1st Sounding Board meeting

23 March 2020

EFSA's overall approach to the implementation of TR and timeline

Claudia Paoletti

Programme Manager

Trusted science for safe food

European Food Safety Authority

REGULATION (EU) 2019/1381

6.9.2019 EN Official Journal of the European Union L 231/1

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2019/1381 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Timing of Transparency Regulation

ART Programme

EFSA establishes the ART Programme to drive the implementation of the Transparency Regulation

Mar 2019

Publication

The Union publishes the Transparency Regulation

Sep 2019

Implementation

EFSA completes all designs for process, data formats, organisation model and technology

Jul 2020

We are here

Completion

New policies, processes, PAs, GDs & IT are operational

Dec 2020

Entry into application

The new rules will not apply to requests for scientific output submitted to EFSA before its entry into application

Mar 2021

Management Board

As of 1 July 2022:
New Management Board

Jul 2022

New documents - Practical Arrangements

PA

EFSA obliged by TR to develop 7 Practical Arrangements (PA):

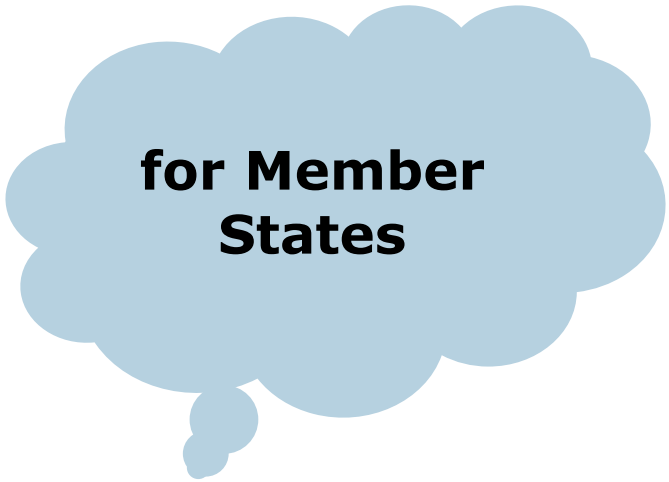
1. Access to Documents/Aarhus Regulation (Art 41)
2. Transparency (Art 38)
3. Confidentiality (Art 39)
4. Assessment of confidentiality on the PPP for new active substances and renewals (revised Art 7(3) and 16 of the PPP)
5. Pre-Submission Advice (Art 32a)
6. Notification of Studies (Art 32b)
7. Public consultation (Art 32c)

Update of EFSA's guidance documents GDs

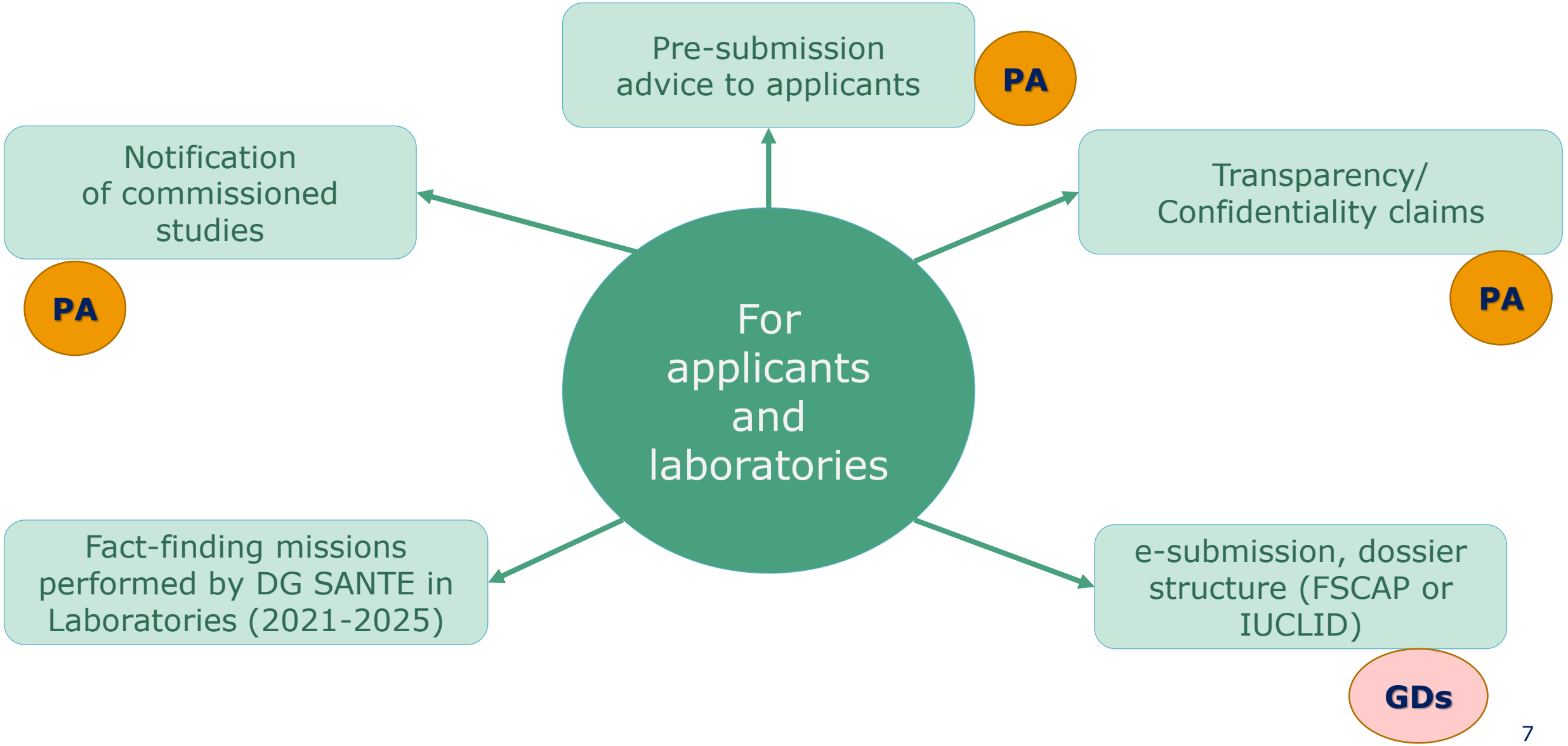
EFSA's scientific and administrative guidance documents to be updated in the areas of:

- ✓ FEED additives
- ✓ GMO (GM Food and Feed, deliberate release directive)
- ✓ Food ingredients (food additives, enzymes, flavourings, extraction solvents),
- ✓ Food contact materials
- ✓ Nutrition (Novel foods, Traditional foods, health claims, infant formulae, food allergens, food supplements)
- ✓ Pesticides (new active substances, re-evaluation of active substances, maximum residue levels, basic substances)
- ✓ Biological hazards

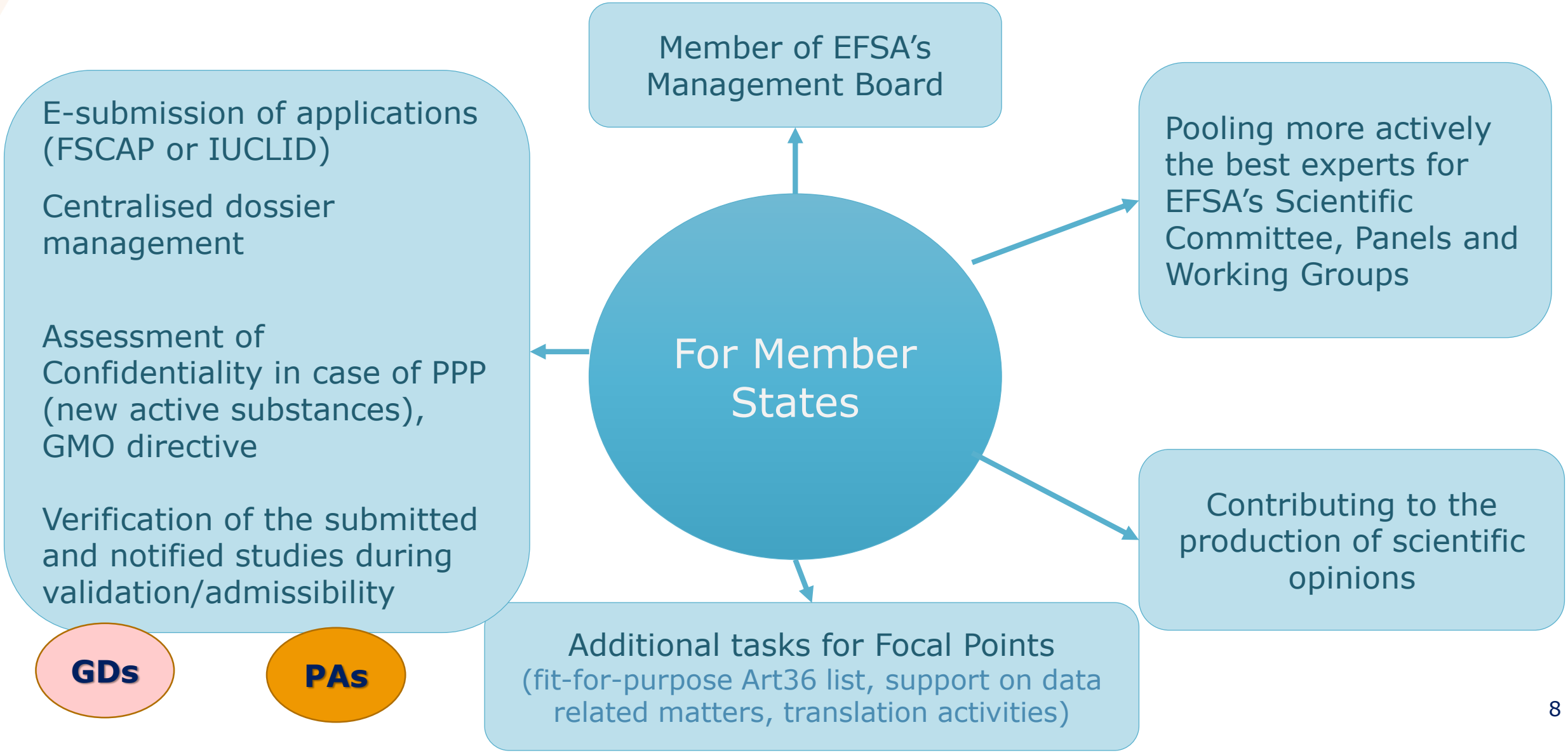
What does the Transparency Regulation change?



What does the Transparency Regulation change for applicants / laboratories?



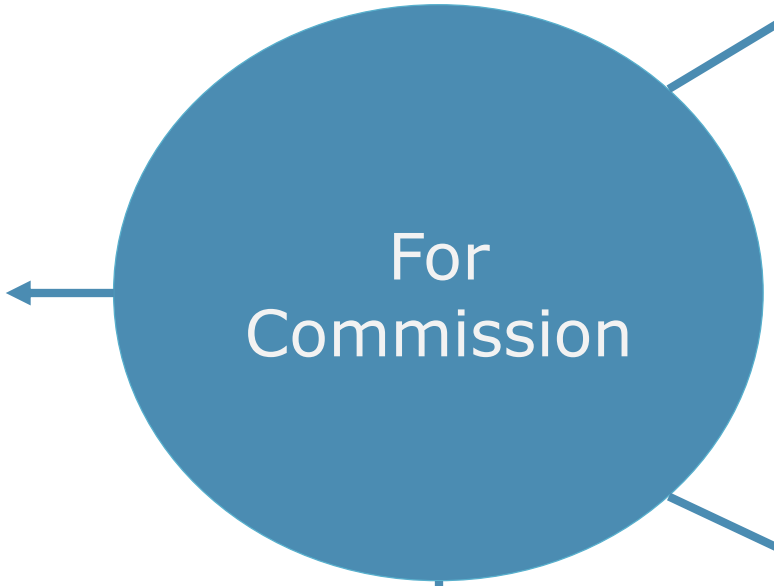
What does the Transparency Regulation change for Member States



What does the Transparency Regulation change for the Commission?

Under the **Novel Foods** Regulation (traditional foods) and in the context of the common authorisation procedure for **food additives/enzymes/ flavourings:**

- Assessment of confidentiality claims
- During validation/ admissibility checks, verifying the match between submitted and notified commissioned studies (in close collaboration with EFSA)

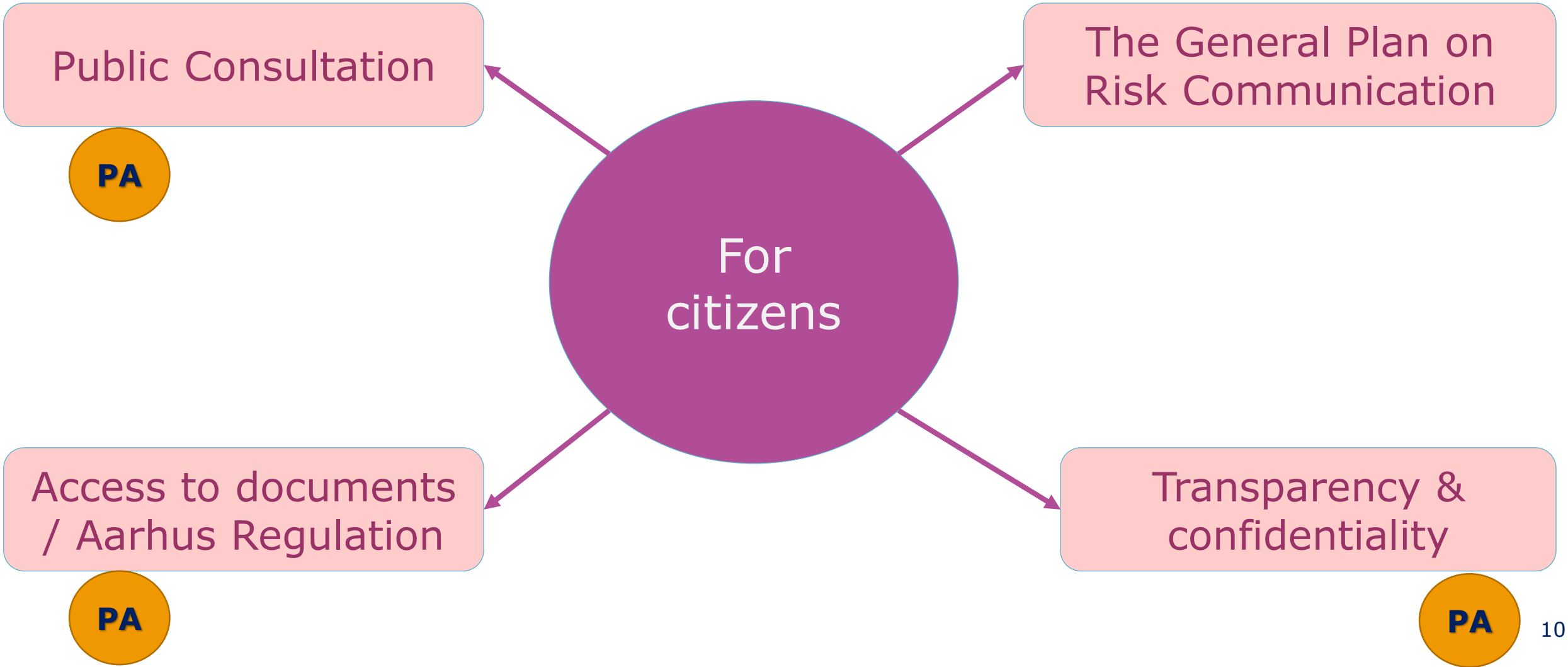


Adoption of a General plan on risk communication with input from EFSA and the MSs

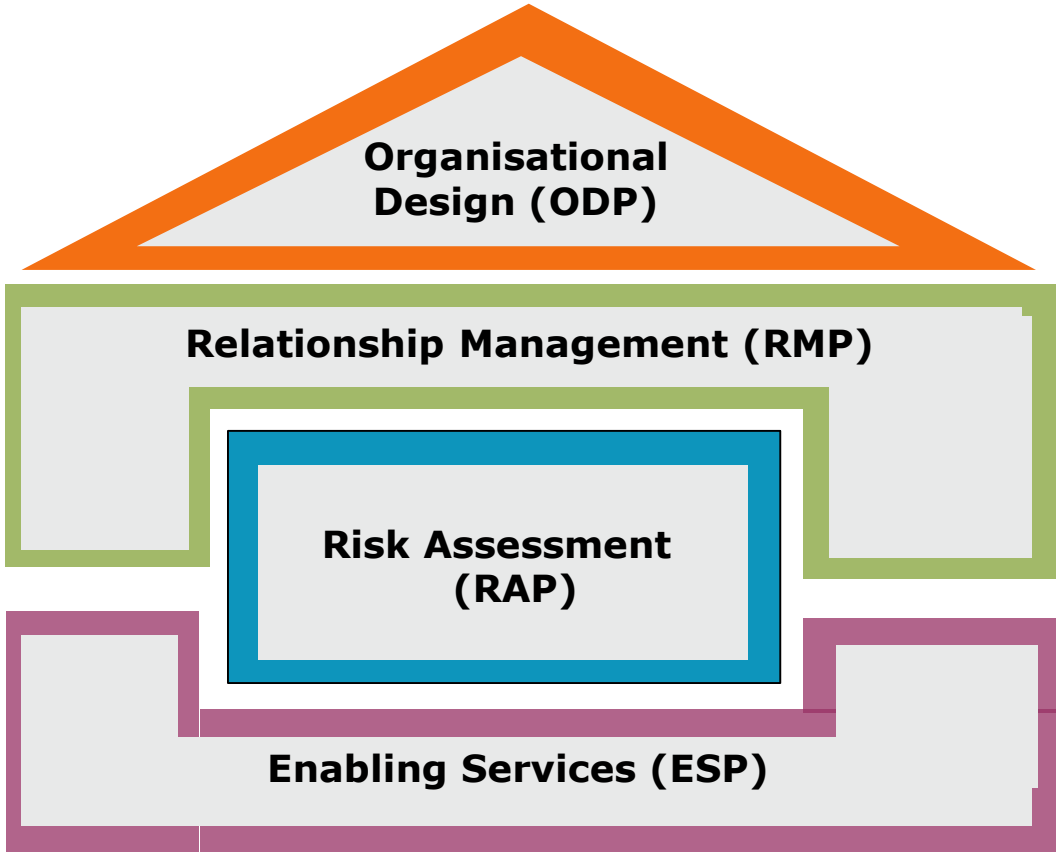
Fact finding missions performed by DG SANTE (2021-2025)

e-submission of applications (FSCAP or IUCLID)

What does the Transparency Regulation change for citizens?



ART programme implementation Structure



- Fit-for-purpose organisational structure with right competencies, right number in the right place
- Transparent and structured engagement with EC, MSs, applicants and stakeholders (from pre-submission advice, dossier intake, notification of studies, public consultation to publication) and input to General Plan on Risk Communication.
- Effective and efficient Risk Assessment processes (scientific production, confidentiality assessment)
- Effective and efficient transversal, administrative and scientific enabling services and outsourcing scientific activities

Conclusions

Challenges

Complexity of changes:
- ✓ new processes
- ✓ new tools
- ✓ newcomers

High budget

Tight schedule

Alignment with MSs

Solutions

Training
- ✓ on new processes
- ✓ on new tools
- ✓ for newcomers

Outsourcing with good quality

Re-prioritisation

Structured cooperation

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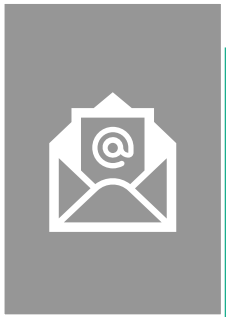

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