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P29. TECHNICAL EQUIVALENCE

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One of the conditions set by the EU BPR (EU (No) 528/2012) for authorisation of a biocidal product is the requirement to demonstrate Technical Equivalence of the Active Substance(s) contained within.
The concept of Technical Equivalence is defined (Article 3) in the BPR as '*means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54;'*
However, the concept is not defined under Turkish Biocidal Products Regulation (27449-4th bis.)
As part of the first EU evaluation of an Active Substance (AS) dossier the evaluating Competent Authority must be establish a reference composition (Reference Source) against which any new sources (this can cover changes to the reference source itself) can be compared.
Thus, the Technical Equivalence of any alternative source of the AS being placed on the market, must be established by the Authorities before a product containing it can be authorised. The European Chemicals Agency (ECHA) has established a guidance document to clarify the data required and the procedure for confirming equivalence of different sources.
Technical equivalence is split into two Tiers. Tier I is based on composition, assessing the similarity of the purity of the new AS source and the associated impurity profile to the Reference Source. Data requirements for Tier II depends on the type of AS, but testing is required. The applicant must demonstrate that the Human Health and Environmental hazard properties are not affected by any changes in composition identified in Tier I.
The EU guidance identifies five scenarios where technical equivalence will need to be demonstrated. This includes new sources of AS or significant changes to existing manufacturing processes. However at present Technical Equivalence does not need to be demonstrated for the purpose of being listed on Article 95, this is only required at subsequent product authorisation.
If a source of AS is shown to be Technically Equivalent to the Reference Source then ECHA and all Member State Competent Authorities can be confident that the data contained within the AS dossier is applicable to the new source. In other words, if the new source was tested it would be expected to give an equivalent profile for Physical Properties, Efficacy, Toxicity and Ecotoxicology to the Reference Source. The same would apply to any Biocidal Product containing the alternative AS source.
Without the requirement for demonstrating Technical Equivalence, there is the risk that alternative AS sources placed on the market, may not have similar profiles to the Reference Source. This may be reflected in reduced Efficacy (with the associated risk of resistance) or impurities causing undesirable Toxicological or Eco-toxicological properties with the potential for affecting public health. Therefore it is important to have a requirement to demonstrate Technical Equivalence, especially where access is being granted to data generated on one source of Active Substance, to another.