

10 steps for compliance with the obligations under Regulation (EU) No 511/2014 for users in Germany

Step	When collecting genetic resources for the purpose of utilisation	When obtaining genetic resources from third parties for the purpose of utilisation
First	<p>Check that the requirements for applicability of Regulation (EU) No 511/2014 and hence the German Implementing Act are fully met. <i>For this to be the case, genetic resources must be used in Germany where</i></p> <ul style="list-style-type: none"> – <i>access took place on or after 12 October 2014</i> – <i>in a country that is a Party to the Nagoya Protocol.</i> – <i>Access and benefit sharing (ABS) rules must apply in that country and those rules must relate to the specific genetic resource in question.</i> – <i>Utilisation of genetic resources within the meaning of the EU Regulation means to conduct research and/or development on the genetic and/or biochemical composition of genetic resources.</i> <p>If all the above requirements are met, work through the following steps:</p>	
1	<p>Check whether it is possible to implement in your institution a best practice for which recognition has already been granted (see Article 8 of Regulation (EU) No 511/2014). <i>The application of any best practices is taken into account in checks of compliance with the obligation to exercise due diligence</i></p>	
2	<p>Before collecting/acquiring/utilising genetic resources, inform yourself about the legal position and the competent authorities in the provider country. <i>Initial information can be found via the ABS Clearing House (https://absch.cbd.int).</i></p>	
3	<p>Contact the competent national authorities with regard to access procedures, benefit sharing rules, restrictions on use, responsibilities, etc. <i>The exact legal position is best clarified with the competent authorities.</i></p>	
4	<p>Apply for/negotiate any ABS documentation needed, stating what you plan to do with the resources (e.g. including whether you intend to pass them on to others, or to upload data). <i>Collaboration with local partners may simplify the procedure.</i></p>	<p>Require the necessary ABS documentation and information from the third party (trader/collection) providing the genetic resources. <i>The documentation and information to be sought are listed in Article 4.3 of Regulation (EU) No 511/2014.</i></p>

	<i>It may be necessary to obtain different approvals from different authorities.</i>	<i>When resources are obtained from a registered collection within the meaning of Article 5 of Regulation (EU) No 511/2014, due diligence is considered to have been exercised.</i>
5	<p>Document what you have done in order to demonstrate that you have exercised due diligence. <i>The documentation/information required under Regulation (EU) No 511/2014 must be retained for 20 years after the end of the period of utilisation. It may be helpful to keep additional relevant information in case of doubt (e.g. email correspondence with authorities). Any transfer of resources to others must also be documented.</i></p>	
6	<p>When obtaining research funding from private or public sources, submit a due diligence declaration in accordance with Article 7(1) of Regulation (EU) No 511/2014 on time to BfN (via https://webgate.ec.europa.eu/declare/). <i>The declaration must be submitted at the latest by project completion.</i></p>	
7	<p>In the case of a patent application, state the geographical origin of the genetic resource underlying the invention.</p>	
8	<p>When developing a product, submit a due diligence declaration in accordance with Article 7(2) of Regulation (EU) No 511/2014 on time to BfN. Submit via https://webgate.ec.europa.eu/declare/ at the latest four weeks before the first of the events listed in Implementing Regulation (EU) 2015/1866.</p>	
9	<p>Ensure that in utilisation of the genetic resources the obligations and benefit sharing arrangements stipulated in the ABS approvals and contractual agreements have been fulfilled in their entirety. <i>If there is a change in use during the course of research and/or development (such as a transition from initially purely scientific to commercial research), any necessary ABS approvals and contractual agreements will have to be renegotiated or amended.</i></p>	
10	<p>If there is any uncertainty about the legality of access and the utilisation of genetic resources, obtain the necessary ABS documentation retrospectively or discontinue the utilisation.</p>	