TARGET MALARIA STATEMENT ON SYNTHETIC BIOLOGY

COP14 Plenary Session of Working Group II

November 18 2018

Thank you Chair.

My name is Austin Burt. I am a professor at Imperial College London, and I speak on behalf of Target Malaria, a not-for-profit research consortium investigating the use of genetic technologies to stop malaria transmission.

Vector-borne diseases and invasive species are complex issues with enormous burdens in terms of human health and ecosystems. Existing approaches and methods have been partly successful in addressing these issues. But we are still far from success. Malaria cases are on the rise again after decades of progress, with 216 million cases of malaria worldwide in 2016.

We need to invest in research to develop novel approaches to complement the existing tools. Without new solutions, we will fail to meet the Sustainable Development Goals and the Aichi Targets.

Researchers have been investigating possible uses of gene drive for over 50 years. Current research is focused on whether it is possible and appropriate to use gene drive technology to help control vector-borne diseases and invasive species in sensitive native ecosystems.

We believe that the Convention on Biological Diversity can be a platform to foster knowledge and experience-sharing on the topic of gene drive research, in order to build the capacity of countries to assess future applications of the technology on a case-by-case basis.

The decisions taken by Parties should enable research, including fully regulated and risk-assessed small-scale experimental releases. This will help provide the knowledge and evidence needed to resolve the *"current uncertainties"* that are noted in the conclusions from SBSTTA 22. This important message is supported by many experts and scientists around the world, as demonstrated by the Open Letter published on Wednesday.

We urge Parties to avoid taking decisions that would stifle research, by creating scientifically unjustifiable barriers, high uncertainty, and open-ended delays. We encourage Parties to draw on prior experience, existing knowledge, and ongoing efforts by national authorities and expert institutions to guide researchers working on gene drive - work that is aiming to help some of the world's poorest people and most fragile ecosystems.

Thank you Chair.

ISLAND CONSERVATION STATEMENT ON SYNTHETIC BIOLOGY

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Salam Alaikum and thank you madam Chair for this opportunity to address the topic of synthetic biology.

My name is Royden Saah and I represent Island Conservation, and the Genetic Biocontrol of Invasive Rodents Partnership -- a group of seven NGO, government and academic research institutions from the United States, New Zealand, and Australia. Together we are cautiously investigating the feasibility and suitability of gene drive approaches to help prevent extinctions and achieve Sustainable Development Goals by eradicating invasive rodents from islands.

Gene drives are a natural phenomenon that can bias inheritance of key traits. First observed in the 1920s they have been studied for decades. Like in many other areas of research, there are many uncertainties that must be addressed before any decision on use can be made. If there were no unknowns, we would not need to conduct research. We are still years away from a gene drive organism being submitted to any regulatory agency for consideration for release.

The ability for communities and regulators to evaluate whether possible applications of gene drive technology are desirable, useful, and safe depends on scientists' abilities to conduct research, including potential field trials and evaluations after laboratory development phases are complete.

To ensure safety, we support processes that enable case-by-case assessment of each proposal by the national regulatory authorities, before field evaluations can proceed. The current proposals calling for a ban on field evaluations would effectively stop research on gene drive, undermine the principle of case-by-case assessments, and foreclose communities' opportunities to consider these tools in the future.

We should build on previous experience but avoid duplication of existing policies and guidance for research. Several national governments are undertaking reviews and updates of regulatory frameworks to ensure their readiness for gene drive evaluations--including the partner governments mentioned previously; and, many international organisations such as IUCN, US National Academy of Sciences, WHO, and others are also developing policies to guide or regulate this research.

We urge the Parties to ensure that prior and informed consent requirements for gene drive release be made explicitly consistent with national policies and frameworks to avoid confusion about which frameworks apply and which groups need to be involved.

Thank you Madam Chair

TARGET MALARIA STATEMENT ON RISK ASSESSMENT AND RISK MANAGEMENT

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November 18 2018

Thank you Chair,

My name is Delphine Thizy, and I speak on behalf of Target Malaria, a not-for-profit research consortium investigating the use of genetic technologies to stop malaria transmission

The CBD has an important role to play in supporting the capacity of national countries to assess different technologies, gene drive amongst them. Managing risk assessment of gene drive technologies does not require starting from scratch. There is a lot of experience to build on, as well as existing frameworks, such as those applied to other LMOs like GM crops.

We support the proposal to first review existing guidelines at the international and national level and other supporting documents available for guiding research on gene drive organisms. This review could be used to inform the decision by Parties on whether any specific questions would benefit from being discussed in the AHTEG.

We would stress that synthetic gene drive is an approach at an early stage and is being considered for a variety of possible applications. The risks and benefits associated with each gene drive application will vary, depending on the type of modification made, the species it is applied to, and the ecosystem and geography where the organism with the drive system would be used. As a result, it may be difficult to make broad generalizations about whether there are gaps in existing risk assessment methods that could apply to all evaluations of gene drive organisms.

However, understanding differences and the guiding questions that need to be answered would be useful. In that regard, we encourage Parties to consider existing published work, such as the paper by James et al., published in 2018: “Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group”.

While this conversation progresses, we urge Parties to refrain from putting a ban on experimental releases. These play a fundamental role in the research process and are needed to fully assess possible gene drive technologies. To ensure safety, each proposal for field evaluation should be subject to a case-by-case evaluation by regulatory authorities before it is allowed to proceed. Putting a ban in place will effectively act as a moratorium on research, hindering our ability to provide answers to the questions that are being asked.

Thank you Chair

TARGET MALARIA STATEMENT ON STAKEHOLDER ENGAGEMENT AND SYNTHETIC BIOLOGY

COP14 Plenary Session of Working Group II

November 28 2018

Dear Madam Chair,

My name is Delphine Thizy and I speak on behalf of Imperial College London for the Target Malaria project, a not-for-profit research consortium aiming at developing and sharing an innovative vector control technologies for malaria control in Africa.

We welcome the constructive discussions that have taken place during the last weeks on the topic of gene drive research, and the considerations made for both the benefits from potential applications and the need to manage this process carefully to ensure safety.

In reference to the genome editing discussion, our understanding is that gene drive is a LMO and that this would be managed under the Cartagena Protocol and that it would not be part of this discussion on genome editing.

While any potential regulatory application for an experimental release of mosquitoes containing a gene drive organism is still many years away, our project considers that engagement with stakeholders, at villages and national level, is as important as the scientific development in the laboratories. For over 5 years, we have been investing time and resources to establish a constructive dialogue with the communities and other stakeholders in the countries in which we work. This approach is based on a step-by-step engagement to ensure that potentially affected communities have access to evidence-based information and have sufficient time to make an informed decision about the research process, not only about potential releases of gene drive mosquitoes, but along the way about all the intermediate steps in the research. In addition to this, it aims at ensuring that stakeholders' perspectives feedback into our research and product design, in particular in risk assessment.

This process is guided by ethics protocols that are reviewed by institutional ethics committees in the countries where the research is taking place. It is framed by responsible research principles and follows national requirements.

Researchers in the field of gene drive have also started discussions about stakeholder engagement and consultation processes to understand how this may be best done if and when a gene drive organisms is proposed for release. These conversations are based on the recommendations of a number of Academies of Science around the world. There is an ongoing dialogue to learn from other relevant fields, including the field of area-wide vector control, to establish a set of principles for engagement. In addition, the funders and supporters of gene drive research forum has also clearly stated and committed to the importance of open and continuous engagement as part of responsible research.

Thank you Madam chair.