

Management Board
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Update on Speed of Risk Assessment

Guilhem de Sèze
Head of Risk Assessment Production Dept.

Bénédicte Vagenende
Head of Risk Assessment Services Dept. a.i.

PERFORMANCE MEASUREMENT FRAMEWORK

EXTERNAL OUTCOMES

(Stakeholder & Market Impact)



- Stakeholder Satisfaction (Annual Survey)

SYSTEM HEALTH

(Pipeline & Capacity Health)



- Annual Production (Questions Closed)
- Total Stock (Active & Bulk)

OPERATIONAL PERFORMANCE

(Delivery Excellence)



- End-to-End Throughput Time – **SPEED (new)**
- Legal & Customer Timeliness

PROCESS INDICATORS

(Early Warning System)

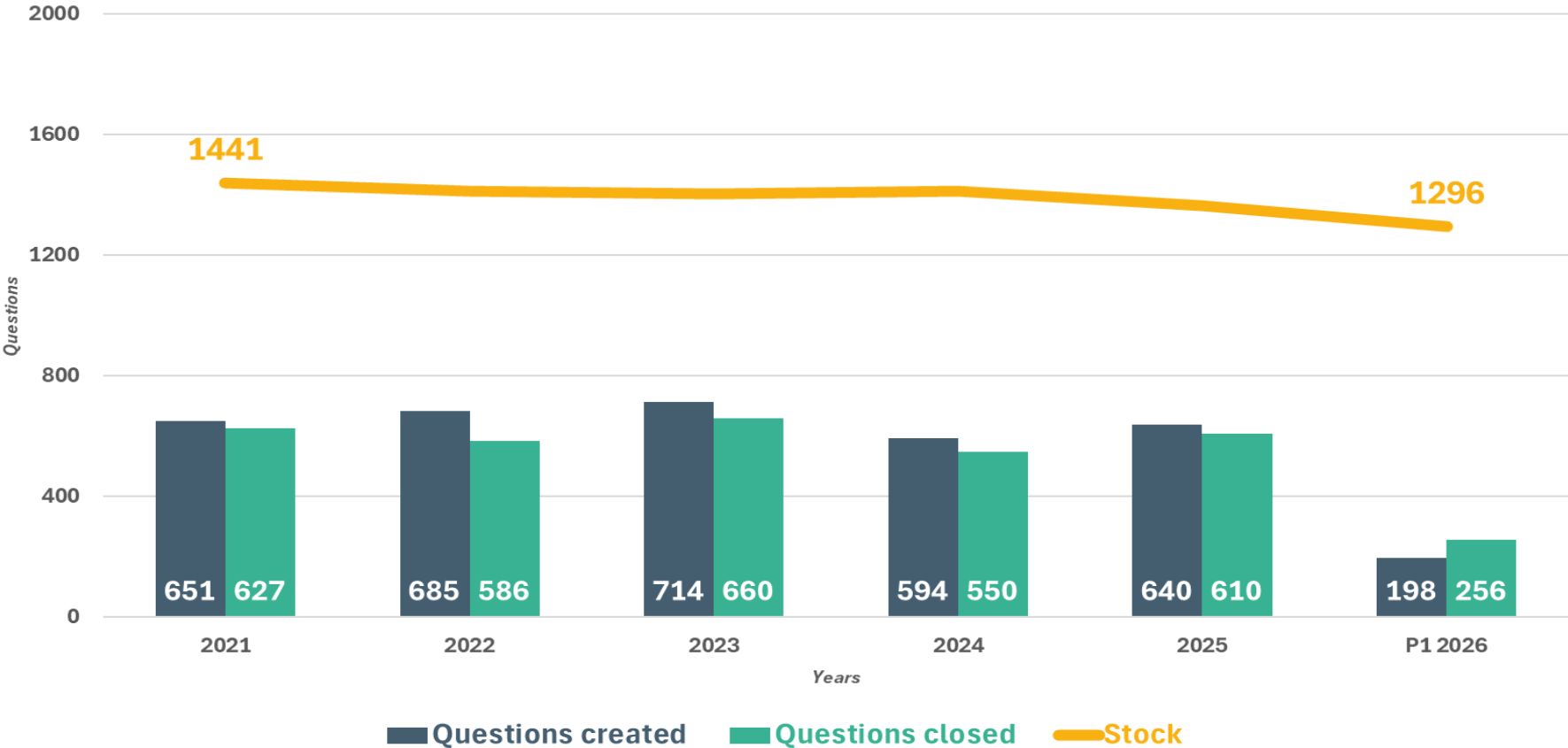


- e.g. Number of clockstops opened



SCIENTIFIC PRODUCTION AT EFSA

Satisfaction	→	N/A	73%	69%	65%	70%	N/A
Timeliness	→	79%	84%	85%	89%	89%	93%

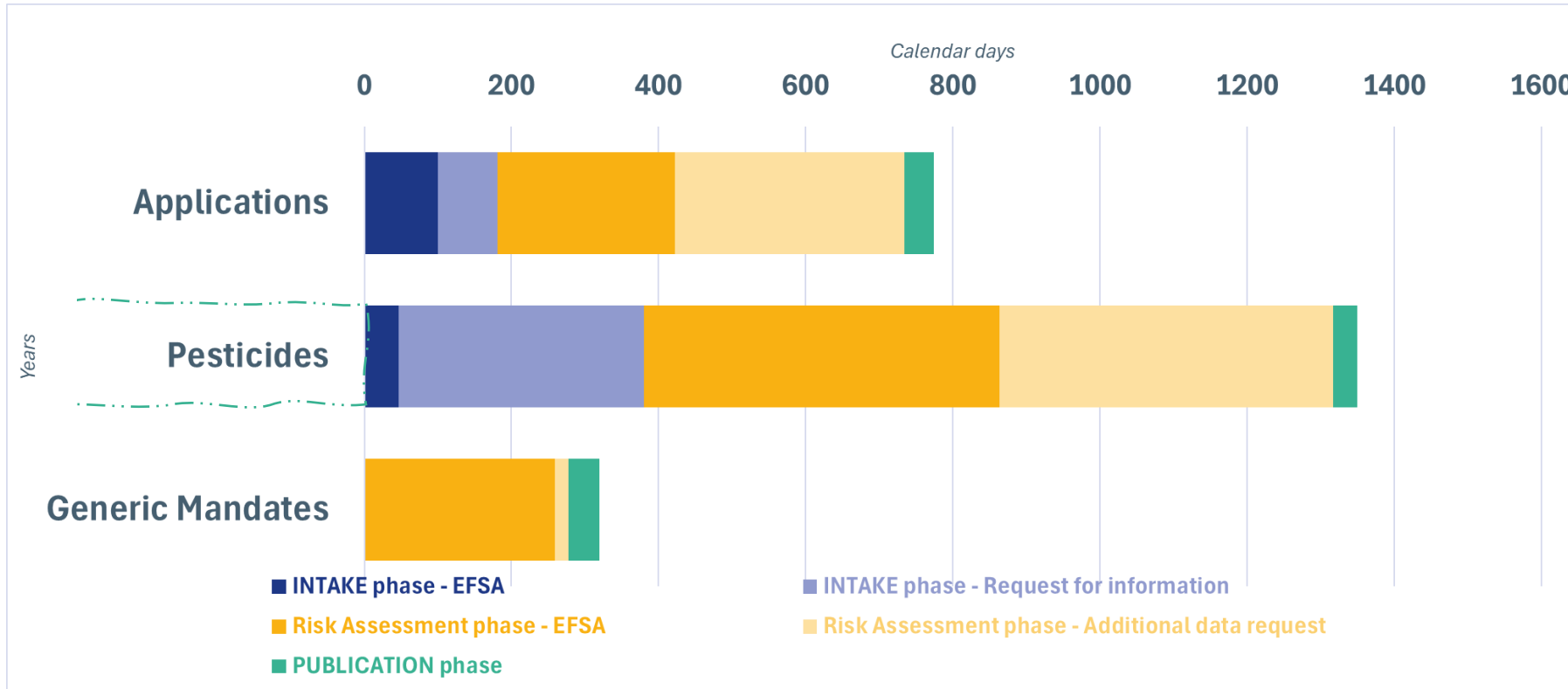


- Key challenges include:
- Stakeholder dissatisfaction with the speed of regulated products
 - Excessive stock concentrated in some areas

Please note that discrepancies with figures reported in previous documents might be present, due to database cleaning, or reclassification of questions
Please note that as of 2026 the timeliness of adoption is calculated using an updated calculation
Questions created are not considering certain questions in pesticides that are in the early phase of the Member States' assessment
Non validated and withdrawn questions are not shown, but the effect is visible in the stock numbers.



RISK ASSESSMENT SPEED - THROUGHPUT TIME (2023 BASELINE)



Delays due to awaiting additional information from applicants:

-Requests for information during administrative validity check

-Additional data requests during the risk assessment (clockstop)

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

*e.g. Services to applicants /
MS*

High impact / medium-term



02

Efficient RA Process

*e.g. Stricter approach
with ADRs and RFIs*

Medium impact / short-term



03

Increased RA capacity

e.g. Partnerships with MS

Medium impact / long-term



04

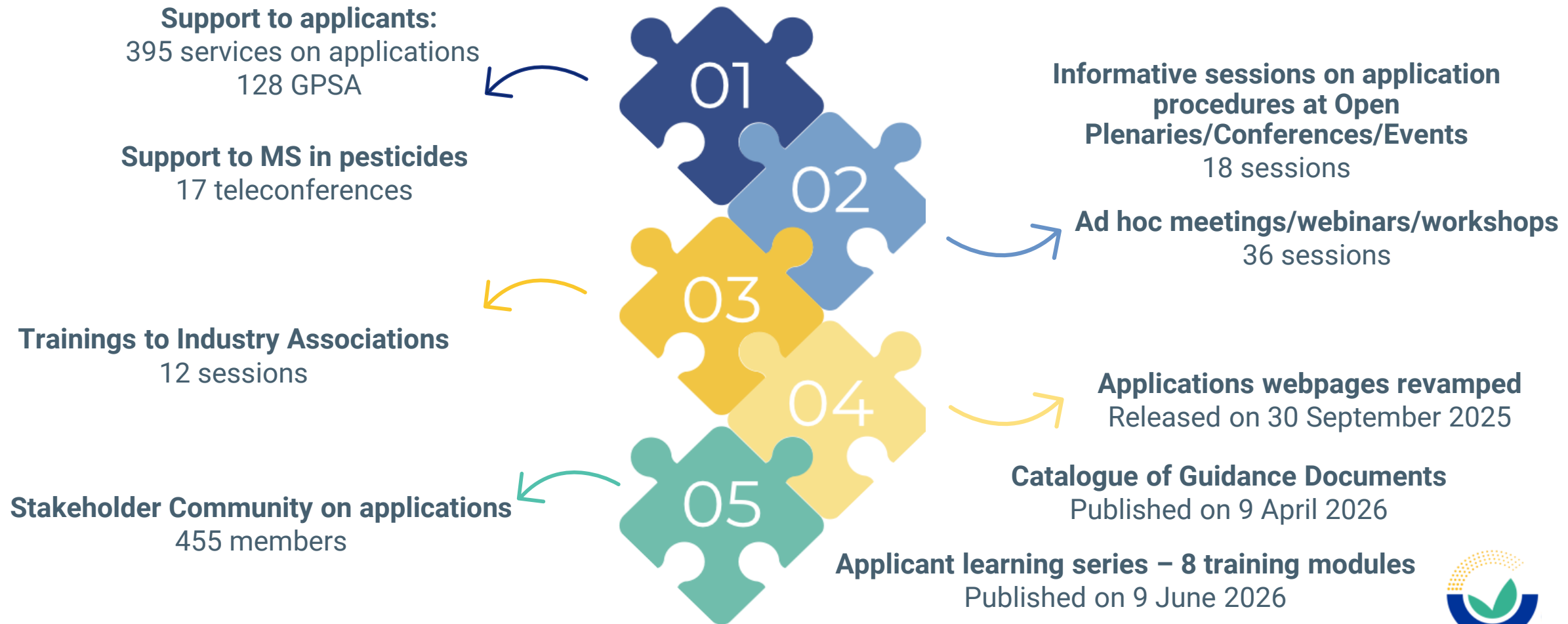
Fit-for- purpose outputs

*e.g. Scientific Guidance
rationalisation*

Medium impact / medium-term

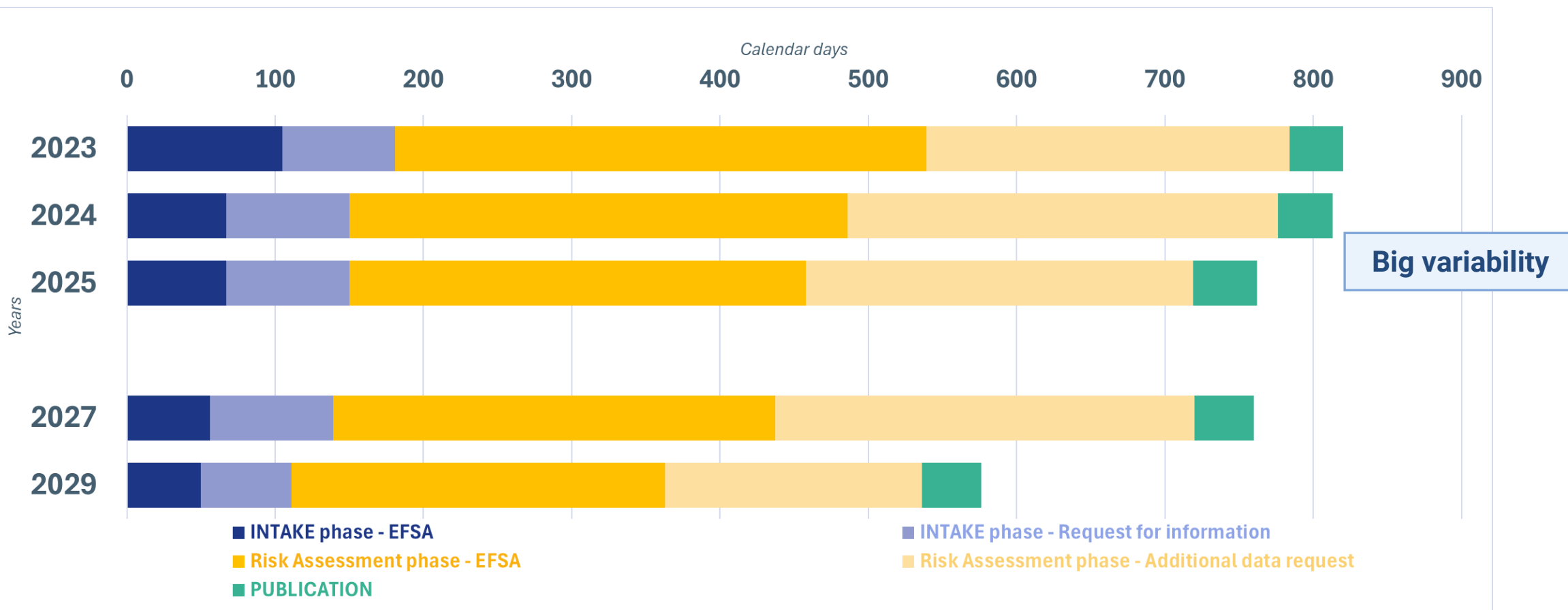
THE FOUR PILLARS OF OUR PLAN OF ACTION

READY APPLICATIONS: INCREASED SUPPORT INITIATIVES SINCE 2025



REGULATED PRODUCTS: THROUGHPUT TIME

REDUCTION OF ADDITIONAL INFORMATION AND DATA REQUESTS TO APPLICANTS/MEMBER STATES



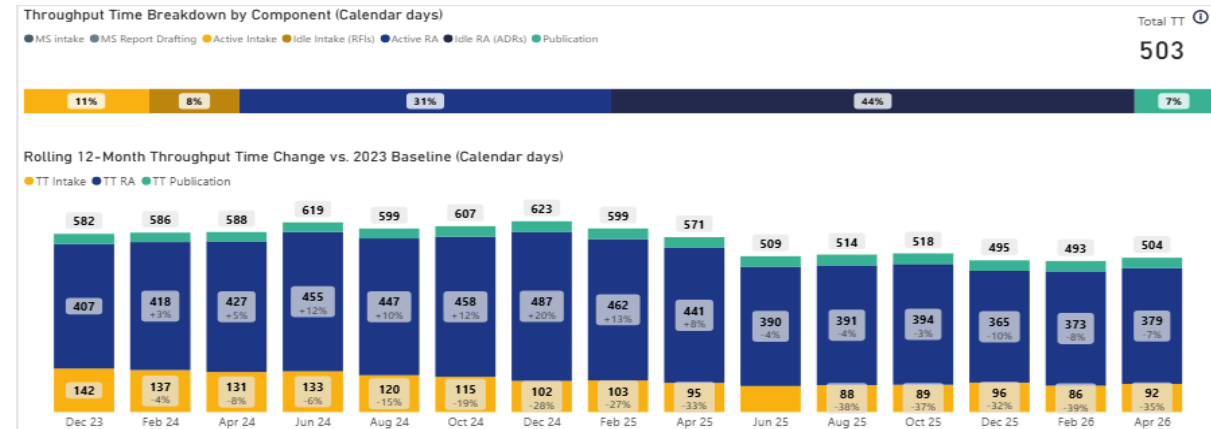
2029 targets with key assumptions:

- Implementation of scientific pre-submission advice
- Regulatory simplification
- Additional envisaged resources

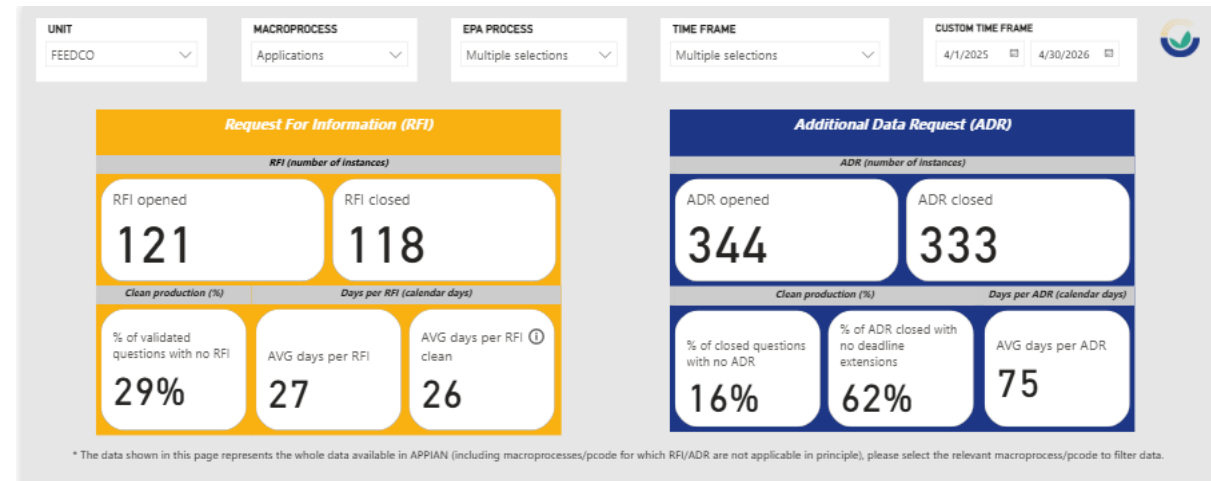


DIGITALISATION & AUTOMATION: REAL-TIME DASHBOARD

- **Real-time dashboard:** to support Scientific Units
- **KPI overview:** smart visuals for a rapid view of overall performance
- **Drill-down insight:** lead metrics and early warning signs on assessment speed



Overview view: throughput KPI trends and 12-month performance



Detail view: set of metrics on delays awaiting for additional information from applicants

FIT FOR PURPOSE OUTPUTS

GUIDANCE RATIONALISATION – FOOD ENZYMES EXAMPLE

- 2022 Guidance update
- Stakeholder engagement for clarity and buy-in
- Simpler requirements with a user-friendly exposure tool

