



EFSA's approach to facilitating innovation and improving engagement with stakeholders

Brussels, 07 November 2017

OUTLINE

Art 13.5 Claims

Pre-submission
meetings

Engagement with
stakeholders

HEALTH CLAIMS CLASSIFICATION

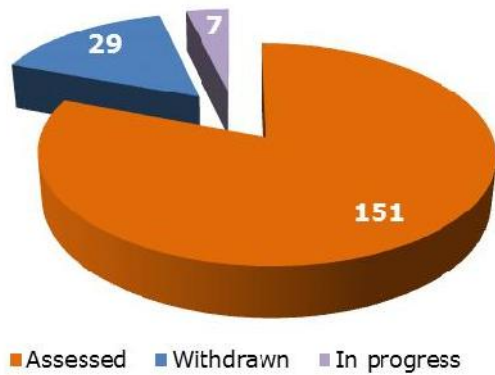
Regulation (EC) 1924/2006		
List Claims	Applications	
Art.13.1 Generally accepted scientific evidence	Art.13.5 Newly developed scientific data / proprietary data	Art.14 Reduction of disease Risk Children's development & health

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

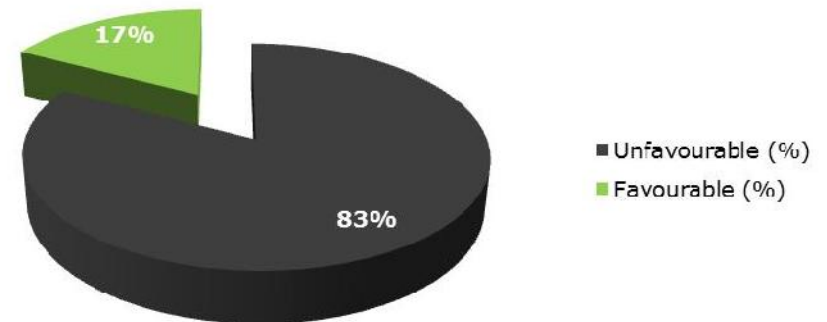
- possibility to restrict the use of the claim in favour of the applicant
- supplementary information within 15 days from the date of receipt of EFSA's request

Art. 13.5 CLAIMS

Art. 13.5 Claims (n=187)

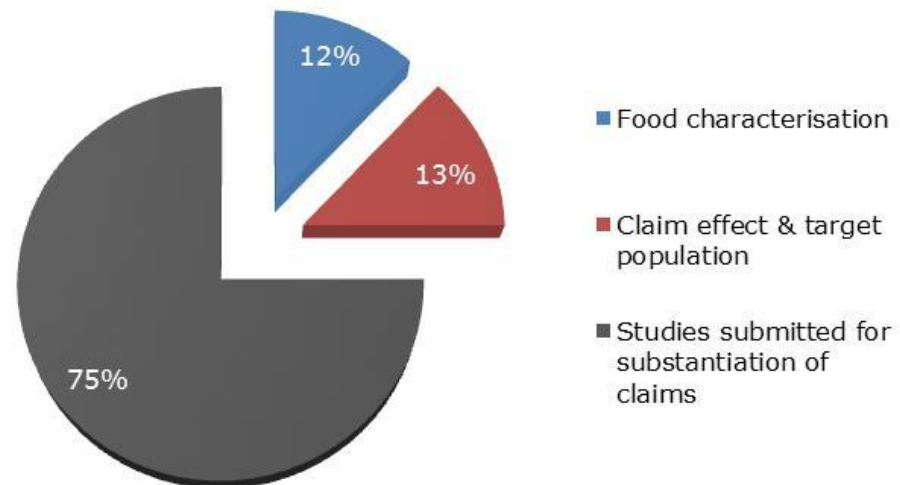


Conclusions on Art. 13.5 Claims applications
(n=151)



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)

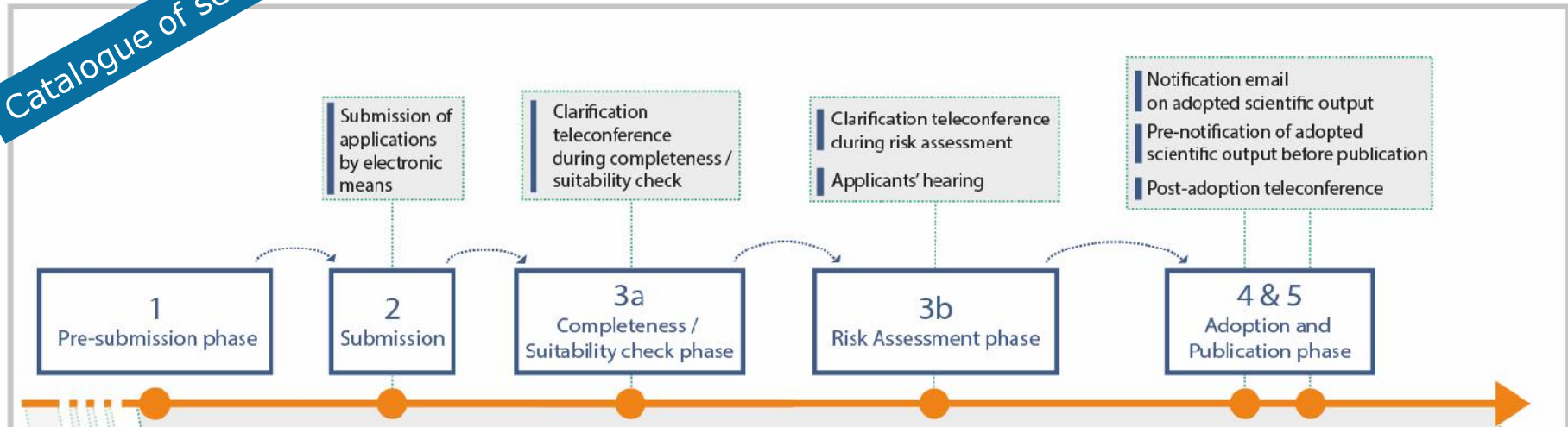
WHAT DOES EFSA OFFER?

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?

Catalogue of services



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

