



# EFSA 3<sup>rd</sup> Roundtable with industry associations

27 June 2016, Brussels


# AGENDA

Time	Items
<b>13.30 14:00</b>	Registration, welcome coffee
<b>14:00</b>	
<b>14:15</b>	Welcome by the Head of REPRO Department a.i.
<b>14.15 14:30</b>	Annual meeting <ul style="list-style-type: none"> <li>➤ Update issues from last correspondence (ALL)</li> </ul>
<b>14.30 15:30</b>	Transparency and Stakeholders Engagement <ul style="list-style-type: none"> <li>➤ Transparency ERA project (EFSA)</li> <li>➤ Stakeholder Engagement Approach (SEA) (EFSA)</li> <li>➤ Consultations, surveys versus direct dialogue with stakeholders (Industry)</li> <li>➤ Publication/access to submitted data - status (Industry)</li> <li>➤ Mandate development process (Industry)</li> <li>➤ Pilot projects (Industry)</li> </ul>
<b>15.30 15:50</b>	Coffee break
<b>15.50 16:15</b>	Evaluations <ul style="list-style-type: none"> <li>➤ Dialogue with applicants (pre- and during evaluation) (Industry)</li> <li>➤ Communication of final EFSA evaluation (Industry)</li> </ul>
<b>16.15 16:30</b>	Communications <ul style="list-style-type: none"> <li>➤ EFSA Press Release Communication (Industry)</li> </ul>
<b>16:30</b>	AOB
<b>16:45</b>	<ul style="list-style-type: none"> <li>➤ GLP@EFSA (EFSA)</li> <li>➤ REPRO Catalogue – update (EFSA)</li> </ul>
<b>16:45</b>	
<b>17:00</b>	Closing remarks

# ANNUAL MEETING



# TRANSPARENCY AND STAKEHOLDER ENGAGEMENT

- 
- TERA project (EFSA)
  - Stakeholder Engagement Approach (SEA) (EFSA)
  - Consultations, surveys versus direct dialogue with stakeholders (Industry)
  - Publication/access to submitted data - status (Industry)
  - Mandate development process (Industry)
  - Pilot projects (Industry)

# EVALUATIONS – COMMUNICATIONS – AOB

## Evaluations

- Dialogue with applicants (pre- and during evaluation) (Industry)
- Communication of final EFSA evaluation (Impact) (Industry)

## Communications

- EFSA Press Release Communication (Industry)

## AOB

- GLP@EFSA (EFSA)
- REPRO Catalogue – update (EFSA)

## REPRO - GLP INITIATIVE (1)

Implementation of a Standard Operating Procedure (SOP\_022\_S) on the "Selection of studies performed in compliance with Good Laboratory Practice for audit purposes"

→ in place since 14<sup>th</sup> March 2016

- Part I: EFSA **Yearly** GLP Studies Audit Programme
- Part II: EFSA **Ad-hoc** GLP studies audit

## REPRO - GLP INITIATIVE (2)

### Part I - Selection of the studies for audit purpose

#### Criteria

- The study is part of the applications for regulated products for which EFSA has published an opinion/conclusion in the past year
- The study report includes a statement from the study director that the study was conducted in compliance to the GLP principles and a statement of Quality Assurance
- The study has been performed in a test facility for which the relevant GLP Monitoring Authority has scheduled an inspection

# REPRO - GLP INITIATIVE (3)

## PART I

- EFSA GLP Studies Audit Programme 2016 launched (13 studies)
- Report – end of 2016

## PART II (if relevant)

- Ad-hoc requests for triggered audits – **none as of today**
- Report – end of 2016

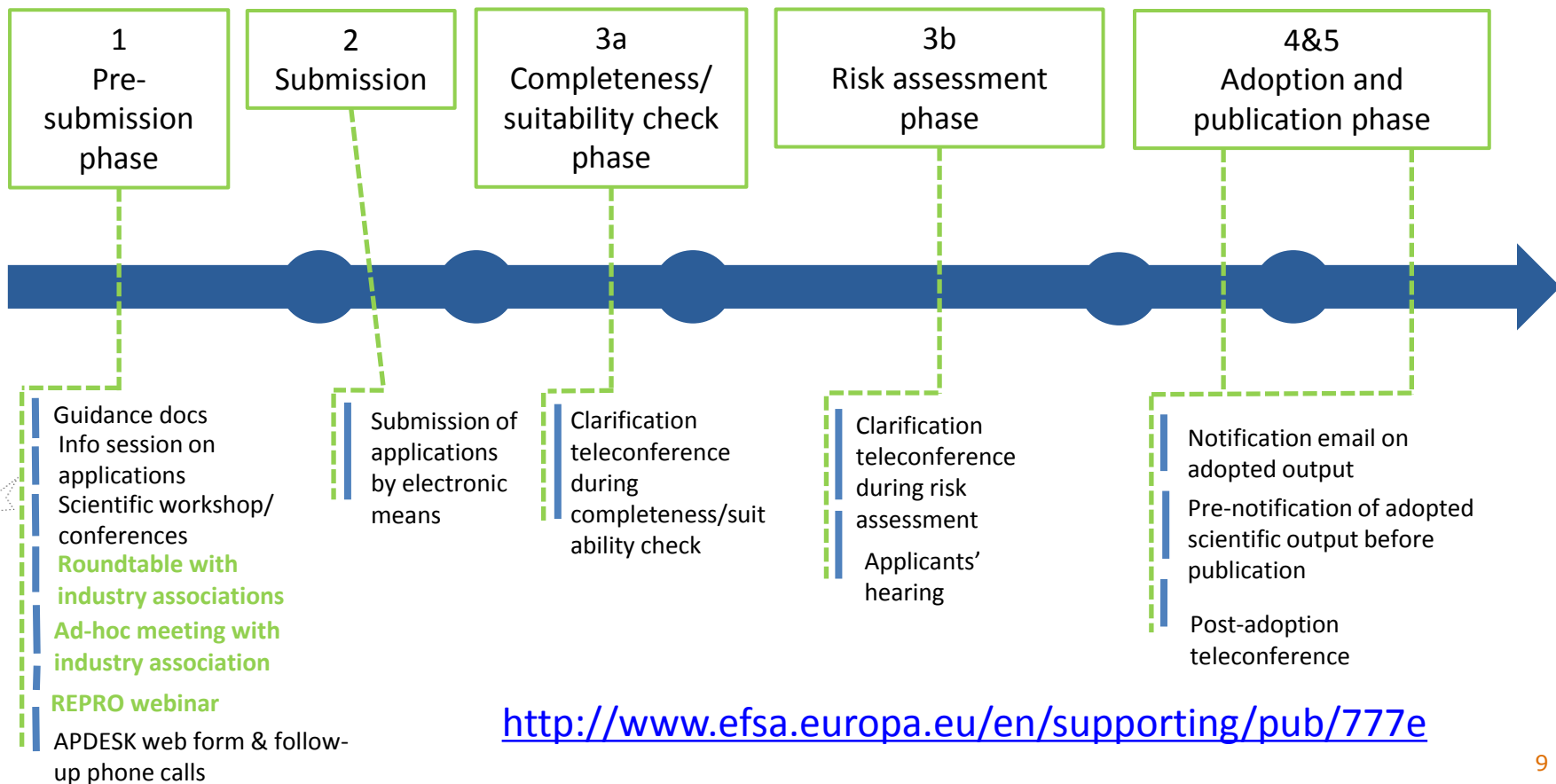
## Contact

APDESK – Karine Lheureux

APDESK – Simona Radulescu (GLP@EFSA coordinator)



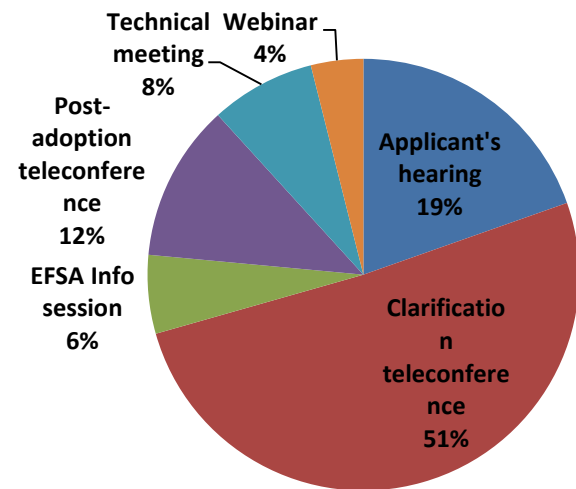
# REPRO - CATALOGUE OF SUPPORT INITIATIVES (1)



# REPRO - CATALOGUE OF SUPPORT INITIATIVES (2)

Status March 2015 – JUNE 2016

Count of Number							
Row Labels	FEED	FIP	GMO	NUTRI	PESTICI DE	APDESK	Grand Total
Applicant's hearing Clarification	3	2	5				10
Teleconference	5	3	3	5		10	26
EFSA Info session	1	1	1				3
Post-adoption teleconference	2	1	1	2			6
Technical meeting			1	2		1	4
Webinar				1	1		2
<b>Grand Total</b>	<b>11</b>	<b>7</b>	<b>11</b>	<b>10</b>	<b>1</b>	<b>11</b>	<b>51</b>



# REPRO - EXAMPLES OF ENGAGEMENT INITIATIVES

	Focus group	Concept paper / Scoping document	Workshop (early stage)
<b>GMO</b>	GD allergenicity (EFSA-Q-2014-00549)		GD allergenicity (EFSA-Q-2014-00548)
<b>NUTRI</b>		GD gut immune (EFSA-Q-2014-00353)	
<b>FIP</b>		ENZYME – refinement method exposure estimates for Food ENZ (EFSA-Q-2015-00515)	Info Session ENZ – refinement method exposure estimates for F.ENZ (EFSA-Q-2015-00515)
		ANS GD nutrient source (EFSA-Q-2016-00150)	
<b>FEED</b>			Info Session JULY 2016, exchange of views on upcoming updates of Guidance Documents
<b>PESTICIDE</b>			Workshop with Stakeholders on the Use of Epidemiological findings in Regulatory Pesticide Risk Assessment. Paris February 2015 ( <a href="#">EFSA-Q-2015-00133</a> )
			Workshop on Developmental Neurotoxicity Testing Strategy (Brussels 18 October 2016)