

Synthetic Biology

viewpoint of Austrian Federal Ministry of Health

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Synthetic Biology

- Challenges to
 - Risk assessment and risk management
- Recommendations
 - for actions
- Study funded by the Federal Ministry of Health
 - Ribarits A., Stepanek W., Wögerbauer M., Peterseil V., Kuffner M., Topitschnig C., Brüller W., Hochegger R., Gansberger M., Widhalm I. und Leonhardt C. (2014) Synthetic Biology. Federal Ministry of Health, Vienna.
http://www.bmg.gv.at/cms/home/attachments/2/6/8/CH1052/CMS1422371020012/synthetic_biology_02122014_final.pdf

Risk assessment

- Risk assessment for Synthetic Biology Organisms is in principle analog to Genetically Modified Organisms-Risk assessment, i.e.
 - Molecular genetics
 - Comparative analysis
 - Toxicology
 - Allergenicity
 - Environmental Risk Assessment & Monitoring
 - Genetic exchange between synthetic organisms (biological entities) and natural occurring organisms
- special situation for Xenobiology

Recommendations

- Clear definition and delimitation of terms
- Public information
 - in particular on biosafety and biosecurity issues
- Coordinated exchange of information and central collection of data
 - analysis of risks of applying Synthetic Biology
 - detailed description of the projects
- Establishment of high standards for regulatory requirements
 - EU-Standards
 - preferably international

Recommendations

- Risk research
- Synthetic Biology falls under the scope of regulatory framework like Contained Use activities of GMOs
- Commercial provision of Synthetic Biology material needs surveillance
- Safety and security of workers
 - Establishment of containment strategies
 - Worker safety
 - Training needs
- Possibility to track Synthetic Biology organisms

Actions

- Undisclosed opinion regarding inter alia Synthetic Biology by
 - Scientific committee for Contained Use
 - Scientific committee for Deliberate Release and Placing on the Market

Thank you for your attention.