



STATUTORY INSTRUMENTS.

**S.I. No. 324 of 2020**



EUROPEAN UNION (PROTECTION OF ANIMALS USED FOR  
SCIENTIFIC PURPOSES) (AMENDMENT) REGULATIONS 2020

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## EUROPEAN UNION (PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES) (AMENDMENT) REGULATIONS 2020

I, STEPHEN DONNELLY, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010<sup>1</sup>, and giving full effect to Article 6 of Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019<sup>2</sup> and Commission Implementing Decision (EU) 2020/569 of 16 April 2020<sup>3</sup>, hereby make the following regulations:

*Citation*

1. (1) These Regulations may be cited as the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2020.

(2) The Principal Regulations, the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2013 (S.I. No. 434 of 2013), the Regulations of 2014, the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2016 (S.I. No. 552 of 2016), the Regulations of 2018 and these Regulations may be cited together as the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 to 2020.

*Definitions*

2. In these Regulations—

“Principal Regulations” means the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S.I. No. 543 of 2012);

“Regulations of 2014” means the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2014 (S.I. No. 174 of 2014);

“Regulations of 2018” means the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2018 (S.I. No. 553 of 2018).

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<sup>1</sup> OJ No. L 276, 20.10.2010, p. 33.

<sup>2</sup> OJ No. L 170, 25.6.2019, p. 115.

<sup>3</sup> OJ No. L 129, 24.4.2020, p. 16.

*Amendment of Regulation 3*

3. Regulation 3(1) (as amended by Regulation 3 of the Regulations of 2018) of the Principal Regulations is amended by inserting after the definition of “IMB” the following definition:

“‘Implementing Decision’ means Commission Implementing Decision (EU) 2020/569 of 16 April 2020<sup>3</sup>.”

*Amendment of Regulation 33*

4. Regulation 33 of the Principal Regulations is amended by substituting for paragraph (4) the following paragraphs:

“(4) From 1 January 2021, where a retrospective assessment is required pursuant to paragraph (3), the non-technical project summary shall be updated by the IMB within 6 months of the completion of the retrospective assessment with the results thereof.

(5) Until 31 December 2020, the IMB shall publish the non-technical project summaries of authorised projects and any updates thereto.

(6) From 1 January 2021, the IMB shall submit for publication the non-technical project summaries of authorised projects, at the latest within 6 months of authorisation, and any updates thereto, by electronic transfer to the Commission.

(7) For the purpose of paragraph (6), the IMB shall submit the information specified in Annex I to the Implementing Decision using the database established by the Commission in accordance with the third sentence of Article 43(4) of the Directive and the non-technical project summaries, and updates thereto, shall correspond to the templates laid down in the said Annex.”

*Amendment of Regulation 52*

5. Regulation 52 of the Principal Regulations is amended by inserting “or arrange to have paid,” after “under this Part shall pay,”.

*Amendment of Regulation 67*

6. The Principal Regulations are amended by substituting for Regulation 67 the following:

*“Information on implementation*

67. The IMB shall by 10 November 2023, and every 5 years thereafter, submit to the Commission, information on the

implementation of the Directive, and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46, as specified in Annex II to the Implementing Decision, using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of the Directive.”.

*Amendment of Regulation 68*

7. The Principal Regulations are amended by substituting for Regulation 68 (as amended by Regulation 3 of the Regulations of 2014) the following:

*“Provision of statistical data*

68. (1) The IMB shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures.

(2) The IMB shall submit to the Commission, at the latest by 10 November the following year, the statistical information collected pursuant to paragraph (1), as specified in Annex III to the Implementing Decision, using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of the Directive.”.

*Amendment of Regulation 69*

8. The Principal Regulations are amended by substituting for Regulation 69 the following:

*“Information on exemptions in relation to method of killing*

69. The IMB shall submit to the Commission, on an annual basis, detailed information on exemptions granted under Regulation 8(4)(a), as specified in Annex IV to the Implementing Decision, using the template laid down in that Annex.”.

*Amendment of Regulation 84*

9. Regulation 84(1) (as amended by Regulation 11(a) of the Regulations of 2018) of the Principal Regulations is amended by deleting “68(3),”.



GIVEN under my Official Seal,  
24 August, 2020.

STEPHEN DONNELLY,  
Minister for Health.

EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

These Regulations amend the European Union (Protection of Animals used for Scientific Purposes) Regulations 2012, primarily to give full effect to Article 6 of Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 and Commission Implementing Decision (EU) 2020/569 of 16 April 2020.

These Regulations may be cited as the European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2020.

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