## CONCERNS

Public administrations need to establish an end-to-end communication with their entities and the industry for the enforcement of new regulations or changes in a regulation. Stakeholders each have their own priorities.

## CHALLENGES

Enforcing a new regulation needs to be done while improving competitiveness of the EU industry and keeping costs minimal for the administrations. A common approach and solution should be found by aligning all parties.

## SOLUTION

Our solution enables a smooth exchange of information between the European Commission, the Member States and the industry. Components of our solution include the clear definition of data exchange protocols, the use of reusable, secure architectures and components. An example is our reusable workflow component controlling the key processes of Registration, Evaluation and Authorisation. It is currently used by many customers in the context of medicines, chemicals, food additives, or genetically modified organisms.

### Definition of data exchange formats

- Based on international standards
- Designed towards change
- Assuring authenticity (digital signature)
- Optimising Administrations-to-Business (A2B) and Business-to-Administrations (B2A) communication

### Implementation of REA Case Management System

- Centralised or decentralised architecture
- Flexible workflow support
- Secure access to information
- Online and offline options

## FROM REGULATION TO PROJECT OPERATION

### Specification and architecture

- On-site information gathering
- Design fully in line with the regulation
- Compliant to EC enterprise framework
- Open data and message format

### Roll-out

- Progressive roll-out according to predefined priorities

### Implementation

- Based on open source reusable components
- Cost-effective nearshore center in Greece
- Standard information exchange format

### One stop shopping

- Design, implementation, maintenance and hosting services

## TANGIBLE BENEFITS

- Increased efficiency and credibility, clear file status and fast access to data
- System fully in line with the regulation

## REGISTRATION, EVALUATION & AUTHORISATION (REA)

Our solution is based upon a 'one-stop-shop' approach to a comprehensive IT system, defining system requirements in line with and an architecture that is open to be implemented at various levels, such as European administrations, local governments and industrial companies. Based on data exchange standards and a flexible workflow engine, the system is designed to support technological, organisational and regulatory changes.

## WHY OUR CUSTOMERS WORK WITH US

### One Stop Shopping

Offering system specification based on the regulation, architecture, definition, development, roll-out and support.

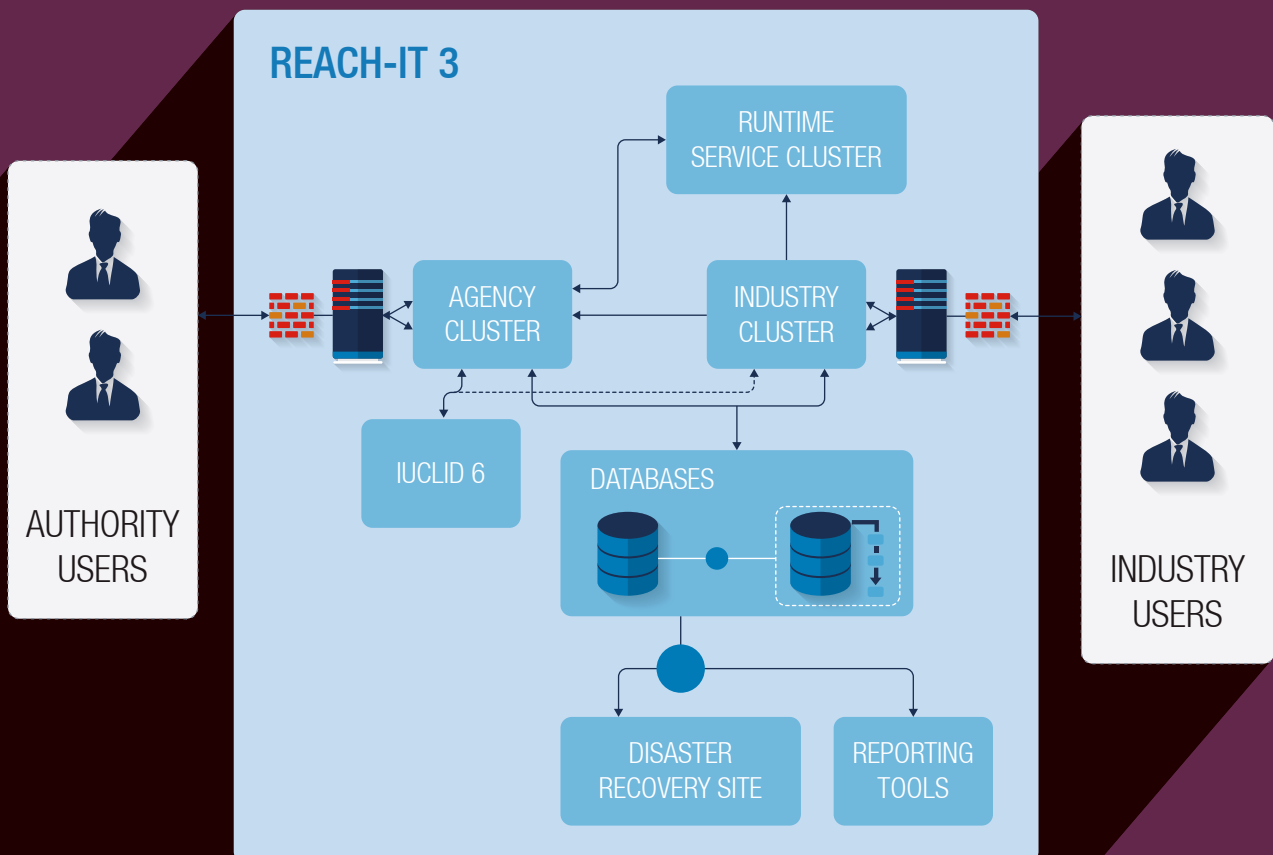
### Efficiency & effectiveness

Leveraging reusable components into a solution design that facilitates day-to-day work.

### Expertise

Similar challenges for peers have been solved before (REACH, KYOTO, EMA, OHIM, eGovernment).

## REA SOLUTION - EXAMPLE OF THE REACH-IT SYSTEM





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