Data Management Platform

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Provision of Deficiency data to R-IT

Business Requirement Document

Distribution and Revision History

| Version | Date issued | | Prepared by | Description of Change |
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| v1.0 | 18/09/2020 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Initial version |
| v1.1 | 08/10/2020 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Incorporation of R\_IT comments and addition (section 13) of the technical interface. |
| v1.2 | 04/12/2020 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Update the JSON object returned due to change of data element’s data type in the source. |
| v1.3 | 05/01/2021 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Update to support the R-IT need to get all Registration Numbers of a Joint Submission (in the array) in one call. 2. Sections 9.1.1, 9.1.2, 13.2 changed. |
| v2.0 | 16/04/2021 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Update document to adopt extension for existing Web service 2. Cover R-It need for a second Web Service to notify Industry for substances under compliance check   More specifically, focus on sections 1.2, 3.1.1, 3.2, 6.2, 7, 9.1.6, 9.2, 10, 13.2. |
| v2.1 | 14/05/2021 | | [Kollaros Nikolaos](mailto:Nikolaos.KOLLAROS@trasys.gr) | 1. Support multiplicity of Binders in source interface (9.1.6, 13.1.2) |
| Distribution list | | ECHA, TRASYS Greece | | |

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# Introduction

## Purpose

The purpose of the document is to capture the functional and non-functional requirements of the Data Integration related to the provision of Deficiency data to REACT-IT.

## Scope of work

The scope of the work presented in this Business Requirement Document focus on the provision of data that belong to the Deficiency (Information Requirements) data domain.

The goal of REACH IT is:

1. To display information on the Joint submission (JS) page on the dossier evaluation processes (CCH/TPE) that have been initiated by ECHA. The provision of Deficiency data to REACH IT is the scope of this task and this requirement will form the aspects of the solution design for this phase within the scope of planned release 3.5 for DIP. The work to fulfil IP’s request is reported in related Jira Epic (*ref.* [*DATA-3098*](https://pmo.trasys.be/jira/browse/DATA-3098)). Moreover, in the context of DIP 3.7 release, an extension of the set of elements requested is needed and provided in the same data structure (item [628031](https://dev.azure.com/echa-ecm/DIP/_workitems/edit/628031)).
2. To trigger an automated notification for the Industry to inform them in a daily basis for substances that are under Compliance Check (item [628031](https://dev.azure.com/echa-ecm/DIP/_workitems/edit/628031)).

## Objectives

While the purpose and scope state the overall direction, the document intents to achieve the following objectives with their stated meaning:

Correctness· accurate and valid description of the system functionality as perceived by all project stakeholders. The word all deserves particular mention since there are numerous project stakeholders not always sharing the same expectations for certain aspects of the system functionality. If such cases occur, the document should capture the decisions taken that satisfy all project stakeholders.

Completeness· all the intended functionality should be included in the document without omissions and without neglecting to explain important concepts. The context of completeness is functional; therefore, it should not contradict with conciseness (see below), which has a general context. In rare cases where the two objectives are found to be contradicting, then completeness should be considered as a higher priority and take precedence.

Unambiguousness· explicit and comprehensible descriptions conveying only one meaning and in particular the intended meaning. Wording should be carefully chosen such that it leads any reader to the intended interpretation, thus avoiding misapprehensions. Moreover, the words denoting business concepts should be established and consensual terms from the business vocabulary.

Consistency· the document follows a defined and predictable structure. In addition, the functionalities specified throughout the document should not be conflicting with one another and the same terms should be used for the same concepts without conflicting statements.

Conciseness· while the document should capture all important aspects (see completeness objective above), it should avoid lengthy and comprehensive explanations and instead aim at simplicity and compactness in a way that is useful and manageable. Towards this objective, conceptual models are used to capture the subject matter entities and their relationships following industry standard semantics and notation.

## Structure

This document is structured as follows:

1. [Introduction](#_Introduction): general introduction to the document.
2. Part A - Project Drivers and Constraints: brief description of the business requirements that is planned to be fulfilled, including all identified assumptions, constraints, and future enhancements, closing with an overview of the basic stakeholders and their role in the current implementation.
3. [Part B - Functional Requirements](#partB): functional requirements within the scope of the corresponding business needs.
4. [Part C - Non-Functional Requirements](#partC): non-functional requirements within the scope of the corresponding business needs.
5. [Part D – Interface Requirements](#partD): Detailed presentation of Inbound and outbound interfaces
6. [Part E – Appendix.](#_Appendix-list_of_referenced)

## References

The referenced documents are listed in the table below.

| Ref. | Document Title | Confluence Link(s) / SharePoint / File(s) |
| --- | --- | --- |
| R01 | Business Request Document, v1.3, Demi Rigou, 28/08/2020 | [DMP Consumer Business Request\_DEV\_data\_REACH-IT\_v1.3 (docx)](#_Appendix-list_of_referenced) |
| R02 | Business requirements and mock-ups, Demi Rigou | [Business requirements and mock-ups (confluence page)](#_Appendix-list_of_referenced) |
| R03 | Information Requirement Enterprise Logical Data Model | [Deficiencies LDM](#_Appendix-list_of_referenced) |
| R04 | Business Request Document, v.1 Demi Rigou, 12/3/2021 | [Business Request Document BRD-Provision of additional DEV data to REACH-IT](https://echa.sharepoint.com/:w:/r/sites/REACH-IT/_layouts/15/Doc.aspx?sourcedoc=%7B5D56EB0D-E61D-48E2-9B8E-3AADA624FF8C%7D&file=BRD-Provision%20of%20additional%20DEV%20data%20to%20REACH-IT.docx&wdLOR=cB354E008-E83F-4D8B-803A-427B501777F7&action=default&mobileredirect=true) |

Table 1 - List of References

## Abbreviations

A glossary containing the meanings of all names, acronyms, and abbreviations used by the stakeholders.

| Abbreviation | Description |
| --- | --- |
| ECHA | European Chemicals Agency |
| BIDI | Business Intelligence and Data Integration |
| BIS | Business Intelligence Suite (*ref. Reporting and Visualization via SAP BusinessObjects BI Suite*) |
| BO | Business Objects Business Intelligence Suite |
| DIP | Data Integration Platform (*ref. Oracle Data Integrator*) |
| DMP | Data Management Platform (BIDI, DIP and DMP refer to the same integration platform depicting different eras of its evolution) |
| EDM | Enterprise Data Model |
| DWH | Data Warehouse Database |
| MDS | Master Data Services (*ref. Microsoft Master Data Management system)* |
| R-IT | REACH IT (*ref. Registration, Evaluation, Authorisation and Restriction of Chemicals*) |
| IUCLID | International Uniform Chemical Information Database |

Table 2 - List of Abbreviations

Part A - PROJECT DRIVERS AND CONSTRAINTS

# Stakeholders

## Data Management Platform (DMP)

Data Management Platform unifies data from several transactional case management systems and flat files and makes them available to various consuming systems. It also produces business intelligence reports to facilitate day-to-day operations and decision making.

## REACH\_IT (R-IT)

REACH-IT (hereafter R-IT) is the central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers. These three parties each have access to specific functions of R-IT which they can use to fulfil their requirements under the REACH and CLP regulations. R-IT is the source for providing administrative data related to AFA, as well as data related to the uses applied for authorisation.

## Dynamic Case (DyCa)

Dynamic Case is one of the main Case management systems of ECHA. The assessment of the dossier evaluations cases are handled within Dynamic Case and it is the main source of the data required for the Information Requirements data domain. The Assessment Module is a software module that is encapsulated within DyCa, exchange Case related data and is responsible to support the assessment functionality.

## SIGMA (RML)

A single, central, IT system that collects, stores, and synchronises substance identifiers, groups and regulatory context from all sources relevant to all ECHA business processes. This system fulfils ECHA’s strategic objective to maximise the availability of high quality data to enable the safe manufacture and use of chemicals.

## Master Data Services (MDS)

MDS stands for Master Data Services (MDS) and it is the Microsoft SQL Server solution for master data management. Master Data Services enables administrators to manage a master set of organization's data. They can organize the data into models, entities and attributes, create rules for updating the data, and control who updates the data. ECHA uses MDS as a single point of truth for Concern Data.

## Actors & Roles

The following table specifies the actors and their role for describing the use case scenarios.

| Actor Code | Actor | Role |
| --- | --- | --- |
| DyCas-S | Dynamic Case System | Source |
| DMP-I | Data Integration Platform | Integrator |
| RIT-C | REACH IT System | Consumer |

Table 3 - List of Actors

# Business requirements

This section provides a holistic overview of the business need of the consuming system – and more specifically R-IT – to have data in the context of the Deficiency data domain. A detailed description of the data requirements is documented in the following paragraphs of this section.

## Background

The need of REACH IT is to present information related to the dossier evaluation processes (CCH/TPE) that have been initiated by ECHA for Joint submissions. This information will be displayed on the Joint submission (JS) page in order to:

1. Enhance transparency of regulatory processes (CCH/TPE) for all members of a JS
2. Facilitate transparency and more effective communication with Industry users

The source system in which dossier evaluation data is stored, is Dynamic case (case related information) and Assessment Tool (Module encapsulated in Dynamic Case source system). The purpose of this tool is to capture assessment information in a more accurate, structured, detailed and informative way.

The steps of the Dossier evaluation process could be summarized in the following points:

1. The dossier evaluation procedure applies to any registration dossier once selected for evaluation: namely, when a dossier contains one or more testing proposals or when a substance has been selected for compliance check, according to pre-defined criteria.
2. The dossier evaluation process covers compliance checks (CCH) and the examination of testing proposals (TPE).
3. Information provided in the dossiers of registered substances are assessed by the ECHA with regard to the adequacy of the proposed tests and compliance of the information provided.
4. Following the assessment, registrants may be required to submit or generate additional information on the substance.
5. Information on Dossiers that are or have been under Dossier evaluation can be found [here](https://echa.europa.eu/information-on-chemicals/dossier-evaluation-status).
6. Currently registrants do not have visibility of all the steps of the process (from initiation to conclusion). Concerned registrants are informed when the draft or final decision has been issued, as they receive a task in R-IT. The rest of the (interested) registrants have no visibility of this.

A dossier evaluation process is launched in DyCa and passes through different steps (statuses) until it is concluded. It is mentioned that the evolution of the process status, as **R-IT defines process status in accordance with information presented to its UI**, will be calculated by R-IT as:

* Under assessment
  + The Dossier evaluation process (CCH/TPE) has been initiated and is under evaluation
* Ongoing
  + Draft decision (DD) has been published to registrant(s)
  + Registrants comment on the DD
  + PfAs (if any) are sent to the registrants
* Information requested
  + FD has been published to registrant(s), specifying further information that the registrant(s) need to provide by a specific deadline
* Follow-up
  + ECHA checks whether the information requirements have been addressed by the registrant(s) (by submitting an updated registration dossier)
* Concluded
  + If multiple follow-up processes exist for a case, the dossier evaluation is considered is 'Concluded' when all follow-up cases have been closed
  + Cases that are terminated with no action (no FUP case created) after the DD is published, are considered 'Concluded' (Information requested & Follow-up steps are skipped)

This status evolution is not the one that is provided by DyCa on EDM (process map) level.

Generally, information requested belongs to the Deficiency (Information Requirements) Data Domain and data required to populate the information on the dossier evaluation processes will be retrieved from DMP. In a **high level** description, business requirements are depicted in the table below since detailed description of each one can be found in the [Confluence page, Section: Requirements](https://pmo.trasys.be/confluence/pages/viewpage.action?pageId=129017480) of REACH IT.

|  | Requirement | Description |
| --- | --- | --- |
| 1 | Display Dossier evaluation processes on JS page | The Dossier evaluation processes that have been launched for a JS should be displayed on the JS page in REACH-IT (in both Industry and Agency view) |
| 2 | Display information on each Dossier evaluation process | When clicking on each dossier evaluation process, additional information should be displayed (e.g. type, start date, progress of dossier evaluation, recipients of current decision) |
| 3 | Display progress of Dossier evaluation process | The progress of each dossier evaluation process should be displayed (i.e. history of statuses changed) |
| 4 | Display recipients of the current decision for each Dossier evaluation process | The recipients of the current (draft or final) decision should be displayed for each dossier evaluation process |
| 5 | Display endpoints requested in the draft decision | The endpoints requested in the draft decision should be displayed under the appropriate status |
| 6 | Display endpoints requested in the final decision when it is published | The endpoints requested in the final decision should be displayed under the appropriate status |
| 7 | Display endpoints requested in the final decision upon follow-up | Endpoints requested in the final decision should be displayed under the appropriate status with a status indicator for each endpoint (compliant or not) |
| 8 | Display additional information about the case | Display information from new 'Additional information' fields in DC |
| 9 | Inform active registrants when a compliance check has been initiated | Registrants with an active registration should be notified when a compliance check (CCH) has been initiated |

Table 4 – High level Business requirements

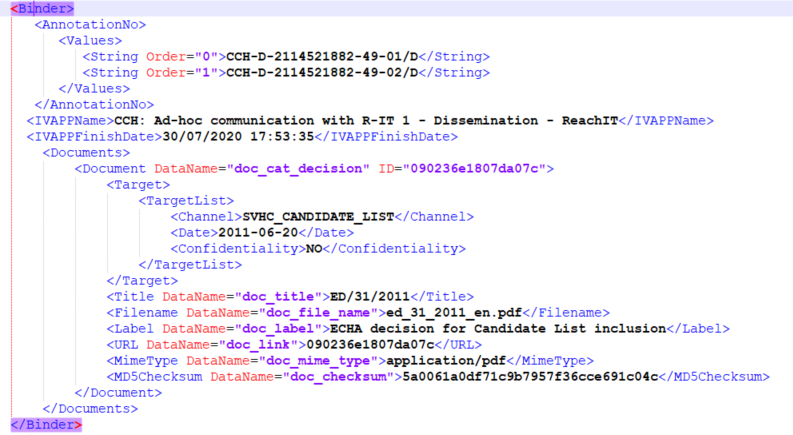
### Additional data elements

In order to support the integration between REACH-IT & DyCa and in addition to the already available information, it was agreed, in the context of [CR2245](https://dev.azure.com/echa-ecm/Dynamic%20Case/_workitems/edit/38817), that DyCa will expose to the XML (unified and simple) the following information for every IVAPP with publishing system = 'REACH-IT', which has been published successfully:

* **Published annotation numbers** for each DEV case (at binder level) used to publish the DD and FD
* **IVAPP configuration name** used to publish the annotations for the DD and FD
* **Finish date** of the IVAPP's Publish step

The above information will be exposed for every IVAPP with publishing system = 'REACH-IT' which has been published. Though the alignment is only about DEV BAPs, the exposure of these new elements from DyCa will not only apply to cases that belong to a dossier evaluation process map, but to **all Process Maps**.

Note, that due to another implementation (CR266242) of R-IT/DyCa alignment for AFAOD BAP, there is possibility of publishing documents to REACH-IT without the need of annotation numbers. As a result, for the aforementioned attributes that will be exposed to the XML, annotation number element will be blank.

More specifically, the data elements required by R-IT are embedded in the XML files (Unified or Standard) sent daily by DyCa and are located in **Binder section** on **BAP Case level**:

|  |  |  |
| --- | --- | --- |
| *XML file examples:* | *(Unified xml)* | *(Standard xml)* |

The extension of the Dossier evaluations feature in REACH-IT, is in place in order to display the list of Recipients of the draft or final decision in REACH-IT. The goal is for each Dossier evaluation to display the companies that have received the decision, their registration number and the Annex of each Company’s submission at the time the Draft decision was sent. R-IT is going to rely on the published annotation numbers in order to identify the recipients of the draft/final decision.

## Data requirements

More analytically, the whole data set of the requested data points are summarized in the following exhaustive list submitted by R\_IT.

|  | Data element name | Data Type | Definition | Source System | Relevant  Use cases / Mock-up screen | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 01 | Dossier evaluation processes for a registration | Numeric | ID | DC | * R-IT should be able to retrieve all the dossier evaluation processes for a registration number * Each dossier evaluation process should have a unique identifier that follows the whole journey of the dossier evaluation (from 'Under assessment' to 'Follow-up')   A dossier evaluation process includes all the relevant cases (pre-check, DEV, FD, FUP) | | |
| 02 | Joint submission identifier | Numeric | RegistrationNumber | DC | R-IT must be able to link each dossier evaluation process to the correct JS by using an identifier (registration number) | | |
| 03 | BAP cases for each dossier evaluation process | Array of BAP Cases | CaseNo | DC | * R-IT should be able to identify the BAP cases that have been created under a dossier evaluation process * A dossier evaluation process can have multiple FUP cases   Pre-check cases are out of scope | | |
| 04 | Creation date of process | Date | CreationDate | DC | R-IT should know the creation date of the dossier evaluation process | | |
| 05 | CCH/TPE start date of DEV case of DEV BAP case | Date | dte\_cch\_start  dte\_tpe\_start | DC | * R-IT should display the dossier evaluation process under the relevant JS, once the CCH or TPE start date of the DEV case has been specified in DC   R-IT should notify all active JS members that a CCH has started, via message in R-IT, once the CCH date has been specified in DC | | |
| 06 | Overall status of dossier evaluation process (process map level) | Text | Status | DC | * R-IT should know the status of the dossier evaluation process at process map level   Based on current DC logic, the process map status is the BA lifecycle of the latest created case within the process map instantiation | | |
| 07 | Current lifecycle of each BAP case | Text | Current value for each DEV, FUP and FD case:  cse\_ba\_lifecycle  cse\_public\_lifecycle | DC | * R-IT should know the current lifecycle of each BAP case of a dossier evaluation process in order to display the current status on the JS page   The status displayed on the JS page should be calculated based on the lifecycle of the individual BAP cases (Pre-check cases are of scope) | | |
| 08 | Previous lifecycle(s) of each BAP case  ***[out of scope\*]*** | Text | Previous values for each DEV, FUP and FD case:  cse\_ba\_lifecycle  cse\_public\_lifecycle | DC | R-IT should know all the lifecycles each BAP case has gone through, in order to display the status history of each dossier evaluation process | | |
| 9 | Dossier evaluation type (DEV case) | Text | prc\_dep\_type | DC | * R-IT should display the dossier evaluation type (CCH or TPE) for each dossier evaluation process   Value should be extracted from the DEV case | | |
| 10 | Published annotations for DD and FD for each BAP case  ***[out of scope\*\*]*** | Alphanumeric | * Published annotation numbers for each DEV case (at binder level) used to publish the DD and FD * IVAPP configuration name used to publish the annotations for the DD and FD * Finish date of the IVAPP's Publish step   R-IT should be able to distinguish the most up to date (latest) annotation numbers used to publish the DD and FD (e.g. a timestamp could be exposed at binder level) | DC | * R-IT should be able to identify which DEV case triggered the publishing of the DD and the FD in R-IT, in order to display the recipients of each decision under the right dossier evaluation process * R-IT should be able to identify the latest (most up to date) annotations used to publish the DD and FD (in case more than one DD, FD were published due to error)   Link between annotation - submission - registration number already exists in R-IT, however no link between annotation and dossier evaluation exists (neither at case nor process map level) | | |
| 11 | Case events for DEV and FUP BAP cases | Number | The following cases events should be retrieved:  For DEV case, events with:   * Case event TypeID = 8 (DD Sent to Registrant) * Case event TypeID = 73 (Final Decision Sent to Registrant) * For each FUP case, events with: * Case event TypeID = 9 (Final Decision Deadline Date) * Case event TypeID = 75 (Enforcement Start Date) * Case event TypeID = XX – Follow-up intermediate conclusion date (CR requested)   ***[Note: this Case event will be rolled-out in DC at the end of October. Since BIDI will provide all case events to REACH-IT, the new case event should be included as well.]***   * Case event TypeID = 10 (Follow-up Conclusion Date)   If more than one case events with the same case event TypeID exist in the same BAP case, only the latest case event should be retrieved | DC | The case events should be used to retrieve the assessment points included in the DEV and FUP cases and display them on the JS page under the appropriate status  If more than one case events with the same TypeID exist in a BAP case (e.g. this can happen if due to human error, ECHA needs to publish the DD of FD again), R-IT should display information only from the latest (most current) case event | | |
| 12 | Assessment points for DEV and FUP BAP cases |  | For DEV case with prc\_dep\_type = CCH and for case events with TypeID = 8, 73, the assessment points with TypeID = 7 (Deficiencies-assessments) and outcome result code = INCOMPL should be retrieved   * For DEV case with prc\_dep\_type = TPE and for case events with TypeID = 8, 73, the assessment points with TypeID = 7 and outcome result code = ACCEPTED, MODIFIED, ADDITIONAL\_TEST should be retrieved * For FUP case and for case events with TypeID = 9, the assessment points with TypeID = 7 and outcome result code = NOT\_ASSESS\_FUP\_CCH, NOT\_ASSESS\_FUP\_TPE should be retrieved * For FUP case and for case events with TypeID = 75, 10 & the new case event XX-Follow-up intermediate conclusion date when made available in DyCa, the assessment points with TypeID=7 should be retrieved (without taking into account the outcome result) * If more than one case events with the same case event TypeID exist in the same BAP case, only the assessment points from the latest case event should be retrieved * The following information should be retrieved for each assessment point: * ClassID (Annex name) * SubClassID (Annex Section Description) * OutcomeResultID * RequestedInformationType * RegulationArticleCode * Guideline * Species * Route * TestMaterial * Deadline | | | DC/  Assessment module | * R-IT should display information on the endpoints (i.e. assessment points) under the appropriate status * Only assessment points for deficiency data should be retrieved * Only assessment points for specific case events should be retrieved (also see above data requirement ‘Case events for each BAP case’)   The endpoints should be displayed in R-IT the following format: ‘In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1, deadline)’ |
| 13 | Additional information on the case (from DEV BAP case)  ***[not available in source system yet\*\*\*]*** | Text (may contain a link) | * prc\_dissemination\_reason (if multiple values are selected in DC, they should be provided in the same order as they appear in the drop-down list)   Expected values:   * + ECHA has considered it necessary to issue a new decision according to Article 42(1) and has therefore started or performed a new assessment.   + ECHA has performed an assessment and did not issue a decision.   + ECHA has stopped the assessment because the registrant(s) ceased manufacture.   + ECHA has stopped the assessment after the registrant(s) submitted new information.   + ECHA has stopped the assessment because the testing proposal was inadmissible; ECHA did not issue a decision.   + ECHA has stopped the assessment because the test was already on-going or performed; ECHA did not issue a decision.   + This Decision has been annulled in its entirety by the Board of Appeal in its decision in Case No.   + This Decision has been partly annulled by the Board of Appeal in its decision in Case No.   + This Decision has been upheld by the Board of Appeal in its decision in Case No.   + An Appeal on this Decision was withdrawn, Case No.   + An Appeal on this Decision was withdrawn following its rectification by ECHA in Case No.   + An Appeal on this Decision was withdrawn following its partial rectification by ECHA in Case No.   + This Decision is currently under Appeal, Case No. * prc\_dissemination\_add\_info | DC | * R-IT should display the additional information fields when they are completed in DC * R-IT should display the reason values (prc\_dissemination\_reason) specified in the drop-down list in DC in the same order as they appear in the drop-down list (not in alphabetical order)   Fields are available in the DEV BAP case only | | |
| 14 | Dates related to the DD and FD from DEV and FUP case(s) | Date | dte\_dd\_sent\_to\_reg  dte\_final\_decision  dte\_fd\_deadline | DC | * R-IT should display the endpoint information on the JS page under the appropriate status, only if these dates exist in DC (date value not null)   If dte\_fd\_deadline is deleted from a FUP case in DC due to an appeal, the endpoints from that FUP case should not be displayed on the JS page | | |

Table 5 - List of requested Data Elements

|  |  |
| --- | --- |
| A picture containing drawing, sign  Description automatically generated | The list of requested data elements is the result of collaborative and supporting effort of all stakeholders i.e. R-IT, DyCa and DMP teams. More detailed comments are embedded in the Business Request Document, v1.3 as presented in [References List](#_References). |

|  |  |
| --- | --- |
| \* | Note that requirement No 8. Previous lifecycle(s) of each BAP case cannot be fulfilled due to the fact that DMP does not keep the historicity of the BAP Case Status and additionally, this is not embedded in the XML interface (file) received by the source system (DyCa). In general terms, DMP keeps only the current state of the data except of predefined data elements for which a special mechanism is build (e.g. Asset owner historicity) in accordance with specialized consumer’s need. The evolution of the BAP Case BA lifecycle is stored and available in DyCa i.e. the dates in which the BAP Case changed status - it is even visible in DyCa UI. Regarding the public lifecycle, this information is not stored but it can be extracted taking into consideration that each Public status(es) is related to a BA lifecycle status. Unfortunately, this information is not part of the XML interface and not available to DMP. As a result, it may be concluded that this requirement is out of the scope of this work. |
| \*\* | Planned for next phase of implementation. Analysis from R-IT/DyCa is still ongoing. DyCa will expose this information in the Case Unified Xml in February 2021. |
| \*\*\* | At the time of the analysis, these fields are not present in XML file yet. DyCa replied that after July of 2020, these fields are going to be propagated automatically in Unified XML files produced. If not present, then, by default, value NULL will be provided to R-IT. |

### Extension of Data Requirements

The ‘Dossier evaluation’ Web service that was implemented to support REACH-IT v3.9.0 in February 2021 should be extended providing some additions to present related data in the ‘Recipients’ section in the Dossier evaluation page. Moreover, there is need for R-IT business to build an automated notification to Industry users when a Compliance Check (CCH) Dossier evaluation has been initiated. The goal is to enhance transparency for Industry users concerning DEVs for Joint submissions (JSs) that they are member of:

* Ability for JS members to see the recipient(s) of the draft/final decisions concerning the DEVs of their JSs. **(Requirement A)**

Based on the existing (R-IT v3.9.0) implementation, all Dossier evaluation processes (CCH or TPE) that have been launched for a JS, are displayed in the ‘ECHA Dossier evaluation status’ section of the JS page populated via the web service provided by DIP. Details on each Dossier evaluation process are displayed in the new ‘Dossier evaluation’ page.

* Ability for registrants to be notified automatically when a CCH has been triggered for a substance they have registered for. **(Requirement B)**

#### Requirement A

|  | Data element name | Definition | Data Type | Source System | Relevant Use cases / Mock-up screen |
| --- | --- | --- | --- | --- | --- |
| 001 | Dossier evaluation unique identifier | ID (edmCaseID) | Numeric | DyCa | **Note:** EDM Case Id is already provided in the current implemented Web Service. |
| 002 | Registration number | RegistrationNumber | Numeric | DyCa | **Note:**  Registration number is already provided in the current implemented Web Service. |
| 003 | Date DD was sent | dte\_dd\_sent\_to\_reg  (taken from BAP case) | Date | DyCa | **Note:** BAP Case Draft Decision sent to Registrant (dte\_dd\_sent\_to\_reg) is already in the Return Items Lists of the current implemented Web Service. |
| 004 | Date FD was sent | dte\_final\_decision  (taken from BAP case) | Date | DyCa | **Note:** BAP Case Final Decision (dte\_final\_decision) is already in the Return Items Lists of the current implemented Web Service. |
| 005 | Annotation numbers used to publish the DD and FD | AnnotationNo  (exposed at BAP case level) | Alphanumeric | DyCa |  |
| 006 | IVAPP configuration name used to publish the annotations | IVAPPName |  | DyCa | Only the IVAPPs listed in Req1 are relevant to the publishing of the DD/FD. Can the WS return only the annotations published by the relevant IVAPPs? |
| 007 | Finish date of the IVAPP’s Publish step | IVAPPFinishDate | Date (Timestamp) | DyCa |  |

Table 6 - List of additional requested Data Elements for Req. A.

**Note:**

1. Given that the existing web service (see [WS-01 Dossier Evaluation process data Information](#_WS-01_Dossier_Evaluation)) already provides relative data elements, it is decided to extend it to cover “Annotation numbers used to publish the DD and FD”, “IVAPP configuration name used to publish the annotations”, “Finish date of the IVAPP’s Publish step”
2. The web service will include these 3 additional elements where available by the source system, avoiding filtering them for specific BAP case types preserving data completeness, and the form of the service as generic as possible.

#### Requirement B

|  | Data element name | Definition | Data Type | Source System | Relevant Use cases / Mock-up screen |
| --- | --- | --- | --- | --- | --- |
| 001 | Substance identifiers for the substance for which CCH DEV case was triggered | TBC | TBC | DyCa | More than one substance identifiers should be provided (e.g. EC number/List No, CAS number, IUPAC name) in case an identifier (EC number) does not exist for that substance.  Case data requested are originated from DyCa, ie. are associated with RML ID. **EC number, CAS number** and **Substance name** should be sufficient to identify the substance |
| 002 | CCH Dossier evaluation identifier | prc\_dep\_type = CCH  (taken from DEV BAP case) | Text | DyCa | Only CCH cases should be returned. Could be taken from Process map sub-type? |
| 003 | CCH start date | dte\_cch\_start  (taken from DEV BAP case) | Date | DyCa |  |

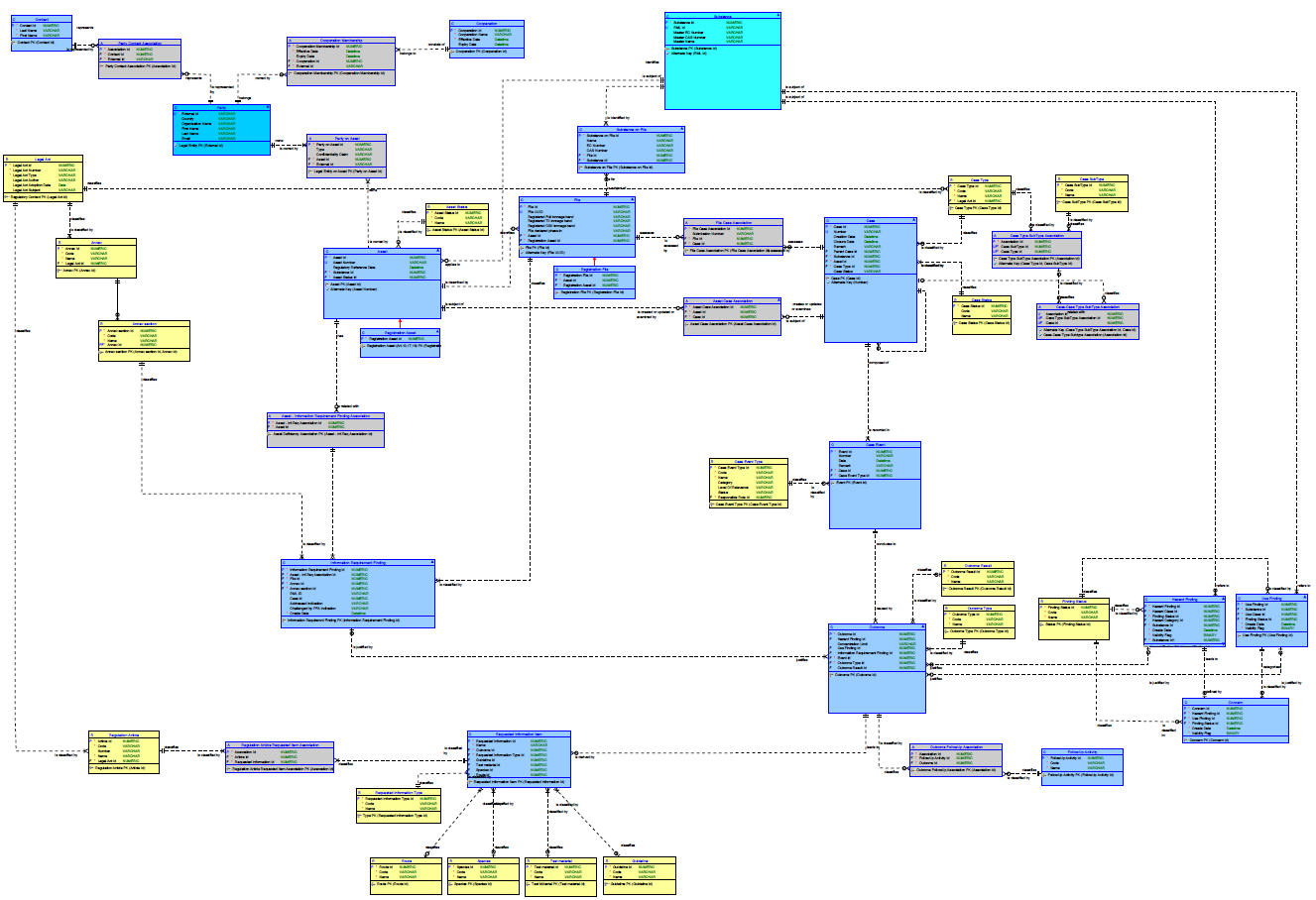
Table 7 - List of additional requested Data Elements for Req. B.

**Note:**

1. It is decided to implement a new dedicated web service (see WS-02 Support automated notification)

# Enterpise Logical Data Model Coverage

To fully support the need of IP to have Concern data available, the proposed solution will cover the whole range of information as presented in the “Information Requirements” (Deficiencies) domain of EDM data model. This ensures that data requirements are met and data will be promoted to R-IT in the highest degree of data integrity and quality. Master entities of the model (blue entities in figure below) cover the main areas of interest including Substance, Case and Concern related information supported by the corresponding (yellow entities) reference lists.

The current version of the Information Requirements logical data model is depicted in the figure below.

It should be noted that the following model is depicted at the time of writing the current deliverable. The following table provides the definitions, on enterprise level, of the essential entities for the Information Requirements data domain. The central entity for Information Requirements is “Information Requirement Finding” where the findings of a Dossier Evaluation assessment under REACH legislation are captured.

| EDM Entity | Definition |
| --- | --- |
| Substance | A substance is any material that is subject of one or more of the regulations under ECHA's responsibility. Substance is understood to include chemical substances, biological substances as well as group substances. |
| Asset | An asset describes an intangible benefit or value for its owner. This ownership might be private or public. An asset records the owner's fulfilment of a legal obligation. For example:  1. Private ownership; for a customer (a.k.a. company, industry)  a. An asset typically represents “a license to be on the market”, e.g. via  i. Having fulfilled the obligation to register their substance – registration asset;  ii. Having successfully applied for authorisation for a substance placed on the authorisation list – authorisation asset;  iii. Having successfully applied for product authorisation for their biocidal product – national/Union authorisation asset; etc.  b. Some other benefit/value, e.g. via  i. Obtaining confirmation of a company’s SME status – SME asset;  ii. Having successfully applied for technical equivalence of an active substance – technical equivalence asset  2. Public ownership; for a regulatory authority, an asset typically represents a risk management measure related decision to limit "the placing on the market", e.g. via  a. Deciding to add a substance to the restriction list – restriction list entry asset;  b. Deciding to add a substance to the authorisation list – authorisation list entry asset;  c. Approving an active substance onto BPR Union list – active substance asset  Each asset has one owner at any given time. Since the ownership of an asset can be transferred, an asset may have many owners over time. Each asset has a lifecycle which is described by its status at any given time. An asset can have a validity period or can be valid indefinitely. |
| File | A file represents the collection of information fulfilling the data requirements needed to establish the related asset. For example, the data requirements for a REACH registration asset are defined in REACH Annexes VI to XI. |
| Party | An entity that takes part or is involved in any activity being managed by ECHA in such a manner that this involvement requires specifically identifying and keeping record of this entity.Parties can be broadly thought of as ECHA's "business partners".Note that party is a subset of stakeholders. Stakeholders includes everybody in the world as everybody is potentially impacted by ECHA's activities. However, ECHA will not keep record of every instance of stakeholder, only those that are considered a party. |
| Case | ​A case is a collection of work that is “opened” and “closed” over a period of time to achieve resolution of some complex activity (e.g. approving an application or registration, completing an evaluation, etc.). It is likely to involve multiple persons inside and outside of ECHA, with varying relationships to each other, as well as multiple documents and messages. Each case records a unique instance/occurrence of a workflow or process. |
| Case event | A case event is a transaction occurring in the context of a case which is deemed of such importance that it needs to be recorded. A case event occurs at a specific point in time, i.e. will have a timestamp recorded. |
| Case outcome | The recorded result of a specific case event. Usually this will be related to either an update of the case subject(s) or the creation of a new thing (e.g. asset, case, concern, etc.). The Outcome result is the outcome of an assessment performed by the event responsible (e.g. Submitter, ECHA), based on the information available at the moment of the event and activities performed. This can be positive (Yes) or negative (No) or recorded as inconclusive. |
| Information Requirements (Deficiency) Finding | A deficiency is a recorded instance of a shortcoming of a registration asset in meeting an individual information requirement type. For example, a complete lack of or insufficient quality of the required information. E.g.: A. IX - 8.7.2. Pre-natal developmental toxicity study - Data Waiving |
| Information Requirement Type | An information requirement type defines the information requirement (e.g. boiling point). What information requirement types are needed per type of file are normally defined in the legal texts. Information requirement types may also be established due to operative business needs. E.g.: A. IX - 8.7.2. Pre-natal developmental toxicity study |
| Provided Information Item | Describes the collection of information provided by the registrant in the context of submitted file on the data requirements for the establishment of the related asset. E.g.: Endpoint Study, CSR, Use, Substance Identification |

Table 8 - List of Entities

# Assumptions & Constraints

The following list contain all assumptions and constraints that will be taken under consideration during the implementation and following the release of the specific business requirements.

1. Data Quality issues related with source systems are not part of DMP’s responsibility.
2. DMP will provide a complete set of data elements in a predefined structure agreed by both parts of this interface (DMP and R-IT). Any filtering actions needed or calculations on top of this data set is responsibility of R-IT. For example, R-IT will apply specific Business Rules to calculate the evolution status of each Dossier evaluation process.
3. In the context of requirements submitted by R-IT, ‘Dossier evaluation process’ is used in the requirements to refer to the dossier evaluation at EDM Case level (process map level referring to DyCa terminology), differentiated from the distinct (BAP) cases (DEV, FD, FUP) that can be included in each EDM Case (process map).
4. The technical interface to provide this kind of information to R-It will be a web service following the practice applied so far to exchange information between R-IT and DMP.
5. The need for R-IT is to display information on the Joint submission page on the regulatory processes (CCH/TPE) that have been initiated by ECHA. Nevertheless, the web service to be implemented will provide data for any Registration Number set up as an input parameter.

PART B - Functional Requirements

# Use Cases

This section provides a detailed description of the DMP use cases for covering the requirements for the provision of Information Requirements (Deficiency) data to R-IT.

## UC-RITDEF-01. Provide Deficiency data to R-IT

|  |  |
| --- | --- |
| Use Case Description | DMP provides, on request, master and process specific information related to Case and Case assessment integrated in DMP in the context of Dossier evaluation regulatory processes |
| Actors | RML-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by R-IT |
| Frequency | Ad-hoc, on request:   1. Whenever a new Case is created in Dynamic Case in the context of DEV process 2. Whenever a new Case assessment is created in Assessment Tool in the context of DEV process |
| Preconditions | 1. DEV Data are produced in DyCa/Assessment tool source systems 2. DyCa has sent successfully the Unified XML file to DMP that contains the requested Case/Case Assessment information. 3. DMP has successfully parsed and integrated XML file. |
| Basic Flow | 1. R-IT makes a request for regulatory information for the Dossier Evaluation process by specifying:  * The Registration Number assigned to a Case * No value for any specific Registration Number  1. DIP responds with a predefined data set that fulfils the searching criteria |
| Alternate Flow(s) | 1. No data available in the context of Dossier Evaluation process for one Registration Number. This means that no data will be made available at all in the response to this service request, neither master nor process specific ones. 2. Dossier Evaluation process specific data are retrieved for multiple Cases matched under a single Registration Number |
| Exception Flow(s) |  |
| Post Conditions | R-IT consumes the data elements received through the agreed web services interface with DIP and presents information on JS submission page. |
| Notes |  |

## UC-RITDEF-02. Provide data to notify registrants

|  |  |
| --- | --- |
| Use Case Description | DMP provides, on request, Substance and Case information integrated in DMP in the context of Dossier evaluation regulatory processes to notify registrants automatically when a CCH has been triggered for a substance. |
| Actors | RML-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by R-IT |
| Frequency | 1. Ad-hoc, i.e. whenever R-IT triggers related web service 2. On a daily basis i.e. R-IT tends to et up a daily mechanism to get via Web Service call the Substances that are in compliance check state. |
| Preconditions | 1. DEV Data are produced in DyCa/Assessment tool source systems 2. DyCa has sent successfully the Unified XML file to DMP that contains the requested Case/Case Assessment information. 3. DMP has successfully parsed and integrated XML file. |
| Basic Flow | 1. R-IT makes a request – searching in a predefined time period- for regulatory information for the Dossier Evaluation process by specifying Substance identifiers for the substance for which CCH DEV case was triggered. |
| Alternate Flow(s) | 1. No data available in the context of CCH of Dossier Evaluation process for the defined time interval. |
| Exception Flow(s) |  |
| Post Conditions | R-IT consumes the data elements received through the agreed web services interface with DIP and presents information on JS submission page. |
| Notes |  |

# Business Rules

This section provides the list of business rules that have an impact on the business domain that is the source of the requirements.

| BR ID | Description | Consumer |
| --- | --- | --- |
| BR001 | R-IT should be able to retrieve all the dossier evaluation processes for a registration number which is a unique identifier of the dossier evaluation process (Related to WS-01 web service, Return Item 01). | R-IT |
| BR002 | Requirement to provide “Previous lifecycle(s) of each BAP case” is out of scope. | R-IT |
| BR003 | The Process status as displayed on the JS page will be calculated based on the lifecycle of the individual BAP cases, but it will not be calculated in DMP. Business rules will be applied in REACH-IT to calculate the current status of each Dossier evaluation process. | R-IT |
| BR004 | R-IT must be able to link each dossier evaluation process to the correct JS by using an identifier (registration number) (Related to WS-01 web service, Return Item 02). | R-IT |
| BR005 | R-IT should be able to identify the BAP cases that have been created under a dossier evaluation process (Related to WS-01 web service, Return Item 05). | R-IT |
| BR006 | Specific rules apply for retrieving the deficiency assessment points based on the type of BAP case, case events and outcome results (see Return Items list). | R-IT |
| BR007 | Each Dossier evaluation process (EDM Case) is split in multiple cases (BAPs) as displayed below:   * Pre-check (1 case) * DEV (1 case) * FD (0-1 case) * FUP (0-5 cases) | R-IT |
| BR008 | Although Pre-check BAP cases are out of scope for R-IT, DMP will return all types of BAP Cases – for reasons of homogeneity and potential future need. The same approach will be followed with Case events. Although R-IT requires Case events for DEV and FUP BAP cases, all types of Case events will be provided to cover all possible business scenarios. Of course, all needed data elements to apply an effective filtering can be applied, will be provided to the web service consumer. | R-IT |
| BR009 | The Latest Case event is calculated on BAP Case level based on the most recent Case event Date. Note that due to low data quality from the source system it is possible to have more than one Case events of a BAP Case with the indication TRUE for “Latest BAP Case event”. In such a case, the consuming system should open a remedy ticket to the source system (DyCa) to proceed with data correction actions. Nevertheless, the occurrence of “double latest case event” is relatively rare. [Note that - in the case of multiple cases events of the same type – R-IT team plans not to display any information in REACH-IT UI regarding that case event, until the data in the source system are rectified by ECHA.] | R-IT |
| BR010 | The Substance identifier linked to which DIP is going to search the related ones, is located in DyCa Unified XML file, on the EDM process level and more specifically, in the RML ID tag. Having this data element, other substance identifier could be retrieved. |  |

Table 9 - List of Business Rules

# Acceptance Criteria

Acceptance criteria are the conditions that the delivered interface must meet to be accepted by the consuming system. In this context, for each functional area, the following conditions should be valid:

* Data oriented criteria :
  + - Data accessibility
    - Data Correctness
    - Data Completeness
    - Data Unambiguousness
    - Data Consistency
    - Data Conciseness
    - Data accessibility
    - Test Deliverables reviewed and published
* FAT - Testing Acceptance Criteria
  + - All tests cases planned have been run.
    - Level of requirement coverage has been met.
    - No Critical or high severity defects that are deferred.
    - All high risk areas are completely tested.
    - Regression testing is completed
    - Test Deliverables reviewed and published
* UAT - Acceptance Criteria

The following minimum conditions for success in terms of test criteria for UAT testing phase of Data Management are listed as below:

* + - When one critical issue is raised during the Acceptance Testing, the Acceptance Testing may be interrupted, and the software may be rejected.
    - When more than three major issues are raised during the Acceptance Testing, the Acceptance Testing may be interrupted, and the software may be rejected.
    - When more than seven minor issues are raised during the Acceptance Testing, the Acceptance Testing may be interrupted, and the software may be rejected.

# Web Services

## WS-01 Dossier Evaluation process data Information

The scope of this web service is to provide information on master and/or process specific attributes for Cases and Case Assessments, identified by the unique Registration Number which it is assigned to a Case during the ECHA Dossier Evaluation process. In this context, the design of this service will be in the most generic framework possible trying to a) fulfil the need of R-It to present JS information on the corresponding UI page but also b) be a useful tool for any potential consumer to get Dossier Evaluation related information.

### Input Items

|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| 01 | regNumber | Registration Number. The registration number of an Asset | Array of strings | No | [“01-2119459351-41-00000”, “01-2119985166-27-00000”, “01-2119496058-28-1234”] | Example of a WS call for 3 registration numbers |

Table 10 – List of Input Items WS 01

The input parameter is a dynamic one-dimensional Array of Strings which can hold one Registration Number per array element. The web service will return integrated EDM Cases and BAP Case data bound to them, linked with the given Registration Numbers (as stored in the array input parameter).

|  |  |
| --- | --- |
| Following the format of Unified XML that is supported by the Assessment Tool, **Registration Number** is defined on EDM Case (process map) level, on the top of the XML file, and is common for all BAP Cases included. |  |
| **Note:** R-IT needs to know, for all Registration Numbers that participate in a Joint Submission, if there are related Deficiency Data. The consecutive WS calls for each Registration Number in a Joint Submission may cause performance issues. This is the reason why the input parameter turned to Array of Strings instead of a single String as initially planned. So, it has been decided to put all Registration Numbers of a Joint Submission (in an array) and perform just one WS call. | |

### Error handling

An error should be returned in the following cases:

1. regNumber contains letters.
2. regNumber contains special characters other than ‘-‘.

**Note:** if even one element of the Array (i.e. a registration number) is given in a wrong format or is NULL, then the whole process stops and an error will be returned.

### No Results

An empty list will be returned if:

1. The value of input item regNumber is not linked with any EDM Case integrated in DMP platform.
2. There aren’t any integrated Dossier Evaluation processes in DMP originated from Unified XML files.

### Execution business logic rules

|  | Description | Comments |
| --- | --- | --- |
| EX-BR-01 | Search for cases that belong to the Dossier Evaluation Process. This rule is translated to the following focal points:   1. EDM Case type = 25, Evaluate dossier 2. Registration Number equals to the given input item (regNumber) |  |
| EX-BR-02 | Data set retrieved order by;   1. Registration Number asc 2. EDM Case Id asc 3. BAP Case Number asc |  |
| EX-BR-03 | Display only those Outcome records (assessment points) that refer to Deficiencies i.e. Assessment Point Type id equals 7.  *XML file: BAPCase.Event.AssessmentPoint.TypeID=7* |  |
| EX-BR-04 | Return Items for which there is no value, should be set to NULL. | This NULL value could be criterion for applied business logic from R-IT side e.g. Final decision deadline |

Table 11 – List of Execution business logic rules WS 01

### Successful execution

A successful service execution should include one collection of the information elements described in Return items section below.

### Return items

**Note:** There are additional data elements requested in the context of the extension of the already provided web service (see section [Additional data elements](#_Additional_data_elements)) are located on BAP Case level and are marked with an **[\*]** (i.e. rows 17, 18,19).

|  | Item Name | Item Description | Format | Mandatory | Sample data | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| 01 | EDM Case Id | Unique identifier for EDM Case (DEV process Id) | Numeric | Yes | 5765165 | Note: that if EDM Case encapsulates more than one BAP Case, this value will be multiplied accordingly.  *XML file: EDMProcessMap. ID* |
| 02 | Registration Number | The registration number of an Asset | Text | Yes | 01-2119475101-50-0000 | *XML file: EDMProcessMap. RegistrationNumber* |
| 03 | EDM Case creation date | The date EDM Case (Process Map) is created. | Date | No | 2017-02-16 | *XML file: EDMProcessMap. CreationDate* |
| 04 | EDM Case status | The status of EDM Case. | Text | No | Evaluation of Registrants Comments | *XML file: EDMProcessMap. Status* |
| 05 | BAP Case Number (1) | BAP Case Numbers that belong in the EDM Case | Text | Yes | DEV-01-2119475101-50-0000-CCH-1 | *XML file: BAPCase.CaseNo* |
| 06 | BAP Case Type | Case Type Name | Text | Yes | Dossier evaluation | It will help R-IT to filter out data elements that belong to BAP cases of specific Case type. |
| 07 | BAP Case CCH start date | Date data element on BAP level (dte\_cch\_start) | Date | No | 17-10-2019 | It is applied only for DEV BAP Cases (cse\_business\_application=” Dossier evaluation”). Otherwise is NULL.  *XML file: BAPCase.Dates.dte\_cch\_start* |
| 08 | BAP Case TPE start date | Date data element on BAP level (dte\_TPE\_start\_date) | Date | No | 11-12-2019 | It is applied only for DEV BAP Cases (cse\_business\_application=” Dossier evaluation”). Otherwise is NULL.  *XML file: BAPCase.Dates.dte\_tpe\_start* |
| 09 | BAP Case BA Status | Current BA lifecycle of each BAP case | Text | Yes | Evaluation of Registrants Comments | *XML file: BAPCase.LifecycleStates.* *cse\_ba\_lifecycle* |
| 10 | BAP Case public Status | Current public lifecycle of each BAP case | Text | No | Ongoing | *XML file: BAPCase.LifecycleStates. cse\_public\_lifecycle* |
| 11 | DEV BAP Case evaluation type | The Case type of the DEV BAP Case (prc\_dep\_type= CCH or TPE) | Text | No | CCH | It is applied only for DEV BAP Cases (cse\_business\_application=” Dossier evaluation”). Otherwise is NULL.  *XML file: BAPCase.* *ProcessData.prc\_dep\_type* |
| 12 | DEV BAP Case Dissemination reason | **Note**: At the time of the analysis, these fields are not yet present in XML file. If not present, then value NULL will be returned. | Text | No | ["ECHA has performed an assessment and did not issue a decision.", "An Appeal on this Decision was withdrawn, Case No."] | It is applied only for DEV BAP Cases (cse\_business\_application=” Dossier evaluation”). Otherwise is NULL. If multiple values are selected in DyCa, they should be provided in the same order as received)  *XML file: BAPCase.ProcessData.* *prc\_dissemination\_reason* |
| 13 | DEV BAP Case Dissemination additional info | **Note**: At the time of the analysis, these fields are not yet present in XML file. If not present, then value NULL will be returned. | Text | No | Random text | It is applied only for DEV BAP Cases (cse\_business\_application=” Dossier evaluation”). Otherwise is NULL.  *XML file: BAPCase.ProcessData prc\_dissemination\_add\_info* |
| 14 | BAP Case Draft Decision sent to Registrant | Date related to the DD from DEV and FUP case(s) | Date | No | 11-11-2019 | *XML file: BAPCase.Dates.* *dte\_dd\_sent\_to\_reg* |
| 15 | BAP Case Final Decision | Date related to the FD from DEV and FUP case(s) | Date | No | 12-11-2019 | *XML file: BAPCase.Dates.* *dte\_final\_decision* |
| 16 | BAP Case Final Decision Deadline | Date related to the FD from DEV and FUP case(s) | Date | No | 11-11-2019 | *XML file: BAPCase.Dates.* *dte\_fd\_deadline* |
| [\*]17 | BAP Binder Annotation number (5) | Annotation number used to publish the DD and FD | Text, **Part of the binders JSON array** | No | "CCH-D-2114521882-49-20/D" | *(see section* [*Additional data elements*](#_Additional_data_elements)*) XML file: BAPCase.Binders.Binder. AnnotationNo* |
| [\*]18 | BAP Binder IVAPP name | IVAPP configuration name used to publish the annotations | Text, **Part of the binders JSON array** | No | CCH: Ad-hoc communication with R-IT 1 - No Dissemination | *(see section* [*Additional data elements*](#_Additional_data_elements)*) XML file: BAPCase.Binders.Binder. IVAPPName* |
| [\*]19 | BAP Binder IVAPP Finish date | Finish date of the IVAPP’s Publish step | DateTime, **Part of the binders JSON array** | No | 27/07/2020 17:53:35 | *(see section* [*Additional data elements*](#_Additional_data_elements)*) XML file: BAPCase.Binders.Binder.* *IVAPPFinishDate* |
| 20 | Case event Number (2) | Unique technical and business identifier for the case event. | Text | No | DEV-DraftDec-2020-01590 | *XML file: BAPCase.Event.Number* |
| 21 | Case event Type Id | Unique identifier for Case Event Type | Numeric | No | 8 | Based on ‘BAP Case Type’ and ‘Case event Type Id’, R-IT can filter successfully e.g. events of type 8, DD Sent to Registrant, for DEV BAP cases. Normally, it should not be more than one Case events with the same Case event Type Id in a BAP case but this could happen due to source system limitations.  *XML file: BAPCase.Event.TypeID* |
| 22 | Case event Type Name | Case event types reflect the steps of the process being recorded in that specific case type. | Text | No | DD Sent to Registrant | Based on the Reference List description (MDS): Case event Type |
| 23 | Case event Date | Date when the instance of the case event actually took place. | Date | No | 17-04-2020 | Normally, it should not be more than one Case events with the same Case event Type Id and the same Date in a BAP case, but this could happen due to source system limitations.  *XML file: BAPCase.Event.Date* |
| 24 | Latest BAP Case event | Indication to specify the Case event with the most recent Case event date within a BAP Case | Boolean | No | TRUE | Note that due to low data quality from the source system it is possible to have more than one Case events of a BAP Case with the indication TRUE for “Latest BAP Case event”. |
| 25 | Outcome id (3) | The combination of Case event Number and Assessment point id that defines uniquely the Finding id | String | No | AXIV-AuthListIncl-2017-06094-assnt-Use-Overall Use-2014-00408 | It is not requested by R-IT but it will enforce data completeness.  Note: Display only those outcomes that refer to Deficiencies i.e. in XML AssessmentPoint.Type id =7. |
| 26 | Inf. Req. Finding id | Reference to the Inf. Req. finding | String | No | 01-0000000275-79-0000- REACH\_AnXIV-2.3. | It is not requested by R-IT but it will enforce data completeness. The Inf. req. Finding id is the concatenation of Registration Number, REACH Annex and REACH Annex Section. |
| 27 | Annex Name | The addendum to an Legal act that contains rules or technical data that, for practical reasons, do not appear in the enacting terms, and that frequently take the form of a list or table. The annex of the REACH legislation. | String | No | Annex XIV | Based on the Reference List description (MDS): Annex  *XML file: BAPCase.Event.AssessmentPoint.* *ClassID* |
| 28 | Annex Section Number | Number of the subdivision of Annex in a form of section, part, table, etc. | String | No | 2.3. | Based on the Reference List description (MDS): Annex Section  *XML file: BAPCase.Event.AssessmentPoint.* *SubClassID* |
| 29 | Annex Section Description | Subdivision of Annex in a form of section, part, table, etc. | String | No | Composition of each substance | Based on the Reference List description (MDS): Annex Section  *XML file: BAPCase.Event.AssessmentPoint.* *SubClassID* |
| 30 | Outcome Result Code | Result of the outcome, in form of a technical identifier referring to the Outcome Result entity. | String | No | INCOMPL | *XML file: BAPCase.Event.AssessmentPoint.* *OutcomeResultID* |
| 31 | Outcome Result Name | Business name of the outcome result. | String | No | Incompliant | Based on the Reference List description (MDS): Deficiency Outcome results |
| 32 | Requested Information Type Name (4) | Reference to types of requested information e.g. "Experimental study", "CSR", "SID" | String | No | Robust Study Summary | Based on the Reference List description (MDS): Requested Information Type  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.* *RequestedInformationType* |
| 33 | Regulation Article Number | Regulation Article | String | No | Article 41(1) | Based on the Reference List description (MDS): Regulation Article  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.* *RegulationArticleCode* |
| 34 | Guideline Name | Guideline | String | No | OECD 451 | Based on the Reference List description (MDS): Guideline  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.Guideline* |
| 35 | Species Name | Species | String | No | Guinea pig | Based on the Reference List description (MDS): Species  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.Species* |
| 36 | Route Name | Route | String | No | Dermal | Based on the Reference List description (MDS): Route  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.Route* |
| 37 | Test Material Name | Test Material | String | No | Constituent or breakdown product | Based on the Reference List description (MDS): Test Material  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.TestMaterial* |
| 38 | Deadline Name | Deadline | String | No | 3 Months | Based on the Reference List description (MDS): Deadline  *XML file: BAPCase.Event.AssessmentPoint.* *RequestedInformationItem.Deadline* |

Table 12 – List of Return Items WS 01

1. Multiple instances of BAP Cases related to an EDM Case will cause an increase of the number of rows for the whole data set.
2. Multiple instances of Case events related to a BAP Case will cause an increase of the number of rows for the whole data set.
3. Multiple instances of Outcomes related to a Case event will cause an increase of the number of rows for the whole data set.
4. Multiple instances of Requested Information Items related with an Outcome will cause an increase of the number of rows for the whole data set.
5. In the XML file received by the source, it is possible to get multiple instances of BINDERS (that contain Annotations number, IVAPPName, IVAPPFinishDate).

|  |  |
| --- | --- |
| A picture containing drawing, sign  Description automatically generated | The web service return codes are presented analytically in section [Service Execution Status Codes](#_Service_Execution_Status). |

## WS-02 Support automated notification

The scope of this web service is to support an automated notification that will provide R-IT to Industry. Searching for a defined time interval, R-IT needs to know for which Substance there are cases in compliance check state. The web service should check for Dossier Evaluation Cases (DEV) that are of compliance check (CCH) case type and their start date is within given dates. To summarize, R-IT needs to know, all Substances which are in compliance check (CCH) state. After that, R-IT is going to notify all Companies interested in those Substances.

### Input Items

|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| 01 | Start date | The starting date of the time interval (included) | Date | Yes | 15-03-2021 |  |
| 02 | End date | The ending date of the time interval (included) | Date | Yes | 17-03-2021 | End date can be the same as Start date defining a time interval of one day |

Table 13 – List of Input Items WS 02

Input parameters are Start and End date defining a time interval. The web service will return Substances linked to Cases for which their start date belongs (included) within this time interval.

### Error handling

An error should be returned in the following cases:

1. Start date or End date are missing.
2. Start date or End date are not of Date format
3. Start Date is chronologically following End Date (i.e. End Date should always be greater or equal than Start Date)

**Note:** If there is even one error, then the whole process stops and an error will be returned.

### No Results

An empty list will be returned if:

1. There aren’t Substances related with Cases of Compliance Check type that started with the given time interval.

### Execution business logic rules

|  | Description | | Comments |
| --- | --- | --- | --- |
| EX-BR-01 | Search for cases that belong to the Dossier Evaluation Process of compliance check (CCH) case type. This rule is translated to the following focal points:   1. Get all EDM Case type = 25, Evaluate dossier (Unified XML. <EDMProcessMap>. <TypeID> =25) 2. Detect DEV BAP Cases (BAPCase. BusinessApplicationInformation. BusinessApplication = “Dossier Evaluation” | | |
| EX-BR-02 | Filter those BAP Cases where in process data section prc\_dep\_type has value CCH |  | |
| EX-BR-03 | Filter those BAP Cases for which Compliance Check Start Date is within the given time interval i.e. In case section find date element dte\_cch\_start which should fulfil the condition: Input item Start date >= dte\_cch\_start <= Input item End Date | |  |
| EX-BR-04 | If records found, then detect the substance identifier RML ID (BAP Case.References.SML\_ID). Given the RML ID, retrieve linked substance identifiers EC number, CAS number and Substance name | | Although conceptually it would be more appropriate to reach RML in Process MAP level, it is decided to follow the RML as defined on BAP level since (a) other required attributes are checked on BAP level (b) the source system may not have the related validation to set Process Map level correctly.  Note that RML ID should be associated with the **master record of Substance identifiers**. DIP possess only publishable Substance info made available by SIGMA. |
| EX-BR-05 | 1. Distinct Substances/Date result set. 2. Sort result set by date ascending. | |  |

Table 15 – List of Execution business logic rules WS 02

### Successful execution

A successful service execution should include one collection of the information elements described in Return items section below.

**Note:** To prevent the return of large amount of data (e.g. in case of setting as input parameters a quite extended time period), it would be possible to apply pagination to the returned result set.

### Return items

|  | Item Name | Item Description | Format | Mandatory | Sample data | Comments |
| --- | --- | --- | --- | --- | --- | --- |
| 01 | CCH Start Date | The date on which a CCH case started | Date | Yes | 15-03-2021 |  |
| 02 | RML ID | RML Substance Identifier | Text | No | 100.013.880 |  |
| 03 | EC number | European Community number (EC number) assigned to substances for regulatory purposes | Text | No | 215-267-0 |  |
| 04 | CAS number | CAS Registry Number, unique numerical identifier assigned by the Chemical Abstracts Service to every chemical substance | Text | Yes | 1317-36-8 |  |
| 05 | Substance name | Master Substance Name | Text | Yes | Lead monoxide |  |

Table 16 – List of Return Items WS 02

|  |  |
| --- | --- |
| A picture containing drawing, sign  Description automatically generated | The web service return codes are presented analytically in section [Service Execution Status Codes](#_Service_Execution_Status). |

PART C - Non-functional Requirements

# Access Management

The pre-existing access conditions for the affected DMP web services will remain. No new access management requirements were raised or discussed in the context of extending the set of existing web services to support the new functionality.

Additionally, a potential improvement to the existing integration between REACH-IT and BIDI has been added in the Non-functional requirements section, in order to improve the way errors are handled.

|  | Description | Comment |
| --- | --- | --- |
| NFR. 01 | Improve error handling when DIP WS is unavailable or unexpected error occurs | In the current implementation of the ‘Dossier evaluation’ feature in REACH-IT, when there is an error in the DIP refresh, the refresh is incomplete, or still in progress, or an unexpected error occurs, an error is returned the WS response. As a result, no information can be retrieved about any of the reference numbers (input) and therefore no results are displayed for any of the Joint Submissions.  It is decided that in case of DIP’s flow failure, the Web Services will return data available so far (i.e. do not check the “ready to use flag”). The only case for which the Web services could not return data is when the DIP’s flow to populate Dossier Evaluation data is in progress, but this could happen for a very short period during the first hours of a day. So, an improvement will be applied on the WS so that in case of error in the DIP refresh, the results of the previous successful refresh can be retrieved and displayed by R-IT.  In addition, R-IT developed an improved version of the page that differentiates the message shown to the user if DIP’s data are not available or an error in WS call happened. |
| NFR.02 | REACH-IT should be informed when there is an error in the provision of data for the automatic notification | The same approach described above will be followed avoiding a failure in the provision of data for the automatic notification. |

# Performance

No performance requirements are foreseen for implementing the specific demands.

# Data Refresh frequency

DMP is updated once a day, according to the defined and agreed frequency that fulfils the overall business requirements. More analytically:

* DMP data refresh frequency: DMP is refreshed on daily base. This means that the integrated data are one day back.
* DMP & DyCa synchronization frequency: DMP integrates data from Dynamic Case once per day. This means that the integrated data are one day back.
* DMP & R-IT synchronization frequency: R-IT can call provided Web Service on demand. This means that the consumed data are one day back.

PART D - Interface requirements

# Web services interface requirements

The source of the requested information is the XML files in the Unified format provided by DyCa/Assessment Module for the Dossier Evaluation Process.

## WS-01 Dossier Evaluation process data Information

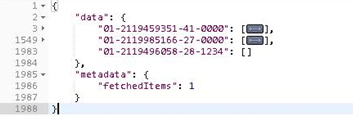
### Input

|  | Parameter name | Value type | Min. occurrence of input parameter | Max. occurrence of input parameter | Mandatory value |
| --- | --- | --- | --- | --- | --- |
| 01 | regNumber | xsd:complexType | 0 | 1 | No |

### Output

The structure of the returned object is in the form of Map<String, Object> wrapped in a JSON, as presented below, where:

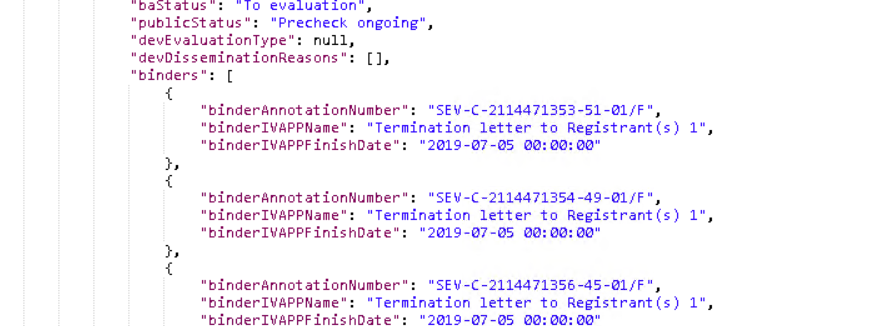
* “String” is the Map key (e.g. “01-2119459351-41-00000”,”), equal to Registration Number
* “Object” is an object, of a predefined structure, in JSON format containing Deficiency data



If for a given Registration Number (e.g. “01-2119496058-28-1234”) there isn’t any results associated, then the corresponding “Object” will be empty. Otherwise, the “Object” part of the Map is structured as follows:



Additional elements, depicted as bold, are inserted on BAP Case level attributes:



The new structure of the JSON object is formed now as shown below:

{

"EDM Case Id": 5765165,

"Registration Number": "01-2119475101-50-0000",

"EDM Case creation date": "2017-02-16",

"EDM Case status": "Evaluation of Registrants Comments",

"BAP Case": [

{

"BAP Case Number”: "DEV-01-2119475101-50-0000-CCH-1",

"BAP Case Type”: "Dossier evaluation",

"BAP Case CCH start date”: "17-10-2019",

"BAP Case TPE start date”: "11-12-2019",

"BAP Case BA Status”: "Evaluation of Registrants Comments",

"BAP Case public Status”: "Ongoing",

"DEV BAP Case evaluation type”: "CCH",

"DEV BAP Case Dissemination reasons”: [{

“ECHA has performed an assessment and did not issue a decision.”

“An Appeal on this Decision was withdrawn, Case No.”

}]

"DEV BAP Case Dissemination additional info”: "",

"BAP Case Draft Decision sent to Registration date”: "11-11-2019",

"BAP Case Final Decision”: "12-11-2019",

"BAP Case Final Decision Deadline”: "11-11-2019",

**"binders": [**

**{**

**"binderAnnotationNumber": "SEV-C-2114471353-51-01/F",**

**"binderIVAPPName": "Termination letter to Registrant(s) 1",**

**"binderIVAPPFinishDate": "2019-07-05 00:00:00"**

**},**

**{**

**"binderAnnotationNumber": "SEV-C-2114471354-49-01/F",**

**"binderIVAPPName": "Termination letter to Registrant(s) 1",**

**"binderIVAPPFinishDate": "2019-07-05 00:00:00"**

**},**

**{**

**"binderAnnotationNumber": "SEV-C-2114471356-45-01/F",**

**"binderIVAPPName": "Termination letter to Registrant(s) 1",**

**"binderIVAPPFinishDate": "2019-07-05 00:00:00"**

**}**

**],**

"Case Event”: [

{

"Case event Number”: "DEV-DraftDec-2020-01591",

"Case event Type Id”: 8,

"Case event Type Name”: "DD Sent to Registrant",

"Case event Date”: "19-04-2020",

"Latest BAP Case event”: "FALSE",

"Outcome”: [{

"Outcome id": "AXIV-AuthListIncl-2017-06094-assnt-Use-Overall Use-2014-00408",

"Inf. Req. Finding id”: "01-0000000275-79-0000- REACH\_AnXIV-2.3.",

"Annex Name”: "Annex XIV",

"Annex Section Number”: "2.3.",

"Annex Section Description”: "Composition of each substance",

"Outcome Result Code”: "INCOMPL",

"Outcome Result Name”: "Incompliant",

"Requested Information”: [{

"Requested Information Type Name”: "Robust Study Summary",

"Regulation Article Number”: "Article 41(1)",

"Guideline Name”: "OECD 451",

"Species Name”: "Guinea pig",

"Route Name”: "Dermal",

"Test Material Name”: "Constituent or breakdown product",

"Deadline Name”: "3 Months"

}]

}]

},

{

"Case event Number”: "DEV-DraftDec-2020-01590",

"Case event Type Id”: 8,

"Case event Type Name”: "DD Sent to Registrant",

"Case event Date”: "17-04-2020",

"Latest BAP Case event”: "TRUE",

"Outcome”: [{

"Outcome id": "AXIV-AuthListIncl-2017-06094-assnt-Use-Overall Use-2014-00408",

"Inf. Req. Finding id”: "01-0000000275-79-0000- REACH\_AnXIV-2.3.",

"Annex Name”: "Annex XIV",

"Annex Section Number”: "2.3.",

"Annex Section Description”: "Composition of each substance",

"Outcome Result Code”: "INCOMPL",

"Outcome Result Name”: "Incompliant",

"Requested Information”: [{

"Requested Information Type Name”: "Robust Study Summary",

"Regulation Article Number”: "Article 41(1)",

"Guideline Name”: "OECD 451",

"Species Name”: "Guinea pig",

"Route Name”: "Dermal",

"Test Material Name”: "Constituent or breakdown product",

"Deadline Name”: "3 Months"

}]

}]

}

]

}

]

}

## Support automated notification

### Input

|  | Parameter name | Value type | Min. occurrence of input parameter | Max. occurrence of input parameter | Mandatory value |
| --- | --- | --- | --- | --- | --- |
| 01 | Start date | Date | 1 | 1 | Yes |
| 02 | End date | Date | 1 |  | Yes |

### Output

Array of objects, of a predefined structure, as the following:



{

"data": [

{

"cchStartDate": "2021-02-25",

"rmlId": "100.002.136",

"ecNumber": "202-349-6",

"casNumber": "94-63-3",

"substanceName": "Pralidoxime iodide"

},

{

"cchStartDate": "2021-03-15",

"rmlId": "100.013.880",

"ecNumber": "215-267-0",

"casNumber": "1317-36-8",

"substanceName": "Lead monoxide "

}

],

"metadata": {

"fetchedItems": 2

}

}

PART E - Appendix

# List of referenced documents

The list of referenced documents are embedded in this appendix to ensure accessibility.

| Ref. | Document Title | Embedded files | Confluence Link(s) / SharePoint / File(s) |
| --- | --- | --- | --- |
| R01 | Business Request Document, v1.3, Demi Rigou, 28/08/2020 |  |  |
| R02 | Business requirements and mock-ups, Demi Rigou |  | [Business requirements and mock-ups (confluence page)](https://pmo.trasys.be/confluence/pages/viewpage.action?pageId=129017480) |
| R03 | Information Requirement Enterprise Logical Data Model |  |  |

Appendix - List of References

# Service Execution Status Codes

| Status Code | Description |
| --- | --- |
| 200 | OK |
| 201 | Created |
| 202 | Accepted (Request accepted, and queued for execution) |
| 400 | Bad request |
| 401 | Authentication failure |
| 403 | Forbidden |
| 404 | Resource not found |
| 405 | Method Not Allowed |
| 409 | Conflict |
| 412 | Precondition Failed |
| 413 | Request Entity Too Large |
| 422 | Unprocessable Entity – mandatory fields are missing. |
| 500 | Internal Server Error |
| 501 | Not Implemented |
| 503 | Service Unavailable |