



EcoNexus



TWN  
Third World Network

## SIDE EVENT

### Current guidance on risk assessment with focus on gene drive organisms is unfit for purpose

**Wednesday 23 October 2024, 16:30 - 17:50**  
**Nuqui - Academia & Research meeting room**  
**Plaza One**

#### Organised by:

European Network of Scientists for Social and Environmental Responsibility (ENSSEER)  
Third World Network (TWN)  
EcoNexus  
Federation of German Scientists (VDW)  
African Centre for Biodiversity (ACB)

Living modified organisms containing engineered gene drives (EGD-LMOs) are a novel form of genetic engineering technology that aims to spread a genetic modification throughout entire wild populations (of insects, other animals or plants), with the explicit design intention of spread and persistence. This is crucially different from other LMOs, which are intended not to spread. Due to these novel characteristics and broad application aims, EGD-LMOs pose fundamental challenges to current risk assessment (RA) methodologies, that were largely designed for annual crop species. As such, additional guidance materials on risk assessment were drafted by the 2023-2024 Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment.

#### PROGRAMME

Moderator: Dr Ricarda Steinbrecher, Federation of German Scientists  
Each presentation will include a few minutes for questions.

**16:30 Introduction**                      **Dr Ricarda Steinbrecher, Federation of German Scientists**

**16:45 Dr Angelika Hilbeck, ret. from Swiss Federal Institute of Technology, Switzerland**

The current guidance materials on risk assessment (RA) of EGD-LMOs adopt a Problem Formulation (PF) approach that is unsuitable for the task. PF is a key entry step that defines the inclusiveness or exclusiveness of the subsequent risk assessment process. What is excluded at this decisive step will not come in later. Hence, developers have great vested interest in making RA an exclusive rather than inclusive process to lower costs, responsibility and accountability for both efficacy and risks. The current approach taken in the guidance materials rather meets the needs of the developers than complying with precaution. Most importantly, the underpinning concepts are outdated as they were designed for RA of primarily Bt crop plants. Also, suitable alternative RA and PF concepts were ignored.

**17:00 Dr Nicolas Defarge, IICAR-CONICET-UNR, Argentina**

The process by which the Problem Formulation approach was adopted in the elaboration of the guidance materials on RA of EGD-LMOs was inadequate and, regrettably, unduly influenced by a limited number of experts. This brings into question the utility of the approach for risk assessment. Regarding the content of the guidance materials, it should be mentioned that the potential benefits of synthetic biology applications received more attention than potential risks that are specific to EGD-LMOs (these will be detailed during the side event), which is more than counterintuitive in a guidance on Risk Assessment.

**17:15 Dr Eva Sirinathsinghji, Third World Network**

There is a potential lack of alignment of the guidance materials with the Cartagena Protocol on Biosafety, in particular with its precautionary approach and its Annex III on risk assessment. Concerns around conflicts of interest also question the integrity and reliability of the guidance materials.

**17:30 Discussion**

**17:50 End**