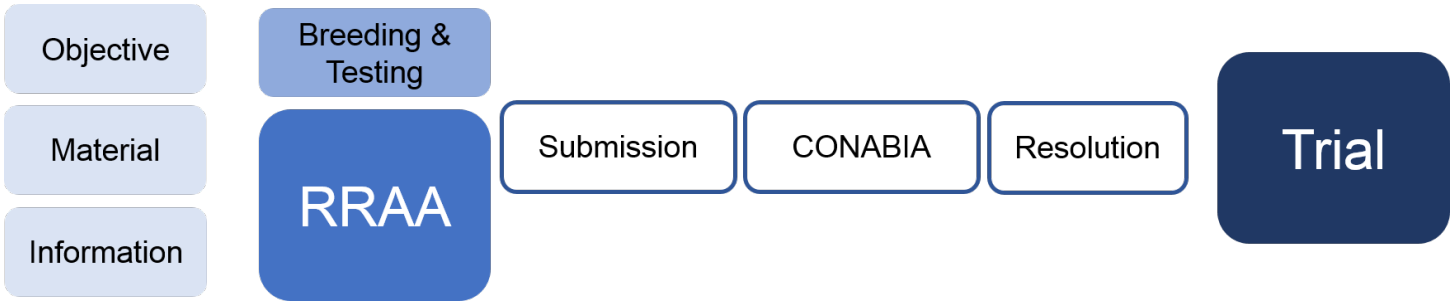
REGULATORY AFFAIRS

We provide different services linked to advanced development and/or approval of biotech products including from the design of the regulatory strategy to the comercial approval.

FIELD TRIAL PERMITS FOR REGULATED MATERIAL

- The client should provide detailed technical information related to the material to be tested and the intended goals of the trial.
- RRAA group working together with other areas within INDEAR, will design pertinent activities and fill the oficial permit form.
- After submission to CONABIA, we take care of any questions and/or observation and modify the presentation accordingly until the permit is granted.
- Reception of the oficial document (Resolution) from the Secretaría de Alimentos y Bioeconomía is the final milestone that allow the beginning of the activities.



REGULATORY STUDIES

We design, coordinate and execute a wide set of studies

COMPOSITIONAL

Comparative compositional analysis

BIOINFORMATIC

ORF search. Homology with allergens and toxins

TOXICOLOGY

Coordination of toxicologycal studies

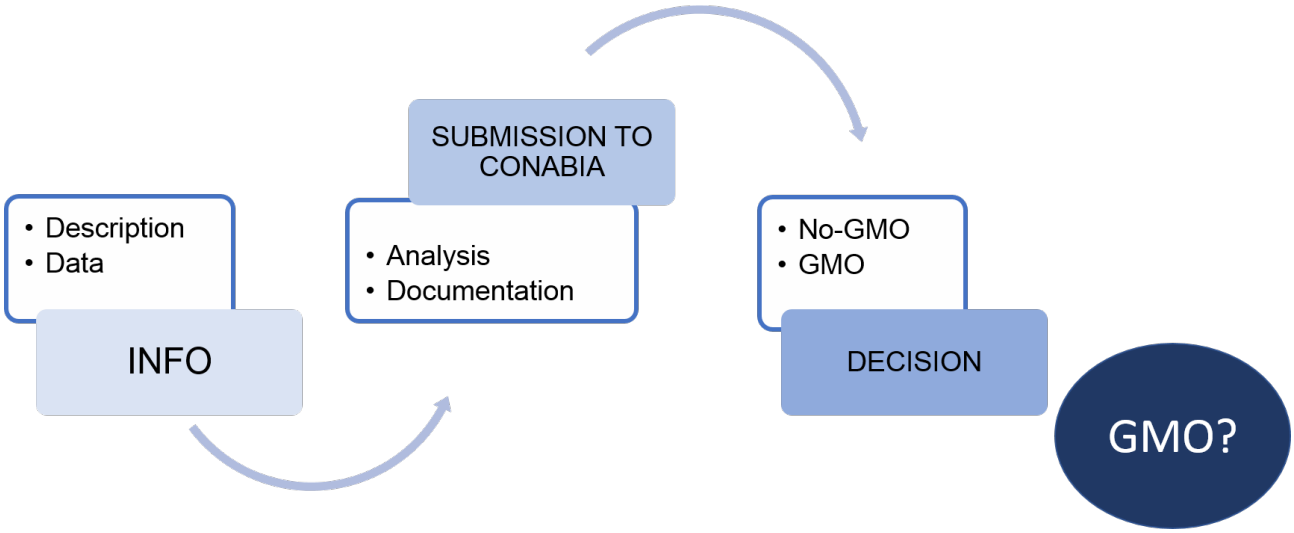
NUTRITIONAL

Design and coordination of efficacy or nutritional equivalence studies

REGULATORY STATUS VERIFICATION

The products obtained by new breeding techniques might be considered non-GMO

- The client should provide detailed information for the product (production method, new features introduced, molecular analysis that sustains the non-GMO request).
- All the data provided is analyzed and processed to be presented to CONABIA. After submission, we take care of any questions and/or observation and modify the presentation accordingly untill a final decisión is granted.



REGULATORY SUBMISSION FOR COMMERCIAL APPROVAL

- The information (provided and/or generated) is processed to prepare specific dossiers to be submitted to each regulatory agency.
- Pre and post-submission service: interaction with the client and the regulatory authorities untill approval is granted.
- Submission to other regulatory agencies within LATAM.