Commission Implementing Decision (EU) 2020/569 of 16 April 2020 establishing a common format and information content for the submission of the information to be reported by Member States pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes and repealing Commission Implementing Decision 2012/707/EU (notified under document C(2020) 2179) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2020/569

of 16 April 2020

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(notified under document C(2020) 2179)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes[(1)], and in particular Article 43(4) and Article 54(4) thereof,

Whereas:

(1) Following the amendments provided for in Regulation (EU) 2019/1010 of the European Parliament and of the Council[(2)], Directive 2010/63/EU now requires Member States to submit non-technical project summaries of authorised projects, and any updates thereto, by electronic transfer to the Commission. In order to enable the Commission to establish and maintain a central database for those summaries and updates and to ensure that meaningful searches can be carried out on that data, a uniform presentation of those summaries and updates is needed. Therefore, templates should be established for submitting the non-technical project summaries, and any updates thereto, and Member States should be required to upload such summaries and updates to the database established by the Commission.

(2) Directive 2010/63/EU also requires Member States to submit information on the implementation of that Directive, as well as statistical information on the use of animals in procedures, by electronic transfer to the Commission.

(3) On the basis of the information submitted by the Member States on the implementation of Directive 2010/63/EU, the Commission services are to publish and regularly update a Union overview. Directive 2010/63/EU also requires the Commission services to make the statistical data submitted by the Member States and a summary report thereof

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/569. (See end of Document for details)*

publicly available on an annual basis. To enable the Commission to satisfy both of those requirements, the content of that information should be established by laying down information categories.

(4) As regards information on implementation, the information categories to be reported on should correlate with the relevant requirements of Directive 2010/63/EU. As regards statistical information, it is necessary to specify the statistical data input categories available in the searchable, open access database established by the Commission pursuant to Directive 2010/63/EU.

(5) In order to improve transparency and to reduce the administrative burden, Member States should be required to use the database established by the Commission for the purposes of submitting the information on the implementation of Directive 2010/63/EU as well as the statistical information on the use of animals in procedures.

(6) The content and format of the detailed information to be submitted by Member States on the methods considered to be at least as humane as those contained in Annex IV to Directive 2010/63/EU should be specified in a way that allows the list of methods for the killing of animals contained in that Annex to be kept up to date. Therefore, it is appropriate to lay down a template allowing for the submission of information on the type of method, the species concerned and the justification for granting an exemption, and to require Member States to use that template.

(7) The empowerments on which this Decision is based are closely linked as they both deal with the reporting of information by Member States under Directive 2010/63/EU. Given this substantive link, and to ensure a consistent and coherent approach, it is appropriate to adopt a single Decision establishing all requirements falling within the scope of those empowerments. It is therefore necessary to replace Commission Implementing Decision 2012/707/EU[(3)], in which the common format for the submission of the information referred to in Article 54 of Directive 2010/63/EU is laid down, by a new Implementing Decision based on both Article 43(4) and Article 54(4) of Directive 2010/63/EU. Implementing Decision 2012/707/EU should therefore be repealed.

(8) The measures provided for in this Decision are in accordance with the opinion of the Animals in Science Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of the second sentence of Article 43(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex I to this Decision using the database established by the Commission in accordance with the third sentence of Article 43(4) of that Directive. The non-technical project summaries, and updates thereto, shall correspond to the templates laid down in Annex I to this Decision.

Article 2

For the purposes of Article 54(1) of Directive 2010/63/EU, Member States shall submit the information specified in Annex II to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/569. (See end of Document for details)*

Article 3

For the purposes of Article 54(2) of Directive 2010/63/EU, Member States shall submit the information specified in Annex III to this Decision using the database established by the Commission in accordance with the first sentence of the third subparagraph of Article 54(2) of that Directive.

Article 4

For the purposes of Article 54(3) of Directive 2010/63/EU, Member States shall submit the information specified in Annex IV to this Decision using the template laid down in that Annex.

Article 5

Implementing Decision 2012/707/EU is repealed with effect from 17 April 2020. References to the repealed Decision shall be construed as references to this Decision and read in accordance with the correlation table in Annex V.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 16 April 2020.

For the Commission

Virginijus SINKEVIČIUS

Member of the Commission

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/569. (See end of Document for details)*

ANNEX I

PART A

Template for the submission of non-technical project summaries referred to in article 43(1) of directive 2010/63/EU

Title of the project	
Duration of project (in months)	
Key Words (maximum of 5)[a]	
Purpose of project[b] (multiple choices possible)	— Basic research[c] — Translational and applied research[c] — Regulatory use and routine production: — Quality control (including batch safety and potency testing) — Other efficacy and tolerance testing — Toxicity and other safety testing including pharmacology — Routine production — Protection of the natural environment in the interests of the health or welfare of human beings or animals — Preservation of species — Higher education — Training — Forensic enquiries — Maintenance of colonies of genetically altered animals, not used in other procedures
Objectives and predicted benefits of the project	
Describe the objectives of the	

a	Including scientific terms which may consist of more than 5 individual words and excluding species and purposes entered elsewhere in the document
b	To be provided via a dropdown menu
c	List of purposes in accordance with statistical reporting categories and sub-categories in Annex III to this Decision
d	Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases
e	Species to be populated from the previous response to select from under the relevant category (proportions)
f	Multiple choices per species possible
g	Multiple choices possible; applicable to those MS where this information is required by the legislation

project (for example, addressing certain scientific unknowns, or scientific or clinical needs).	
What are the potential benefits likely to derive from this project? Explain how science could be advanced, or humans, animals or environment may ultimately benefit from the project. Where applicable, differentiate between short-term benefits (within	

a	Including scientific terms which may consist of more than 5 individual words and excluding species and purposes entered elsewhere in the document
b	To be provided via a dropdown menu
c	List of purposes in accordance with statistical reporting categories and sub-categories in Annex III to this Decision
d	Species in accordance with statistical reporting categories in Annex III to this Decision, with an additional option of 'non-specified mammal' to safeguard anonymity in exceptional cases
e	Species to be populated from the previous response to select from under the relevant category (proportions)
f	Multiple choices per species possible
g	Multiple choices possible; applicable to those MS where this information is required by the legislation