

UNOFFICIAL TRANSLATION DISCLAIMER

THIS IS AN UNOFFICIAL TRANSLATION OF GOVERNMENT DECREE NO. 3/2016 TO ENGLISH. THE OFFICIAL TEXT IS THE HUNGARIAN VERSION.

**Government Decree No. 3/2016. (I.20.)
on certain rules of implementation of international and
European Community legal acts on access to genetic
resources and the fair and equitable sharing of the
benefits arising from their utilisation**

Based on the authorisation granted in Article 4 (4) of Act VIII of 2014 publishing the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity and, with regard to Article 9, in Article 110 (7) 6 of Act LIII of 1995 on the General Rules of the Protection of Environment and proceeding within its tasks specified in Article 15 (1) of the Fundamental Law, the Government hereby adopts the following decree:

1. Scope of the Decree

Section 1. This Decree shall be applied in procedures relating to the implementation of

- a) the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity (hereinafter referred to as: Protocol), and
- b) Regulation of the European Parliament and of the Council No. 511/2014/EU of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (hereinafter referred to as Regulation).

2. Proceeding authorities and intermediary bodies

Section 2. (1) The national focal point specified in Article 13 (1) of the Protocol shall be the Ministry led by the Minister responsible for nature conservation (hereinafter referred to as: Ministry).

- (2) The reporting tasks defined in Article 16 (1) of the Regulation shall be performed by the Ministry.
- (3) The control plan referred to in Article 9 (3) a) of the Regulation shall be prepared by the Ministry.

Section 3. The competent authority referred to in Article 6 (1) of the Regulation shall be the national nature conservation authority.

Section 4. The tasks of

UNOFFICIAL TRANSLATION DISCLAIMER

THIS IS AN UNOFFICIAL TRANSLATION OF GOVERNMENT DECREE NO. 3/2016 TO ENGLISH. THE OFFICIAL TEXT IS THE HUNGARIAN VERSION.

- a) deliberation and the notification referred to in Article 5 (2) of the Regulation and
- b) the control tasks referred to in Article 5 (4) of the Regulation shall be performed by the Minister responsible for nature conservation.

Section 5. (1) Checkpoints referred to in Article 17 of the Protocol:

- a) in research funding involving the utilisation of genetic resources or traditional knowledge associated with genetic resources shall be
 - aa) the National Office of Research, Development and Innovation,
 - ab) the Hungarian Academy of Sciences;
 - b) in the course of licensing, distribution and control of products developed with the utilisation of genetic resources or traditional knowledge associated with genetic resources shall be
 - ba) the Pest County Government Office, acting in its competence of crop production, food chain management, forestry, hunting and fisheries management and
 - bb) the National Institute of Pharmacy and Nutrition.
- (2) Apart from those listed in paragraph (1), checkpoints also include any agency that
- a) assesses any request for the funding of research involving the utilisation of,
 - b) as a specialized authority assesses the product or distribution of any product developed with the utilisation of,
 - c) licenses any product or the distribution of any product developed with the utilisation of, or
 - d) controls any product or the distribution of, any product developed with the utilisation of
- genetic resources or traditional knowledge associated with genetic resources.

3. Obligation to provide a declaration

- Section 6.** (1) Anyone submitting a request for funding of research involving the utilisation of genetic resources or traditional knowledge associated with genetic resources shall provide a declaration to the national nature conservation authority on the fulfilment of the obligation specified in Article 4 of the Regulation in compliance with Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices.
- (2) The national nature conservation authority orders anyone to make a declaration who failed to submit the declaration required
- a) under paragraph (1) simultaneously with the submission of a request for the funding of research involving the utilisation of, or
 - b) in Article 7 (2) of the Regulation prior to the licensing or distribution of,
- a product developed with the utilisation genetic resources or traditional knowledge associated with genetic resources.
- (3) The party obliged to make a declaration submits a declaration to the national nature conservation authority within 15 days from the order specified in paragraph (2).

UNOFFICIAL TRANSLATION DISCLAIMER

THIS IS AN UNOFFICIAL TRANSLATION OF GOVERNMENT DECREE NO. 3/2016 TO ENGLISH. THE OFFICIAL TEXT IS THE HUNGARIAN VERSION.

- (4) The national nature conservation authority uploads the declaration to the information centre and its disclosure is approved by the Ministry.

4. Information supply

- Section 7.** (1) The checkpoints listed in Article 5 (1) inform the national nature conservation authority on any request or notification received in the course of any proceedings falling within their competence and concerning the utilisation of genetic resources and traditional knowledge associated with genetic resources within 8 days from the receipt of the request or notification or, if the proceedings are closed with a decision, then not later than simultaneously with the decision closing the basic procedure.
- (2) The national nature conservation authority informs the agencies and institutions competent according to Article 5 of the declaration received pursuant to Article 6 and on the failure of submitting declarations as specified in Article 6 (2) in all cases falling within its competence or activity.
- (3) The national nature conservation authority informs the Ministry on the performed checks and measures taken electronically as and when required or at least once a year, by 31 March of the subsequent year.

5. Legal consequences relating to access to and utilisation of genetic resources

- Section 8.** (1) No funding can be granted for any research involving the utilisation of genetic resources or traditional knowledge associated with genetic resources to anyone who fails to submit a declaration referred to in Section 6 (1) in view of Section 6 (2)–(3).
- (2) If, in view of Section 6 (2)–(3), the user fails to provide a declaration as referred to in Article 7 (2) of the Regulation,
- a) the licensing authority will not license the distribution of, or
 - b) the authority responsible for checking the adequacy and safety of the product or the authority responsible for the surveillance of the market of the product shall prohibit the distribution of, any product developed with the utilisation of genetic resources or traditional knowledge associated with genetic resources.
- (3) If in the course of any check conducted pursuant to Article 9 of the Regulation it is concluded that the user did not fulfil the obligation specified in Article 4 at all or in part, the national nature conservation authority will inform the agencies and institutions referred to in Article 5 about the result of the checks and propose
- a) the withdrawal of the licence for any licensed product,
 - b) the deletion from the register of any registered product and
 - c) the withdrawal of the disclosure of the respective data at the information centre.

UNOFFICIAL TRANSLATION DISCLAIMER

THIS IS AN UNOFFICIAL TRANSLATION OF GOVERNMENT DECREE NO. 3/2016 TO ENGLISH. THE OFFICIAL TEXT IS THE HUNGARIAN VERSION.

- Section 9.** The national nature conservation authority imposes a fine on the user in the amount of
- a) one hundred thousand Forints for the failure of the obligation referred to in Section 6 (3),
 - b) five million Forints for the failure to apply due diligence referred to in Article 4 (3) of the Regulation, with the exception of the case specified in paragraph c),
 - c) ten million Forint for the failure to apply due diligence referred to in Article 4 (3) of the Regulation when a product made with the utilisation of genetic resources or traditional knowledge associated with genetic resources is distributed in trade.

6. Closing provisions

- Section 10.**(1) This Decree enters into force on the 16th day from its publication.
- (2) This Decree lays down provisions required for the implementation of the Regulation of the European Parliament and of the Council No. 511/2014/EU of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation.