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# Introduction

## Purpose

The goal is to display information on the Joint submission (JS) page on the dossier evaluation processes (CCH/TPE) that have been initiated by ECHA for that Joint submission, in order to:

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

The source system where dossier evaluation data is stored is Dynamic case (which also extracts information from the Assessment module).

## References

Business requirements and mock-ups can be found here:

<https://pmo.trasys.be/confluence/pages/viewpage.action?pageId=129017480>

# High Level Business Consumer’s Requirements

Below there is a **high-level** description of the business requirements (detailed description of each one can be found in the [Confluence page](https://pmo.trasys.be/confluence/pages/viewpage.action?pageId=129017480), Section: Requirements).

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

# Assumptions & Constraints

Assumptions:

* Data required to populate the information on the dossier evaluation processes will be retrieved from BIDI.
* Data on recipients of draft/final decisions communicated during each dossier evaluation process will be retrieved by R-IT based on the published annotations for each case.

# Functional Requirements

## Data Requirements

The following data points will be used to populate the necessary information in the new 'ECHA Dossier evaluation status' section on the JS page.

Table 6‑1

|  | Data element name | Data Type | Definition | Source System | Relevant  Use cases / Mock-up screen |
| --- | --- | --- | --- | --- | --- |
| 1 | Dossier evaluation processes for a registration | Numeric | ID | DC | * R-IT should be able to retrieve all the dossier evaluation processes for a registration number * Each dossier evaluation process should have a unique identifier that follows the whole journey of the dossier evaluation (from 'Under assessment' to 'Follow-up') * A dossier evaluation process includes all the relevant cases (pre-check, DEV, FD, FUP) |
| 2 | Joint submission identifier | Numeric | RegistrationNumber | DC | R-IT must be able to link each dossier evaluation process to the correct JS by using an identifier (registration number) |
| 3 | BAP cases for each dossier evaluation process | Array of BAP Cases | CaseNo | DC | * R-IT should be able to identify the BAP cases that have been created under a dossier evaluation process * A dossier evaluation process can have multiple FUP cases * Pre-check cases are out of scope |
| 4 | Creation date of process | Date | CreationDate | DC | R-IT should know the creation date of the dossier evaluation process |
| 5 | CCH/TPE start date of DEV case of DEV BAP case | Date | dte\_cch\_start  dte\_tpe\_start | DC | * R-IT should display the dossier evaluation process under the relevant JS, once the CCH or TPE start date of the DEV case has been specified in DC * R-IT should notify all active JS members that a CCH has started, via message in R-IT, once the CCH date has been specified in DC |
| 6 | Overall status of dossier evaluation process (process map level) | Text | Status | DC | * R-IT should know the status of the dossier evaluation process at process map level * Based on current DC logic, the process map status is the BA lifecycle of the latest created case within the process map instantiation |
| 7 | Current lifecycle of each BAP case | Text | Current value for each DEV, FUP and FD case:  cse\_ba\_lifecycle  cse\_public\_lifecycle | DC | * R-IT should know the current lifecycle of each BAP case of a dossier evaluation process in order to display the current status on the JS page * The status displayed on the JS page should be calculated based on the lifecycle of the individual BAP cases (Pre-check cases are of scope) |
| 8 | Previous lifecycle(s) of each BAP case | Text | Previous values for each DEV, FUP and FD case:  cse\_ba\_lifecycle  cse\_public\_lifecycle | DC | R-IT should know all the lifecycles each BAP case has gone through, in order to display the status history of each dossier evaluation process |
| 9 | Dossier evaluation type (DEV case) | Text | prc\_dep\_type | DC | * R-IT should display the dossier evaluation type (CCH or TPE) for each dossier evaluation process * Value should be extracted from the DEV case |
| 10 | Published annotations for DD and FD for each BAP case | Alphanumeric | * Annotation numbers for each BAP case (at binder level) used to publish the DD and FD * IVAPP configuration name used to publish the annotations for the DD and FD * R-IT should be able to distinguish the most up to date (latest) annotation numbers used to publish the DD and FD (e.g. a timestamp could be exposed at binder level) | DC | * R-IT should be able to identify which DEV case triggered the publishing of the DD and the FD in R-IT, in order to display the recipients of each decision under the right dossier evaluation process * R-IT should be able to identify the latest (most up to date) annotations used to publish the DD and FD (in case more than one DD, FD were published due to error) * Link between annotation - submission - registration number already exists in R-IT, however no link between annotation and dossier evaluation exists (neither at case nor process map level) |
| 11 | Case events for DEV and FUP BAP cases | Number | The following cases events should be retrieved:   * For DEV case, events with:   + Case event TypeID = 8 (DD Sent to Registrant)   + Case event TypeID = 73 (Final Decision Sent to Registrant) * For each FUP case, events with:   + Case event TypeID = 9 (Final Decision Deadline Date)   + Case event TypeID = 75 (Enforcement Start Date)   + Case event TypeID = XX – Follow-up intermediate conclusion date (CR requested)   + Case event TypeID = 10 (Follow-up Conclusion Date) * If more than one case events with the same case event TypeID exist in the same BAP case, only the latest case event should be retrieved | DC | * The case events should be used to retrieve the assessment points included in the DEV and FUP cases and display them on the JS page under the appropriate status * If more than one case events with the same TypeID exist in a BAP case (e.g. this can happen if due to human error, ECHA needs to publish the DD of FD again), R-IT should display information only from the latest (most current) case event |
| 12 | Assessment points for DEV and FUP BAP cases |  | * For DEV case with prc\_dep\_type = CCH and for case events with TypeID = 8, 73, the assessment points with TypeID = 7 (Deficiencies-assessments) and outcome result code = INCOMPL should be retrieved * For DEV case with prc\_dep\_type = TPE and for case events with TypeID = 8, 73, the assessment points with TypeID = 7 and outcome result code = ACCEPTED, MODIFIED, ADDITIONAL\_TEST should be retrieved * For FUP case and for case events with TypeID = 9, the assessment points with TypeID = 7 and outcome result code = NOT\_ASSESS\_FUP\_CCH, NOT\_ASSESS\_FUP\_TPE should be retrieved * For FUP case and for case events with TypeID = 75, 10, the assessment points with TypeID=7 should be retrieved (without taking into account the outcome result) * If more than one case events with the same case event TypeID exist in the same BAP case, only the assessment points from the latest case event should be retrieved * The following information should be retrieved for each assessment point: * ClassID (Annex name) * SubClassID (Annex Section Description) * OutcomeResultID * RequestedInformationType * RegulationArticleCode * Guideline * Species * Route * TestMaterial * Deadline | DC/Assessment module | * R-IT should display information on the endpoints (i.e. assessment points) under the appropriate status * Only assessment points for deficiency data should be retrieved * Only assessment points for specific case events should be retrieved (also see above data requirement ‘Case events for each BAP case’) * The endpoints should be displayed in R-IT the following format: ‘In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1, deadline)’ |
| 13 | Additional information on the case (from DEV BAP case) | Text (may contain a link) | * prc\_dissemination\_reason (if multiple values are selected in DC, they should be provided in the same order as they appear in the drop-down list) * prc\_dissemination\_add\_info | DC | * R-IT should display the additional information fields when they are completed in DC * R-IT should display the reason values (prc\_dissemination\_reason) specified in the drop-down list in DC in the same order as they appear in the drop-down list (not in alphabetical order) * Fields are available in the DEV BAP case only |
| 14 | Dates related to the DD and FD from DEV and FUP case(s) | Date | dte\_dd\_sent\_to\_reg  dte\_final\_decision  dte\_fd\_deadline | DC | * R-IT should display the endpoint information on the JS page under the appropriate status, only if these dates exist in DC (date value not null) * If dte\_fd\_deadline is deleted from a FUP case in DC due to an appeal, the endpoints from that FUP case should not be displayed on the JS page |

## Business Rules

‘**Dossier evaluation process**’ is used in the requirements to refer to the dossier evaluation at process map level (parent case), and differentiate it from the distinct cases (DEV, FD, FUP) that can be included in each process map.

Pre-check cases are out of scope for this implementation.

Specific rules apply for retrieving the deficiency assessment points based on the type of BAP case, case events and outcome results (see data req. #13).

Business rules will be applied in REACH-IT to calculate the current status of each Dossier evaluation process (analysis available in the [Confluence page](https://pmo.trasys.be/confluence/pages/viewpage.action?pageId=129017480), Section ‘Displaying Dossier evaluation status on JS page’).

# Non-Functional Requirements

**Performance**

Some statistics to help assess possible performance issues when retrieving dossier evaluation information:

* Currently ~5,400 dossier evaluations have been launched on 3,410 substances
  + Currently 3% of the substances have over 5 dossier evaluations launched
  + As time passes the percentage of substances with over 5 dossier evaluations launched is expected to increase
* The information of dossier evaluation events displayed on the JS page needs to be accessed both by Industry users and ECHA users:
  + Industry users can only see information for JSs they are member of
  + ECHA users can see information for all JSs