

Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

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The Commission presents a report on Regulation (EU) No 511/2014 of the European Parliament and of the Council 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 (EU ABS Regulation).

In accordance with the EU ABS Regulation, the Commission is required to submit a report on the application of the Regulation, including a first assessment of its effectiveness, not later than one year after the time-limit for submission of the national reports.

The report is based on information from the national reports submitted by all 28 Member States to the Commission, as well as other information available. It covers the first three years of application of the EU ABS Regulation, i.e. the period between October 2014 and August 2017, which is reduced to two years of application for provisions concerning due diligence (Art. 4), monitoring of user compliance (Art. 7) and compliance checks (Art. 9).

State of play

Implementation and enforcement

This report stated that the Regulation is in its early days of implementation. Many Member States started relatively late to take measures to set up the institutional and administrative framework necessary to implement the Regulation. The Commission proactively promoted compliance by reminding Member States of their obligation to designate competent authorities and to adopt rules on penalties. Although most Member States took the necessary measures to address the implementation gaps, letters of formal notice were sent in January 2018 to 9 Member States that were still non-compliant. Further on, reasoned opinion were issued in 2 of these cases in November 2018.

The implementation and enforcement of the Regulation was slow and uneven during the first years and remains work in progress. While many Member States have fulfilled the formal requirements of the Regulation, only a few have moved on into the actual implementation on the ground.

Member States adopted different solutions to set up the institutional framework. In some cases, consultations and coordination among different administrations contributed to slow down the process of designation. 6 Member States still need to designate competent authorities. Lack or limited human and financial resources devoted to the implementation of the EU ABS Regulation is often reported as a major obstacle. Lack of specialized personnel and qualified experts is also identified as a problem. Trainings to strengthen the institutional capacity of staff are therefore necessary. At the same time, some Member States expressed worries about the administrative burden and costs implied by the Regulation.

20 Member States adopted legislative measures setting up sanctions for infringements of the obligations of the Regulation. A varied range of sanctions (from administrative to criminal law) can be observed, which entails also a variation in the levels of sanctions.

Awareness of the Regulation

Despite the efforts undertaken both by the Member States and the Commission, a low level of awareness among stakeholders about the obligations stemming from the Nagoya Protocol and the EU ABS Regulation is often reported. Also, institutions and administrations in Member States often lack awareness of the topic. Both the Nagoya Protocol and the EU ABS Regulation are relatively new regulatory instruments and ABS issues are thus still quite an unknown subject.

Additional efforts to foster the level of awareness among a wide range of stakeholders are needed.

Several Member States reported that it is rather difficult for stakeholders to understand the complexity of the EU ABS Regulation.

Challenges

Some Member States also highlighted additional challenges related to the interpretation of some provisions of the EU ABS Regulation and mentioned the issue of unclear wording of some terms in the Regulation (which results from the use of the same concepts as those enshrined in the Nagoya Protocol). In this context, it was claimed that further guidance would be useful to clarify some terms. Also some concerns of the users were reported, namely about an excessive administrative and financial burden, while the added value deriving from the Regulation is not perceived.

In this context, the Commission will continue to use the existing tools to contribute to a more uniform application of the Regulation across the EU. Further efforts from Member States in the implementation and enforcement of the EU ABS Regulation are needed. In particular, all non-compliant Member States urgently need to designate national competent authorities, adopt sanctions, put measures in place to implement the first checkpoint and step up their efforts to develop risk-based plans to carry out checks. The current level of technical capacity and resources (both human and financial) allocated to the competent authorities does often not match the needs and should therefore be reinforced in most of the Member States.