FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
29 FEBRUARY 2024

EUROPEAN FOOD SAFETY AUTHORITY

FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France:

- - general
- - related to physchem and analytical methods

FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France – General

What are the possibilities to adapt the report generator (RG) ***in case of a AS dossier with several applicants who are NOT in a task force ?***

- Currently the RMS can generate reports via IUCLID only for each dossier separately.

  => the RMS merges these documents manually when producing the RAR.

- **But** it could be very useful if the RG could merge the reports from the different dossiers, for example for :
  - Generating the list of studies
  - documents M
  - Others…

⇒What is the opinion of the other MSs ?

⇒Would it be technically possible to create such merged reports?

FEEDBACK **FROM [FR]**

Needs and proposed improvements for RMS related to the report generator: feedback from France – physchem and analytical methods

User manual indicates how to prepare the analytical part correctly.

1/ MRL application report in IUCLID / document M - analytical methods part

Currently, the report generator does not work correctly because in lots of cases the dossier is not completed correctly regarding the analytical methods part of the IUCLID dossier.

Indeed, in most cases, all data are copy-past in a free-text box where additionnal data without any format can be added.

- **What**: details of validation data (recovery, repeatbility ...) are not completed in the correct boxes and the report generator does not recognise them => they are not reported in the generated report
- **Why**? It seems that the work to add the validation data manually in each box is too time consuming for companies.
- **Request**: the template of the analytical methods part of the IUCLID should be redesigned in order to simplify the work of applicants and of MS.

The same observation was made for physical chemical properties.

FEEDBACK FROM [FR]

Example on validation data for analytical methods:

OFTEN: Validation data are not filled in the right place in IUCLID but somewhere else

- ❑ RMS does not know where the information will be in the automatic generated report
- ❑ (or at least **if** the information will be reported in any case!)

=> Is the information reported?

- ❑ If no, how to extract the information from IUCLID ?
- ❑ If yes, where can it be found ?

__In IUCLID__: 5 boxes are present to fill in 5 recoveries

__In the dossier__: the 5 results are presented in a table in the first box with a summary text

⇒The report generator does not recognise the 5 individual values, no certainty the table is recognised or not

How RMS knows if we can trust the automatic report and have access to all the information available in IUCLID via this report?

- ➢ RMS cannot do this check
- ➢ Validation assistant report is not sufficiently precise and/or explicit to obtain this information

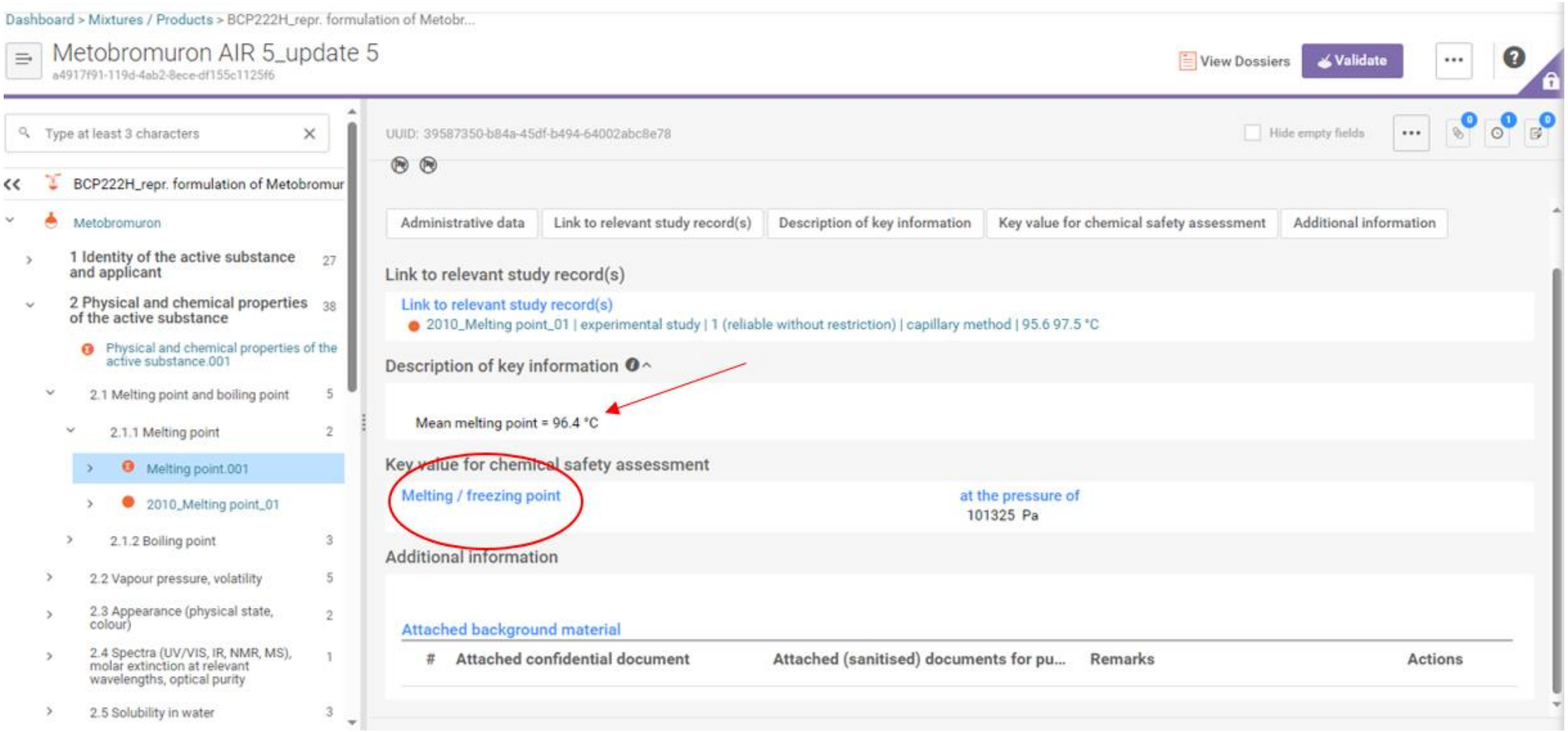
prothioconazole MRL dossier : the information was present but not at the right place

=> Efsa has provided assistance to extract the information, RMS not autonomous

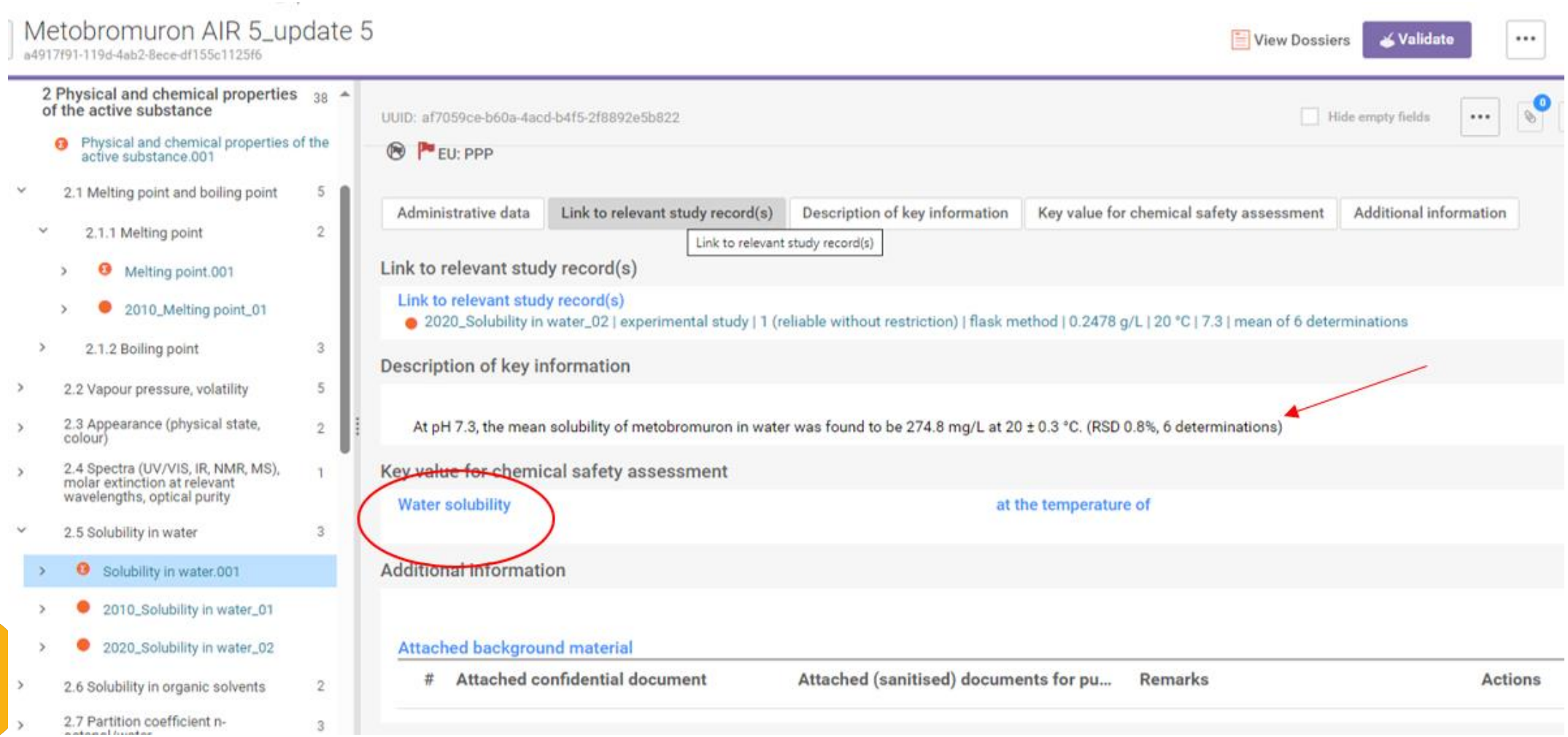
FEEDBACK FROM [FR]

Example on physchem properties:

The same issues are observed, e.g. melting point, solubility:



FEEDBACK FOMR [FR]



FEEDBACK **FROM [FR]**

Needs and proposed improvements for RMS related to the report generator: feedback from France – physchem and analytical methods

2/ Validation data of analytical methods in all sections

- Validation data of analytical methods (AM) concern all sections for RA.
- In IUCLID, all validation data for AM should be provided for monitoring and pre-registration methods, sorted by section and for each matrix, **within the dedicated section for analytical methods** (and **not** in each section for RA e.g. fate, residues,…).
- **Warning**: please avoid including this information in the general analytical methods part, without sorting hem section by section => *no business rule exists for this*
- **Consequence for the RMS**: need to open every study report to see to which section the method corresponds ; no overview per section / matrix available => **not workable for the experts as too much time consuming**

➢ **FR identifies the need of a business rule**:

The methods should be included in the AM part of IUCLID and sorted out by section and by matrix within a section

FEEDBACK **FROM [FR]**

In a nutshell :

- *It seems too much timeconsuming for the applicant to copy every item in a specific box for AM and physchem properties*
- *Applicants prefer filling as much information as possible in one free text box, sometimes in presented in tables*
- *For the experts : no specific interest in having all the information in separate boxes, and in theory, could use the data as they are currently provided (even though not filled in as described in the user manual)*
- *However, unfortunately currently the RMS cannot export this information through the report generator and thus cannot use this compiled information provided by the applicants in IUCLID*

- We cannot use the report generator for doc M or MRL application report as the data are not reported: **no trust in the automatic generated report – loss of information**
- **We continue to ask for 'manually prepared' doc M and MRL application reports** in order to have all the information that we need
- This **questions** also the future planned **deletion of doc J in IUCLID** – FR volunteers by participating in a WS on this issue if Efsa plans one.

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