GENETICALLY MODIFIED MICROORGANISMS FOR AGRICULTURAL USE

The need for a fit for purpose regulatory approach

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The development and use of biologicals in agriculture is of growing interest globally. In the Latin American region, agricultural countries like Brazil and Argentina have extensive experience with biologicals for bicontrol and as seed inoculants. The potential for improving the efficacy of these products by means of gene technologies is very promising, however, the regulatory oversight of these innovations needs adaptation to become fit for purpose.

1 Define potential harms to protection goals

Preservation of agricultural production and Ecosystem services	Human and animal health	Protection Goals Drive the PF process

2 Gather relevant information

Familiarity (knowledge and experience), phenotype and intended use allow to define plausible risk hypotheses

3 Identify plausible and testable risk hypotheses

Based on available information and the similarity to the non-modified host (comparative approach)

4 Refine risk hypotheses

Analyze the possible paths to harm under probable exposure scenarios

Proceed to registration — Proceed to step 5

5 If relevant hypotheses cannot be responded with available information, define a study plan with measurable objectives

A thorough characterization is possible under contained conditions - specific cases could need field studies

The Biotechnology Working Group at ICCAS* identified the need for a scientific discussion on this matter and considered alternatives to the current paradigm, developed over 30 years ago for transgenic plants.

Discussions were intended to contribute to a science-based approach adapted to the nature of these products -which are not chemicals nor plants- and bring to light the need for a paradigm shift to assess their biosafety.

The unique challenges posed by GMM, the profound differences between the biology and genetics of microorganisms and those of higher organisms makes it very difficult to apply the same criteria developed for plants.

A recent publication summarizes current scientific knowledge on the complexities of the microbial world and proposes to use established conceptual risk assessment tools like Problem Formulation, the Comparative Approach and Familiarity, also considering that for microorganisms, it is possible to develop a complete biosafety data package under lab and contained conditions. This approach would make efficacy field testing possible with adequate pre-release biosafety information.

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