Draft Regulations laid before Parliament under paragraph 1(3) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2022 No.

HEALTH AND SAFETY

The Biocidal Products (Health and Safety) (Amendment) Regulations 2022

Made - - - - ***

Coming into force *31st December 2022*

The Secretary of State, in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**) makes the following Regulations.

In accordance with paragraph 1(3) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Biocidal Products (Health and Safety) (Amendment) Regulations 2022.

(2) These Regulations come into force on 31st December 2022.

(3) An amendment made by these Regulations has the same extent as the provision being amended.

Amendment of Regulation (EU) No 528/2012

2.—(1) 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 is amended as follows(**b**).

(2) In Article 26—

(a) after paragraph 2, insert—

"2A. Where the application is one to which paragraph 2B applies, paragraph 2 applies as if for "shall inform the applicant of the appropriate fees" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fees".

2B. This paragraph applies to—

(**a**) 2008 c. 16. Section 8 was amended by section 27 of the European Union (Withdrawal Agreement) Act 2020 (c. 1). Paragraph 21 of Schedule 7 was amended by paragraph 53 of Schedule 5 to that Act.
(**b**) EUR 2012/528; amended by S.I. 2019/720.

(a) an application in respect of a relevant category B product that is resubmitted by virtue of Article 95E; or

(b) an application that is resubmitted under Article 95FA.

2C. A "relevant category B product" is a product containing an active substance falling within category B of the Simplified Active Substance List that before IP completion day was—

(a) approved; or

(b) included in Annex 1 to 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(**a**).";

(b) at the beginning of paragraph 3, insert "Subject to paragraph 3A,";

(c) after paragraph 3, insert—

"3A. Where a relevant application is accepted before 2nd October 2027, the competent authority must authorise the application before 31st December 2027 if it is satisfied that the product meets the conditions laid down in Article 25.

3B. In paragraph 3A, "relevant application" is one that is submitted in respect of a product containing an active substance that before IP completion day was—

(a) approved; or

(b) included in Annex 1 to 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(**b**).";

(d) in paragraph 4, after the second subparagraph, insert—

"Where paragraph 3A applies, the deadline of 31st December 2027 referred to in that paragraph is to be extended by a number of days equal to the number of days beginning with the date on which the competent authority requested additional information and ending with the date on which the information was received by the competent authority plus 90 days.".

(3) In Article 29, after paragraph 1, insert—

"1A. Where the application is one that has been resubmitted by virtue of any of the Articles listed in paragraph 1B, paragraph 1 applies as if for "shall inform the applicant of the appropriate fees" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fees".

1B. The Articles are—

(a) Article 95B;

(b) Article 95D;

(c) Article 95F;

(d) Article 95H.".

(4) In Article 30—

(a) in paragraph 1, at the beginning, insert "Subject to paragraph 1A,";

(b) after paragraph 1, insert—

"1A. Where an application for a relevant product is validated in accordance with Article 29 before 31st December 2026, the competent authority must decide before 31st December 2027 whether to grant an authorisation in accordance with Article 19. It must take into

(**a**) O.J. L. 167, 27.6.2012, p.1 - 123.
(**b**) O.J. L. 167, 27.6.2012, p.1 - 123.

account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

1B. In paragraph 1A a "relevant product" is a product containing an active substance in respect of which the implementing regulation providing that the substance is approved entered into force before IP completion day.

1C. In paragraph 1B "implementing regulation" has the same meaning as in 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(**a**) as it had effect immediately before IP completion day.";

(c) in paragraph 2, at the beginning, insert "Subject to paragraph 2A,";

(d) after paragraph 2, insert—

"2A. Where paragraph 1A applies and it appears that additional information is necessary to carry out the evaluation, the competent authority must ask the applicant to submit such information within a specified time limit. The deadline of 31st December 2027 referred to in paragraph 1A is to be extended by a period equal to the number of days beginning with the date on which the applicant is asked for additional information and ending with the date on which that information is received by the competent authority. But the deadline may not be extended by more than 180 days in total, unless it is justified by the nature of the data requested or by exceptional circumstances.

The competent authority must reject the application if the applicant fails to submit the requested information within the specified time limit and must inform the applicant accordingly.";

(e) in paragraph 3, at the beginning, insert "Subject to paragraph 4,";

(f) after paragraph 3 insert—

"4. Where paragraph 1A applies, the competent authority must comply with the requirements in paragraph 3(a), (b) and (c)—

(a) before 31st December 2027; or

(b) where the applicant has been asked to submit additional information under paragraph 2A, before the date to which the deadline of 31st December 2027 has been extended under that paragraph.".

(5) In Article 89—

(a) in paragraph 7, at the beginning, insert "Subject to paragraph 7A,";

(b) after paragraph 7 insert—

"7A. By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1, 2 and 9 of this Article, where paragraph 7B or 7C applies the current system or practice of making available on the market or using a biocidal product is to apply until the relevant date or, if earlier, the date on which the product is authorised under this Regulation. The competent authority may, in accordance with the current system or practice, authorise the making available on the market or use of the biocidal product.

7B. This paragraph applies to a biocidal product—

(a) that contains at least one existing active substance that was approved before IP completion day; and

(b) the application in respect of which—

(i) is one to which a relevant provision applies;

(**a**) O.J. L. 167, 27.6.2012, p.1 - 123.

(ii) was received no later than the date of approval of the last of the active substances to be approved for that product-type; and

(iii) was resubmitted by virtue of Article 95B, 95D, 95E, 95F, 95FA or 95H.

7C. This paragraph applies to a biocidal product—

(a) that contains at least one active substance in respect of which the implementing regulation providing that the substance is approved entered into force before IP completion day;

(b) to which paragraph 7B does not apply; and

(c) the application in respect of which—

(i) is one to which a relevant provision applies;

(ii) was received no later than the date of approval of the last of the active substances to be approved for that product-type; and

(iii) was received after IP completion day.";

(c) in paragraph 8, for "paragraph 7" substitute "paragraphs 7 and 7A";

(d) in paragraph 9, after "of approval" insert "or, where paragraph 7A applies, before the relevant date";

(e) after paragraph 9, insert—

"9A. Where, in relation to a particular case the application in respect of which is one to which a relevant provision applies, the deadline by which a competent authority must authorise a biocidal product is extended under Article 26(4), Article 29(3) or Article 30(2A), the relevant date for the purposes of paragraphs 7A and 9 is to be extended by the same number of days in relation to that particular case.";

(f) after paragraph 11 insert—

"12. In this Article—

"implementing regulation" has the same meaning as in 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(**a**) as it had effect immediately before IP completion day;

"relevant date" means—

(a) where Article 26(2A) applies, 29th April 2028;

(b) where Article 26(3A) or 30(1A) applies, 31st December 2027;

(c) where Article 29(1A) applies, 1st March 2029; or

(d) where Article 5(2) or 6A(1A) 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(**b**) applies, 31st December 2027;

"relevant provision" means—

(a) Article 26(2A);

(b) Article 26(3A);

(c) Article 29(1A);

(d) Article 30(1A);

(e) Article 5(2) of Commission Implementing Regulation (EU) No 414/2013 specifying a procedure for the authorisation of same biocidal products in

(**a**) O.J. L. 167, 27.6.2012, p.1 - 123.
(**b**) EUR 2013/414; amended by S.I. 2019/720.

accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; or

(f) Article 6A(1A) of that Regulation.".

(6) In Article 95B, after paragraph 4, insert—

"4A. But paragraph 4 does not apply so as to shorten—

(a) the deadline in paragraph 1 of Article 29, as it is modified by paragraph 1A of that Article; or

(b) the deadlines in paragraphs 1A, 2A and 4 of Article 30.".

(7) In Article 95C, after paragraph 4, insert—

"4A. But paragraph 4 does not apply so as to shorten the deadlines in paragraphs 1A, 2A and 4 of Article 30.".

(8) After Article 95F, insert—

"Article 95FA

Transitional measures for applications for same biocidal product authorisations under the simplified procedure

1. This Article applies where—

(a) an application was 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; and

(b) a decision was not made before IP completion day.

2. The application is to be treated as having been made under Article 4a of Regulation (EU) 414/2013.

3. The applicant must—

(a) resubmit the application and any supporting data to the competent authority; or

(b) where the applicant relies on a letter of access—

(i) resubmit the application; and

(ii) ensure that the data owner resubmits the data.

4. Where the applicant does not meet the requirements of this Article, the application must be rejected by the competent authority and Article 89(11) applies as if the application had been submitted in accordance with Article 89(9).

5. For the purposes of this Article, data resubmitted by the applicant or the data owner must include relevant data for the reference product.

6. The resubmission of any application and data referred to in paragraph 3 must be completed in accordance with Article 71 before 31 January 2023.".

(9) In Article 95H, after paragraph 4, insert—

"4A. But paragraph 4 does not apply so as to shorten—

(a) the deadline in paragraph 1 of Article 29, as it is modified by paragraph 1A of that Article; or

(b) the deadlines in paragraphs 1A, 2A and 4 of Article 30.".

Amendment of Commission Implementing Regulation (EU) No 354/2013

3.—(1) 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(**a**) is amended as follows.

(2) In Article 7—

(a) after paragraph 2, insert—

"2A. Where the application is one that has been resubmitted by virtue of Article 95M of Regulation (EU) No 528/2012, paragraph 2 applies as if for "shall inform the applicant of the appropriate fee" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fee".";

(b) in paragraph 4, at the beginning, insert "Subject to paragraph 4A,";

(c) after paragraph 4, insert—

"4A. Where an application is validated before 2nd October 2027, the competent authority must, before 31st December 2027—

(a) evaluate the application;

(b) draft an assessment report;

(c) send the report to the applicant; and

(d) where relevant, send the revised summary of the biocidal product characteristics to the applicant.";

(d) in paragraph 5, at the beginning, insert "Subject to paragraph 5A,";

(e) after paragraph 5, insert—

"5A. Where paragraph 4A applies and it appears that additional information is necessary to carry out the evaluation, the competent authority must ask the applicant to submit such information within a specified time limit. The deadline of 31st December 2027 referred to in paragraph 4A is to be extended by a period equal to the number of days beginning with the date on which the applicant is asked for additional information and ending with the date on which that information is received by the competent authority. But the deadline may not be extended by more than 45 days in total, unless it is justified by the nature of the data requested or by exceptional circumstances.

The competent authority must reject the application if the applicant fails to submit the requested information within the specified time limit and must inform the applicant accordingly.".

(3) In Article 8—

(a) after paragraph 2, insert—

"2A. Where the application is one that has been resubmitted by virtue of Article 95M of Regulation (EU) No 528/2012, paragraph 2 applies as if for "shall inform the applicant of the appropriate fee" there were substituted "shall inform the applicant before 31st December 2027 of the appropriate fee".";

(b) in paragraph 4, at the beginning, insert "Subject to paragraph 4A,";

(c) after paragraph 4 insert—

"4A. Where the application is validated but not authorised before 4th July 2027, the competent authority must, before 31st December 2027—

(a) evaluate the application;

(b) draft an assessment report;

(**a**) EUR 2013/354; amended by S.I. 2019/720.

(c) send the report to the applicant; and

(d) where relevant, send the revised summary of the biocidal product characteristics to the applicant.";

(d) in paragraph 5, at the beginning, insert "Subject to paragraph 5A";

(e) after paragraph 5 insert—

"5A. Where paragraph 4A applies and it appears to the competent authority that additional information is necessary to carry out the evaluation, the competent authority must ask the applicant to submit such information within a specified time limit. The deadline of 31st December 2027 referred to in paragraph 4A is to be extended by a period equal to the number of days beginning with the date on which the applicant is asked for additional information and ending with the date on which that information is received by the competent authority. But the deadline may not be extended by more than 90 days in total, unless it is justified by the nature of the data requested or by exceptional circumstances.

The competent authority must reject the application if the applicant fails to submit the requested information within the deadline and must inform the applicant accordingly.".

Amendment of Commission Implementing Regulation (EU) No 414/2013

4.—(1) 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 is amended as follows.

(2) In Article 5—

(a) renumber the existing paragraph as paragraph 1;

(b) at the beginning of that paragraph insert "Subject to paragraph 2,";

(c) after that paragraph insert—

"2. By way of derogation from Article 30 of Regulation No 528/2012, where an application for authorisation of a same product is validated in accordance with Article 3 before 1st November 2027, or, where applicable, the subsequent date of adoption of the corresponding decision concerning the related reference product is before 1st November 2027, the competent authority must decide whether to grant or refuse the authorisation in accordance with Article 19 of that Regulation before 31st December 2027.".

(3) In Article 6a—

(a) at the beginning of paragraph 1 insert "Subject to paragraph 1A,";

(b) after paragraph 1, insert—

"1A. By way of derogation from Article 26(3) and (4) of Regulation No 528/2012, where an application for authorisation of a same product is accepted in accordance with Article 4a(2) before 1st November 2027, or, where applicable, the subsequent date of adoption of the corresponding decision concerning the related reference product is before 1st November 2027, the competent authority must decide whether to grant or refuse the authorisation in accordance with Article 25 of that Regulation before 31st December 2027.".

Signed by authority of the Secretary of State for Work and Pensions

Name
Parliamentary Under Secretary of State
Department for Work and Pensions

Date

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.

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.

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