



Transparency and Engagement in Risk Assessment (TERA): implementation plan to “Open EFSA”

62nd Advisory Forum Meeting,
Parma, EFSA,
8-9 December 2016

EFSA JOURNEY TO "OPEN EFSA"



**2013
2014**

EFSA consults widely its stakeholders to learn about their expectations

2015

Requests expressed by stakeholders are translated in measures to be applied to the Risk Assessment cycle

2016

Measures are assessed for their internal/external impact

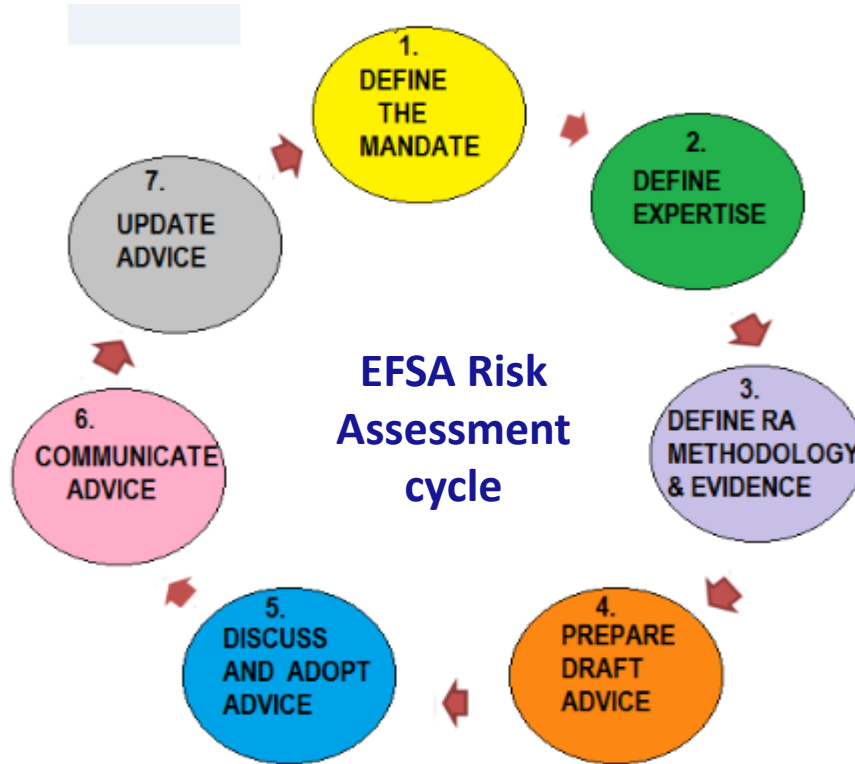
2016

Final measures implementation plan is endorsed by MB

2020

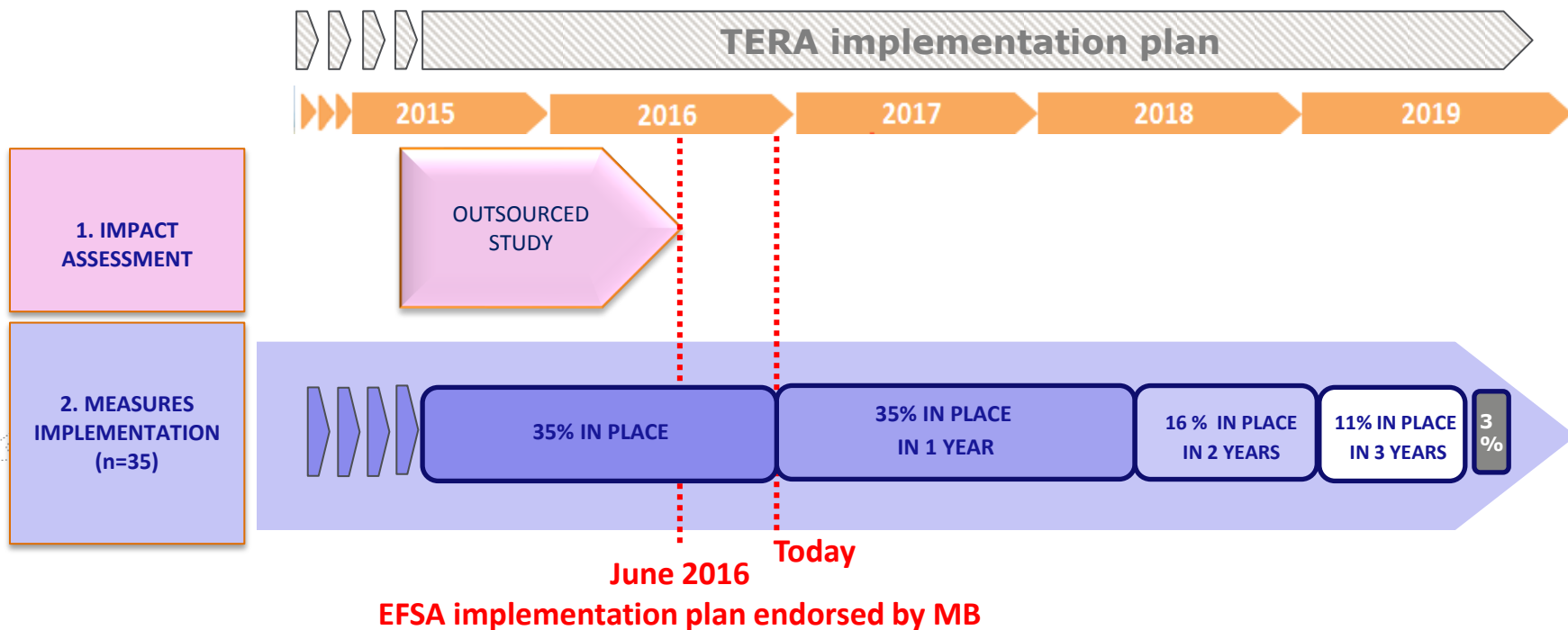
Roll out implementation plan

CONSULTATION PHASE RESULTS



- ✓ 35 MEASURES AIMING AT INCREASING TRANSPARENCY AND ENGAGEMENT IN THE SCIENTIFIC PROCESS
- ✓ APPLICABLE TO DIFFERENT STEPS OF THE RISK ASSESSMENT CYCLE

FINAL IMPLEMENTATION PLAN TO "OPEN EFSA"



IMPACT ASSESSMENT RESULTS

1. Methodology, developed together with EFSA, to be applied to the 35 measures

2. Preliminary impact assessment for all 35 measures

3. Fully-fledged impact assessment for the 10 prioritised measures

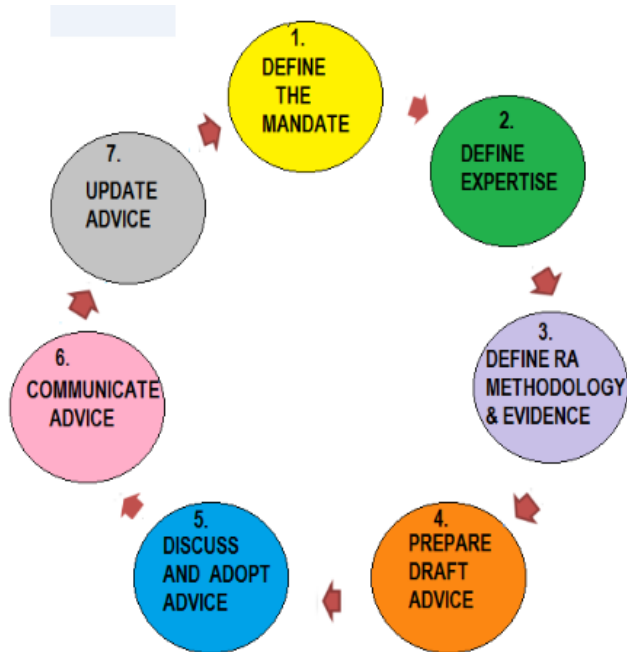


**DECISION TAKEN ON THE MEASURES
IMPLEMENTATION AND TIMELINES**



IMPLEMENTATION PLAN TO "OPEN EFSA" (1)

MEASURES IN PLACE @ Q2 2016



- Scientific Experts: Full CV published (panels), full documentation of selection process (WGs)

- Intensified use of Calls for data

- Extended use of Consultation (including technical hearings)
- Standardised confidentiality procedure
- Support to applicants during clock-stops and post-adoption

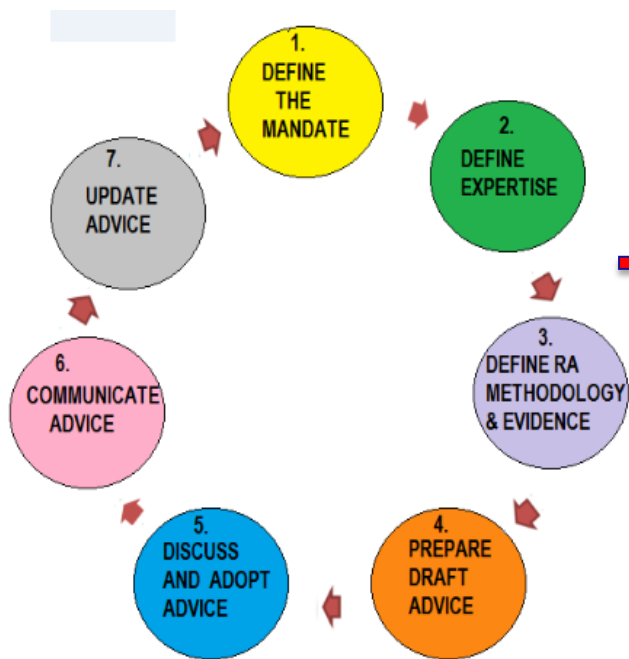
- Extended open plenary meetings in Brussels

- Data sharing: opening of Data Warehouse and 'Circle of Trust' among MSs

- New structure and content of EFSA's opinions

IMPLEMENTATION PLAN TO "OPEN EFSA" (2)

MEASURES IN PLACE BY Q2 2017



- New guidance on consultations

- Framing of mandates: consultation + meetings (groups of applicants). Discussion groups from the new stakeholder engagement approach

- Consultation with MSs (meetings) on draft opinions

- Pilot external ("peer") review (controversial opinions)

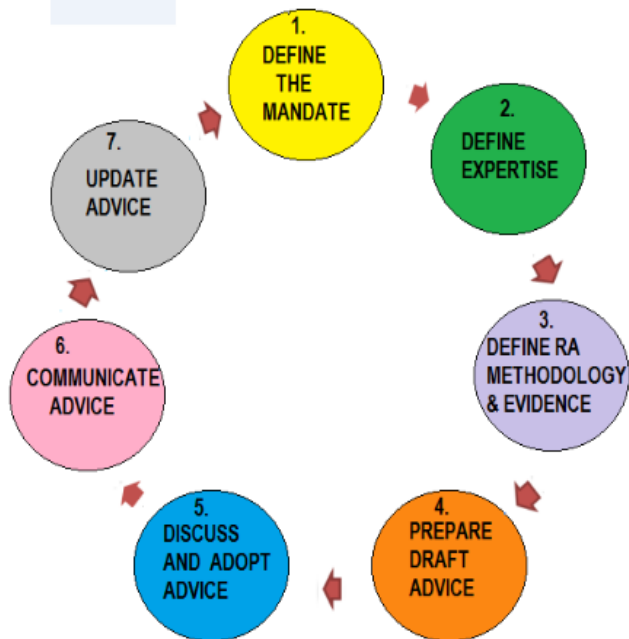
- Data sharing: Information access management + Extension of 'Circle of Trust'

- Flash summaries of plenary meeting + extended minutes

- Re-opening of opinions: new SC guidelines

IMPLEMENTATION PLAN TO "OPEN EFSA" (3)

MEASURES IN PLACE BY Q2 2018



- Scientific experts: full CV automatically published (WGs)

- Transparency on use/exclusion of evidence (Prometheus-decision on implementation)

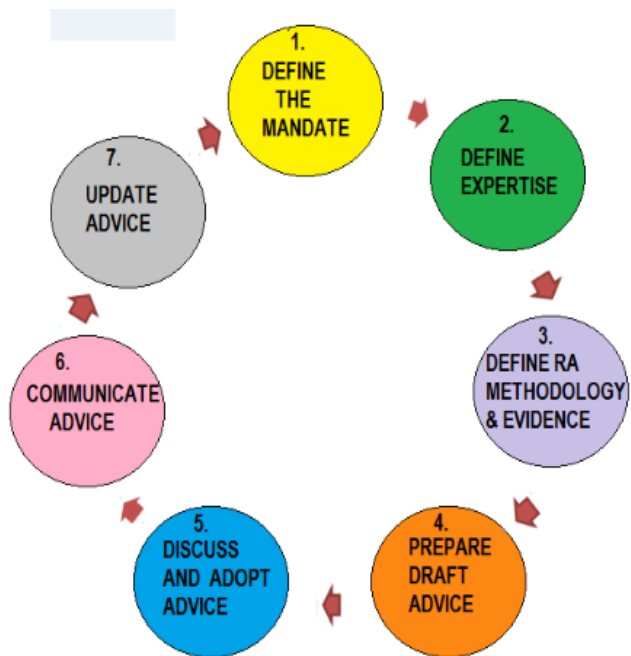
- Transparency of weight of evidence: new SC guidelines

- Commercially sensitive data: agreed definition

- Risk assessment data and methods: accessible central repository

IMPLEMENTATION PLAN TO "OPEN EFSA" (4)

MEASURES IN PLACE BY Q2 2019

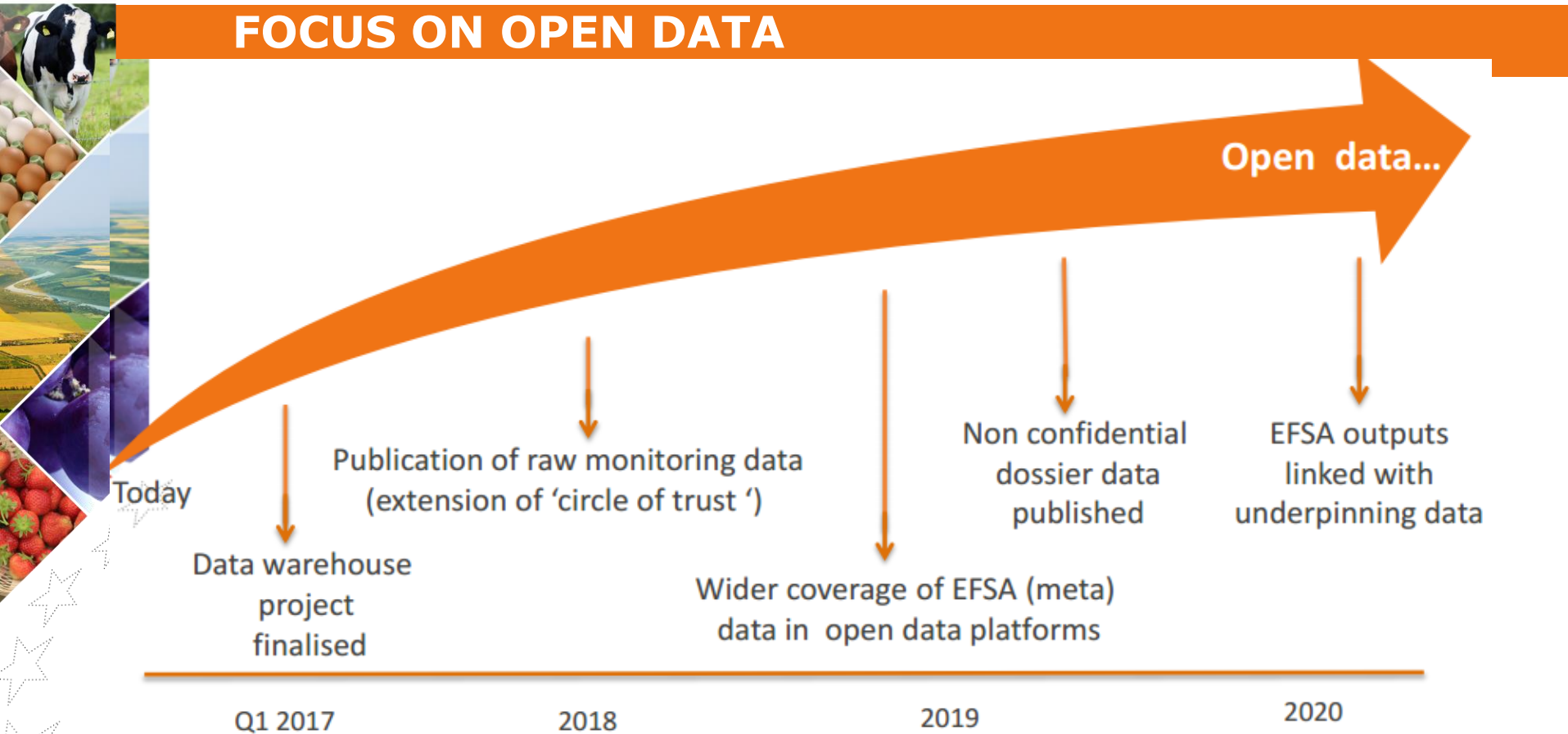


- New, "user-friendly" application guidances in all areas

- Data summary from applicants' dossiers immediately available
- Harmonised and accessible chemical data among MSs and other EU Agencies

- Readable and reusable EFSA risk assessment information (with access rules)

FOCUS ON OPEN DATA



Close cooperation with the EC and other EU Agencies



THANK YOU FOR YOUR ATTENTION!

