



Preparatory support on bioinformatics for the evaluation of the risk assessment of GMO dossiers

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Trusted science for safe food

As part of the pre-market RA requirements for genetically modified (GM) plants:

- **Bioinformatic analysis (BI)** using updated databases
- Singles and stacks
- According to applicable regulations and EFSA guidances

Aim: Preparatory support on bioinformatics for the evaluation of the risk assessment of GMO dossiers

Document Number	Title of Document
1	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms
2	FAO/WHO, 2001 . Evaluation of allergenicity of genetically modified foods
3	EFSA, 2010a . Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed
4	EFSA, 2010b . Guidance on the environmental risk assessment of genetically modified plants
5	EFSA, 2011 . Guidance for risk assessment of food and feed from genetically modified plants
6	EFSA, 2013 . EFSA guidance on the submission of applications for authorisation of genetically modified plants under Regulation (EC) No 1829/2003 ²

7	Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 Text with EEA relevance
8	EFSA, 2017a . Guidance on allergenicity assessment of genetically modified plants
9	EFSA, 2017b . Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms
10	EFSA, 2021 . Administrative guidance for the preparation of applications on genetically modified plants. EFSA supporting publication 2021:EN-6473. 40 pp.
11	EFSA, 2021 . Administrative guidance for the preparation of renewal applications on genetically modified food and feed. EFSA supporting publication 2021:EN-6474. 38 pp

Timeline:

- **Publication date: 22/12/2021**
- Question deadline: 21/02/2022
- Time limit for receipt of tenders: 01/03/2022
- Conditions for opening tenders (date): 02/03/2022
- **Start of the contract: 30/6/2022**

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.
 - Step 1: Completeness check -> Qs? -> an **interim report** to EFSA
 - Step 2: Assessment of the compliance and quality of the BI analysis -> Qs? -> **final report**
 - Step 3: Archiving the outcome of the BI analysis

Objectives 2:

- Propose a harmonized structure for the BI analysis submission in GMO applications (after 1 year).
 - The proposed structure must be compliant with the requirements described in the relevant guidance documents
 - If needed, the structure of BI analysis submission and reporting by applicants shall be revised, based on the applicants' feedback after the implementation of the harmonised structure

Contract's deadline:

- **Task 1** (Completeness): 6 working days
- **Task 2** (Question on completeness): 3 working days
- **Task 3** (Compliance and quality): 12 working days
- **Task 4** (Question on Task 3): 6 working days
- In case of BI update: 12 working days
- Proposal for harmonized structure: 12 months from start FWC

Details:

- EcoMole s.r.o (Czech Republic)
 - UK-based company with an EU-based branch established in Prague, Czech Republic in January 2019
- OC/EFSA/GMO/2021/06
- 4 years



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