

Implementation of Transparency Regulation

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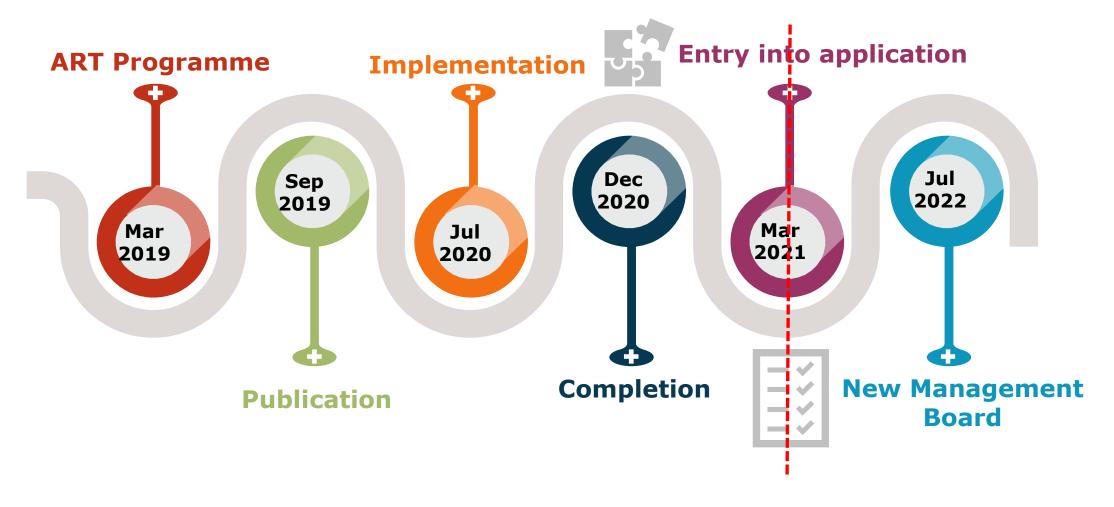
Programme Manager



Trusted science for safe food

Progresses with respect to plan





Content



What is done / achievements How was done / approach What is next

What is done: Documents



Practical arrangements
- adopted, published

Guidance documents

– endorsed, published

Internal documents -approved, shared

SOPs

Public Access to Documents

Pre-submission advice and Public Consultation

Transparency and Confidentiality Assessment by EFSA

Consistency of MS confidentiality assessments (PPPs)

Administrative GDs

15 Scientific GD

+ 1 Scientific GD on Stunning methods

WINs

User manuals

Training material

What is done: Processes



TR required new processes:

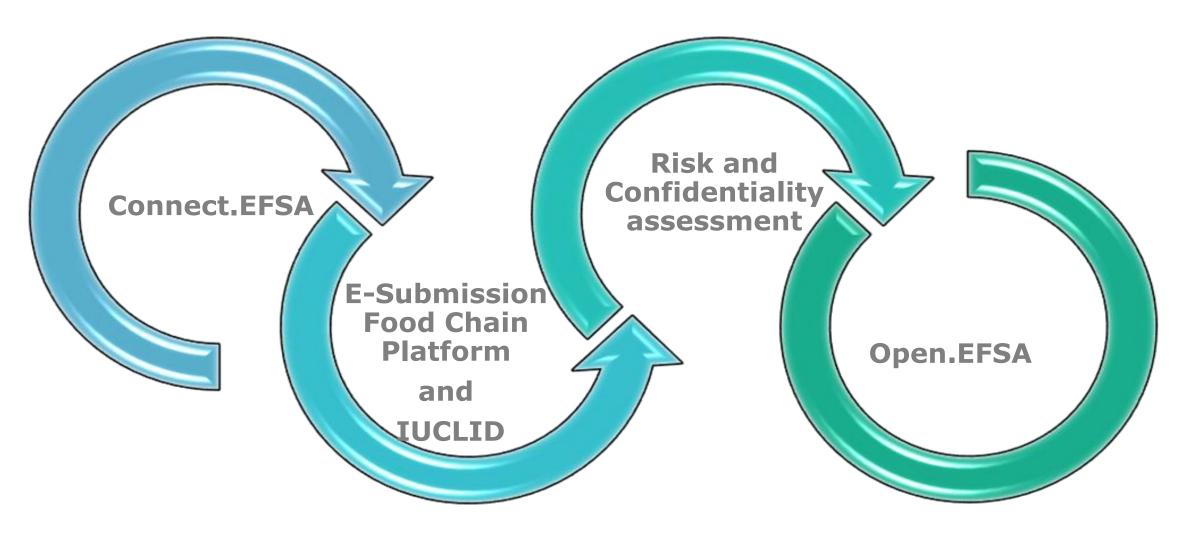
- Pre-submission activities:
 - Pre-submission advice
 - Advice for renewal
 - Notification of studies
- Confidentiality assessment
- Proactive dissemination
- Verification studies

Changed processes due to TR:

- Public consultation
- Risk assessment flow management

Technology integration: application flow





Temporary disruption



Concept of minimum viable product:

- All processes and tools are ready to go live
- All critical part of TR will be implemented

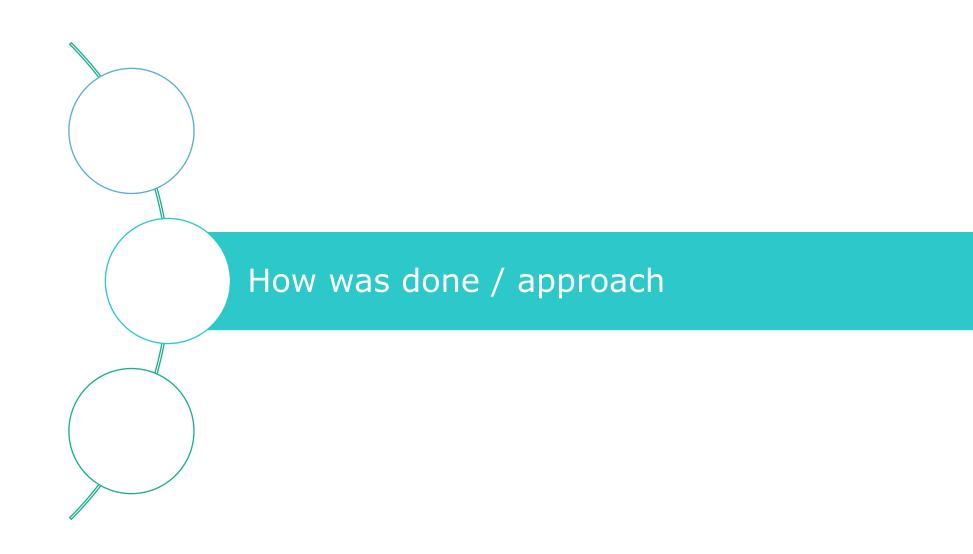
Difficulties:

- The final rush: upload master data in the new systems
- Cleansing of master data is complex: possibly underestimated



Content





How was done: Cooperation



DG SANTE:

- Regular TR implementation updates (9 meetings)
- Working meetings
- Formal / Informal consultation on PAs and GDs
- Development of e-Submission Food Chain Platform

ECHA

Development of IUCLID

Member States

- Confidentiality assessment for PPPs
- Establishment of VPN connection for PPPs and MRLs dossiers
- Development of enhanced partnership strategy

How was done: Engagement



Meetings:

- Sounding Board (3 meetings)
- Technical groups:
 - Notification of studies database (3 meetings)
 - IUCLID for pesticides (5 meetings)

Meeting agendas are published on EFSA website

External trainings:

- 7 Webinars
- 7 Video tutorials
- 7 Video introductions

All are available on EFSA website

Date	Title	Target audience	Material
20/11/2020	Implementing the Transparency Regulation: Requirements, tools and services	All	Webinar
20/11/2020	Transparency Regulation: What's new for business operators and applicants?	Business Operators	Video Introduction
20/11/2020	Table of Contents (TOC) for application submission	Business Operators	Video Introduction

TR Ext Comms plan | Objectives & Audiences



High level

Target audience

Concerned citizens
Academia
Media



- Increase awareness and understanding of measures put in place by to improve transparency
- Position EFSA as an organisation that cares for and respond to citizens' concerns, ultimately increasing trust in the EU food safety system
- Position EFSA as an organisation embracing technology & innovation to improve RA and enhance public health

Technical/Operational

Target audience

Applicants and BOs Stakeholders' groups EFSA's partners

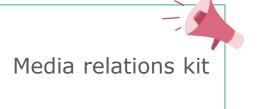


- Organise information related to TR in an accessible and meaningful way for interested stakeholders
- Provide relevant audience with resources to achieve a suitable level of awareness and understanding of TRderived changes, including related new tools and services



TR Ext Comms plan | Leading up to 27 March







Animated explainer video (with EC)







Dedicated website entry points

Promotion via CRM & newsletter





Third parties' engagement

EC-EFSA
celebratory event

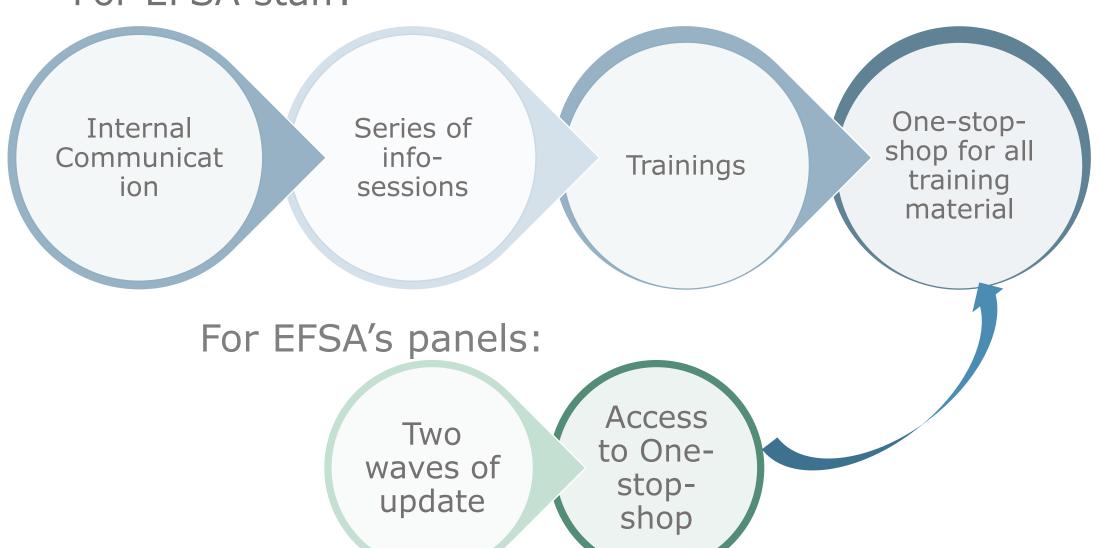
Support in promoting technical content & changes



How was done: Change management



For EFSA staff:



How was done: Hypercare

25/1



What?

Hyper care is a **temporary** programme function. The main **purpose** of the Hyper care period is to give EFSA's internal and external SH a smooth landing by providing them crucial end-user support

When?

Phase 1: new tools

27/3 27/5 **Phase 2**: new tools & TR processes

Internal & external SH

Service Desk

ECHA

Who & how?

Internal SH Knowledge transfer Technical issues **Service Desk Super Users**

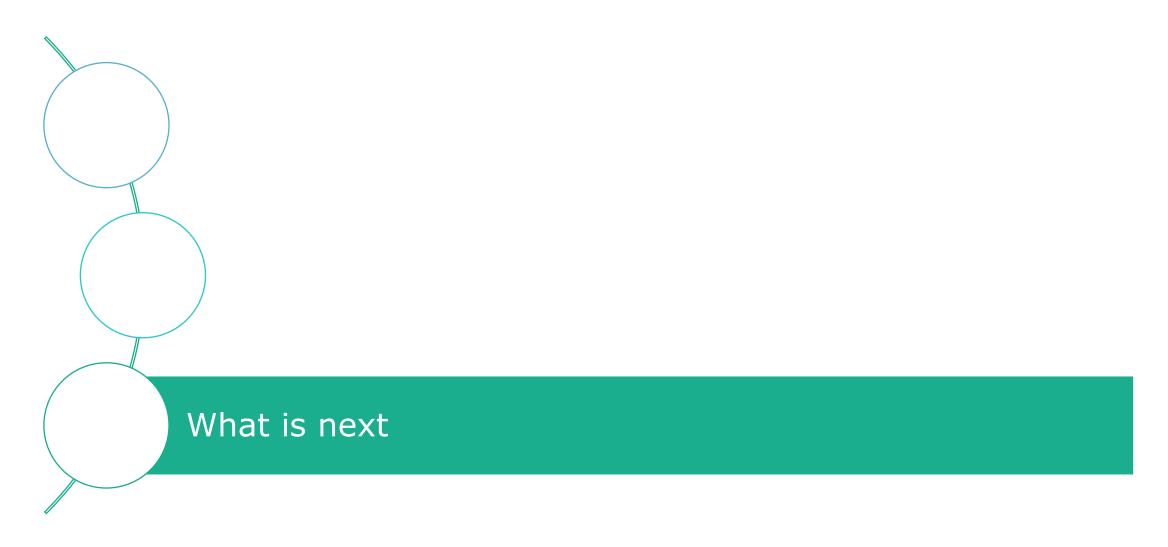
EFSA IT and Super Users

Purpose: answer all questions (not on PAs) received from external SH Taskforce via the functional mailboxes (SH and TR), webinars and trainings When: 1 Feb - 27 March 2021

SANTE

Content





Next steps



from MVP (Minimum Viable Product)....

....to MLP (Minimum Lovable Product)

We are taking on board and implementing:

- ✓ RFCs to improve IT tools
- ✓ Activities placed on hold in 2020
- ✓ Remaining TR requirements (next slide)

TR requirements after 27th March 2021



Remaining requirements of Transparency Regulation:

- Contribution to the general plan for risk communication
- Preparation for new Management Board
- Preparation for new Scientific Committee and Scientific Panels
- Sustainability and Partnership