

20-21 October 2020
NoS Technical Group Meeting

List of Intended Studies for Renewal Process

Stefano Cappè
Evidence Management Unit

Trusted science for safe food

Transparency Regulation¹ Article 32c



- Where the relevant Union law provides that an approval or an authorisation ... may be renewed, the **potential applicant** ...shall **notify** the Authority **of the studies it intends to perform** for that purpose, **including information on how the various studies are to be carried out** ...
- Following such notification of studies, the **Authority shall launch a consultation** of stakeholders and the public **on the intended studies for renewal, including** on the **proposed design** of studies.
- Taking into account the received comments ...which are relevant for the risk assessment of the intended renewal, the **Authority shall provide advice on the content of the intended** renewal application or notification, **as well as on the design of the studies**

¹) 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

What We Talk About

In Scope

Out of Scope

- Potential Applicant creates list of intended studies for renewal
- Potential Applicant links intended studies to the list
- Potential Applicant submits list of intended studies for renewal
- Potential Applicant notifies intended studies for renewal

- Third parties consultation processes on the list of intended studies for renewal
- Renewal pre-submission advice

Potential Applicant



is notifying for Potential Applicant A

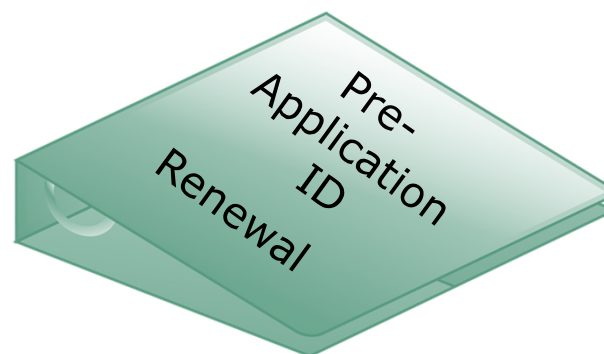
1st step before any interaction with the systems supporting the pre-application phase is the registration



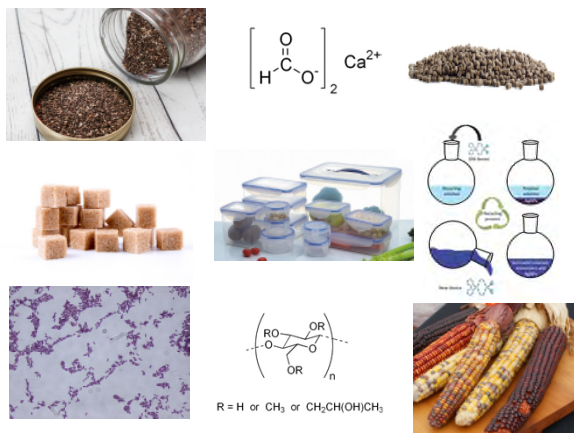
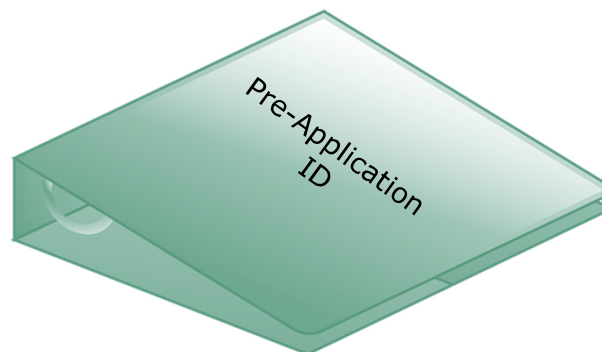
Pre-Application identification for renewal



Request a pre-application ID for renewal



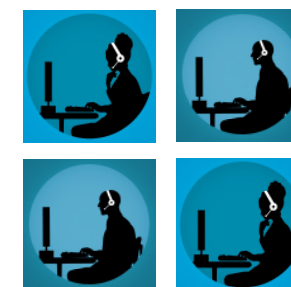
Pre-Application Identification for renewal



Subject of the application

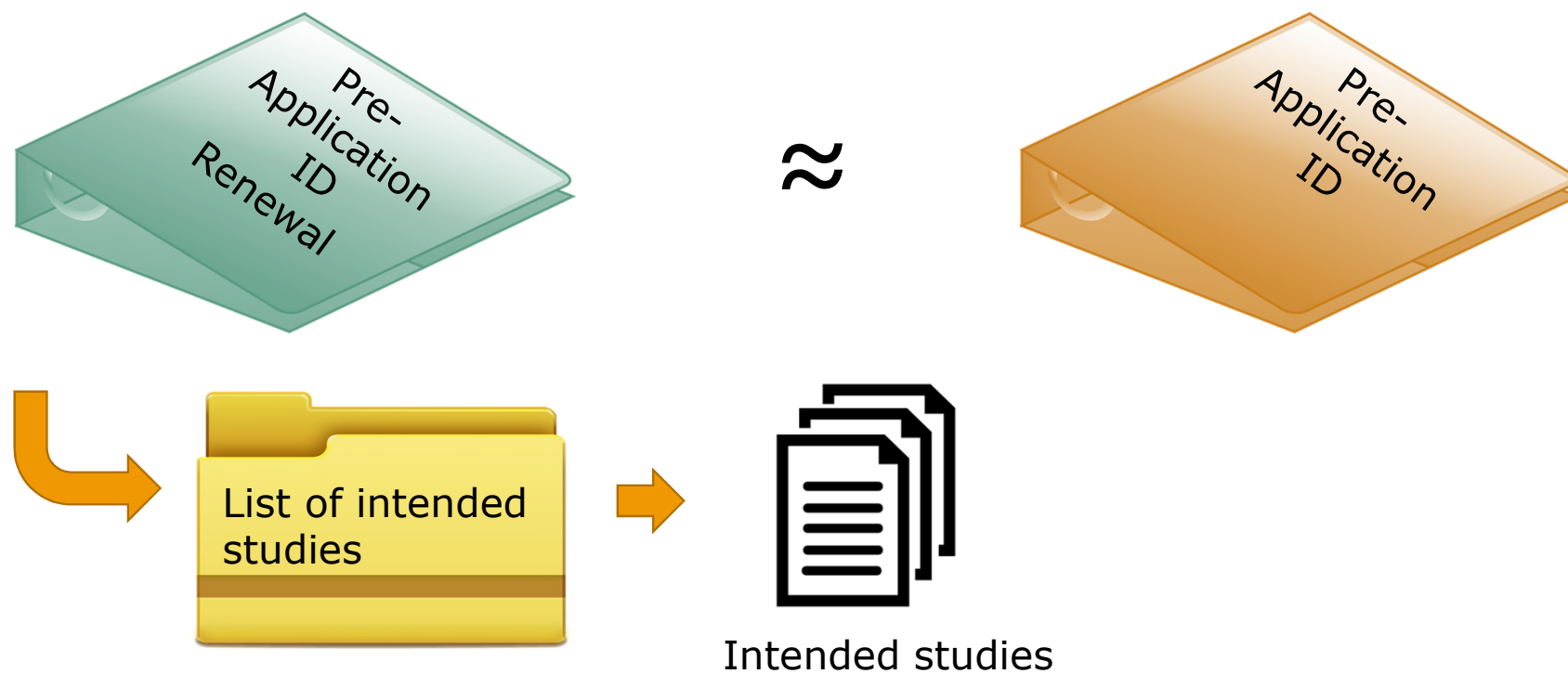


Intended Area



Business Operator(s)

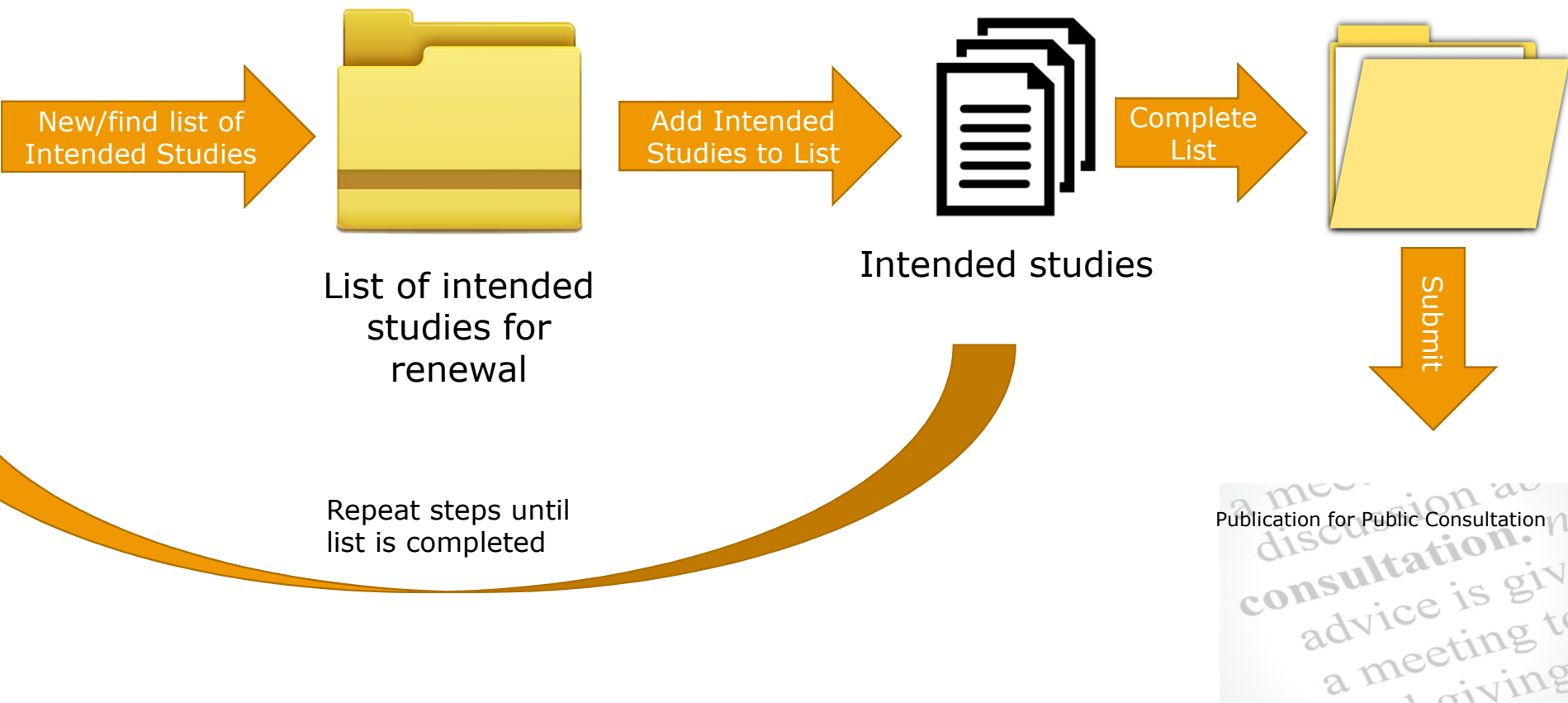
Pre-Application identification for renewal



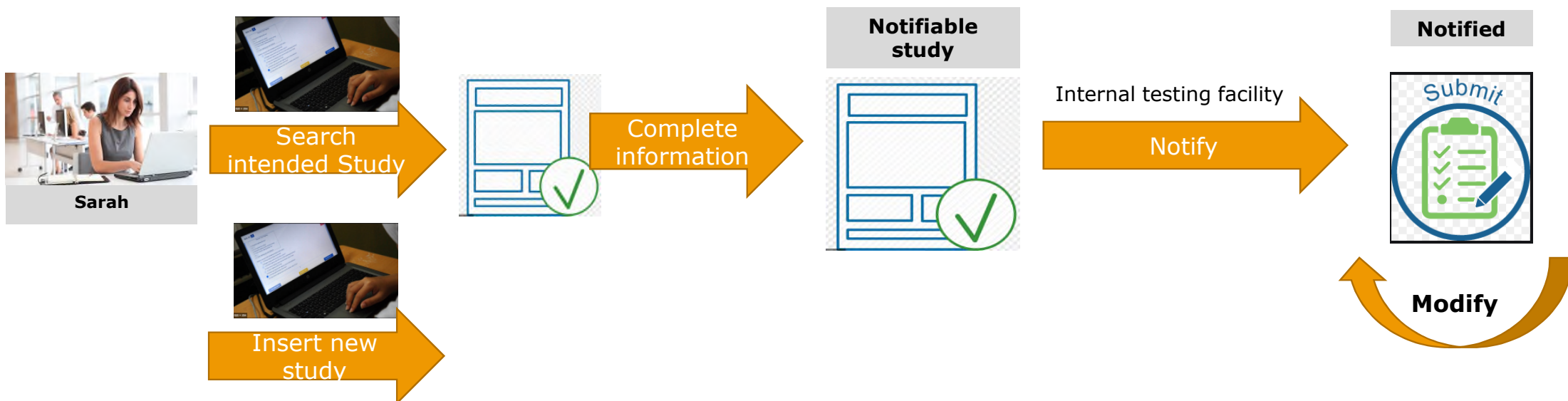
Application Renewal Pre-submission Process



Linking Intended Studies for renewal to the List



Business Operator Notifies Intended Study under 32b



Business Operator Notifies Intended Study under 32b

