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Dear Mrs. Palmer,

attached you will find information and our practical experiences on situations in which it is not possible to grant or obtain prior informed consent.

Kind Regards,

Hilke Marie Püschner
p.p. Prof. Dr. Jörg Overmann



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Information and practical experiences on situations in which it is not possible to grant or obtain prior informed consent

Thank you for the opportunity to offer feedback and comments on this important issue. The Leibniz Institute DSMZ GmbH is one of Europe's largest and most diverse biological resource centers with more than 57,000 holdings, 80% of all bacterial species, 10,000+ customers from 86 countries worldwide, and with deliveries of 40,000 resources annually. We offer these brief statistics to confer a sense of the scale on which our institute operates and the enormity of impact that the Nagoya Protocol and the resulting EU and German legislation will have upon our work. All of this is in the context of only a single commercialization request on average per year, which indicates that the vast majority of our work is with and for basic research and, ultimately, for the sustainable preservation of biodiversity.

In order to fulfil the requirements of the Nagoya Protocol, the DSMZ GmbH has begun to proactively check if deposits to our collection are in scope ("Scope-Check"). A deposit is in scope if the country where the isolate was originally collected is a party to the Nagoya Protocol and if the country was already a party when the sample was collected *in situ*. To determine the country's party status and effective date we directly check the ABS Clearing House (<https://absch.cbd.int/>).

In order to save time and gather initial information about all CBD and Nagoya Protocol countries, the DSMZ GmbH contacted the national focal point (NFP; also taken from the ABS CH) and inquired about the requirements for legal access and deposit in a microbial culture collection. In particular we asked whether access restrictions exist and whether any specific documentation was needed in order to accept a deposit in a public collection.

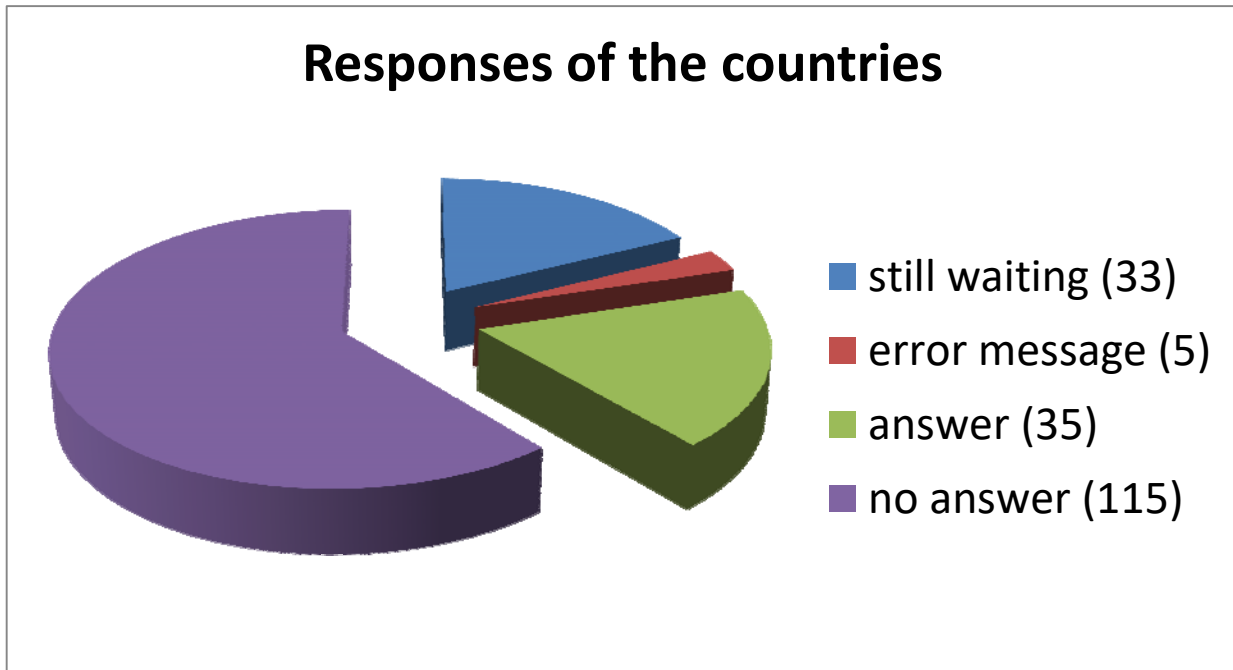
We quickly learned that contacting the NFP once we already had a deposit request was not the most efficient way to proceed. Often, the NFP either did not respond or if they responded, the answer was hesitant or inconclusive. As a result, depositors were left without an answer and, in the mean time, deposited their isolates elsewhere, or, alternatively, some samples died.

For this reason the DSMZ GmbH tried a different approach. At the end of October 2017, we sent an email with a standard request about the country's the Nagoya Protocol and CBD legislation and their possible requirements that would be needed for a microbial deposit to 188 countries from the ABS CH. Our results from contacting every country in the ABS CH are as follows:

- Five weeks later we received a useful response from only 35 countries.
- Often we got the response only because of a subsequent (second or third) request.
- Five countries email addresses generated an error message (technical error or some type, e.g., mailbox full, email address doesn't exist). We tried to reach these countries again via the general ministry homepage but were still unsuccessful.
- We are "on hold" in 33 countries. Here, for example, we were referred to another contact person or the answers were incomplete and further information had to be obtained.

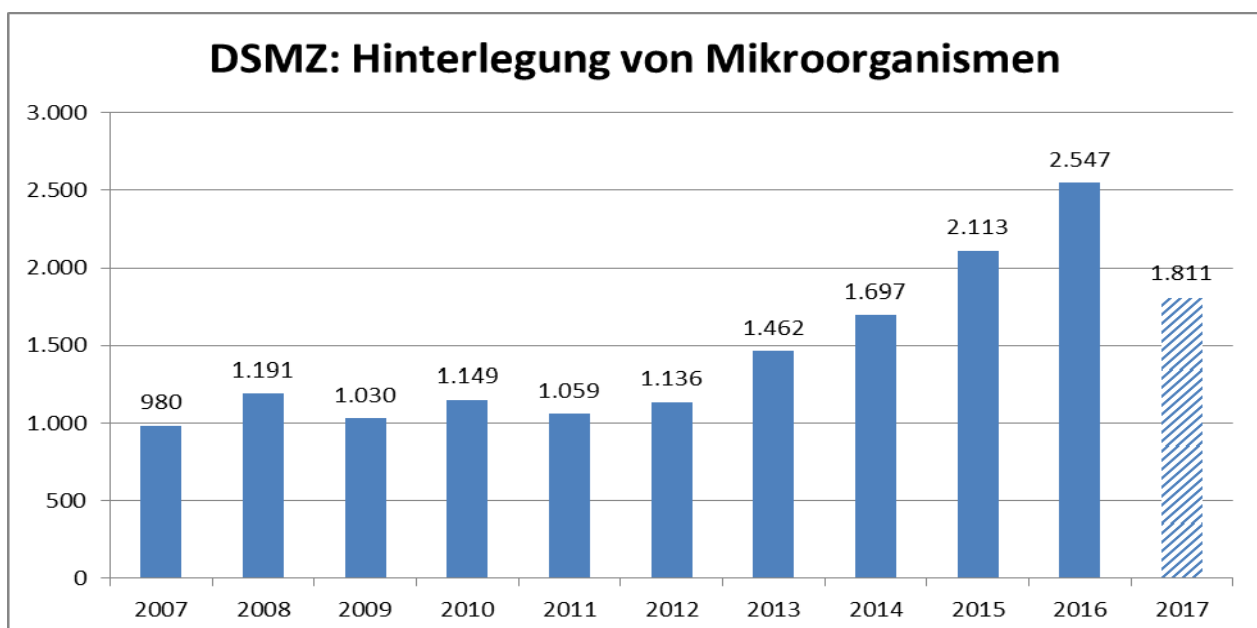


- From 115 countries (61%) we haven't received a response to-date (6 weeks later).



This result stands for itself. A particular problem for us is that there is no feedback from countries such as China, not even upon subsequent requests, from which we receive 25% of our annual deposits (around 500 per year).

If we haven't received any feedback from Nagoya parties, we reject the deposit, which has resulted in a 20% drop off in deposits this year.





Because of taxonomic nomenclature rules established by the scientific community, Microbiologists are required to deposit new bacterial species in two public collections in two different countries. Deposit must be certified by both collections, accompanied by a certificate, and then submitted to the journal as a prerequisite for the publication of a paper describing the new bacterial species. Many researchers now find themselves in a predicament where they are unable to deposit and, therefore, unable to publish. Many of the rejected deposits, we have learned, subsequently deposit in a collection that does not respect the Nagoya Protocol and does not perform scope checks.

Summary:

- We haven't received a valid Nagoya PIC / MAT from a depositor yet.
- The feedback from the NFP takes a long time and is often incomplete.
- Frequently, NFPs do not respond at all.
- Many deposits must be rejected because the requirements of the Nagoya Protocol cannot be fulfilled.

