



81st Advisory Forum meeting  
Virtual meeting, 27-28 October 2021

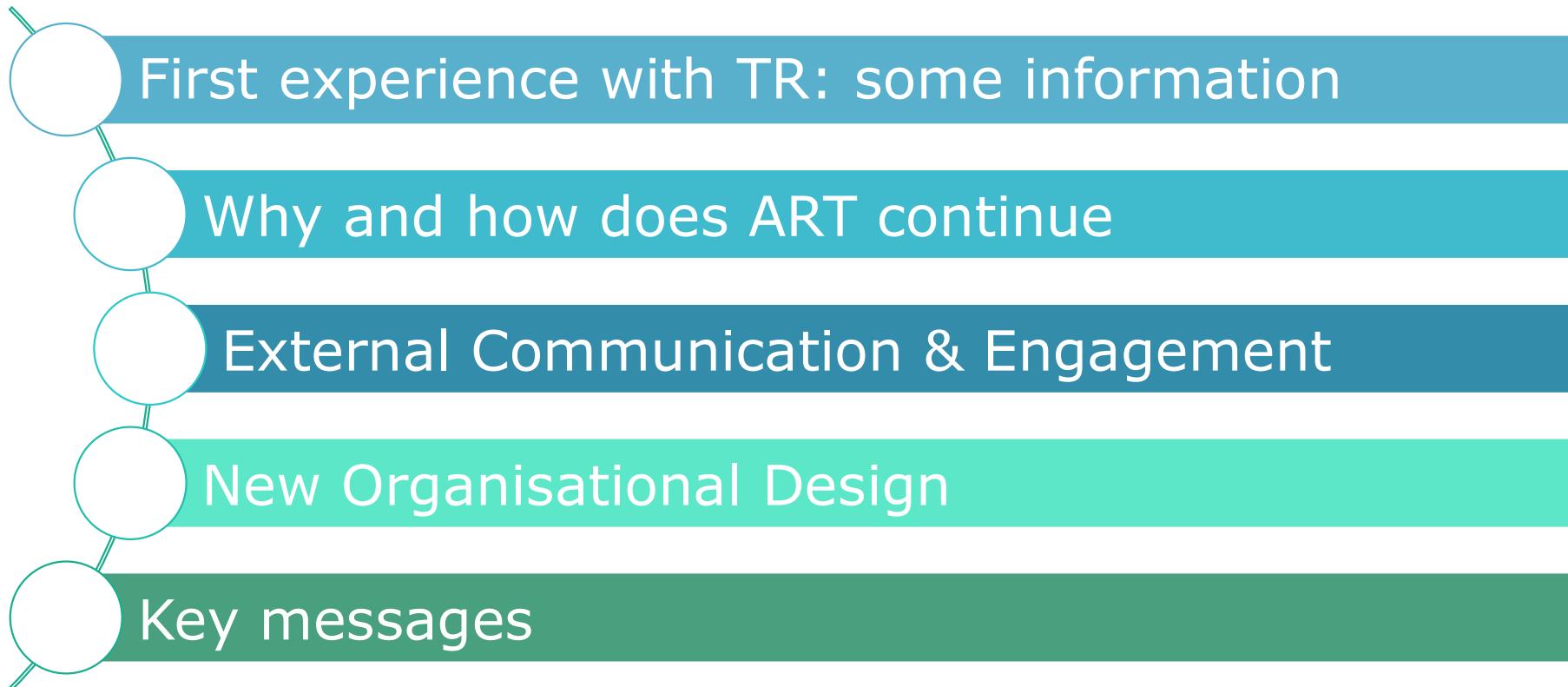
## Update on the implementation of the TR

**Guilhem de Seze**

Head of the Scientific Evaluation  
of Regulated Products Department

Trusted science for safe food





# First experience with TR: some information

- Non-pesticides applications received\* by EFSA (ESFC): 44
- Pesticides applications received\* by EFSA (IUCLID): 41
- Art 29 mandates: 22 Feed datasets
- Pre-submission advice: 32 general PSA + 67 renewal PSA
- Notifications of Studies (new applications): 1699

\* on 15 October



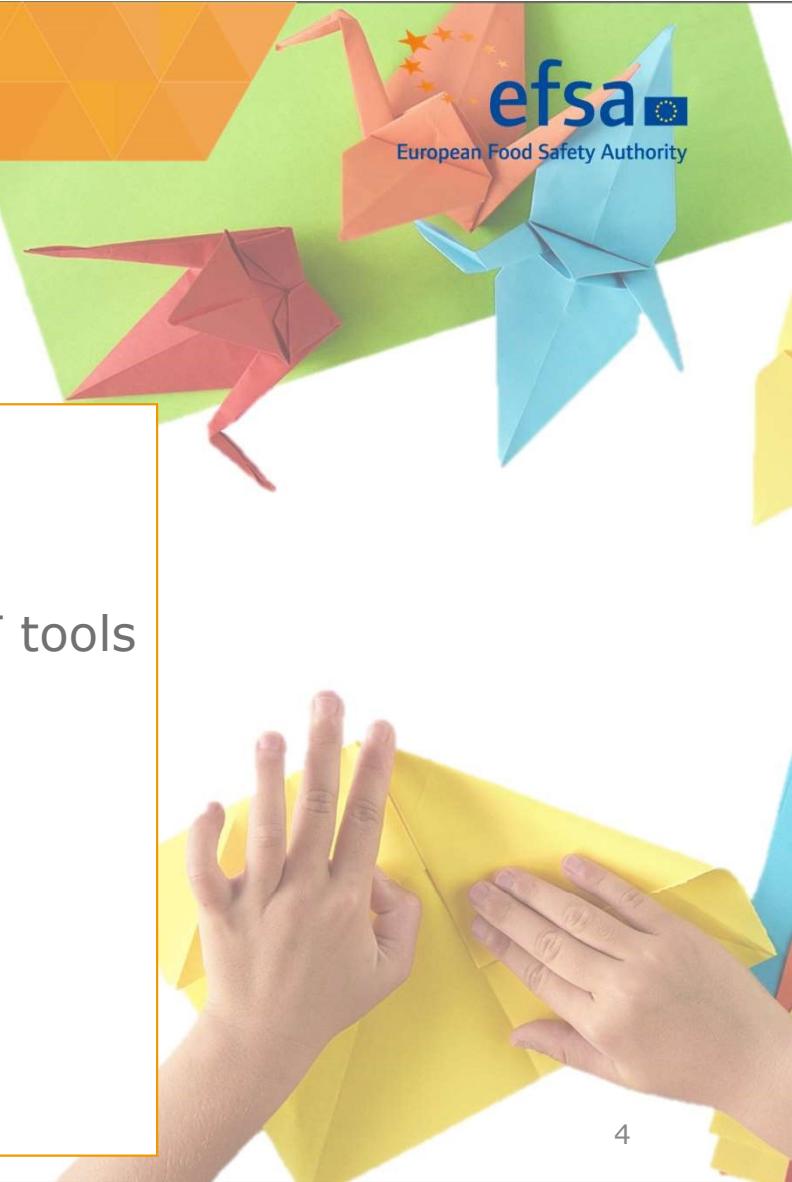
**Positive outcome**  
➤ TR is being implemented



**Main challenge**  
➤ Workarounds necessary to circumvent start-up problems

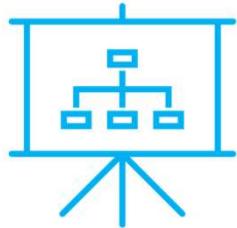
## Why does ART continue?

Focus of ART 2021 was the implementation of minimum requirements for the Transparency Regulation, delivered in short time and on budget.



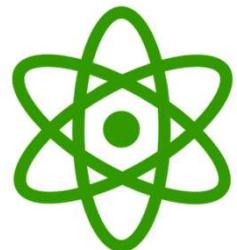
## The ART 2022 projects:

- enhancement of new processes and supporting IT tools
- implementation of the new organigramme



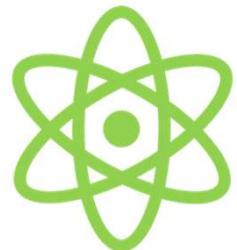
## Organisational Design Project (ODP)

- Postponed due to COVID. Necessary to align the organisation to the new TR capabilities and Strategy 2027



## Risk Assessment Project (RAP)

- Enhancing the minimum viable solution delivered for TR compliance



## IUCLID Release 2

- Mainly enhancing and filtering dissemination and dossier structure
- Integrating IUCLID with EFSA confidentiality assessment



## **Confidentiality Assessment and Sanitisation Project (CASA)**

- Mainly to address PA comments requiring EFSA redaction and sanitisation of dossier



## **Customer Relationship Management Project (CRM)**

- To improve the process for managing third parties and master data



## **Enabling Services Project (ESP)**

- To consolidate management services and complete post-COVID new normal building works

- Why and how does ART continue
- First experience with TR: some information
- External Communication & Engagement
- New Organisational Design
- Key messages

## Targeted proactive external communication and engagement across all projects



- **Based on** collection and analysis of external parties' expectations and needs
- **To ensure** stakeholders, Member States and the public receive timely information
- **Through** EFSA website, targeted communication via Salesforce, stakeholder newsletters, social media
- **In close liaison** with DG SANTE
- **Stakeholder initiatives:**
  - Continuous updated training programme
  - Targeted webinars 1/month
  - Targeted communication following tool upgrades/new release
  - Dedicated LinkedIn group
  - Dedicated SME event (Q1, 2022 TBC)
  - IUCLID: IUCLID Hypercare, Pesticides Steering Network (PSN) IUCLID sub-group
  - Technical Group on the Notification of Studies Database

# Agenda

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# Rationale for redesigning EFSA's organisation

## Implement Transparency Regulation

- Increased staff and budget/external resources
- New/enlarged activities and processes (pre-submission advice, transparency, confidentiality checks, work sharing with MS, verification studies etc.)

## Fit to new EFSA strategy

- Deliver risk assessment and communication – SO1
- Ensure preparedness for the future – SO2
- Empower people, organizational agility – SO3

## Fit to revised ART processes/ correct operational shortfalls

- Increase cooperation and integration
- Improve the management of knowledge
- Strengthen accountability and culture



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## Key messages



- Work in progress, building on lessons learned: focus on enhancement of processes and tools
- Specific change management support in place to assist all staff in the transition:
- Tailored on-boarding of staff to new organisation
  - Socialising and teambuilding activities
  - Training and coaching to new Managers
- Further incentives for partnering (MSs)

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