LEAN EXERCISE IN MRL APPLICATIONS - HOW TO REDUCE IMPACT OF CLOCK-STOPS

EFSA

PREV Unit – MRL Art.10 team

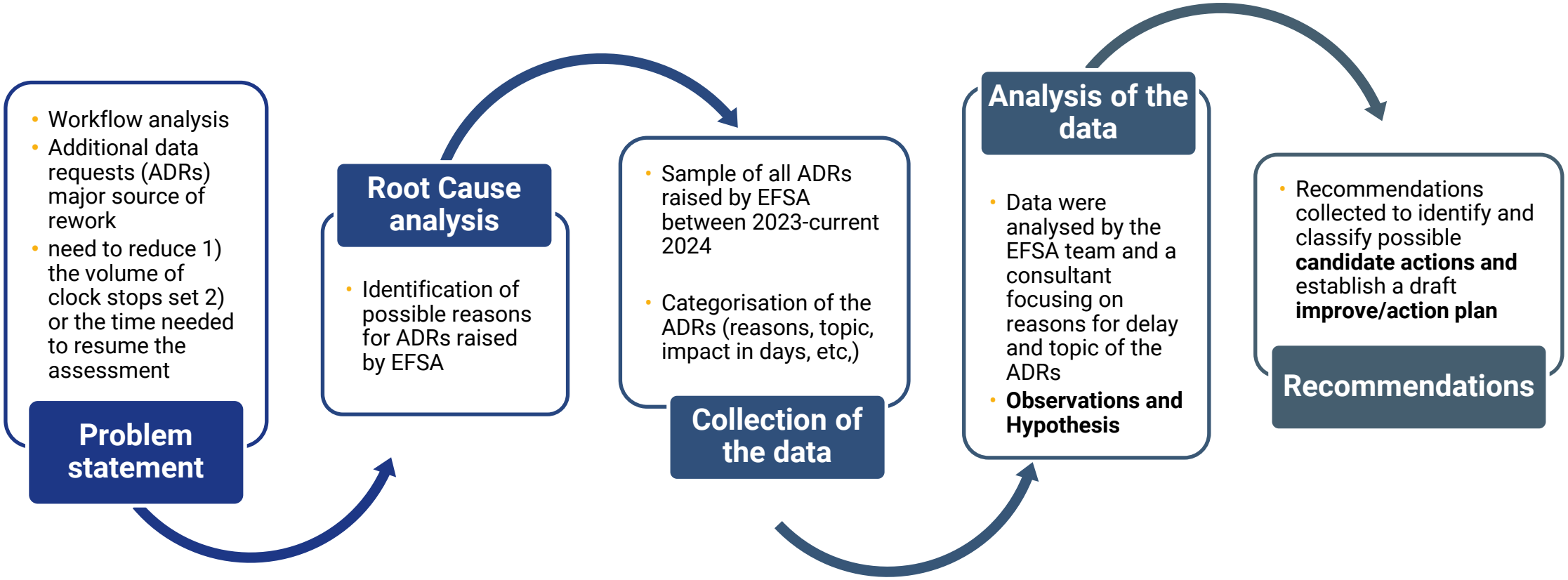
Alessia Verani

PESTICIDE STEERING NETWORK (PSN) 32nd meeting

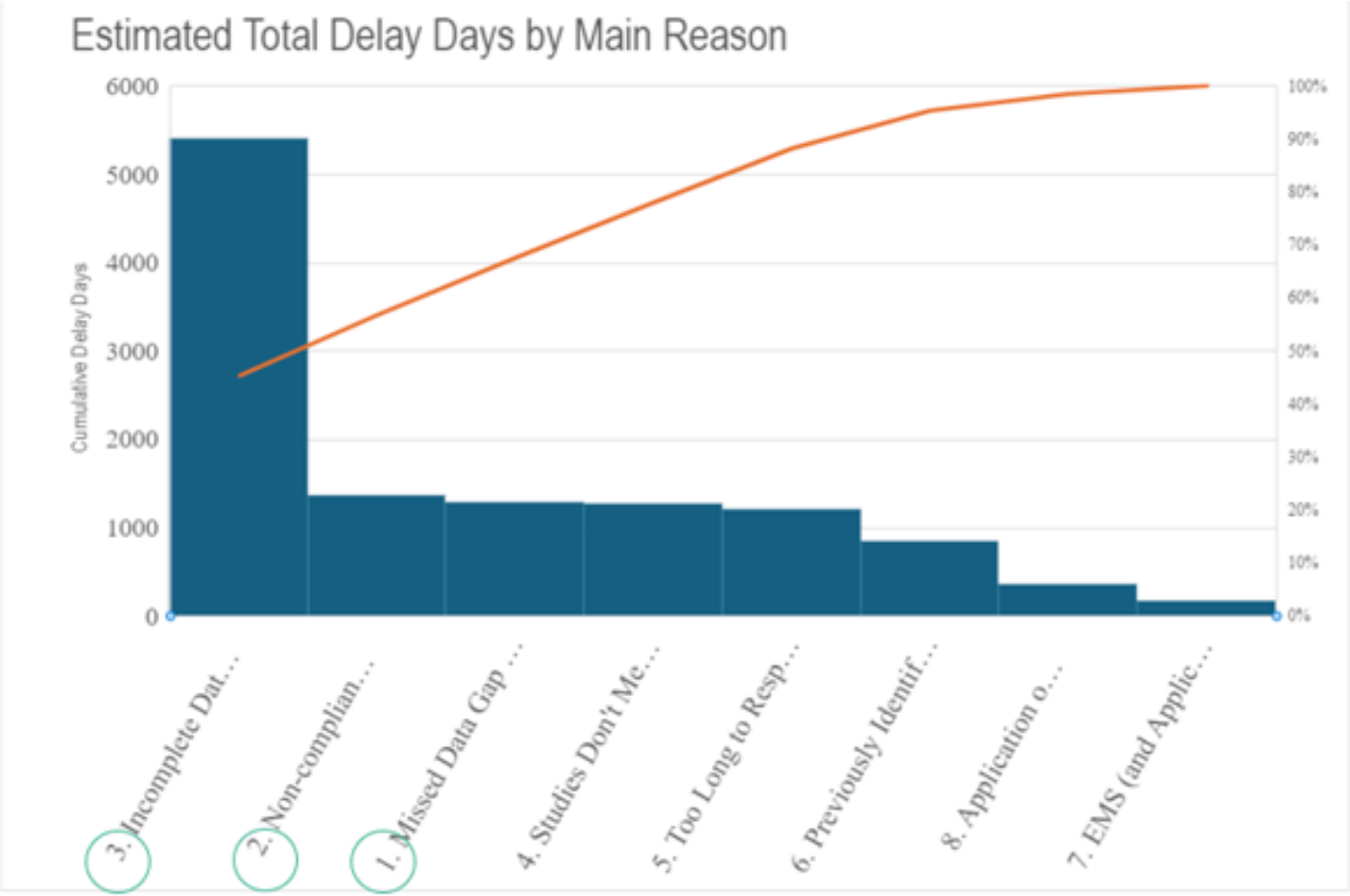
30/10/2024

EUROPEAN FOOD SAFETY AUTHORITY

THE LEAN EXERCISE



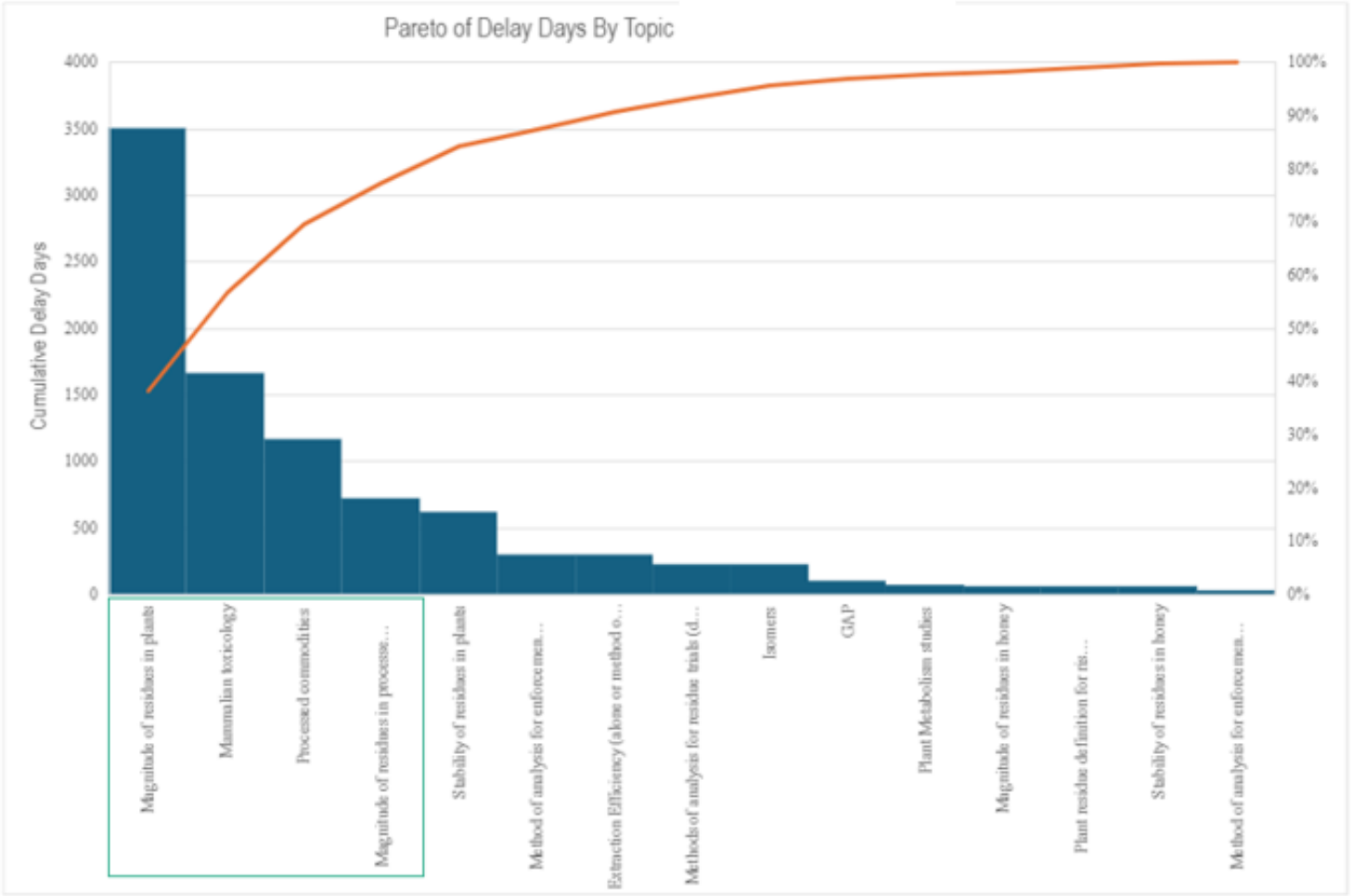
1ST ANALYSIS: PARETO BY REASON



- **Incomplete data package (missing studies/justifications)**
- Non-compliant format
- Missed data gap (new or from previous assessments)
- Studies Don't Meet Technical Guidance
- Too Long to Respond to Minor Issues

Main reasons: 1. Missed Data Gap (A Data Gap Was Not Identified by EMS) 2. Non-compliant Format/Protocol 3. Incomplete Data Package 4. Studies Don't Meet Technical Guidance 5. Too Long to Respond to Minor Issue 6. Previously Identified Data Gap Missed 7. EMS (and Applicant) Apply Incorrect Guidance 8. Application of Guidance Less Stringently than EFSA

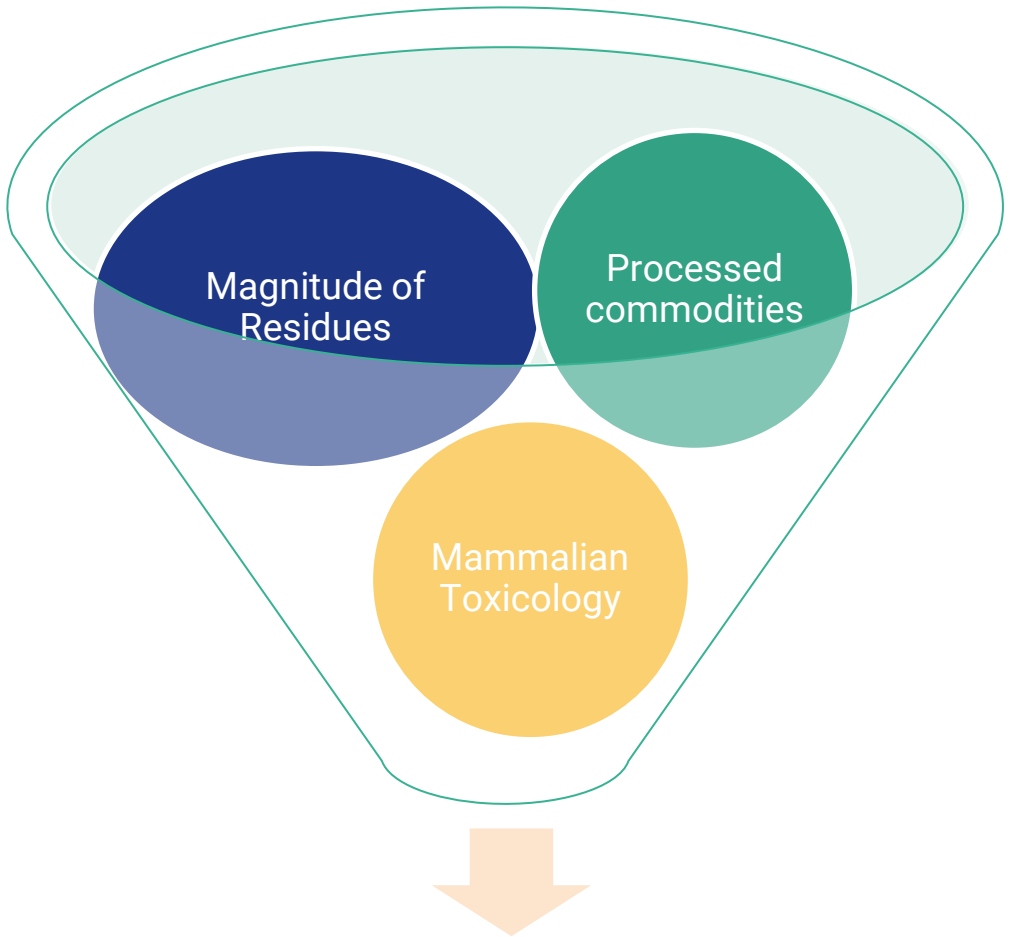
2nd ANALYSIS: PARETO BY TOPIC



The main three topics causing delays are:

- Magnitude of residues in plants
- Mammalian Toxicology
- Processed commodities (nature and magnitude)

MAIN OBSERVATIONS



The first analysis suggested "**Incomplete Application**" has the greatest impact (particularly when weighted by the delay days for that type of problem)

The second analysis suggested that:

- For **MoR** ADRs, the data requirements and guidances are sufficiently clear but applied differently by EFSA/MSs
- For **processed commodities** ADRs, the requirements seem more open to different interpretation
- For **Mammalian Toxicology** ADRs, they are generally raised under applications where EFSA is expected to deliver a “mini peer review process” (e.g. Import tolerances/ outstanding data gaps from AIR). Therefore, the process is naturally longer. Further investigations would be required to underline clearer reasons behind these ADRs.

PROPOSED RECOMMENDATIONS-MAGNITUDE OF RESIDUES

Harmonised Scientific check at MSs level

EFSA to investigate with MSs whether there is a **scientific check point** when drafting ER, if yes, to share and compare the steps undertaken by the different MSs.
EFSA and MSs to discuss a **harmonized check list** for early scientific checkpoint at EMS level (via IPREP)
EFSA and MSs to consolidate a **final check list to be shared with MSs for piloting**

More details on ADRs set by EMS during intake phase

Start including more details in Evaluation Report (ER) on requests made by the EMS during their risk assessment.
to share more info on the EMS process of requesting ADRs (e.g via clock stop letter/meetings/etc)
In future, EMS to specify more transparently e.g in the ER, the ADRs and reply of the applicant during their risk assessment

Any MS volunteering for piloting?

PROPOSED RECOMMENDATIONS-PROCESSED COMMODITIES

Flowchart for clarifying Data Requirements

EFSA to prepare an easy tool for identification of applicable data requirements

The EFSA-tested tool would be shared with MSs for consolidation and piloting (via IPREP)

The MS-consolidated tool could be the basis for establishing new validation rules in IUCLID

Stay tuned for EFSA's updates

Flowchart for trigger values for new NoR/MoR processing studies

EFSA aims to prepare an easy tool on trigger values for new Nature of Residues/Magnitude of Residues processing studies (per Data Requirements and process)

To share with MSs via IPREP, collect comments and distribute final version for piloting

FURTHER PROPOSED RECOMMENDATIONS

Consider more use of clarification Tele Conferences (TCs)

- minor clarifications requests (not leading to a clock stop letter) are usually handled via email and may require several reiterations between MSs and EFSA experts. Short clarfication TCs can be organised upon need
- The applicant and EMS can consider more use of the 'clarification TC on ADRs' as provided in the EFSA catalogue of services for complex additional data requests

Use of MRL report in IUCLID

- EFSA is finalizing a report generator feature in IUCLID that can support EMS in checking the completeness of the dossier and preparing the Evaluation Report

Any other ideas?

- Any other ideas MSs have in mind and would like to discuss with EFSA?
- Which kind of support would you need? Q&A sessions, Webinars, info sessions (on which specific issues? Which areas of the scientific check of the dossier?)

THANK YOU! - STAY CONNECTED

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