Activities of German Chemical and Biotech Industry

EU Regulation No. 511/2014

…on compliance measures for users from the Nagoya Protocol on Access & Benefit Sharing

- Articles 5 and 8 provide for voluntary tools to assist users in complying with their due diligence obligations: collections, best practices.
- Industry supports concepts, but draft regulations raise number of legal issues
  - Registered Collections
    - Industry: draft best practices for the business sector
    - Industry: coordinate with established biological resource centers

      Leibnitz-Institute DSMZ – German Collection of Microorganisms and Cell Cultures
  - Best practices/User Associations
    - Industry: refine draft of best practices for business sector

      10 Steps basic principles proposed by biotech-industry (published in 2006)
- Coordinate with downstream and upstream along the value creation chain - as far as possible

How does Biotech in Germany address the Nagoya Protocol?

Preliminary basic principles proposed by biotech-industry

1. Identify the competent national authority of the country of origin and take up contact.
2. In consultation with the national authority, identify all necessary access requirements imposed by the country of origin.
3. Where relevant, check whether the providing organization is authorized to this effect by the country of origin.
4. For the purpose of obtaining a PIC, submit a statement from the recipient on the proposed utilization to the national authority authorized by the country of origin.
5. Reach an agreement with the national authority on the provisions of the license agreement, including benefit sharing in accordance with the possibilities set out in the “Bonn Guidelines”.
6. Ratify the license agreement.
7. Take physical possession of the genetic material.
8. Transfer the genetic material to the utilization resources defined in the contract.
9. Comply strictly with the contractual obligations.
10. Sell or relinquish the genetic resource to subsequent users only under the provisions of the Standard Material Transfer Agreement (SMTA).