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to ensuring that Europe's food is safe



EFSA Applications desk

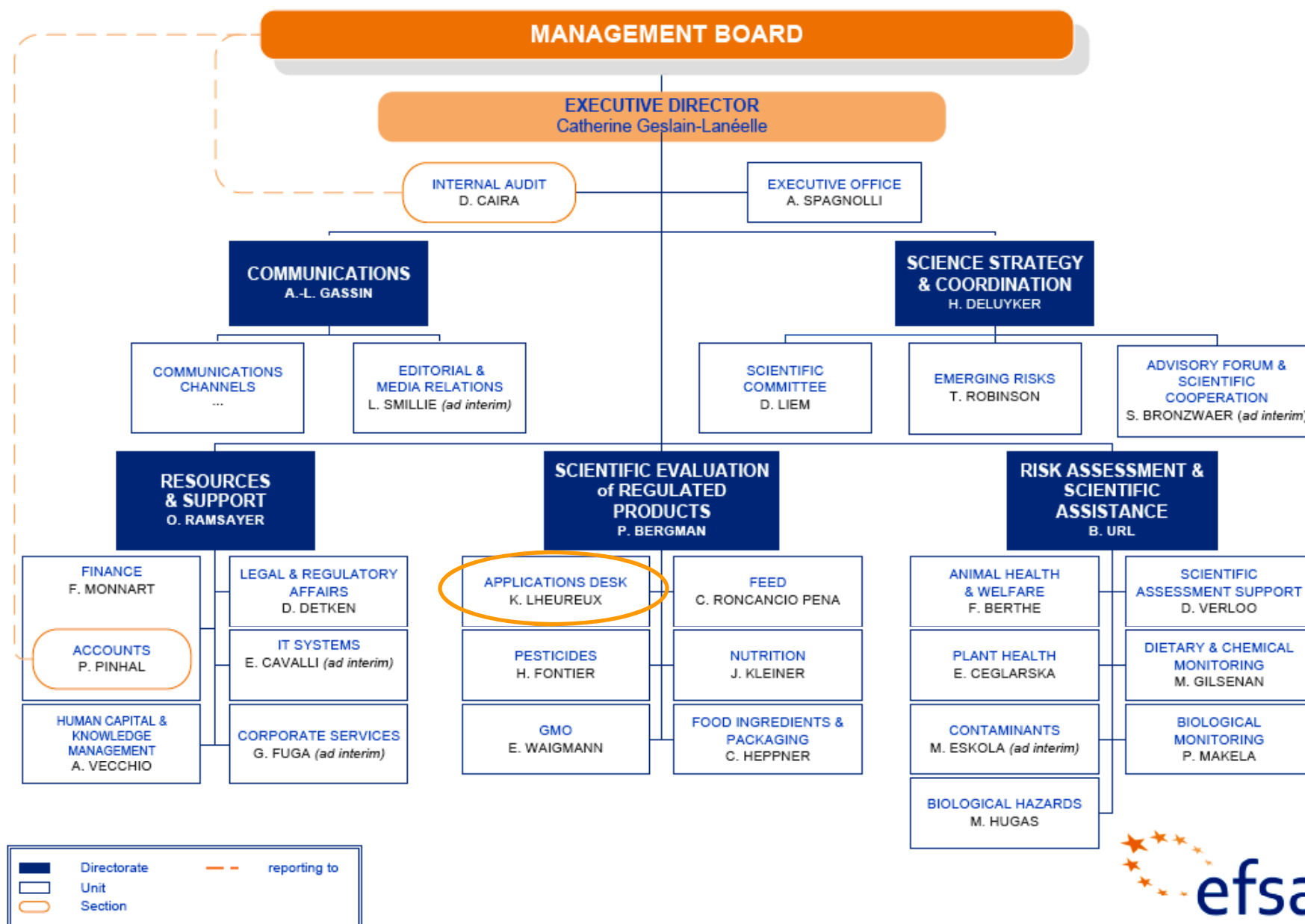
Karine Lheureux, Head of Unit, APDESK Unit

EFSA Info session on Applications
Technical meeting with Applicants on Food Enzymes
Parma, 17th January 2013

EFSA Recent reorganisation: The APDESK Unit

- ❖ **Creation of 5 new Directorates:** COMM (COMMunications), RASA (Risk Assessment & Scientific Assistance) REPRO (REgulated PROducts), RESU (REsources & SUPport), SCISTRAT (SCientific STRATegy)
- ❖ Scientific **meeting organisation** moved to a specialised new unit within RESU
- ❖ Application assessment in a **dedicated directorate** (REPRO)
- ❖ The **APDESK unit** created within REPRO to:
 - ✓ provide **internal coordination** (back office)
 - ✓ **support desk** for applicants, Member States and other stakeholders (front office)
 - ✓ **harmonise** the workflow of applications
 - ✓ increase **transparency** and **communication**

Organisational Structure on 01/07/2012



REPRO – Assessment of regulated products

Food & Feed regulatory areas	Scientific Panel	Supported by
Food additives Nutrient sources	Food additives & nutrient sources added to food	FIP ←
Flavourings Enzymes Food contact material	Food Contact Materials, Enzymes, Flavourings & Processing Aids	
Feed additives	Additives & Products or Substances used in Animal Feed	FEED
Genetically Modified Organisms (GMO)	Genetically Modified Organisms	GMO
Health claims Novel food Infant formulae Food allergies	Dietetic Products, Nutrition & Allergies	NUTRITION
Plant Protection Products: active substances (PPP) and Maximum Residual Levels (MRL)	Plant Protection Products & their Residues	PESTICIDES



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Applications desk Plan

Since Oct 2011

- ✓ Staffing
- ✓ Front office and support desk
- ✓ Harmonise workflow on applications (reception to validation)
- ✓ Elaborate plan for 2012-2015

2012 - 2015

- ✓ Further develop front office and support desk
- ✓ Submission of applications: centralise initial administrative steps (reception, registration and verifying administrative completeness)
- ✓ Map and harmonise working practices and workflows (reception to publication)
- ✓ Launch a survey on « *stakeholders' needs* » (2012)
- ✓ Launch a survey on « *stakeholders' satisfaction* » (from 2014 on a yearly basis)
- ✓ Development of electronic submission for applications

APDESK – front office, support desk



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Feed additives

Food contact materials

Food ingredients

Food processing

GMO

Nutrition

Pesticides

About Applications helpdesk

► Ask a question

Ask a question about applications

First name

Last name

E-mail address

Re-enter e-mail address

Affiliation

-- Select --

Name of organisation (optional)

Country

-- Select --

Scientific area

-- Select --

Subject

-- Select --

Question number e.g. EFSA-Q-YYYY-XXXX (optional)

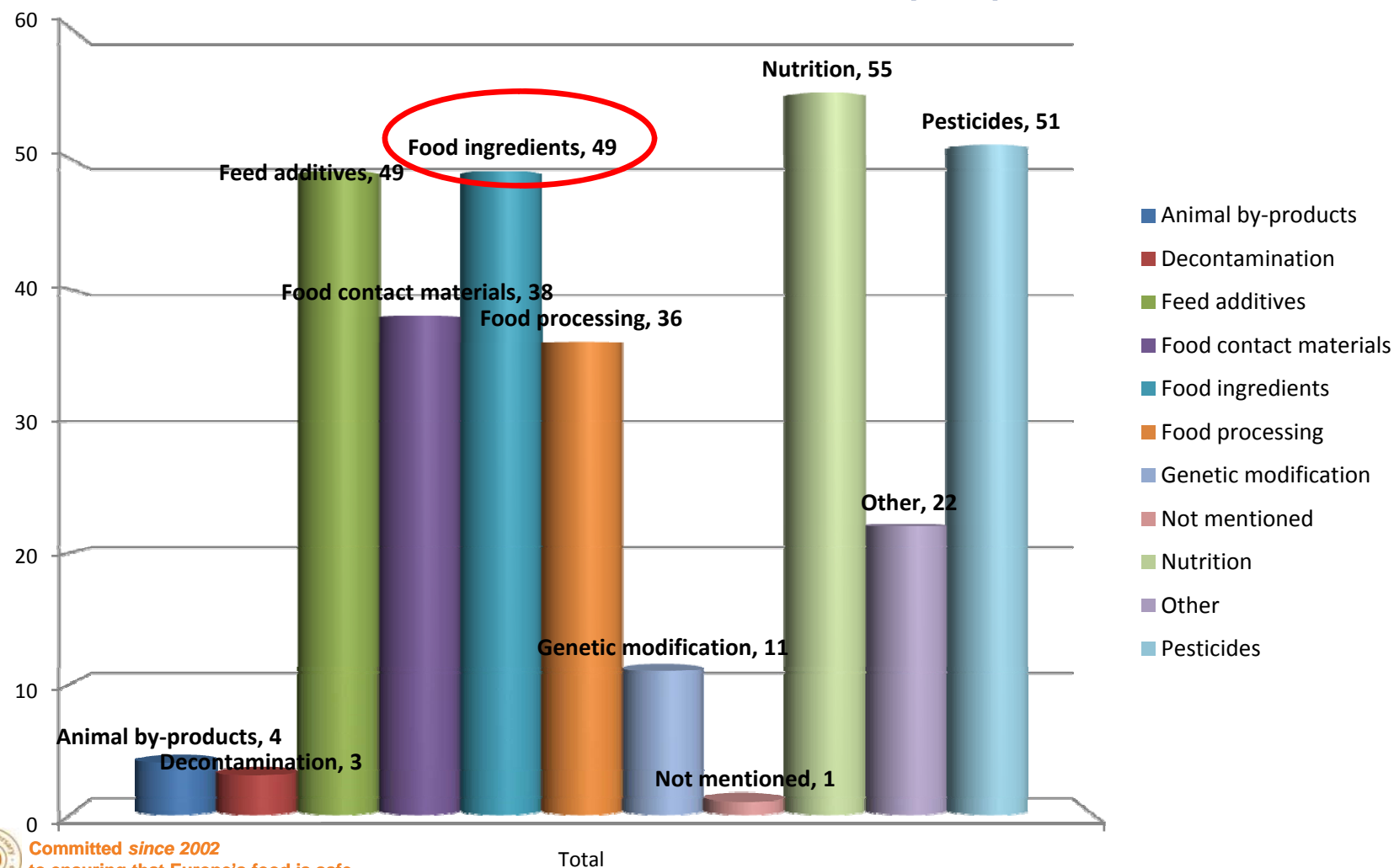
EFSA-Q-

Your question

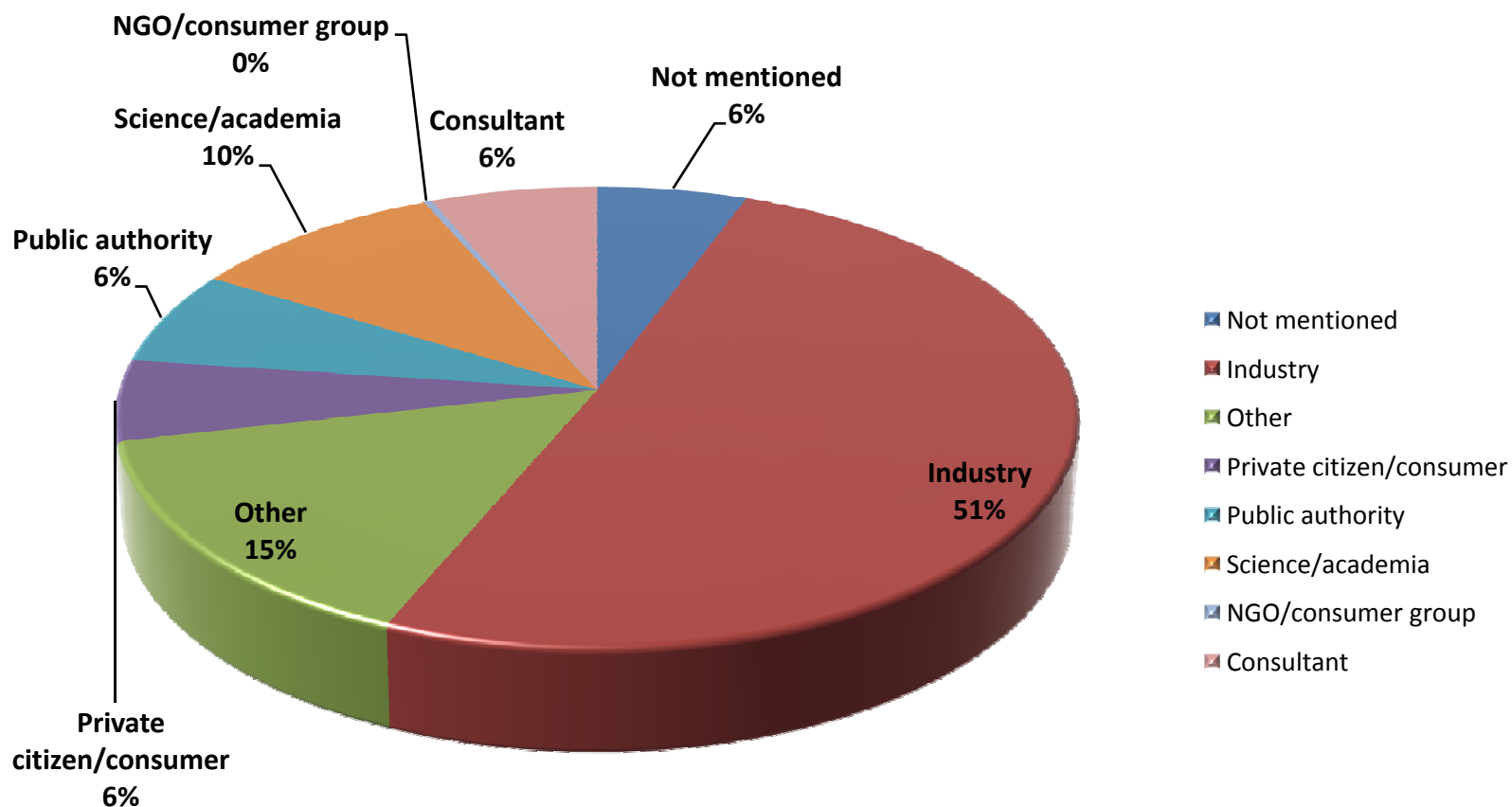
Submit

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

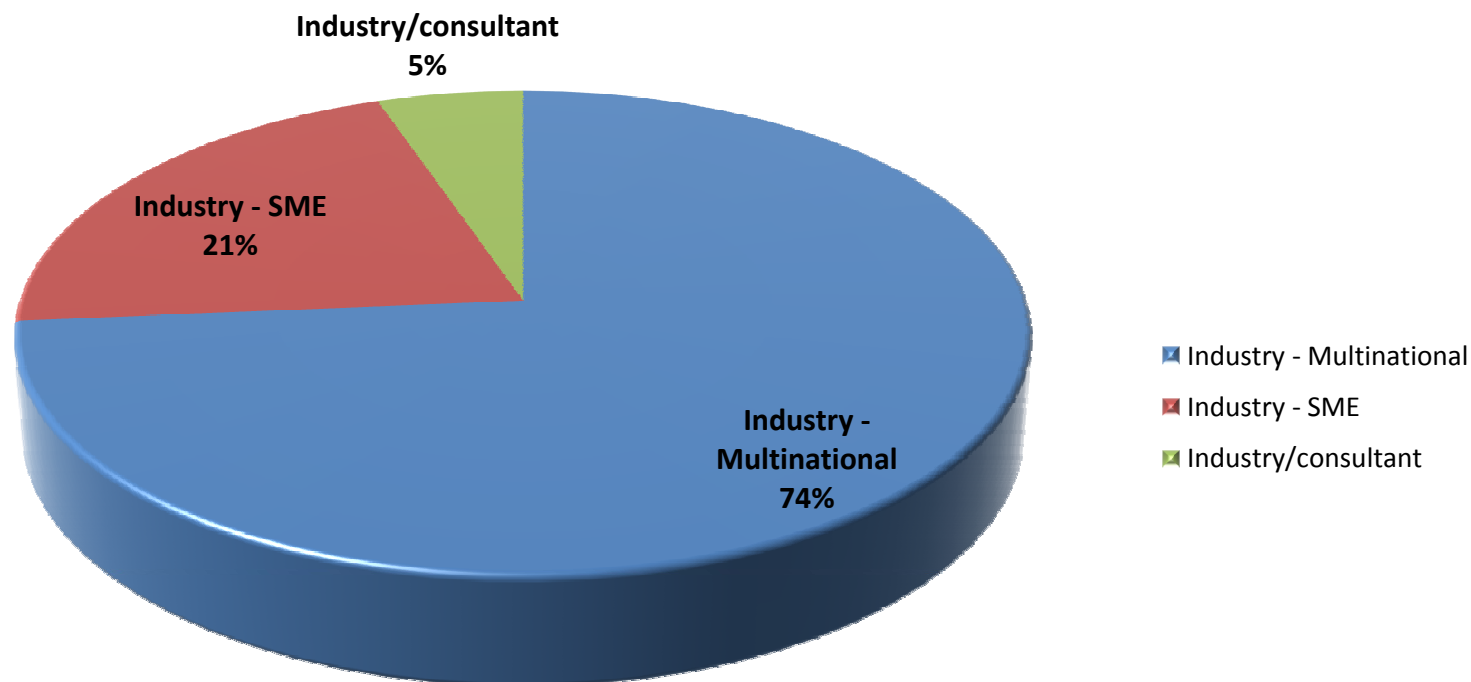
Requests per scientific area Nov 2011 – Dec 2012 (319)



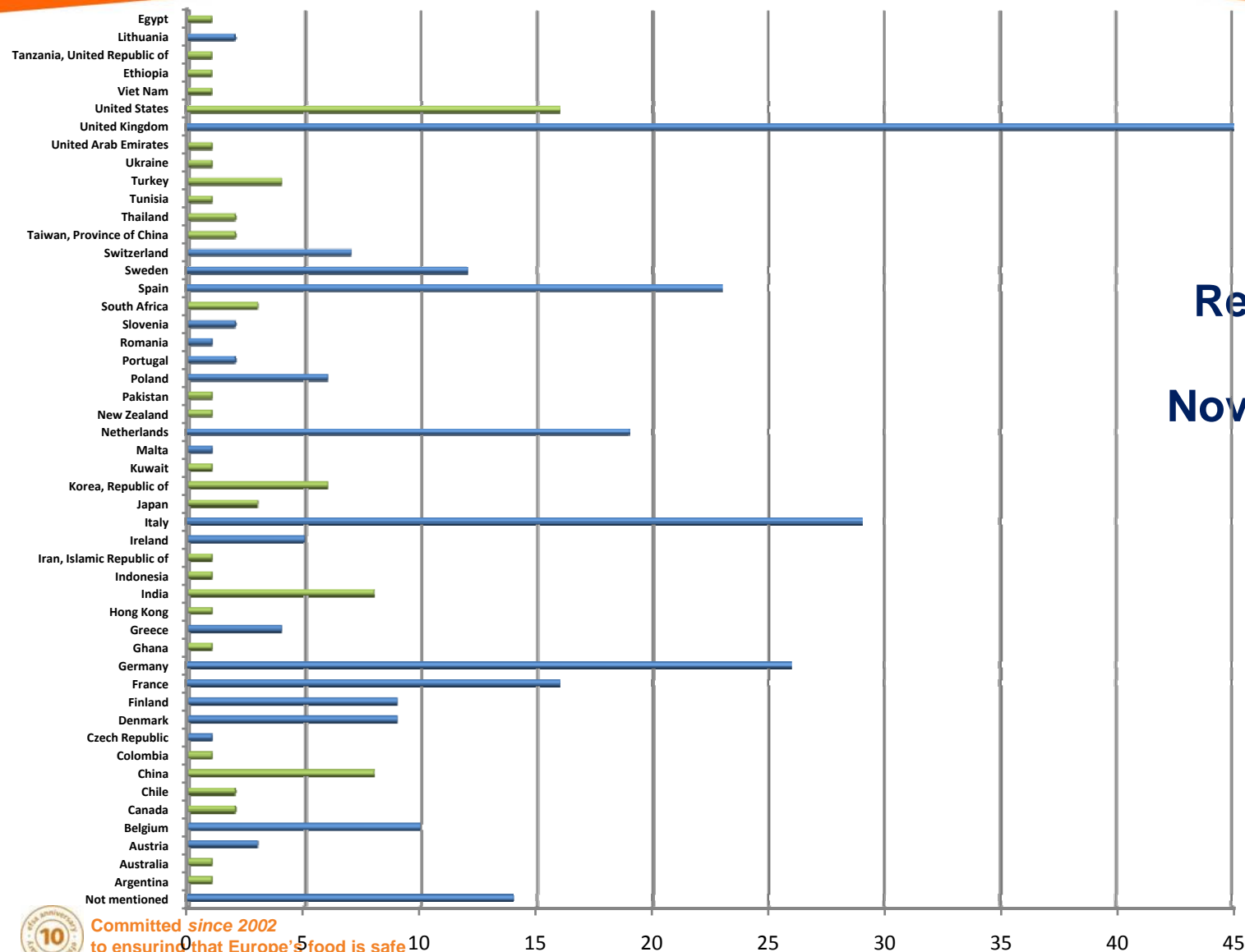
Requests per affiliation - Nov 11 – Dec 12 (319)



Requests per affiliation: Industry Nov 12 – Dec 12 (19)



APDESK – front office, support desk



**Requests per
Country
Nov 11 – Dec 12
(319)**



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APDESK - front office, support desk

How and where to submit an application:

<http://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf>



APPLICATIONS DESK UNIT – OCT 2012

How to prepare and where to submit an application:

AREA	HOW TO PREPARE AN APPLICATION	
Animal by-products treatment	Regulatory framework and Guidance	
Decontamination substance	Regulatory framework and Guidance	
Feed Additives	Regulatory framework and Guidance	
Flavourings	Regulatory framework and Guidance	
Flavourings - Smoke Flavourings	Regulatory framework and Guidance	
Food Additives	Regulatory framework and Guidance	
Food Contact Material (FCM)	Regulatory framework and Guidance	
Food Enzymes	Regulatory framework and Guidance	
GMOs	Regulatory framework and Guidance	
Health Claims Art. 13.5 & 14.1	Regulatory framework and Guidance	
Novel Foods	Regulatory framework and Guidance	European Commission (EC)
Nutrient Sources	Regulatory framework and Guidance	European Commission (EC)
Pesticides active substances	Not yet available	Member States Competent Authorities
Pesticide MRLs	Not yet available	Member States Competent Authorities
TSE testing	Regulatory framework and Guidance	European Commission (EC)

Understanding Applications Helpdesk:

http://www.youtube.com/watch?feature=player_embedded&v=cUF22EIWWyU



APDESK - front office, support desk

How and where to submit an application:

<http://www.efsa.europa.eu/en/apdesk/docs/apdeskhow.pdf>

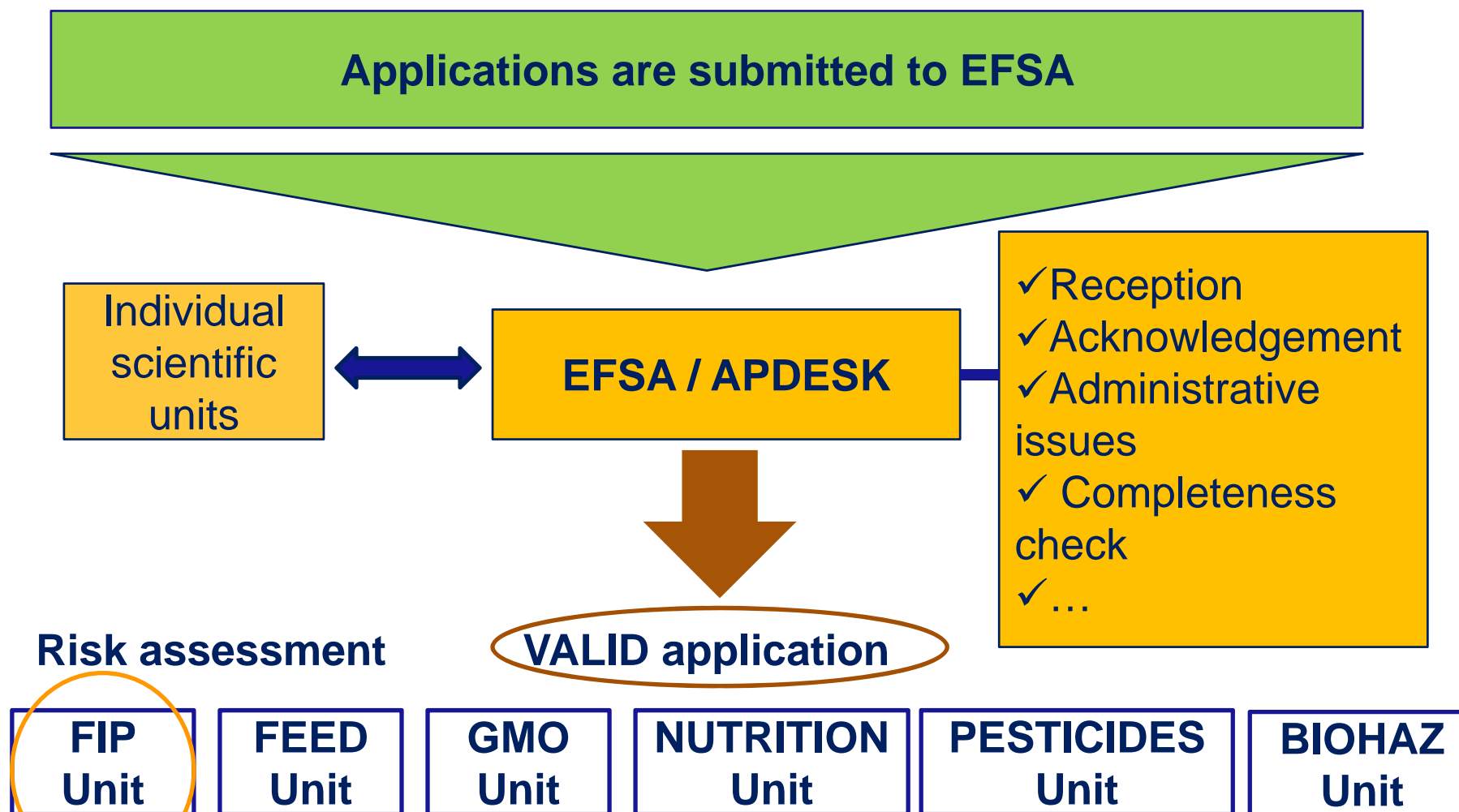
APPLICATIONS DESK UNIT – DEC 2012

Area	Regulatory framework	Administrative Guidance	Scientific Guidance
Food enzymes	<p>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</p> <p>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</p> <p>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, Council Directive 2001/112/EC and Regulation (EC) No 258/97</p> <p>Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data</p>	<p>EC practical guidance for applicants on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated May 2012)</p>	<p>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). (EFSA-Q-2010-01152)</p> <p>EFSA 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 (August 2009). doi:10.2903/j.efsa.2009.1305 (EFSA-Q-2007-080)</p> <p>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</p>

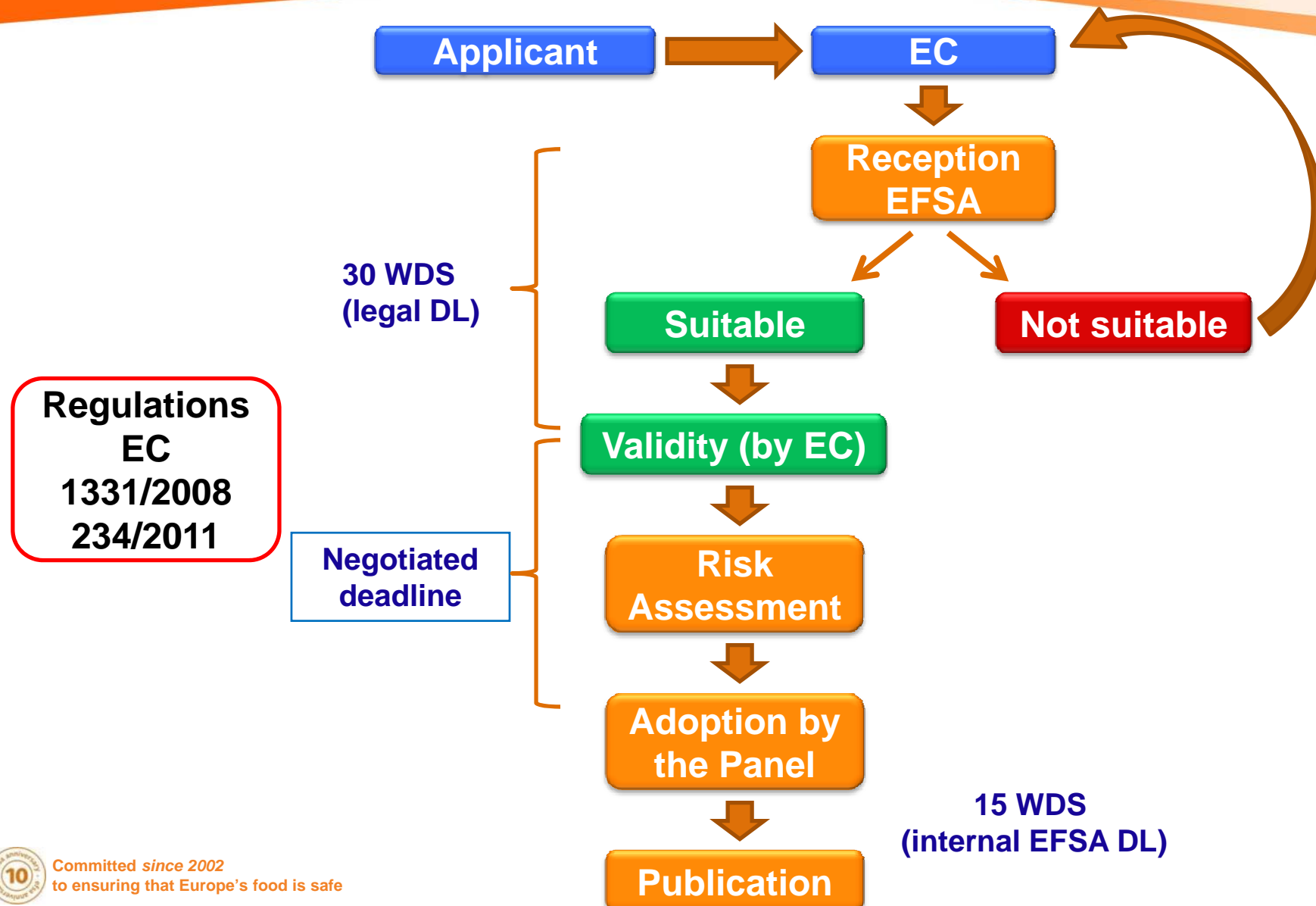
Harmonise workflows to gain efficiency

- ✓ Map and **harmonise working practices** on applications within EFSA
- ✓ **Centralise** initial administrative steps (reception, registration and verifying **administrative completeness**)

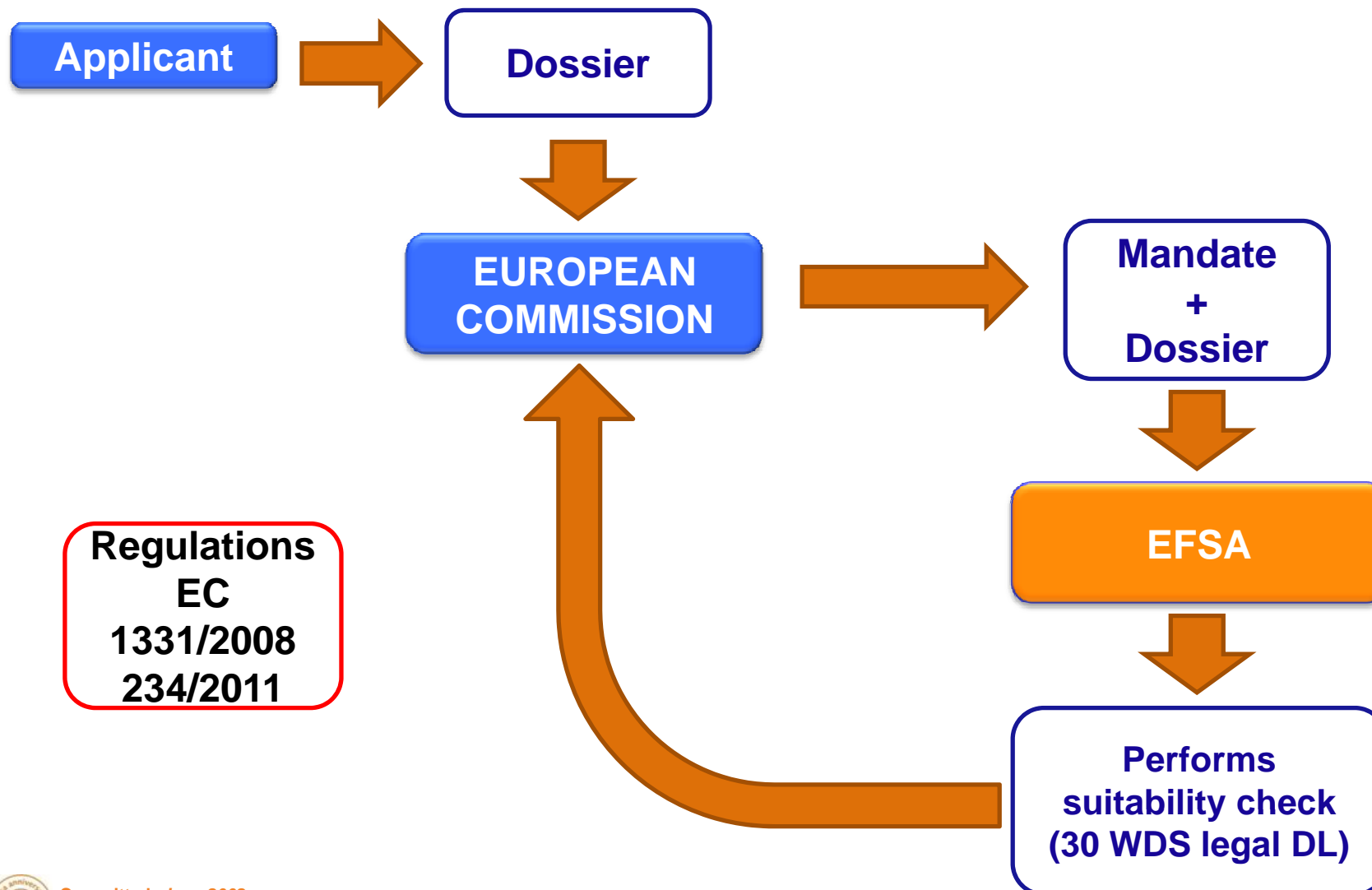
APDESK – Workflow new applications



APDESK –Workflow NEW food additives, flavourings, enzymes applications



APDESK – Workflow NEW food additives, flavourings, enzymes applications (Suitability check)



Food enzymes applications received by EFSA

Food Enzymes applications	Number of applications
Food enzymes - <i>Reg (EC) No 1331/2008</i>	4

Q-number	Status
EFSA-Q-2012-00897	In progress
EFSA-Q-2012-00898	In progress
EFSA-Q-2012-01009	Under consideration
EFSA-Q-2012-01010	Under consideration

→ Possibility to monitor the status of a submitted application through the **EFSA Register of Questions (ROQ)**

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader>

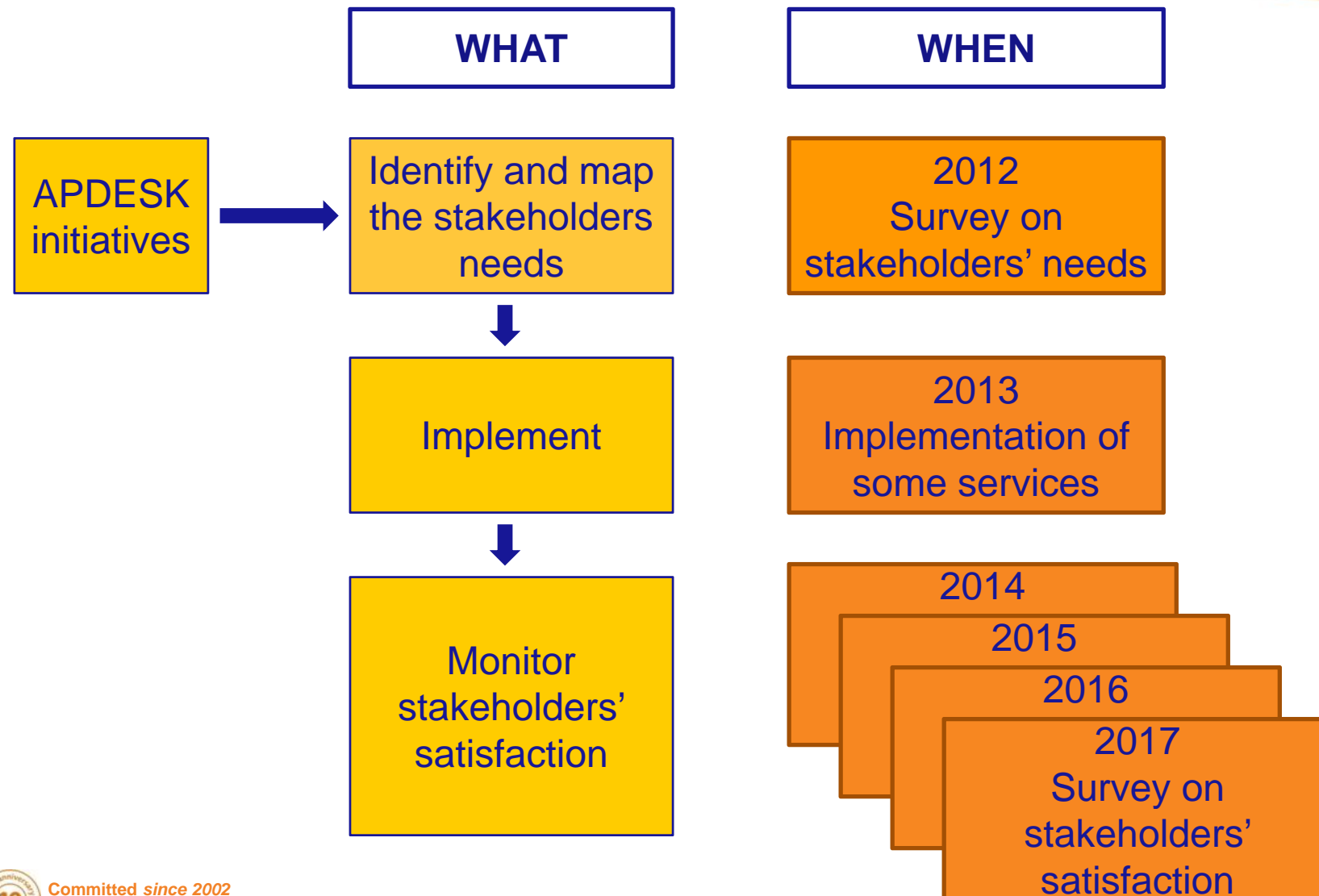
Launch a **survey on stakeholders' needs** for the future development of services to stakeholders

Objective: to launch a questionnaire to stakeholders on their expectations on the type, nature, quality of services they would like to be put at their disposal by EFSA and its new APDESK unit in the area of regulated products (targeted audience)

Stakeholders: applicants, Member States, European institutions and bodies, MSs and national agencies, other stakeholders, specialized media

Timelines: 6 months from 31st October 2012

APDESK 2012-2015: interactions with stakeholders / surveys



APDESK Plan 2012-2015

Continued support to submission of applications:

- ✓ Provide pre-submission support to applicants
- ✓ Answer requests through the web form
- ✓ Update information available in the website
- ✓ Available to answer to request via phone

Provide dedicated support to SMEs and/or new applicants:

- ✓ Develop an APDESK SME office
- ✓ Develop a specific area in EFSA APDESK webspace

Support scientific units in the organisation of technical workshops and trainings:

<http://www.efsa.europa.eu/en/applicationshelpdesk/apdeskabout.htm>

- ✓ Stakeholder workshop on New Guidance for **Food Additive** evaluations - **21 Sep 2012**, Brussels
- ✓ Technical meeting with applicants – **Flavourings 14 Nov 2012**, Parma
- ✓ Technical meeting with applicants – **Food Enzymes 17 Jan 2013**, Parma

Development of E-submission for applications

- ✓ **Feasibility study**
- ✓ Electronic submissions Project

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>

To know more... Watch us on Youtube!

http://www.youtube.com/watch?feature=player_embedded&v=cUF22EIWWyU



GRAZIE



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