UPDATE OF THE EXPLANATORY NOTE OF THE NEWLY EXPRESSED PROTEINS

AD HOC MEETING WITH INDUSTRY REPRESENTATIVES
30 OCTOBER 2025

NUTRITION AND FOOD INNOVATION UNIT

EUROPEAN FOOD SAFETY AUTHORITY

EXPLANATORY NOTE ON NEPS, 2018

TECHNICAL REPORT

efsa European Food Safety Authority Supporting Publications

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Explanatory note on the determination of newly expressed protein levels in the context of genetically modified plant applications for EU market authorisation

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SCOPE OF THE NEP NOTE

- The explanatory note provides details on the key methodological aspects of the determination of NEP levels to be reported by applicants

- Assists with harmonization of the submitted information

- Aims at warrantying equal treatment in all applications, while maintaining the case-by-case risk assessment

7 YEARS LATER

- Applications are harmonised with regards to the data and information submitted
- New applicants have made use of the Explanatory Note
- Overall, the provided information complies with the recommendations of the Explanatory Note; in some cases, additional clarifications are needed
- EFSA updates its guidance documents regularly (see e.g., Technical Note on DNA Sequencing 2024, EFSA guidance RNAi off target 2025)

HOW DOES EFSA ASSESS THE NEED FOR UPDATES

- Are the recommendations clearly explained in our guidance?
- Do we have recurring questions across applicants?
- Is the number of questions overall reduced?
- Do applicants use methodologies other than the ones mentioned in our Explanatory Note?

- In some cases, there is some space for interpretation of the indications of the Note
- Recurring questions across different applicants
- Increased number of questions despite reduced number of ADRs
- Use of new methodologies to produce data for RA → lack of sufficient guidance in the current Explanatory Note

EXAMPLES OF AREAS WITH HIGH NUMBER OF QUESTIONS

- Extraction efficiency calculation
- Western blots
- Antibody information
- Storage and stability of tissues and proteins
- Description of the material used
- LC-MS and validation of the method
- ….

NEXT STEPS

- MC WG to reflect and clarify the points where a high number of questions were sent
- Better describe recommendations for LC-MS methods
- Timeline: 1 year
- Regularly update stakeholders on the process. The updated document will be shared before its publication for consultation
- Any suggestions already? Open for discussion

THANK YOU

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