A MODERNISED APPROACH TO GM CROP REGULATION

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INTRODUCTION

After more than twenty-five years of experience regulating GM crops, the time has come to modernise the safety assessment process for GM crops. Despite scientific consensus around the safety of genetically modified (GM) crops, and the evidence of the benefits they provide, GM crops continue to be subject to extensive data requirements and long regulatory approval timelines which delay or prevent commercialisation. This is partially due to the lack of harmonised regulations for GM crops around the world. Furthermore, current regulations often require data that are not proportionate to the potential risk posed by GM crops or that do not contribute to the safety assessment. If different governments had more consistent and risk proportionate regulatory frameworks and requirements, agricultural innovations could move more quickly to farmers and consumers, further helping with the adoption of more sustainable farming practices that benefit biodiversity and the environment.

METHODOLOGY

The regulatory harmonisation project of CropLife International drew on the wealth of experience that has been accumulated since the first GM crops were commercialised in 1994, as well as on the enhanced understanding of plant genomes and the history of safe use of GM crops over the last decades. The project re-examined the data requirements for GM crops to determine what data is relevant to the safety assessment of specific GM events. The project also considered the long history of safe conventional breeding as it applies to stacked GM trait products (also known as 'breeding stacks').

RESULTS

A modernised assessment should be based on a weight-of-evidence, stepwise approach that uses a set of core studies to perform the safety assessment of GM plants. Depending on the nature of the introduced trait, intended use, and data obtained from core studies, supplementary (case-by-case) studies may be required to fully evaluate the safety of the GM plant. Any requirements for supplementary studies should be hypothesis driven. For example, compositional assessment is a supplementary study, for consideration only when

the trait mode of action could alter a metabolic pathway. Compositional assessment should also be limited to the components that are hypothesised to be affected by the trait and that are also relevant to safety or nutrition.

In the case of stacked trait products, combining currently approved single traits by conventional breeding does not result in additional risk. Any potential for trait interaction can be assessed based on the mode of action of each trait without the need for additional experimental data in most cases. The assessment of large stacks, if necessary, should consider the approval of all lower-order stacks possible.

DISCUSSION

Regulatory harmonisation encompasses a spectrum of practices that includes the use of consistent criteria and alignment of data requirements among regulatory bodies, as well as the sharing of safety assessments, and the implementation of streamlined processes when a product has already been approved by a harmonised regulatory body. Aligning on data requirements creates opportunities for further harmonisation, therefore the science-based data package requirements described in the papers can serve as a standard for regulatory harmonisation.

Regulatory modernisation and harmonisation should increase transparency and reduce regulatory burden, allowing agricultural innovations to reach the market faster, providing important benefits to farmers, consumers, and the environment. Small developers in particular would benefit from these changes, stimulating investment in this sector. With the increasing repertoire of GM plant products anticipated in the future, a science-based, harmonised regulatory paradigm will enable innovation and delivery of products that will have a positive impact on the global economy, the environment, and agricultural sustainability.