



LITERATURE SEARCH ASSESSMENT CONTRACTOR



**AD HOC MEETING WITH
INDUSTRY REPRESENTATIVES
8TH OCTOBER 2024**

Pietro Piffanelli - NIF Unit

LITERATURE SEARCH ASSESSMENT – CONTRACTOR'S OVERVIEW

- External Contractor is currently involved in preparatory work for assessment of compliance to the [EFSA Explanatory Note on Literature Searching \(2019\)](#)
- BIOMATH, Applied Statistics and Informatics in Life Sciences [Germany]
- Contract duration: 15 months (as of July 1st, 2024)
- Assessment of **new LIT Search** and **LIT Update** packages
- New Applications and Renewals dossiers: single and stack events
- Appraisal based on Critical Appraisal Tool [CAT] in use by the previous Contractor
- Report available to the applicant upon publication of the Scientific Opinion [upon request]



LITERATURE SEARCH ASSESSMENT – NEXT STEPS

➤ **EFSA is collecting observations made by BIOMATH in the assessment of LIT packages**

- search strategy eligibility (inclusion/exclusion) criteria
- search terms & free text terms
- appropriate use of search terms
- implications for risk assessment

Objectives:

- enhance the effectiveness/quality of systematic LIT Search carried out by the applicants
- harmonise LIT systematic search strategy [i.e. scoping vs systematic review] across applicants
- reduce the number of LIT Search/Update Qs in ADRs





GMO DOSSIERS RISK ASSESSMENT STATE-OF PLAY



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PRE-TR GMO APPLICATIONS: RISK ASSESSMENT STATE-OF-PLAY

N° of **pre-TR** GMO dossiers ongoing Risk Assessment by GMO Panel: **9**

- **% in STOP-the-CLOCK** **70%**

< 2 months	3
> 2 months	2
> 2 months + EURL	1

- **% stopped by “single first principle”** **30%**



POST-TR GMO APPLICATIONS: RISK ASSESSMENT STATE-OF-PLAY

N° of **post-TR** GMO dossiers ongoing Risk Assessment by GMO Panel: **8**

- **% in STOP-the-CLOCK** **75%**

< 2 months	4
> 2 months	1
> 2 months + EURL	1

- **% stopped by “single first principle”** **25%**

- N° of post-TR GMO dossiers at Completeness Check by EFSA: 3



POST-TR GMO RENEWALS: RISK ASSESSMENT STATE-OF-PLAY

N° of **post-TR** GMO Renewal dossiers ongoing Risk Assessment by GMO Panel: **17**

- % in **STOP-the-CLOCK** **60%**
- % **running** **40%**

