

DZIENNIK USTAW RZECZYPOSPOLITEJ POLSKIEJ

Warsaw, 26 August 2016

Item 1340

ACT

of 19 July 2016.

on Access to Genetic Resources and Sharing of Benefits Arising from their Utilization^{1, 2}

Article. 1. The Act shall determine:

- competence and tasks of public administration authorities with regard to provisions of the Regulation (EU) No 511/2014 of the European Parliament and Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (OJ L 150, 20.05.2014, p. 59), hereinafter referred to as "the Regulation No. 511/2014", and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015, laying down detailed rules for the implementation of the Regulation (EU) No 511/2014 of the European Parliament and the Council as regards to the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4), hereinafter referred to as "Regulation 2015/1866";
- principles and procedure of conducting control of compliance measures on access and utilization of genetic resources and the traditional knowledge related to genetic resources referred to in Article 2 (1) and (4) of the Regulation No. 511/2014 acquired from outside of the Republic of Poland and sharing benefits arising from their utilization;
- 3) liability principles for any breach of provisions of the Regulation No. 511/2014.

Article 2. The terms used in the Act shall have the following meaning:

- 1) access access as defined by Article 3 (3) of the Regulation No. 511/2014;
- 2) collection collection as defined by Article 3 (9) of the Regulation No. 511/2014;
- 3) register of collections register of collections within the EU referred to in Article 5 (1) of the

Regulation No. 511/2014;

- 4) traditional knowledge associated with genetic resources traditional knowledge associated with genetic resources as defined by Article 3(7) of the Regulation No. 511/2014;
- 5) user user as defined by Article 3 (4) of the Regulation no. 511 /2014;

¹ This Act shall serve the application of the 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 Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (OJ L 150, 20.05.2014, p. 59) and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015, laying down detailed rules for the implementation of the Regulation (EU) No 511/2014 of the European Parliament and the Council as regards to the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4).

² This Act shall amend the Act of 20 July 1991 on Inspection of Environmental Protection.

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6) utilization of genetic resources - utilization of genetic resources as defined by Article 3 (5) of the Regulation No. 511/2014.

Article 3. The national authority referred to in Article 6 (1) of the Regulation No. 511/2014, shall be the minister competent for environment, provided that the tasks related to checks on user compliance and the register of collections as listed in the Act, are performed by Inspection of Environmental Protection authorities.

Article 4. 1. The Chief Inspector of Environmental Protection shall prepare the plan of checks on user compliance referred to in Article 9 (3) letter a of the Regulation No. 511/2014.

2. The plan of checks on user compliance shall contain:

- 1) first name and last name or name of the user;
- 2) the date of conducting the control;
- 3) the scope of control;
- 4) indication of the regional inspector of environmental protection, hereinafter referred to as "regional inspector", competent for carrying out checks.

3. Until the end of November each year the Chief Inspector of Environmental Protection shall submit to the minister competent for environment the plan of checks on user compliance for the following year for the approval.

Article 5. 1. The checks on user compliance shall be carried out by the regional inspector competent for the place of residence or the site of the user, or the place of conducting activities related to utilization of genetic resources, if it is justified by the scope of the control.

2. Protocol of the conducted user check shall be transferred immediately to the Chief Inspector of Environmental Protection.

3. In the case referred to in Article 9 (6) of the Regulation No. 511/2014, the regional inspector shall issue a notice, referred to therein, of remedial action or measures to be taken by the user, and shall determine the deadline for their execution.

4. The minister competent for environment shall determine, by a regulation, the detailed scope of the checks on user compliance, bearing in mind the need of standardisation of control activities.

Article 6. A collection holder shall submit the application for inclusion of the collection or part thereof into the register of collections to the regional inspector, competent for the place of residence or the site of the collection holder.

Article 7. The regional inspector shall check and verify the application referred to in Article 6 if the collection or part thereof meets the criteria set out in Article 5 (3) of the Regulation No. 511/2014 and:

- 1) transfer the application to the minister competent for environment in a case that the collection or part thereof meets the criteria set out in Article 5 (3) of the Regulation No. 511/2014;
- issue a decision on non-compliance of the collection or part thereof with the criteria set out in Article 5 (3) of the Regulation No. 511/2014 - in a case that the collection or part thereof does not meet those criteria.

Article 8. 1. The Chief Inspector of Environmental Protection shall develop a plan of control of collections or parts thereof registered in the register of collections.

2. Until the end of November each year the Chief Inspector of Environmental Protection shall submit to the minister competent for environment for the approval the plan of control of collections or parts thereof registered in the register of collections for the following year.

Article 9. 1. Controls of the collections or parts thereof registered in the register of collections shall be carried out by the regional inspector competent for the place of residence or the site of a collection holder.

2. Protocol from the conducted control of collection or part thereof registered in the register of collections shall be transferred immediately to the Chief Inspector of Environmental Protection.

3. In a case referred to in the second sentence of the Article 5 (4) of the Regulation No. 511/2014, the regional inspector shall identify remedial actions or measures referred to therein and shall determine the deadline for their execution.

4. A collection holder shall submit to the regional inspector the report referred to in Article 4 (5), third sentence of the Regulation 2015/1866.

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5. In a case when the remedial actions and measures have not been executed in the designated time, the regional inspector shall issue a decision stating that the collection or part thereof no longer complies with criteria specified in Article 5 (3) of the Regulation No. 511/2014. The decision shall be transferred immediately to the minister competent for environment.

Article 10. The Chief Inspector of Environmental Protection shall cooperate with the minister competent for environment in evaluation of the applications for recognition as the best practice referred to in the Article 8 (1) of the Regulation No. 511/2014 and in evaluation of changes or updating of the recognized best practice.

Article 11. Whoever, despite the obligation specified in the Article 4 (2) of the Regulation No. 511/2014, transfers or utilizes the genetic resources or traditional knowledge related to genetic resources without mutually agreed terms or inconsistently therewith, shall be subject to a penalty in the amount from PLN 5000 to PLN 50 000.

Article 12. Whoever, despite the obligation specified in:

- Article 4 (3) of the Regulation No. 511/2014, does not seek, keep nor transfer to subsequent 1) users information and documents referred to in therein,
- Article 4 (6) of the Regulation No. 511/2014, does not keep the information relevant to access 2) and benefit sharing for twenty years after the end of the period of utilization

- shall be subject to a penalty in the amount from PLN 1000 to PLN 50 000.

Article 13. Whoever, despite the obligation specified in the Article 4 (5) of the Regulation No. 511/21) 14, utilizes genetic resources despite failure to obtain an access permit or its equivalent and to establish mutually agreed terms, shall be subject to a penalty in the amount from PLN 10 000 to PLN 100 000.

Article 14. Whoever, despite the obligation specified in Article 7 (1) of the Regulation No. 511/2014, did not submit a declaration on due diligence, shall be subject to a penalty in the amount from PLN 1000 to PLN 10 000.

Article 15. Whoever, despite the obligation specified in Article 7 (2) of the Regulation No. 511/20147, did not submit a declaration on due diligence or did not submit the information referred to therein, shall be subject to a penalty in the amount from PLN 5000 to PLN 50 000.

Article 16. The penalty shall be determined by a decision of the regional inspector competent for the place of residence or the site of the user, or the place of conducting operations related to the utilization of genetic resources.

Article 17. When determining the amount of penalties, the type and scope of a breach, including its impact on biological diversity, the value of the utilised genetic resources and potential benefits from utilization thereof and the traditional knowledge related to genetic resources, previous activities of the entity which committed the breach within the scope covered by the provisions of the Regulation No. 511/2014 as well as the effects of a breach are taken into account.

Article 18. Should the circumstances of the case and the evidence indicate that the entity which committed the breach had made all possible efforts to prevent the breach, or that the breach was beyond its control, and it occurred as a result of circumstances that could not have been foreseen, the regional inspector shall waive imposition of the penalty and discontinue the proceedings.

Article 19. The penalty shall be paid within 14 days from the date when the decision on imposing the penalty became final to the bank account specified in this decision.

Article 20. The revenue from penalties shall constitute the State budget income.

Article 21.1. Penalty shall not be imposed after 5 years from the date when the breach was observed.

2. The obligation to pay the penalty shall expire after 5 years from the last day of the term in which the penalty should have been paid.

Article 22. In cases concerning the penalties, the provisions of Section III of the Act of 29 August 1997 - Tax Ordinance Act (Journal of Laws of 2015, Item 613, as amended³) shall apply, provided that the regional inspector shall be vested in the competence of the tax authority.

³ Amendments to the uniform text of the above mentioned Act were published in Journal of Laws of 2015, item 699, 978, 1197, 1269, 1311, 1649, 1923, 1932 and 2184 and of 2016, item 195, 615, 846 and 1228.

Article 23. In the Act of 20 July 1991 on Inspection of Environmental Protection (Journal of Laws of 2013, item 686, as amended⁴) in Article 2 (1) item 17b shall be added after 17a, in the following wording:

"17b) performance of the duties specified in the Act of 19 July 2016, on Access to Genetic Resources. and Sharing Benefits Arising from their Utilization (Journal of Laws item 1340) and resulting from the 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 Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (OJ L 150, 20.05.2014, p. 59) and Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015, laying down detailed rules for the implementation of the Regulation (EU) No 511/2014 of the European Parliament and the Council as regards to the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4);"

Article 24. 1. In the period 2016-2025 the maximum limit of expenses from the state budget being the financial effect of the Act amounts to PLN 14 732 842, given that in:

- 1) 2016 PLN 0
- 2) 2017 PLN 1 800 538
- 3) 2018 PLN 1 616 538
- 4) 2019 PLN 1 616 538
- 5) 2020 PLN 1 616 538
- 6) 2021 PLN 1 616 538
- 7) 2022 PLN 1 616 538
- 8) 2023 PLN 1 616 538
- 9) 2024 PLN 1 616 538
- 10 2025 PLN 1 616 538

2. In case of risk of exceeding the limit of expenses for a given fiscal year referred to in (1), there shall be utilised corrective mechanisms consisting, in relation to the persons employed for performance of new tasks, in:

- 1) reduction in the amount of remuneration;
- 2) reduction in working time;
- 3) reduction in the number of people employed.

3. The authorities competent for implementation of corrective mechanisms referred to in (2) shall be the minister competent for environment and voivodes.

4. The authority competent for monitoring of use of the limit of expenses referred to in (1) shall be the minister competent for environment.

Article 25. The Act shall enter into force 14 days from its publication.

President of the Republic of Poland: A. Duda

⁴ Amendments to the uniform text of the above mentioned Act were published in Journal of Laws of 2013, item 888, of 2014, Item 1101, of 2015, item 277, 671, 881, 1223, 1434 and 1688 and of 2016, item 903.