**SYNTHESIS OF VIEWS IN RESPONSE TO PARAGRAPH 10 of   
DECISION XIII/17 ON SYNTHETIC BIOLOGY**

1. In response to paragraph 10 of decision XIII/17, the Executive Secretary issued a notification on 16 March 2017 inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information and supporting documentation on the six topics referred to in the decision. A total of 27 submissions were received by the Secretariat. Among the submissions, 13 were from Parties, 1 from a non-Party, and 13 from organizations.[[1]](#footnote-1)
2. **Research, cooperation and activities**
3. In describing their involvement in research, cooperation and activities most Parties indicated that they support the undertaking of research on synthetic biology in their countries and in some cases do so through the provision of funds to the relevant research groups. One Party also indicated that it has a database on synthetic biology projects that are being carried out in its country[[2]](#footnote-2).
4. Several described the existence of specialised scientific committees, panels and advisory boards that focus on multidisciplinary research on various aspects of synthetic biology. The submissions indicated that these panels are not only involved in the assessing the scientific and technical impacts of synthetic biology but are also mandated to research social, ethical, regulatory, and legal issues related to synthetic biology.
5. In addition, Parties are also involved, through the aforementioned committees, in holding awareness-raising activities, such as publishing reports, information notes and hosting and participating in seminars in order to encourage public and multi-stakeholder dialogues on the potential benefits and potential adverse effects of organisms, components and products of synthetic biology on biodiversity.
6. In contrast, other Parties indicated that they have limited or no capacity to carry out synthetic biology research. However, some indicated that they continue to make an effort to stay abreast of developments that occur in the field of synthetic biology through regional cooperation and participation in trainings and workshops focusing on synthetic biology.
7. **Evidence of benefits and adverse effects of synthetic biology**
8. Some submissions acknowledged that synthetic biology is a further development and new dimension of modern biotechnology. They also noted that many of the applications of synthetic biology aim at developing efficient and effective ways to respond to challenges associated with bioenergy, agriculture, health and chemical production, amongst other applications. They also listed some of the corresponding potential adverse effects that may come with the use of synthetic biology such as invasiveness, persistence, unintentional introduction into the environment and the potential of altering natural populations.
9. However, some submissions also indicated that they do not have specific evidence of benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention, noting that the benefits and adverse effects of synthetic biology are to be considered on a case-by-case basis using robust risk assessment methodology and implementing sound risk management procedures.
10. Other submissions listed references, as indicated in Annex 1, to literature pointing to case studies and experiences gained from the application of synthetic biology to various uses, to demonstrate possible benefits and adverse effects of synthetic biology vis-à-vis the three objectives of the Convention.
11. **Experiences in conducting risk assessments of organisms, components and products of synthetic biology**
12. In describing their experiences in conducting risk assessments of organisms, components and products of synthetic biology, including any challenges encountered, lessons learned and implications for risk assessment frameworks, several Parties pointed to their existing risk assessment methodologies that have been in place and successfully applied in conducting risk assessments of living modified organisms for several years.
13. They also indicated that as organisms become more complex with advances in modern biotechnology, adaptations have been made to their exiting risk assessment frameworks in order to perform an adequate risk assessment. They also highlighted that in the event a risk assessment of an organism developed through synthetic biology is conducted that similar adaptations can be applied in order to obtain a methodology that satisfies the requirements posed by the organism at hand given the case-by-case nature of risk assessments.
14. Other submissions, however, highlighted that given that there are specific challenges posed by synthetic biology, existing risk assessment methodologies are inadequate when applied to the risk assessment of organisms developed through synthetic biology. Some of the gaps identified include the absence of suitable comparators, the presence of multiple modifications which may interact in unknown ways resulting in unexpected outcomes and that the accelerated rate of developing organisms using synthetic biology all of which pose challenges to regulatory systems in implementing current risk assessment methodologies. As such, there may be a need for additional research and the development of revised risk assessment frameworks to address these gaps.
15. **Examples of risk management and other measures**
16. With regards to examples of risk management and other measures that have been put in place to avoid or minimize the potential adverse effects of organisms, components and products of synthetic biology, including experiences of safe use and best practices for the safe handling of organisms developed through synthetic biology, some Parties listed several avenues through which this is being achieved, as follows.
17. With respect to LMOs that that are intended for release into the environment some countries indicated that their existing biosafety legislations, which also apply to organisms developed through synthetic biology, establish specific conditions which must be met and approved by the competent national authorities prior to the release of any such organisms. In addition, a monitoring plan should be put in place prior to the release. Furthermore, monitoring plans may include inspection measures and the use of testing methods to detect unauthorized LMOs that have been released into the environment.
18. With regards to organisms developed through synthetic biology that are intended for contained use, some countries indicated that their existing biosafety legislations set out specific containment guidelines for LMOs. These guidelines outline the varying levels of containment that are required when handling different types of LMOs and what measures are to be put in place when doing so.
19. **Regulations, policies and guidelines**
20. When describing regulations, policies and guidelines in place or under development which are directly relevant to synthetic biology, several submissions noted that their existing biosafety laws for regulating LMOs have been in place and successfully applied for several years. They also explained that within their national frameworks, the biosafety laws also extend to organisms developed through synthetic biology and that there is no specific legislation for synthetic biology.
21. Parties also reiterated the importance, under such regulations, of conducting risk assessments of any LMO or organism developed through synthetic biology on a case-by-case basis.
22. Regarding products of synthetic biology, in their submissions some Parties indicated that other regulations and instruments are already in place that provide the necessary risk assessment frameworks.
23. No guidelines focusing specifically on synthetic biology, either in place or under development, were mentioned in the submissions.
24. **Knowledge, experience and perspectives of indigenous peoples and local communities**
25. In discussing the knowledge, experience and perspectives of indigenous peoples and local communities in the context of living in harmony with nature for comparison and better understanding of the potential benefits and adverse effects of synthetic biology, Parties stressed importance of indigenous peoples and local communities being actively involved in the different deliberations on synthetic biology under the Convention and its Protocols.
26. In their submissions, Parties indicated that their existing biosafety frameworks, which they also apply to organisms developed through synthetic biology, have provisions for public participation, including specific provisions for consulting indigenous peoples and local communities. Such consultations take place through various means including having a specific liaison to work closely with them where activities may have applications or implications for the natural environment.
27. One Party also noted the importance of having the Ad Hoc Technical Expert Group on Socioeconomic Considerations under the Cartagena Protocol analyse the impact of synthetic biology on “productive chains of socio-biodiversity”.

**Annex 1**

**List of documents provided with submissions**

|  |  |
| --- | --- |
| **Title** | **Submitted by** |
| Synthetic Biology and Relevant International Law  <http://bch.cbd.int/database/attachment/?id=17559> | TWN |
| Biosafety aspects of genome-editing techniques  http://bch.cbd.int/database/attachment/?id=17560 | TWN |
| Biosafety Risks of Genome Editing Techniques in Plant Breeding  <http://bch.cbd.int/database/attachment/?id=17561> | TWN |
| Biosafety Considerations of Novel Plant Breeding Techniques  http://bch.cbd.int/database/attachment/?id=17562 | TWN |
| A CRISPR-Cas9 gene drive system targeting female reproduction in the malaria mosquito vector *Anopheles gambiae*  http://bch.cbd.int/database/attachment/?id=17564 | Imperial College London |
| A synthetic sex ratio distortion system for the control of the human malaria mosquito  <http://bch.cbd.int/database/attachment/?id=17565> | Imperial College London |
| Comite scientifique: Avis en réponse à la saisine du 12 octobre 2015 concernant l’utilisation de moustiques génétiquement modifiés dans le cadre de la lutte antivectorielle  <http://bch.cbd.int/database/attachment/?id=17566> | Imperial College London |
| Genome editing: scientific opportunities, public interests and policy options in the European Union  <http://bch.cbd.int/database/attachment/?id=17567> | Imperial College London |
| Synthetic Gene Drives in Australia: Implications of Emerging Technologies  <http://bch.cbd.int/database/attachment/?id=17568> | Imperial College London |
| Recommandation du CEES relative à la Saisine du 12 octobre 2015 sur l’utilisation de moustiques modifiés par les biotechnologies pour la lutte antivectorielle  <http://bch.cbd.int/database/attachment/?id=17569> | Imperial College London |
| Genetically Modified Insects  <http://bch.cbd.int/database/attachment/?id=17570> | Imperial College London |
| Impact of mosquito gene drive on malaria elimination in a computational model with explicit spatial and temporal dynamics  <http://bch.cbd.int/database/attachment/?id=17571> | Imperial College London |
| Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values  <http://bch.cbd.int/database/attachment/?id=17572> | Imperial College London |
| Requirements for effective malaria control with homing endonuclease genes  <http://bch.cbd.int/database/attachment/?id=17573> | Imperial College London |
| Position statement of the ZKBS [Central Committee on Biological Safety] on the classification of genetic engineering operations for the production and use of higher organisms using recombinant gene drive systems  <http://bch.cbd.int/database/attachment/?id=17574> | Imperial College London |
| Safeguarding gene drive experiments in the laboratory  <http://bch.cbd.int/database/attachment/?id=17575> | Imperial College London |
| Target Malaria’s response to the NAS Recommendations in: ‘Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values’  <http://bch.cbd.int/database/attachment/?id=17576> | Imperial College London |

|  |  |
| --- | --- |
| A decision analytic model to guide early-stage government  regulatory action: Applications for synthetic biology  <http://bch.cbd.int/database/attachment/?id=17579> | North Carolina State University |
| Synthetic Biology Governance: Delphi Study Workshop Report  <http://bch.cbd.int/database/attachment/?id=17580> | North Carolina State University |
| Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology  <http://bch.cbd.int/database/attachment/?id=17581> | North Carolina State University |
| Learn from DIY biologists  <http://bch.cbd.int/database/attachment/?id=17582> | North Carolina State University |
| Creating A Research Agenda For The Ecological Implications Of Synthetic Biology  <http://bch.cbd.int/database/attachment/?id=17583> | North Carolina State University |
| Engineering The Wild: Gene Drives And Intergenerational Equity  <http://bch.cbd.int/database/attachment/?id=17584> | North Carolina State University |
| Reboot the debate on genetic engineering  <http://bch.cbd.int/database/attachment/?id=17585> | North Carolina State University |
| Shaping ecological risk research for synthetic biology  <http://bch.cbd.int/database/attachment/?id=17586> | North Carolina State University |
| Societal Risk Evaluation Scheme (SRES): Scenario-Based Multi-Criteria Evaluation of Synthetic Biology Applications  <http://bch.cbd.int/database/attachment/?id=17587> | North Carolina State University |
| U.S. Trends In Synthetic Biology Research Funding  <http://bch.cbd.int/database/attachment/?id=17588> | North Carolina State University |
| The DNA Of The U.S. Regulatory System: Are We Getting It Right For Synthetic Biology?  <http://bch.cbd.int/database/attachment/?id=17589> | North Carolina State University |
| Genetically Engineered Crops: Experiences and Prospects  <http://bch.cbd.int/database/attachment/?id=17601> | North Carolina State University |
| Population Genetics Of Autocidal Control And Strain Replacement  <http://bch.cbd.int/database/attachment/?id=17602> | North Carolina State University |
| Broadening The Application Of Evolutionarily Based Genetic Pest Management  <http://bch.cbd.int/database/attachment/?id=17603> | North Carolina State University |
| Evaluating strategies for reversing CRISPR-Cas9 gene drives  <http://bch.cbd.int/database/attachment/?id=17604> | North Carolina State University |
| License to Kill? – Disease eradication programs may not be in line with the Convention on Biological Diversity  <http://bch.cbd.int/database/attachment/?id=17592> | European Network Of Scientists For Social And Environmental Responsibility |
| Mass Releases of Genetically Modified Insects in Area-Wide Pest Control Programs and Their Impact on Organic Farmers  <http://bch.cbd.int/database/attachment/?id=17593> | European Network Of Scientists For Social And Environmental Responsibility |
| Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis  <http://bch.cbd.int/database/attachment/?id=17598> | GenØk - Centre for Biosafety |
| Synthetic biology – biosafety and contribution to addressing societal challenges  <http://bch.cbd.int/database/attachment/?id=17599> | GenØk - Centre for Biosafety |
| Biofuelwatch Responds To First Open Pond Testing Of GMO Algae  <http://bch.cbd.int/database/attachment/?id=17612> | Biofuelwatch |
| Monster potential meets potential monster: pros and cons of deploying genetically modified microalgae for biofuels production  <http://bch.cbd.int/database/attachment/?id=17613> | Biofuelwatch |
| Microalgae Biofuels: Myths and Risks  <http://bch.cbd.int/database/attachment/?id=17614> | Biofuelwatch |
| Comments submitted to: EPA Workshop for Public Input on Considerations for Risk Assessment of Genetically Engineered Algae <http://bch.cbd.int/database/attachment/?id=17615> | Biofuelwatch |
| Beware False Promises: Algal Oils and Other Products of Synthetic Biology Aren’t About to Save the Orangutan.... But Carry Serious New Risks.  <http://bch.cbd.int/database/attachment/?id=17616> | Biofuelwatch |
| Unexpected mutations after CRISPR– Cas9 editing in vivo  <http://bch.cbd.int/database/attachment/?id=17617> | Biofuelwatch |
| Square Brackets synbio containment not possible  <http://bch.cbd.int/database/attachment/?id=17620> | Biofuelwatch |
| The Sustainability Council of New Zealand Trust v The Environmental Protection Authority  <http://bch.cbd.int/database/attachment/?id=17619> | Sustainability Council of New Zealand |
| The spread of commensal species of *Rattus* to oceanic islands and their effects on island avifaunas  <http://bch.cbd.int/database/attachment/?id=17621> | Island Conservation |
| The next generation of rodent eradications: Innovative technologies and tools to improve species specificity and increase their feasibility on islands  <http://bch.cbd.int/database/attachment/?id=17622> | Island Conservation |
| Memo: Genetic Biocontrol of Invasive Rodents Partnership and Investigation  <http://bch.cbd.int/database/attachment/?id=17623> | Island Conservation |
| Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values  <http://bch.cbd.int/database/attachment/?id=17624> | Island Conservation |
| Invasive mammal eradication on islands results in substantial conservation gains  <http://bch.cbd.int/database/attachment/?id=17625> | Island Conservation |
| Have the harmful effects of introduced rats on islands been exaggerated?  <http://bch.cbd.int/database/attachment/?id=17626> | Island Conservation |
| Recommandation du CEES relative à la Saisine du 12 octobre 2015 sur l’utilisation de moustiques modifiés par les biotechnologies pour la lutte antivectorielle  <http://bch.cbd.int/database/attachment/?id=17630> | France |
| Comite scientifique: Avis en réponse à la saisine du 12 octobre 2015 concernant l’utilisation de moustiques génétiquement modifiés dans le cadre de la lutte antivectorielle  <http://bch.cbd.int/database/attachment/?id=17629> | France |
| Report of the Synthetic Biology, Politics, and Philosophy Workshop  <http://bch.cbd.int/database/attachment/?id=17628> | University of Bristol |
| CRISPR/Cas9 targeting events cause complex deletions and insertions at 17 sites in the mouse genome  <http://bch.cbd.int/database/attachment/?id=17666> | Federation of German Scientists |
| Concerning RNA-guided gene drives for the alteration of wild populations  <http://bch.cbd.int/database/attachment/?id=17667> | Federation of German Scientists |

|  |  |
| --- | --- |
| Using CRISPR/Cas in three dimensions: towards synthetic plant genomes, transcriptomes and epigenomes  <http://bch.cbd.int/database/attachment/?id=17668> | Federation of German Scientists |
| Synthetic nucleases for genome engineering in plants: prospects for a bright future  <http://bch.cbd.int/database/attachment/?id=17669> | Federation of German Scientists |
| Unexpected mutations after CRISPR– Cas9 editing in vivo – Supplementary information  <http://bch.cbd.int/database/attachment/?id=17670> | Federation of German Scientists |
| Unexpected mutations after CRISPR– Cas9 editing in vivo  <http://bch.cbd.int/database/attachment/?id=17671> | Federation of German Scientists |
| Transformation-induced mutations in transgenic plants: Analysis and biosafety implications.  <http://bch.cbd.int/database/attachment/?id=17672> | Federation of German Scientists |

1. The notification and submissions are available online at <http://bch.cbd.int/synbio/submissions/2017-2018.shtml>. [↑](#footnote-ref-1)
2. http://www.biosintetica.mx/ [↑](#footnote-ref-2)