
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of powers in the European Union (Withdrawal) Act 2018 (c. 16) (in particular under section 8(2)(d)) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

These Regulations amend retained EU law relating to the applications for authorisation of biocidal products. In particular, they impose new deadlines within which certain actions must be taken by the competent authority in relation to an application for the authorisation of a biocidal product.

Regulation 2 amends Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. Regulation 2(2)(a) amends Article 26 to provide that the competent authority must inform certain applicants using the simplified authorisation procedure of the appropriate fees before 31st December 2027. Regulation 2(2)(c) amends the same article to provide that applications accepted before 2nd October 2027 in respect of products containing an active substance that were approved or in Annex 1 to Regulation (EU) No 528/2012 before IP completion day must be authorised before 31st December 2027 if the competent authority is satisfied that the product complies with Article 25.

Regulation 2(3) amends Article 29 to provide that the competent authority must inform certain applicants of the appropriate fees before 31st December 2027.

Regulation 2(4) amends Article 30 to provide that the decision to grant an authorisation in respect of applications validated before 31st December 2026 for “relevant products” (as defined) must be made before 31st December 2027. It adds related mechanisms, including an obligation on the competent authority to draft and send an assessment report to the applicant by 31st December 2027 (unless extended).

Regulation 2(5) amends Article 89 to provide that the current system or practice of making available on the market or using certain biocidal products is to apply until a “relevant date” (as defined), which depends on the provisions applicable to the product.

Regulation 2(8) inserts Article 95FA. This makes transitional provision for applications made to the United Kingdom competent authority before IP completion day under Article 4a of Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council day and in respect of which a decision was not made before IP completion day.

Regulation 3 amends Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

Regulation 3(2)(a) amends Article 7 to provide that the competent authority must inform certain applicants applying for a minor change to a product of the appropriate fees before 31st December 2027. Regulation 3(2)(c) amends the same Article to include an obligation on the competent authority, where an application is validated before 2nd October 2027, to evaluate the application and draft and send an assessment report, along with a revised summary of the biocidal product characteristics (where relevant), to the applicant by 31st December 2027 (unless extended).

Regulation 3(3) amends Article 8. It makes similar amendments to regulation 3(2) in respect of applications for major changes to products.

Draft Legislation: This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 No. 1291

Regulation 4 amends Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

Regulation 4(2) amends Article 5 to provide that the competent authority must decide to grant or refuse an application before 31st December 2027 of a same product that was validated before 1st November 2027.

Regulation 4(3) makes similar amendments to Article 6a in respect of applications made using the simplified procedure set out in the Regulation.

No impact assessment has been produced for this instrument as no, or no significant, impact on the private or voluntary sectors is foreseen.