Assessment of equivalence of batches according to the Technical report “Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology “ and ”How to present the assessment for the equivalence of batches” according to Appendix D of EFSA Supporting publication 2019:EN-1673

| **Batch No.** | **Purity**  **(% w/w)** | **Impurity Profile**  **(% w/w)** | **Study type** | **Reference to studies done with that batch** |
| --- | --- | --- | --- | --- |
| A |  |  |  |  |
| B |  |  |  |  |
| C |  |  |  |  |
| etc. |  |  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Short name or code of the substance** | **content (g/kg) proposed in the new specification** | **Content (g/kg) reference specification** | **Batch** | | | | **Tier I assessment** | **Remarks** |
| **A** | **B** | **C** | **etc.** |
| a.s. |  |  |  |  |  |  |  |  |
| impurity 1 |  |  |  |  |  |  | Tier II assessment needed |  |
| impurity 2 |  |  |  |  |  |  |  |  |
| impurity 3 |  |  |  |  |  |  |  |  |
| etc. |  |  |  |  |  |  |  |  |

Tier II assessment for ecotoxicological equivalence of the batches according to SANCO/10597/2003 – rev.10.1 13 July 2012

A tier 2 assessment is considered necessary for the impurity/ies XX etc. The prediction of toxicity was calculated using following formula:

Impurity 1:

The new specification contains impurity 1 with a content of XX %, which was contained in the batches (A, B,C etc) at an amount of XX %, XX % and XX %.

With the parameter of f = 10 or f = 100, pold(A) = xx, xx, xx and pnew(A) = xx, the relation of predicted toxicity to the known effect value is calculated as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **Batch** | **Study** | **Calculations** | **Trigger** |
| A |  |  | < 2 |
|  |  | < 2 |
| B |  |  | < 2 |
| C |  |  | < 2 |

A Tier 1 assessment should be presented for all the batches used in the ecotoxicological studies while a Tier 2 assessment should only be performed for those batches used in key studies (i.e. studies used for risk assessment).[[1]](#footnote-1)

**Significant impurities**

Impurities that occur due to process variability[[2]](#footnote-2) in quantities ≥ 1 g/kg in the active substance as manufactured, based on dry weight, are regarded as significant.

**Relevant impurities**

All impurities of toxicological and/or ecotoxicological or environmental concern[[3]](#footnote-3) compared with the active substance, even if present in technical material at < 1 g/kg.

1. EFSA Supporting publication 2019:EN-1673 [↑](#footnote-ref-1)
2. Significant impurities may be present as a direct result of the chemical synthesis process/conditions employed or may be present as a result of cross contamination within the production cycle. [SANCO/10597/2003 –rev. 10.1, 13 July 2012] [↑](#footnote-ref-2)
3. Considering the Regulation, the following definition is proposed for relevant impurities: such substances include, but are not limited to, substances meeting the criteria to be classified as hazardous in accordance with Regulation (EC) No. 1272/2008 [extract from Art. 3(4)] or the available information (e.g. (Q)SAR, genotoxicity) indicates that the impurity has a toxicological hazard. Relevant impurities have the inherent capacity to cause harmful/unacceptable effects within the meaning of Article 4(2) and (3). Compared to the active substance, relevant impurities show additional (or more severe) toxic properties (in the sense of the above given properties). [SANCO/10597/2003 –rev. 10.1, 13 July 2012] [↑](#footnote-ref-3)