

BIOINFORMATIC HARMONIZED SUBMISSION STRUCTURE

Tommaso Raffaello
Meeting with Industry
8 April 2024



CONTRACTOR'S OVERVIEW

- External contractor currently involved in preparatory work for assessment of BI analyses (pre- and post-TR)
- Ecomole s.r.o.
- UK-based company with an EU-based branch established in Prague, Czech Republic in January 2019
- **Objective 1: Preparatory work on completeness, compliance and quality of the BI analysis provided in GMO dossiers for the risk assessment of GM plants for FF use. Each dossier may contain BI analysis for a single event or a number of stacked GM events.**
 - Assessing data package since September 2022
 - Several data package evaluated from different applicants/applications
- **Objective 2: Propose a harmonized structure for the BI analysis submission in GMO applications**



PROPOSE A HARMONIZED STRUCTURE FOR THE BI ANALYSIS (OBJECTIVE 2)

- Contractor proposed a **harmonized submission structure** – data entry form
- Based on the experience gained in assessing BI data package (Sept 2022 and 2023)
- Objectives of the harmonized submission structure:
 - Standardize analyses across applicants (new applicants)
 - Increase transparency
 - Shorten RA timelines
 - Reduce clarification questions



HARMONIZED SUBMISSION STRUCTURE

Excel file including the following 7 tabs:

- General
- BI completeness checklist
- 1. Gene interruption
- 2. Allergenicity - Celiac disease
- 3. Allergenicity
- 4. Toxicity
- 5. Horizontal gene transfer



TAB: *GENERAL*

- An overview of the analyses conducted in all areas
- Similar to the BI Summary Table currently in the Administrative Guidance ([link](#))
- Proposal to include the study number where the analysis can be found



TAB: *BI COMPLETENESS CHECKLIST*

- Checklist (YES/NO) to assist the inclusion of essential information about the analyses:
 - Databases
 - Methods
 - Results/Summary of Results
 - Assessment of the Results/Discussion
 - **Appendices**



5 TABS SPECIFIC FOR EACH ANALYSIS

Five BI analyses:

- 1. Gene interruption
 - 2. Allergenicity - Celiac disease
 - 3. Allergenicity
 - 4. Toxicity
 - 5. Horizontal gene transfer
- Each tab is specific for each analysis
 - Database: distinction between in-house and publicly available database
 - Methods: more clarity on the use of default settings
 - Results



SUMMARY

- Ecomole to become more accustomed to the data package submitted by applicants
- Harmonized submission structure for BI analyses proposed
- Open dialogue with applicants
 - Comments welcome to the current proposal
 - Revision of harmonized structure after implementation by applicants (Deliverable 8) of the FWC Contract OC/EFSA/GMO/2021/06)



STAY CONNECTED

SUBSCRIBE TO

efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
[Careers.efsa.europa.eu](https://careers.efsa.europa.eu) – job alerts



LISTEN TO OUR PODCAST

Science on the Menu – Spotify, Apple Podcast and YouTube



FOLLOW US ON TWITTER

[@efsa_eu](https://twitter.com/efsa_eu) [@methods_efsa](https://twitter.com/methods_efsa)
[@plants_efsa](https://twitter.com/plants_efsa) [@animals_efsa](https://twitter.com/animals_efsa)



FOLLOW US ON LINKEDIN

[Linkedin.com/company/efsa](https://linkedin.com/company/efsa)



FOLLOW US ON INSTAGRAM

[@one_healthenv_eu](https://instagram.com/one_healthenv_eu)



CONTACT US

efsa.europe.eu/en/contact/askefsa

