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to ensuring that Europe's food is safe



European Food Safety Authority

## **Application Desk Food Additives**

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**Head of Application Desk, EFSA**

**Stakeholders workshop  
21 September 2012, Brussels**

# REPRO Directorate and the APDESK Unit

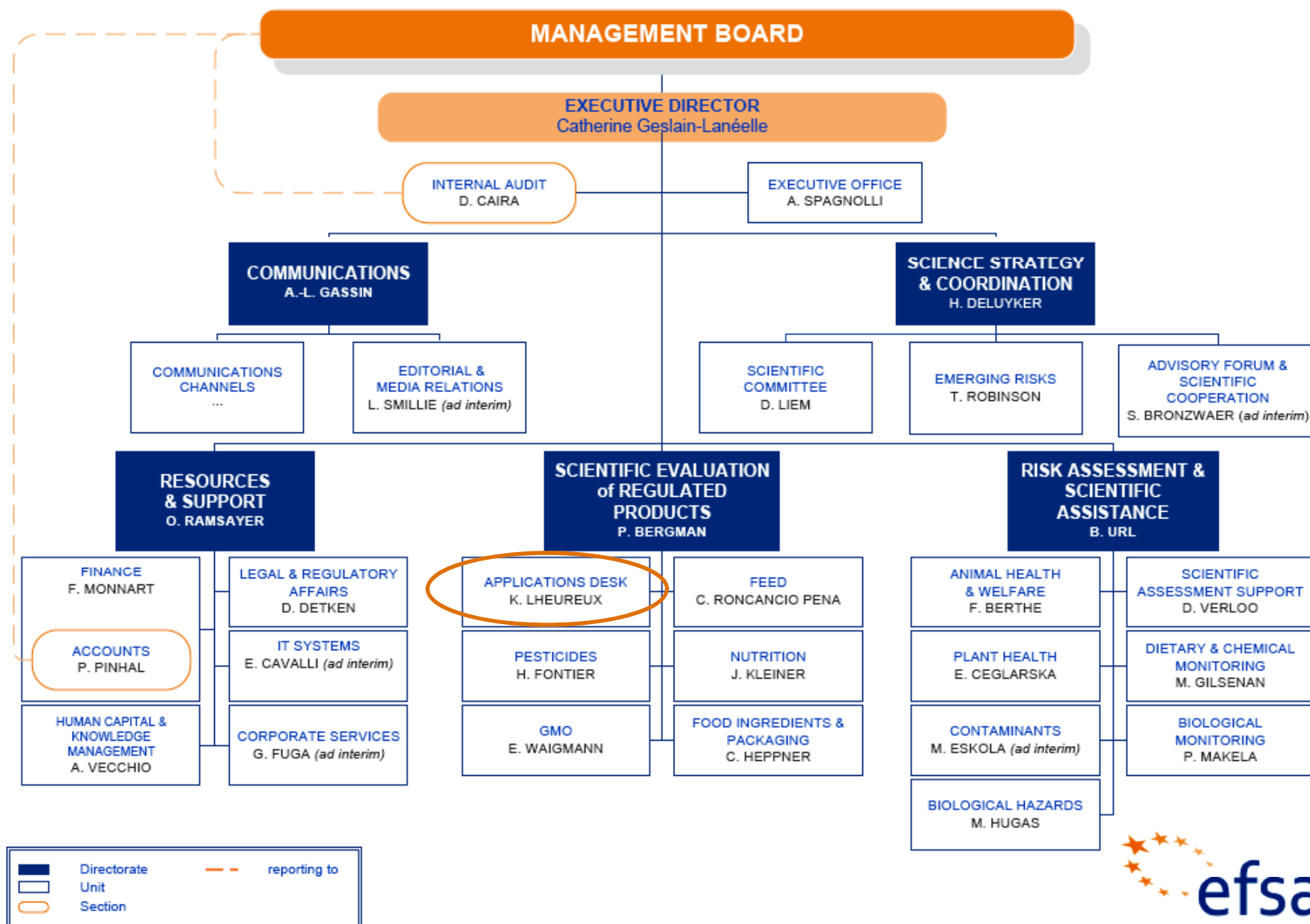
## REPRO (Regulated PROducts) Directorate:

- FEED
- FIP
- GMO
- NUTRITION
- PESTICIDES
- **APPLICATIONS  
HELPDESK**

## APDESK unit:

- ☐ to provide **internal coordination** (back office)
- ☐ to **support desk** for applicants, Member States and other stakeholders (front office)
- ☐ to **harmonise** the workflow of applications
- ☐ To increase **transparency** and **communication**

## Organisational Structure on 01/07/2012



# Applications Helpdesk Plan

## 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



Animal by-products

Decontamination

Feed additives

Food contact materials

Food ingredients

Food processing

GMO

Nutrition

Pesticides

► Ask a question

## Ask a question about applications

Email\*

First name

Last name

Affiliation

Name of organisation

Country

Scientific area\*

Subject\*

Application registration number

Your question\*

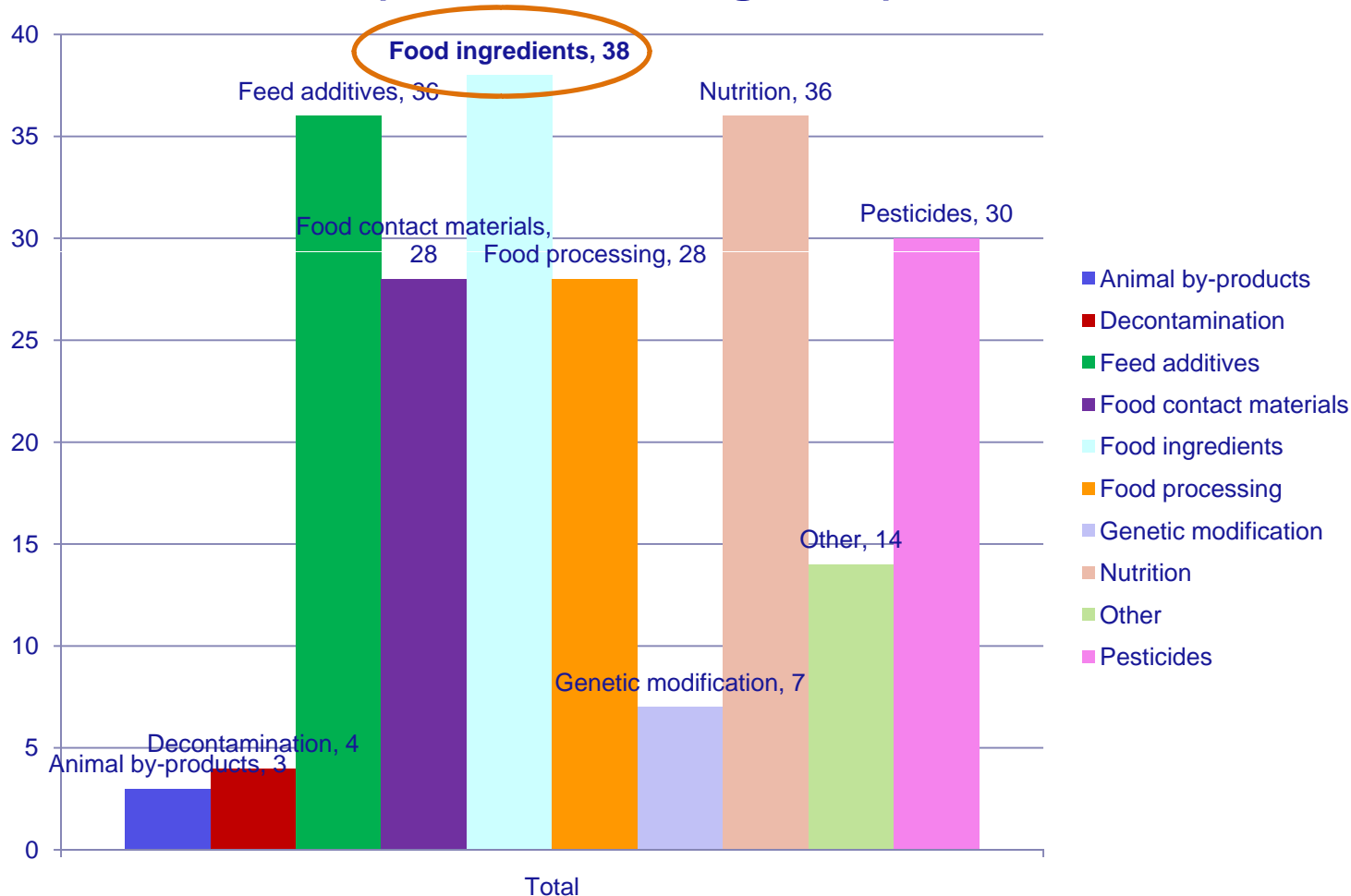
\* Mandatory field

Submit

[www.efsa.europa.eu/it/applicationshelpdesk.htm](http://www.efsa.europa.eu/it/applicationshelpdesk.htm)

# APDESK – front office, support desk

## Requests per scientific area (224) (Nov. 2011 – Aug 2012)

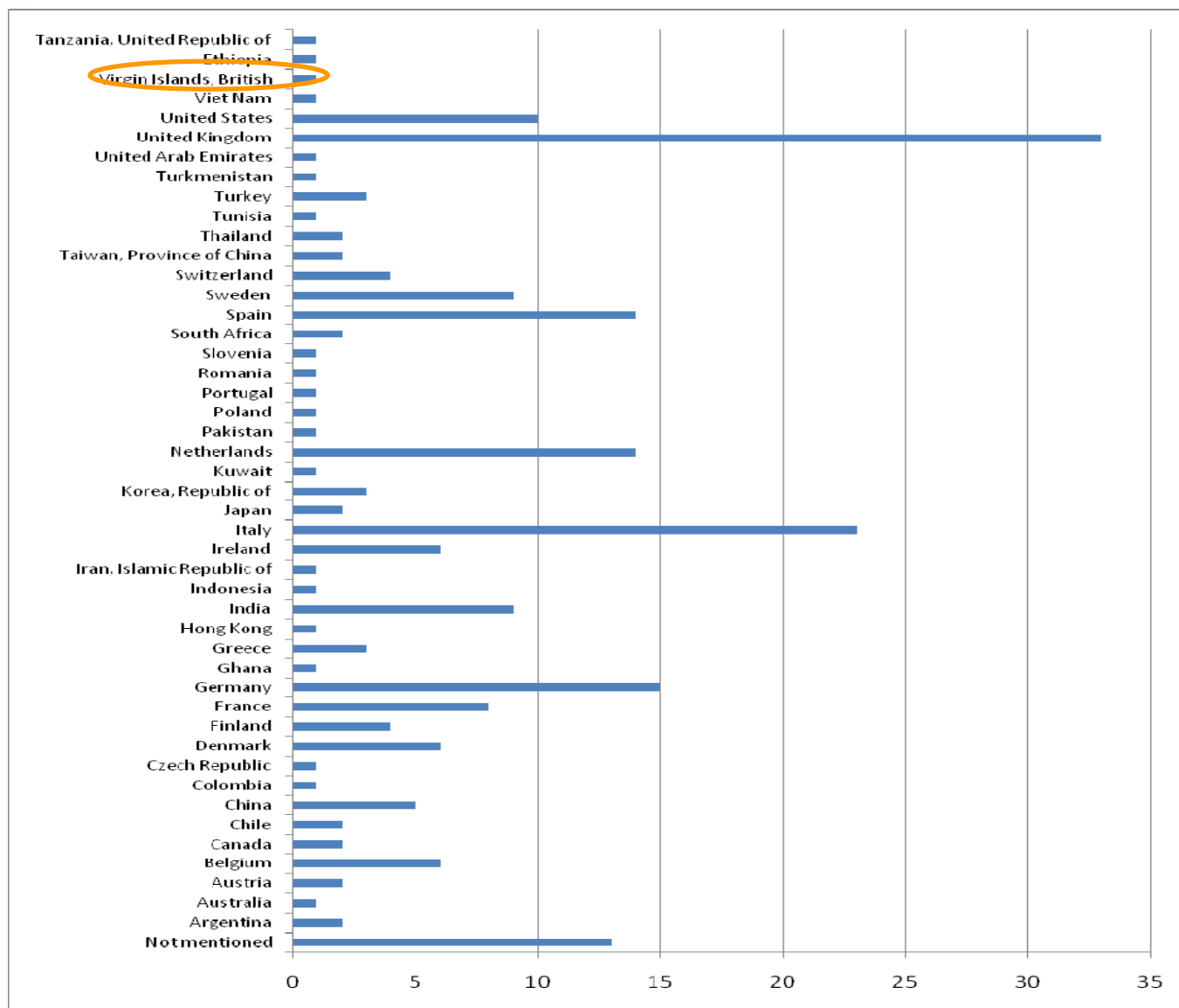


# APDESK – front office, support desk

## Requests per affiliation - Nov. 11 – Aug 12 (224)

Affiliation	Number of requests
Industry	123
Other	33
Private citizen/consumer	14
Public authority	17
Science academia	21
NGO/Consumer Group	2
Not defined	14
<b>TOTAL</b>	<b>224</b>

# APDESK – front office, support desk



**Requests  
per Country  
(224)  
(Nov. 2011 –  
Aug 2012)**



# APDESK - front office, support desk

## How and where to submit an application:



APPLICATIONS HELPDISK UNIT – AUG 2012

How to prepare and where to submit an application:





AREA	HOW TO PREPARE AN APPLICATION	WHERE TO SUBMIT
GMOs	<a href="#">Regulatory framework and Guidance</a>	Member States
Health Claims Art. 13.5 & 14.1	<a href="#">Regulatory framework and Guidance</a>	Member States
Novel Foods	<a href="#">Regulatory framework and Guidance</a>	European Commission
Food Contact Material (FCM)	<a href="#">Regulatory framework and Guidance</a>	Member States
Flavourings	<a href="#">Regulatory framework and Guidance</a>	European Commission
Smoke Flavourings	<a href="#">Regulatory framework and Guidance</a>	European Commission
Enzymes	<a href="#">Regulatory framework and Guidance</a>	European Commission
<b>Food Additives &amp; Nutrient Sources</b>	<a href="#">Regulatory framework and Guidance</a>	European Commission
Feed Additives	<a href="#">Regulatory framework and Guidance</a>	The Mandate is sent to the European Commission The Dossier is sent to EFSA
Pesticides active substances	Not yet available	Not yet available
Pesticide MRLs	Not yet available	Not yet available

## Understanding Applications Helpdesk:



# APDESK - front office, support desk

## How and where to submit an application:

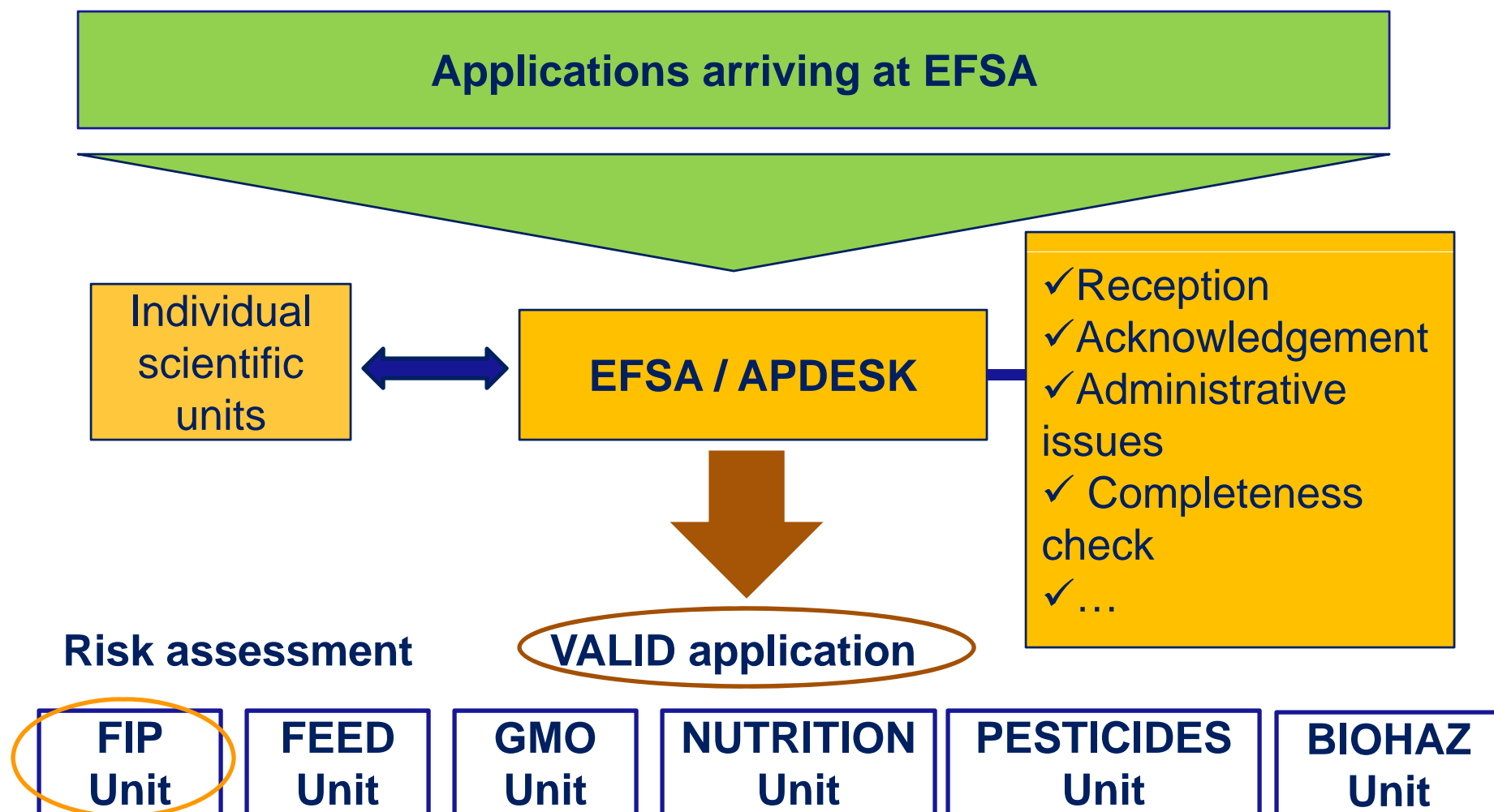
Area	Regulatory framework	Administrative guidance	Scientific guidance
Food Additives & Nutrient Sources	<p><a href="#">Regulation (EC) No 1331/2008</a> of 16 December 2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings</p> <p><a href="#">Commission Regulation (EU) No 234/2011</a> of 10 March 2011 implementing Regulation 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><a href="#">Regulation EC No 1333/2008</a> of 16 December 2008 of the European Parliament and of the Council on food additives</p> <p><a href="#">Commission Regulation (EU) No 231/2012</a> of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008</p> <p><a href="#">Regulation (EU) No 257/2010</a> of 25 March 2010 setting up a programme for the re-evaluation of approved food</p>	<p><a href="#">EC practical guidance for applicants</a>  on the submission of applications on food additives, food enzymes and food flavourings (September 2011- updated May 2012)</p> <p><b>Nutrient sources</b></p> <p><a href="#">EC Administrative guidance</a>  on submissions for safety evaluations of substances added for specific nutritional purposes in the manufacture of foods</p>	<p><b>Food additives</b></p> <p><a href="#">EFSA Data requirements for the evaluation of food additive applications</a> (published August 2009). doi:10.2903/j.efsa.2009.1188 (EFSA-Q-2007-188)</p> <p><a href="#">Guidance for submission for food additive evaluations</a> (July 2012). EFSA Journal 2012;10(7):2760 (EFSA-Q-2010-00675)</p> <p><a href="#">EC Guidance (SCF) on submissions for food additive evaluations by the Scientific Committee on Food</a> (July 2001) </p> <p><b>Nutrient sources</b></p> <p><a href="#">EC Guidance on submissions for safety evaluations of sources of nutrients or of other ingredients proposed for use in the manufacture of foods</a> (July 2001) </p>



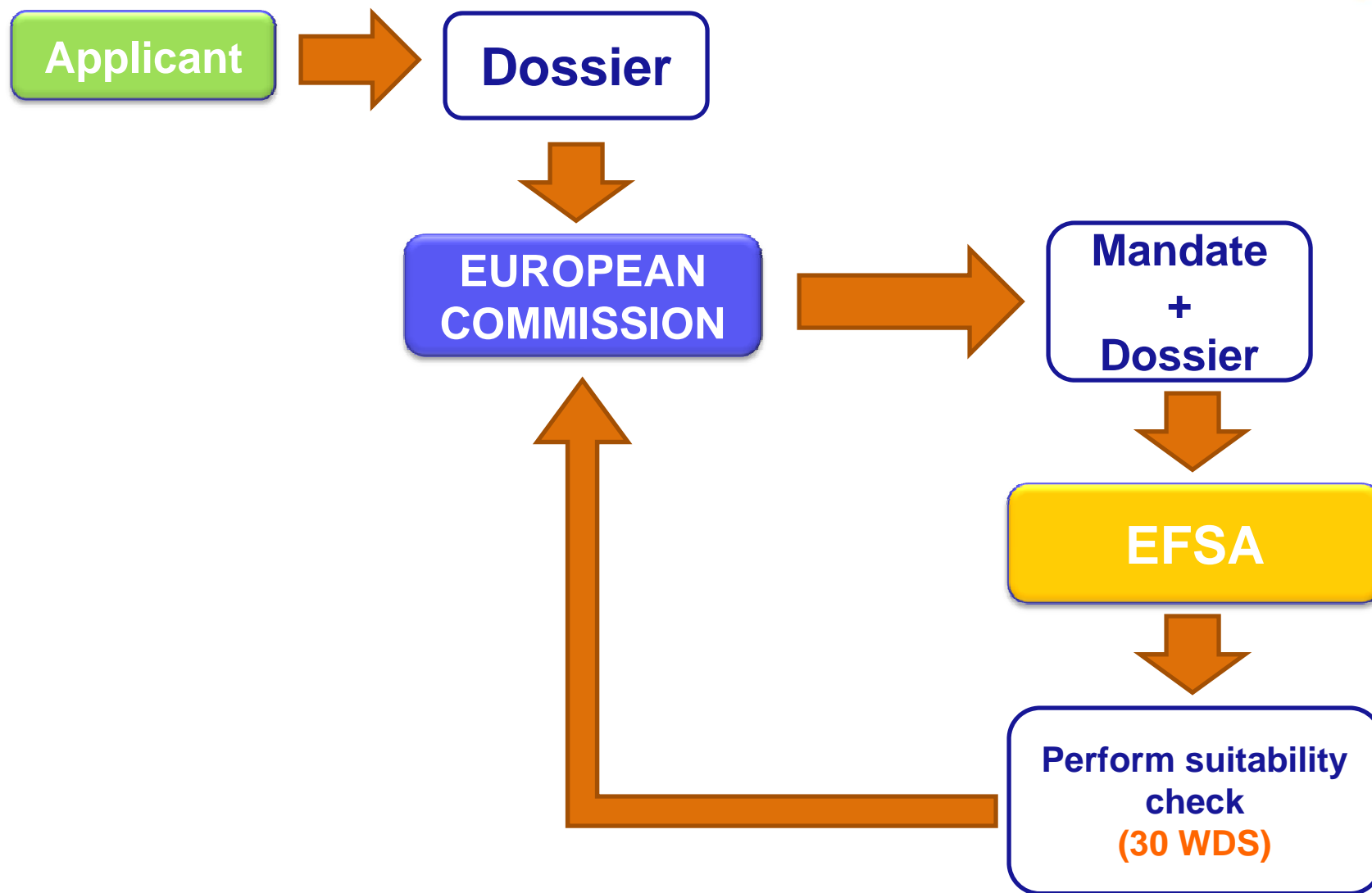
## Harmonise workflows to gain efficiency

- ✓ Map and **harmonise working practices** on applications within EFSA
- ✓ Centralise initial administrative steps (reception, registration and verifying administrative completeness)
- ✓ For NEW food additive applications, 3 registrations
  - ✓ EFSA-Q-2012-00446      **Iron(III) meso-Tartrate**
  - ✓ EFSA-Q-2012-00447      **Polyvinyl alcohol polyethylene glycol-graft-co-polymer**
  - ✓ EFSA-Q-2012-00748      **Gaseous chlorine dioxide**

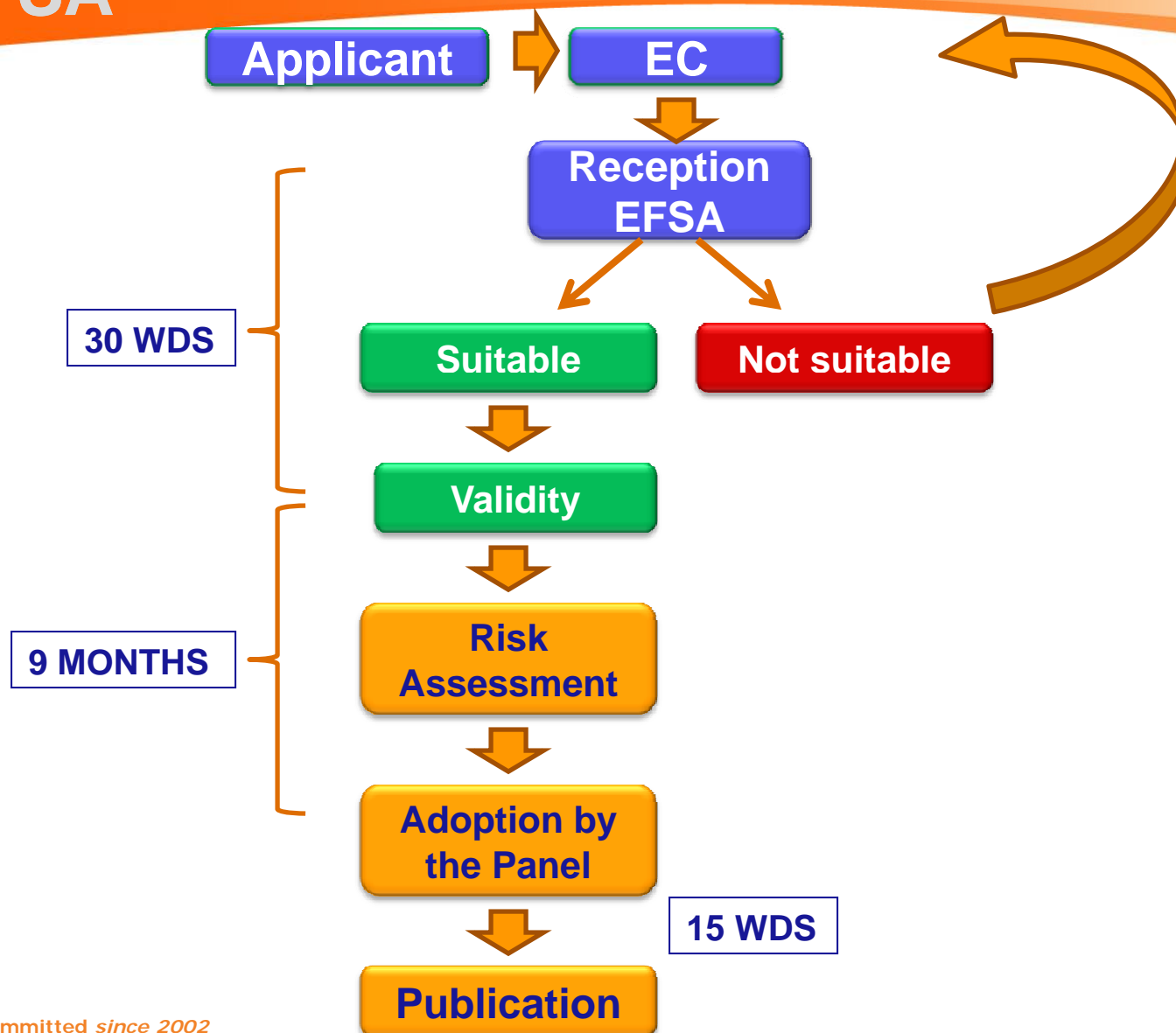
# APDESK – Workflow new applications food additives



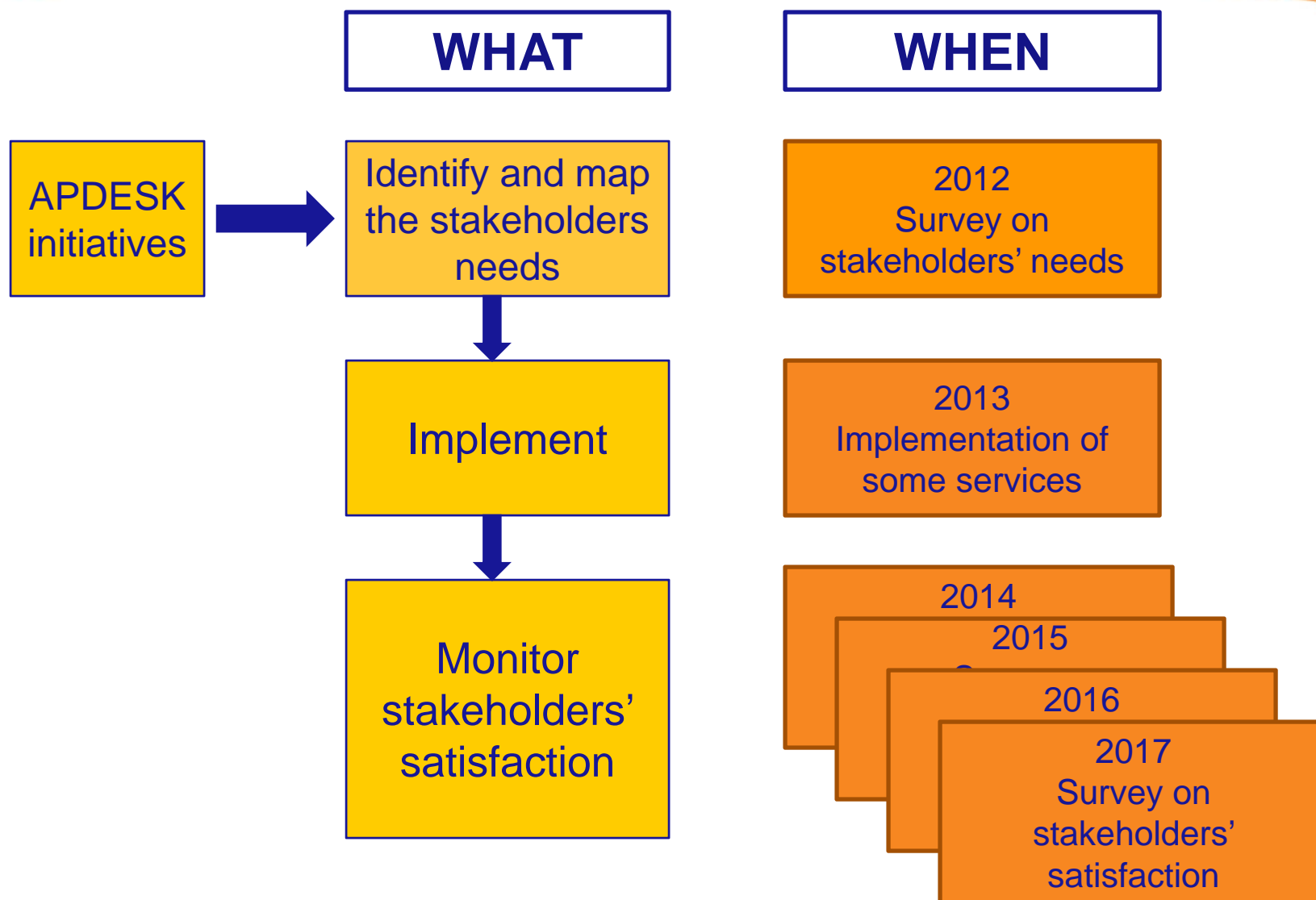
# APDESK – Workflow new applications food additives



# Overall workflow and timeline EFSA



# 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 (on-going)**
- **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](http://www.youtube.com/watch?feature=player_embedded&v=cUF22EIWWyU)



**GRAZIE**