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ACT
of 17 May 2018
on conditions of utilisation of genetic resources under the Nagoya Protocol

The Parliament has adopted the following Act of the Czech Republic:

Section 1

Subject Matter

This Act regulates, in relation to the directly applicable legal acts of the European Union¹⁾, the rights and obligations of persons and the scope of administrative authorities regarding the compliance with the conditions of access to genetic resources and traditional knowledge associated with genetic resources and sharing of benefits arising from their utilisation.

Section 2

Inclusion of a Collection or Part Thereof in the Register

(1) A request referred to in Article 5(2) of the Regulation (EU) No 511/2014 of the European Parliament and the Council shall be submitted to the Ministry of the Environment (hereinafter referred to as the "Ministry").

(2) The Ministry shall issue the decision on the request within 90 days of the commencement of the procedure.

(3) The Ministry shall inform the Czech Environmental Inspectorate (hereinafter the "Inspectorate") on the inclusion of the collection²⁾ or part thereof in the register of collections within the Union³⁾ (hereinafter referred to as the "register") without undue delay.

(4) The collection holder shall notify the Ministry of any changes referred to in Article 3(1) of the Commission Implementing Regulation (EU) 2015/1866 without undue delay.

Section 3

Declaration and Further Evidence

(1) Declaration under Article 7(1 or 2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council shall be submitted to the Ministry.

¹⁾ Regulation (EU) No 511/2014 of the European Parliament and the Council 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 Utilization in the Union.

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the regulation (EU) No 511/2014 of the European Parliament and the Council regarding the register of collections, monitoring of compliance by users and best practices.

²⁾ Article 3(9) of the Regulation (EU) No 511/2014 of the European Parliament and the Council.

³⁾ Article 5(1 and 2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council.

(2) Further evidence under Article 7(2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council shall be provided to the Ministry upon its request within the timeline set by the Ministry.

Section 4

Check on a Collection or Part Thereof

(1) Checking whether a collection or part thereof included in the register meets the criteria for inclusion in the register after the inclusion⁴⁾ shall usually be conducted on the basis of an annual plan of checks on collections⁵⁾.

(2) If it is detected that the collection or part thereof does not meet the criteria for inclusion in the register, the Ministry is entitled to impose remedial measures on the holder of the collection or part thereof included in the register⁶⁾.

(3) The collection holder shall inform the Ministry on the implementation of remedial measures without undue delay. If the collection holder fails to take the properly imposed remedial measures, the Ministry shall decide on the removal of the collection or part thereof from the register. The Ministry shall inform the Inspectorate without undue delay.

Section 5

Check on User Compliance

Checking whether users comply with their obligations provided for in the Regulation (EU) No 511/2014 of the European Parliament and the Council and this Act shall usually be conducted on the basis of an annual plan of checks on users⁷⁾.

Section 6

The Ministry

The Ministry

- a) decides on the inclusion of a collection or part thereof in the register and on its removal,
- b) receives declarations pursuant to Article 7(1 and 2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council,
- c) issues the annual plan of checks on collections and the annual plan of checks on users,
- d) imposes remedial measures under this Act,
- e) is responsible for offence proceedings under this Act,
- f) decides on appeals against decisions issued under this Act by the Inspectorate,
- g) is the competent authority⁸⁾ responsible for the implementation of the Regulation (EU) No 511/2014 of the European Parliament and the Council and the Commission Implementing Regulation (EU) 2015/1866, except for the powers delegated by this Act to the Inspectorate.

⁴⁾ Article 5(3) of the Regulation (EU) No 511/2014 of the European Parliament and the Council.

⁵⁾ Article 5(4) of the Regulation (EU) No 511/2014 of the European Parliament and the Council.
Article 4(1) of Commission Implementing Regulation (EU) No 2015/1866.

⁶⁾ Article 5(4) of the Regulation (EU) No 511/2014 of the European Parliament and the Council.
Article 4(5) of Commission Implementing Regulation (EU) No 2015/1866.

⁷⁾ Article 9(1 and 3) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council.

⁸⁾ Article 6(1) of the Regulation (EU) No 511/2014 of the European Parliament and the Council.

Section 7

The Inspectorate

The Inspectorate

- a) cooperates with the Ministry in the preparation of the annual plan of checks on collections and the annual plan of checks on users,
- b) checks whether the collection or part thereof included in the register meets the criteria for inclusion in the register, and whether users comply with the obligations provided for in the Regulation (EU) No 511/2014 of the European Parliament and the Council and this Act,
- c) imposes remedial measures under this Act,
- d) is responsible for offence proceedings under this Act,
- e) informs the Ministry without undue delay on the results of checks carried out, imposed remedial measures and penalties,
- f) exercises the powers of the competent authority under the Regulation (EU) No 511/2014 of the European Parliament and the Council and the Commission Implementing Regulation (EU) 2015/1866, except for the powers delegated by this Act to the Ministry.

Section 8

Remedial Measures

(1) The Ministry is entitled to order the holder of a collection or part thereof included in the register that does not meet the criteria for inclusion in the register⁴⁾ to ensure meeting these criteria by the timeline set by the Ministry and to inform a user to whom the genetic resources are provided before the criteria is met, that the collection or part thereof does not meet the criteria for inclusion in the register.

(2) The Inspectorate is entitled to order the user who fails to comply with any of the obligations under Article 4 or 7 of the Regulation (EU) No 511/2014 of the European Parliament and the Council to fulfil this obligation by the deadline determined by the Inspectorate and not to utilise those genetic resources or traditional knowledge associated with genetic resources, during the utilisation of which this obligation was not complied with, until it is fulfilled.

Section 9

Offences

(1) A natural person, a legal person or a natural person – entrepreneur commits an offence in the capacity of user if this person

- a) fails to exercise due diligence under Article 4(1) of the Regulation (EU) No 511/2014 of the European Parliament and the Council,
- b) fails to seek, keep and transfer to subsequent users the information and relevant documents under Article 4(3) of the Regulation (EU) No 511/2014 of the European Parliament and the Council,
- c) does not discontinue the utilisation of genetic resources or traditional knowledge associated with genetic resources under Article 4(5) of the Regulation (EU) No 511/2014 of the European Parliament and the Council,
- d) fails to keep the information relevant to access and benefit-sharing under Article 4(6) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council,

- e) contrary to Article 4(8) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council, does not discontinue the utilisation or claims exclusive rights, or
- f) fails to submit a declaration under Article 7(1 or 2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council or further evidence as referred to in Article 7(2) of the Regulation (EU) No 511/2014 of the European Parliament and of the Council.

(2) A natural person, a legal person or a natural person – entrepreneur commits an offence in the capacity of holder of a collection or part thereof included in the register if this person fails to notify any changes as referred to in Article 3(1) of the Commission Implementing Regulation (EU) 2015/1866.

(3) A penalty may be imposed up to the amount of

- a) CZK 50,000 for offences pursuant to paragraph 1(a) through (e) or paragraph 2,
- b) CZK 20,000 for offences pursuant to paragraph 1(f).

(4) Offence proceedings under this Act shall be conducted by the Inspectorate, with the exception of the offence under paragraph 2, which shall be conducted by the Ministry.

(5) Penalties imposed under this Act shall form income of the budget of the State Environmental Fund of the Czech Republic.

Section 10

Effect

This Act shall come into force on the fifteenth day after its publication.