Part I. Endorsement of submission

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Part II. Submission of information

Issue and Trend 2: Transient modification of agricultural plants, pests and pathogens using RNAi or nanomaterials

1.Trend and issue in synthetic biology chosen

China started early and had a high starting point in the field of basic research. However, no products related to RNAi pesticides which due to the lack of scaled and systematic research investment. As of 2022, only Shanghai Zhi Sheng You Gu Biotechnology Co., Ltd. has achieved good control effects in field tests against pests such as cotton aphids (*Aphis gossypii*), peach aphids (*Myzus persicae*), and striped flea beetles (*Phyllotreta striolata*).

Additionally, Silray Technology (Shanghai) Co., Ltd., obtained approval from the National Pesticide Standardization Committee, and received three naming certificates for RNA biopesticides under the name "Nucleic Acid Interference Factors." These biopesticides mainly target nucleic acid interference factors against Tobacco Mosaic Virus (TMV) and have already entered the field testing stage.

2. Potential positive and potential negative impacts on the three objectives of the Convention

a. Conservation of biological diversity

The positive impact of RNAi pesticides is evident in their rapid degradation in the environment, low toxicity, and strong specificity. These advantages make them a potential gradual replacement for chemical pesticides, reducing the impact of chemical pesticides on biodiversity. However, potential negative effects are reflected in the impact of RNAi pesticides on non-target species. Different RNAi pathways and mechanisms in different organisms may lead to off-target effects. There is also the potential issue of resistance in target organisms after long term application.

b. Sustainable use of its components

The RNAi target genes of target organisms are crucial for the development of RNAi pesticide technology. Simultaneously, they represent a vital aspect of the sustainable utilization of biodiversity.

c. Fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Developed countries are leading in the research and development of RNAi pesticide technology, with some related products already entering the commercial production stage. Ensuring fair and equitable sharing of the benefits derived from genetic resources in developing countries requires further consideration.

3. Potential gaps or challenges for risk assessment, risk management and regulation, including availability of tools for detection, identification and monitoring

China has not yet established standards and technical indicators for the environmental risk assessment and risk management of RNAi pesticides. Simultaneously, there is a lack of a convenient, rapid, and highly sensitive detection method specifically designed for measuring dsRNA in the environment.

4. Potential linkages to the Kunming-Montreal Global Biodiversity Framework and potential contribution to other internationally relevant goals and targets

The development, application, and safety management of RNAi pesticides are closely related to Action Target 7 of the Kunming-Montreal Global Biodiversity Framework. Action Target 7 aims to "by 2030, reduce all sources of pollution and their adverse impacts on biodiversity and ecosystem functions and services to levels that are not harmful to biodiversity and have overall pesticide and high-risk chemical risks at least by half." RNAi pesticides, with their advantages of rapid degradation, low toxicity, and strong specificity, have the potential to reduce the impact of chemical pesticides on biodiversity. Their application aligns with the goals of minimizing pollution risks and adverse effects on biodiversity and ecosystem services outlined in Action Target 7.

Issue and Trend 3: Genome-edited plants

1. Trend and issue in synthetic biology chosen

China has conducted extensive and in-depth research in the field of genome-editing breeding. It has initiated and implemented major agricultural biotechnology projects, and genome-editing technology has been supported as a key breeding technology. Several genome-editing technology systems have been established, including targeted gene knockout, single base editing, allelic gene replacement and guide editing. These technologies have been successfully applied to the genetic improvement of major crops such as rice, wheat, and maize.

Among these techniques, CRISPR/Cas-mediated gene knockout and single-base editing are the most widely used. However, the efficiency of precise gene replacement and other forms of precise gene editing remains relatively low, limiting their application in crop improvement. Therefore, future efforts in genome-edited plants may focus on improving the genome editing system itself. This could include exploring more types of editing systems, reducing off-target effects to enhance editing efficiency, utilizing CRISPR editing for fine mapping and identifying new functional genes, and other improvements.

2. Potential positive and potential negative impacts on the three objectives of the Convention

Genome editing is one of the crucial tools for studying genome function and modifying the genome. It is also a novel breeding technology used to improve key economic traits in crops. The precision, controllability, and efficiency of genome editing significantly enhance the efficiency of biological breeding, making it more precise. The development and application of genome editing technology are of paramount importance for increasing the yield and quality of biological products, promoting sustainable development of agricultural resources, sustainable utilization of biodiversity, and ensuring global food security.

Genome editing technology itself has some problems and drawbacks, such as non-targeted editing. There is also the challenge of effectively distinguishing changes caused by gene editing from those caused by plant mutations and physicochemical mutagenesis. This may pose challenges in the precise detection and safety regulation of genome-edited plants. Careful research and effective management are necessary to address these issues and ensure that the application of gene editing technology is safe and sustainable.

3. Potential gaps or challenges for risk assessment, risk management and regulation, including availability of tools for detection, identification and monitoring

China has conducted research on the detection of genome-edited plants using techniques such as quantitative real-time PCR (qPCR), digital PCR (dPCR), and high-throughput sequencing technology (NGS). However, the detection of genome-edited plants involving only point mutations or the insertion or deletion of a few bases without the introduction a repair template or any exogenous genes still poses challenges.

To standardize and promote the research and application of gene-edited plants, in January 2022, China's Ministry of Agriculture and Rural Affairs officially issued the Guidelines for Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial), which outlines the declaration procedures and data requirements for gene-edited plants based on the principles of classification management and case analysis. In April 2023, the Ministry of Agriculture and Rural Affairs issued the Rules for Review of Gene-Edited Plants for Agricultural Use (Trial), which clarifies the classification criteria and requirements for evaluating gene-edited plants. The rules provide operational guidance in the areas of molecular function, environmental safety, and food safety, including acceptable data. It enhance the operability of the Guidelines for the Safety Evaluation of Gene-Edited Plants for Agricultural Use (Trial).

4. Timeframe to commercialization or release into the environment

In April 2023, China's Ministry of Agriculture and Rural Affairs issued the first safety certificate for plant gene editing for a high oleic acid soybean. However, to date, China has not yet issued operational rules on how to enter the new variety approval process for gene-edited crops that have received safety certificates.

5. Potential linkages to the Kunming-Montreal Global Biodiversity Framework and potential contribution to other internationally relevant goals and targets

The research, application, and associated safety risks of gene editing technology are directly relevant to Action Target 17 of the Kunming-Montreal Global Biodiversity Framework. Action Target 17 emphasizes "Establish, strengthen capacity for, and implement in all countries, biosafety measures as set out in Article 8(g) of the Convention on Biological Diversity." Strengthening the detection, identification, risk assessment, and safety management of genome-edited plants is a important component of enhancing biosafety capacity.

Issue and Trend 9：Interaction of synthetic biology organisms in the environment and potential for cumulative effects

1. Trend and issue in synthetic biology chosen

China started its research in this field relatively late but has made significant progress. On the positive side, the focus has been primarily on environmental monitoring and bioremediation. For instance, synthetic microorganisms with degradation genes have been utilized to achieve the degradation of persistent organic pollutants.

The team of Ningyi Zhou from Shanghai Jiao Tong University integrated a gene module encoding a cytochrome P-450cam variant into the non-essential gene region of a PCP-degrading bacterium by homologous recombination, and the recombinant strain was able to degrade hexachlorobenzene at an hourly rate of 0.67 nmol/ mg (dry weight) per hour and identified the intermediate product pentachlorophenol.

The iGEM team from Peking University has designed a sensor for detecting aromatic hydrocarbon pollutants using transcription factors (TFs). TFs are coupled to a fluorescent protein expression system to form a gene circuit that fluoresces when an aromatic hydrocarbon target molecules are present, thus realizing dynamic monitoring of specific pollutants in the environment.

On the negative side, the genetically modified genomes of synthetic organisms differ from those of natural organisms. When released into the natural environment, they may undergo mutations or introduce their DNA into natural organisms, potentially affecting biodiversity and disrupting ecological balance. Additionally, they may release DNA that was originally absent in the environment, impacting the existing gene pool in the natural environment. Moreover, synthetic organisms may hybridize with other organisms during the hybridization process, potentially leading to unknown species and associated risks. Therefore, there is a need for enhanced safety risk regulation for synthetic biology products.

2. Potential positive and potential negative impacts on the three objectives of the Convention

In terms of biodiversity conservation, synthetic organisms can help us understand the interactions between different species, thereby facilitating better protection and maintenance of ecosystems. It also opens up possibilities for developing new conservation measures, such as artificial ecosystems or gene banks, to address the damage to natural ecosystems caused by human activities.

In the context of sustainable utilization of biodiversity, the application of synthetic biology helps in developing new drugs, materials, and fuels, thereby reducing dependence on natural resources. Additionally, it contributes to the development of more efficient agricultural and industrial production methods, thereby reducing negative environmental impacts.

Concerning the benefit-sharing of genetic resources, the democratization and development of biotechnology are promoted through open-source code and shared resources, enabling more countries and organizations to benefit from biodiversity. Furthermore, understanding and preserving traditional knowledge and culture are crucial to maintaining and promoting human cultural diversity.

3. Potential gaps or challenges for risk assessment, risk management and regulation, including availability of tools for detection, identification and monitoring

Complexity of risk assessment: A comprehensive assessment of the interactions and potential cumulative effects of synthetic organisms in the environment requires interdisciplinary research and collaboration, including biology, environmental science, sociology, law, and ethics, and also requires consideration the impacts of the environment and other factors, which adds to the difficulty of risk assessment.

4. Potential linkages to the Kunming-Montreal Global Biodiversity Framework and potential contribution to other internationally relevant goals and targets

Synthetic biology is closely linked to the "Kunming-Montreal Global Biodiversity Framework." The framework aims to ensure the conservation and sustainable use of global biodiversity, while synthetic biology can contribute by designing and constructing biological systems with specific functions to protect species diversity in ecosystems and enhance the sustainable utilization of biodiversity. For example, synthetic organisms can assist in developing more effective biological control agents to manage the reproduction of harmful organisms or in creating new drugs and materials to reduce reliance on natural resources. Additionally, the framework provides guiding principles and regulatory foundations for synthetic biology to ensure its development does not have negative impacts on biodiversity. For instance, Action Target 17 in the framework addresses biotechnology and biosafety.

Synthetic biology can contribute to other international goals and targets, such as some of the United Nations Sustainable Development Goals (SDGs), including reducing poverty, promoting economic development, and improving health. Additionally, synthetic biology can further global environmental conservation and sustainable development through measures like protecting ecosystems and enhancing resource utilization efficiency.