



Supporting applicants in the area of regulated products (REPRO)

Margherita Guidi
Communications Officer

17 September 2018

CONTENT OF THIS PRESENTATION

- **Regulated products Department**
- **Regulated products applications (flows and units in charge)**
- **Monitoring of applications and RAW**
- **Engagement with & support to applicants:**
(Application section, Catalogue of services, Administrative guidance, Webinars, SMEs support)

YOUR ROLE

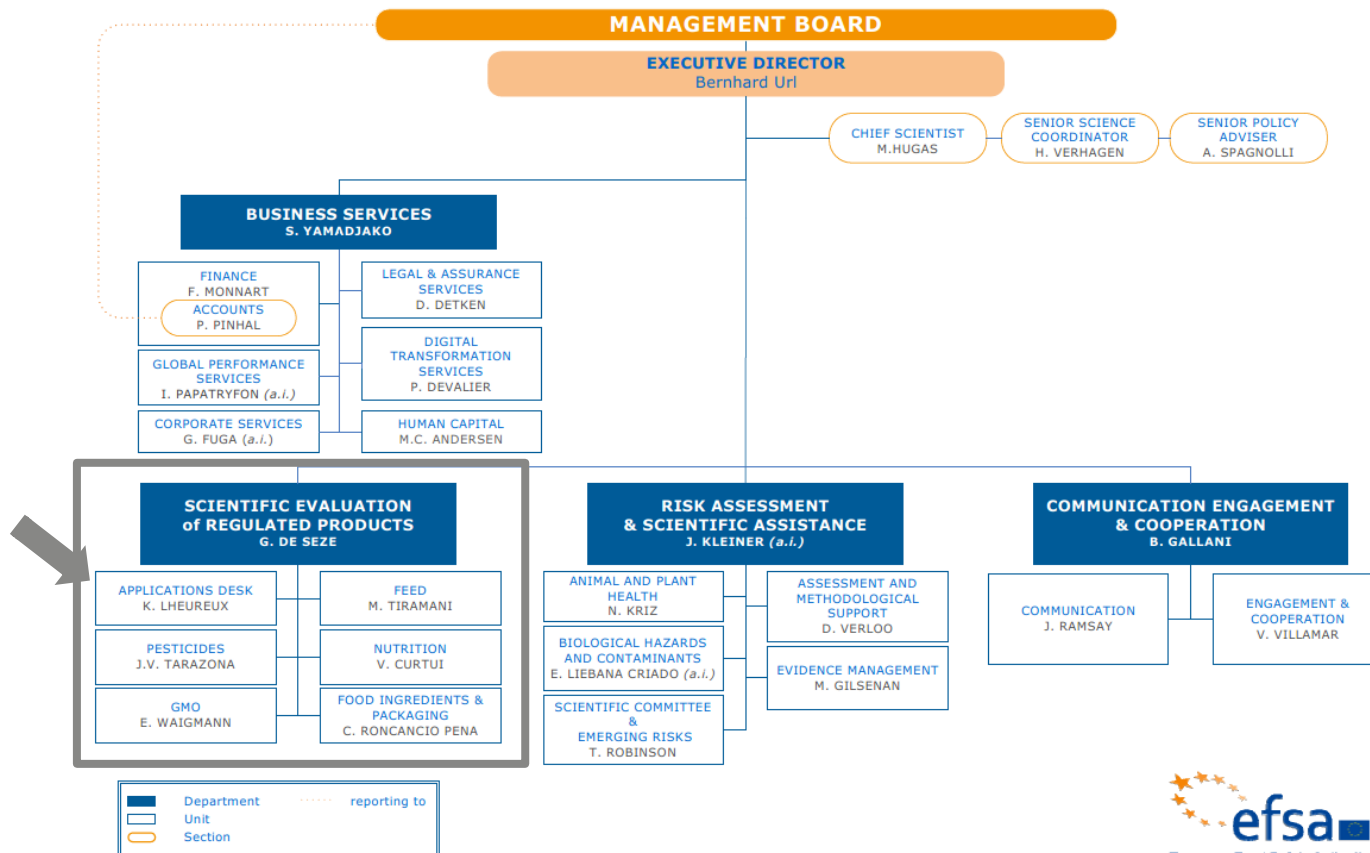
Focal Points agreement

5. FP provides information at national level, as required, on available EFSA services in the area of regulated products during the entire applications life-cycle enabling relevant national institutions the provision of targeted support to applicants (e.g. Small and medium-sized enterprises (SMEs)).

Regulated products Department

EFSA ORGANISATIONAL STRUCTURE

Organisational Structure on 01/09/2018



APPLICATION AREAS: PANELS AND UNITS

Application process general support	APDESK
Regulated product area (Scientific Panel)	Unit
<p>Panel on Food Additives and Flavourings (FAF) deals with food additives and nutrient sources added to food</p> <p>Panel on Food Contact Materials, Enzymes and Processing Aids (CEP)</p>	<p>Food ingredients & packaging</p>
<p>Feed additives (FEEDAP Panel)</p>	<p>Feed</p>
<p>Genetically Modified Organisms (GMO Panel)</p>	<p>GMO</p>
<p>Health claims, Novel food, Infant formulae, Food allergies (NDA Panel)</p>	<p>Nutrition</p>
<p>Plant protection products (PPR Panel): active substances & Maximum Residue Levels (MRL)</p>	<p>Pesticides</p>

The Applications Desk

APDESK UNIT: OBJECTIVES

- **Stakeholders support** (develop new services for applicants during the life-cycle of applications for regulated products);
- **Engagement** with applicants on EFSA's work (EFSA engagement strategy);
- **Support to scientific** REPRO units.



APDESK ROLES AND RESPONSIBILITIES

Karine Lheureux
HEAD OF UNIT



Sara De Berardis
JUNIOR SCIENTIFIC OFFICER
Feed additives, Pesticides



Remigio Marano
JUNIOR SCIENTIFIC OFFICER
FCM, Novel foods



Patricia Romero
JUNIOR SCIENTIFIC OFFICER
GMO, Food ingredients, Novel foods



Irene Baratto
TRAINEE
Feed additives, FCM



Konstantinos Sofianidis
JUNIOR SCIENTIFIC OFFICER
(Temporarily allocated to FEED Unit)



Alessandro De Tommasi
JUNIOR OFFICER
Pesticides, Quality



Margherita Guidi
JUNIOR OFFICER
Communications, Webinars, Reporting



Nikola Burelli
ADMINISTRATIVE ASSISTANT
Feed additives, Health claims, DMC



Gabrielle Kubanski
TECHNICAL ASSISTANT
Pesticides, Sciforma, Budget, Info sessions

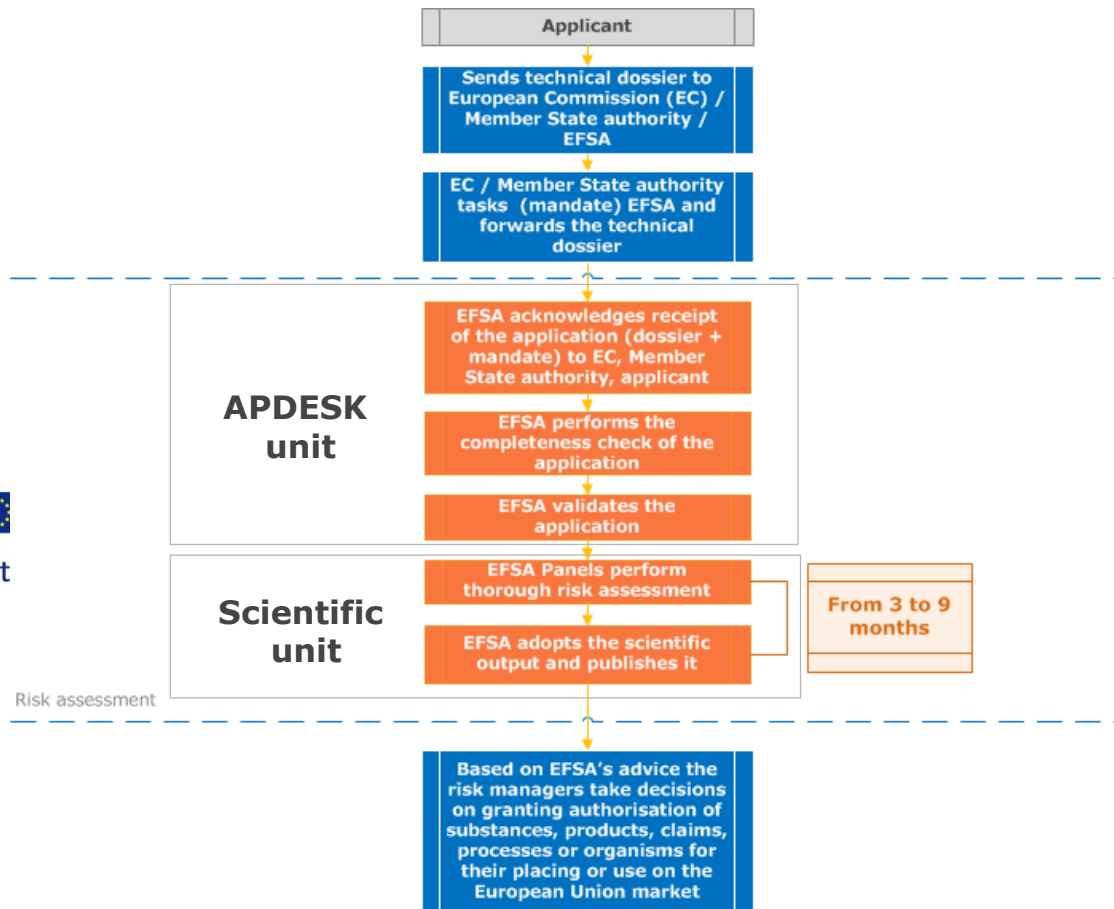


Stefania Mori
ADMINISTRATIVE ASSISTANT
Novel foods, Pesticides

Ingrida Miliute
ADMINISTRATIVE ASSISTANT (interim staff)
Biocontam, Food ingredients, GMO

■ Regulated products applications (flows and units in charge)

GENERAL APPLICATION PROCESS



GENERAL WORKFLOW OF APPLICATIONS

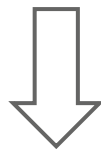
Applications are submitted to EFSA

Individual
scientific
units



EFSA / APDESK

- ✓ Reception
- ✓ Acknowledgement
- ✓ Administrative issues
- ✓ Completeness check
- ✓ Validity/Suitability



VALID/SUITABLE application

Risk assessment

FIP
Unit

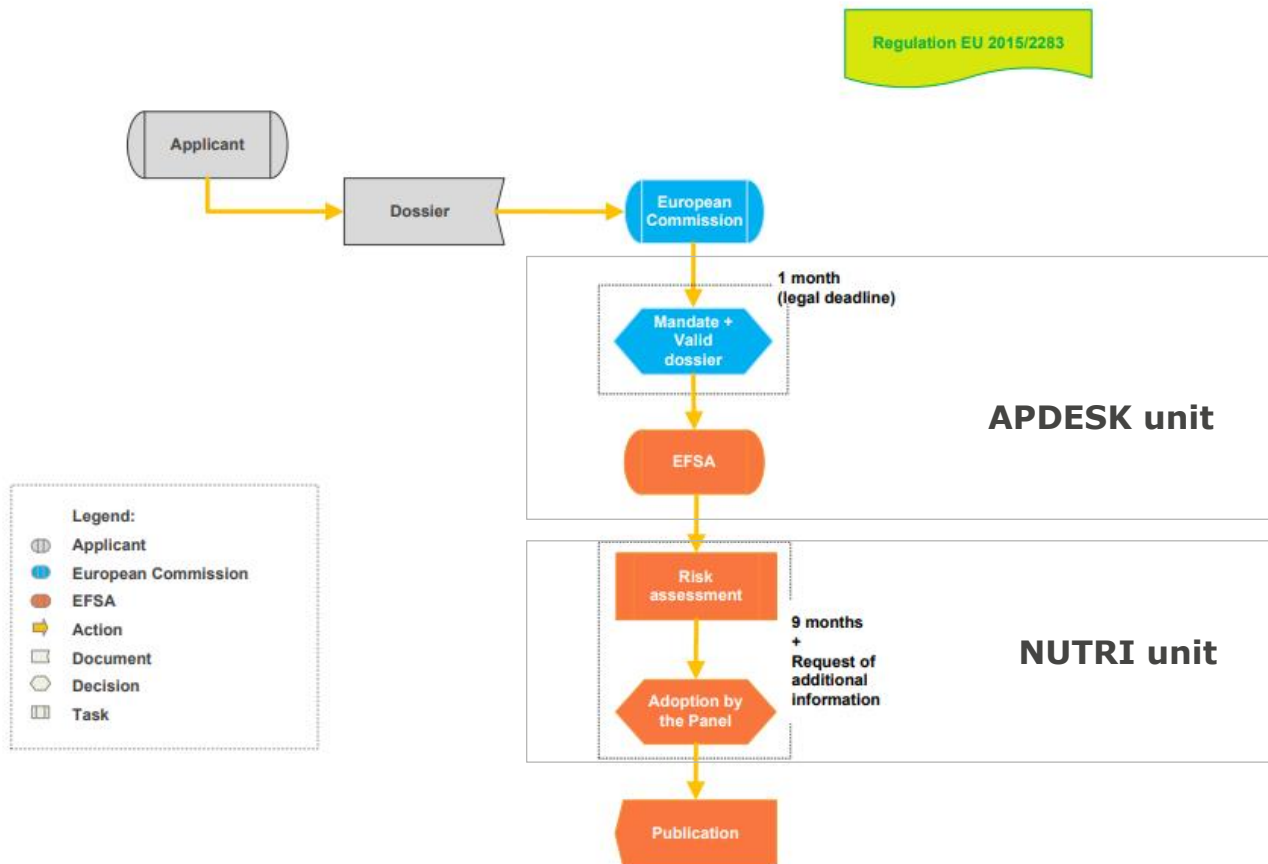
FEED
Unit

GMO
Unit

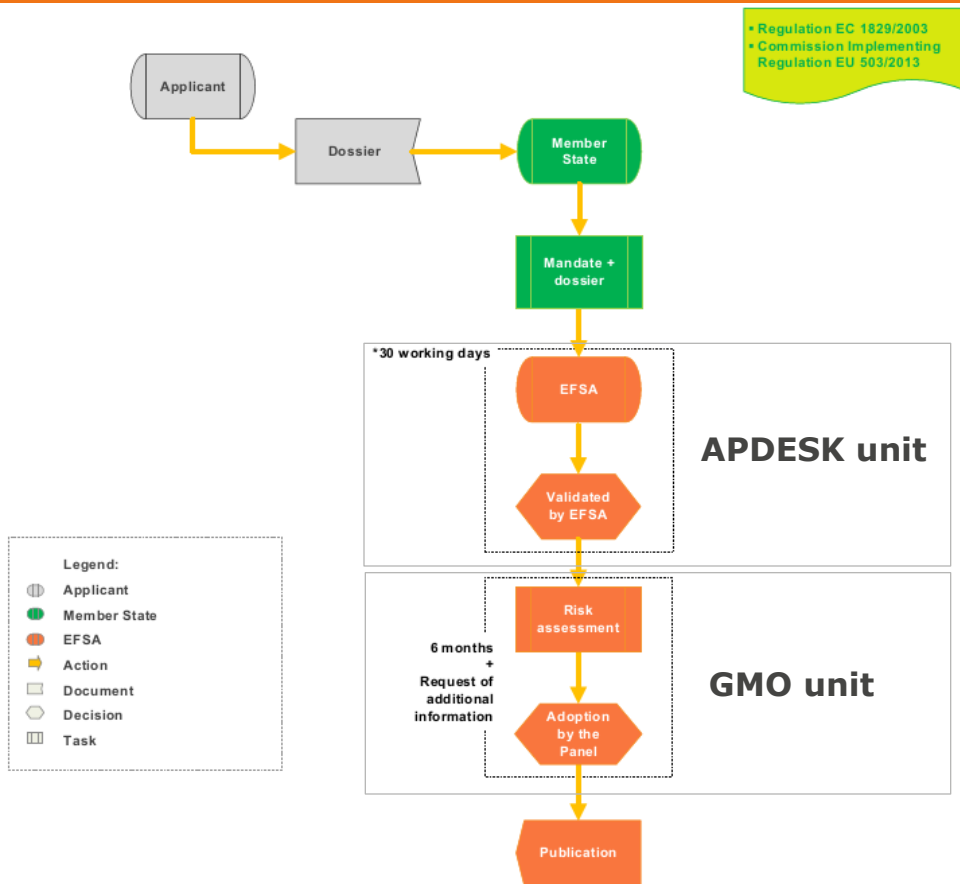
NUTRITION
Unit

PESTICIDES
Unit

APPLICATION WORKFLOW: NOVEL FOODS (NUTRITION)



APPLICATION WORKFLOW: GENETICALLY MODIFIED ORGANISMS (GMO)



Monitoring applications and RAW

EFSA REGISTER OF QUESTIONS DATABASE

Database of all EFSA registered mandates

efsa
European Food Safety Authority

Login
6.22.4.

Mandate Question Output Pesticides Dossier Help

Advanced Search

Unit Filter: Filter Unit Panel Filter: Filter children questions To Date: 17

Filter by Date: Filter Date From Date: 17

Keyword: Status Filter: a

Application Number: Question Type: a

Deadline type: Deadline Type Food Sector Area: a

Deadline within (months): Filter Deadline Month

Mandate Number: a

Mandate Type: Filter Mandate Type Mandate Requestor: a

Output Number: a Output Type: a

Search Clear

Questions Download

Mandate Number	Question Number	Subject	Unit	Panel	Status	Output Number	Last Updated
M-2018-0172	EFSA-Q-2018-00692	Request to the European Food Safety Authority to review an opinion on the safety of D-Ribose as a novel food.	Nutrition	N/A	In progress		12/09/2018 14:50
M-2014-0264	EFSA-Q-2018-00694	Public consultation on Rapporteur Member State assessment	Pesticides	N/A	In progress		11/09/2018 09:02
M-2012-0276	EFSA-Q-2018-00692	Pesticide risk assessment and peer review of bixlozone (F96 (EC) No 1107/2009 (application for approval)	Pesticides	N/A	RMS Risk Assessment on-going		10/09/2018 18:01
M-2014-0264	EFSA-Q-2018-00692	Request for an EFSA peer review (EFSA Conclusion) on the Article 13 of Regulation (EU) No 844/2012 (AIR IV).	Pesticides	N/A	RMS Risk Assessment on-going		10/09/2018 17:22
M-2016-0238	EFSA-Q-2018-00688	Request for a scientific opinion on the health risk of hydrocyanic acid in foods other than raw apricot kernels	Biological hazards and contaminants	N/A	In progress		07/09/2018 17:49
M-2013-0119	EFSA-Q-2018-00687	Report of the third Joint Meeting of the ECDC's Food- and V and of the EFSA's Zoonoses Monitoring Data Network - 'One foodborne disease outbreaks in EU/EEA'	Biological hazards and contaminants	N/A	Finished	EN-1487	10/09/2018 10:53
M-2018-0021	EFSA-Q-2018-00686	Request for a scientific opinion on graines de chia (Salvia hispanica)	Nutrition	NDA	Under Consideration		05/09/2018 18:48
M-2018-0021	EFSA-Q-2018-00686	Request for a scientific opinion on Xia Powder 435 as a novel food (NF 2018/0542).	Nutrition	NDA	Under Consideration		05/09/2018 17:26

Register of Questions database video tutorial:



<http://registrofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>

Engagement with applicants: Applications web section

APPLICATIONS SECTION

Applications helpdesk



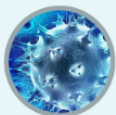
All the resources you need to assist you with the submission and the monitoring of an application for regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union.

[Discover our services catalogue](#)

Application resources by food sector area

Biological hazards

Animal by-product treatments, decontamination substances



Feed additives

Additives and products or substances used in animal feed



Food contact materials

Materials, plastic recycling processes, active and intelligent substances



Food ingredients

Food additives, food enzymes and flavourings, smoke flavourings, nutrient sources



Highlights

[Webinar: Guidance document on safety of feed additives for target animals - What is new?](#)

11 April 2018

[New guidance on processing of applications for regulated products](#)

16 January 2018

[Novel food applications: new administrative guidance for applicants](#)

16 February 2018

Application toolbox



Track your application



Event calendar



Ask a question

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

Engagement with applicants: web form and webinars

ASK APDESK

About ▾ News ▾ Discover ▾ Science ▾

Home > Applications helpdesk > About Applications helpdesk > A

Biological hazard
Feed additives
Food contact materials
Food ingredients
GMO
Nutrition
Pesticides

About Applications
helpdesk

Submitting an application

Services for applicants

Ask a question

Ask a question

You can check the relevant food sector area:

- [Biological hazard](#)
- [Feed additives](#)
- [Food contact materials](#)
- [Food ingredients](#)
- [Genetic modification](#)
- [Nutrition](#)
- [Pesticides](#)

☐ I have read the FAC

First name

Last name

E-mail address

Affiliation

-- Select --

Name of organisation (optional)

Country

-- Select --

Scientific area

-- Select --

Subject

-- Select --

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

EFSA-Q-

Your question

Submit as:

Calendar

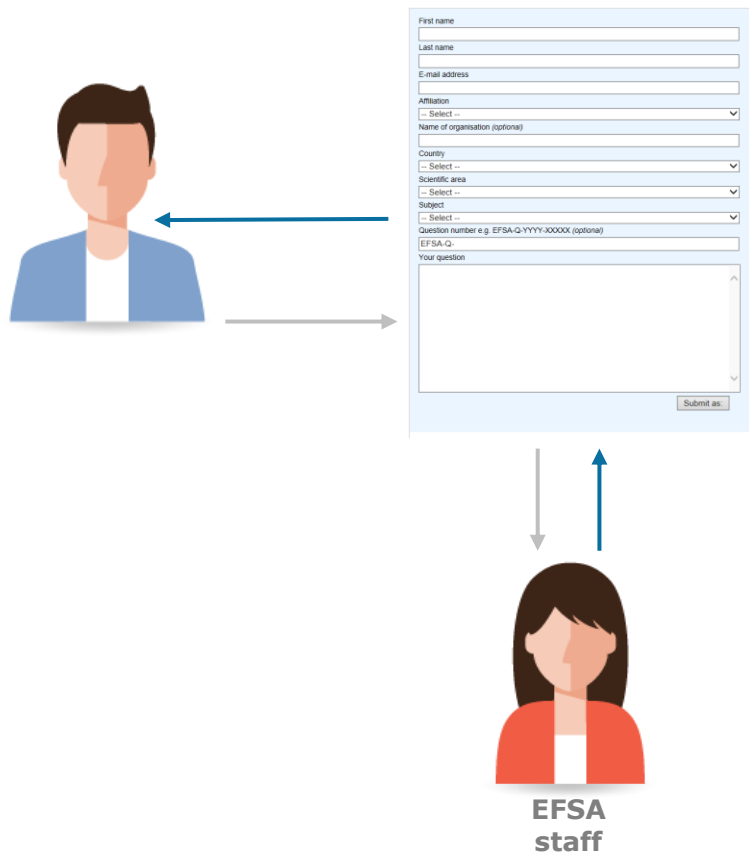
English (en) ▾

Search site



the relevant food sector

ASK APDESK



Any stakeholder interested on regulated products



Front office and support desk on regulated products related matters



EFSA staff, web form requestor



Responses to web form requests are provided within 15 working days



Fill-in the web form available on EFSA's Applications web section

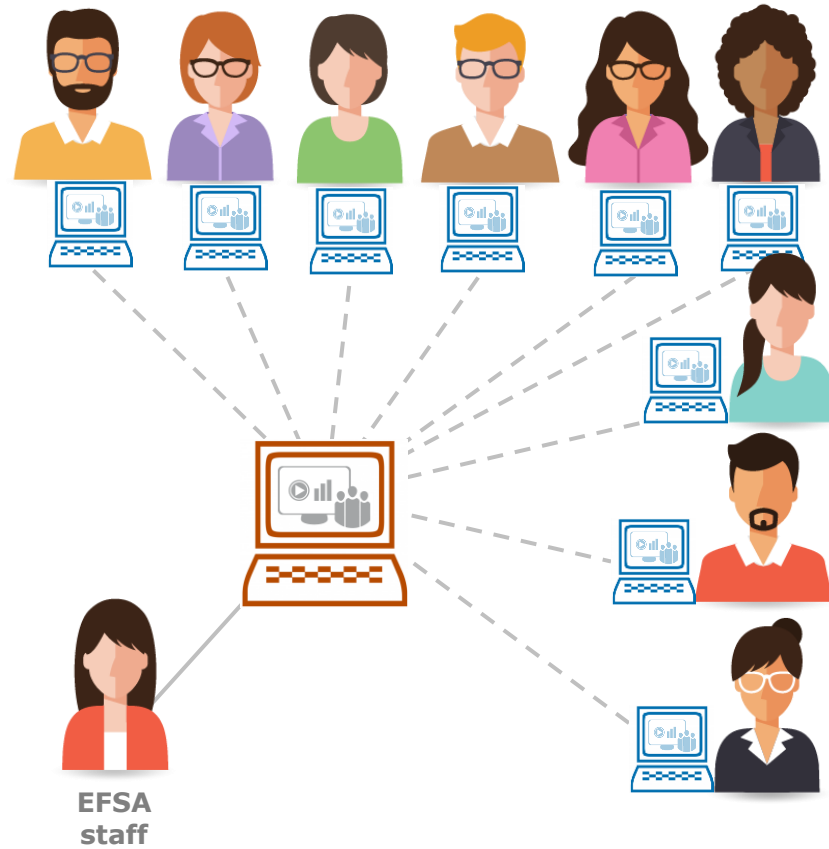


Administrative and scientific issues, EU regulatory framework, guidance documents requirements, procedural steps, status of specific applications



Individual answer to requests within 15 working days from receipt

REPRO WEBINARS



APDESK unit together with REPRO units



Online event to exchange views and enhance an open dialogue on practical scientific and administrative issues as well as tools



EFSA experts of Working Groups/Panels, EFSA staff, EC, Online registrants



30 minutes, 1 hour, 2 hours



Online registration once public registration to a webinar is opened on EFSA website



Methodological and procedural aspects, scientific requirements, approach(es) unique to particular scientific areas



Final agenda, presentations, post-event summary, webinar recording

REPRO WEBINARS

Webinar evolution

1- Calculation tool webinar.pptx

efsa
European Food Safety Authority

INTRO

Web

The w

Speaker

Q&A

Speaker

Concl

Speaker

2015

efsa
European Food Safety Authority

5. EVALUATE QUALITY OF

- Different tools available to assess the design/quality of human studies to the risk of bias
- Common core concepts of study quality
- In principle, human studies assessed first
- Randomised controlled trials at the top of the hierarchy of evidence

Video (1)

Chat (Everyone)

Pilar Pascual 2: Yes, All the studies are of high quality.

Lidia Tomás Cobos 2: till with EFSA-Pascal: Hi Anna, you can click next to the chat, just highlighting the chat box.

Anna Daniel: thank you very much.

EFSA-Pascal: if you have any questions, click the green button and 3) adjust the sound on your device.

Video (2)

Chat (Everyone)

Pilar Pascual 2: Yes, All the studies are of high quality.

Lidia Tomás Cobos 2: till with EFSA-Pascal: Hi Anna, you can click next to the chat, just highlighting the chat box.

Anna Daniel: thank you very much.

EFSA-Pascal: if you have any questions, click the green button and 3) adjust the sound on your device.

2017

Share - EFSA VIDEO

Duration

Pets and non food-producing

Growing

Reproductive

Fish

0 28 42 56 90 Days

Chat (Technical chat) (Everyone)

with a comprehensive answer. The Chat box is reserved for technical questions only.

EFSA Event: Thank you

Pascal Richez 2: I don't know what is the chatbox?

EFSA Event: thank you will copy paste your question in the Q&A box

2018

Video (1)


efsa
European Food Safety Authority

Q & A

Ruud Huibers: what is the minimal requirement for highly purified?

EFSA_Montserrat: For nutritional additives there is a waiver for tolerance studies when the active substance is sufficiently purified. In point 2 of the guidance it is given the conditions for considering the additive as sufficiently purified, ie, if the unidentified fraction would not contribute to more than 1% (in dry matter) when the inclusion rate does not exceed 1,000 mg additive/kg complete feed. Higher inclusion rate would need a higher degree of purity.

INTRODUCTION TO THE CATALOGUE




Calendar
english (en)

Search site

About
News
Discover
Science
Publications
Applications
Engage

Home
Applications helpdesk

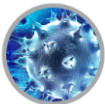



Applications helpdesk



All the resources you need to assist you with the submission and the monitoring of an application for regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union.

> Discover our services catalogue

Application resources by food sector area

<h4>Biological hazards</h4> <p>Animal by-product treatments, decontamination substances</p> 	<h4>Feed additives</h4> <p>Additives and products or substances used in animal feed</p> 	<h4>Food contact materials</h4> <p>Materials, plastic recycling processes, active and intelligent substances</p> 	<h4>Food ingredients</h4> <p>Food additives, food enzymes and flavourings, smoke flavourings, nutrient sources</p> 
--	--	---	---

Highlights

[Webinar: what services does EFSA offer to regulated products' applicants? – Registrations open](#)

5 December 2016

[New guidance adopted by the NDA Panel for the preparation and presentation of an application for authorisation of Novel Foods \(EFSA-Q-2014-00216\)](#)

Nutrition
published: 21 September 2016

[New guidance adopted by the NDA Panel for the preparation and presentation of a notification of traditional foods from third countries \(EFSA-Q-2015-00108\)](#)

Nutrition
published: 22 September 2016

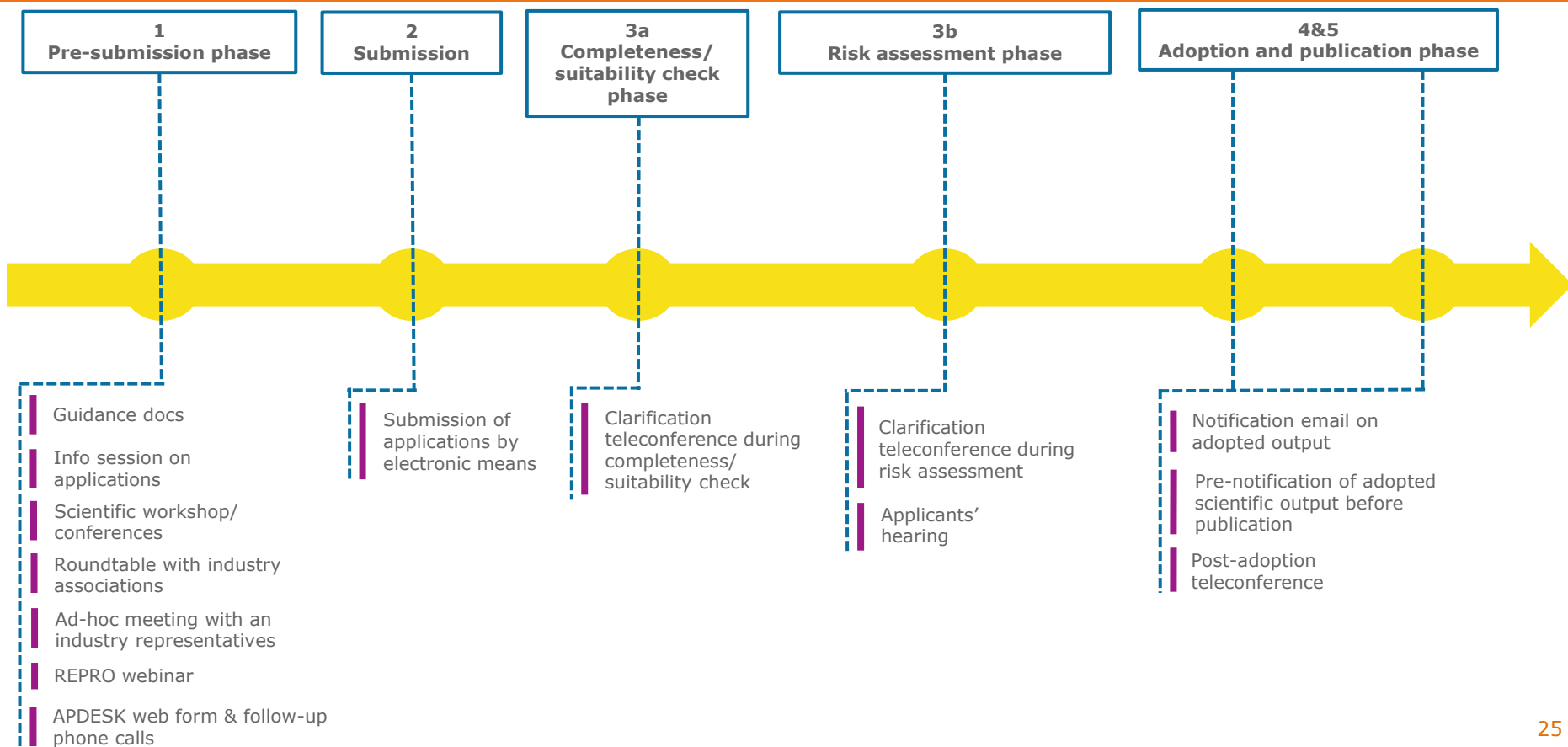
Application toolbox

- Track your application
- Event calendar
- Ask a question

Webinar recording: 

What services does EFSA offer to regulated products' applicants

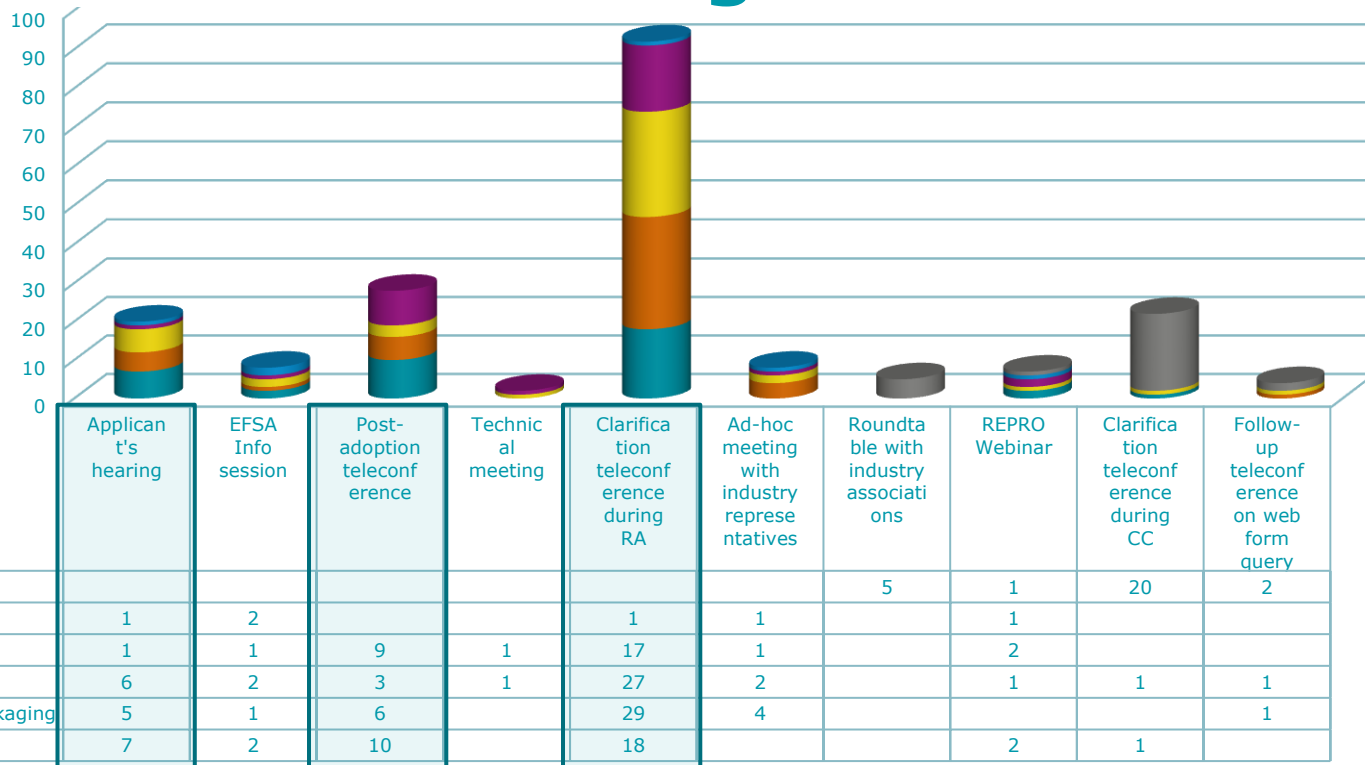
CATALOGUE OF SERVICES



OVERVIEW ON SERVICES REQUESTED

Status: March 2015 – August 2018

Total: 196



Engagement with applicants: Administrative guidance on the processing of applications

INTRODUCTION TO THE GUIDANCE

- Biological hazard
- Feed additives
- Food contact materials
- Food ingredients
- GMO
- Nutrition
- Pesticides
- About Applications helpdesk

Applications helpdesk



[Discover our services catalogue](#)

All the resources you need to assist you with the submission and the monitoring of an application for regulated products, substances and processes, and the substantiation of claims submitted for authorisation in the European Union.

Application resources by food sector area

Biological hazards

Animal by-product treatments, decontamination substances



Feed additives

Additives and products or substances used in animal feed



Food contact materials

Materials, plastic recycling processes, active and intelligent substances



Food ingredients

Food additives, food enzymes and flavourings, smoke flavourings, nutrient sources



Highlights

[Explanatory note on the selection of forage material suitable for the risk assessment of GM feed of plant origin](#)

29 January 2018

[Novel food applications: new administrative guidance for applicants](#)

16 February 2018

[New guidance on processing of applications for regulated products](#)

16 January 2018

Application toolbox



[Track your application](#)



[Event calendar](#)



[Ask a question](#)

TECHNICAL REPORT

APPROVED: 15 December 2017
 doi:10.2903/tp.efsa.2018.EN-1362

Administrative guidance for the processing of applications for regulated products

European Food Safety Authority

Abstract

EFSA is continuously striving to enhance its support initiatives in the area of regulated products, enhancing a customer-oriented approach, supporting applicants during the whole life-cycle of the applications for regulated products. EFSA is registering around 500 mandates on applications for regulated products on a yearly basis governed by more than 34 different EU Directives and Regulations and following 39 workflows. In this context, EFSA developed this administrative guidance on the principles followed to process applications for regulated products in order to enhance transparency and understanding, and to ensure that a coherent, sound, systematic and efficient process is carried out, in compliance with each sectorial legislation. This administrative guidance for the processing of applications for regulated products describes in a harmonised way: the general workflow of applications; the key steps of the scientific risk assessment process; the mechanism of suspension/extension of the scientific assessment; its restart; the conclusion of the scientific risk assessment process and the publication of the scientific output. This administrative guidance does not apply to pesticides processes and to the re-evaluation of food additives which will be integrated in the document in a next version. EFSA will update the administrative guidance for the processing of applications for regulated products, when needed, in line with amendments to the legal acts, to relevant changes to guidance documents and/or approaches, and according to the experience gained in handling and assessing applications. Applicants are advised to always consult the latest published version of this document available on the EFSA website.

© European Food Safety Authority, 2018

Key words: Application for regulated products, EFSA scientific outputs, mandates, sectorial legislation, processes, risk/scientific assessment, workflows

Requestor: European Food Safety Authority

Question number: EFSA-Q-2015-00504

Correspondence: apdesk.applications@efsa.europa.eu

WHY THE GUIDANCE

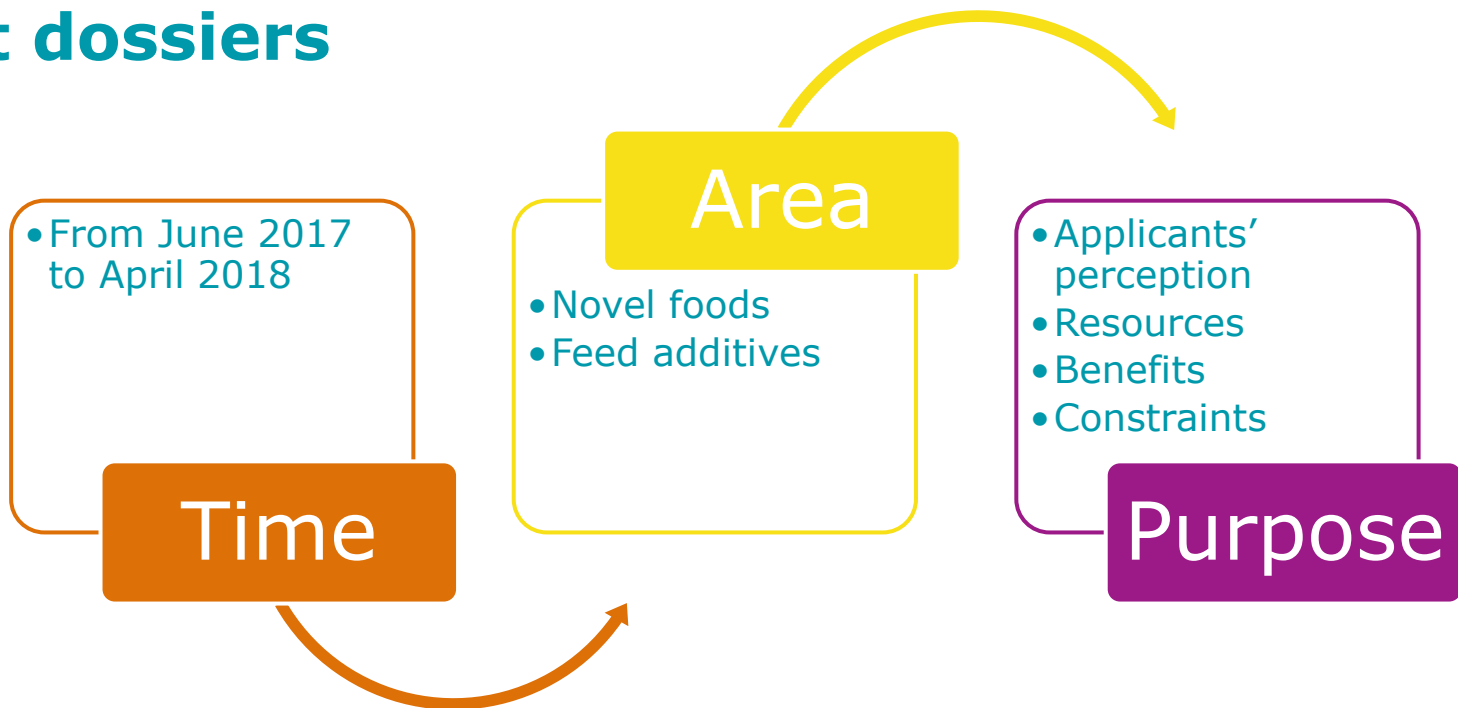
■ Objectives

- To **describe** and **harmonise** the processing of applications for regulated products by EFSA
- To enhance **transparency, understanding** and ensure systematic and **efficient process**
- **Outside scope** (but to be included in next revision): pesticides processes, re-evaluation of food additives
- To be read in conjunction with each **sectorial legislation** (applicable legal act).

Engagement with applicants: SMEs support

PRE-SUBMISSION ADMINISTRATIVE CHECK

PILOT: pre-submission administrative check of draft dossiers



REQUESTS OVERVIEW

FEED ADDITIVES: 2 requests

- 2 teleconferences organised


NOVEL FOODS: 14 requests

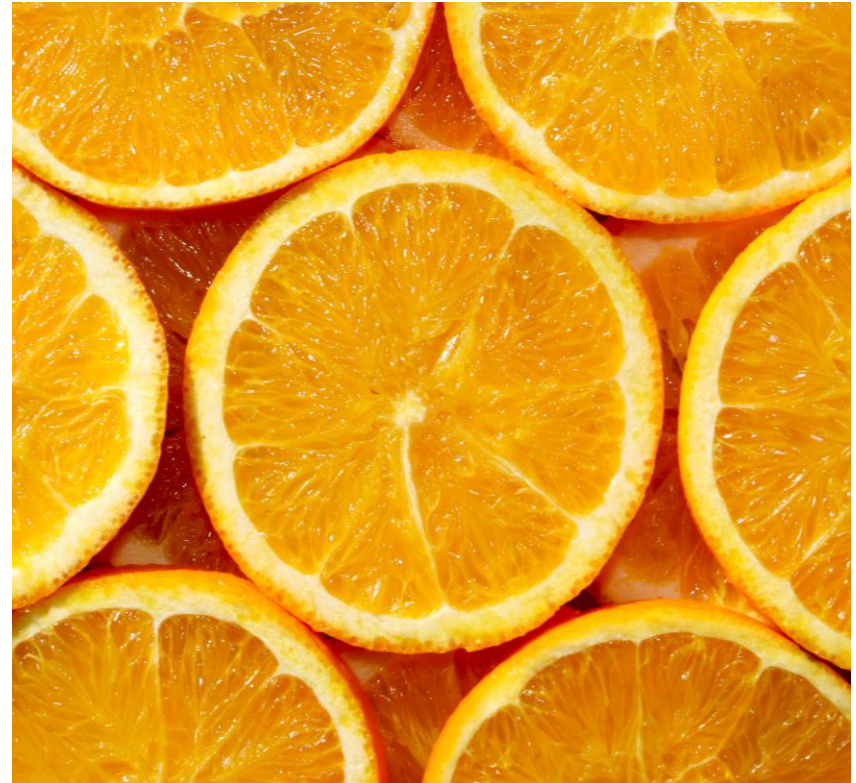
- 3 teleconferences organised

Excluded: 11

- 1 traditional food
- 2 not-novel foods
- 1 food for special medical purpose
- 4 at the beginning of the dossier
- 3 never came back to EFSA

Thank you!

- Do you want to consult the **Catalogue**? Go to the [EFSA website](#)
- Do you want to check the **administrative guidance**? Look it up on the [EFSA website](#)
- Are you looking for information on **regulated products**? Check the [Applications section](#)
- Do you **have a question** on applications? Contact EFSA via the [APDESK webform](#)
- To **follow me** on : [@margheguidi](#)



INTERACTIVE EXERCISE

1. According to your knowledge and experience what **services** are most of interest to MSCA and applicants?
2. What do you think **SMEs** need when it comes to applications for regulated products and how EFSA with the help of Focal Points can better reach them?
3. What info would you need/you would like to find on **Applications section** to ease the spreading of information and updates on specific regulated products matters? You can also propose specific communications products such as infographics, layman summary, fact sheets, videos, FAQs, etc