

Guidance on Technical Specifications at Renewal

Where there is no change in the renewal conditions of the active substance the technical equivalence assessments conducted under 91/414 will remain valid. If there is any change to the minimum purity and/or relevant impurity levels in the renewal regulation, some new consideration will be required. It is the authorisation holder's responsibility to ensure that the agreed specifications for all sources of active substance that they intend to use in their product comply with the renewal requirements. There should be a step wise approach to considering this.

1. If appropriate, provide a declaration in Form CRD-R that the existing agreed technical specification complies with the renewal requirement.
2. If the previously agreed specification does not comply with the requirements of the Renewal Regulation then it may not be used in a renewed product until a revised specification is agreed.
 - (a) It may be possible that the renewal regulation has changed how the active substance and/ or relevant impurities are expressed. If this is the case it may be possible to base a reasoned argument for a revised specification on the previous technical equivalence assessment. E.g. if the active substance was previously expressed in the hydrated form but the renewal expresses this in the hydrated form, the minimum purity is likely to change.
 - (b) If (a) is not suitable then a new technical equivalence assessment based on new batch data will be required ensuring that all relevant and significant impurities are analysed for. Such a consideration should be by way of a separate technical equivalence application which can run concurrently to the renewal assessment. This approach will allow applicants to change the source (or the specification of an existing source) to one which is compliant with the renewal requirements within the necessary time frame.