STATUTORY INSTRUMENTS

2022 No. 1291

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

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(**1**) 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—

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

(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;

(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.".