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ISBR Webinar 1, 5Mar26: Data requirement considerations for GEd/NGTs

AI-generated meeting notes from Microsoft Teams, please confirm accuracy.

Quick read

A video recording of the webinar is available HERE.

The ISBR webinar focused on regulatory frameworks and data requirements for plants developed using new genomic techniques (NGTs) in the European Union and Latin America, especially Brazil. It highlighted the evolving legislative landscape, regulatory categories, and international cooperation challenges related to biotechnology and biosafety.

- **Webinar overview and purpose:** The webinar introduced speakers and the EU-Mercosur partnership agreement's relevance to biotechnology, structured with presentations and discussions aimed at ISBR members. It is the first in a planned series addressing current regulatory topics.
- **EU regulatory framework for NGT plants:** The EU legislative process involves the Council, Parliament, and Commission, with current GMO laws classifying NGT plants as GMOs. A new regulation is proposed to better fit certain NGT plants, expected by 2026, categorizing plants into two groups based on equivalence to conventional plants and defining distinct data requirements.
- **Biosafety data and GeneBEcon insights:** Category 1 plants require technical information and declarations without risk assessment, whereas Category 2 plants need authorization and adaptive risk assessments. The GeneBEcon project found that adapted regulatory approaches could reduce costs and regulatory uncertainty affects investment decisions.
- **Brazilian and Latin American regulatory approaches:** Brazil's biosafety law and CTNBio regulatory body oversee gene editing with a case-by-case consultation system since 2018, focusing on absence of recombinant DNA and natural mutation criteria. Similar regulatory alignments exist across several Latin American countries.
- **Regulatory discussion highlights:** Participants discussed exclusion of herbicide and insecticidal traits from EU Category 1 due to policy aims, criteria for nutritional equivalence, and data requirements for off-target effects, with some details still pending finalization in the EU.
- **Market status and definitions:** It was noted that most gene-edited products, especially microorganisms, are already in use in Brazil. Clarifications were provided on what constitutes naturally occurring mutations, with examples from animal breeding.
- **Import and trade alignment challenges:** The EU regulation is intended to cover both cultivation and imports of NGT plants, though implementation details remain unclear. Aligning data requirements between the EU and Mercosur countries poses challenges essential for facilitating trade.
- **Webinar conclusion and follow-up:** The webinar closed with invitations for future topic suggestions, announcements of upcoming ISBR events, and commitments to share presentation materials and recordings with participants. Follow-up tasks include sharing market status of gene-edited products in Brazil and making the webinar recording available.

Meeting notes

- **Introduction to ISBR Webinar and EU-Mercosur Agreement Context:** Detlef Bach opened the ISBR webinar, outlining its structure, introducing speakers Katharina Unkel and Marcos Pupin, and providing context on the EU-Mercosur partnership agreement's relevance to biotechnology and biosafety data requirements.
    - **Webinar Structure and Objectives:** Detlef Bach explained the webinar's format, consisting of two 20-minute presentations followed by a 20-minute discussion, and emphasized the focus on current topics relevant to ISBR members, with the session being recorded for later publication.
    - **Speaker Introductions:** Detlef Bach introduced the speakers: Katharina Unkel, who would present the EU perspective on data requirements for new genomic techniques, and Marcos Pupin, who would provide the Brazilian and Latin American regulatory perspective.
    - **EU-Mercosur Agreement Overview:** Detlef Bach described the EU-Mercosur partnership agreement, highlighting its impact on biotechnology, the member states involved, and the establishment of a framework for cooperation on agricultural biotechnology, including asynchronous GMO authorization and information exchange.
    - **Webinar Series and Future Plans:** Detlef Bach announced that this webinar is the first in a series, with future sessions planned and encouraged participants to suggest topics via a provided email address.

- **EU Regulatory Framework for New Genomic Techniques in Plants:** Katharina Unkel presented an overview of the EU's legislative process, the current and proposed regulations for plants developed with new genomic techniques (NGTs), and the associated biosafety data requirements, referencing the GeneBEcon project.
    - **EU Legislative Process and Genetic Engineering Law:** Katharina Unkel explained the EU's ordinary legislative procedure involving the Council, Parliament, and Commission, and described the shared legal framework for GMOs, including field trials, cultivation, and import, as well as the definition of GMOs in EU law.
    - **Emergence of New Genomic Techniques:** She detailed the development of new genomic techniques (NGTs) such as CRISPR/Cas9, TALENs, and cisgenesis, and noted that a 2018 decision classified plants bred with these techniques as GMOs under EU law.

    - **Proposal for New Regulation:** Katharina outlined the EU Commission's study concluding that the current genetic engineering law is not fit for certain NGT plants, leading to a provisional agreement on a new regulation, expected to be adopted and published in 2026, with application starting two years later.
    - **Categories of NGT Plants and Criteria:** She described the two categories of NGT plants: Category 1 (equivalent to conventional plants, with verification and labeling but no risk assessment) and Category 2 (not equivalent, requiring authorization, adaptive risk assessment, and traceability), along with the specific criteria for equivalence.
    - **Biosafety Data Requirements:** Katharina explained the data requirements for both categories, including technical information, declarations, and scientific evidence for Category 1, and a case-by-case, trait-dependent approach for Category 2, with the possibility for the Commission to update requirements as needed.
- **GeneBEcon Project Insights:** She presented findings from the GeneBEcon project, which analyzed regulatory options and cost implications for NGT plant data requirements, showing that adapted approaches could significantly reduce costs and that regulatory uncertainty impacts investment decisions.

- **Brazilian and Latin American Regulatory Approaches to Gene Editing:** Marcos Pupin provided an overview of Brazil's biosafety law, the evolution of its regulatory framework for gene editing, the case-by-case consultation system, and the alignment of Latin American countries with international best practices for gene-edited products.
    - **Brazilian Biosafety Law and Regulatory Evolution:** Marcos Pupin described Brazil's biosafety law, its focus on scientific advancement and safety, and the establishment of CTNBio as the regulatory body, with updates to regulations in response to technological advances such as CRISPR-Cas9.
    - **Case-by-Case Consultation System:** He explained the 2018 Normative Resolution implementing a case-by-case system to determine if products developed with new breeding techniques (NBTs) should be classified as GMOs, based on criteria such as absence of recombinant DNA and the nature of induced mutations.
    - **Data Requirements and Workflow:** Marcos outlined the information required from developers, the comparative study package requirements for GMOs versus gene-edited products, and the workflow for regulatory review, including timelines and committee involvement.
    - **Product Examples and Regulatory Impact:** He provided examples of approved products, such as edited yeasts for ethanol production, drought-resistant soybeans, and high-protein fish, and discussed the broader adoption of similar regulatory criteria across Latin American countries.
    - **Regional and International Alignment:** Marcos highlighted the alignment of regulatory approaches among Argentina, Brazil, Chile, Colombia, Ecuador, Guatemala, Honduras, Paraguay, and Uruguay, and noted ongoing debates or prohibitions in other countries.
- **Discussion on Regulatory Details, Data Requirements, and International Trade Alignment:** Participants including Ben Durham, German Viggy, Salvatore Apaya, Luis, Hennie, Detlef Bach, Katharina Unkel, and Marcos Pupin discussed specific regulatory questions regarding EU and Brazilian frameworks, data requirements for off-target effects, equivalence criteria, and challenges in aligning EU and Mercosur regulations for international trade.

    - **Exclusion of Herbicide and Insecticidal Traits from EU Category 1:** Katharina Unkel clarified that herbicide tolerance and insecticidal traits are excluded from Category 1 in the EU due to policy aims to minimize herbicide use and potential risks to non-target organisms, with Detlef Bach noting the political nature of this compromise.
    - **Nutritional Equivalence and Category Assignment:** Katharina explained that for Category 1, only equivalence criteria are considered, not compositional data, and that significant changes in nutritional characteristics would move a plant to Category 2 for further assessment.
    - **Off-Target Effects and Data Requirements:** Ben Durham and others raised questions about requirements to check for non-target modifications in gene-edited plants; Katharina and Marcos confirmed that absence of off-target effects should be analyzed, but the extent of required data is still to be determined in the EU.
    - **Market Status of Gene-Edited Products in Brazil:** German Viggy inquired about the number of gene-edited products on the market in Brazil; Marcos responded that most are already in use, especially microorganisms, and offered to provide more detailed information later.
    - **Definition of Natural Mutations:** Salvatore Apaya asked for clarification on what constitutes a 'mutation that may occur naturally'; Marcos provided examples from animal breeding, such as hair length and horn size, to illustrate the concept.
    - **Application of EU Regulation to Imports:** Luis questioned whether the EU's Category 1 and 2 distinctions apply to imports as well as cultivation; Katharina and Detlef indicated that the regulation is intended to cover both, but details on implementation and cost allocation remain unclear.
    - **Alignment of EU and Mercosur Data Requirements:** Hennie and Detlef discussed the challenges of aligning data requirements between the EU and Mercosur countries, noting that ongoing negotiations and regulatory developments will be crucial for facilitating trade without unnecessary barriers.
- **Webinar Conclusion and Next Steps:** Detlef Bach closed the webinar by inviting suggestions for future topics, announcing the next ISBR conference in Indonesia, and confirming that presentation materials and recordings would be made available to participants.
    - **Future Webinars and Conference Announcements:** Detlef Bach encouraged participants to submit ideas for future webinars and highlighted the upcoming ISBR conference in Indonesia, inviting further engagement and session proposals.
    - **Access to Materials and Recordings:** He assured attendees that presentation slides and the webinar recording would be shared, with details to be provided via the ISBR website and YouTube.

Recommendations

- **Webinar Topic Suggestions:** Send suggestions for future webinar topics to the provided ISBR email address. (All participants)
- **Gene-Edited Product Market Status:** Check and share which gene-edited products are already on the market in Brazil, including those using NBTS, with German. (Marcos Pupin)
- **Webinar Recording Availability:** Ensure the webinar recording is made available (e.g., on YouTube) and notify participants of the link. (Detlef)