Viewpoint: India's proposed CRISPR crop rules could 'severely constrain' geneediting innovation

At long last, [India's] Department of Biotechnology has [published] <u>draft genome editing guidelines</u> on January 9 for month-long public comments. But, the regulatory pathway it has proposed for approval of plants with novel traits developed with the technology is dismaying.

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The guidelines propose a tiered regulatory approval process. In Group I, are plants whose genomes have been minimally-modified with one or a few base pair edits or deletions The risk assessment for this category would be to confirm that only targeted genome edits have been done and to rule out significant off-target changes.

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In Group II, are those plants whose cells harbor a few or several base pair edits. The plants will have to undergo trait efficacy trials and will be assessed for equivalence with similar varieties (except for the targeted changes). In Group III, are plants with large DNA changes, including insertion of foreign DNA. The risk assessment will be the same as for plants that are genetically-modified (GM) with foreign genes.

Given the propensity of our bureaucrats for control, and the tendency of lawmakers and environment ministers to be swayed by fear-mongering political and anti-GM activists, the proposed regulatory requirements might severely constrain the use of genome-editing techniques.

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