

## **Validation rules for PPP dossiers (July 2021)**

The **Portal validation rules** currently applied to PPP dossiers are the following:

### **General rules (checked for all the files sent to Portal):**

**[BR565]** Currently only the following submission types are accepted in 'ECHA Submission Portal':

- 'Poison centre notifications'
- 'SCIP notifications'
- 'EU PPP Active substance application (product)'
- 'EU PPP Basic substance application'
- 'EU PPP Microorganisms - active substance application (product)'
- 'EU PPP MRL application'

**[QLT732]** The maximum number (500) of IUCLID Validation Assistant rules that can be reported for the submitted dossier has been exceeded.

### **PPP rules:**

**[BR900]** Same dossier should not be submitted twice (compares dossier UUID's)

**[BR903]** Legal entity in '*EU PPP Active substance application (product)*': Submitting **Legal entity in Portal** must be same as **Legal entity owner in IUCLID** (compares legal entity UUID's)

**[BR904]** Legal entity in '*EU PPP Basic substance application*': Submitting **Legal entity in Portal** must be same as **Legal entity owner in IUCLID** (compares legal entity UUID's)

**[BR905]** Legal entity in '*EU PPP Microorganisms – active substance application (product)*': Submitting **Legal entity in Portal** must be same as **Legal entity owner in IUCLID** (compares legal entity UUID's)

**[BR906]** Legal entity in '*EU PPP MRL application*': Submitting **Legal entity in Portal** must be same as **Legal entity owner in IUCLID** (compares legal entity UUID's)

**[BR907]** Indicated '**European reference number**' should not be associated with **different substances** in ECHA Submission Portal. (compares EC number/CAS number/IUPAC names of 'Substance' and 'Reference substance' datasets that are marked to be 'Active substances')<sup>1</sup>

**[BR909]** Indicated '**European reference number**' should not be associated with **other PPP dossier types** in ECHA Submission Portal

**[QLT908]** Indicated '**European reference number**' should not be associated with **other legal entities** in ECHA Submission Portal. (compares legal entity UUID's)

**[BR910]** Dossier could not be imported in EFSA Agency IUCLID (When a PPP dossier passes IUCLID VA and Submission Portal rules but doesn't get stored in EFSA Agency IUCLID then a relevant BR is logged on the validation report of the dossier's submission)

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<sup>1</sup> Note that IUCLID validation rules do not force that there would be a single substance correctly reported (have EC number/CAS number/IUPAC name) as 'active substance'. If that information is missing, then [BR907] cannot guarantee that notifications with same 'European reference numbers' do have matching substances.