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| Data Management Platform | | | |
| **BIDI Web Services for R4BP3 – DC Integration**  TrasysInternational-LD - RVB | | | |
| Contract: | |  | |
| File location: | | | Project directory\-\- |
| Ref.: | FWC10\_SC21\_R3.6-R4BP3\_DC Integration\_BIDI Web Services Description | | |

Status information

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Security classification: | RESTRICTED | | State : | | Submitted for Review |
| Current version number: | 1.2 | Date of first issue : | | | 27/09/2019 |
| Prepared by: | OIKONOMIDOU Dimitra (TRASYS), KOLLAROS Nikolaos (ATOS) | | | Date: | 30/11/2020 |
| Verified by: | -- | | | Date: | --/--/---- |
| Approved by: | -- | | | Date: | --/--/---- |

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*(I = for information, A = for action)*

Document change record

| Version | Date | Description | Affected sections | Prepared By |
| --- | --- | --- | --- | --- |
| V1.0 | 27/09/2019 | First version of the document produced for describing necessary extensions and adjustments to existing Web Services between ECHA’s Data Management Platform and Dynamic Case tool for satisfying the latter’s data needs in the context of the tool’s integration with ECHA’s R4BP3 system. | ALL | OIKONOMIDOU Dimitra |
| V1.1 | 20/12/2019 | Updated version of the document to support the creation of a new web service, triggered by DyCa and responsible to detect changed R4BP cases in a specified time interval. | 1.2, 3.2, 6.4, 8.3, 12.4 | KOLLAROS Nikolaos |
| V1.2 | 30/11/2020 | Updated version of the document to cover the extension of the Case Update Web service in order to support 3 additional case types. | 3.3, 8.3, 12.4 | KOLLAROS Nikolaos |

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# Introduction

## Purpose

The purpose of the document is to capture the functional and non-functional requirements for web services to be provided by ECHA’s Data Integration Platform, also known as BIDI, in the context of R4BP-DyCa integration project. The ultimate goal of this document is to provide a reliable supportive tool to developers since it presents in detail the functionality and use cases required to satisfy business needs but also the technical information and specifications required for development.

## Scope

The scope of the analysis work includes the description of the services that are needed for supporting those data needs of R4BP-DyCa integration implementation that have been indicated by ECHA’s architectural team that should be fulfilled via BIDI (For the use cases which require data from BIDI please refer to R01).

The services that will be provided by BIDI to Dynamic Case in the context of its integration with R4BP3 will be implemented by extending the scope of existing web services, already implemented in BIDI and consumed by DyCa. Thus the scope of the current analysis work, does not include neither focuses on existing functionality and use cases already supported by the affected BIDI web services, but deals only with the new, additional functionality by which the current web services will need to be extended in order to support the new use cases of the R4BP-DyCa integration implementation.

At the same time, in the framework of the second phase of R4BP3 – DyCa Integration project, will be analytically presented the approach followed to cover the need of expanding the current functionality i.e. to provide automatically to Dynamic Case application updated case-related Information coming from R4BP through BIDI.

## Objectives

While the aforementioned purpose and scope states the overall direction, the document intents to achieve 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

The document is structured as follows:

* Introduction: provides a general introduction to the document.
* Part A Project Drivers and Constraints: provides a brief description of
  + Stakeholders involved and their role in the current implementation.
  + High level Business Requirements
  + EDM Coverage on conceptual level
  + Assumptions and constraints that should be taken into consideration during the implementation of the specific demands.
* Part B Functional Requirements: provides the functional requirements following the use case approach along with the related business rules.
* Part C Non Functional Requirements: provides the non-functional requirements.
* Part D Interface Requirements: provides the interface requirements (inbound / outbound).
* Part E Appendix: provides any supportive material.

## References

The referenced documents are listed in the Table 1‑1.

Table 1‑1

|  |  |  |
| --- | --- | --- |
| Ref. | Title | SharePoint/ Confluence Link |
| R01 | Data demands per R4BP-DyCa integration use case described in the Requirements Definition document prepared by Trasys – George Chaitas and UniSystems – Michaelidou Natassa | [link](https://echa.sharepoint.com/:w:/r/sites/ecm/cm/ProjectDocuments/DCRM/07.%20DCRM%20Release%203.3.0/R4BP%20-%20DC%20Integration/Requirements%20definition%20document%20for%20R4BP3-DC%20integration_v0.8.docx?d=w81fa79f09b17408991594f3ec64440e0&csf=1&e=gr40HX) |
| R02 | Documentation of the existing WS interfaces between DyCa and BIDI | [link](https://pmo.trasys.be/confluence/pages/viewpage.action?spaceKey=DATA&title=3+-+Dynamic+Case) |
| R03 | Finalized list of data elements to function as criteria for Case Update | [link](https://pmo.trasys.be/confluence/download/attachments/99300498/R4BP%20-%20DC%20Integration%20Case%20Update_v8.xlsx?version=1&modificationDate=1583170704344&api=v2) |
| R04 | Clarifications for data elements specifications required in the context of Case Update. | [link](https://pmo.trasys.be/confluence/download/attachments/99300498/Missing%20Fields%20R4BP%20that%20are%20required%20by%20DyCa%20in%20the%20Context%20of%20Case%20Update%20web%20service.docx?version=1&modificationDate=1583235228921&api=v2) |
| R05 | List of data elements eligible for the third phase of integration (extension of Case Update web service). | [link](https://pmo.trasys.be/confluence/download/attachments/99300498/R4BP-DC%20Integration_SupersetFor_TE_SBP_UA_20201204_v.1.4.xlsx?version=1&modificationDate=1607858902841&api=v2) |

## Abbreviations

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

Table 1‑2

|  |  |
| --- | --- |
| Abbreviation | Description |
| ECHA | European Chemicals Agency |
| EDM | Enterprise Data Modelling |
| DIP | Data Integration Platform |
| DyCa | Dynamic Case |
| R4BP 3 | Register for Biocidal Products |
| RML | Regulatory Master List |
| WSDL | Web Service Definition Language |

Part A Project Drivers and Constraints

# Stakeholders

This section presents the stakeholders (mainly systems) that interact with the Data Integration Platform (DIP) for implementing the data requirements for R4BP3-DyCa Integration.

## Dynamic Case (DyCa)

Dynamic Case is one of the main Case management systems of ECHA. The assessment of the substance regulatory activities are handled within Dynamic Case and it is also a consumer of RML data for Substance-related cases.

## Data Integration Platform (DIP)

Data Integration Platform (also known as BIDI) 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.

## Register for Biocidal Products (R4BP)

R4BP is the central hub through which all biocides applications are made. It provides functions which enable the industry and the authorities to comply with BPR legislative requirements and exchange information between them.

The management of all BPR regulatory activities i.e. applications for authorisation, decisions and approvals are handled within R4BP and it is the single source of Biocides information.

## Regulatory Master List (RML)

ECHA has acknowledged the need for a list of Substance Masters. That is a list of Substances consistently used by all cross-ECHA systems. More specifically, any Substance that has been subjected within any business process data, shall be identified by ECHA with a unique identifier.

These Substance-information (business process data) concern:

* either data that have been created within ECHA; or
* data that have been submitted by the outside world.

Currently this information is stored in Regulatory Master List (RML) module developed in the context of BIDI development stream. RML is a module designed and developed to perform as a reference list of the registered Substance-entities in BIDI. RML comprises the processes, governance, policies, standards, and tools that consistently define and manage the Substance-entity of ECHA to provide a single point of reference for all systems. The relevant widely accepted identifier for the Substance (or for a Group of Substances) is called RML-ID.

In general, RML-ID is intended to be the unique identifier for master data of a Substance (or a Group of Substances), being the authoritative, most accurate data available about a Substance (or a Group of Substances), used to establish the context for transactional data.

## Identity Management System (IDM)

IDM (Identity Management System) is a set of software applications and technologies that are used for enterprise identity management. Enterprise identity management allows to manage individual entities, their authentication, authorisation, roles and privileges across system and enterprise boundaries

## Actors & Roles

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

Table 2‑1

|  |  |  |
| --- | --- | --- |
| Actor Code | Actor | Role |
| DyCa-C | Dynamic Case System | Consumer |
| DIP-I | Data Integration Platform | Integrator |
| R4BP-S | R4BP | Source |
| IDM-S | Identity Management System | Source |
| RML-S | Regulatory Master List | Source |

# High Level Business Requirements

## First phase – Case create

Data Integration Platform (DIP) already supports, with a set of existing web services, the integration between Dynamic Case and REACH-IT, for the purpose of automating the business processes of REACH regulation currently supported in Dynamic Case.

As of November 2019 Dynamic Case, which is also currently used for supporting the automation of a set of business processes specified in BPR regulation, will start a direct integration with R4BP 3 system. The specific scope extension of DyCa processes and system interfaces will demand significant data exchange between the target system, DyCa, and the system where a large scope of BPR related activities are already supported, namely R4BP.

At the same time, DIP already integrates a wealth of information related to BPR processes, hosted in R4BP system. Thus, it has been identified by ECHA’s architecture team that for a number of integration scenarios between DyCa and R4BP, a set of required data could be retrieved by DyCa from DIP, by re-using a set of existing web services, already established for supporting DyCa’s data needs for REACH processes. The web services in question will be extended by providing data for a new set of regulatory activities from BPR regulation as well as from a new source system, namely R4BP.

The R4BP 3 – DC integration user stories, for which data need to be propagated to DyCa from DIP are[[1]](#footnote-2):

2.1.1 Creation of rejections case in DC

2.2.1 Create Active Substance approval case in DC

2.3.1 Create a new case in DC due to an Article 95 application in R4BP

The existing DIP web services that will need to be modified in order to support delivery of data from DIP for satisfying correspondingly each of the above user stories are:

Table 3‑1

|  |  |
| --- | --- |
| R4BP 3 – DC Integration User Story | Involved DIP Web Service(s) |
| 2.1.1 Creation of rejections case in DC | - RmlIDcByRmlProcQf  - SubstanceInfo  - DC\_LegalEntity |
| 2.2.1 Create Active Substance approval case in DC | - RmlIDcByRmlProcQf  - SubstanceInfo  - DC\_LegalEntity |
| 2.3.1 Create a new case in DC due to an Article 95 application in R4BP | - RmlIDcByRmlProcQf  - SubstanceInfo  - DC\_LegalEntity |

As has been already specified in section 1.2 Scope of the current document, the scope of the analysis performed and documented in sections of this report covers only the DIP use cases and consequent data demands derived from the R4BP 3 – DC integration user stories, listed above.

## Second phase – Case update

Dynamic Case started, as of November 2019, a direct integration with R4BP 3 system which supported successfully the automation of a set of business processes specified in BPR regulation. Consequently, an expanding version of this communication between R4BP 3 and Dynamic Case has been proposed to cover the detection of any case related information updated in R4BP and its promotion to DyCa. The project originated from the ECHA, to depict automatically the updates of R4BP cases to DyCa. The update will not take place directly from R4BP to DyCa, but BIDI – as the responsible integration platform - has to gather the updated cases and serve the information back to DyCa.

The solution will apply, as in the first phase of the integration, to the BAPs:

* Active Substance Approval,
* Article 95 Applications
* Rejections BPR

The data elements that will be eligible for updates, through the automated process, is a strict set of predefined data elements that expand the list of the elements included in the first phase of the integration. The detailed list is presented and categorized per BAP in reference document R03. Additionally, in the last sheet of the excel file are presented the distinct elements in a homogenized form that compose actually the total set of items checked for update. This list is the one that should be reviewed against test scenarios and specifications to cover the needs of Case Update. In other words, a case in R4BP will be considered as updated and fetched from BIDI, in order to be also updated in DyCa, if at least one of the listed fields is changed in R4BP. BIDI has the obligation to return the whole data set that corresponds to the updated Case without indicating which fields suffered a change.

BIDI will offer a dedicated web service that will be triggered for a defined date interval and for the - in scope of the integration - R4BP case types. If the case is not updated within the date interval it will not be returned by the service.

## Third phase – Case update extension

The interconnection between Dynamic and R4BP supports – as described in the second integration phase - the detection of any case related information updated in R4BP and its promotion to DyCa. This has been achieved with the Case Update web service provided by DIP which supports the **Active Substance Approval**, **Article 95 Applications** and **Rejections** BPR processes (BAPs). In the third phase, the proposed solution is going to cover the extension of this automatic communication between R4BP 3 and DyCa application for three new BAPs. The extension of the Case Update Web Service functionality will cover additionally **Technical Equivalence**, **Union Authorisation** and **Same Biocidal Products** BAPs. A strict set of predefined data elements composes the eligible criteria to detect any change in R4BP cases. These data elements expand the list of elements as defined in the previous phase of the integration ([see reference R05](#_References)). This final list is the one that should be reviewed against test scenarios and specifications to cover the needs of Case Update web service.

DIP will provide an updated web service that will be triggered having as input a defined date interval and/or a **set of 6 R4BP case types**. Only R4BP Cases that suffered a change within the date interval will be returned by the service. Finally, DIP is responsible to return the whole data set that corresponds to the updated Case without indicating which fields suffered a change.

It is noted that the whole process and **functionality of Case Update remains exactly the same** as the one in second phase. The only differentiation is the new case types for which the service is applied and the additional data elements returned, appended to the existing ones.

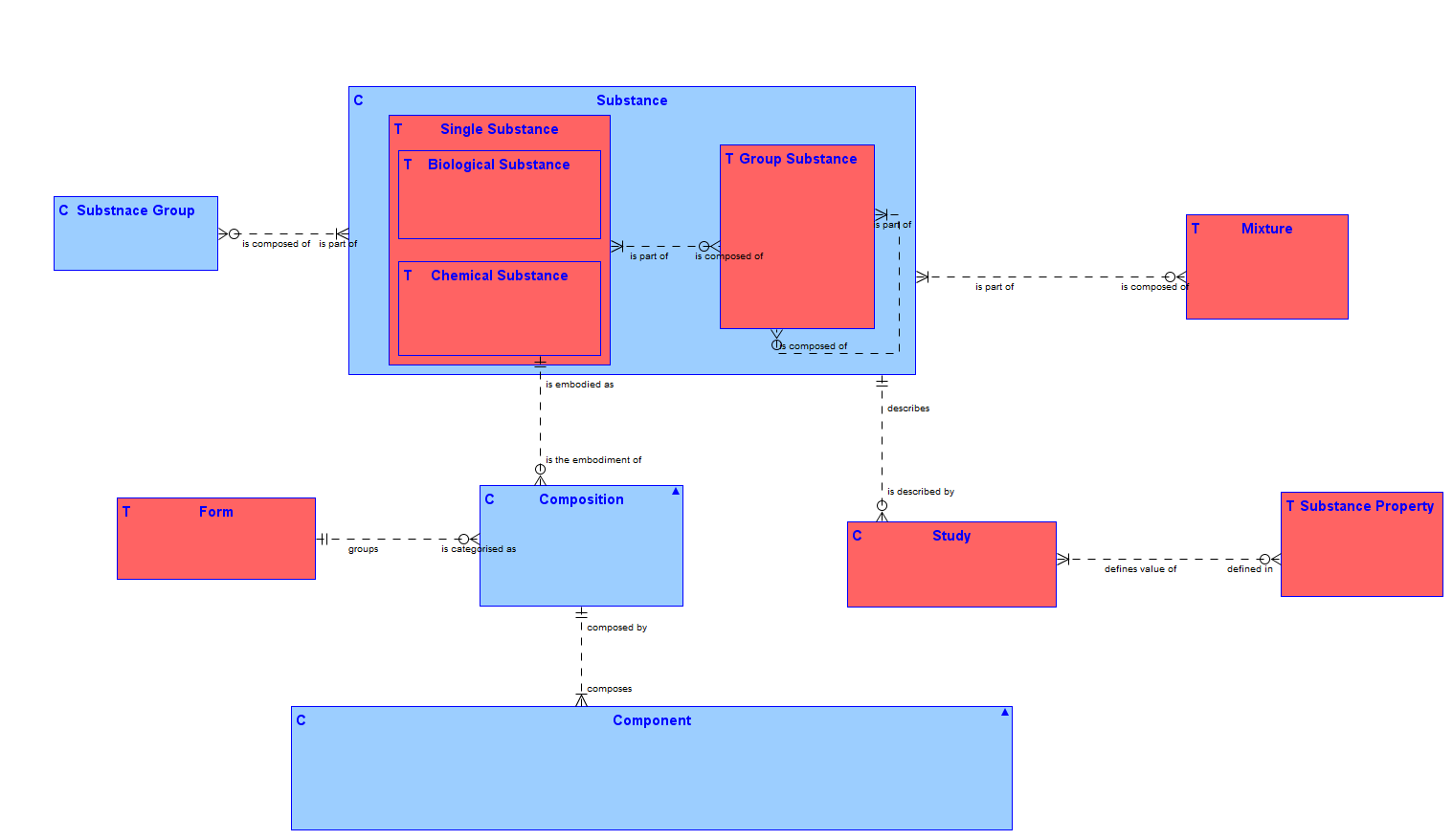
# EDM Coverage Conceptually

This section describes the business domain(s) on conceptual level that cover the scope of the demands described in the present report.

## Substance

Part of the data requirements for R4BP – DC integration are covered by the “Substance” domain of EDM. Especially those data needs that relate to Master, Regulation and R4BP Case specific Substance information.

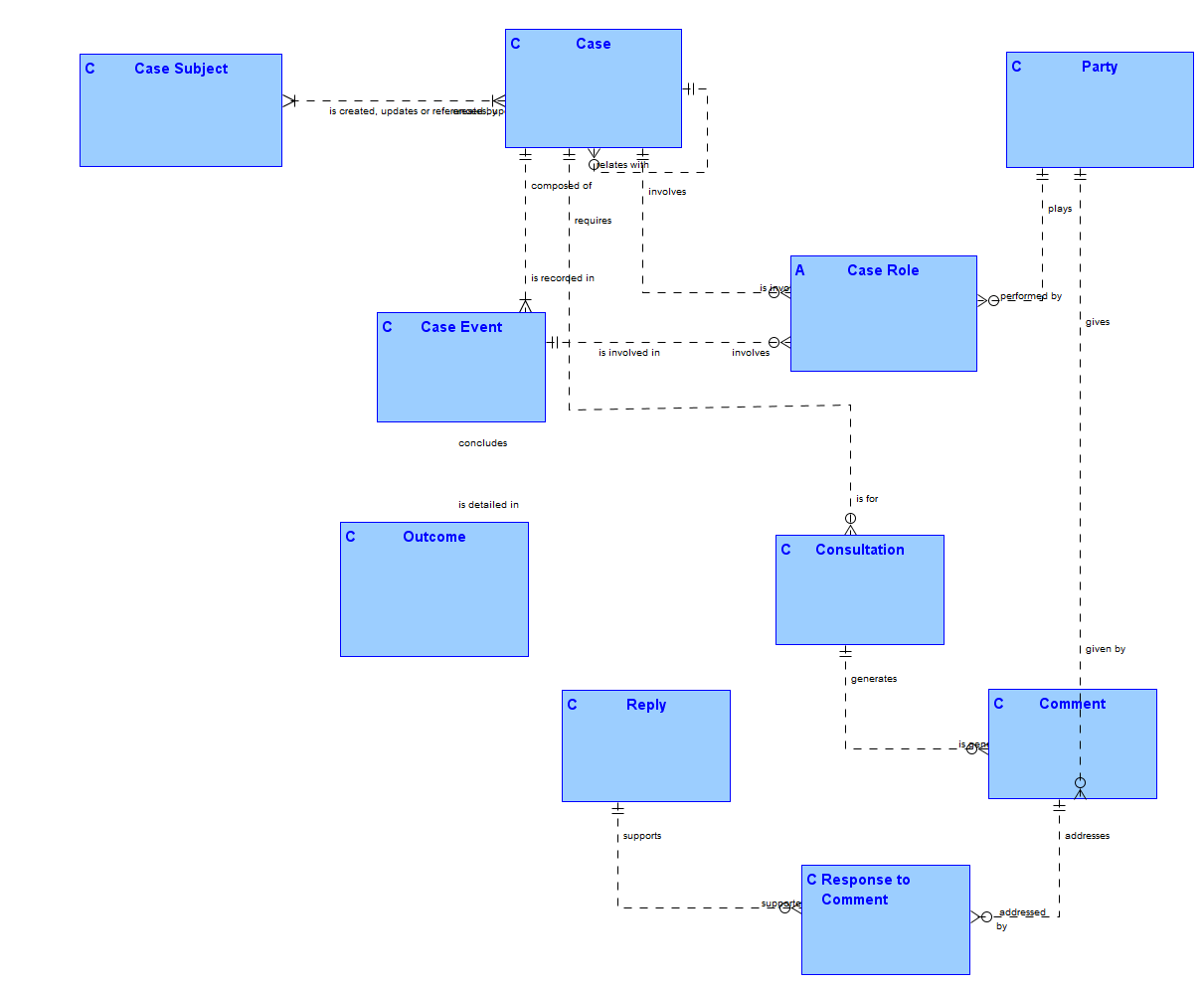
The current version of the Substance conceptual data model is depicted in the figure below. It should be noted that the below conceptual model was taken at the time of writing the current deliverable.



## Case

Part of the data requirements for R4BP – DC integration are covered by the “Case” domain of EDM. Specifically, information needs on target Substance and Current Owner of an R4BP Case.

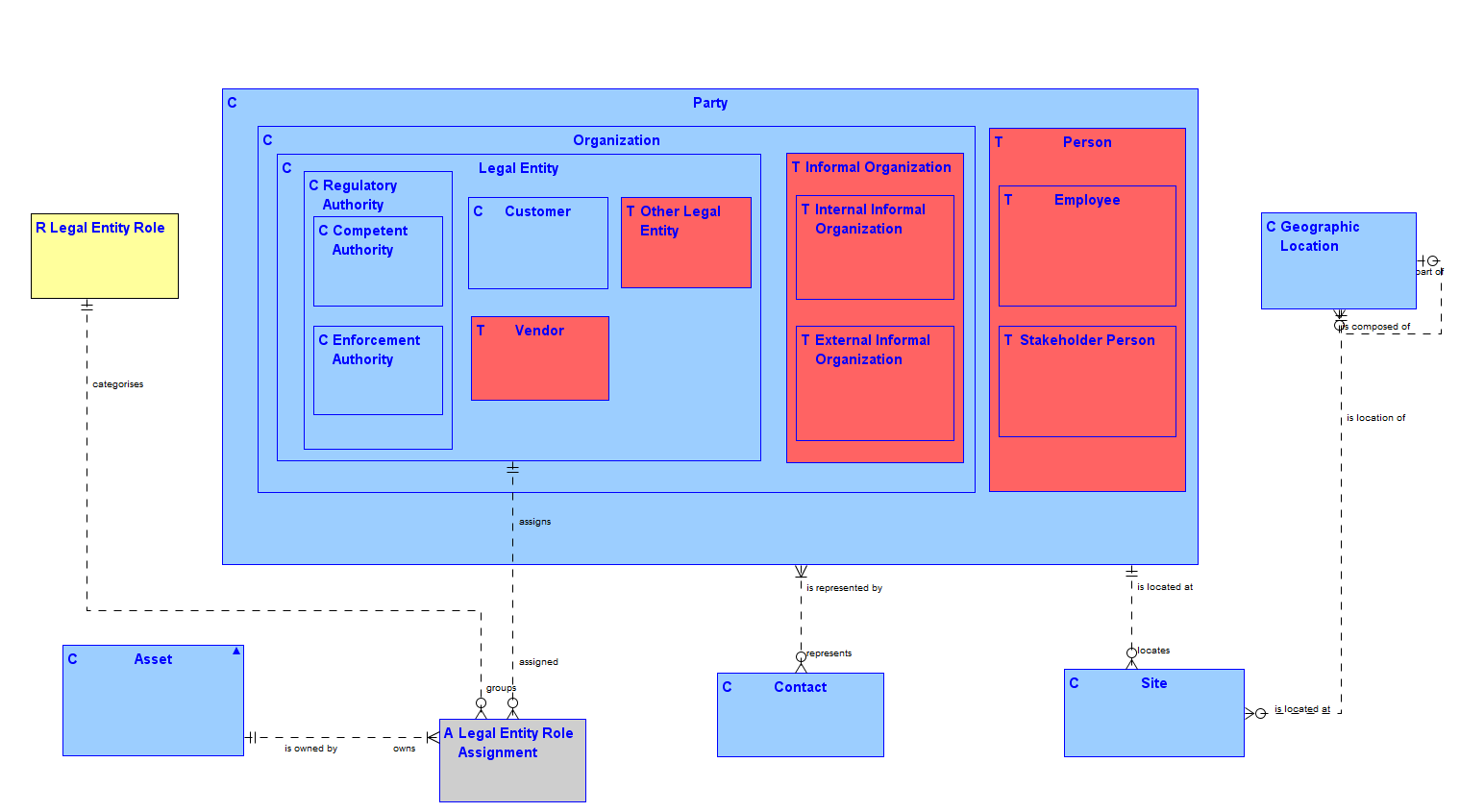
The current version of the Case conceptual data model is depicted in the figure below. It should be noted that the below conceptual model was taken at the time of writing the current deliverable.



## Party

Part of the data requirements for R4BP – DC integration are covered by the “Party” domain of EDM. Specifically, information needs on the Company being the Current Owner of an R4BP Case.

The current version of the Party conceptual data model is depicted in the figure below. It should be noted that the below conceptual model was taken at the time of writing the current deliverable.



The following table provides the definitions on enterprise level[[2]](#footnote-3) for the entities that are being covered in this document:

Table 3‑1

|  |  |
| --- | --- |
| 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. |
| Single Substance | A single substance is a substance characterised by a single set of identifiers (EC#, CAS#, etc), or by a chemical structural formula. Single substances can be members of Group substances. |
| Group Substance | Two or more substances which are grouped for a specific reason other than the intention of regulating the substances as one entity (e.g. batching for regulatory efficiency).Where the group of substances is intended to be regulated as single entity, this is known as group substance (NOTE: the order of the words!). |
| 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 role | ​Case role describes the involvement of a specific party in a specific case.For example, staff member is a case worker, company is the submitter, MSCA is the evaluator, etc. |
| Case type | Provides a categorisation for cases. Case type reflects the specific activity/process that is being recorded. |
| Legal entity | A legal entity is a legal construct through which the law allows a group of natural persons to act as if they were a single person for certain purposes. The most common purposes are lawsuits, property ownership, and contracts.Some examples of legal entities: companies, corporations, municipalities, states, and non-governmental organisations.The legal entity is a subtype of organisation and supertype for regulatory authority, customer, vendor, and other legal entity. |
| Party Role | Role describes the part, or the nature of the involvement, a party plays in the context of a specific asset or case.Examples include manufacturer, importer, downstream user, third party representative, only representative, data holder, data submitter, data owner, etc. |

# Assumptions & Constraints

The following assumptions and constraints were considered for the services in scope of the current analysis work:

* All the data needs of Dynamic Case in the context of R4BP – DyCa integration should be covered by existing DIP web services, after implementation of necessary modifications.
* No new web services should be designed and built by DIP for the purpose of servicing data needs for the R4BP – DyCa integration.
* Web services presented are only those required by Dynamic Case for covering the system’s data needs in the context of R4BP – DyCa integration.
* Many of the data elements output by the web services presented are not required by Dynamic Case for any of the supported R4BP – DyCa integration user stories and thus will not be consumed by the specific system in question. However, these data elements will be provided in service responses by DIP, irrespective of whether the consuming system, DyCa, chooses to consume them or not.
* Each R4BP – DyCa integration user story that needs data sourced from DIP, requires a combination of data which are delivered by multiple DIP web services.
* The analysis of R4BP – DyCa integration requirements for DIP data is performed and presented in a “web service-centric” approach, that is driven by the DIP web services affected by R4BP – DyCa user stories and not with an “R4BP – DyCa user story-centric” approach. At the end of every DIP use case, which is implemented with a corresponding web service, we present a mapping of every service output element to the relevant R4BP – DyCa integration user story element.
* We cannot modify by any means neither the use cases nor the functionality and business logic of the pre-existing DIP web services, to this moment consumed by Dynamic Case, to be adjusted for supporting R4BP – DyCa integration. We can only extend their functionality with additional use cases, required by the R4BP – DyCa integration.
* It is not possible to fulfil the data needs of each R4BP – DyCa integration user story with one DIP web service, as the solution for delivering such data was designed with the main target being on the one hand making the most out of re-using and on the other hand incurring minimum impact on existing web service interfaces between DIP with DyCa.
* The link between an R4BP Case and Active Substance(s) is maintained in DIP at the Case level and not at Case Submission level, although at source system R4BP this is an association maintained at Submission level.
* The “Case Update” functionality, as it is supported by the dedicated web service, will be based on the following assumptions:
  + Eligible cases to be checked for potential updates considered all Cases (of the in scope of the 3 BAPs i.e. Active Substance Approval, Article 95 Applications, and Rejections BPR) produced and maintained in R4BP. As such are included - but are not limited to - the cases created after the release to prod of the 1st phase of the integration (case Create).
  + The updates will take place for a final set of data elements that co-exist both in R4BP – DyCa systems. The list is finalized after several iterations with the collaboration of all involved teams.
  + A case in R4BP will be considered as updated and fetched from BIDI, if at least one of the fields listed is changed in R4BP. BIDI has the obligation to return the whole data set that corresponds to the updated Case without indicating which fields have been updated. Update will be based on R4BP Case Number – DC External Identifier relationship (same data) since the relationship between an R4BP case and a DC case is always 1-1.
  + As it is known across ECHA systems, BIDI refreshes data from the sources once a day and makes information available to any potential consumer the next day. As a result, BIDI can detect updates that are revealed because of the comparison of the Cases at the end of the day. This is a limitation/assumption derived from the overall BIDI mechanism/functionality. Having that in mind, BIDI can provide updates performed for existing Cases and not for those created within the same date.

PART B: Functional Requirements

# Use Cases

This section provides a detailed description of the DIP use cases for covering the information requirements for R4BP3 – DC Integration.

## UC-R4BP2DC-01. Provide Active Substance Identity Information from RML

|  |  |
| --- | --- |
| Use Case Description | DMP-I provides, on request, master and process specific identity information about an Active Substance integrated in RML in the context of BPR regulatory processes |
| Actors | RML-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by Dynamic Case |
| Frequency | Ad-hoc, on request:   1. Whenever a new Case is created in Dynamic Case for an R4BP Case 2. Whenever the “Substance” tab of any Case is loaded on the UI of Dynamic Case |
| Preconditions | 1. Data from below two BPR regulatory processes are successfully integrated in RML:    1. Active Substance Approval    2. Inclusion of Active Substance in Annex I of BPR 2. The Active Substance is referenced in either:    1. One or more R4BP Case(s) of the following types: 'AS-APP', 'AS-NAS', 'AS-EVA', 'AS-NPT', 'AS-RNL', 'AS-AAT', 'AS-CAT', 'AS-CHG', 'AS-REV', 'AS-NLS', 'RP-NOT', 'AS-UPD', 'AN-APP','AN-AAT','AN-CHG','AN-REV', 'AN-CAT', 'AN-UPD' ***OR***    2. The latest validity of one or more R4BP Asset(s) of the following types: AS, RP, AN 3. The Active Substance is integrated in RML[[3]](#footnote-4) and matched with exactly one RML ID |
| Basic Flow | 1. Dynamic Case makes a request for regulatory information for an Active Substance by specifying:    * The RML ID assigned to the Active Substance (rmlId)    * ‘BPR’ as the value for the context regulation from which data should be fetched from RML (regulationName)    * ***No*** value for any specific regulatory process (processName) 2. DIP responds with the following data elements for every Active Substance matched with the RML ID specified in the information request:    * A master Name for the requested RML-ID (<rmlName>)    * A master EC Number for the requested RML-ID (<rmlEc>)    * A master CAS Number for the requested RML-ID (<rmlCas>)    * One or more values (<identityAttributeValue>) for each of the following attribute types (<identityAttributeType>):      1. PROCESS\_RELATED\_NAME      2. EC\_NUMBER      3. CAS\_NUMBER      4. BAS\_NUMBER   delivered per process configured for BPR Regulation in RML[[4]](#footnote-5), and depending on data availability in RML for the requested RML-ID. |
| Alternate Flow(s) | 1. No data available in the context of BPR regulatory processes for one RML ID. 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. Process specific data are retrieved for one Active Substance matched with one RML ID from MULTIPLE or ALL regulatory processes configured in RML for BPR regulation, namely:    1. Active Substance Approval (ACTIVE\_SUBSTANCE\_APPROVAL)    2. Inclusion of Active Substance in Annex I of BPR (ACTIVE\_SUBSTANCE\_ANX1)    3. Inclusion on the list of active substance suppliers (Article 95) (ACTIVE\_SUBSTANCE\_ART95)[[5]](#footnote-6) 3. Process specific data are retrieved for multiple Active Substances matched under a single RML ID |
| Exception Flow(s) | 1. No Active Substance information *will* be delivered under the following circumstances:    1. The input regulationName parameter value is set to be any valid Regulation configured in RML, other than BPR.    2. Only a valid RML ID is specified as the *sole* input parameter value. 2. No Active Substance information *may* be delivered under the following circumstances:    1. A valid RML processName is provided in the service request that is not any of the following:       1. ACTIVE\_SUBSTANCE\_APPROVAL       2. ACTIVE\_SUBSTANCE\_ANX1 3. *No data* will be delivered at all under the following circumstances:    1. An invalid RML ID is provided as the input parameter of the service request.    2. Multiple RML ID values are provided as input parameters.    3. The input regulationName parameter value is set to be a Regulation that is not defined in RML.    4. Multiple regulationName values are provided in the service request.    5. A processName is provided in the service request that is not defined in RML.    6. Multiple processName values are provided in the service request.    7. An invalid combination of regulationName and processName values is provided. |
| Post Conditions | Dynamic Case consumes the above data elements through the agreed web services interface with DIP, namely RmlDcByRmlProcQf. |
| Notes | The following web service implements this use case:   * WS-01. Regulatory Substance Information |

## UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP

|  |  |
| --- | --- |
| Use Case Description | DMP-I provides, on request, identity information about the Active Substance currently referenced by an R4BP Case |
| Actors | R4BP-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by Dynamic Case |
| Frequency | Ad-hoc, on request:   1. Whenever a new Case is created in Dynamic Case for an R4BP Case 2. Whenever the “Substance” tab of any Case is loaded on the UI of Dynamic Case, when EXTERNAL\_ID is selected as source of information and the BAP is configured to have R4BP as source of information. |
| Preconditions | 1. Information about the Active Substance referenced by a Case is correctly maintained by R4BP (source system) on the Content Submission for the Case, that is the Submission defining the valid content for the Case. 2. Information about R4BP Cases, Case Submissions and Submission Active Substances is correctly integrated and regularly (daily) refreshed in DIP. |
| Basic Flow | 1. Dynamic Case makes a request for information on the Active Substance currently referenced by a certain R4BP Case by specifying:    * The Case Number as in R4BP (externalIdentifier)    * The Content Submission Number for the Case as in R4BP (submissionNumber)    * ‘R4BP’ as the source system where the information requested should be derived from (sourceSystem) 2. DIP responds with the following data elements for the Active Substance that is currently associated with the specified R4BP Case:    * Active substance name (<chemicalName>)    * BAS number (<basNumber>)    * EC number (<ecNumber>)    * CAS number (<listOfCasNumbers>)    * IUPAC name (<listOfIupacNames>) |
| Alternate Flow(s) | 1. The Case currently references multiple Active Substances in R4BP. In this flow the service will return one collection of below elements, per Active Substance found to be currently associated with the R4BP Case:    * Active substance name (<chemicalName>)    * BAS number (<basNumber>)    * EC number (<ecNumber>)    * CAS number (<listOfCasNumbers>)    * IUPAC name (<listOfIupacNames>) |
| Exception Flow(s) | 1. *No data* will be delivered at all under the following circumstances:    * The Case does NOT currently relate to any Active Substance in R4BP    * No Submissions have been yet made for the Case in R4BP, and thus the Content Submission for the Case is not existent |
| Post Conditions | Dynamic Case consumes the above data elements through the agreed web services interface with DIP, namely SubstanceInfo. |
| Notes | The following web service implements this use case:   * WS-02. Submission (Case) Substance Information |

## UC-R4BP2DC-03. Provide Case Owner Information from R4BP

|  |  |
| --- | --- |
| Use Case Description | DMP-I provides, on request, information on the current Owner (Applicant) of an R4BP Case |
| Actors | R4BP-S, IDM-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by Dynamic Case |
| Frequency | Ad-hoc, on request:   1. Whenever a new Case is created in Dynamic Case for an R4BP Case 2. Whenever the “Contacts” tab of a Case is loaded on the UI of Dynamic Case when the BAP is configured to have R4BP as source of information. |
| Preconditions | 1. Information about the company (aka legal entity) that currently holds the role of ‘Case Owner’ for a Case is correctly maintained by R4BP (source system). 2. Contact information for the Company that is the Case owner of an R4BP Case is maintained in IDM. 3. Information about Cases, Case Parties (aka legal entities) and their roles on Cases from R4BP as well as contact and identification information for Legal Entities from IDM is correctly integrated and regularly (daily) refreshed in DIP. |
| Basic Flow | 1. Dynamic Case makes a request for information on the Company currently holding the role of the Owner of a certain R4BP Case by specifying:    1. The Case Number as in R4BP (externalIdentifier)    2. The Content Submission Number for the Case as in R4BP (submissionNumber)    3. ‘R4BP’ as the source system where the information requested should be derived from (sourceSystem) 2. DIP responds with the following data elements for the current Case Owner of the specified R4BP Case:    1. Legal Entity Name (<LE\_NAME>)    2. Legal Entity UUID (<LE\_UUID>)    3. Legal Entity Type (<LE\_TYPE>)    4. Legal Entity Country (<LE\_COUNTRY\_NAME>)    5. Legal Entity Phone (<LE\_PHONE>)    6. Legal Entity Email (<LE\_EMAIL>)    7. Legal Entity Address (<LE\_STREET>, <LE\_STREET2>, <LE\_CITY>, <LE\_REGION>, <LE\_ZIPCODE>) |
| Alternate Flow(s) | N/A |
| Exception Flow(s) | 1. *No data* will be delivered at all under the following circumstances:    * The Case does NOT currently have an Owner    * No contact information exists for the Case Owner in IDM |
| Post Conditions | Dynamic Case consumes the above data elements through the agreed web services interface with DIP, namely DC\_LegalEntity. |
| Notes | The following web service implements this use case:   * WS-03. Legal Entity Information |

## UC-R4BP2DC-04. Provide Case Update Information from R4BP

|  |  |
| --- | --- |
| Use Case Description | DMP-I provides, on request, information on the updated Cases of R4BP for a specific time interval |
| Actors | R4BP-S, IDM-S, DIP-I, DyCa-C |
| Trigger | Information request initiated by Dynamic Case |
| Frequency | 1. Ad-hoc, on request 2. The web service will be triggered at 8:00 (every morning) till 00:00 (midnight), except Saturday and Sunday. DIP WS will be responsible to check if the refresh has been completed and data are ready to use. If not ready, the WS will reply with the corresponding message. The WS will be triggered every one hour from 8:00 in the morning until successful response. After successful response, the WS will be triggered again next morning at 8:00. |
| Preconditions | 1. Information on Case level for the defined data elements is correctly maintained and updated by R4BP (source system).  2. Information about Cases, Case Parties (aka legal entities) and their roles on Cases from R4BP as well as contact and identification information for Legal Entities from IDM is correctly integrated and regularly (daily) refreshed in DIP. |
| Basic Flow | 1. Dynamic Case makes a request for information on the Cases that are updated in determined time interval. 2. The web service is called for defined input items (Date from, Date to). If web service is triggered every day then Date from equals date to. 3. DIP responds with the following data elements as defined analytically in the list of return items (section 8.3.1) |
| Alternate Flow(s) | N/A |
| Exception Flow(s) | *No data* will be delivered at all under the following circumstances:   * + There are not Cases updated in R4BP source system for the parameters specified (Date from, Date to, Case types)   + DIP failed to be refreshed |
| Post Conditions | Dynamic Case consumes the returned data elements through the agreed web services interface with DIP. |
| Notes | The web service that implements this use case:  WS-04. R4BP Updated Case Information |

# Business Rules

This section provides a list of business rules that might have an impact on the work/business/domain that is the source of the requirements. Relevant business rules will be the trigger for requirements.

|  |  |  |
| --- | --- | --- |
| BR ID | Related Use Case | Description |
| BR001 | UC-R4BP2DC-03. Provide Case Owner Information from R4BP | There may be multiple companies (aka legal entities) simultaneously involved in a single R4BP Case. |
| BR002 | UC-R4BP2DC-03. Provide Case Owner Information from R4BP | A single company (aka legal entity) may be involved in one given R4BP Case with one or multiple roles. |
| BR003 | UC-R4BP2DC-03. Provide Case Owner Information from R4BP | At any given time, there can only be one company (aka legal entity) that holds the role of Case Owner of an R4BP Case. |
| BR004 | UC-R4BP2DC-03. Provide Case Owner Information from R4BP | The holder company of the Case Owner role for an R4BP Case can change over time. |
| BR005 | UC-R4BP2DC-03. Provide Case Owner Information from R4BP | The Owner of an R4BP Case can change irrespective of any Submission(s) made for that Case. |
| BR006 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | One R4BP Case may be actively linked with more than one Active Substances. |
| BR007 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | One R4BP Case may be linked with no Active Substance. |
| BR008 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | The Active Substance linked with one R4BP Case can change over time. |
| BR009 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | The Active Substance linked with one R4BP Case can change irrespective of any Submission(s) made for that Case. |
| BR010 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | R4BP does not maintain the history of Active Substances linked with an R4BP Case. |
| BR011 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | The unique identifier for every Active Substance is the BAS number. |
| BR012 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | The Active Substance(s) linked with one R4BP Case are identified by their BAS number. |
| BR013 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | One R4BP Case is uniquely identified by a Case Number. |
| BR014 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | One or more Submissions can be made for one R4BP Case. |
| BR015 | UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP  UC-R4BP2DC-03. Provide Case Owner Information from R4BP | One Submission Number in R4BP always belongs to a single R4BP Case, and can therefore be used for uniquely identifying the container R4BP Case. |
| BR016 | UC-R4BP2DC-01. Provide Active Substance Identity Information from RML | All active Substances managed in **either** of below BPR regulatory processes:   * Approval of Active Substances * Inclusion of Active Substance in Annex I of BPR   will be assigned an RML ID. |
| BR017 | UC-R4BP2DC-01. Provide Active Substance Identity Information from RML  UC-R4BP2DC-02. Provide Active Substance Identity Information from R4BP | An Active Substance may not have an EC Number assigned. |
| BR018 | UC-R4BP2DC-01. Provide Active Substance Identity Information from RML | RML will assign an RML ID to an Active Substance that does not have an EC Number. |
| BR019 | UC-R4BP2DC-01. Provide Active Substance Identity Information from RML | Multiple Active Substances may be assigned the same RML ID. This means that multiple BAS numbers may be associated with a single RML ID. |
| BR020 | UC-R4BP2DC-01. Provide Active Substance Identity Information from RML | An Active Substance referenced in an “Inclusion on the list of active substance suppliers (Article 95)” R4BP may have an RML ID assigned, if the Active Substance was prior to its inclusion in Article 95 the subject of at least one from below BPR regulatory processes:   * Approval of Active Substances * Inclusion of Active Substance in Annex I of BPR |

# Web Services

## Substance Identity Information related

### WS-01. Regulatory Substance Information

Provides information on master and/or process specific attributes for one Substance, identified by the unique Index (RML-ID) it is assigned in ECHA’s Regulatory Master List (RML) of substances. The scope of the information provided is regulatory, in the sense that the source of data to be served by the current service is RML system, which integrates substance identifiers collected or generated by ECHA in the context of processes defined in Regulations, enforced by ECHA.

#### Input items

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
| 1. 1. | **rmlId** | A unique index for a Substance assigned by ECHA’s Substance MDM | Text | Yes | 100.014.129 | This input is used for defining the substance for which information must be provided. |
| 1. 2. | **regulationName** | The name of a Regulation, enforced by ECHA, in the context of which substance identifiers are integrated in RML. | Text | No | BPR | This input is used for defining (filtering) the scope / origin of identity attributes for the input RML ID to be included in the service response. |
| 1. 3. | **processName** | The name of a Process defined by a Regulation, enforced by ECHA, in the context of which substance identifiers are integrated in RML. | Text | No | ACTIVE\_SUBSTANCE\_APPROVAL | This input is used for defining (filtering) the scope / origin of identity attributes for the input RML ID to be included in the service response.  Every Process defined and supported in RML can only belong to exactly one Regulation. |

#### Error handling

An error should be returned in the following cases:

1. No input rmlId is provided.
2. The input rmlId is invalid (not conforming to nnn.nnn.nnn), non-existent or inactive.
3. Multiple rmlId values are provided as input parameters.
4. Multiple regulationName values are provided in the service request.
5. Multiple processName values are provided in the service request.

#### No Results

An empty list will be returned if:

* 1. The input regulationName value is either not defined in RML or no data exist in RML for this regulation.
  2. A processName is provided in the service request that is not defined in RML or no data exist in RML from the input Process.
  3. An invalid, in the sense it is not defined in RML, combination of regulationName and processName values is provided.
  4. An input regulationName and/or processName value(s) have been provided, but the input rmlId has no process specific attribute values available in the context of the regulatory processes defined by the service input parameters.

#### Execution business logic rules

1. If only *rmlid* input item value is provided in the request, the service should return only Master Substance information, and more specifically it should:
   1. Return one set of *Master attributes* for the input RML ID. The set of return items for this block of information is presented under Block A of Return items section.
   2. *If* the input RML ID is actively related, as the parent or the child, to other RML ID(s), the service should additionally return one set of *Master attributes* *for each* RML ID related with the input *rmlid*. The set of return items that should be included in the service response per related RML ID is defined under Block B of Return items section.
2. If *rmlId* and *regulationName* input values are only provided, the service should return Master as well as Process specific information, and more specifically it should:
   1. *Retrieve* the regulatory Process(es) configured in RML for the input *regulationName.*
   2. ***For each*** identity attribute that has any of the following types: EC\_NUMBER, CAS\_NUMBER, IUPAC\_NAME, PROCESS\_RELATED\_NAME, PROCESS\_RELATED\_DESCRIPTION, BAS\_NUMBER, and is associated with the input *rmlId* in the context of the Process(es) identified in step a., and ***per*** each context Process, return a combination of information for the identity attribute value as well master information for the input RML ID. The information that is to be returned for each retrieved identity attribute per Process corresponds to one set of items defined under **Block C** of Return itemssection.
   3. If the input RML ID is actively related, as the parent or the child, to other RML ID(s), the service should additionally return for each related RML ID and for every available identity attribute value associated with the related RML ID in the context of one of the Process(es) defined in step a. one instance of the elements specified in **Block D** below.
3. If *rmlId* and *processName* input values are only provided, the service should return Master as well as Process specific information, and more specifically it should:
   1. ***For each*** identity attribute that has any of the following types: EC\_NUMBER, CAS\_NUMBER, IUPAC\_NAME, PROCESS\_RELATED\_NAME, PROCESS\_RELATED\_DESCRIPTION, BAS\_NUMBER, and is associated with the input *rmlId* in the context of the *processName*, return a combination of information for the identity attribute as well master information for the input RML ID. The information that is to be returned *per each* retrieved identity attribute for the input regulatory process corresponds to one set of items defined under **Block C** of Return itemssection.
   2. If the input RML ID is actively related, as the parent or the child, with other RML ID(s), the service should additionally return for each related RML ID and for every available identity attribute value associated with the related RML ID in the context of the input *processName* one instance of the elements specified in **Block D** below.
4. If a value is provided for all *rmlId, regulationName* and *processName* input values are provided, the service should return Master as well as Process specific information, and more specifically it should:
   1. ***For each*** identity attribute that has any of the following types: EC\_NUMBER, CAS\_NUMBER, IUPAC\_NAME, PROCESS\_RELATED\_NAME, PROCESS\_RELATED\_DESCRIPTION, BAS\_NUMBER, and is associated with the input *rmlId* in the context of *processName* which is defined in *regulationName*, return a combination of information for the identity attribute as well master information for the input RML ID. The information that is to be returned *per each* retrieved identity attribute for the input regulatory process corresponds to one set of items defined under **Block C** of Return itemssection.
   2. If the input RML ID is actively related, as the parent or the child, with other RML ID(s), the service should additionally return for each related RML ID and for every available identity attribute value associated with the related RML ID in the context of the input *processName* and *regulationName* one instance of the elements specified in **Block D** below.

#### Successful execution

A successful service execution should include one or more block of items and the elements described in Return items section below.

In more details, the successful execution of the service should return per each of the scenarios identified below, the stated block(s) of return items:

1. If only *rmlid* input item value is provided in the request, the service should return:
   1. Zero or One collection of return items defined in *Block A Master Attributes for input RML ID*, and
   2. Zero or More collections of return items defined in *Block B Master Attributes per RML ID related with the input RML ID*
2. If *rmlId* and *regulationName* input values are only provided, the service should return:
   1. Zero or More collections of return items defined in *Block C. Process Specific & Master Attributes for input RML ID*, and
   2. Zero or More collections of return items defined in *Block D. Process Specific & Master Attributes per RML ID related with the input RML ID*
3. If *rmlId* and *processName* input values are only provided, the service should:
   1. Zero or More collections of return items defined in *Block C. Process Specific & Master Attributes for input RML ID*, and
   2. Zero or More collections of return items defined in *Block D. Process Specific & Master Attributes per RML ID related with the input RML ID*
4. If a value is provided for all *rmlId, regulationName* and *processName* input values are provided, the service should return:
   1. Zero or More collections of return items defined in *Block C. Process Specific & Master Attributes for input RML ID*, and
   2. Zero or More collections of return items defined in *Block D. Process Specific & Master Attributes per RML ID related with the input RML ID*

#### Return items

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Block A. Master Attributes for input RML ID | | | | | |
|  | **Item Name** | **Item Description** | **Format** | **Examples** | **Comments** |
|  | **associationPriority** | The origin / derivation method for a Group Member association | Text | 0 | This item always has value 0, when it is reported in this block of items. |
|  | **inRmlId** | The input RML-ID | Text | 100.239.153 |  |
|  | **rmlCas** | Master CAS Number of the input RML-ID | Text | - |  |
|  | **rmlCategory** | Master Substance Category of the input RML-ID | Text | GROUP | Possible values: UVCB, CHEMICAL, BIOLOGICAL, GROUP |
|  | **rmlChecked** | Master attribute denoting if the input RML ID has been manually verified by a data steward | Text | F |  |
|  | **rmlDescription** | Master Substance Description of the input RML-ID | Text |  |  |
|  | **rmlEc** | Master EC Number of the input RML-ID | Text | - |  |
|  | **rmlId** | The output RML-ID, for which Master Attributes are returned. It should always match the input RML-ID | Text | 100.239.153 |  |
|  | **rmlInchi** | Master Substance INCHI of the input RML-ID | Text |  |  |
|  | **rmlIupac** | Master IUPAC Name of the input RML-ID | Text |  |  |
|  | **rmlMolformula** | Master Molecular formula of the input RML-ID | Text |  |  |
|  | **rmlName** | Master Substance Name of the input RML-ID | Text | Acids generated from chromium trioxide and their oligomers |  |
|  | **rmlRowMaster** |  | Text | Master attributes | Always has value 'Master attributes' |
|  | **rmlRowProcess** |  | Text | Process specific attributes | Always has value 'Process specific attributes' |
|  | **rmlSmiles** | Master Substance SMILES notation of the input RML-ID | Text |  |  |
|  | **rmlStatus** | Status of the input RML-ID | Text | ACTIVE | Possible values: ACTIVE or INACTIVE |
|  | **rmlType** | Master Substance Type of the input RML-ID | Text | GROUP | Possible values: SUBSTANCE or GROUP |
| Block B. Master Attributes per RML ID related with the input RML ID | | | | | |
|  | **Item Name** | **Item Description** | **Format** | **Examples** | **Comments** |
|  | **associationPriority** | The origin / derivation method for a Group Member association | Text | 0 | This item always has value 0, when it is reported in this block of items. |
|  | **inRmlId** | The input RML-ID | Text | 100.239.153 |  |
|  | **relatedRmlId** | An RML-ID that is related to the input RML-ID, either as its child or as its parent. | Text | 100.028.910 |  |
|  | **relationshipType** | The type of relationship between the input and the related RML ID. The type characterizes the relationship that the related RML-ID has with the input RML-ID. | Text | Child | Possible values: Parent or Child |
|  | **rmlCas** | Master CAS Number of related RML-ID | Text | 7738-94-5 |  |
|  | **rmlCategory** | Master Substance Category of related RML-ID | Text | CHEMICAL |  |
|  | **rmlChecked** | Master attribute denoting if the related RML-ID has been manually verified by a data steward | Text |  |  |
|  | **rmlDescription** | Master Substance Description of related RML-ID | Text |  |  |
|  | **rmlEc** | Master EC Number of related RML-ID | Text | 231-801-5 |  |
|  | **rmlId** | The output RML-ID, for which Master Attributes for any related RML-IDs are returned. It should always match the input RML-ID | Text | 100.239.153 |  |
|  | **rmlInchi** | Master Substance INCHI of related RML-ID | Text | InChI=1S/Cr.2H2O.2O/h;2\*1H2;;/q+2;;;;/p-2 |  |
|  | **rmlIupac** | Master IUPAC Name of related RML-ID | Text | dioxochromiumdiol |  |
|  | **rmlMolformula** | Master Molecular formula of related RML-ID | Text | CrH2O4 |  |
|  | **rmlName** | Master Substance Name of related RML-ID | Text | Chromic acid |  |
|  | **rmlRowMaster** |  | Text | Master attributes |  |
|  | **rmlRowProcess** |  | Text | Process specific attributes |  |
|  | **rmlSmiles** | Master Substance SMILES notation of related RML-ID | Text | O[Cr](O)(=O)=O |  |
|  | **rmlStatus** | Status of related RML-ID | Text | ACTIVE |  |
|  | **rmlType** | Master Substance Type of related RML-ID | Text | SUBSTANCE |  |
| Block C. Process Specific & Master Attributes for input RML ID | | | | | |
|  | **Item Name** | **Item Description** | **Format** | **Examples** | **Comments** |
|  | **associationPriority** | The origin / derivation method for a Group Member association | Text | 0 | This item always has value 0, when it is reported in this block of items. |
|  | **attrConfidentialityFl** | Flag indicating the confidentiality level of the retrieved process specific attribute value. | Text | F | Possible values: T / F. |
|  | **attributeStatus** | The status of the retrieved process specific attribute value. | Text | ACTIVE |  |
|  | **identityAttributeType** | The type of the retrieved substance attribute. Supported attribute types for which information is returned by the service include only the following types: EC\_NUMBER, CAS\_NUMBER, IUPAC\_NAME, PROCESS\_RELATED\_NAME, PROCESS\_RELATED\_DESCRIPTION, BAS\_NUMBER | Text | CAS\_NUMBER |  |
|  | **identityAttributeValue** | The value for the attribute type indicated by element no. 4, sourced in RML for the input RML ID in the context of the regulatory process indicated in element 9. processName | Text | - |  |
|  | **inRegulationName** | The name of a Regulation in the context of whose regulatory processes specific attribute values are requested from the service for the input RML ID. | Text | - |  |
|  | **inProcessName** | The name of the regulatory process in the context of which process specific attribute values are requested from the service for the input RML ID. | Text | SVHC\_CANDIDATE\_LIST |  |
|  | **inRmlId** | The input RML-ID | Text | 100.239.153 |  |
|  | **processName** | The name of the regulatory process in the context of which the value indicated in data element no. 5 for the attribute type indicated in data element no. 4 was associated with the queried substance (input RML ID). | Text | SVHC\_CANDIDATE\_LIST |  |
|  | **rmlCas** | Master CAS Number of the input RML-ID | Text | - |  |
|  | **rmlCategory** | Master Substance Category of the input RML-ID | Text | GROUP |  |
|  | **rmlChecked** | Master attribute denoting if the input RML-ID has been manually verified by a data steward | Text |  |  |
|  | **rmlDescription** | Master Substance Description of the input RML-ID | Text |  |  |
|  | **rmlEc** | Master EC Number of the input RML-ID | Text | - |  |
|  | **rmlId** | The output RML-ID, for which Master Attributes are returned. It should always match the input RML-ID | Text | 100.239.153 |  |
|  | **rmlInchi** | Master Substance INCHI of the input RML-ID | Text |  |  |
|  | **rmlIupac** | Master IUPAC Name of the input RML-ID | Text |  |  |
|  | **rmlMolformula** | Master Molecular formula of the input RML-ID | Text |  |  |
|  | **rmlName** | Master Substance Name of the input RML-ID | Text | Acids generated from chromium trioxide and their oligomers |  |
|  | **rmlRowMaster** |  | Text | Master attributes |  |
|  | **rmlRowProcess** |  | Text | Process specific attributes |  |
|  | **rmlSmiles** | Master Substance SMILES notation of the input RML-ID | Text |  |  |
|  | **rmlStatus** | Status of the input RML-ID | Text | ACTIVE |  |
|  | **rmlType** | Master Substance Type of the input RML-ID | Text | GROUP |  |
| Block D. Process Specific & Master Attributes per RML ID related with the input RML ID | | | | | |
|  | **Item Name** | **Item Description** | **Format** | **Examples** | **Comments** |
|  | **associationConfidentialityFl** | Flag indicating the confidentiality level of the association between the input and the related RML-ID value. | Text | F | Possible values: T / F. |
|  | **associationPriority** | The priority of the parent - child relationship between the input RML-ID and the fetched related RML-ID. | Text | 20 |  |
|  | **associationStatus** | The status of the relationship between the input RML-ID and the returned related RML-ID. | Text | ACTIVE |  |
|  | **attrConfidentialityFl** | Flag indicating the confidentiality level of the retrieved process specific attribute value for the related RML-ID. | Text | F |  |
|  | **attributeStatus** | The status of the retrieved process specific attribute value for the related RML-ID. | Text | ACTIVE |  |
|  | **identityAttributeType** | The type of a retrieved substance attribute for the related RML-ID. Supported attribute types for which information is returned by the service include only the following types: EC\_NUMBER, CAS\_NUMBER, IUPAC\_NAME, PROCESS\_RELATED\_NAME, PROCESS\_RELATED\_DESCRIPTION, BAS\_NUMBER | Text | CAS\_NUMBER |  |
|  | **identityAttributeValue** | The value for the attribute type indicated by element no. 6, sourced in RML for the related RML-ID in the context of the regulatory process indicated in element 11. processName | Text | 7738-94-5 |  |
|  | **inRegulationName** | The name of a Regulation in the context of whose regulatory process(es) specific attribute values are requested from the service for the RML-ID related with the input RML ID. | Text | REACH |  |
|  | **inProcessName** | The name of the regulatory process in the context of which process specific attribute values are requested from the service for the RML-ID related with the input RML ID. | Text | SVHC\_CANDIDATE\_LIST |  |
|  | **inRmlId** | The input RML-ID | Text | 100.239.153 |  |
|  | **processName** | The name of the regulatory process in the context of which the value indicated in data element no. 7 for the attribute type indicated in data element no. 6 was associated with the RML-ID that is related with the queried substance (input RML ID).[[6]](#footnote-7) | Text | SVHC\_CANDIDATE\_LIST |  |
|  | **relatedRmlId** | The RML-ID that is related to the input RML-ID |  | 100.028.910 |  |
|  | **relationshipType** | The type of the relationship between the input and the related RML ID. |  | Child | Possible values: Parent or Child |
|  | **rmlCas** | Master CAS Number of related RML-ID | Text | 7738-94-5 |  |
|  | **rmlCategory** | Master Substance Category of related RML-ID | Text | CHEMICAL |  |
|  | **rmlChecked** | Master attribute denoting if the related RML-ID has been manually verified by a data steward | Text |  |  |
|  | **rmlDescription** | Master Substance Description of related RML-ID | Text |  |  |
|  | **rmlEc** | Master EC Number of related RML-ID | Text | 231-801-5 |  |
|  | **rmlId** | The output RML-ID, for which Master Attributes for any related RML-IDs are returned. It should always match the input RML-ID | Text | 100.239.153 |  |
|  | **rmlInchi** | Master Substance INCHI of related RML-ID | Text | InChI=1S/Cr.2H2O.2O/h;2\*1H2;;/q+2;;;;/p-2 |  |
|  | **rmlIupac** | Master IUPAC Name of related RML-ID | Text |  |  |
|  | **rmlMolformula** | Master Molecular formula of related RML-ID | Text |  |  |
|  | **rmlName** | Master Substance Name of related RML-ID | Text |  |  |
|  | **rmlRowMaster** |  | Text |  |  |
|  | **rmlRowProcess** |  | Text |  |  |
|  | **rmlSmiles** | Master Substance SMILES notation of related RML-ID | Text |  |  |
|  | **rmlStatus** | Status of related RML-ID | Text |  |  |
|  | **rmlType** | Master Substance Type of related RML-ID | Text |  |  |

#### Notes

1. Dynamic Case already uses service RmlDcByRmlProcQf, for retrieving Master as well as Process Specific information for Substances managed in RML. Nevertheless the scope of regulatory processes for which process specific information was requested, before R4BP3 – DC Integration, was limited only to processes specified in REACH Regulation. As of November 2019, the scope of processes for which data could be requested from the current service was expanded to include BPR regulation processes.
2. Before the implementation of R4BP3 – DC Integration and the relevant adaptation of the current service, Dynamic Case would consume the current service by specifying in some cases only an input value for *rmlId* input parameter while in other cases by specifying input values to both input parameters: *rmlId* and *processName.* This configuration of values for input parameters to this service is performed by Business Users of Dynamic Case, on a per BAP case, and in some cases BUs have specified a value for the input *processName* while in some other they have not.
3. The information retrieved by Dynamic Case from invoking the current service is not persisted in DC’s DB, but is only presented on the UI of the tool. Thus said, the service is called every time the returned information needs to be displayed on Dynamic Case.
4. Active Substance information can be delivered to RML through any of the processes specified in BPR regulation, namely:
   1. Active Substance Approval (ACTIVE\_SUBSTANCE\_APPROVAL)
   2. Inclusion of Active Substance in Annex I of BPR (ACTIVE\_SUBSTANCE\_ANX1)
   3. Inclusion on the list of active substance suppliers (Article 95) (ACTIVE\_SUBSTANCE\_ART95)

This means that in order for Dynamic Case to retrieve identity attributes which are specific to Active Substances, such as i.e. the BAS Number, in the pre-existing format of the service 3 successive calls, each referencing each of the above 3 BPR processes would need to be made to the current service. By extending the service with an additional input parameter for the Regulation name, information retrieval for all identity attributes from ALL processes defined in a specific Regulation with one service call will be made possible.

1. The configuration of all current calls made by Dynamic Case to RmlDcByRmlProcQf service are not affected by any means by the inclusion of the additional input parameter for the Regulation name and do not need to change.

### WS-02. Submission (Case) Substance Information

Provides information on the Substance of:

1. A Submission made for a REACH-IT Registration Reference number (BIDI/REACH-IT is the source for Substance information in this case), or
2. A Submission made for an R4BP Case number (BIDI/R4BP is the source for Substance information in this case)

#### Input items

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
| 1. 1. | **externalIdentifier** | The reference number of a Registration in REACH-IT  *OR*  The number of a Case in R4BP | Text | No | BC-CK051708-37 |  |
| 1. 2. | **submissionNumber** | The submission number of a successful Registration submission in REACH-IT  *OR*  The number of a submission made for a Case in R4BP | Text | No | BC-CK051708-37/3 | A value for this input item may not always be provided when information is requested from R4BP |
| 1. 3. | **sourceSystem** | Indicates ECHA’s transactional system that will serve the requested Substance information | Text | Yes | R4BP | Possible values:  - REACH-IT  - R4BP |

#### Error handling

An error should be returned in the following cases:

1. Neither input externalIdentifier nor input submissionNumber values are provided.
2. Multiple externalIdentifier values are provided as input parameters.
3. Multiple submissionNumber values are provided as input parameters.
4. No input sourceSystem is provided.
5. Multiple sourceSystem values are provided in the service request.
6. An input value is provided for sourceSystem parameter, other than the allowed ones: REACH-IT and R4BP

#### No results

An empty list will be returned if:

1. The combination of input externalIdentifier and submissionNumber values do not match. This means that the provided submissionNumber has not been made for the Reference Number or Case Number indicated by the externalIdentifier.
2. No Substance is currently linked with the externalIdentifier and/or submissionNumber at the targeted source system.
3. If only an externalIdentifier input value has been provided, the *sourceSystem* is set to R4BP, and there exists no corresponding Content Submission for it at the targeted source system.

#### Execution business logic rules

1. If *sourceSystem* input value is REACH-IT, then:
   1. If only an *externalIdentifier* (Registration Reference Number)input item value is provided in the request, the service should return:
      1. Information about one Substance, chosen among all those substances who have ever been referenced in any of the successful submissions made in REACH-IT for the Reference Number identified by the *externalIdentifier*
   2. If either only a *submissionNumber* input value is providedorboth *externalIdentifier* and *submissionNumber* input values are provided in the request, the service should return:
      1. Information about the Substance on the REACH-IT submission identified by the input *submissionNumber*
2. If *sourceSystem* input value is R4BP, then:
   1. If either only an *externalIdentifier* (Case Number)input item value is provided orboth *externalIdentifier* and *submissionNumber* input values are provided in the request, the service will return:
      1. Information about ***all*** Active Substances currently referenced by the Content Submission[[7]](#footnote-8) made in R4BP for the Case which is identified by the input *externalIdentifier*
   2. If only a *submissionNumber* input value is providedin the request, the service will:
      1. Retrieve the R4BP Case Number for which the Submission identified by the input *submissionNumber* was made[[8]](#footnote-9)
      2. Return information about ***all*** Active Substances currently referenced by the Content Submission[[9]](#footnote-10) made in R4BP for the Case which is identified by the Case Number retrieved in previous step i.

#### Successful execution

A successful service execution should include, per each retrieved Substance, one collection of the information elements described in Return items section below.

In more details, the successful execution of the service should return per each of the scenarios identified below, the stated block(s) of return items:

1. If *sourceSystem* input value is **REACH-IT**, then the service should return per retrieved Registered Substance:
   1. Zero or One collection of return items defined in Return items section below.
2. If *sourceSystem* input value is **R4BP**, then the service will return per retrieved Active Substance:
   1. Zero or More collections of return items defined in Return items section below.

#### Return items

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Examples | Comments |
|  | **chemicalName** | The Substance name provided in section 1.1 of the IUCLID dossier for a REACH-IT Submission  *OR*  The name of an Active substance as maintained in R4BP | Text | Garlic, ext. |  |
|  | **ecNumber** | The EC Number of the Substance linked with the Submission in REACH-IT  *OR*  The EC Number used as an identifier for an Active Substance in R4BP | Text | 232-371-1 | Note that for REACH-IT Submissions this is not the EC Number provided in the submitted IUCLID dossier |
|  | **basNumber** | The unique identifier for an Active Substance in R4BP | Text | 2144 | Not relevant for Substances on REACH-IT Submissions |
|  | **listOfCasNumbers** | The CAS Numbers for the Substance linked with one Submission in REACH-IT  *OR*  The CAS Number used as an identifier for an Active Substance in R4BP | Text | 8008-99-9 | Note that for REACH-IT Submissions this is not the CAS Number provided in the submitted IUCLID dossier |
|  | **listOfClpIndexNumbers** | The CLP Index Number (where available) assigned to a Substance linked with one Submission in REACH-IT | Text |  | Not available for Active Substances |
|  | **listOfIupacNames** | The IUPAC Name provided in section 1.1 of the IUCLID dossier for a REACH-IT Submission  *OR*  The IUPAC Name used for describing an Active Substance in R4BP | Text | Food grade garlic juice concentrate |  |
|  | **listOfMolecularFormula** | The molecular formula of the reference substance used in the IUCLID dossier for a REACH-IT Submission | Text |  | Not available for Active Substances |
|  | **listOfSmilesNotation** | The SMILES notation of the reference substance used in the IUCLID dossier for a REACH-IT Submission | Text |  | Not available for Active Substances |
|  | **publicName** | The public name provided for a substance in section 1.1 of the IUCLID dossier for a REACH-IT Submission | Text |  | Not available for Active Substances |
|  | **substanceType** | The type of substance declared in section 1.1 of the IUCLID dossier for a REACH-IT Submission | Text |  | Not available for Active Substances |

#### Notes

1. Dynamic Case already uses SubstanceInfo service, for retrieving information for substances referenced on REACH-IT Registration Reference and Submission numbers.
2. For the purpose of supporting R4BP3 – DC Integration, the existing service’s functionality will be extended with the possibility to serve information for active substances referenced in Biocides related Cases, as these substances are identified in the respective transactional system where such cases are managed, that is R4BP.
3. Before the implementation of R4BP3 – DC Integration and the relevant adaptation of the SubstanceInfo service described with the current document, Dynamic Case would consume the service by providing an input value for both service input parameters: *externalIdentifier* and *submissionNumber,* and never by specifying only an input value for either of the parameters*.*
4. The information retrieved by Dynamic Case from invoking the SubstanceInfo service is not persisted in DC’s DB, but is only presented on the UI of the tool. Thus said, the service is called every time the returned information needs to be displayed on Dynamic Case.

## Legal Entity (Party) Information related

### WS-03. Legal Entity Information

Provides Legal Entity and Contact information on the Party that is:

1. The main company that has made a Submission for a Registration Reference Number (BIDI/REACH-IT is the source for Substance information in this case), or
2. The company that is the current Owner of an R4BP Case (BIDI/R4BP is the source for Substance information in this case)

#### Input items

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
|  | **externalIdentifier** | The reference number of a Registration in REACH-IT  *OR*  The number of a Case in R4BP | Text | No | BC-AD054035-67 |  |
|  | **submissionNumber** | The submission number of a successful Registration submission in REACH-IT  *OR*  The number of a submission made for a Case in R4BP | Text | No |  | A value for this input item may not always be provided when information is requested from R4BP |
|  | **sourceSystem** | Indicates ECHA’s transactional system that will serve the requested Substance information | Text | Yes | R4BP | Possible values:  - REACH-IT  - R4BP |

#### Error handling

An error should be returned in the following cases:

1. Neither input externalIdentifier nor input submissionNumber values are provided.
2. Multiple externalIdentifier values are provided as input parameters.
3. Multiple submissionNumber values are provided as input parameters.
4. No input sourceSystem is provided.
5. Multiple sourceSystem values are provided in the service request.
6. An input value is provided for sourceSystem parameter, other than the allowed ones: REACH-IT and R4BP

#### No results

An empty list will be returned if:

1. The combination of input externalIdentifier and submissionNumber values do not match. This means that the provided submissionNumber has not been made for the Reference Number or Case Number indicated by the externalIdentifier.
2. No Legal Entity is currently linked with the externalIdentifier and/or submissionNumber at the targeted source system, which is no Company is currently specified for a Reference Number / Submission in REACH-IT or no Company currently holds the role of an r4BP Case Owner.
3. A Legal Entity is defined for a Reference Number / Submission in REACH-IT or for an R4BP Case, however no data exist for the Legal Entity in IDM.

#### Execution business logic rules

1. If *sourceSystem* input value is REACH-IT, then:
   1. If only an *externalIdentifier* (Reference Number)input item value is provided in the request, the service should return:
      1. Information about ***all*** Legal Entities who have ever made successful submissions in REACH-IT for the Reference Number identified by the *externalIdentifier*
   2. If either only a *submissionNumber* input value is providedorboth *externalIdentifier* and *submissionNumber* input values are provided in the request, the service should return:
      1. Company and contact information about the ***single*** Legal Entity currently linked with the REACH-IT Submission identified by the input *submissionNumber*
2. If *sourceSystem* input value is R4BP, then:
   1. If either only an *externalIdentifier* (Case Number)input item value is provided orboth *externalIdentifier* and *submissionNumber* input values are provided in the request, the service will return:
      1. Company information only about the ***single*** current Owner[[10]](#footnote-11) of the R4BP Case which is identified by the input *externalIdentifier*
   2. If only a *submissionNumber* input value is providedin the request, the service will:
      1. Retrieve the R4BP Case Number for which the Submission identified by the input *submissionNumber* was made[[11]](#footnote-12)
      2. Return information about the ***single*** current Owner of the R4BP Case which is identified by the Case Number retrieved in previous step i.

#### Successful execution

A successful service execution should include, per each retrieved Legal Entity, one collection of the information elements described in Return items section below.

In more details, the successful execution of the service should return per each of the scenarios identified below, the stated block(s) of return items:

1. If *sourceSystem* input value is **REACH-IT**, then the service will return Zero or More collections of return items defined in Return items section below, that is will return data for possibly multiple Legal Entities.
2. If *sourceSystem* input value is **R4BP**, then the service will return Zero or maximum One collection of return items defined in Return items section below, that is will return data for at most one Legal Entity.

#### Return items

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Examples | Comments |
|  | LE\_NAME | The name of the Legal Entity | Text | Ecospray Limited |  |
|  | LE\_TYPE | The type of the Legal Entity | Text | INDUSTRY |  |
|  | LE\_COUNTRY\_NAME | The country name of the Legal Entity | Text | United Kingdom |  |
|  | LE\_PHONE | The phone number of the Legal Entity | Text | +44 (0)1760756100 |  |
|  | LE\_EMAIL | The email of the Legal Entity | Text | awais@ecospray.com |  |
|  | CP\_FIRSTNAME | Contact Person’s First Name | Text |  | Case Owner Contact Person Info is not available in DIP for R4BP Cases |
|  | CP\_LASTNAME | Contact Person’s Last Name | Text |  | Case Owner Contact Person Info is not available in DIP for R4BP Cases |
|  | CP\_TITLE | Contact Person’s Title | Text |  | Case Owner Contact Person Info is not available in DIP for R4BP Cases |
|  | CP\_PHONE | Contact Person’s Phone Number | Text |  | Case Owner Contact Person Info is not available in DIP for R4BP Cases |
|  | CP\_EMAIL | Contact Person’s Email | Text |  | Case Owner Contact Person Info is not available in DIP for R4BP Cases |
|  | LE\_UUID | The UUID of the Legal Entity | Text | ECHA-c123ecd8-13df-4d2a-9e6d-d544e1bc58a3 |  |
|  | LE\_STREET | 1st part of Street Address of the Legal Entity | Text | Cockley Cley Road |  |
|  | LE\_STREET2 | 2nd part of Street Address of the Legal Entity | Text | Grange Farm, Hilborough |  |
|  | LE\_CITY | The city location for the Legal Entity | Text | Thetford |  |
|  | LE\_REGION | The region where the Legal Entity is located | Text |  |  |
|  | LE\_ZIPCODE | The zipcode of the Legal Entity’s address | Text | IP26 5BT |  |

#### Notes

1. Dynamic Case already uses DC\_LegalEntity service, for retrieving information for Legal Entities on REACH-IT Reference and Submission numbers.
2. For the purpose of supporting R4BP3 – DC Integration, the existing service’s functionality will be extended with the possibility to serve information for companies which are owners of Biocides related Cases, as these are maintained in the respective transactional system where such cases are managed, that is R4BP.
3. Before the implementation of R4BP3 – DC Integration and the relevant scope extension for the DC\_LegalEntity service, described in the current document, Dynamic Case would consume the service by providing an input value for both service input parameters: *externalIdentifier* and *submissionNumber,* and never by specifying only an input value for either of the parameters*.*
4. The information retrieved by Dynamic Case from invoking the DC\_LegalEntity service is not persisted in DC’s DB, but is only presented on the UI of the tool. Thus said, the service is called every time the returned information needs to be displayed on Dynamic Case, and will always fetch the current Case Owner of an R4BP Case.

## Case Update Information

### WS-04. R4BP Updated Case Information

Provides R4BP Cases for which a change may took place in a defined time interval.

#### Input items

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Mandatory | Examples | Comments |
|  | **Date from** | Start date of time period to search for results | Date | Yes | 01-01-2020 |  |
|  | **Date to** | End date of time period to search for results | Date | Yes | 05-01-2020 |  |
|  | **Case Types** | Array of Case Types | String Array | No | UA-BBS | Case Types as defined in R4BP |

#### Error handling

An error should be returned in the following cases:

1. Neither input Date from nor input Date to values are provided.
2. If the number of dates between “Date from” and “Date to” exceeds 7

#### No results

An empty list will be returned if:

1. There is not a Case in R4BP source system for which even one element of the predefined list has been updated during the time interval defined by “Date from” and “Date to”.
2. If the Case Types set up as Input parameter do not belong in the set of which the web service is designed to i.e. Active Substance Approval, Article 95 Applications, Rejections, Technical Equivalence, Union Authorization and Same Biocidal Products (total of 6 case types).

#### Execution business logic rules

1. Maximum date interval: start – end date = 7 days
2. If this web service returns more than one Substance, DyCa is responsible to handle it.
3. Substance information is originated by R4BP source system, not RML.
4. The data element “dossierSubmissionNumber” is in the form of “TSBP\_CASES.UUID||'/'||TSB\_SUBMISSION.SUBMISSION\_IDX”
5. The data element “substanceName” is considered as the process data element “SubstanceCommonName” which will be included as array of substances including EC, CAS and Name.
6. Product type (multiple instances: array)
7. Contact (of different types) per Case (multiple instances: array)
   1. Regards three contacts: 1) Case Owner 2) Prospective Asset Owner 3) non EU Entity
   2. Array that could contain max 3 rows, one for every contact type.
   3. Every row has this set of attributes (Role, Type, Country, Name, Phone, Email, UUID, Postal Code, Address, City, Region)
8. Supplier Type (multiple instances: array)
9. Asset number (multiple instances: array)
10. If there are more than one Active Substance, Active Substance names should be concatenated and separated by “//”

#### Successful execution

A successful service execution should include, per each retrieved Case, one collection of the information elements described in Return items section below. When the web service is triggered, the [JSON object (see section12.4)](#_WS-04._Case_update) returned is an extension of the already existing one that already covers Active Substance Approval, Article 95 Applications, and Rejections BPR processes. In the new implementation, Technical Equivalence, Union Authorization and Same Biocidal Products processes are additionally supported. The list of return items contains the common data elements eligible for all mentioned processes.

***Note****: Input parameters, business rules and way of functioning will* ***remain exactly the same*** *as described in the Specifications Document delivered in the context of the first implementation (BIDI 3.3. release) of Case Update Web Service and is available in production environment.*

#### Return items

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Item Name | Item Description | Format | Examples | Comments |
|  | Submission Number | Numeric index indicating the sequence number of a successful submission/resubmission for a Case, during which a specific dossier File was uploaded. | Text | BC-JU057599-97/1 | Submission should have Submission Number = 1, while the File Case Association record corresponding to the 3rd submission should have Submission Number = 3. |
|  | File (Dossier) UUID | It is the UUID of a dossier submitted for a Case in R4BP. | Text | a4084daa-ca93-457d-8cfa-a67276787adc | This UUID should normally point to a valid Dossier in IUCLID, however it should be expected that in some cases a dossier UUID used in R4BP may not be yet or at all available in IUCLID. |
|  | Submission date | The timestamp of the submission | Date | 28-FEB-20 11.52.27.823000000 |  |
|  | Invoice number | Number of new invoice issued | Number | 50002054 |  |
|  | Product Type | Biocidal product-types specified in Annex V of Regulation (EU) No 528/2012. | Text | PT08 |  |
|  | EC number | The European Community number (EC number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission. The EC Inventory comprises three individual inventories, EINECS, ELINCS and the NLP list | Text | 231-442-4 |  |
|  | CAS number | A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by the Chemical Abstracts Service to every chemical substance | Text | 7553-56-2 |  |
|  | Substance name | 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 | Text | Iodine |  |
|  | Submitter Country | The Country of the submitter of the Case. Equivalent to Case Owner Country in R4BP. | Text | Spain |  |
|  | Submitter | The Organization of Case submitter. Equivalent to Case Owner Type in R4BP. | Text | FUMI-HOGAR S.L. |  |
|  | Submitter Type | The Type of the submitter indicated as 'Industry' or 'Agency ' | Text | INDUSTRY |  |
|  | Contact Company/Organization | Contact Company/Organization | Text | EBA AISBL |  |
|  | Contact Role | Contact Role | Text | Case Owner |  |
|  | Contact Type | Contact Type | Text | INDUSTRY |  |
|  | Contact Country | Contact Country | Text | Belgium |  |
|  | Contact Name | Concatenation of: “Contact First Name” and “Contact Last Name” | Text | Roger Doome | Apply a space character between first and Last Name |
|  | Contact Phone | Contact Phone | Text | 3222104420 |  |
|  | Contact Email | Contact Email | Text | r.doome@ima-europe.eu |  |
|  | Contact UUID | Contact UUID | Text | ECHA-4684b924-6744-4f33-8a83-e3113cdaa51c |  |
|  | Contact Postal Code | Contact Postal Code | Text | 1000 |  |
|  | Contact Address | Contact Address | Text | Rue des Deux Eglises 26 |  |
|  | Contact City | Contact City | Text | Brussels |  |
|  | Contact Region | Contact Region | Text | Brussels region |  |
|  | Decision sent date | The decision is sent to the applicant at the completion of the EAA task (Only for Financial Rejections). | Date | 16/9/2015 |  |
|  | Supplier Type | The type of Supplier | Text | PRODUCT |  |
|  | Asset number | Asset number | Text | EU-0005372-0000 |  |
|  | Evaluation Start Date | The date when EAA is finished | Date | 5/11/2015 | ggg |
|  | Sending of Draft Decision | The date when ad hoc communication dedicated for the draft decision is completed | Date | 12/11/2016 |  |
|  | Sending of Final Decision | The date when the task Evaluate and Decide dedicated for the final decision is completed. | Date | 12/7/2017 |  |
|  | Case Approval status | The status of Case Approval | Text | IN\_PROGRESS |  |
|  | Active Substance Common name | Common Name of Active Substance (this value is the same with Substance Name) | Text | Iodine |  |
|  | 1st draft CAR submitted date (latest submission) | Date of Ad-hoc communication with First Draft CAR received from eCA | Date | 12/7/2017 |  |
|  | Final CAR reception date | The date of the ad-hoc communication with the Final CAR received from eCA | Date | 12/7/2017 |  |
|  | Comments/information to Draft Decision date | The date that the company answers back to the DD sent to it. | Date | 12/7/2017 |  |
|  | First dossier submitted successfully date | The date when the first dossier that arrives in Business rule check. | Date | 12/7/2017 |  |
|  | Case number\* | The DyCa Case id linked with the R4BP Case | Text | TE\_PM\_NEKTA12-TPE-1 | It is generated by DyCa on case creation web service call.  [rbp\_case.dyca\_id] |
|  | Annex I, Category 6\* | Indication to determine if the Case belongs to Annex I, Category 6 | Text | Yes | Information retrieved from Active Substance table: if query returns any result rbp\_active\_substance\_cat for inclusion\_category = 5 and status = 'Approved' --> 'Yes'.  If no such entry exists, R4BP will not send any value to DyCa. |
|  | R4BP 3 product / family name\* | Product name or Family name (product information area) | Text | Product name value string | [rbp\_submission\_spcs.name\_] |
|  | Active substance(s)\* | Active Substance names (separated by //) | Text | Active Substance1//Active Substance2 | [From the query select rc.uuid, ras.name\_ from rbp\_case rc join rbp\_submission rs on rs.owner\_case\_id = rc.id join rbp\_submission\_substances rss on rss.submission\_id = rs.id  join rbp\_active\_substance ras on ras.id = rss.active\_substance\_id;] |
|  | eCA\* (Country) | Evaluating Authority | Text | Spain | [rbp\_case.evaluating\_country] |
|  | Family or single product\* | Single product or Family of products | Text | Product type value string | [rbp\_submission\_spcs.family\_UUID] |
|  | Invoice sent\* | Sending date (financial management tab, section: financial information/ handling invoices) | Date | 04/05/2020 | [select max(send\_date) from msg\_message mm join msg\_communication mc on mm.communication\_id = mc.id join rbp\_case rc on rc.id = mc.ctx\_case\_id join rbp\_financial\_record rfr on rfr.communication\_id = mc.id where TOPIC\_ = 'INVOICING' and rfr.type\_ = 'Invoice' and SENDER\_ROLE = 'AGENCY' and rc.type\_ = 'TE-APP' and FEE\_STATUS = 'AWAITING\_PAYMENT' and rc.uuid = 'BC-HL063041-50';] |
|  | BPC opinion on reference product sent to COM\* | UA-BBP: The date on which for the reference UA-APP case the ECHA Opinion task was completed - namely the date on which the Commission Decision task was created for the reference UA-APP case.  UA-BBS: The date on which for the UA-APP case due to which the reference asset (of the UA-BBS case) was created, the ECHA Opinion task was completed - namely the date on which the Commission Decision task was created. | Date | 14/06/2020 | [For SBP process case type can be UA-BBP or UA-BBS.  -- For UA-BBP cases the date can be found through the following query:  select min(start\_date) from rbp\_case rc join case\_path cp on cp.case\_id = rc.id join case\_step cs on cs.path\_id = cp.id\_ join rbp\_task\_data rtd on rtd.step\_id = cs.id\_ join rbp\_task\_action rta on rta.task\_data\_id = rtd.id where rc.type\_ in ('UA-APP') and task\_key = 'DEC' and rtd.head\_ = 1 and rc.id = (select rbp\_case.ctx\_case\_id from rbp\_case where rbp\_case.uuid = 'BC-YN018814-15'); where rbp\_case.uuid refers to the UA-BBP case involved in the case\_update process  -- For UA-BBS cases the following can be used:  select min(start\_date) from rbp\_case rc join case\_path cp on cp.case\_id = rc.id join case\_step cs on cs.path\_id = cp.id\_ join rbp\_task\_data rtd on rtd.step\_id = cs.id\_ join rbp\_task\_action rta on rta.task\_data\_id = rtd.id where rc.type\_ in ('UA-APP') and task\_key = 'DEC' and rtd.head\_ = 1 and rc.id = (select rc.id from rbp\_asset ra join rbp\_asset\_validity rav on rav.asset\_id = ra.id join rbp\_case rc on rc.id = rav.start\_case\_id where ra.type\_ = 'UA' and TAIL\_ = 1 and rc.type\_ = 'UA-APP' and ra.id = (select rbp\_case.ctx\_asset\_id from rbp\_case where rbp\_case.uuid = 'BC-SQ060501-26')); where the uuid belongs to the UA-BBS case for which the start date of the corresponding task is needed.] |
|  | ECHA Opinion and SPC sent to COM\* | UA-BBP & UA-BBS: The date of the completion of ECHA Evaluation task, namely the date of the creation of the Commission decision task for this case. | Date | 11/09/2020 | [select min(start\_date) from rbp\_case rc] |

***(\*)*** *Data elements added to support Technical Equivalence, Union Authorization and Same Biocidal Products processes.*

#### Notes

1. The web service will be triggered at 8:00 (every morning) till 00:00 (midnight), except Saturday and Sunday.
2. BIDI WS will be responsible to check if the refresh has been completed and data are ready to use. If not ready, the WS will reply with the corresponding message. The WS will be triggered every one hour from 8:00 in the morning until successful response. After successful response, the WS will be triggered again next morning at 8:00.
3. The web service will be triggered for a defined date interval and for the in scope of the integration R4BP case types. If the case is not updated within the date interval it will not be returned by the service. The maximum time interval is defined in 7 days.
4. DC will timeout at 3 minutes
5. The web service should be constructed in such a way that it could be relatively easily extensible, taking into consideration that more attributes could be updated in DC in future phases.
6. The data elements, provided back to DyCa via the Web Service, have been collected in the attached excel file (version 1.4. see reference 05) which presents the super set of all requested elements for the new processes (Case types). These data elements will be **returned for all processes** and will contain **values where available** in the source system. As a consequence, it is DyCa side’s responsibility to distinguish which data elements returned, will be used for which process. **Note:** In the excel file mentioned above, column “Compared to previous Case Update phase” contains an indication for the new, additional elements that will be added in the JSON interface to support Technical Equivalence, Union Authorization and Same Biocidal Products.
7. All new elements will be not mandatory (i.e. it is possible to return null value) since didn’t have any values for the initial set of Case Types.
8. The returned Case number is the current, unique Case id which is related with an R4BP Case. **Only one Case number** can be considered valid at a certain point in time. In matter of fact, there is a business scenario when a Technical Equivalence case related to a DyCa Case number may switch to Rejection (if the invoice is not paid in time) and linked with a second DyCa Case number. But this historicity is kept in a supporting side-table of R4BP that includes the multiplicity of case-relevant information and does not disturb the 1-to-1 relationship between an R4BP case and a DyCa case at a specific point in time.
9. New “process data” return items are appended at the end of the current JSON object format. On the contrary, “Date” data elements are included in the dedicated Date section of the JSON object.
10. For the “Active Substance names” element, which is defined as the concatenation of string values, there is a length limitation of maximum 4000 characters.

PART C Non functional Requirements

# Access Management

The pre-existing access conditions for the affected DIP web services will remain. No new access management requirements were raised or discussed with Dynamic Case in the context of extending the existing web services with new functionality for enabling the R4BP3-DC integration.

# Performance

Dynamic Case does not have particular expectations for non-functional requirements for the DIP web services that will support the R4BP3-DC integration.

Thus, no specific performance requirements are foreseen for the implementation of the services specified in the current report.

# Maintenance

* DIP data refresh frequency: DIP is refreshed on a daily basis. This means that the data integrated in DIP from R4BP are one day back.
* RML data refresh frequency: RML is refreshed on a daily basis. RML daily data frequency includes Substance Master Confidentiality calculation.
* RML & R4BP synchronization frequency: RML integrates data from R4BP once per day. This means that the data integrated in RML from R4BP are one day back.

PART D Interface Requirements

# Web Services Interface requirements

## WS-01. Regulatory Substance Information

#### Input

The input parameters of the Regulatory Substance Information (RmlDcByRmlProcQf) service are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MIN OCCURRENCE OF INPUT PARAM | MAX OCCURRENCE OF INPUT PARAM | MANDATORY VALUE |
| 1 | processName | xsd:string | 0 | *undefined* | No |
| 2 | rmlId | xsd:string | 0 | *undefined* | Yes |
| 3 | regulationName | xsd:string | 0 | *undefined* | No |

Examples of correctly formulated service requests are:

<!--1.Querying for Master information on a Substance (and any of its related Substances) identified by its unique index number (RML ID)-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:RmlDcByRmlProcQf>

         <arg0>

            <rmlId>100.031.732</rmlId>

         </arg0>

      </ser:RmlDcByRmlProcQf>

   </soapenv:Body>

</soapenv:Envelope>

<!--2.Querying for Master and Regulatory Process Specific information on a Substance (and any of its related Substances) identified by its unique index number (RML ID)-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:RmlDcByRmlProcQf>

         <arg0>

            <rmlId>100.239.153</rmlId>

            <processName>SVHC\_CANDIDATE\_LIST</processName>

         </arg0>

      </ser:RmlDcByRmlProcQf>

   </soapenv:Body>

</soapenv:Envelope>

<!--3.Querying for Master and Process Specific information delivered in the context of one Process defined for a specific Regulation for a Substance (and any of its related Substances) identified by its unique index number (RML ID)-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:RmlDcByRmlProcQf>

         <arg0>

            <rmlId>100.031.732</rmlId>

            <processName>ACTIVE\_SUBSTANCE\_APPROVAL</processName>

<regulationName>BPR</regulationName>

         </arg0>

      </ser:RmlDcByRmlProcQf>

   </soapenv:Body>

</soapenv:Envelope>

<!--4.Querying for Master and Process Specific information delivered in the context of ALL Processes of a specific Regulation for a Substance (and any of its related Substances) identified by its unique index number (RML ID)-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:RmlDcByRmlProcQf>

         <arg0>

            <rmlId>100.239.153</rmlId>

<regulationName>BPR</regulationName>

         </arg0>

      </ser:RmlDcByRmlProcQf>

   </soapenv:Body>

</soapenv:Envelope>

#### Output

The output of the service, once successfully called and completed, will be a list containing the following data elements for the RML ID provided as the input parameter of the service call:

|  |  |  |  |
| --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MANDATORY VALUE |
| 1 | associationConfidentialityFl | xsd:string | No |
| 2 | associationPriority | xsd:string | No |
| 3 | associationStatus | xsd:string | No |
| 4 | attrConfidentialityFl | xsd:string | No |
| 5 | attributeStatus | xsd:string | No |
| 6 | identityAttributeType | xsd:string | No |
| 7 | identityAttributeValue | xsd:string | No |
| 8 | inProcessName | xsd:string | No |
| 9 | inRmlId | xsd:string | Yes |
| 10 | inRegulationName | xsd:string | No |
| 11 | processName | xsd:string | No |
| 12 | relatedRmlId | xsd:string | No |
| 13 | relationshipType | xsd:string | No |
| 14 | rmlCas | xsd:string | No |
| 15 | rmlCategory | xsd:string | No |
| 16 | rmlChecked | xsd:string | No |
| 17 | rmlDescription | xsd:string | No |
| 18 | rmlEc | xsd:string | No |
| 19 | rmlId | xsd:string | Yes |
| 20 | rmlInchi | xsd:string | No |
| 21 | rmlIupac | xsd:string | No |
| 22 | rmlMolformula | xsd:string | No |
| 23 | rmlName | xsd:string | No |
| 24 | rmlRowMaster | xsd:string | No |
| 25 | rmlRowProcess | xsd:string | No |
| 26 | rmlRowType | xsd:string | No |
| 27 | rmlSmiles | xsd:string | No |
| 28 | rmlStatus | xsd:string | No |
| 29 | rmlType | xsd:string | No |

#### WSDL File



## WS-02. Submission Substance Information

#### Input

The input parameters of the Submission Substance Information (SubstanceInfo) service are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MIN OCCURRENCE OF INPUT PARAM | MAX OCCURRENCE OF INPUT PARAM | MANDATORY VALUE |
| 1 | externalIdentifier | xsd:string | 0 | *undefined* | *conditional* |
| 2 | submissionNumber | xsd:string | 0 | *undefined* | *conditional* |
| 3 | sourceSystem | xsd:string | 0 | *undefined* | No |

Examples of correctly formulated service requests are:

<!--1.Querying for information on the Substance linked with a REACH-IT Reference Number-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:SubstanceInfo>

         <arg0>

<!—REACH-IT Reference Number-->

            <externalIdentifier>01-2120816354-59-0000</externalIdentifier>

            <sourceSystem>REACH-IT</sourceSystem>

         </arg0>

      </ser:SubstanceInfo>

   </soapenv:Body>

</soapenv:Envelope>

<!--2.Querying for information on the Substance linked with a REACH-IT Submission Number-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:SubstanceInfo>

         <arg0>

<!—REACH-IT Submission Number-->

            <submissionNumber>YH630733-27</submissionNumber>

            <sourceSystem>REACH-IT</sourceSystem>

         </arg0>

      </ser:SubstanceInfo>

   </soapenv:Body>

</soapenv:Envelope>

<!--3.Querying for information on the Substance linked with a REACH-IT Reference Number and a certain Submission Number-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:SubstanceInfo>

         <arg0>

<!—REACH-IT Reference Number-->

            <externalIdentifier>01-2120816354-59-0000</externalIdentifier>

<!—REACH-IT Submission Number-->

            <submissionNumber>YH630733-27</submissionNumber>

            <sourceSystem>REACH-IT</sourceSystem>

         </arg0>

      </ser:SubstanceInfo>

   </soapenv:Body>

</soapenv:Envelope>

<!--4.Querying for information on the Substance linked with an R4BP Case-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:SubstanceInfo>

         <arg0>

<!—R4BP Case Number-->

            <externalIdentifier>BC-TY053316-01</externalIdentifier>

            <sourceSystem>R4BP</sourceSystem>

         </arg0>

      </ser:SubstanceInfo>

   </soapenv:Body>

</soapenv:Envelope>

<!--5.Querying for information on the Substance linked with an R4BP Case, using both an R4BP Case and Submission Number as input parameters -->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:ser="<http://services.bidi.echa.europa.eu/>">

   <soapenv:Header/>

   <soapenv:Body>

      <ser:SubstanceInfo>

         <arg0>

<!—R4BP Case Number-->

            <externalIdentifier>BC-TY053316-01</externalIdentifier>

<!—R4BP Submission Number-->

            <submissionNumber>BC-TY053316-01/1</submissionNumber>

            <sourceSystem>R4BP</sourceSystem>

         </arg0>

      </ser:SubstanceInfo>

   </soapenv:Body>

</soapenv:Envelope>

#### Output

The output of the service, once successfully called and completed, will be a list containing the following data elements per each retrieved Substance that is the targeted object of the Reference Number, Case or Submission that matches the input parameter values:

|  |  |  |  |
| --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MANDATORY VALUE |
| 1 | chemicalName | xsd:string | No |
| 2 | ecNumber | xsd:string | No |
| 3 | basNumber | xsd:string | No |
| 4 | listOfCasNumbers | xsd:string | No |
| 5 | listOfClpIndexNumbers | xsd:string | No |
| 6 | listOfIupacNames | xsd:string | No |
| 7 | listOfMolecularFormula | xsd:string | No |
| 8 | listOfSmilesNotation | xsd:string | No |
| 9 | publicName | xsd:string | No |
| 10 | substanceType | xsd:string | No |

#### WSDL File



## WS-03. Legal Entity Information

#### Input

The input parameters of the Legal Entity Information (DC\_LegalEntity) service are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MIN OCCURRENCE OF INPUT PARAM | MAX OCCURRENCE OF INPUT PARAM | MANDATORY VALUE |
| 1 | INPUT\_EXT\_IDENTIFIER | xsd:string | 1 | unbounded | No |
| 2 | INPUT\_SUB\_NUMBR | xsd:string | 1 | unbounded | No |
| 3 | sourceSystem | xsd:string | 1 | unbounded | Yes |

Examples of correctly formulated service requests are:

<!--1.Querying for information on the Legal Entity who is the main Submitter (Owner) of a REACH-IT Submission made for a specific Reference Number -->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:dc="<http://localhost:7001/DC_LegalEntity/>">

   <soapenv:Header/>

   <soapenv:Body>

      <dc:DC\_LegalEntity>

<!—REACH-IT Reference Number-->

       <INPUT\_EXT\_IDENTIFIER>01-2120816354-59-0000</INPUT\_EXT\_IDENTIFIER>

<!—REACH-IT Submission Number-->

       <INPUT\_SUB\_NUMBR>YH630733-27</INPUT\_SUB\_NUMBR>

        <sourceSystem>REACH-IT</sourceSystem>

      </dc:DC\_LegalEntity>

   </soapenv:Body>

</soapenv:Envelope>

<!--2.Querying for information on the Legal Entity that is the current Case Owner (Applicant) of an R4BP Case, using a Case Number as input parameter-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:dc="<http://localhost:7001/DC_LegalEntity/>">

   <soapenv:Header/>

   <soapenv:Body>

      <dc:DC\_LegalEntity>

<!--R4BP Case Number-->

       <INPUT\_EXT\_IDENTIFIER>BC-JF053317-47</INPUT\_EXT\_IDENTIFIER>

       <sourceSystem>R4BP</sourceSystem>>

      </dc:DC\_LegalEntity>

   </soapenv:Body>

</soapenv:Envelope>

<!--3.Querying for information on the Legal Entity that is the current Case Owner (Applicant) of an R4BP Case, using both the Case and the Submission Numbers as input parameters-->

<soapenv:Envelope xmlns:soapenv="<http://schemas.xmlsoap.org/soap/envelope/>" xmlns:dc="<http://localhost:7001/DC_LegalEntity/>">

   <soapenv:Header/>

   <soapenv:Body>

      <dc:DC\_LegalEntity>

<!--R4BP Case Number-->

       <INPUT\_EXT\_IDENTIFIER>BC-JF053317-47</INPUT\_EXT\_IDENTIFIER>

<!--R4BP Submission Number-->

       <INPUT\_SUB\_NUMBR>BC-JF053317-47/1</INPUT\_SUB\_NUMBR>

       <sourceSystem>R4BP</sourceSystem>

      </dc:DC\_LegalEntity>

   </soapenv:Body>

</soapenv:Envelope>

#### Output

The output of the service, once successfully called and completed, will be one LegalEntityCollection element per each retrieved Legal Entity that matches the input parameter values specified in the service request. Each LegalEntityCollection element contains the following data elements for exactly one retrieved Legal Entity:

|  |  |  |  |
| --- | --- | --- | --- |
|  | PARAMETER NAME | VALUE TYPE | MANDATORY VALUE |
| 1 | LE\_NAME | xsd:string | No |
| 2 | LE\_TYPE | xsd:string | No |
| 3 | LE\_COUNTRY\_NAME | xsd:string | No |
| 4 | LE\_PHONE | xsd:string | No |
| 5 | LE\_EMAIL | xsd:string | No |
| 6 | CP\_FIRSTNAME | xsd:string | No |
| 7 | CP\_LASTNAME | xsd:string | No |
| 8 | CP\_TITLE | xsd:string | No |
| 9 | CP\_PHONE | xsd:string | No |
| 10 | CP\_EMAIL | xsd:string | No |
| 11 | LE\_UUID | xsd:string | No |
| 12 | LE\_STREET | xsd:string | No |
| 13 | LE\_STREET2 | xsd:string | No |
| 14 | LE\_CITY | xsd:string | No |
| 15 | LE\_REGION | xsd:string | No |
| 16 | LE\_ZIPCODE | xsd:string | No |

#### WSDL File



## WS-04. Case update Information

The service has been implemented following the REST (Representational state transfer) approach which is a software architectural style that defines a set of constraints to be used for creating Web services. Web services that conform to the REST architectural style, called RESTful Web services, provide interoperability between computer systems on the Internet.

|  |  |  |
| --- | --- | --- |
| * Documentation for the service is provided in the following link: <http://epcecha02582.echa.europa.local:15101/bidi/api/v1/caseUpdates> | |  |
| * The Web Service returned object in JSON format: |  | |

PART E APPENDIX

1. For detailed information on the referenced user stories, please advise the R4BP 3 – DC Integration Requirements Definition document (R01) [↑](#footnote-ref-2)
2. ECHA’s Data Glossary: <https://echa.sharepoint.com/sites/dm/dg/kb/Lists/ECHA%20entities/AllItems.aspx> [↑](#footnote-ref-3)
3. Special conditions for the status and task that has been reached by an R4BP Case apply in order to make it eligible for integration in RML. [↑](#footnote-ref-4)
4. The processes currently configured in RML for BPR Regulation are:

   Active Substance Approval (ACTIVE\_SUBSTANCE\_APPROVAL),

   Inclusion of Active Substance in Annex I of BPR (ACTIVE\_SUBSTANCE\_ANX1)

   Inclusion on the list of active substance suppliers (Article 95) (ACTIVE\_SUBSTANCE\_ART95) [↑](#footnote-ref-5)
5. Although “Inclusion on the list of active substance suppliers (Article 95)” is configured as a process of BPR regulation in RML, it is currently not linked with any incoming data source, and therefore there are no data for substances on this list integrated in RML. [↑](#footnote-ref-6)
6. **Attention**: this is not the Regulatory Process which defined the relationship between the input and the related RML-ID. This is a Regulatory Process in the context of which substance identifiers have been matched with the related RML-ID. When either a single Process Name is specified as the input parameter of the service or Process Name(s) are implied by the input Regulation name provided in the service request, the service looks for the existence of any related RML-IDs for the input RML-ID, and will return any attribute values associated with the related RML-IDs in the context of the Processes in scope of the service request. The service will NOT use the scope of Process Names specified in the request to filter for RML-IDs associated with the input RML-ID only under these Processes. [↑](#footnote-ref-7)
7. R4BP system does not maintain a direct link between a Case and Active Substance(s). The link is established via Submissions made for an R4BP Case. The Active Substance(s) currently assigned to a Case is always derived from the Content Submission for that Case, which, among all Submissions that have ever been made for the Case, is the one that defines the valid content of the case. The Content Submission for a Case defaults to the latest submission if none is valid yet. [↑](#footnote-ref-8)
8. A Submission Number in R4BP is always formatted by appending the Case Number for which the Submission was made i.e. BC-CK051708-37, followed by a ‘/’ character and suffixed with a numeric index indicating the sequence number of a successful submission/resubmission for a Case. For example, BC-CK051708-37/1 indicates the first submission made for Case Number BC-CK051708-37. Therefore, using an R4BP Submission Number it is always possible to identify the Case Number for which the Submission was made. [↑](#footnote-ref-9)
9. R4BP system does not maintain a direct link between a Case and Active Substance(s). The link is established via Submissions made for an R4BP Case. The Active Substance(s) currently assigned to a Case is always derived from the Content Submission for that Case, which, among all Submissions that have ever been made for the Case, is the one that defines the valid content of the case. The Content Submission for a Case defaults to the latest submission if none is valid yet. [↑](#footnote-ref-10)
10. Multiple Legal Entities may be linked with one R4BP Case at any given time but only one can be the current owner for that Case, and Legal Entities linked with one R4BP Case can change over time. In DIP we maintain both information about the history of Legal Entities linked with one R4BP Case and information on the role each Legal Entity plays for one R4BP Case. To retrieve the single, current case owner for an R4BP Case, it is needed to isolate that Legal Entity that has the ‘Case Owner’ role for the Case and this role is Active (the end date for which the Case Owner role is granted to the Legal Entity is empty). [↑](#footnote-ref-11)
11. A Submission Number in R4BP is always formatted by appending the Case Number for which the Submission was made i.e. BC-CK051708-37, followed by a ‘/’ character and suffixed with a numeric index indicating the sequence number of a successful submission/resubmission for a Case. For example, BC-CK051708-37/1 indicates the first submission made for Case Number BC-CK051708-37. Therefore, using an R4BP Submission Number it is always possible to identify the Case Number for which the Submission was made. [↑](#footnote-ref-12)