



**74th Advisory Forum meeting
Parma, Italy, 27-28.11.2019**

Update on the implementation of the Transparency Regulation

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Trusted science for safe food

Priorities in a nutshell

Transparency &
Confidentiality



Scientific value



Engagement & Risk
Communication



Governance



Transparency and Confidentiality status

Transparency &
Confidentiality



Practical arrangements developed in 2019:

- Practical arrangements for implementing access to documents Regulation and Aarhus: first draft finalised for consultation with SANTE
- To be adopted by EFSA's MB in March 2020

Practical arrangements under Pesticides Regulation



- **Confidentiality assessments in pesticides assigned to Rapporteur Member States** on new substance dossiers **and to EFSA** on renewals of active substance dossiers
- **Articles 7 and 16 of Regulation (EC) No 1107/2009** require EFSA to develop practical arrangements
- **Objective:** ensuring consistency of confidentiality assessments done by Rapporteur Member State and EFSA

Practical arrangements under Pesticides Regulation



- **Adoption** of Practical arrangements **after “consultation with Member States”**
- EFSA plans to **engage** with Member States:
 - In preparatory phase, as of Q2 2020 **via Pesticides Steering Network**
 - After a draft text has been validated internally and following consultation with the Commission, **with PAFF Committee and/or the Expert Group of the General Food Law** managed by SANTE, latest by Q3 2020
- Previous engagement on Practical Arrangements under Article 39d(5) of Regulation (EC) No 178/2002 as amended in first half of 2020

TO-BE processes under finalisation:

- Harmonization and integration
- Identification of necessary actors/competences
- Impact on current tools and identification of tool needs
- Estimation of feasibility & resource needs

Scientific value



**Design phase
done in 2019**



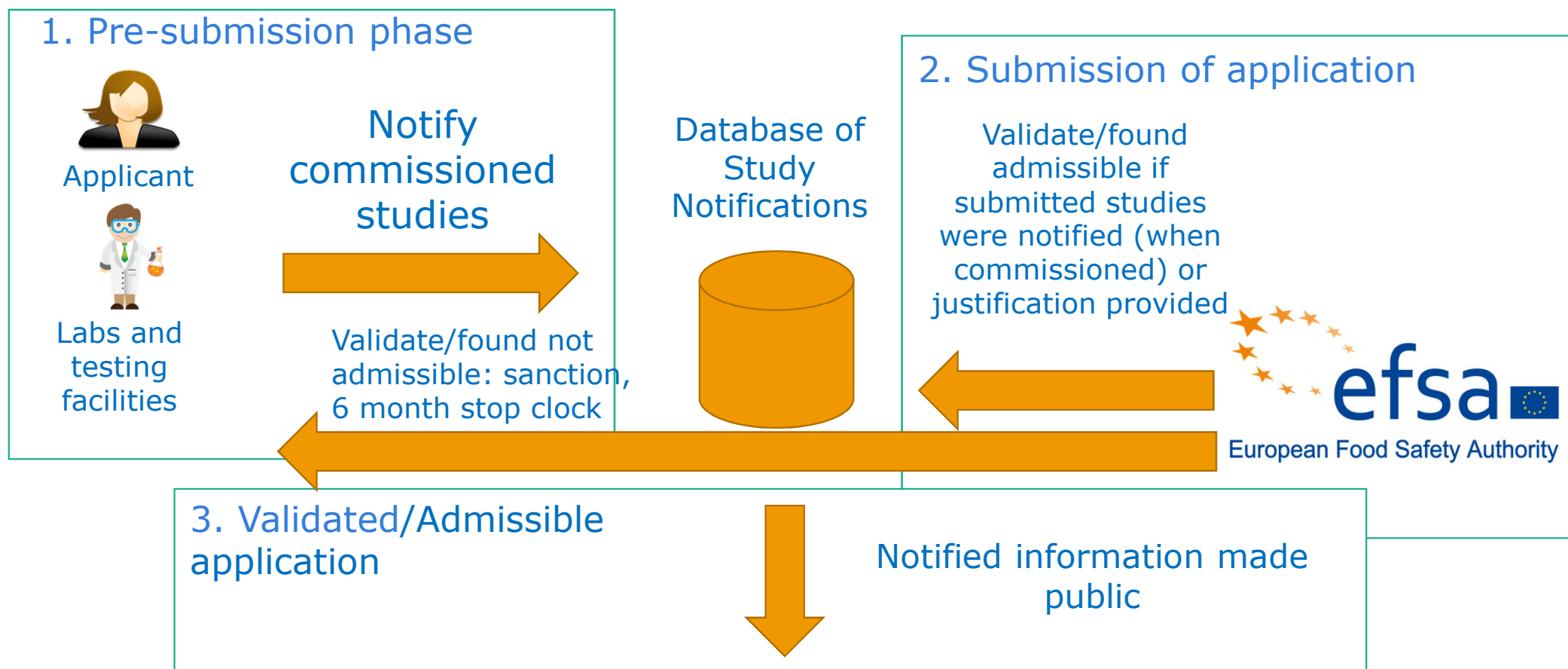
**Implementation
phase in 2020**

9 Newly mapped processes

- Consultation of 3rd parties
- Verification of studies
- Pre-submission advice
- Good Laboratory Practice (GLP)
- Art.36 organisations experts drafting; experts suggested by Art36 organisation, same RA workflow as used by EFSA
- Training for Panel Expert/staff
- Proactive publication
- Confidentiality assessment
- Standard data format
- **Notification of studies**

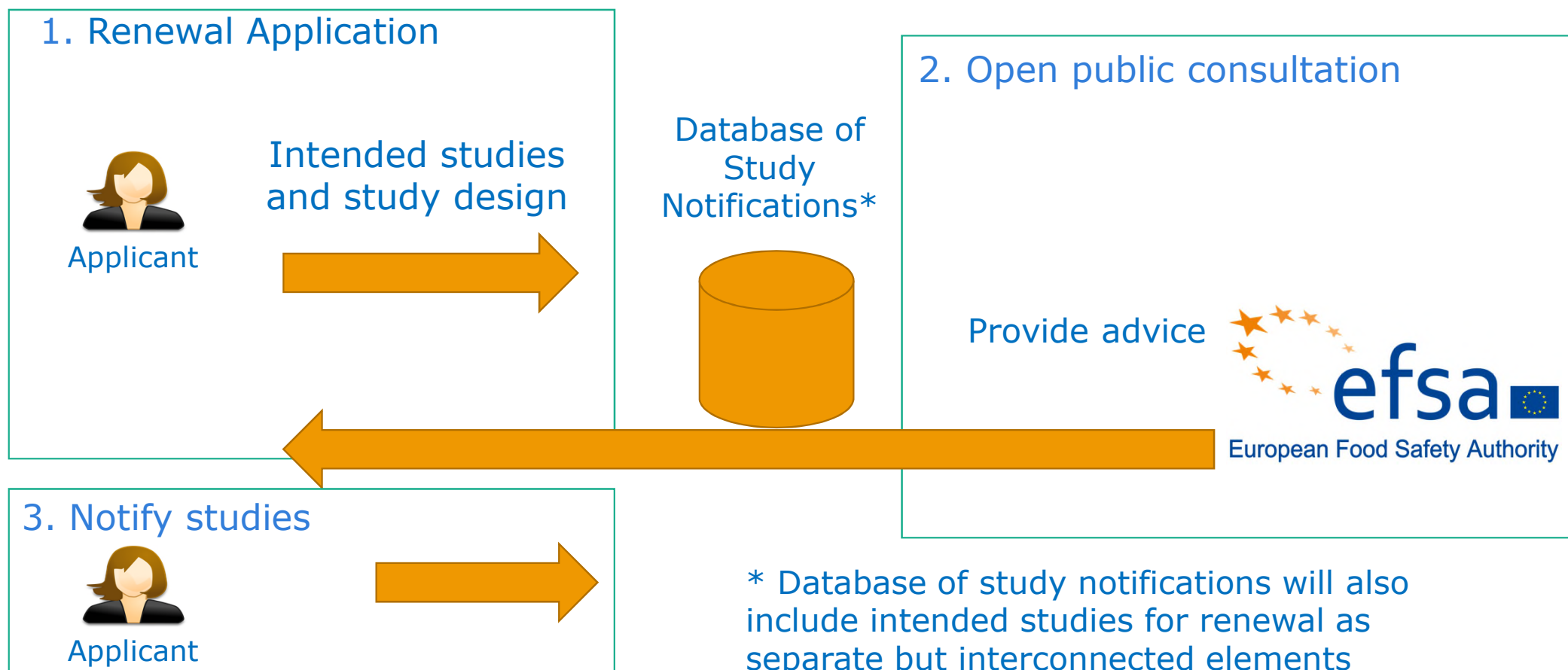
Notification of Studies Supporting New Applications

Transparency in the generation and submission of studies in an application. [Article 32b]



Open Public Consultation on Intended Studies Supporting Renewal Applications

EFSA consults with third parties on the intended studies (and their design) proposed by applicants for application renewal [Article 32c (1)]



Engagement and Risk communication status



- First steps towards the establishment of a **Steering Group** to provide input to DG SANTE's work on a proposal for a **General Plan on Risk Communication** (CEN meeting, Berlin, 20-21 October)
- **Increased budget** and **additional tasks** for **scientific cooperation** (amended FP Agreements, G&P, EU-FORA) to implement new sustainability provisions
- **Engagement principles** jointly prepared by EFSA/DG SANTE to be finalized
- **Sounding Board**: composition identified (MSs volunteers (SE, HU, ES), Stakeholder Bureau, DG SANTE)
- **Technical groups**: 1 IUCLID pilot launched; 1st physical IUCLID technical group meeting took place on 6-7 November; additional technical groups under discussion

Engagement and Risk communication status



- **FP workshop & meeting** (12-15.11.2019) allowed discussions on new FP tasks
- Contractual support and flexibility for **implementation of new tasks during 2020** by EFSA Procurement Team + **Training** to support implementation
- **4 main categories of new FP tasks:**
 - A. Support to mapping of Art36 org. & other org. for EFSA to outsource work
 - B. Capacity building: Development of module 4 for the EU-FORA on DATA
 - C. Additional support on Data collection activities
 - D. Translation activities

High Level Timeline (Reminder)

TODAY

Translate the law into procedures in collaboration with SANTE: transparency, confidentiality updating processes for data-work-flow, notification of studies, open public consultations, preparing the ground for standard data formats

Prepare implementation (including development of necessary supporting tools)

Start delivering the added value enshrined in the Transparency Regulation

2019

2020

2021... and beyond