Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

CHAPTER XIV

DATA PROTECTION AND DATA-SHARING

Article 64

Use of data for subsequent applications

1 Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities.

Where the relevant data protection period according to Article 60 has expired in relation to a biocidal product, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.

An appeal may be brought, in accordance with Article 77, against decisions of the Agency under the first and second subparagraphs of this paragraph.

2 Notwithstanding paragraph 1, subsequent applicants shall provide the following data accordingly to the receiving competent authority or the Agency, as applicable:

a all necessary data for the identification of the biocidal product, including its composition;

b the data needed to identify the active substance and to establish technical equivalence of the active substance;

c the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of the authorised biocidal product.

Status:
Point in time view as at 22/05/2012.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 528/2012 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.