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ISBR Webinar 2, 4Jun26: Biosafety considerations for gene drive organisms

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Quick Read

A video recording of the webinar is available HERE.

This webinar explored the latest developments in the biosafety assessment of engineered gene drive organisms, with particular emphasis on the recently published *Biosafety Technical Series No. 7 (BTS-7)* guidance under the Cartagena Protocol on Biosafety and the rapidly evolving scientific evidence underpinning gene drive technologies.

Key takeaways

BTS-7 provides practical guidance for regulators.
Dr Brinda Das outlined the development of BTS-7, an internationally developed voluntary guidance document that supports environmental risk assessments for living modified organisms containing engineered gene drives. The guidance complements existing biosafety frameworks by addressing the unique characteristics of gene drive organisms, including their potential for preferential inheritance, wide dispersal, persistence and population-level effects.

Risk assessment remains science-based and iterative.
The guidance emphasises structured problem formulation, pathways to harm and the translation of broad protection goals into measurable assessment endpoints. It also highlights the importance of ongoing monitoring and adaptive risk assessment to incorporate new information as evidence emerges.

The evidence base continues to expand rapidly.
Dr. Felix Moronta Barrias presented the *Monitoring Gene Drive* project, which continuously reviews new scientific literature relevant to gene drive biosafety. Emerging research is improving understanding of technical safeguards, ecological interactions, indirect effects and approaches to community engagement.

Safer gene drive designs are under active development.
A range of confinement and control strategies—including split drives, Daisy-chain drives, threshold-dependent systems and reversal drives—are being investigated to improve controllability while recognising that ecological performance remains uncertain until tested under realistic conditions.

Environmental deployment is still some way off.
Although gene drive research has advanced considerably, speakers noted that significant scientific, regulatory and societal challenges remain before environmental releases can occur. Field trials will be essential to generate the data needed for robust regulatory decision-making, with geographically isolated locations likely to be considered first.

Existing guidance is considered sufficient—but implementation capacity is critical.
Rather than developing additional guidance documents, speakers stressed the need to strengthen regulatory

capacity, improve dossier preparation, enhance evidence synthesis and support practical implementation of existing biosafety frameworks.

The webinar concluded with an invitation to participate in the next ISBR Webinar, focusing on AI-designed protein sequences, and the 2027 ISBR Symposium in Bali, Indonesia.

Meeting notes

- **Biosafety Guidance for Gene Drive Organisms:** Dr. Vibha introduced the webinar and Dr. Brinda Das presented a comprehensive overview of the development, contents, and methodologies of the Biosafety Technical Series 7 (BTS-7), a voluntary guidance document for risk assessment of living modified organisms containing engineered gene drives, with a focus on mosquitoes, highlighting its international adoption and practical application for regulators and assessors.
    - **Cartagena Protocol Overview:** Dr. Brinda Das explained the Cartagena Protocol on Biosafety as an international agreement obligating signatory countries to protect biodiversity and human health from potential risks associated with modern biotechnology, including GMOs and LMOs, and described its adoption and implementation by 173 countries.
    - **Development of BTS-7 Guidance:** Dr. Brinda Das detailed the multi-year process leading to BTS-7, including initial discussions at COPMOP 9 in 2018, recommendations from expert groups, drafting and review by international parties, and its final adoption and public launch by the CBD Secretariat, emphasizing the collaborative and iterative nature of its creation.

- **Unique Features of Gene Drives:** Dr. Brinda Das highlighted the unique attributes of gene drive organisms, such as biased inheritance, potential for wide dispersal, persistence, and population-level impacts, which necessitate additional risk assessment considerations compared to traditional LMOs, including the need for guidance on spread, reversal, and uncertainty management.
- **Risk Assessment Methodology:** Dr. Brinda Das described the risk assessment process outlined in BTS-7, emphasizing problem formulation, pathways to harm, and the translation of broad policy objectives into measurable scientific endpoints, using examples such as ecosystem services and bat population impacts to illustrate the approach.
- **Monitoring and Iterative Assessment:** Dr. Brinda Das explained that BTS-7 includes a dedicated section on monitoring, stressing its importance for iterative risk assessment, ongoing data collection, and adaptive oversight, with both case-specific and general surveillance to detect anticipated and unanticipated effects.

- **Evolving Evidence and Safeguards in Gene Drive Research:** Dr. Felix Moronta Barrias presented insights from the 'Monitoring Gene Drive' project, discussing the rapidly evolving evidence base, technical safeguards, ecological complexity, and community engagement approaches in gene drive research, emphasizing the need for continuous evidence synthesis and adaptive biosafety assessment.
  - **Continuous Evidence Synthesis:** Dr. Felix Moronta Barrias described the 'Monitoring Gene Drive' project as a living literature review that tracks and synthesizes emerging scientific evidence relevant to gene drive biosafety, addressing the challenge of keeping up with fast-moving research across multiple disciplines.
  - **Technical Safeguards and Confinement:** Dr. Felix Moronta Barrias outlined various technical strategies for safer gene drives, including split drive systems, Daisy chain drives, threshold-dependent and toxin-antidote systems, and reversal drives, noting their potential for increased confinement, controllability, and reversibility, as well as the uncertainties associated with their ecological behavior.
  - **Ecological Complexity and Indirect Effects:** Dr. Felix Moronta Barrias discussed the growing attention in the literature to ecological complexity, indirect effects, and context-dependent outcomes of gene drive interventions, highlighting the limitations of laboratory studies and the importance of modeling spatial dynamics, seasonality, and uncertainty in real-world settings.
  - **Community Engagement and Participatory Approaches:** Dr. Felix Moronta Barrias emphasized the increasing integration of community engagement, stakeholder participation, and interdisciplinary collaboration in gene drive research, noting that engagement should accompany technical development from early stages and be adapted to local contexts.
- **Challenges and Timeline for Environmental Application of Gene Drives:** Professor Detlef and Professor B.K. Tyagi raised questions about the expected timeline and challenges for the first environmental application of gene drives, with Dr. Brinda Das and Dr. Felix Moronta Barrias explaining the scientific, regulatory, and ecological hurdles, the need for field trials, and the unpredictability of which candidate organisms may reach field testing first.
  - **Scientific and Regulatory Hurdles:** Dr. Brinda Das explained that despite predictions for field applications by 2026, stable gene drive systems are difficult to develop due to scientific challenges, regulatory requirements, and the need for stakeholder feedback, resulting in slower progress than anticipated.

    - **Field Trials and Data Requirements:** Dr. Felix Moronta Barrias stressed the necessity of field trials in real environments to gather data for public health applications, noting that developers are considering geographically confined settings such as oceanic islands for initial releases, and that existing biocontrol technologies provide useful data but are not sufficient for gene drive organisms.
    - **Uncertainty in Candidate Organisms:** Dr. Brinda Das highlighted ongoing work in mosquitoes, rodents, and New World Screw Worm, but stated that it is difficult to predict which organism will be the first to reach field testing or market due to scientific and regulatory complexities.
    - **Impact of Biological and Environmental Factors:** Dr. Brinda Das noted that evolving disease vectors and climate change further complicate the timeline for gene drive interventions, as these factors can alter the spread and effectiveness of new technologies.
- **Capacity Building and Use of Existing Guidance:** Dr. Brinda Das and Dr. Felix Moronta Barrias responded to questions about the need for further guidance, agreeing that current biosafety frameworks and guidance are sufficient, but emphasizing the importance of capacity building, dossier preparation, and regulatory review to enable practical implementation.
    - **Implementation of Existing Guidance:** Dr. Brinda Das stated that no additional guidance is currently needed, but capacity building and practical use of existing frameworks are essential, including preparing dossiers and engaging regulators to assess sufficiency.
    - **Combination of Scientific, Regulatory, and Societal Conditions:** Dr. Felix Moronta Barrias added that successful field trials and implementation depend on a combination of scientific, regulatory, and societal factors, and that the bottleneck is not guidance but the integration of these aspects.
- **Upcoming ISBR Symposium and Webinar Announcements:** Dr. Vibha announced the next ISBR symposium in Bali, Indonesia in October 2027 and the third webinar in the series scheduled for October 2026, inviting participants to attend and highlighting opportunities for collaboration and learning.
    - **ISBR Symposium Details:** Dr. Vibha shared that the ISBR symposium is held every two years, bringing together scientists, regulators, policy makers, industry, and communicators, with the next event scheduled for Bali in October 2027.
    - **Webinar Series Continuation:** Dr. Vibha announced the third webinar in the series will take place on 26th October 2026, focusing on AI-designed protein sequences.

Recommendations

- **Capacity Building for Biosafety Guidance:** Build capacity around the existing biosafety guidance (BTS-7) by encouraging its use and collecting feedback on its sufficiency from users and regulators.
- **Evidence Synthesis for Gene Drive Developments:** Continue synthesizing and updating the evidence base on gene drive research, including technical, ecological, and engagement aspects, to support informed and adaptive discussions.