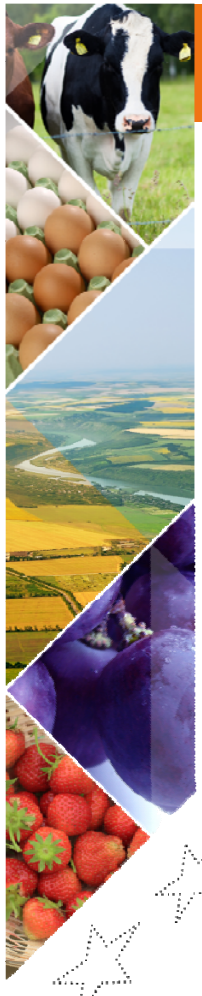
Suitability Check of dossiers on Food Enzymes and services for applicants and other stakeholders

Carla Martino
Applications Desk Unit

Info Session on Applications
Technical meeting on Food Enzymes
27/05/2014

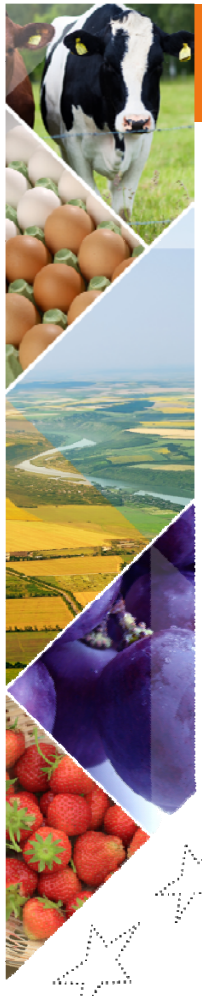
efsa
European Food Safety Authority



TODAY'S PRESENTATION

Applications Desk as a front office and support desk for applicants

- Centralise and harmonise workflow on applications
- Suitability check of dossiers on Food Enzymes
- APDESK web form
- Customer oriented approach



APDESK VISION AND MISSION

Vision

Our vision is to facilitate high quality applications for regulated products that enhance innovation.

Mission

Lead a front office and support desk for all stakeholders with respect to applications for regulated products.

CENTRALISATION OF APPLICATIONS

Applications are submitted to EFSA

Individual scientific units

EFSA / APDESK

- ✓Reception
- ✓Acknowledgement
- ✓Administrative issues
- ✓ Completeness check
- ✓…

VALID application

Risk assessment

FIP Unit	**FEED Unit**	**GMO Unit**	**NUTRITION Unit**	**PESTICIDES Unit**	**BIOHAZ Unit**

FOOD ENZYMES – WORKFLOW APPLICATIONS

Applicant → EC

EC → Reception EFSA

Reception EFSA → Suitable / Not suitable

Regulations
EC
1331/2008
234/2011

30 WDS (legal DL)

- Suitable
- Validity (by EC)

Suitable → Validity (by EC) → Risk Assessment

Negotiated deadline

- Risk Assessment
- Adoption by the Panel
- Publication

Adoption by the Panel → Publication

15 WDs*

*EFSA aims at publishing the opinion 15WDs after adoption

FOOD ENZYMES – WORKFLOW SUITABILITY CHECK

Applicant

Dossier

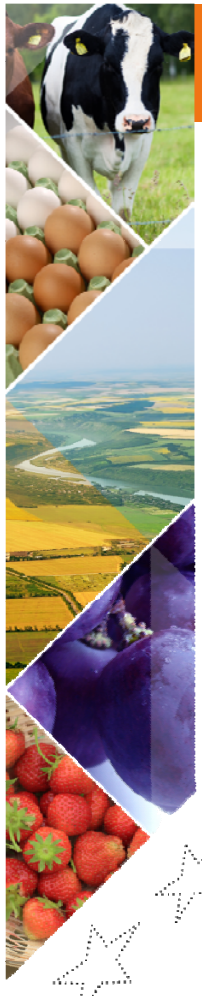
Regulations EC 1331/2008 234/2011

EUROPEAN COMMISSION

Mandate + Dossier

EFSA

Performs suitability check (30 WDs legal DL)



OVERVIEW ON DOSSIERS IN EFSA (update 27.05.2014)

41 dossiers received by EFSA:

Number	Outcome	Status in EFSA Register of Question
23	Suitable	
1	Opinion adopted	Finished
18	Under risk assessment phase	In progress
4	Additional data requested during the risk assessment	Additional data request
10	Under suitability check	Under consideration
8	Not suitable	Waiting for full dossier

Link to check the status of an application in the EFSA Register of Question:
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=**EFSA-Q-20xx-xxxx**

SUITABILITY CHECK (1)

APDESK overview table

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Food enzymes	**Common authorisation procedure**: Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings Commission Regulation (EU) No 234/2011 implements the common authorisation procedure and establishes the derogation from submitting toxicological data in some specific cases and the possibility of grouping food enzymes under one application under certain conditions Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC,	EC practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated 10 April 2014)	EFSA Guidance of the Scientific Panel of Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (May 2013 - replacing earlier version published on 23 July 2009). doi:10.2903/j.efsa.2009.1305 (EFSA-Q-2007-080) EFSA Explanatory Note for the Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (July 2011, last updated 7 April 2014). (EFSA-Q-2014-00183) EFSA Guidance on the risk assessment of genetically modified microorganisms and their products intended for food and feed use (June 2011) (EFSA-Q-2009-00521) EFSA Journal 2011;9(6):2193 [54 pp.]. doi:10.2903/j.efsa.2011.2193
Food enzymes	Regulation (EC) No 258/97 Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes Commission Regulation (EU) No 1056/2012 of 12 November 2012 amending Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures		

Key documents to consult in order to prepare an application

How to prepare and submit an application:
http://www.efsa.europa.eu/en/faqs/docs/apdeskhowtofoodadd.pdf

SUITABILITY CHECK (2)

EFSA SUITABILITY CHECKLIST FOR RISK ASSESSMENT

No.	Type of information / document	Suitable (Yes, No, Not applicable)	Present	Remarks
3.2.1.1	**Identity of the Food Enzyme**			
3.2.1.1.1	**Name(s), synonyms, abbreviations and classification(s) (EC Number) of the enzyme protein**			
	Common Name(s) *and/or Trade Name(s) (if applicable)*			
	Enzyme Classification Number *of Enzyme Commission of the International Union of Biochemistry and Molecular Biology (IUBMB) (if applicable)*			
	Chemical Name(s) *(if applicable)*			
	Chemical Abstract Service *(CAS) Registry Number (if available)*			
	*European Inventory of Existing Chemical Substances Number (**EINECS**) or European List of Notified Chemical Substances Number (**ELINCS**) (if available)*			
3.2.1.1.2	**Chemical composition, properties and specifications**			
3.2.1.1.2.1	**Chemical composition**			
	Molecular mass *of the food enzyme and* ***subunit structure****, and* ***amino acid sequence*** *(if available)*			
	Chemical description *of the food enzyme as tested including chemical purity and identity and percentage or concentration of chemical impurities originating from the source and/or the production process (e.g. metabolites such as mycotoxins, heavy metals, residues of extraction solvents) and the* **methods of analysis**			

Administrative check →

- ✓ **name** of the applicant
- ✓ list of **bibliographical references**
- ✓ **confidential parts** of the dossier

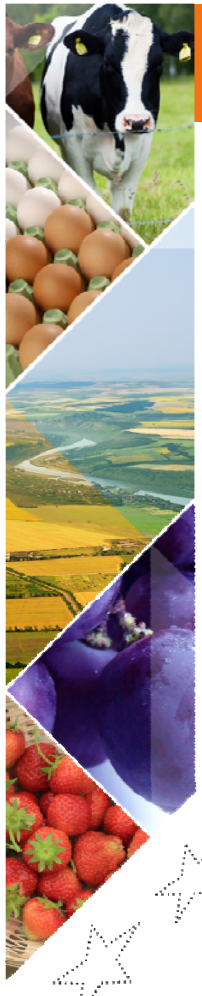
Scientific check →

✓ based on the following guidance documents:

1. Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids **(CEF) on the Submission of a Dossier on Food Enzymes for Safety Evaluation** (EFSA-Q-2007-080) http://www.efsa.europa.eu/en/efsajournal/pub/1305.htm

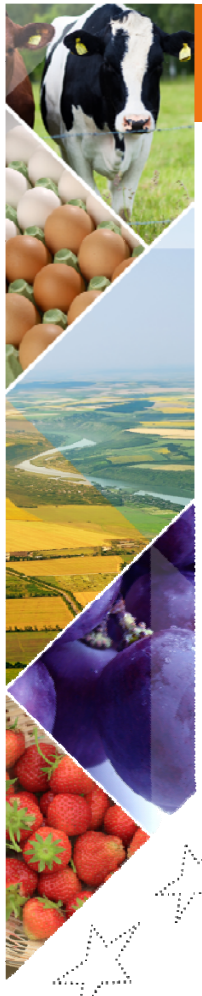
2. Explanatory Note for the Guidance of the Scientific Panel of Food Contact Material, Enzymes, Flavourings and Processing Aids (CEF) on the Submission of a Dossier on Food Enzymes (EFSA-Q-2014-00183) http://www.efsa.europa.eu/en/supporting/doc/579e.pdf

3. Guidance on the risk assessment of **genetically modified microorganisms** and their products intended for food and feed use (EFSA-Q-2009-00521) http://www.efsa.europa.eu/en/efsajournal/pub/2193.htm



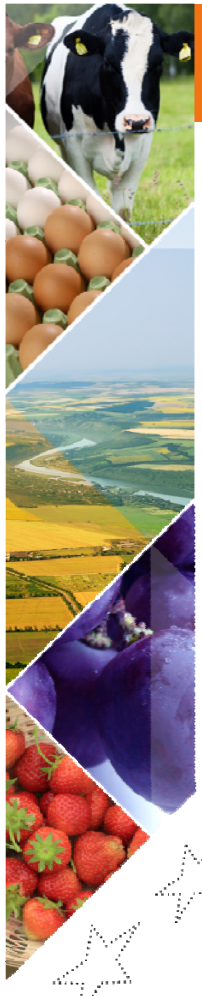
SUITABILITY CHECK – POSITIVE ASPECTS

- Technical dossiers follow the **structure of the EFSA guidance**
- **Administrative information** well documented
- **Bibliography** provided
- Description of **intended uses** provided



NON SUITABILITY – MOST COMMON ISSUES IDENTIFIED (1)

1. Chemical composition	Information to be provided in Technical Dossier
✓ **Batch-to-Batch variability**	Batch identification number Consistent information on the chemical composition between Certificates of Analysis/Annexes and main text Explanation of differences observed
✓ **Methods of analysis**	To be provided for parameters analysed (e.g. enzyme activity, ash, protein)
✓ **Significant side activities**	To be documented with experimental data, information on their inactivation to be provided

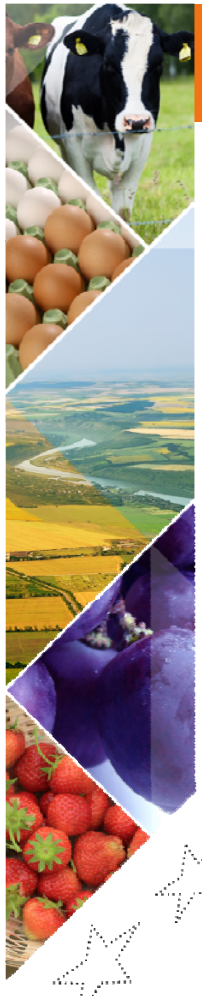


NON SUITABILITY – MOST COMMON ISSUES IDENTIFIED (2)

1. Chemical composition	Information to be provided in Technical Dossier
✓ **Optimum pH/temperature conditions**	To be provided for main enzyme activity/ies
✓ **Amino acids sequence**	To be provided if feasible to determine together with info on potential allerginicity
✓ **Modification of the enzyme by protein engineering**	Rationale for the modification to be provided

NON SUITABILITY – MOST COMMON ISSUES IDENTIFIED (3)

2. Toxicological data	Information to be provided in Technical Dossier
✓ **Conformity of tox batch**	The conformity of the tox batch to specification/chemical composition of food enzyme under evaluation and its representativeness to be provided
✓ Compliance of tox studies with **GLP (OECD, Directive 2004/10/EC)** (Art. 5(7) of Regulation (EC) 234/2011)	GLP/OECD compliance statement to be provided

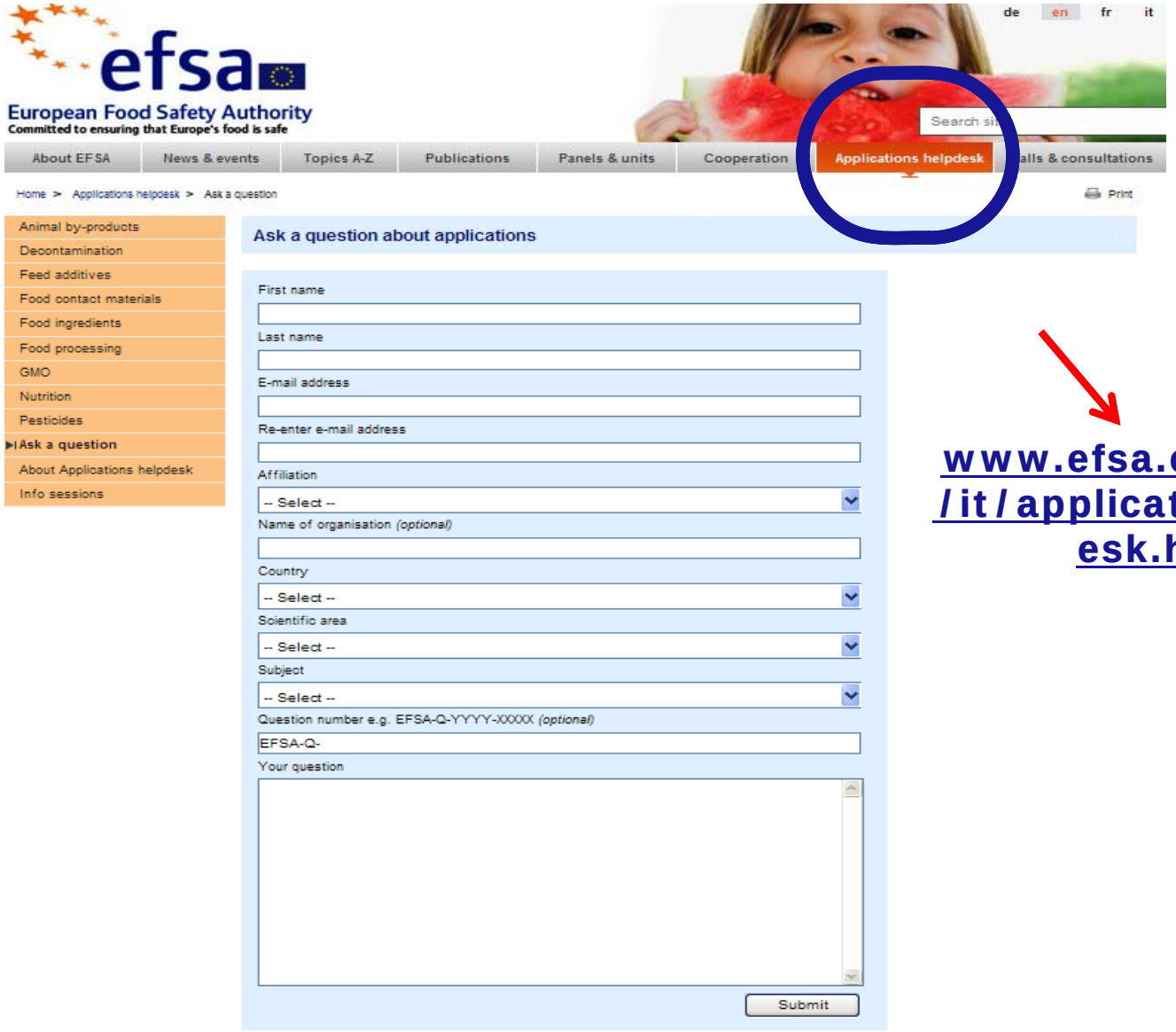


NON SUITABILITY – MOST COMMON ISSUES IDENTIFIED (4)

3. Waiving of tox data	Information to be provided in Technical Dossier
✓ **Rationale for waiving tox data**	Rationale in line with Regulation (EC) No 562/2012 or EFSA Guidance document on food enzymes

4. Omission of any information required by EFSA Guidance	Information to be provided in Technical Dossier
✓ **Rationale for omission of any mandatory information**	Scientifically sound and well elaborated justification for the omission to be provided

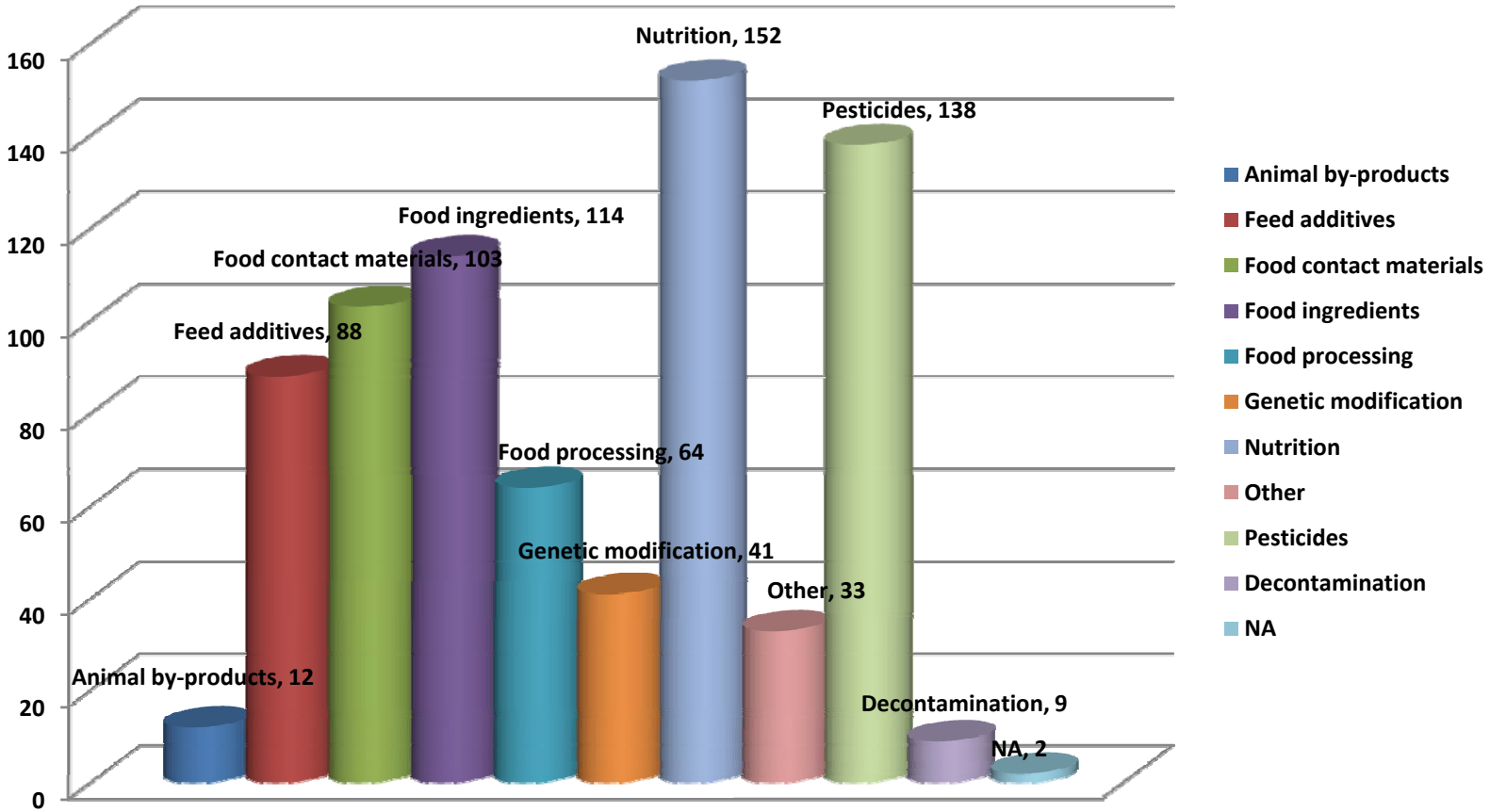
WEB FORM TO ASK A QUESTION



www.efsa.europa.eu/it/applicationshelpdesk.htm

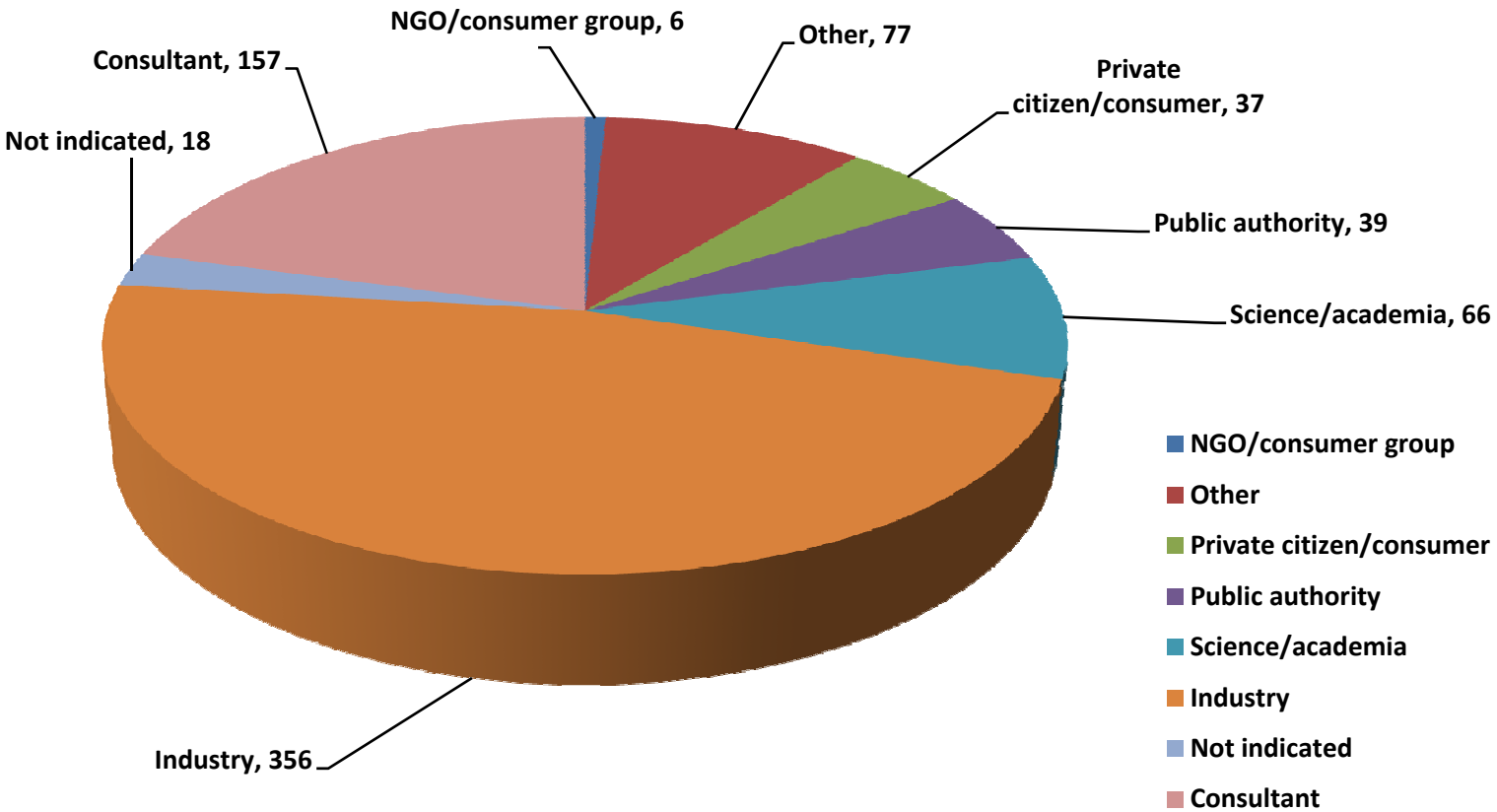
WEB FORM TO ASK A QUESTION

Requests per scientific area (Nov 2011-Apr 2014)



WEB FORM TO ASK A QUESTION

Requests per affiliation (Nov 2011-Apr 2014)



APDESK 2012-2018: INTERACTIONS WITH STAKEHOLDERS

APDESK initiatives

WHAT	WHEN	
Identify and map stakeholders' needs (survey)	2012 - 2013	**Report on stakeholders' needs** http://www.efsa.europa.eu/en/supporting/pub/482e.htm
Monitor stakeholders' satisfaction and customer oriented approach	2014-2018	**Internal mandate** http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=**EFSA-Q-2014-00250** **(mandate M-2014-0106)**
Analysis of the applicant's profile' (report)	Feb 2015	**Internal mandate** http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=**EFSA-Q-2013-00788**

SERVICES ALREADY AVAILABLE IN EFSA

Web form

Info Session on Applications

Submission of dossier

Web form

Direct formal communication with applicants (letters) CC & RA

Adoption of Scientific Opinion

Pre-notification of outputs (24h)

Pre-submission

Evaluation period

Post-adoption

Time

APDESK web section:
- FAQs
-How to prepare an application table
-Application workflow

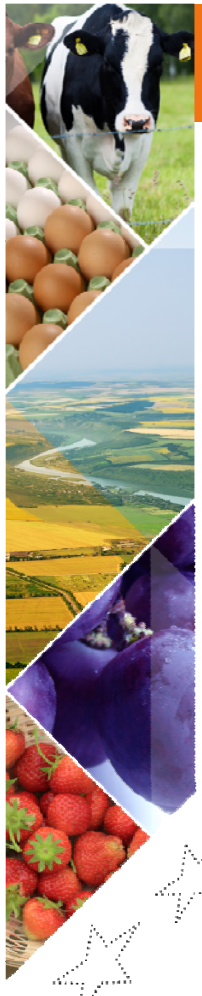
Guidance documents:
-ADMINISTRATIVE
-SCIENTIFIC

Application workflow with estimated deadline

Register of Question update

Plenary meetings Agendas & Minutes

Rationale for reaching conclusions provided in scientific opinions



CUSTOMER ORIENTED APPROACH

➢Work on-going within the REPRO Department under EFSA mandate M-2014-0106: **Development of a Customer oriented approach for regulated products** (May 2013- Dec 2018)

1) Framework contract to **monitor stakeholders' satisfaction on services** provided by EFSA

2) **EFSA Internal Task force** composed of HoUs of REPRO to **analyze in-depth options** for developing a **customer oriented approach for regulated products**

➢ **E-submission of applications** (Matrix project, EFSA mandate M-2014-0076)

Any questions? Get in contact with us through our **web form**!
http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion.htm?ScientificArea=zero

Any information? Check out our **web section**!
http://www.efsa.europa.eu/en/applicationshelpdesk.htm

GRAZIE