

CONTRACTOR BIOINFORMATIC EFSA/GMO/2021/06

AN UPDATE

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Applicants meeting
18 April 2023

CONTRACTOR'S OVERVIEW

- Ecomole s.r.o.
 - UK-based company with an EU-based branch established in Prague, Czech Republic in January 2019
 - Objectives 1: Preparatory work on completeness, compliance and quality of the BI analysis provided in GMO dossiers for the risk assessment of GM plants. Each dossier may contain BI analysis for a single event or a number of stacked GM events.
 - Objectives 2: Propose a harmonized structure for the BI analysis submission in GMO applications (after 1 year)
- Assessing data package since September 2022
- Several data package evaluated from different applications



CONTRACTOR'S MAIN OBSERVATIONS ON GENE INTERRUPTION

- Only reference genome used – justification needed for inter- and intra-species analysis
- Only top alignments are shown when using reference genome



CONTRACTOR'S MAIN OBSERVATIONS ON ALLERGENICITY

- Transparency on how the query sequence is analysed (overlapping 80-mers)
- Transparency on the databases' construction (internal database vs online databases)
- Limiting ORFs length to ≥ 8 amino acids with no justification



CONTRACTOR'S MAIN OBSERVATIONS ON TOXICITY

- Transparency on the databases' construction (internal database)
- Limiting ORFs length to ≥ 8 amino acids with no justification
- Use of e-values for significance with no clear justification how this threshold was derived and whether it is appropriate



SUMMARY

- Ecomole to become more accustomed to the data package submitted by applicants
- Open dialogue with applicants – more feedback at the next meeting?
- [Objectives 2:Propose a harmonized structure for the BI analysis submission in GMO applications (after 1 year)]



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