

*The translation of the Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014 is intended solely as a convenience to the non-German-reading public. Any discrepancies or differences that may arise in translation of the official German version of the Act is not binding and has no legal effect for compliance or enforcement purposes.*

## **Act Implementing the Obligations under the Nagoya Protocol and Transposing Regulation (EU) No. 511/2014**

### Section 1

#### **Tasks and powers**

(1) The competent authority in accordance with section 6 paragraph (1) shall be responsible for the implementation of the present Act, of the statutory instruments adopted on the basis of the present Act, of Regulation (EU) No. 511/2014 of the European Parliament and of 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 (OJ L 150 of 20 May 2014, p. 59), as well as of the implementing acts adopted on the basis of Article 5 paragraph 5, Article 7 paragraph 6 and Article 8 paragraph 7 of Regulation (EU) No. 511/2014.

(2) Users within the meaning of Article 3 No. 4 of Regulation (EU) No. 511/2014 shall provide the information to the competent authority on request which is necessary for the transposition of Regulation (EU) No. 511/2014, and of the implementing acts adopted thereon, of the present Act or of the legal acts adopted for its implementation.

(3) Where required in the context of paragraph (2), persons whom the competent authority has commissioned to carry out the checks shall be entitled

1. to inspect documents and to make copies or duplicates thereof,
2. to carry out examinations, including taking samples,
3. to enter and inspect property, commercial and business premises during operating and business hours.

Users obliged to provide information shall support on request the commissioned persons in the implementation of the checks, and shall submit the necessary documents and samples of genetic resources.

(4) Persons obliged to provide information may refuse to provide information with regard to questions the answers to which would subject themselves or one of their family members designated in section 383 paragraph (1) Numbers 1 to 3 of the Code of Civil Procedure (*Zivilprozessordnung*) to the risk of prosecution in respect of a criminal or regulatory offence.

(5) Business and operational secrets shall be treated confidentially.

### Section 2

#### **Orders and remedial action**

(1) The competent authority adopts the necessary orders to remedy breaches of the legal acts designated in section 1 paragraph (1).

(2) Should a user fail to comply with an order in accordance with paragraph (1), the competent authority may in individual cases seize the unlawfully-utilised genetic resource or prohibit specific utilisation activities. This shall be particularly considered if the user is unable to submit the information required in accordance with Article 4 paragraph 3 of Regulation (EU) No. 511/2014.

(3) The measures taken in accordance with paragraph (2) shall be rescinded if the user complies with the orders adopted in accordance with paragraph (1); otherwise the seized genetic resource may be confiscated. The user shall meet the costs incurred as a result of the storage or accommodation of the seized genetic resource.

(4) Where animals are seized, the general regulations concerning species and animal protection shall be complied with.

### Section 3

#### **Empowerment to issue statutory instruments**

The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to regulate the details of enforcement by means of a statutory instrument which shall not require the consent of the Bundesrat, in agreement with the Federal Ministry of Health, the Federal Ministry of Food and Agriculture, the Federal Ministry of Education and Research and the Federal Ministry for Economic Affairs and Energy, where this is necessary for the transposition of Regulation (EU) No. 511/2014 as well as of the

implementing acts adopted on the basis of Article 5 paragraph 5, Article 7 paragraph 6 and Article 8 paragraph 7 of Regulation (EU) No. 511/2014. It can particularly regulate on the following:

1. the implementation of checks, including the taking of samples and the details of the obligations of toleration, support and submission,
2. the details regarding the duty to make a declaration in accordance with Article 7 paragraph 1 of Regulation (EU) No. 511/2014, and
3. the details regarding the duty to make a declaration in accordance with Article 7 paragraph 2 of Regulation (EU) No. 511/2014.

#### Section 4

##### **Regulations on administrative fines**

(1) Whoever, intentionally or negligently,

1. fails to provide information, provides incorrect or incomplete information, or fails to provide it in good time, in contravention of section 1 paragraph (2),
2. fails to support a commissioned person on request, or fails to provide a document or sample, or fails to do so correctly, completely or in good time, in contravention of section 1 paragraph (3), sentence 2,
3. acts in contravention of an enforceable order in accordance with section 2 paragraph (2), sentence 1, or
4. acts in contravention of a statutory instrument in accordance with section 3, sentence 1 or sentence 2, Number 1 or Number 2 or of an enforceable order adopted on the basis of such a statutory instrument, where the statutory instrument refers to this administrative fine regulation for a specific offence,

shall be deemed to have committed a regulatory offence.

(2) Whoever acts in contravention of Regulation (EU) No. 511/2014 of the European Parliament and of 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 (OJ L 150 of 20 May 2014, p. 59) by, intentionally or negligently,

1. failing to obtain information, failing to do so by the time of commencement of the utilisation, or failing to pass such information to the subsequent user, or failing to do so by the time of a change of user, in contravention of Article 4 paragraph 3,
2. failing to keep information for at least 20 years, in contravention of Article 4 paragraph 6,
3. failing to submit a declaration, or failing to do so correctly, completely or at the latest four weeks prior to the end of the utilisation, in contravention of Article 7 paragraph 2, sentence 1, also in conjunction with a statutory instrument adopted in accordance with section 3, sentence 2, Number 3 of the present Act, or
4. failing to provide documentation, or failing to do so correctly, completely or in good time, in contravention of Article 7 paragraph 2, sentence 2,

shall be deemed to have committed a regulatory offence.

(3) The regulatory offence may be sanctioned with an administrative fine of up to fifty thousand Euro.

(4) The administrative authority within the meaning of section 36 paragraph (1) Number 1 of the Act on Regulatory Offences (*Gesetz über Ordnungswidrigkeiten*) shall be the Federal Agency for Nature Conservation.

#### Section 5

##### **Confiscation**

If a regulatory offence in accordance with section 4 has been committed, objects to which the regulatory offence relates may be confiscated. Section 23 of the Act on Regulatory Offences shall apply.

#### Section 6

##### **Competences**

(1) The competent authority within the meaning of the present Act and of Article 6 paragraph 1 of Regulation (EU) No. 511/2014 shall be the Federal Agency for Nature Conservation. It shall be particularly competent for the enforcement of Article 5 paragraphs 2 and 4, Articles 7 and 9 paragraphs 1, 3, 4 and 6, as well as Articles 10 and 12, of Regulation (EU) No. 511/2014, and for the enforcement of the implementing acts

adopted on the basis of Regulation (EU) No. 511/2014. At the same time, it shall be the competent national authority within the meaning of Article 13 paragraph 2 of the Nagoya Protocol of 29 October 2010 (Federal Law Gazette [*BGBl.*] ... Part II p. ...). It shall be furthermore competent for the use of the genetic resources confiscated in accordance with section 2 paragraph (3).

(2) The competent authority shall make any determinations concerning the organisation of enforcement with regard to genetic resources for food and agriculture and related decisions in agreement with the Federal Office for Agriculture and Food. Details on the procedure for reaching agreement and, where necessary, other cooperation between the authorities, shall be regulated by means of an administrative arrangement.

(3) The competent authority shall make any determinations concerning the organisation of enforcement with regard to human pathogens as a genetic resource and related decisions in agreement with the Robert Koch Institute. Details on the procedure for reaching agreement and, where necessary, other cooperation between the authorities, shall be regulated by means of an administrative arrangement.

(4) The national focal point in accordance with Article 13 paragraph 1 of the Nagoya Protocol shall be the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety. It shall be particularly competent for the duty to report in accordance with Article 16 of Regulation (EU) No. 511/2014.

## Section 7

### **Expenditures**

Expenditures incurred when complying with obligations to provide information and to cooperate with regard to checks, obligations to make a declaration, as well as the procedures for inclusion in the register of collections in accordance with Article 5 of Regulation (EU) No. 511/2014, shall not be refunded.