

Brussels, 07 November 2017





OUTLINE

Art 13.5 Claims

Pre-submission meetings

Engagement with stakeholders



HEALTH CLAIMS CLASSIFICATION

Regulation (EC) 1924/2006								
Applications								
Art.13.5	Art.14							
Newly	Reduction of disease Risk							
developed scientific data / proprietary data	Children's development & health							
	Applica Art.13.5 Newly developed scientific data /							

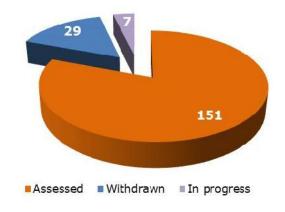
One standard of evidence for substantiation of all categories of health claims

- possibility to <u>restrict the use</u> of the claim in favour of the applicant
- supplementary information within <u>15 days</u> from the date of receipt of EFSA's request

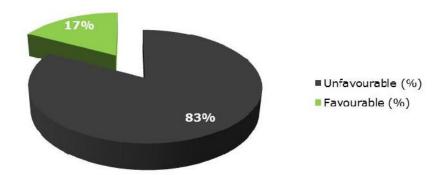


Art. 13.5 CLAIMS

Art. 13.5 Claims (n=187)



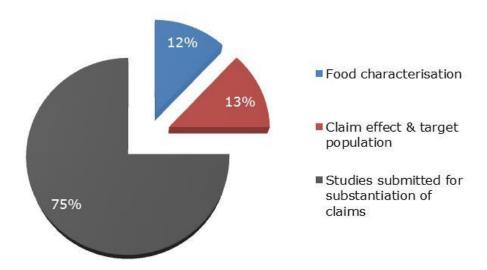
Conclusions on Art. 13.5 Claims applications (n=151)





MAIN WEAKNESSES

■ Reasons for request for supplementary information





PRE-SUBMISSION MEETINGS

- The most requested initiatives by applicants
- May be an efficient tool to optimize the assessment of regulated products
- However, implementation of individual pre-submission meetings is not possible at present:
 - advice to applicants is not requested by the legislation
 - no resources available to offer individual pre-submission meetings
 - public perception on EFSA's independence



WHAT DOES EFSA OFFER?

- Pre-submission phase and throughout the evaluation process:
 - EFSA Guidance Documents
 - 8 Guidance Documents on Claims: updated periodically, public consultation
 - Info Sessions on applications
 - Stakeholder meetings
 - Webinars
 - Online form to submit administrative and scientific queries (APDESK web form)
 - Database on claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims (to be published early in 2018)



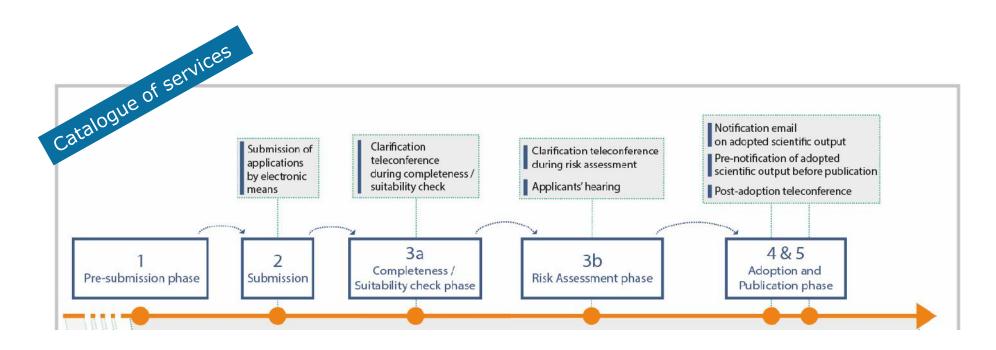
WHAT DOES EFSA OFFER?

Support to SMEs

- Pilot: pre-submission administrative check teleconference of draft dossiers prepared by SMEs (June to December 2017)
 - feed additives and novel foods
 - News Story
 http://www.efsa.europa.eu/en/press/news/170606
 - Description http://www.efsa.europa.eu/sites/default/files/documents/news/170606-ax1.pdf



WHAT DOES EFSA OFFER?



EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products: https://www.efsa.europa.eu/en/supporting/pub/1025e



SERVICES OFFERED

Status March 2015 – JUNE 2017

Service	FEED	FIP	GMO	NUTRI	PRAS	APDESK	Total
Applicant's hearing	7	5	6				18
EFSA Info session	2	1	2	1	1		7
Post-adoption teleconference	3	4	3	6			16
Roundtable with industry associations						4	4
Ad-hoc meeting with industry association		2	1	1			4
Clarification teleconference CC						13	13
REPRO Webinar				2	1	1	4
Clarification teleconference RA	7	14	16	14			51
Follow-up teleconference on web form query		1	1			2	4
Total	19	24	30	25	2	20	118



THANK YOU for your attention

