

Issues in Regulatory Science for Gene Drive-Modified Insects

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Development of tools using new technologies, such as gene drive, may raise questions about the adequacy of existing regulatory paradigms. This workshop aimed to provide a deliberative space for international experts in regulatory science and risk assessment to consider whether gene drive products would present any new issues that are not addressed by regulatory frameworks and procedures currently used to assess regulated insects or regulated insect control products. Some of the aspects discussed at the workshop included, implications of product design and potential uses, implications of spread and persistence in the environment, data that maybe required in regulatory submissions for contained use and field release, and safety criteria for moving from contained use to initial release. There was overall agreement on several key points such as involving all relevant regulatory authorities efficiently and early in the process, evaluation should be case-by-case with the transformed insect being the regulated product, developers should have a clear goal for their product such as pest control or health benefits, risk assessment and data requirements would differ based on the type of gene drive and the strategy- population suppression versus population modification, developers should be ready to provide risk management plans, modeling would be an important tool for addressing gaps, and experience from other regulated products such as biocontrol agents and sterile insect technologies could assist with general expectations of data types and application form questions.

Participants agreed on the value of deliberating these issues among experts and recommended revisiting regulatory application forms for GM organisms with the goal of working towards generating a consensus application form specifically for GM insects for further consideration in a subsequent meeting.