



# Tips and tricks on the assessment of feed additives

FEED Unit Webinar  
4 December 2017

# WEBINAR GUIDE TO ATTENDEES

## Be reminded that:

- This webinar **is being recorded!**

Please ensure that you have carefully read the [EFSA Disclaimer and data protection note.](#)

If you do not agree with the EFSA policy on webinars, please disconnect now.

- The webinar **is in English** and questions should be submitted in English.

# INTRODUCTION - GUIDE TO ATTENDEES

## Volume and speakers

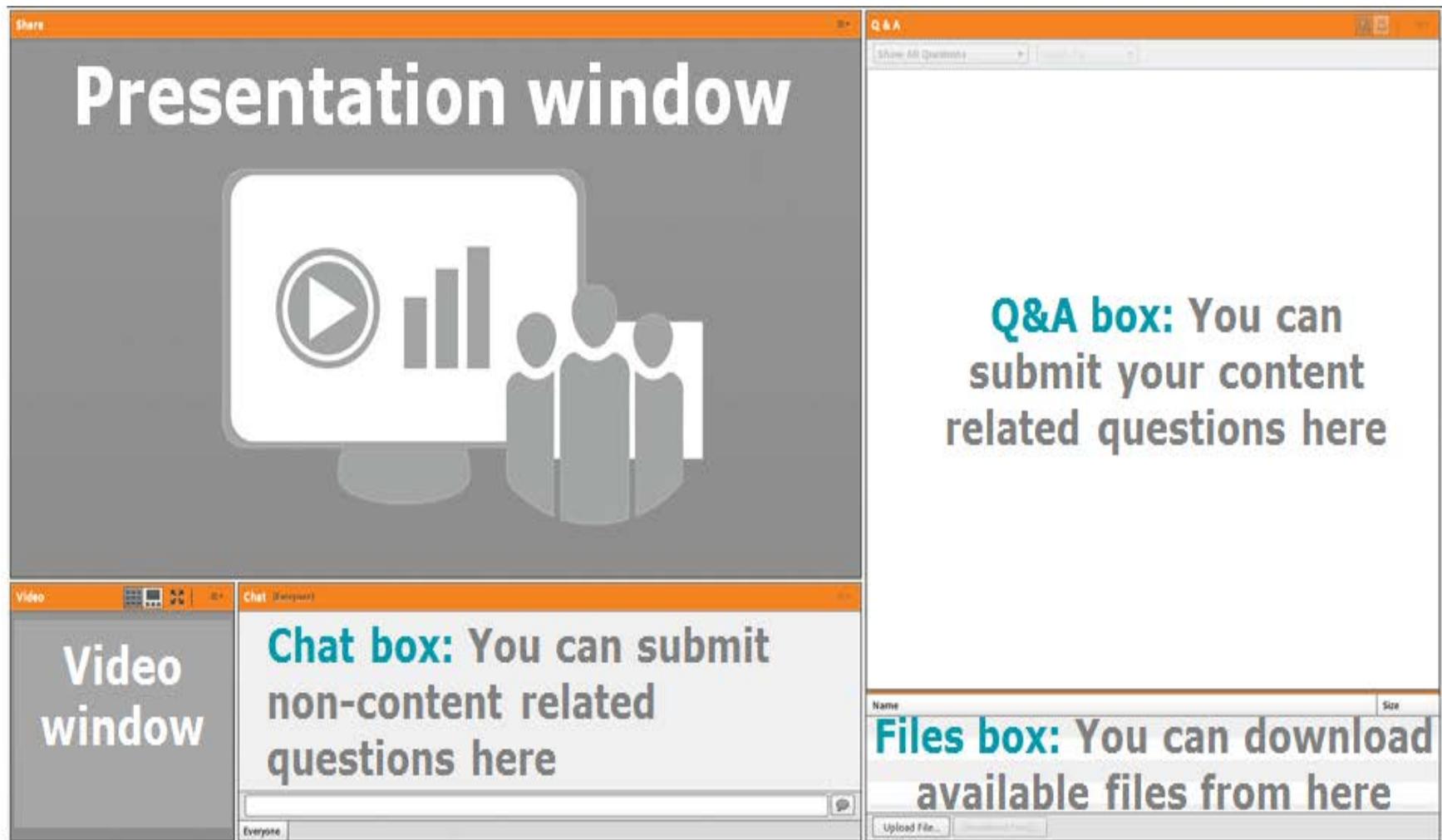
- You are automatically connected to the audio broadcast. One-way audio (listen only mode)
- Check the audio panel to control your volume:



- Make sure you enable sound on your computer and turn on your headphones

# INTRODUCTION - GUIDE TO ATTENDEES

## Virtual Room



**Presentation window**

**Video window**

**Chat box:** You can submit non-content related questions here

**Q & A**

**Q&A box:** You can submit your content related questions here

**Files box:** You can download available files from here

## INTRODUCTION - GUIDE TO ATTENDEES

### Sending questions - Q&A box

- Questions should be **concise** and submitted **once**. Follow-up questions should be **self-explanatory**
- You can ask questions **until 14:50**
- You will see the **answer** right below the question row once replied by EFSA
- We will address all questions as soon as possible and until **15:00**
- If you do not receive an answer to your question, feel free to re-submit it through the **EFSA APDESK** web form later on:

[http://www.efsa.europa.eu/en/applicationshelpdesk/ask\\_aquestion](http://www.efsa.europa.eu/en/applicationshelpdesk/ask_aquestion)

## SCOPE OF THE WEBINAR

Help applicants better understand the **principles of feed additives authorisation process** and to make the **technical dossiers fit for purpose** in the context of risk assessment. This should lead to quicker assessment of applications and **efficiency gains**



## GENERAL PRINCIPLES - THE PLAYERS

### Applicant

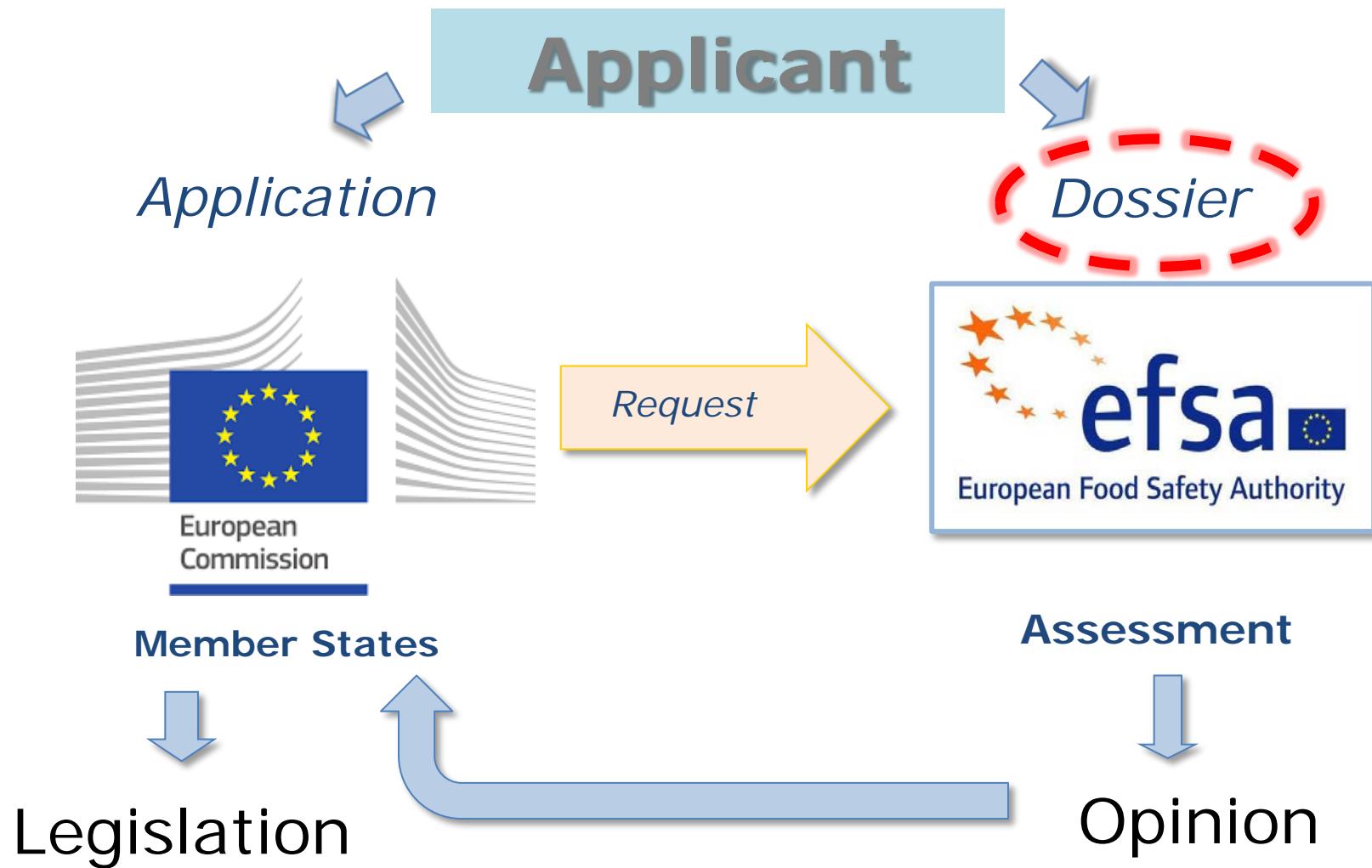


### Risk Manager



### Risk Assessor

# GENERAL PRINCIPLES - THE PROCESS



## GENERAL PRINCIPLES – RISK MANAGERS' RESPONSIBILITIES

### Role of European Commission and Member States

- Decide if a product/substance is a **feed additive**
- Receive applications and send **mandates** to EFSA
- Decide on **confidentiality** status of information in the technical dossiers
- Draft and publish **feed additives authorisations**
- Maintain the [Community Register of feed additives](#)

#### Role of European Reference Laboratory:

- Store feed additives samples
- Evaluate methods of analysis

# GENERAL PRINCIPLES – EFSA'S RESPONSIBILITIES

## Role of EFSA

- Verify **administrative completeness** of the applications and technical dossiers  **APDESK Unit**
- Verify accuracy and **completeness** from **scientific** view point of technical dossiers  **FEED Unit**
- **Manage communication** with applicants (e.g., request for additional information)
- **Communicate** on activities/outputs (e.g., website, meetings with stakeholders)
- Publish **scientific opinions**
- Publish **guidance documents**

## GENERAL PRINCIPLES – APPLICANT'S RESPONSIBILITIES

### Building the dossiers

- Applicants have the **full responsibility** on the strategy to build a dossier and provide evidence of safety and efficacy of their additives at the conditions of use
- Dossiers should be **complete and stand-alone**
- All **supporting information** should be provided and clearly identified
- Applicants should make sure to have **full rights** for usage of proprietary data

# GENERAL PRINCIPLES - LEGAL FRAMEWORK

**General Food Law  
Regulation (EC) No 178/2002**

**Feed Materials  
Reg. (EC) 767/2009**

**Feed Hygiene  
Reg. (EC) 183/2005**

**Feed Additives  
Reg. (EC) 1831/2003**

**Feed Additives  
Reg. (EC) 429/2008**

**Undesirable substances  
Dir. 2002/32/EC**

**GMO Feed  
Reg. (EC) 1829/2003**

# GENERAL PRINCIPLES – GUIDELINES vs GUIDANCE

## GUIDELINES (Reg. 429/2008)



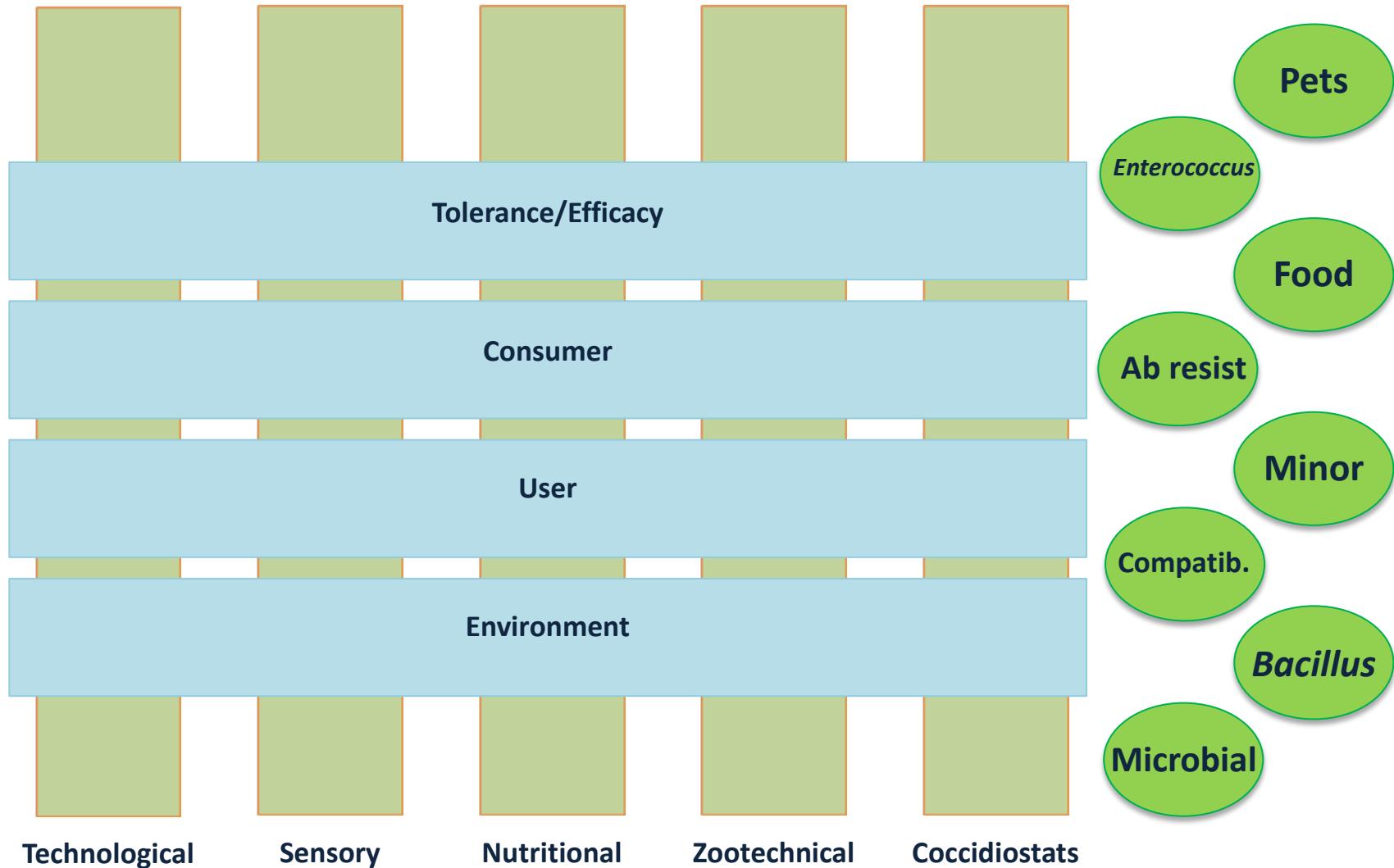
## GUIDANCE

HOW and WHEN



Guidance update to be completed in mid 2018

# GENERAL PRINCIPLES - OLD/CURRENT STRUCTURE GUIDANCES





# GENERAL PRINCIPLES – NEW STRUCTURE GUIDANCES

Identity and characterisation

Characterisation of microorganism  
(include GMM)

Safety for the target species

Safety for the consumer

Safety for the user

Safety for the environment

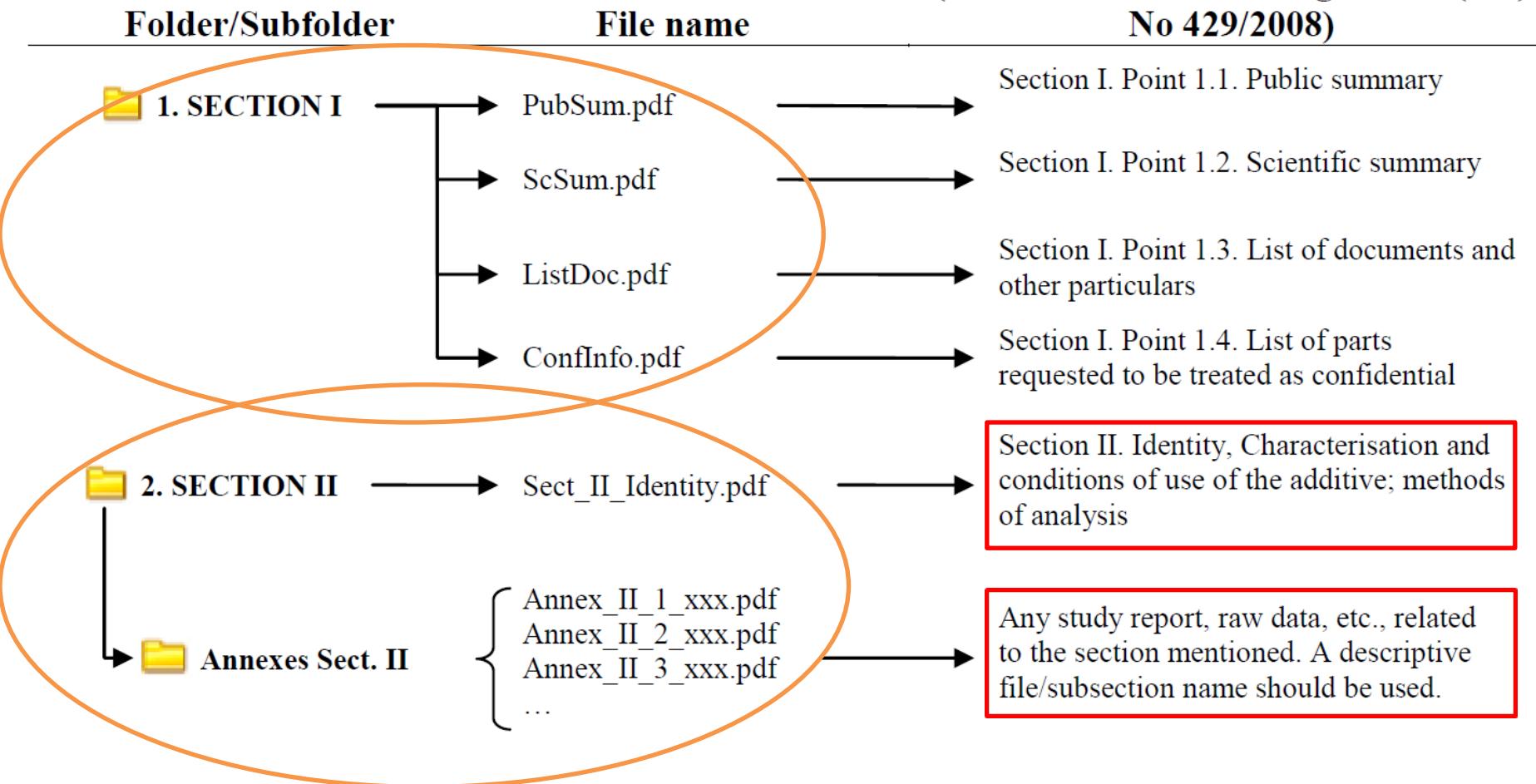
Efficacy

Renewal

# GENERAL PRINCIPLES – STRUCTURE OF DOSSIERS

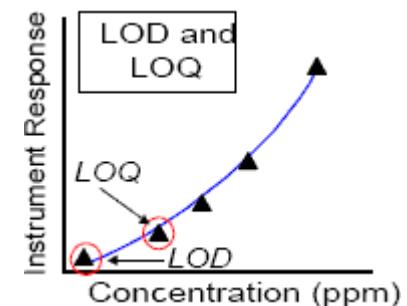
## TECHNICAL DOSSIER

**Contents**  
**(Refer to Annex II of Regulation (EC)**  
**No 429/2008)**



## TIPS AND TRICKS – SECTION II

- Proper identification of test item
- Proper correlation with additive under assessment
- Sufficient number of batches
- Units of the measurements
- Limits of detection/quantification
- Detailed description of production process
- Adequate duration of stability studies



## TIPS AND TRICKS – SECTIONS III AND IV

- Design should reflect the proposed conditions of use
- Involvement of healthy animals
- Use of correct statistical unit
- Sufficient number of replicates
- Inclusion of all the relevant treatments data
- Full reporting of studies (i.e., including raw data, statistical model and output, veterinary records)



## TIPS AND TRICKS – GENERAL ISSUES

- Publications and/or other supporting documents cited should be provided/clearly identified/clearly correlated with other parts of the dossier
- Documents should be word searchable
- Literature searches should be fully described
- Requests for confidential treatment of data
  - clear
  - properly justified
  - reflect legal provisions



## TAKE HOME MESSAGES

### Help us increase efficiency!

- Stick as much as possible to the requirements
- Deviate when relevant but provide a clear and relevant justification
- Make clear, proportionate and properly justified claims for confidential treatment of data
- Learn from experience



# Exploit opportunities to put forward questions/issues and interact with us

- Feed additives mailbox  
[FEEDADDITIVES@efsa.europa.eu](mailto:FEEDADDITIVES@efsa.europa.eu)
- EFSA ask a question tool  
<http://www.efsa.europa.eu/en/applicationshelpdesk/askquestion>
- EFSA catalogue of services  
<http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2016.EN-1025/epdf>
- EFSA public consultations  
<http://www.efsa.europa.eu/en/calls/consultations>
- Sign up to EFSA's email alerts and newsletters  
<https://www.efsa.europa.eu/en/press/news/121002-0>



## FEEDAP INFOSESSION ON UPDATED GUIDANCE DOCUMENTS

**14 and 15 (AM) June 2018**





**KEEP  
CALM**

and

**PREPARE**

(good)

**DOSSIERS**

# Thank you for attending our webinar!



In case we did not manage to answer all your questions, please feel free to re-submit them via e-mail at:

[ask@efsa.europa.eu](mailto:ask@efsa.europa.eu)

Please take **5 more minutes** to fill out the evaluation form that you will receive shortly in your inbox. Your feedback will help us improve our service.

