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Best practice and known issues in SPC IUCLID preparation

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1. How to correctly manage mixture composition document names for successful submission of SPCs

In SPC IUCLID under the "Family, meta SPC, product" section the user has to introduce a number of documents to report: family information (always a single one), metaSPC (one per each relevant meta SPC) and product information (as many as they are included in the family under each meta SPC).

In IUCLID each entry under a section (for example under "Family, meta SPC, product") needs to be characterised by a "document name", as highlighted in the square box on the left in Figure 1 and reporting an entry for reporting the family level of a SPC. Document names are not relevant from regulatory perspective and they are not part of the content of a SPC. On the right pane, you can see where the document name may be edited (in the square box). You may also see where to find the field "Family or meta SPC identifier" (highlighted in the circle). The "Family or meta SPC identifier" is the information corresponding to the product family name which is relevant for regulatory purposes. The information in the "family or meta SPC identifier" field is the only one transferred to R4BP 3.

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Figure 1 – Family or metaSPC document name and Family or meta SPC identifier for family level information

The same logic applies also for metaSPCs, as indicated in Figure 2: the meta SPC document name is in the square box on the left; the editable meta SPC document name is in the square box on the right; the meta SPC name is in the circle on the right.

Figure 2 – Family or metaSPC document name and Family or meta SPC identifier for a meta SPC

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It applies also for the Products in the family, as indicated in Figure 2 where the product document name is in highlighted on the left, the editable product document name in the square box, while the Product name relevant for regulatory puporses is reported in the circle.
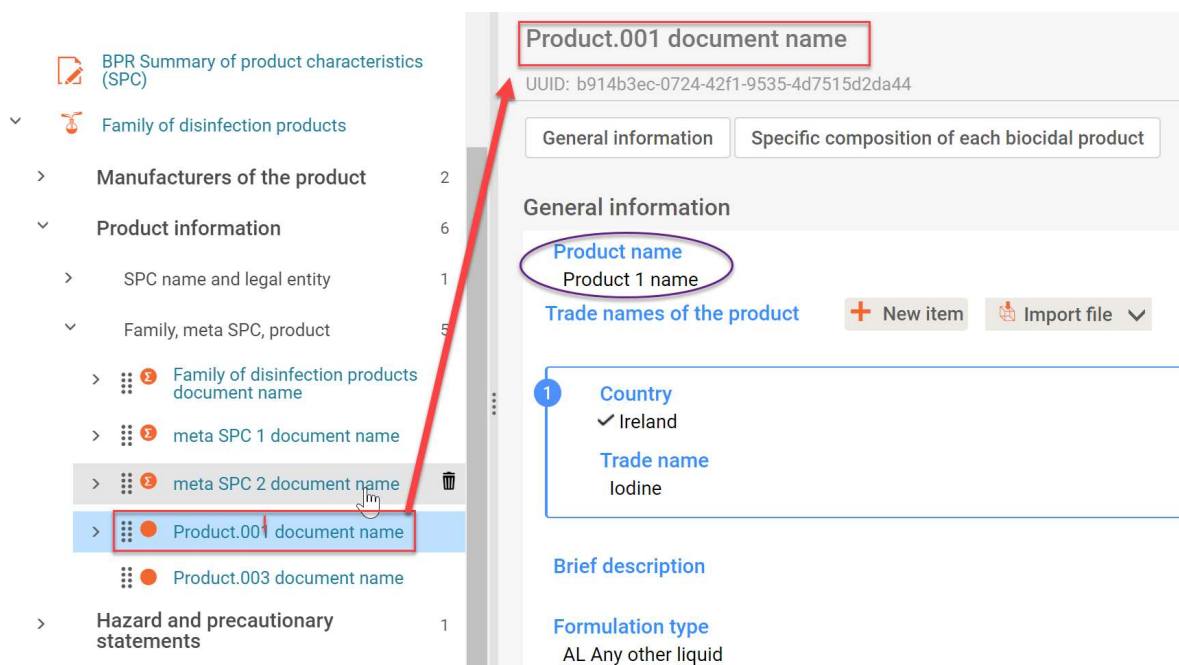

Figure 3 – Product document name and Product name

It is a general rule implemented in R4BP 3 that the list of document names reported on the left for family, meta SPC(s) and product(s) are used to characterise uniquely a product family.

As a consequence, if, for example, an applicant needs to resubmit a product family SPC during the evaluation step of a NA-APP case, they should make sure that the document names of the documents under the "family, meta SPC, product" section of SPC IUCLID in the resubmitted SPC which are common to the latest SPC available in the case are **identical**. This does not mean that product, meta SPC or family names cannot be changed: the names reported in the "family or meta SPC identifier" or in the "Product name" field can differ, from the document names. Consequently the information in these two fields can be changed as required. To be noted that for this resubmission example the identity of document names shall apply only to the documents that were common to the latest submission. Users can add/delete meta SPCs and products as needed: this will not be checked by the system.

NOTE: *The possibility to modify a product name shall not be interpreted as the adequacy to modify a product name, which remains as part of the assessment to be completed by the evaluating authority.*

If any document name is changed, instead, the system will consider the submitted SPC different from the one expectet, and will prompt an error message.
This check is performed upon:
- Resubmission tasks within the same case
- Submissions of SPCs in related cases stemming from reference cases/assets (MRP, MRS, BBP, BBS, ADC, MIC, MAC, AAT, TRS?)
- Evaluation tasks (for authorities)

In Figure 4 it is reported an example, based on the rules above explained, on how the information at family level should be reported, as example, for a successful upload of the

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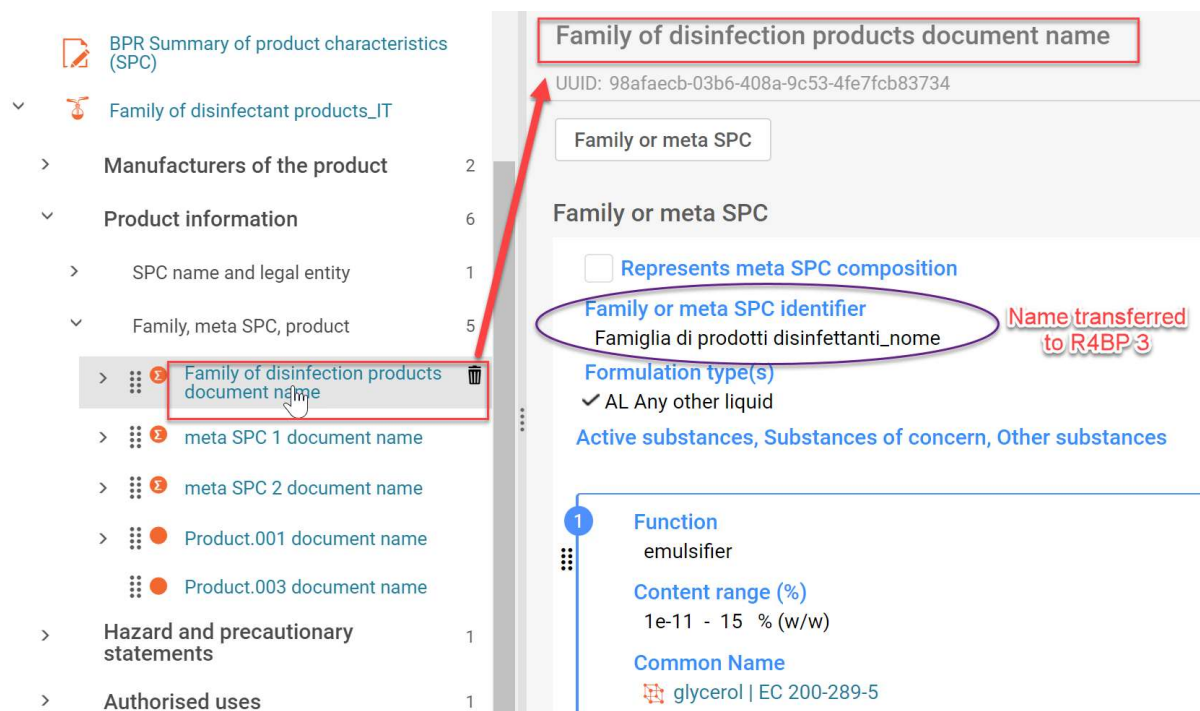Italian translation of the SPC reported in Figure 1.

Figure 4 – Product document name and Product name for translations

As you may see and as it should be done for all the other documents, the document names are identical to the reference, but the specific "family or meta SPC identifier" is different (in Italian)

2. How to manage SPCs contained in ad hoc communications

Based on the rules described in chapter 1, there is a possible scenario which might be happening due to the migration of the SPCs performed during SPC IUCLID roll out: SPCs uploaded in cases and assets were migrated, while those attached to ad hoc communications and messages were not.
Therefore, there is a chance that document names in the SPCs in ad hoc messages are actually not aligned to the ones migrated in the cases. If a user downloads SPCs from messages, uploads them in IUCLID for conversion and creates a dossier out of them, these SPCs might be rejected by R4BP 3 if document names are not aligned.

We would suggest in those cases to download the SPCs, convert them in IUCLID format, run the comparison tool and check the alignment of document names against the SPC uploaded in your case/asset. If there are deviations for the document names which are common between the two versions it is required to fix them by aligning the document names, to ensure a successful upload.

Alternatively, you can download the SPC in i6z format available in the existing case/asset and edit its content, making sure that document names in the family/meta/product remain unchanged.

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3. Dealing with mixture composition document names in a reference SPC

When a new application for biocidal product authorisation is created based on a reference application, e.g., for changes on request, mutual recognitions or same biocidal products, the reference SPC shall be used as starting point to create a SPC for a new related application. A reference SPC shall be considered as:

- Available in an asset, e.g., for changes on request, mutual recognition in sequence, renewals or amendments; or
- Available in a case, e.g., for mutual recognition in parallel or same biocidal product applications in progress.

To avoid any issue with document names, you need to consider:

- downloading the SPC in i6z format of the reference application available in R4BP 3; and
- maintaining the document names available in the "family, meta SPC, product" section of the downloaded SPC.

4. SPCs created for other applicants

If a SPC needs to be created for another applicant, e.g., to allow this applicant to submit their own application for biocidal product authorisation based on your reference application, you will need to create a "clone" of the reference SPC using IUCLID. When working with a "clone", make sure that the respective meta/product combinations are removed if the intention is to apply for a reduced biocidal product family; also remove the family level if the intention is to apply for a single biocidal product. Remember using the validation assistant to ensure that the links between the different sections of a SPC are present in a "clone" SPC.

When editing a SPC, make sure that the document names of the family, meta(s) and/or product(s) mixture composition documents remain the same.

If you have received a "clone" SPC to submit your own application for biocidal product authorisation based on a reference application, you may receive an error message upon upload of a SPC indicating that "the SPC has not been created from the reference SPC (i.e., same product name)". If you have not modified the document names of the family, meta(s), product(s) of the SPC provided to you, you will need to contact the applicant who provided you with the "clone" SPC to make them aware that the principles described in this section should be considered and produce a new "clone" SPC.

5. Handling SPC mixture composition document names in new applications

As mentioned in the previous chapters, a document name in IUCLID is an administrative name aimed at identifying a particular section within a structure.

When entering the documents and their names under the "family, meta SPC, product" section in a IUCLID SPC for a new application without a reference application, you may consider using for each document the corresponding regulatory name of the family for the family level document, of the meta SPC for the meta SPC document and of each product for the product document names.

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If there is a need to introduce a new product name as part of an administrative change to a biocidal product authorisation, or a clone SPC needs to be shared with a different company, it is important to consider that the document names of the original submission cannot be changed in the SPC "family, meta SPC, product" section of these new applications. Upon this background, you should consider the adequacy of using the same family/meta/product names as document names.

Document names are not part of the content of a SPC.