

**Attachment 1**

**LOT 1  
Case Study 1**

**REQUEST FORM**

**Request type: Fixed Price (FP)**

**Title:** Development of an IT tool to characterise datasets of chemicals

**Request Form ID ECHA/2009/39/1-1  
Framework Contract N° ECHA/2009/39**

**To**

Contractor: Your company  
Contact person: You  
Phone n°: Your phone  
FAX n°: your FAX

*Description of required service*

**Specifications:** see below.

**Expected start date:** 1/8/2009

**Delay for delivery** (e.g. in months) : 12 months maximum

**Place of delivery:** Helsinki

**Y/N date :** 15/06/2009

**Expected offer date (optional) :** 30/06/2009

**From the Agency**

## 1. CONTEXT/INTRODUCTION

To fulfil its responsibilities coming from the REACH Regulation (EC Regulation No 1907/2006<sup>1</sup>), the European Chemicals Agency will have to screen through a very high number of registration dossiers and notifications. Three examples to highlight:

- I. **Evaluation of registration dossiers.** The Agency has the responsibility to examine any testing proposal set out in a registration [Art. 40(1) of the REACH Regulation] and to check for compliance a minimum of 5% of dossiers per tonnage band [Art. 41(5)]. A number of criteria must be taken into account when prioritising testing proposals for evaluation or when selecting dossiers for compliance check.  
The prioritisation/selection process will require that a very large number of registration dossiers be screened, selected and possibly ranked, with respect to the prioritisation/selection criteria. As an example, an estimated 25,000-50,000 dossiers will have to be screened in 2010.
- II. **Assessment of PPORD notifications.** The Agency has to identify notifications for which it wants to request further information and impose conditions in accordance with article 9(4).
- III. **Reporting.** The Agency is legally required to publish a number of reports about its REACH activities, as summarised in Table 1. Other 'ad-hoc' reports may be requested by the different stakeholders.

Table 1: Reports legally required from the Agency under REACH

Legal reference	Subject
Art.54	Progress in the area of evaluation, including recommendations to improve the quality of future registrations
Art.83(3)	Activities of the Agency in the previous year
Art.117(3)	Use of non-animal test methods and strategies for risk assessment
Art.117(2)	Overall status of REACH operation

The information necessary in order to build these reports and indicators are available in the REACH-IT and IUCLID databases. In the first one information concerning the submission context (e.g. dossier type: registration, PPORD notification, inquiry; joint submission; updates) are available whereas the second one also stores information about (physico-chemical, toxicological, ecotoxicological) properties and uses of chemicals.

Performing the above mentioned tasks manually would hardly be manageable. An IT solution is needed to automatically retrieve, for each dossier or notification, the relevant information and process it to produce the complex information that will be needed to support decisions or reporting.

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<sup>1</sup> All references to articles in this case study are referring to this Regulation

## 2. SOLUTION TO BE DEVELOPED

The Agency would like to develop an IT solution to automatically retrieve, from various databases, selected information related to a dossier or a notification (registration, PPORD) and process this information to create additional, higher level information (i.e. 'characteristics') about the dossier or notification. Table 2 gives a few examples of dossier characteristics. The IT solution should then use the determined characteristics to help in a number of REACH tasks, like:

- set priority to select dossiers for Compliance check or Testing Proposal Evaluation,
- provide information needed when evaluating a registration dossier,
- provide information needed when assessing a PPORD notification to determine whether to request further information and impose conditions,
- generate reports about the registration, PPORD, Inquiry and C&L processes.

To the user, the tool should appear as an interface enabling him/her to select the type of desired report or priority list and to enter the relevant parameters, (e.g. set of 'characteristics' to process, reporting format, prioritisation rules) to be used for reporting or for setting priority.

The bulk of the data that the tool will have to handle is data from dossiers and notifications. These data are submitted to the Agency via REACH-IT as IUCLID dossiers and are stored in Oracle databases.

The tool should also be able to handle data from other databases.

Table 2: Example of dossier characteristics

Relevance (WHY?)		Dossier characterisation (WHAT?)	
Legal text or other basis	Article	Question to be answered	Dossier characteristic
<p><i>The Agency may examine any registration in order to verify any of the following:</i> [...]</p> <p>that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;</p>	41(1)(b)	<ul style="list-style-type: none"> <li>Is the dossier using data waiving? Is it using too much data waiving? Or for critical endpoints?</li> </ul>	<ul style="list-style-type: none"> <li>Number of data waivers in the dossier</li> <li>Table indicating the endpoints for which data waiving is requested and the basis for the waiving (scientific, technical, exposure or other)</li> </ul>
Check compliance with the obligation to participate in joint submission of data by multiple registrants	11(1)	<ul style="list-style-type: none"> <li>If there is more than one registrant for a substance, have they submitted one single joint submission?</li> <li>Has the registrant participated in a joint submission?</li> </ul>	<ul style="list-style-type: none"> <li>Other dossiers have been submitted on the same substance. (True/False).</li> <li>The dossier belongs to a joint submission (T/F).</li> <li>List of all joint or individual submissions for the same substance</li> <li>All other dossiers submitted on the same substance are part of a joint submission. (T/F).</li> </ul>

### 3. DESCRIPTION OF DELIVERABLES

- After 2 months: Analysis of the system with use case model and design model,
- After 4 months: Functional prototype of the system,
- After 9 months: First release of the system with its technical documentation,
- After 11 months: Final delivery of the system.

### 4. WORK ENVIRONMENT/CONDITIONS

The following technologies can be used for the system:

- Oracle 9i,
- WebLogic 8.1,
- Apache Web Server 3.1,
- Internet Explorer 6.

Developments will be made in Java with PL/SQL stored procedures.

We wish to remind you that this Request Form does not constitute any firm order until such time as a contractual document, signed by the Agency, has been received by you.

An UML tool will be used for design and modelling.

All documents must be provided in MS Word and PDF file formats

The following meetings have to be foreseen at the Agency's premises:

- A project kick-off meeting,
- Monthly progress meetings.

A monthly progress report has to be provided to the Agency by the Contractor.

## **5. CONTENTS OF THE OFFER**

**The offer must include a project plan, the roles, profiles and structure of the project team, the proposed workload of each member of the team.**

**The methodology that will be used for the project has to be described.**

**A technical proposal should as well been included in the offer.**

### ***5.1. Vision for the tool***

#### **5.1.1. Tool functionality**

Describe the main functionalities of the tool.

#### **5.1.2. Tool architecture**

Describe the overall principles for building the tool as well as the main elements of the tool architecture.

## **5.2. Project management**

### **5.2.1. Project Approach**

Describe in this section the structured approach to this project, the stages and, if applicable, the work-streams. The description could include:

- The identification of the foreseeable work-streams in the project,
- The identification of the knowledge skills and attributes required for each work-stream,
- The description of how each of the work-streams (including all required stages of the development lifecycle) would be approached in terms of:
  - o Who is to undertake the work;
  - o The number of people required, from which organisation and over what period;
  - o Where the work would be done (on-site, off-site, or a combination) and what facilities/equipment would be required.

### **5.2.2. Management and organisation structure**

Describe the structure of the project management and organisation.

### **5.2.3. Constraints**

Describe any constraint that the tool development must observe e.g. financial, time, legal, technical, organizational, security, etc.

### **5.2.4. Deliverables**

Describe the final deliverables and the outcome(s) to be achieved through their delivery.

### **5.2.5. Project work plan and expected timeframe**

Identify the proposed project timescale and any known milestone events. Summarise a project roadmap.