Case-by-case assessment of the risks of plants derived from new genomic techniques



Proposed decision tree for site-directed mutagenesis

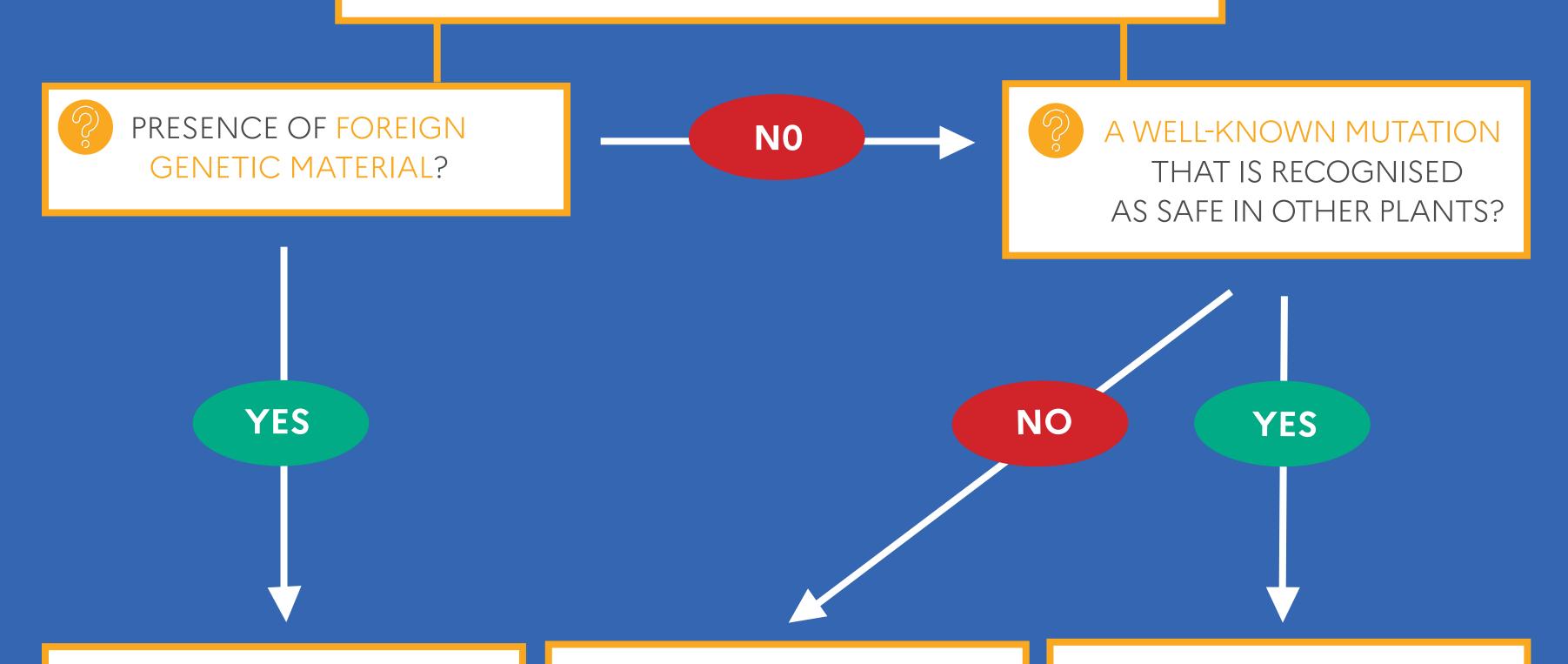
(ANSES Opinion of 22 January 2024 following Request No 2021-SA-0019)



TO BE PROVIDED IN THE DOSSIER

Applicants: manufacturers and start-ups wishing to obtain marketing authorisation (MA) in the European Union

- Complete characterisation of the genetic modification
- Demonstration of the absence of risks in the event of undesirable modifications
- Detection method





CURRENT ASSESSMENT FRAMEWORK

Full risk assessment in accordance with GMO regulations in force



ADAPTED

ASSESSMENT FRAMEWORK

- Verification of the modified trait's impact on the plant (e.g. nutritional composition,
- presence of toxins, biological mechanisms)
- Analysis of any food allergens
- Monitoring of environmental effects specific to the species and new trait



SIMPLIFIED

ASSESSMENT FRAMEWORK

Composition compared with reference plants

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