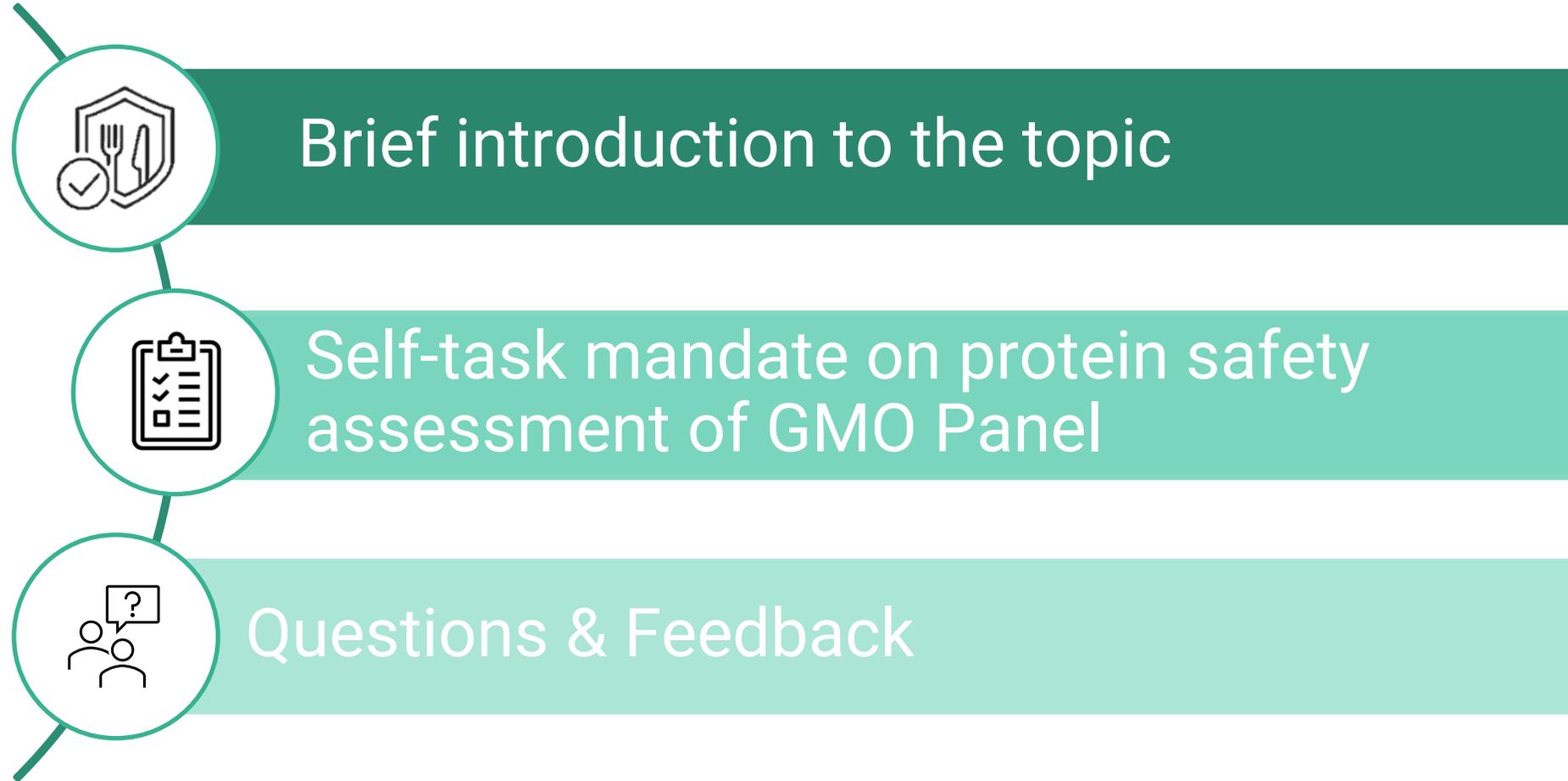




PROTEIN SAFETY ASSESSMENT GMO PANEL MANDATE

Advisory Forum
March 2024
Antonio Fernandez

AGENDA



WHY EFSA IS INVESTING RESOURCES ON PROTEIN SAFETY?

- Society demands for healthier and more sustainable food systems
- Biotechnology advances on what is possible to be produced



- It brings challenges to protein safety assessments
- Preparedness and adaption to embrace new technologies

PROTEIN SAFETY – RISK ASSESSMENT PRINCIPLES



Foods derived from modern biotechnology

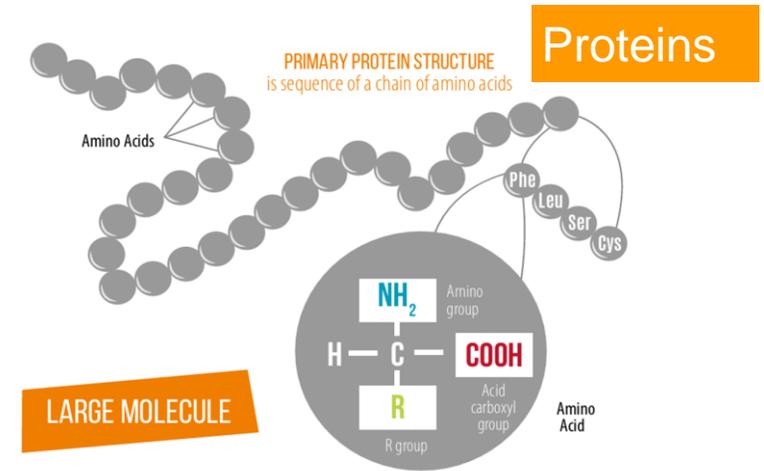
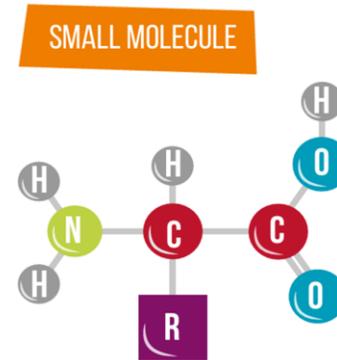
2003-2009

Second edition



Need to improve and modernise protein safety assessments

Principles from chemical risk assessment for small molecules



PROTEIN SAFETY – RISK ASSESSMENT REQUIREMENTS AT PRESENT

Protein safety = protein toxicity and allergenicity

Codex 2003/2009 defined the principles for the assessment

- Regulation 503/EFSA GMO Guidance borrowed such principles
- Main information considered:
 1. Knowledge on the source/protein – HoSU
 2. Bioinformatics analysis
 3. *In vitro* studies
 4. *In vivo* studies

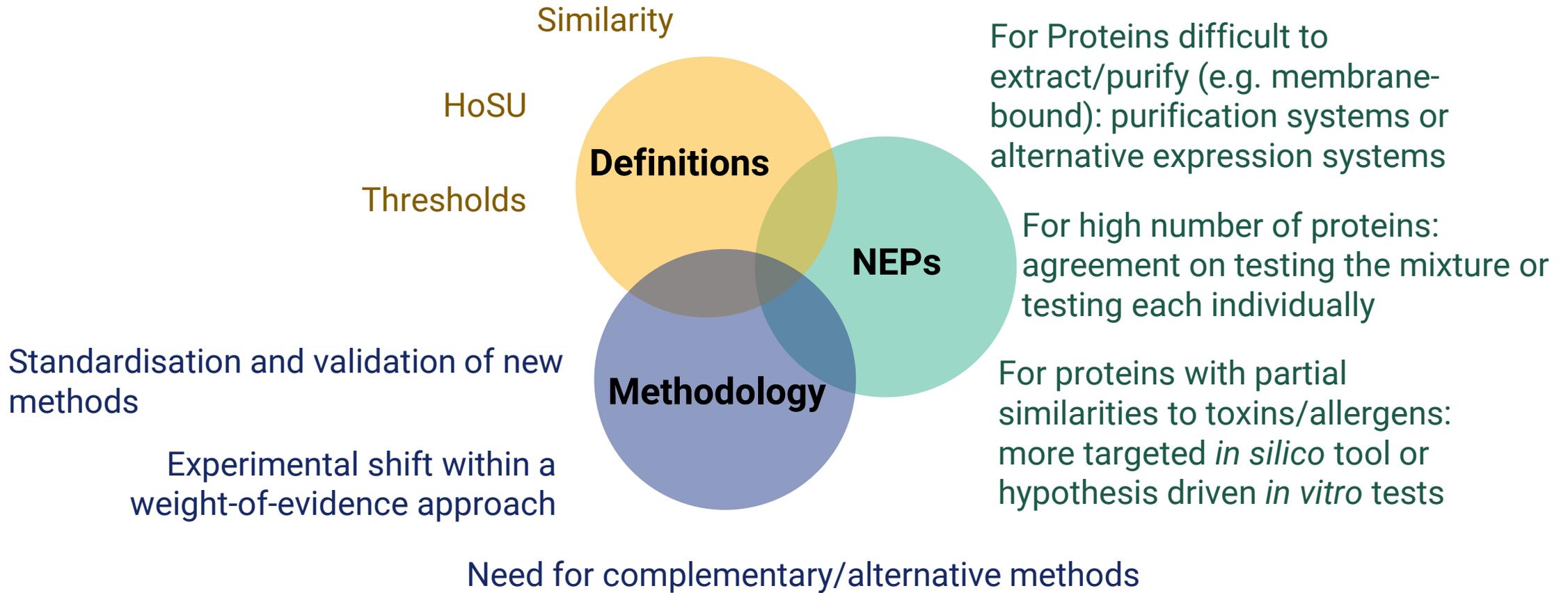


CHALLENGES – FEW EXAMPLES OF NEW NEEDS

- GM plant with 1 protein easy to purify, e.g. mEPSPS protein
- GM plant with high number of proteins easy to purify/test
- GM plant with 1 protein difficult to purify/test
- GM plant with high number of proteins difficult to purify/test



FUTURE ADDITIONAL NEEDS – FROM EXPERIENCE GAINED



WHAT WE TRY TO ACHIEVE? – TERMS OF REFERENCE

Scientific Opinion reflecting on current practice, challenges and future opportunities of protein safety in GMOs

1. Lessons learned from experiences in the assessment of newly expressed proteins in the last 20 years, including more recent complex cases
2. Building on the experience and issues identified, develop a critical appraisal of new methodologies available with the potential to be used as complementary/alternative testing strategies to current methodologies described in legal frameworks
3. Road map for future implementation of such complementary/alternative methods in risk assessment strategies
4. Recommendations for further research to address methodological development needs



ENGAGEMENT - MS

At present:

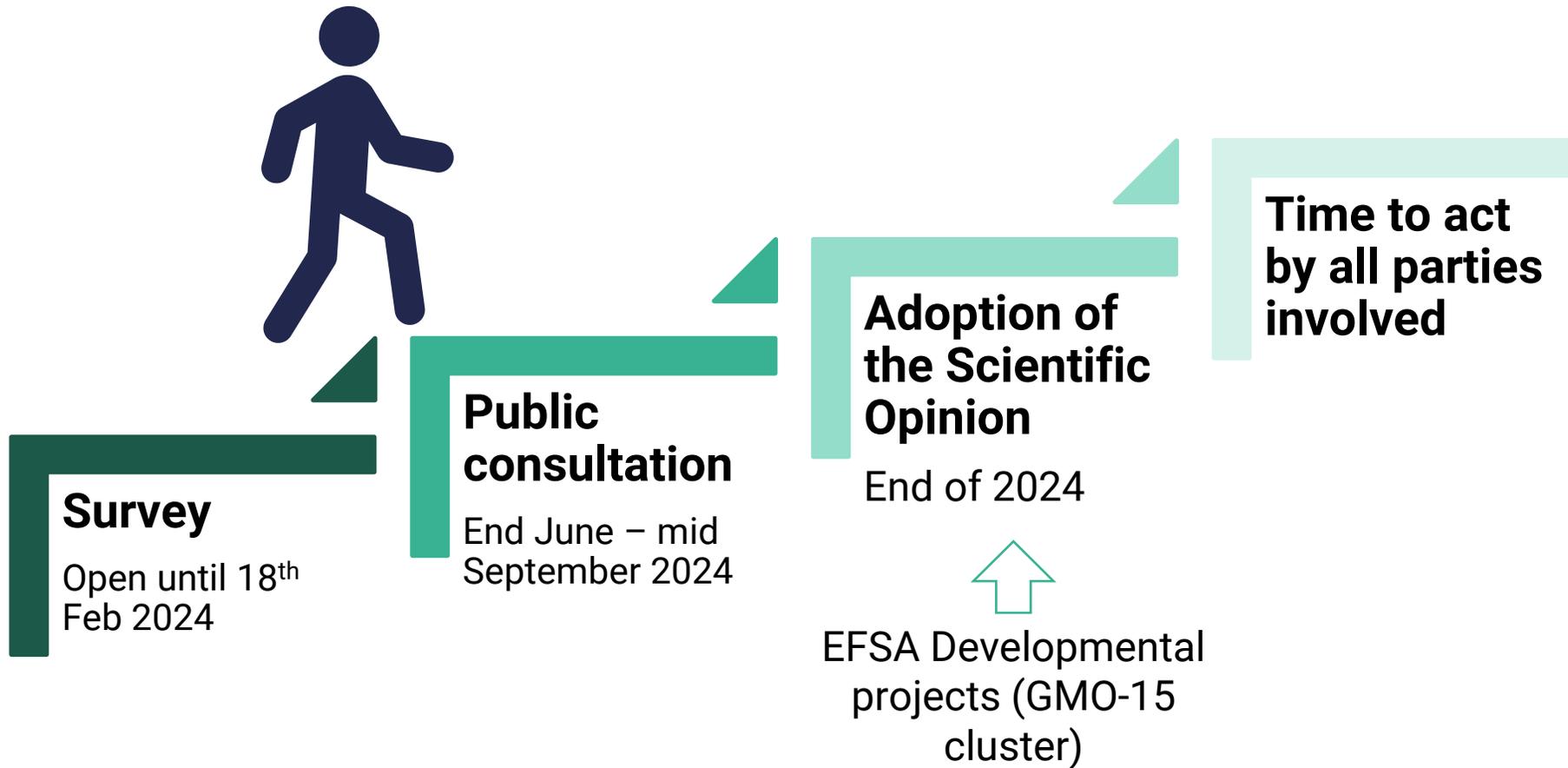
- GMO Network meetings – MS Authorities contributing
- Webinars (one in 2023 and other planned in 2024)
- Survey finalised last month/public consultation (summer 2024)

In future: Sc. Opinion will be starting point for

- Roadmap RA implementation to be followed
- Recommendation for research to be disseminated
- Others...



NEXT STEPS



ACKNOWLEDGMENTS

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Engagement Team: Margherita Guidi/Matthew Ramon





Thank you very much!

Questions?

Feedback?



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