Webinar on the removal of Document J in IUCLID: how to report data for pesticide dossiers | 02 April 2025 | Outstanding Questions & Answers

This document contains answers to the outstanding questions from the webinar that were not addressed during the live event.

1) Question: In the manufacturing process with respect to starting materials, what happens when we have a mixture as a co-formulant?

Reply: In the manufacturing process of the active substance (see section 1.8 of AS dataset - Manufacturer_EFSA' document) any starting material that is a mixture must be listed as a REFERENCE_SUBSTANCE in the 'Starting substances' table. Applicants should clearly indicate that the reference substance is a mixture and provide a list of its components in the 'Remarks' field, to the extent to which the applicant has this information.
In the manufacturing process of the product (see section 1.7 of the PRODUCT dataset – 'Manufacturer_EFSA' document) applicants should cross-reference the relevant 'Mixture composition' document in the 'Related composition' field. In the 'Mixture composition' document applicants must list all components of the formulation used in the manufacturing process, including any co-formulants that can be created as mixture entities.

2) Question: Indeed, another follow-up on the read-across justifications. The fact that the different formulations need to be included in IUCLID is understood. However, a comparison is step 1, but step 2 is the actual justification. Normally, you include the compositions of multiple formulations are substance with impurities in a single table and discuss the differences. This discussion is critical to the read-across. Where to put this?

Reply: A table will be generated automatically comparing the test materials (i.e. formulations) used in the studies submitted in the product dataset: test materials in columns vs components (i.e. active substance, co-formulants etc.) in rows, with the reported concentrations in the cells. Justifications on similarity of this test material (i.e. formulation) with the representative formulation should be provided for each test material (i.e. formulation) under the field "**Confidential details on test material**" (path: TEST_MATERIAL_INFORMATION.Composition.OtherCharacteristics.ConfidentialDetailsOnTestMaterial). This information will be shown below the table in the future report.