

EFSA and MS Partnership on Food
Enzyme Safety Assessment:
concept and pilot





Why to do this?



Stimuli:

☐ Transparency regulation – further involvement of MSs to EFSA's work.

Basis:

- □ EFSA is the centralised RA body in the EU for food enzymes since 2009 (Reg. 1331/2008 and Reg. 1332/2008)
- □ Capacity within some MSs is readily available France and Denmark are two MSs that have been assessing the safety of food enzymes prior of 2009,
- ☐ Heavy workload in food enzyme sector likely to increase due to innovation in food technology and the circular economy concept

Objective:

☐ Partnership between EFSA and MSs for EU-wide RA capacity to meet the demand of innovation

Major challenging issues



Guidelines and data requirement:

- □ Differences between EFSA and MSs are realistically probable how to ensure RA quality and consistency?
- ☐ Only fully harmonised criteria can ensure the same-way of RA

RA methodology and way-of-working:

- □ Differences in expert judgement on the same data are physiological and unavoidable how to minimise?
- ☐ DoI policy, harmonisation of workflow, culture of efficiency

Operational mode:

- ☐ EFSA panel is the owner of the EU evaluation opinion affirmative
- ☐ At which stage MS enters the dossier process workflow to be defined
- □ Role and responsibility definition of the MS partnership in each critical steps to be defined
- > See next slides

Dossier process workflow 'as is' overview

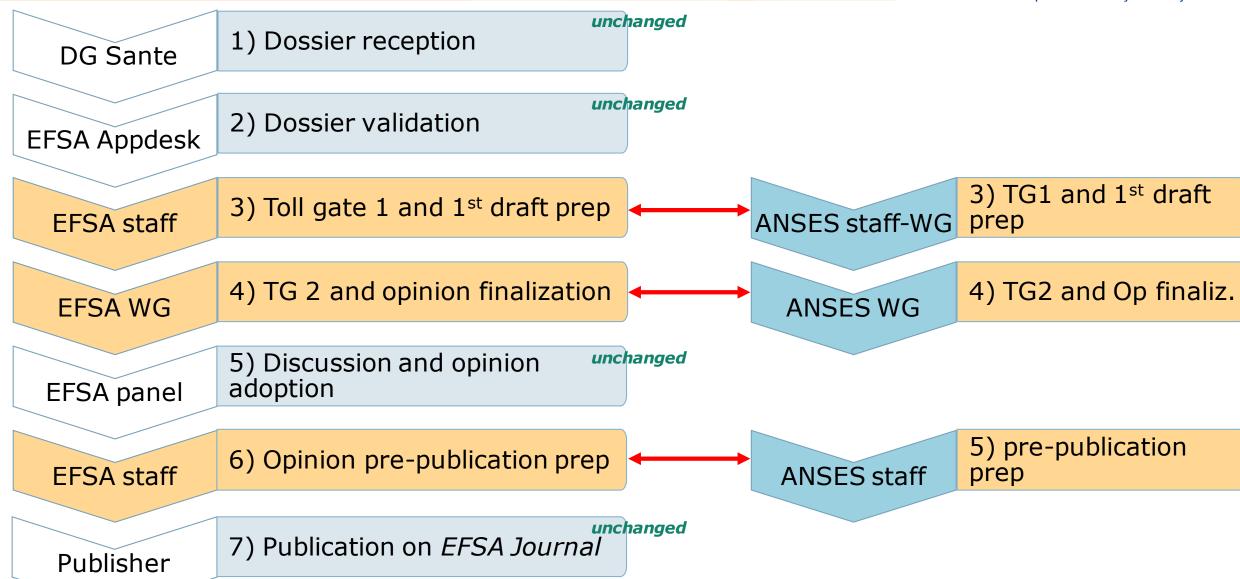


1) Dossier reception DG Sante 2) Dossier validation EFSA Appdesk 3) Toll gate 1 and 1st draft prep **EFSA** staff 4) TG 2 and opinion finalization **EFSA WG** 5) Discussion and opinion adoption EFSA panel 6) Opinion pre-publication prep **EFSA** staff 7) Publication on *EFSA Journal* Publisher

All these steps are of possibility of cooperation, but needs definition with ANSES

Dossier process workflow 'to be' envision





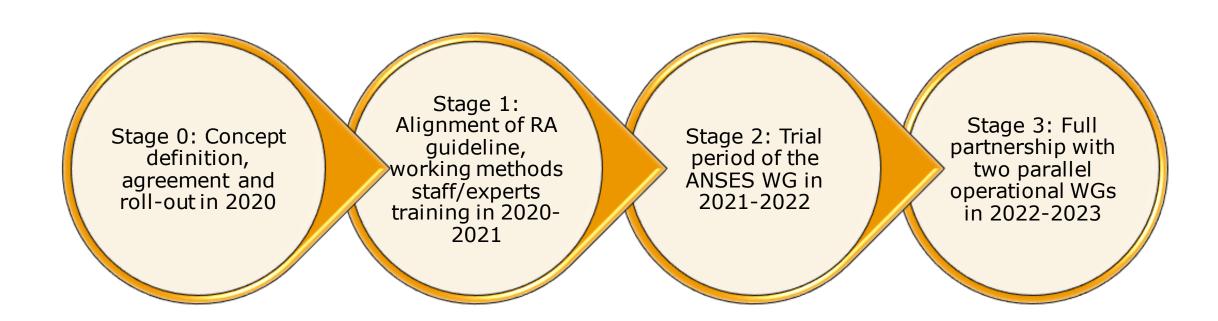
EFSA-ANSES concept blueprint milestones



	24-Mar																																	
Activity/Milestones	Status	25-Feb	26-Feb	2/-Feb	29-Feb	1-Mar	2-Mar 3-Mar	4-Mar	5-Mar 6-Mar	7-Mar	8-Mar	9-Mar	11-Mar	12-Mar	13-Mar 14-Mar	15-Mar	16-Mar	17-Mar	19-Mar	20-Mar	21-Mar 22-Mar	23-Mar	24-Mar	25-Mar	27-Mar	28-Mar	29-Mar	31-Mar	1-Apr	2-Apr	3-Apr 4-Apr	5-Apr	6-Apr	7-Apr 8-Apr
WG consultation with ANSES proposal	Completed		Со																															
Concept envision	Completed						Co			O																								
Presentation to HoD	Completed															Сс	Co	Со																
1st discussion with ANSES	Completed																																	
Send slides to Advisory Forum	Pending																																	
Presentation/discussion in the Advisory Forum	Pending																																	
Check point 1 - Decision on ANSES only or																																		
multiple MSs partnership?	Pending																																	
Concept defintion	Pending																																	
Financial defintion	Pending																																	
Decision by EFSA management: go or no-go?	Pending																																	
Financial execution	Pending																																	
Contract kick-off	Pending																																	
Phase 0 - Concept defintion, agreement and roll-out																																		

EFSA-MS RA partnership concept in a nutshell





Looking forward to your input