16th Stakeholder Bureau
30 April 2025

INCREASED EFFICIENCY IN RISK ASSESSMENT

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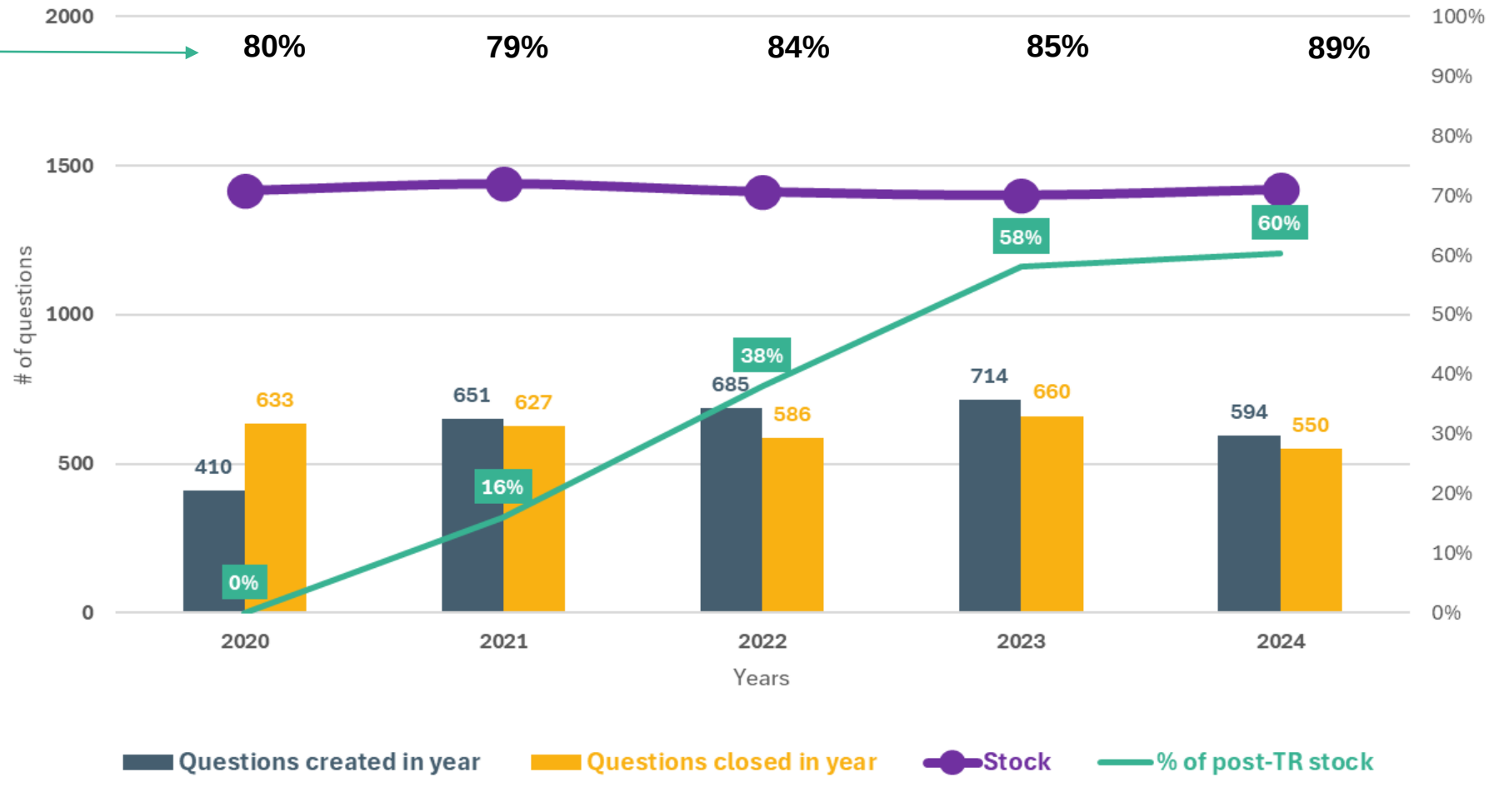
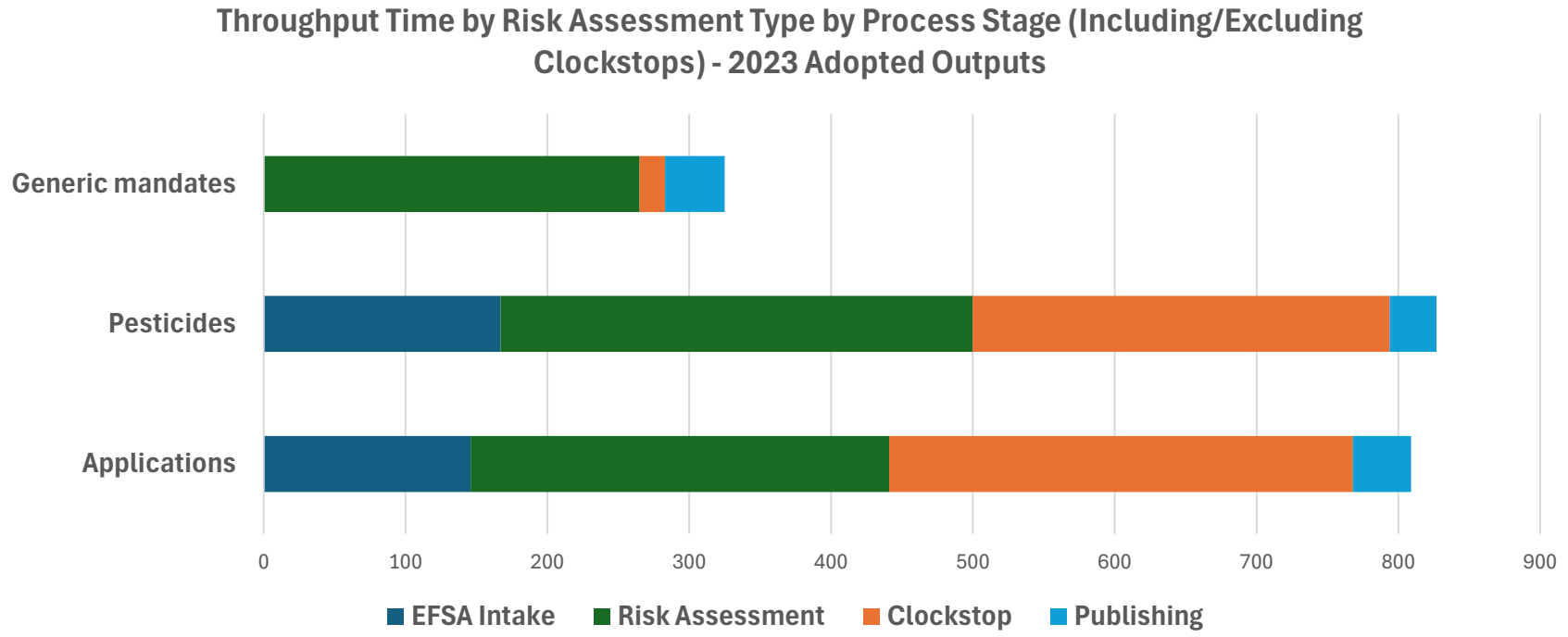
EUROPEAN FOOD SAFETY AUTHORITY

SCIENTIFIC PRODUCTION AT EFSA

Satisfaction	81%	na	73%	69%	65%
Timeliness	80%	79%	84%	85%	89%



RISK ASSESSMENT THROUGHPUT TIME



Clockstop due to:
-Requests for Information during administrative validity check

-Additional data requests during the risk assesment

MAIN OPPORTUNITIES

1. Applications
2. Pesticides
3. Generic mandates

Based on:
- ✓ Length of throughput time
- ✓ Clockstop relevance
- ✓ Workload/output share
- ✓ EFSA “leverage”

01

Ready application

02

Efficient RA process

03

Increased RA capacity

04

Fit-for-purpose outputs

01

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Fit-for-purpose outputs

READY APPLICATION

1. Enhancing the use of services and support for applicants during different assessment phases.

2. Providing clearer guidance on application requirements.

Connected to fit for purpose outputs

3. Leveraging structured data and integrated tools to automate validation and facilitate data reuse in risk assessments.

4. Outreach and support for prospective applicants

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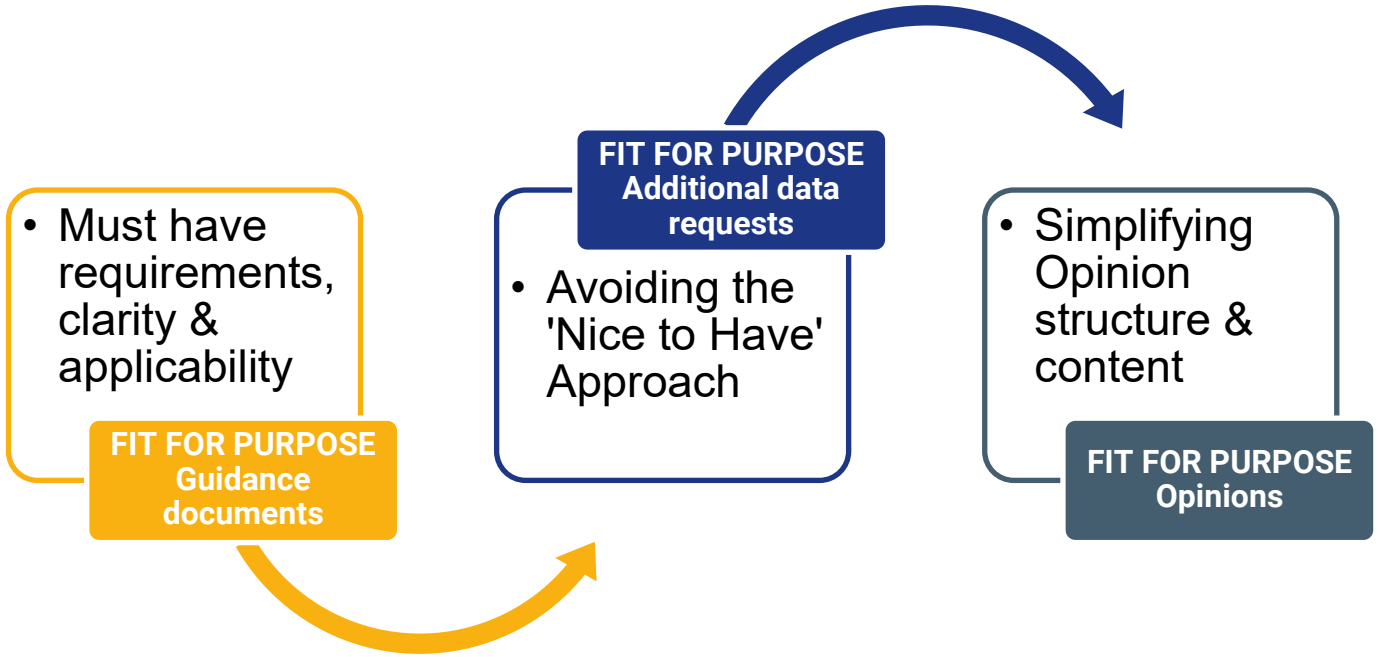
FIT FOR PURPOSE OUTPUTS



Main causes for "additional data requests" @ 60%

- ✓ Applicant data incomplete - guidance document is explicit – 35%
- ✓ Technical reasons – 9%
- ✓ Quality of Data Insufficient to be Deemed Acceptable – 8%
- ✓ Experts judge more data needed – not in / ambiguous GD – 8%

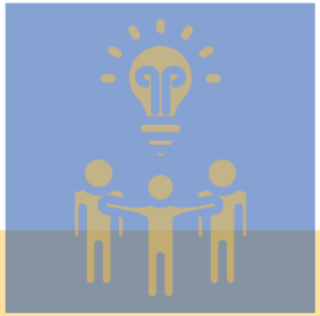
Feed additives
Food contact materials
Novel foods
Food improvement agents
GMOs
Other

01

Ready application

02

Efficient RA process



03

Increased RA capacity

04

Fit-for-purpose outputs

EFFICIENT RISK ASSESSMENT PROCESS

- Leaner approach on managing additional data requests leading to clockstops:

e.g. internal organisation and “stricter” approach (timelines for clock-stops etc.)

- Efficient ways of working with experts:

e.g. working group organisation, roles and responsibilities

- Efficient management of cross-cutting issues:

e.g. cross-cutting substances and modalities with cross cutting working groups

- Tool automations & AI for the different parts of the risk assessment process:

e.g. dossier and opinion collaboration platforms, expert knowledge elicitation, analytical platforms (e.g. exposure, climate data, bioinformatics, cheminformatics)

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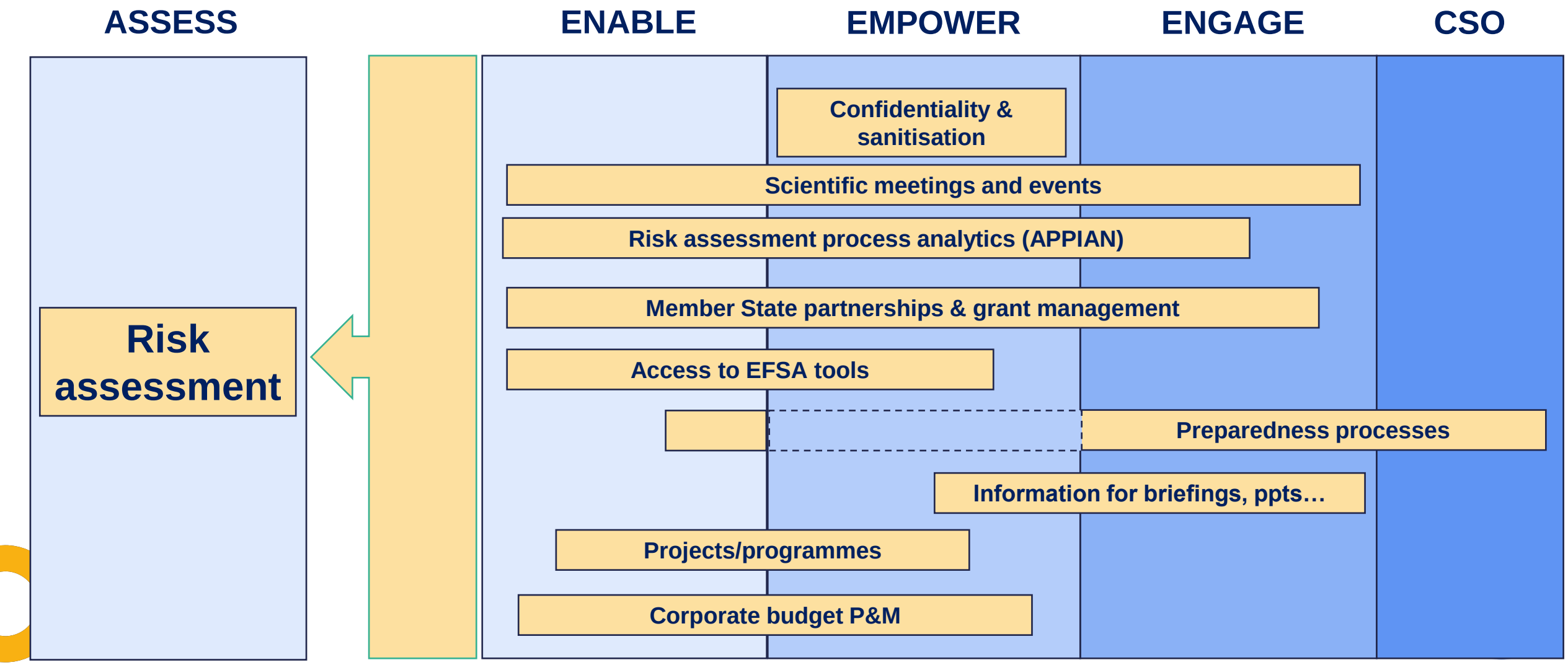
INCREASED RA CAPACITY – SIMPLIFICATION OF NON-RA PROCESSES



NEXT STEPS

- “Speed of RA” report as an input for the external evaluation - May