

Response to the EU call of evidence for an evaluation of the EU Access and Benefit Sharing (ABS) Regulation (Regulation (EU) No 511/2014)

by the German Nagoya Protocol HuB project in cooperation with the Working Group on Access and Benefit-Sharing of the Permanent Senate Commission on Fundamental Issues of Biological Diversity of the German Research Foundation

Elaborated by Melania Muñoz-García* (Leibniz Institute DSMZ - German Collection of Microorganisms and Cell Cultures), Annika Engelhardt* (Leibniz Institute DSMZ - German Collection of Microorganisms and Cell Cultures GmbH and Kiel University, Christian-Albrechts-Universität zu Kiel), Rebecca Aepfler (Alfred Wegener Institute, Helmholtz Centre for Polar and Marine Research), Erwin Beck (University of Bayreuth), Sven Bradler (University of Goettingen), Catharina Caspari (University of Greifswald), Jan Dierking (GEOMAR Helmholtz Centre for Ocean Research Kiel), Nina Farwig (University of Marburg), Jens Freitag (Leibniz Institute of Plant Genetics and Crop Plant Research, Gatersleben), Achim Meyer (Leibniz Centre for Tropical Marine Research ZMT), Alois Palmetshofer (University of Wuerzburg), Martha Schattenhofer, Sabine Schlacke (University of Greifswald), Amber H. Scholz (Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures GmbH), Myriam Schroeder (Leibniz Institute for Zoo and Wildlife Research IZW), Daniela Schmitt (GEOMAR Helmholtz Centre for Ocean Research Kiel), Martin Wiemers (Senckenberg German Entomological Institute)

*These authors contributed equally to this work. All other authors listed alphabetically.

This DFG publication has been compiled with care. The authors, editors and the DFG do not assume any liability whatsoever for the correctness and completeness of any information, references, advice or for any potential printing errors.

The reproduction of product names, trade names or other distinguishing marks in this document does not give rise to the assumption that they may be freely used by anyone. These may in fact be registered trademarks or other legally protected marks, even if they are not specifically designated as such.

The text of this publication is licensed under the Creative Commons Attribution-ShareAlike 4.0 International (CC BY-SA 4.0) Licence. For the full text of the licence, see: <https://creativecommons.org/licenses/by-sa/4.0/legalcode.de>.



February 2026

<p>Contact at the Leibniz DSMZ / GNP-HuB project: Dr. Amber H. Scholz Leibniz-Institute DSMZ German Collection of Microorganisms and Cell Cultures Inhoffenstraße 7B • 38124 Braunschweig Germany Tel. +49-531-2616-400 Mail: amber.h.scholz@dsmz.de</p>	<p>Contact at the DFG Head Office: Dr. Meike Teschke Deutsche Forschungsgemeinschaft e. V. Kennedyallee 40 • 53175 Bonn Germany Tel.: +49 228 885-2336 Mail: meike.teschke@dfg.de</p>
---	---

EXECUTIVE SUMMARY

In response to the [call of evidence](#) for the regulatory review of Regulation (EU) No 511/2014 implementing the Nagoya Protocol in the European Union (EU ABS Regulation), the [German Nagoya Protocol HuB](#) (GNP-HuB) project hosted by the Leibniz Institute DSMZ, in cooperation with the Working Group on Access and Benefit-Sharing of the [Permanent Senate Commission on Fundamental Issues of Biological Diversity](#) (SKBV) of the German Research Foundation (DFG), as well as the listed signatory institutions, respectfully submit the following input.

The submission is based on three sources of evidence. First, an online survey of non-commercial users of genetic resources (see Annex 1), primarily targeting the research community in Germany, but also open to researchers and institutions in other EU Member States. Second, the GNP-HuB's long-standing practical experience helping researchers to comply with the Nagoya Protocol and the EU ABS Regulation since 2019. Third, an analysis of information available through the ABS Clearing-House (ABS-CH).

Key findings of the survey:

1. ABS measures and procedures are causing widespread and significant impacts on non-commercial research, including causing delays up to several years, project cancellations and the loss of funding.
2. Some researchers are restricting their work to genetic resources from countries that do not regulate access, and some have declined international research collaboration. This counteracts the ABS principle of the Nagoya Protocol.
3. In many cases, researchers cannot find clear information on how to obtain ABS permits, even after consulting the ABS-CH or contacting National Focal Points (NFPs) and Competent National Authorities (CNAs).
4. National authorities often respond to ABS-related inquiries with substantial delays or fail to respond at all, further hindering research planning and compliance.
5. Researchers and institutions face persistent legal uncertainty when provider countries claim to regulate access but lack operational or publicly available ABS procedures, making due diligence requirements difficult or impossible to fulfil.

Summary of Key Recommendations:

1. **Due diligence obligations should be deemed to have been fulfilled in cases where provider-country ABS procedures are unavailable or non-operational.**

Where provider countries have not fulfilled their Nagoya Protocol obligations to make ABS procedures clear, accessible, and operational, user obligations under the EU ABS Regulation should be applied in a manner that lifts the regulatory burden from non-commercial users. In particular, when compliance is objectively not possible, because the provider countries do not have and/or do not share the procedure to obtain an ABS permit, non-commercial users should be considered to have exercised due diligence accordingly.

2. A standardised best practice for obtaining ABS permits should be established by the Commission.

Although users may submit a combination of procedures, tools or mechanisms to be recognised as a best practice (see Article 8 of the Regulation and the Best Practices established by CETAF), a best practice from the EU and its Member States would be helpful. For reasons of legal certainty, the actions required and the documentation to be retained when information is not available through the ABS-CH, from NFPs or CNAs should be standardised by the Commission (e.g. by complementing the Commission Notice/Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 or through a recommendation). These standards should be developed in a manner that reduces the regulatory burden for non-commercial users in particular.

3. Strengthen capacity-building and advisory support for non-commercial users.

Support the establishment and coordination of national Nagoya Protocol help desks across Member States to provide practical, user-oriented compliance guidance.

4. Extend due diligence timelines during health emergencies to one year (Article 4(8)).

Allow longer timeframes and continued utilisation where users can demonstrate ongoing efforts to obtain ABS permits relevant to urgent public health research.

5. Reduce the retention period for ABS documentation from 20 to 10 years (Article 4(6)).

Align ABS documentation retention requirements with standard research data management practices and other research-relevant regulations. This avoids administrative burden and high financial costs.

Rationale:

Evidence from the research community shows that the EU ABS Regulation has led to significant unintended negative impacts on non-commercial research. Unintended negative impacts include project delays and cancellations, loss of research funding, and strategic shifts by researchers toward working only with German genetic resources or with biological material from countries that do not regulate access. As a result, international scientific collaboration with provider countries is being reduced as a rational outcome of experiences over the past decade. These outcomes counteract the objectives of the Nagoya Protocol and the core principle of ABS. Moreover, reduced biodiversity research in provider countries would hinder the conservation and sustainable use of their biodiversity.

A central structural problem is the misalignment between user obligations in the EU and provider country obligations under the Protocol. The Nagoya Protocol clearly requires Parties that regulate access to genetic resources to establish clear, transparent, and functional ABS procedures and to make this information publicly available. In particular:

- Article 6.3 obligates Parties to provide legal certainty, clarity, and transparency regarding ABS rules and to supply clear information on how to apply for Prior Informed Consent (PIC).
- Article 13.1 requires NFPs to provide users with information on procedures for obtaining PIC and establishing Mutually Agreed Terms (MAT).
- Article 14.2 requires Parties to publish their legislative, administrative, and policy ABS measures through the ABS-CH.

The above are legally-binding obligations and not optional (i.e. “shall” and not “may”). In practice, however, multiple countries that assert access regulation have not made their operational procedures publicly available, or do not respond to access-related inquiries. This creates situations in which compliance is impossible despite good-faith efforts by researchers.

Taken together, the proposed recommendations would respect provider country sovereignty while preventing unclear or non-functional ABS systems from blocking research and undermining benefit-sharing.

The present submission summarizes the evidence from the survey’s key findings and the experience gained by the implementation of the GNP-HuB project and outlines recommendations for targeted improvements to the Regulation, grounded in empirical evidence and aligned with the objectives of the Nagoya Protocol.

SUBMISSION

This submission was elaborated by the [GNP-HuB](#) project in cooperation with the [SKBV](#) of the DFG, and supported by below listed signatory institutions. It is based on three sources of evidence: an online survey of non-commercial users of genetic resources, the GNP-HuB's long-standing practical experience helping researchers to comply with the Nagoya Protocol and the EU ABS Regulation and an analysis of information available through the ABS Clearing-House (ABS-CH).

The survey questions are listed in Annex 1. It was primarily targeting the research community in Germany, but also open to researchers and institutions in other EU Member States, and open to responses from January 7th-20th, 2026. A total of 37 responses were received: 34 from users in Germany, one from Poland, two unknown. Fifteen respondents are affiliated with research institutes within the Leibniz Association, four within the Max Planck Society, and three within the Helmholtz Association. Ten respondents are affiliated with universities in Germany. Thirteen respondents were ABS compliance officers, personnel in charge of Nagoya Protocol compliance at their institutions and with broader experience on the implementation of the EU ABS Regulation.

Evidence under the five evaluation criteria

The following section provides evidence according to the five evaluation criteria determined by the European Commission: effectiveness, efficiency, coherence, relevance and EU added value. It also addresses the specific questions set by the Commission under each of these criteria. The evidence is based on the survey results, the GNP-HuB project experience implementing the EU ABS Regulation and the analysis of data available through the ABS-CH.

1. Effectiveness:

- *How successful has the legislation been in achieving its objectives?*

The EU ABS Regulation aims “to support the fair and equitable sharing of the benefits arising from the utilisation of genetic resources in accordance with the Nagoya Protocol”. In this regard, the Nagoya Protocol has three pillars: access, benefit-sharing and compliance. The EU ABS regulation has had some success in increasing awareness and thus undoubtedly increasing compliance with access rules from provider countries, when those rules are fully developed and clearly communicated. However, despite increases in compliance, access to genetic resources has been severely impacted. As a result, the overall gains in benefit-sharing are likely to remain flat or may even result in a net decrease.

Germany began compliance checks very soon after entry into force and thus raised awareness of ABS and the Nagoya Protocol quite rigorously for the past 8 years. This not only raised awareness among German users, it also had follow-on effects on German research collaboration partners both in provider countries and in other countries. For example, we have received comments from ABS authorities saying that their domestic researchers have requested ABS permits because German or EU partners require them to demonstrate compliance to be able to perform the research within the EU.

In general, the legislation has achieved its objectives to increase awareness and implementation of the Nagoya Protocol. However, **the main problem is that the due diligence process assumes that all**

countries that regulate access have developed and communicated clear requirements and procedures to grant access, as mandated by the Nagoya Protocol, which is not the case. When information is missing and cannot be obtained, which is not infrequent, the current due diligence system leaves users in a legally uncertain position. The due diligence procedures fail when countries affirm they regulate access but don't have or don't share the corresponding operational procedures to obtain a permit (figure 1). Over half of survey respondents indicated that they have been informed that a country regulates access but received no information on how to obtain PIC and establish MAT. If half of all international research projects fail at this stage, they cannot move forward. This creates a perpetual legal uncertainty among users and forces them to stop utilisation, hindering research and development.

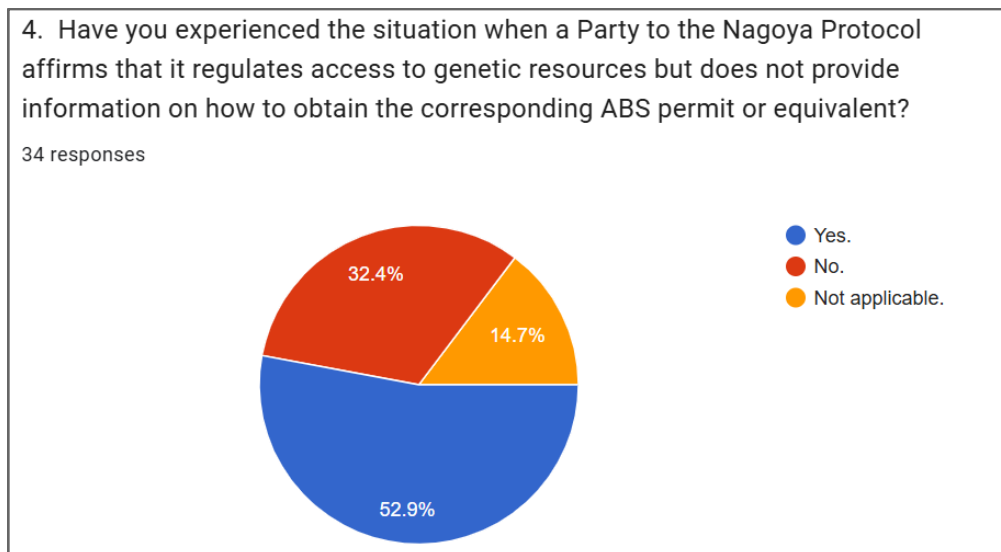


Figure 1. It is common among researchers to face legal uncertainty when provider countries affirm they regulate access but don't provide information on how to comply.

A related problem is that NFPs or CNAs provide delayed responses (or no responses at all) to access-related inquiries (figures 2 and 3). Figure 2 shows that 80% of the respondents said that extensive consultations with NFPs and CNAs are usually or always necessary because the information available on the ABS-CH and national websites is insufficient. Notably, around 53% of respondents said that they were sometimes unable to obtain clear information and instructions from NFPs and CNAs, even after contacting them. For 34% of respondents, this was the usual outcome of direct enquiries. More concerning still, 61.8% of respondents said that they sometimes don't receive an answer after making an inquiry to the NFP/CNA in the provider country and 11.8% said this situation is usual. In total, 73.6% of respondents have experienced this situation (figure 3). **This suggests that the challenge lies not only in navigating information sources, but also in the structural gaps in the availability, clarity and accessibility of ABS procedures in some provider countries. This creates situations in which compliance is impossible despite good-faith efforts by researchers.**

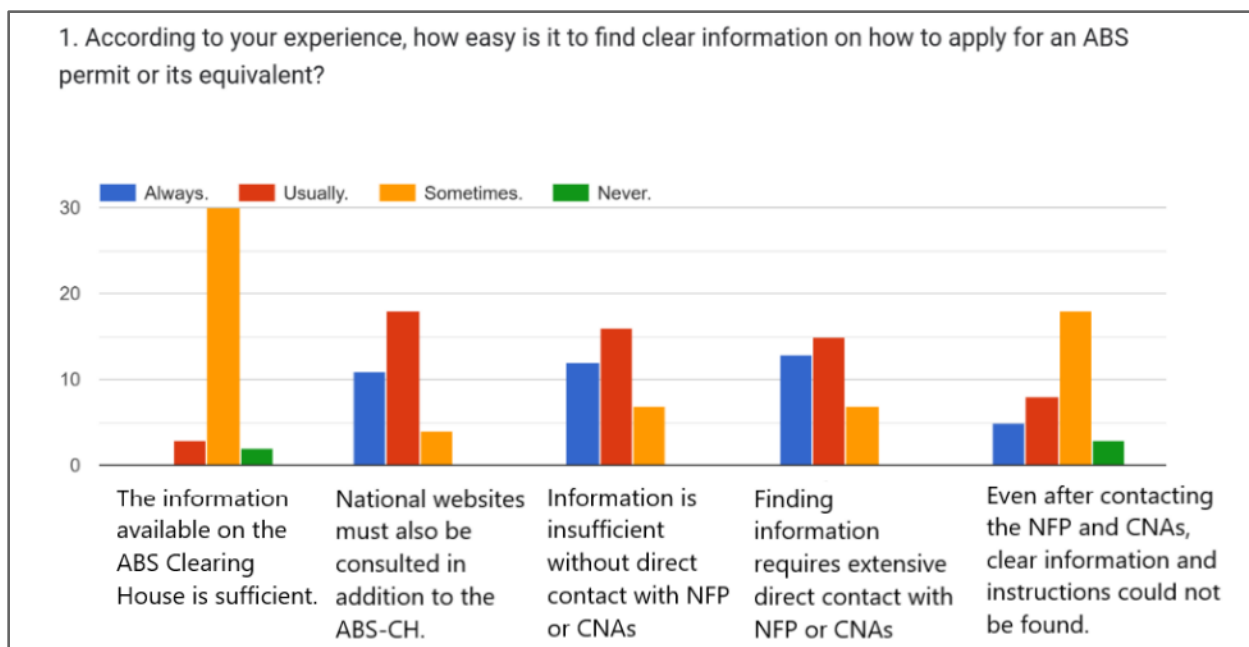


Figure 2. Efforts needed to find clear instructions to request an ABS permit.

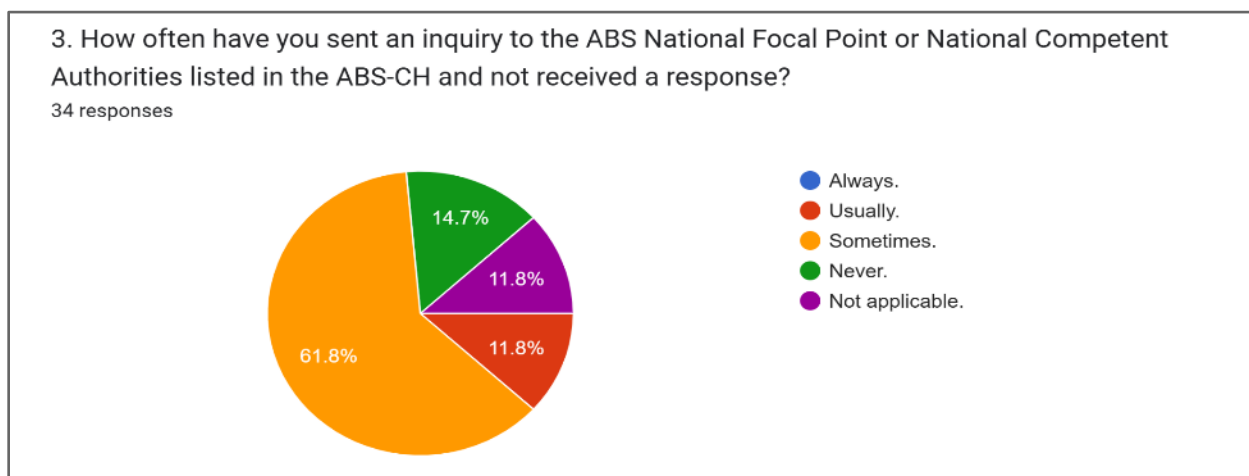


Figure 3. Users report lack of response from NFP/CNAs.

When analysing concrete examples shared by respondents, there are several issues with NFP/CNAs that do not respond to inquiries made in a language other than their country's official language. In these cases, a local partner is necessary, even though it is not always an obligation under the corresponding ABS measures. Researchers also mentioned outdated and unreliable information in the ABS-CH, such as broken links, NFPs who have been retired for years and no forwarding of messages. Concerningly, users also report a lack of responses and information from EU Member States - some of which have been mentioned several times.

- *Have any unexpected or unintended effects occurred? How does the legislation affect the relevant stakeholder groups?*

The lack of information and communication by Parties described above has several unintended consequences for non-commercial scientific activities, hindering research and development in multiple ways, including project delays and cancellations, lost grants, and reduced international collaboration.

According to the survey, **the majority of researchers (77.1%) experienced project delays due to ABS processes**. Respondents identified 41 delayed research projects involving genetic resources from 26 countries. The length of the delays varied considerably. When analysing concrete examples shared by respondents, the delays ranged from two months to six years, with an average delay of approximately 15.7 months per case. Delays caused by ABS processes have also been reported in a previous statement of the SKBV¹.

Even more impactful is the fact that **almost 50% of researchers had to cancel research projects** (figure 4). When analysing the concrete examples shared by respondents, they reported 36 cancelled research projects from 13 named countries. In 17 of the cancellation cases reported, the country names were not mentioned.

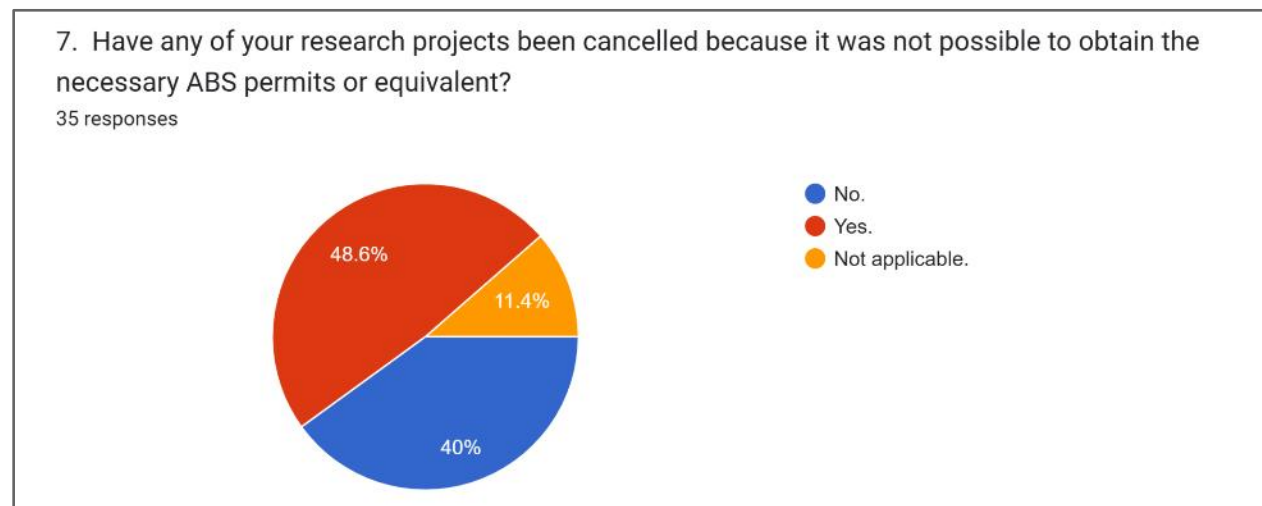


Figure 4. respondents that have experienced project cancellations.

Moreover, three respondents reported losing research grants due to an inability to obtain the necessary ABS permits or equivalent. This issue affects not only German researchers and institutions, but also results in lost funding for international scientific collaborations.

17 researchers shared examples of other unintended effects of the EU ABS Regulation. Eight of these researchers (47%) mentioned that they now avoid performing Nagoya-related research and materials from countries that request ABS permits. Two specifically reported declining collaboration requests: “I

¹ [A decade after the Nagoya Protocol – German biodiversity researchers’ perspective](#) - Statement of the SKBV of the DFG.

have restricted my research to specific countries and excluded cooperation with many” and “I stopped doing Nagoya research. I turn down inquiries of collaborations because of Nagoya”.

Another common effect is the substantial administrative burden on researchers, which consumes substantial personnel resources. Some researchers affirm “scientists cannot focus on research but on bureaucratic burdens”, “the system severely impedes research” and “projects were killed before start”.

Moreover, researchers reported that the regulation has created additional pressure for PhD students who need to finish their research within fixed time frames. They also pointed to uneven competition with researchers in the USA, which is not Party to the Nagoya Protocol and does not check their users. Additional impacts included mandatory co-authorships with local researchers under some ABS requirements, even in cases where contributions would not meet standard authorship criteria under good scientific practice, as well as difficulties recruiting personnel from the USA, who fear they may not be able to continue their research.

One person claimed: “because of these very negative experiences with the global lack of formal application processes for Nagoya permits and the massive collateral damages to my research projects (and to my personal state of health) I am currently completely re-organizing my research profile towards non-genetic research or research on German populations”.

- *What are the differences in impacts between EU countries, and what is causing them?*

The level of implementation varies among Member States, leading to varying levels of impact and an uneven playing field. As noted, Germany applies the Regulation rigorously, carrying out compliance checks every year and imposing sanctions and fines in cases of non-compliance.

Differences in implementation are also reflected in the number of checkpoint communiqués submitted by EU Member States, with France and Germany submitting the clear majority (figure 5). 97 out of 132 checkpoint communiqués submitted by France (73.5%) are the result of due diligence declarations submitted by scientists utilising French genetic resources in France.

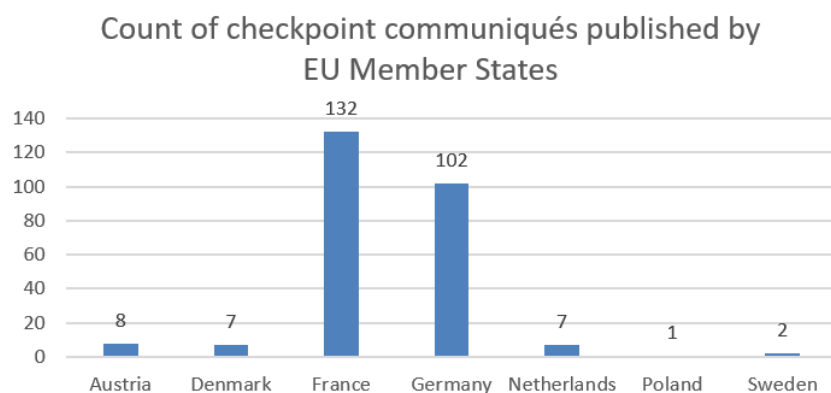


Figure 5. Number of checkpoint communiqués published by EU Member States according to the [ABS-CH](#) (checked on 26.01.2026).

2. Efficiency

- *What are the costs (e.g. administrative costs, adjustment costs) stemming from the Regulation and are they proportionate to the benefits obtained?*

According to responses from ABS compliance officers, the annual cost of implementing the EU ABS Regulation (per research institute) is estimated to range from €10,000 to €50,000 in around 30% of reported cases, and exceeding €50,000 per year in 20% (figure 6). One respondent noted that “the amount of work and responsibility is not commensurate with the benefits received by the institution”.

For institutions that have developed dedicated data management systems for storing ABS-relevant information and documentation, the development costs (when known) ranged from €20,000 to €60,000. These do not include the cost of ongoing system maintenance and improvements.

There are approximately **700–1,000 research institutions in Germany** with a significant life-science research focus (including basic and applied research in biology, medicine, biotechnology, and biomedical engineering)². If each of these institutions invests **€50,000 per year**, the total annual investment required to implement the EU ABS Regulation in German research centres would amount to **€35–50 million**. This estimate does not include additional governmental costs related to operating the ABS CNAs, nor the funding required to maintain support initiatives that help users understand and comply with their ABS obligations, such as the GNP-HuB.

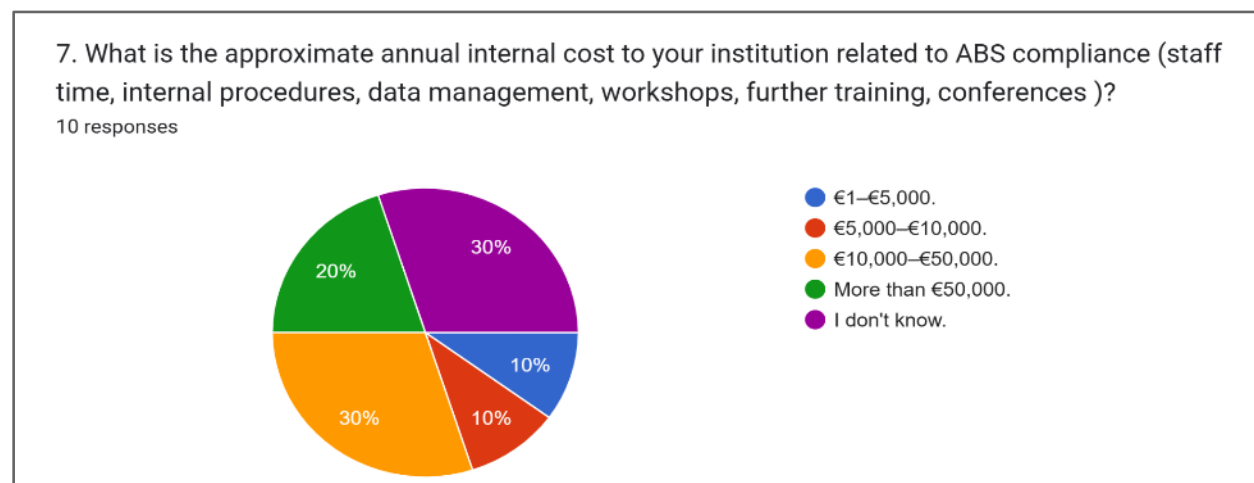


Figure 6. Approximate annual costs per institution to implement the EU ABS Regulation.

The Leibniz DSMZ - German Collection of Microorganisms and Culture Collection is the only German collection in the “Register of Collections” under the EU ABS Regulation. The estimated costs of registering this collection, which includes significant personnel investments from quality management, scientific, and administrative staff, was around €200,000, for a 2.5 years process. The status of

² Major German research organisations — **Max Planck Society, Fraunhofer Society, Leibniz Association, and Helmholtz Association** — together host more than **270 life-science research institutes**. In addition, Germany has around **420 universities and higher education institutions**, as well as hundreds of smaller laboratories, specialised centres, and industry-linked research facilities.

registered collection has certainly strengthened the institutional reputation and legal certainty for DSMZ users, but the number of strains deposited in the DSMZ for the purpose of taxonomic description has decreased. Other trends observed were the increasing number of strains deposited from countries that do not regulate access to genetic resources and the growing interest in depositing strains collected before the Nagoya Protocol entered into force, as part of safeguarding collections from retiring scientists ([Yurkov et al, 2019](#)). When asked why their institute had not attempted to become a registered collection under the EU ABS Regulation, one respondent noted that “the amount of work and responsibility is not commensurate with the benefits received by the institution.”, while another said that it was simply too much work.

- *Have any inefficiencies been identified? Is there any simplification and cost reduction potential, including in terms of the administrative process (e.g. for reporting and monitoring)?*

The time and human and financial resources needed to comply with the EU ABS Regulation would decrease significantly if provider countries published clear, practical instructions for obtaining ABS permits (including requirements, step-by-step procedures, and application forms) in the ABS-CH, and kept their national information up to date, as required under the Nagoya Protocol.

At present, the lack of accessible ABS information and the incomplete Nagoya Protocol implementation by multiple Parties places this burden on researchers and research institutions. Therefore, the EU ABS Regulation should become more proportionate, by taking into account situations where provider country procedures are unclear, unavailable, or not operational.

3. Coherence

- *Given the EU’s political priorities and objectives, the increased use of Digital sequence information on genetic resources (DSI), and relevant international developments, are the legislation, its objectives and measures still relevant?*

As a Party to the Nagoya Protocol, the EU must continue to fulfil its international obligations under the agreement. It should promote compliance with ABS measures while minimising negative impacts on research and innovation.

Regarding benefit-sharing from the use of DSI, the CBD has agreed that this issue will be addressed through a dedicated CBD-DSI multilateral mechanism (CBD COP decisions [15/9](#) and [16/2](#)), rather than under the Nagoya Protocol. Consequently, DSI should not be included within the scope of the EU ABS Regulation.

4. Relevance

- *To what extent is the legislation consistent with other EU policies and priorities (e.g. EU policies for biodiversity conservation, EU policies for sustainable development, EU policies for research). To what extent is the legislation consistent with international commitments and developments?*

The ABS principle established under the CBD and its Nagoya Protocol is relevant to both biodiversity conservation and sustainable development (Sustainable Development Goal’s target 15.6). However, the

unintended negative impacts of the EU ABS Regulation on research and development must be addressed. Based on the data collected (cancelled projects, decreased international collaboration, lack of information and responses from NFPs) and the GNP-HuB project hands-on experience (real-life cases from information sessions, workshops and help desk inquiries), the Regulation and the Nagoya Protocol have likely not had a total net positive outcome for the Convention's objectives at this point in time.

5. EU added value

- *What is the added value resulting from the legislation, compared to what could reasonably have been achieved by EU Member States acting at national and/or regional level? What would be the consequences of revising EU rules?*

While there is room for improvement, the EU ABS Regulation has helped harmonize the interpretation of key concepts and user obligations under the Nagoya Protocol. The Guidance Document has been particularly useful in clarifying this complexity.

However, **there remains clear misunderstanding of the system by some EU Member States, which generates confusion and legal uncertainty among users.** For example, two Member States claim that a due diligence declaration is needed when utilising genetic resources from their country, even though 1) these countries have national legislation that explicitly does not regulate access and 2) the user is not located in that country. This suggests that an important step is for all EU Member States to have clarity on when and why a due diligence declaration should be submitted: 1) only if access is regulated and 2) only submitted to the EU MS in which the scientist operates.

Key recommendations:

Based on the evidence gathered with the survey and the experience of the GNP-HuB project implementing the EU ABS Regulation, the GNP-HuB and SKBV of the DFG would like to propose five recommendations to be considered by the European Commission during the review of the EU ABS Regulation. In the following sections we expand on these recommendations, including the issue identified, evidence gathered from the scientific community in Germany, and the corresponding rationale:

1. Due diligence obligations should be deemed to have been fulfilled in cases where provider-country ABS procedures are unavailable or non-operational.

Where provider countries have not fulfilled their Nagoya Protocol obligations to make ABS procedures clear, accessible, and operational, user obligations under the EU ABS Regulation should be applied in a manner that lifts the regulatory burden from non-commercial users. In particular, when compliance is objectively not possible, because the provider countries do not have and/or do not share the procedure to obtain an ABS permit, non-commercial users should be considered to have exercised due diligence accordingly.

The Regulation should provide legal certainty for users in cases where a Party claims to regulate access but does not supply information on how to obtain an ABS permit.

Issue identified:

Users are required under Article 4 of Regulation (EU) No 511/2014 to exercise due diligence to ensure that genetic resources and associated traditional knowledge have been accessed in accordance with applicable ABS legislation. In practice, however, researchers frequently encounter situations where provider countries indicate that they regulate access but do not publish up-to-date ABS measures or procedures in the ABS-CH, or where NFP or CNAs do not respond to repeated inquiries. In some cases, ABS procedures exist, but permits cannot be obtained despite significant efforts by users.

Evidence from the survey:

Survey responses indicate that researchers often have difficulty obtaining ABS-related information or permits from provider countries. Respondents reported repeated non-responses from the NFP and CNAs listed on the ABS-CH. Twenty-six countries were named as examples where inquiries went unanswered, eight of which were cited at least twice.

According to respondents, delays in obtaining ABS permits substantially impact research projects. When analysing concrete examples shared by respondents, most delays were over one year (27 out of 36 answers).

In addition to these delays, respondents reported 36 cancelled research projects linked to difficulties obtaining ABS permits. Eight researchers indicated that, due to their negative experiences, they avoid conducting research in Low and Middle Income Countries with ABS legislation altogether and even decline collaboration requests.

In at least two cases, a research grant was lost due to delays caused by the ABS permitting process. Another respondent indicated that grants were not extended due to prolonged permitting procedures.

Recommendation:

The EU ABS Regulation should introduce greater legal clarity and by explicitly linking user obligations to the availability of ABS information. In particular, due diligence obligations should apply fully only where provider countries have fulfilled their obligations under the Nagoya Protocol by publishing clear and up-to-date ABS measures and procedures in the ABS-CH and by ensuring functional access procedures.

Rationale:

The Nagoya Protocol places clear obligations on Parties to provide legal certainty, transparency, and accessible ABS procedures (Articles 6, 13, and 14). Aligning user obligations with the fulfilment of these requirements by provider countries would increase legal certainty, reduce disproportionate burdens on research, and remain consistent with the objectives of fair and equitable benefit-sharing.

2. A standardised best practice for obtaining ABS permits should be established by the Commission.

Including the actions required and documents to retain when information is not made available in the ABS-CH, or by NFP or CNAs.

Issue Identified:

According to Articles 4 and 9 of Regulation (EU) No 511/2014, users must exercise due diligence when accessing and utilising genetic resources. However, the regulation and existing guidance do not clearly define what are the actions and documentation needed to show due diligence when information on how to obtain an ABS permit is unavailable in the ABS-CH or from NFP or CNAs. This lack of clarity creates legal uncertainty for users and results in different interpretations and practices among institutions and Member States.

Evidence from the survey:

The survey results indicate a substantial lack of clarity among researchers and compliance officers regarding what constitutes a "best effort" to demonstrate due diligence under the EU ABS Regulation. This is particularly true in cases where information on how to obtain an ABS permit is unavailable in the ABS-CH or from NFP or CNAs. Among researchers, 72.2% reported that it is unclear which measures or documentation are considered sufficient to demonstrate "best efforts" and fulfil due diligence obligations in such situations. Only 22.2% of respondents expressed confidence in their understanding of what constitutes adequate best efforts (figure 7).

Similar uncertainty was reported by ABS compliance officers, who have much more experience implementing the EU ABS Regulation. 55.6% compliance officers stated that it is unclear to them what actions and documentation are sufficient to demonstrate due diligence in the absence of accessible ABS information. Meanwhile, 44.4% indicated that they consider themselves sufficiently informed (figure 7).

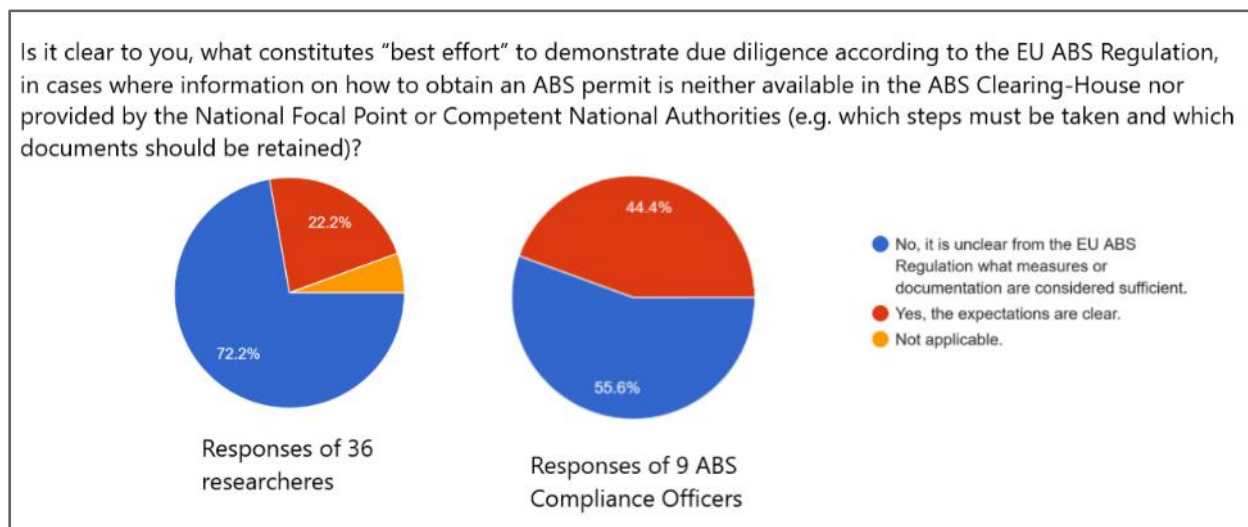


Figure 7. Clarity (or not) regarding the "best effort" to demonstrate due diligence when ABS relevant information is not published on the ABS-CH nor provided by the NFP or CNAs.

In qualitative responses, compliance officers noted that they often rely on case-by-case confirmation from auditing CNAs to assess whether their efforts are sufficient. While this approach is pragmatic, it underscores the absence of clear, harmonized guidance, contributing to uncertainty, administrative burden, and inconsistent practices across institutions and member states.

Recommendation:

The EU ABS Regulation or its accompanying guidance document should clarify what constitutes "best efforts" by users to demonstrate due diligence when ABS information and procedures are unavailable or inaccessible. This clarification should specify:

- which concrete actions are considered sufficient, e.g., documented attempts to consult the ABS-CH and contact the relevant authorities;
- which types of documentation should be retained.

Clear, harmonized guidance would reduce reliance on informal, case-by-case assessments by auditing authorities and support consistent implementation across the EU.

Where such efforts do not result in access to the necessary information or procedures, users should not be required to discontinue utilisation solely due to the failure of provider countries to meet their Nagoya Protocol obligations regarding ABS-relevant information.

Rationale:

Providing clarity on actions and documentation needed to demonstrate due diligence would increase legal certainty for researchers and compliance officers, reduce the administrative burden, and encourage the application of due diligence obligations. This guidance would also support the effective enforcement of the Regulation by establishing transparent and consistent benchmarks for compliance while aligning with the Nagoya Protocol's objectives and the principles of good faith and proportionality.

3. Strengthen capacity-building for non-commercial users

Including support for implementing national Nagoya Protocol help desks in Member States to provide guidance and facilitate compliance.

Issue Identified:

The effective implementation of the Nagoya Protocol within the EU is limited by the lack of capacity-building support for non-commercial users, especially academic researchers and collection professionals. Although the EU ABS Regulation imposes direct legal obligations on users, most researchers lack legal training. Consequently, the highly legalistic language of ABS legislation and guidance documents often creates uncertainty regarding interpretation, scope, and practical compliance responsibilities. This uncertainty can lead to risk-averse behaviour, research delays, or unintentional noncompliance. Nagoya-related compliance questions are fundamentally legal, yet most research institutions lack easily accessible, dedicated legal expertise on ABS. Existing EU-level guidance primarily focuses on regulatory requirements rather than user-oriented interpretation, practical workflows, or case-based advice tailored to non-commercial research contexts. Consequently, researchers and compliance officers often struggle to translate formal requirements into day-to-day research practice.

Evidence from the GNP-HuB's long-standing practical experience:

The GNP-HuB's experience indicates a clear cross-border demand for practical support that many Member States do not adequately meet at the national level. This is evidenced by:

- substantial numbers of visits to the GNP-HuB website originating from other EU Member States;
- recurring inquiries to the GNP-HuB helpdesk from researchers and institutions outside Germany;
- attendance of non-German scientists/people at GNP-HuB events.

Survey responses from researchers and compliance officers indicate a lack of clear, user-friendly communication materials and practical guidance on ABS compliance. Together, these indicators suggest that non-commercial users across the EU actively seek interpretive and advisory support beyond their national structures.

Without targeted capacity building, legal uncertainty will continue to be transferred to individual researchers who are ill-equipped to independently assess compliance risks. This hinders the proportional and effective implementation of the Nagoya Protocol and places unnecessary burdens on non-commercial research. Strengthening advisory capacity would improve legal clarity, foster consistent interpretation across member states, and support the responsible use of genetic resources without hindering research.

Recommendation:

Member states should establish or strengthen national Nagoya Protocol help desks for non-commercial users and support their structured coordination at the EU level. Existing expertise could be shared through a networking model coordinated according to available resources and funding while respecting national responsibilities. This coordination would enable the exchange of best practices, the development of harmonized interpretation guidance, and the creation of user-friendly materials tailored to research needs.

Rationale:

There are multiple expected benefits from the implementation of help desks and ABS-related networking among EU Member States:

- Improved legal certainty for researchers and collection-holding institutions.
- More consistent implementation of ABS rules across Member States.
- The compliance burden would be reduced through clearer guidance and shared expertise.
- There would be stronger support for non-commercial research while maintaining high compliance standards.

There are also some risks. Differences in national legislation may limit full harmonization. This can be mitigated by clearly distinguishing between EU-level interpretation support and member state-specific legal requirements, while using coordinated help desk structures to transparently flag and explain national differences.

4. Extend timelines to exercise due diligence during health emergencies to one year (EU ABS Regulation article 4.8).

Issue identified:

According to Article 4(8) of Regulation (EU) No 511/2014, in cases of present or imminent threats to public health, users must exercise due diligence or discontinue utilisation within three months of

commencement or one month after the threat is terminated, whichever is earlier. In practice, however, this timeframe is often insufficient for research activities addressing health emergencies.

Evidence from the survey:

Evidence from the survey shows that obtaining ABS permits in health emergency contexts can take substantially longer than three months. In the two cases mentioned in the survey, the permitting process took approximately six months and twelve months, respectively. As a result, research relevant to public health responses was placed at risk.

Recommendation:

Aligning due diligence timelines with permitting practices. The EU ABS Regulation should allow for more flexibility in health emergency situations. This can be achieved by extending the timeframe set out in Article 4(8) to at least one year. It could also allow continued utilisation beyond three months for those who can demonstrate ongoing efforts to obtain permits and establish mutually agreed terms.

Rationale:

Article 8(b) of the Nagoya Protocol acknowledges the necessity for prompt access to genetic resources in instances of health emergencies. A modification of the timelines delineated in the EU ABS Regulation would ensure a stronger alignment with practical realities, mitigate unintended barriers to critical research, and maintain congruence with the principles of fair and equitable benefit-sharing.

5. Reduce the retention period for ABS-related documentation from 20 to 10 years (EU ABS Regulation article 4.6)

Issue Identified:

According to Article 4(6) of Regulation (EU) No 511/2014, ABS documentation must be retained for 20 years after the end of resource utilisation. This exceeds the retention periods of most other categories of research documentation, creating a disproportionate administrative burden relative to the demonstrated need for compliance. Retention requirements in other research-relevant regulatory domains are substantially shorter. Documentation that supports good scientific practice and research integrity is usually kept for 10 years after publication or project completion³. Export control and security-relevant documentation are usually required to be stored for five to ten years, depending on the legal framework⁴. Longer retention periods (e.g., 20–25 years) are generally restricted to highly regulated areas, such as clinical trials or pharmacovigilance⁵, where long-term liability and participant safety justify exceptional record-keeping obligations. In this context, a 20-year retention period for ABS documentation seems unnecessarily long.

³ The research integrity policies of universities and research institutes in the EU typically stipulate that research data and associated documentation should be retained for a period of 10 years, to support verification, reproducibility and good scientific practice.

⁴ EU export control rules (Council Regulation (EU) 2021/821 on dual-use items)

⁵ EU Clinical Trials Regulation (Regulation (EU) No 536/2014)

Evidence from the survey and GNP-HuB's long-standing practical experience:

Experience from multiple research and collection-holding institutions shows that establishing a compliant ABS data management and documentation system is highly resource-intensive. According to the survey, developing and operationalizing such systems in three institutions required between six months and two and a half years. This process involved legal analysis, redesigning workflows, training staff, developing IT, and curating retrospective data. This translates into substantial personnel time and financial costs. Long mandatory retention periods increase these costs by extending long-term storage, maintenance, and governance obligations.

Recommendation:

We propose that ABS implementation guidelines and institutional policies adopt a default retention period of ten years for ABS-related documentation, including permits, prior informed consent, mutually agreed terms, and internal due diligence records. This period should be counted from the last active use of the material or final publication.

Rationale:

Reducing the ABS documentation retention period to 10 years would align ABS practice with established research data management standards and improve proportionality. Given the significant effort required to establish and maintain ABS documentation systems, a 20-year requirement could divert limited institutional resources away from core scientific, curatorial, and compliance activities without providing a clear regulatory benefit.

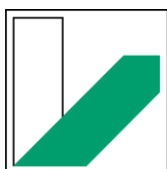
Conclusion:

The EU ABS Regulation has been a recognised example of compliance measures. Nevertheless, there are multiple unintended negative consequences on research and innovation, which consequently may reduce international scientific collaborations and benefit-sharing. To make provider and user's legal obligations more aligned, we suggest **that due diligence obligations should be deemed to have been fulfilled in cases where provider-country ABS procedures are unavailable or non-operational**; and that **a standardised best practice for obtaining ABS permits should be established by the Commission**. We also highlighted that **strengthening capacity-building for non-commercial users across EU Member States**, including support for implementing national Nagoya Protocol help desks, is needed to provide guidance and facilitate compliance.

Supporters of the statement:



UNIVERSITY
OF WARSAW



UNIVERSITÄT
BAYREUTH



Technische
Universität
Braunschweig



ALFRED-WEGENER-INSTITUT
HELMHOLTZ-ZENTRUM FÜR POLAR-
UND MEERESFORSCHUNG



Leibniz Institute
DSMZ-German Collection
of Microorganisms
and Cell Cultures GmbH

MAX PLANCK INSTITUTE
FOR MARINE MICROBIOLOGY



C | A | U

Kiel University
Christian-Albrechts-Universität zu Kiel



MAX-PLANCK-INSTITUT
FÜR CHEMISCHE ÖKOLOGIE

ZMT 
LEIBNIZ CENTRE
for Tropical Marine Research



FLI FRIEDRICH
LOEFFLER
INSTITUT

**LEIBNIZ
IZH**

Leibniz Institute
for Natural Product Research
and Infection Biology
Hans Knöll Institute



JKI

Julius Kühn-Institut
Federal Research Centre for Cultivated Plants



IGB

Leibniz Institute of Freshwater Ecology
and Inland Fisheries



**UNIVERSITÄT
HOHENHEIM**

Technical
University
of Munich

TUM



GEOMAR

Helmholtz Centre for Ocean Research Kiel

universität freiburg



Annex 1

Survey: Contribution to the Review of the EU ABS Regulation (511/2014)

A decade ago, the Nagoya Protocol was implemented in the European Union through Regulation (EU) No 511/2014 creating legal requirements for users of genetic resources. The European Commission is now conducting a review of this regulation under the Nagoya Protocol (EU ABS Regulation) and will soon launch a **call for evidence**, on the "*Have Your Say*"- portal, which will be open for four weeks.

This represents an **important opportunity** for the scientific community to actively contribute to the review process and ensure that the regulation effectively supports research and innovation, while upholding fair and equitable access and benefit-sharing practices.

To present an evidence-based submission to the European Commission, the German Nagoya Protocol HuB (GNP-HuB) together with the Working Group on Access and Benefit Sharing of the Permanent Senate Commission on Fundamental Issues of Biological Diversity of the German Research Foundation have developed a survey **to gather input from researchers and institutions working with genetic resources in Germany on how the EU ABS Regulation has impacted scientific research in practice**, and on what changes could make compliance processes clearer, fairer, and less burdensome.

Your responses will help us identify key challenges and develop key messages to inform the review of the EU ABS Regulation and future policy development. **The deadline to submit your responses is January 20th, 2026.** If you have any questions, please email info@nagoyaprotocol-hub.de.

* Indicates required question

Confidentiality and data protection:*

Personal or identifiable information will be used for internal analysis only and will not be included in the submission to the European Commission. Only aggregated, anonymized information may be used in the final submission.

Additionally, respondents may voluntarily indicate the country or countries relevant to their examples. This information will be treated confidentially and used exclusively for internal analysis to better contextualize the responses. Country names will not be included in the submission to the European Commission; only aggregated and anonymized information may be reflected.

All responses will be treated confidentially and in accordance with applicable data protection regulations. You can withdraw your responses at any time with effect for the future sending a

declaration of revocation by e-mail at any time to info@nagoyaprotocol-hub.de.

- ☐ I agree.
- ☐ I do not agree.

Part I. Personal information.

When you submit this form, it will not automatically collect your details like name and email address unless you provide it yourself.

Name:

Institution:

Parent organization. *Mark only one oval.*

- ☐ Helmholtz Association.
- ☐ Leibniz Association.
- ☐ Deutsche Forschungsgemeinschaft (DFG).
- ☐ Max Planck Society.
- ☐ Hochschulrektorenkonferenz (HRK).
- ☐ Fraunhofer Society.
- ☐ German National Academy of Sciences Leopoldina.
- ☐ Not applicable.
- ☐ Other: _____

e-mail address

Part II. Impact of the EU ABS Regulation in your research.

Under the EU ABS Regulation, users of genetic resources must exercise due diligence to ensure that genetic resources and associated traditional knowledge have been accessed in accordance with applicable ABS legislation or regulatory requirements. Under the Nagoya Protocol, Parties that regulate access are required to develop clear ABS measures and publish them in the ABS- Clearing House.

1. According to your experience, how easy is it to find clear information on how to apply for an ABS permit or its equivalent?

	Always.	Usually.	Sometimes.	Never.
The information available on the ABS Clearing House is sufficient.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
National websites must also be consulted in addition to the ABS Clearing-House.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Information is insufficient without direct contact with National Focal Points and/or Competent National Authorities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Finding information requires extensive direct contact with National Focal Points and/or Competent National Authorities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Even after contacting the National Focal Point and Competent National Authorities, clear information and instructions could not be found.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please share concrete examples.

2. In your experience, when you send an inquiry to the ABS National Focal Point and/or Competent National Authorities you usually receive an answer:

	Always.	Usually.	Sometimes.	Never.
Within one week.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Within one month.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Between 1-3 months.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
After more than 3 months.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I do not receive an answer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please share concrete examples (country names will not be included in the submission).

3. How often have you sent an inquiry to the ABS National Focal Point or National Competent Authorities listed in the ABS-CH and **not received a response**?

-
- ☐ Always.
- ☐ Usually.
- ☐ Sometimes.
- ☐ Never.
- ☐ Not applicable.

Please share concrete examples (country names will not be included in the submission).

4. Have you experienced the situation when a Party to the Nagoya Protocol affirms that it regulates access to genetic resources but does not provide information on how to obtain the corresponding ABS permit or equivalent?

- ☐ Yes.
- ☐ No.
- ☐ Not applicable.

If yes, please share concrete examples. Please explain the situation and the name of the countries (country names will not be included in the submission).

5. Have any of your research projects been delayed due to the process of obtaining the necessary ABS permits or equivalent?

- ☐ No.
- ☐ Yes.
- ☐ Not applicable.

If yes, please indicate the countries and the length of the delay for each (country names will not be included in the submission).

6. When ABS permits (or equivalent) were required, what was the approximate delay to your research caused by the access procedure?

	Always.	Usually.	Sometimes.	Never.
No delay.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Less than 1 mo.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1-3 mos.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3-6 mos.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6-12 mos.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
More than 12 mos.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please share which countries and how long was the delay per country (country names won't be included in the submission).

7. Have any of your research projects been cancelled because it was not possible to obtain the necessary ABS permits or equivalent?

- ☐ No.
- ☐ Yes.
- ☐ Not applicable.

If yes, indicate the number of cancelled projects and share examples. Please include country names and dates (country names will not be included in the submission).

8. Have any of your research grants been lost because it was not possible to obtain the necessary ABS permits or equivalent?

- ☐ No.
- ☐ Yes.
- ☐ Not applicable.

If yes, indicate the number of lost grants and share examples. Please include country's names, dates, funding source and purpose of research (country names will not be included in the submission).

9. How do you typically obtain biological samples for research? (Select all that apply).

- ☐ Collect samples in the field outside Germany.
- ☐ Research collaborators share samples from outside Germany with me.
- ☐ Obtain samples from ex situ collections within the EU.
- ☐ Obtain samples from ex situ collections outside the EU.
- ☐ Purchase from commercial providers.
- ☐ Not applicable.

10. Have you utilised genetic resources obtained from a commercial provider (online or physical shop)?

- ☐ Yes.
- ☐ No.

If yes, was it possible to identify the provider country (the country where the materials originally come from)?

11. Has your institution attempted to become a registered collection under the EU ABS Regulation?

- ☐ Yes. Which aspects hindered or complicated the process? (Please specify below).
- ☐ No. What were the main reasons for not pursuing registration? (Please specify below).
- ☐ No, but it is considering to do it. What challenges have you already identified? (Please specify below).
- ☐ I don't know.
- ☐ Not applicable.

Specify here your response for question 11.

12. Has your institution performed Nagoya Protocol–related research involving genetic resources for human, animal, or plant health during a health emergency (e.g. a pandemic, epidemic, or major disease outbreak)?

- ☐ Yes.
- ☐ No.
- ☐ I don't know.
- ☐ Not applicable.

If yes, how long did it take to obtain the necessary ABS permits or equivalent? (in months).

13. Is it clear to you as a researcher, what constitutes “best effort” to demonstrate due diligence according to the EU ABS Regulation, in cases where information on how to obtain an ABS permit is neither available in the ABS Clearing-House nor provided by the National Focal Point or Competent National Authorities (e.g. which steps must be taken and which documents should be retained)?

- ☐ No, it is unclear what measures or documentation are considered sufficient.
- ☐ Yes, the expectations are clear.
- ☐ Not applicable.

If yes, this is how my institution documents “best efforts”:

14. Do you consider the DECLARE system to submit the due diligence declaration to be:

- ☐ Easy to use and should be kept as it is.
- ☐ Easy to use but could be improved (please explain below).
- ☐ Difficult to use and in need of improvement (please explain below).
- ☐ Not applicable.

Add your explanations for answer to question 14 here:

15. Please share your experience on any unexpected or unintended effects of the EU ABS Regulation in your research.

16. Do you have any institutional responsibilities related to ABS (e.g. ABS compliance officer or similar)? *

- ☐ Yes.
- ☐ No.

If yes, go to section 3 - questions for ABS compliance officers.

If no, go to section 4 - thank you for your participation.

Part III. Questions for ABS Compliance Officers or people supporting implementation of EU ABS Regulation at the institutional level in Germany.

1. Have any research projects at your institution been delayed due to the process of obtaining ABS permits (or equivalent)?

- ☐ Yes.
- ☐ No.
- ☐ I don't know.

If yes, how many research projects have been delayed?

2. For delayed projects, what was the typical length of the delay caused by ABS procedures?

- ☐ Less than 1 month.
- ☐ 1–3 months.
- ☐ 3–6 months.
- ☐ 6–12 months.
- ☐ More than 12 months.
- ☐ I don't know.
- ☐ Not applicable.

Please explain which projects, in which countries, respective delays if listing multiple countries and approximately when this happened (country names will not be included in the submission).

3. Have any research projects at your institution been cancelled because it was not possible to obtain the necessary ABS permits (or equivalent)?

- ☐ Yes.
- ☐ No.
- ☐ I don't know.

If yes, how many research projects have been cancelled? Please provide as many details as possible.

4. Have any research grants at your institution been lost because it was not possible to obtain the necessary ABS permits (or equivalent)?

- ☐ Yes.
- ☐ No.
- ☐ I don't know.

If yes, indicate the number of lost grants and share examples. Please include country's names, dates, funding source and purpose of research (country names will not be included in the submission).

5. Is it clear to you as an **ABS Compliance Officer** (or equivalent) what constitutes “best effort” to demonstrate due diligence according to the EU ABS Regulation, in cases where information on how to obtain an ABS permit is neither available in the ABS Clearing-House nor provided by the National Focal Point or Competent National Authorities (e.g. which steps must be taken and which documents should be retained)?

- ☐ No, it is unclear from the EU ABS Regulation what measures or documentation are considered sufficient.
- ☐ Yes, the expectations are clear.
- ☐ Not applicable.

If yes, this is how my institution documents “best efforts”:

6. Has your institution a data management system (DMS) to compile and keep Nagoya Protocol-related information and documentation?

- ☐ Yes.
- ☐ No.
- ☐ Not yet, but the institution is planning to implement a DMS system.

-If yes in question 6, how much **money** did your institution invest in the process to develop the DMS?

-If yes in question 6, how much time did your institution invest in the process to develop the DMS?

7. What is the approximate annual internal cost to your institution related to ABS compliance (staff time, internal procedures, data management, workshops, further training, conferences)?

- ☐ €1–€5,000.
- ☐ €5,000–€10,000.
- ☐ €10,000–€50,000.
- ☐ More than €50,000.
- ☐ I don't know.

8. Has your institution undergone a compliance check by the German Federal Agency for Nature Conservation (BfN)?

☐ Yes.

☐ No.

If yes, according to your experience, the compliance check was:

☐ Very proportionate.

☐ Proportionate.

☐ Unproportionate.

☐ Very unproportionate.

Please share a concrete experience.

9. Please share any unexpected or unintended effects of the EU ABS Regulation on your institution.

Part IV. Thank you for your participation.

Your responses will support the scientific community's contribution to the review of the EU ABS Regulation and help develop key messages to inform the review process and future policy development.