Ad-hoc meeting with stakeholders' representatives

Brussels, 19 June 2019

efsa
European Food Safety Authority

Draft Agenda

1. Welcome
2. Agreement of the draft Agenda
3. Scope of the meeting
4. Update of the FEEDAP Guidance on the renewal of the authorisation of feed additives
   - EFSA's overview
   - Stakeholders' questions and proposals
   - Discussion

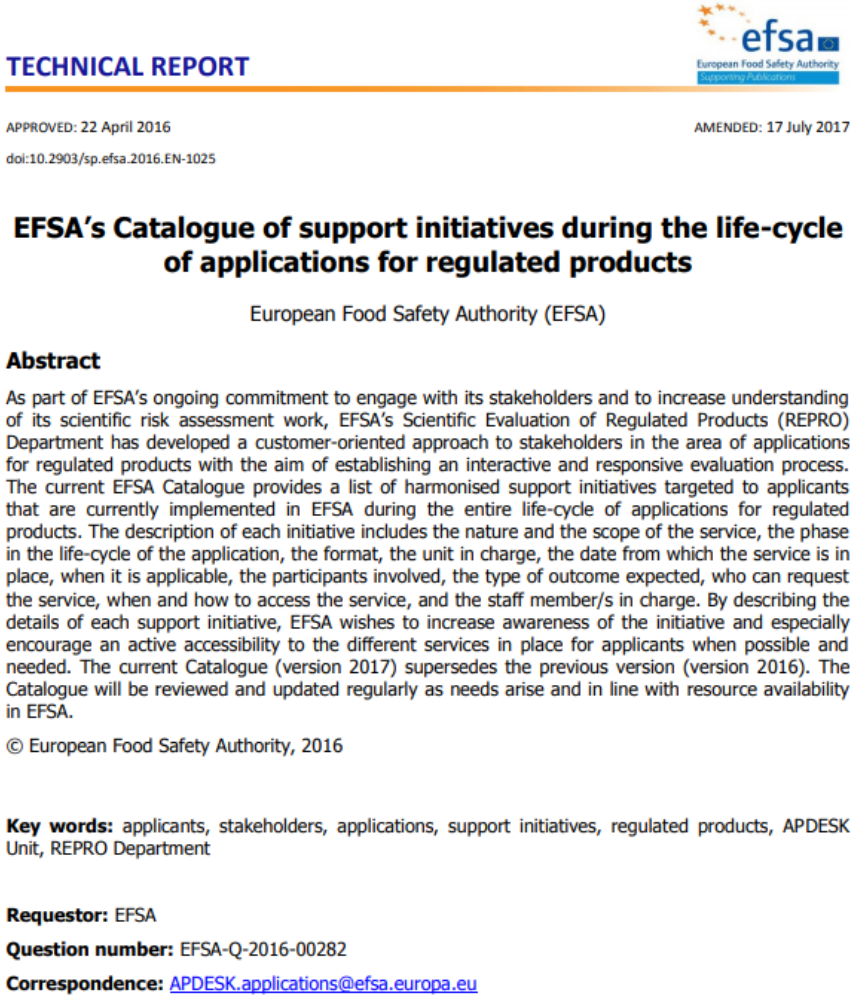
Draft Agenda

5. November info-session
   - Scope and topics suggested by EFSA
   - Stakeholders' views
   - Discussion
6. Ongoing Activities
7. Summary and conclusions of the meeting

3. Scope of the meeting

EFSA catalogue of services

“2.1.5. Ad hoc meeting with industry representatives”



TECHNICAL REPORT

APPROVED: 22 April 2016

AMENDED: 17 July 2017

doi:10.2903/sp.efsa.2016.EN-1025

EFSA’s Catalogue of support initiatives during the life-cycle of applications for regulated products

European Food Safety Authority (EFSA)

Abstract

As part of EFSA’s ongoing commitment to engage with its stakeholders and to increase understanding of its scientific risk assessment work, EFSA’s Scientific Evaluation of Regulated Products (REPRO) Department has developed a customer-oriented approach to stakeholders in the area of applications for regulated products with the aim of establishing an interactive and responsive evaluation process. The current EFSA Catalogue provides a list of harmonised support initiatives targeted to applicants that are currently implemented in EFSA during the entire life-cycle of applications for regulated products. The description of each initiative includes the nature and the scope of the service, the phase in the life-cycle of the application, the format, the unit in charge, the date from which the service is in place, when it is applicable, the participants involved, the type of outcome expected, who can request the service, when and how to access the service, and the staff member/s in charge. By describing the details of each support initiative, EFSA wishes to increase awareness of the initiative and especially encourage an active accessibility to the different services in place for applicants when possible and needed. The current Catalogue (version 2017) supersedes the previous version (version 2016). The Catalogue will be reviewed and updated regularly as needs arise and in line with resource availability in EFSA.

Key words: applicants, stakeholders, applications, support initiatives, regulated products, APDESK Unit, REPRO Department

Requestor: EFSA

Question number: EFSA-Q-2016-00282

Correspondence: APDESK.applications@efsa.europa.eu

3. About ad hoc meetings

- Organised on a case-by-case basis
- Exchange information and views between EFSA and stakeholders on methodological and procedural aspects, scientific requirements or approach(es) which are unique to particular scientific areas and cannot be handled with already available support initiatives
- Setting up direct communication and an open dialogue

Participants

- Participants from stakeholders

FEFANA Asbl	Yara Antonissen Alicia Juárez Pallarés Ludovic Arnaud Aurore Potel Laurence Millot
FEFAC	Arnaud Bouxin
AMFEP	Bas Verhagen
FEDIAF	Julien Taïeb

Participants

- Participants from stakeholders

AnimalhealthEurope	Karen Roels
AVC - Association of Veterinary Consultants	Bill Vandaele
Novozymes, EuropaBio	Mads Mourier
Pen & Tec Consulting	Laura Payo Lewis
REGAL Consulting / EFFSACO	Ruud Bremmers
SAQUAL Consulting	Manfred Lützow

Participants

- Participants from the European Commission

DG SANTE	Marta Ponghellini Almudena Rodriguez Alfons Vazquez Wolfgang Trunk Tommaso Atzeni

Participants

- Participants from EFSA FEED Unit

Head of FEED Unit *a.i.*	Frank Verdonck (Chair)
Scientific Officers	Montserrat Anguita Rosella Brozzi Jaume Galobart Matteo Innocenti

4.Revision of the guidance on renewal

4. Scope

- The guidance on renewal needs to be revised, in order to:
  - consider the implications of the update of the Regulation (EC) No 178/2002
  - update the references to the most recent Guidance documents adopted by the FEEDAP Panel
  - align the requirements for the assessment to the current assessment practices

4.Procedural and methodological aspects

- The dossier should contain:
  - clear indication of which information was already submitted in the original application and which one is new
  - clear and precise conditions of use of the additive (e.g. for mixed applications)
  - all the information needed to support the safety and, if relevant, the efficacy

4. Scientific aspects - Characterisation

A complete Section II is required – Legal requirement Regulation (EC) 429/2008

- Guidance on identity and characterisation (2018) and any specific requirement included in the authorisation should be considered for the purity
- recent data on composition, purity (number of batches?)
- any changes in the manufacturing/composition (e.g., excipients, carriers, physical properties) of the additive should be considered when addressing the safety
- for fermentation products: investigation on the presence of viable cells and DNA, where relevant.

4. Scientific aspects - Characterisation

A complete Section II is required – Legal requirement Regulation (EC) 429/2008

For microorganisms used as the additive or as production strain:

- the requirements of the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (2018) apply
  - Identity (confirmation of the taxonomic classification)
  - Antimicrobial resistance/toxigenic potential
  - For GMM – description of the genetic modification

4. Scientific aspects - Characterisation

A complete Section II is required – Legal requirement Regulation (EC) 429/2008

Conditions of use

i) the same of the authorisation (including other provisions);

ii) modifications of the inclusion levels of the additive in feed;

iii) new species/categories or other new uses;

iv) other (e.g., change of the MRL, of the withdrawal time)

4. Scientific aspects - Safety

Means to confirm the safety of the additive:

- Results of the post marketing monitoring plan, where relevant
- Available reports on any adverse effect to the knowledge of the applicant

4. Scientific aspects - Safety

To take into consideration

- modifications introduced in the new guidance documents
- modified/updated requirements for the studies on genotoxicity studies
- testing of mixtures

4. Scientific aspects - Safety

Potential exclusion criteria (following current guidance documents)

- QPS microorganisms
  - NO need for literature search to support the safety for target animals, consumer and environment
- Nutritional additives
  - NO need of specific demonstration of the safety for the target animals, when specific characteristics are met (e.g., purity, QPS)

4. Scientific aspects - Safety

Specific requirements

Safety for the target animals

- support the safety for additional species not considered before
  - fish to support the safety for all animal species
  - evidence that the additive can have an adverse effect on a specific animal species
- default values (for feed intake/body weight)

4. Scientific aspects - Safety

Safety for the consumer

- Any new information on toxicological properties of the additive, including health-based guidance values (HBGV)
- Any info on exposure via other sources (also for additives for which an HBGV is not available)
- For substances for which a HBGV existed or has become available, information on residues in tissues and products should be provided
- New estimate of consumer exposure with FACE

4. Scientific aspects - Safety

Safety for the user

- any information deriving from the experience in production plants (e.g., reports on adverse effects)
- data missing in the previous assessment
- ECHA evaluation

4. Scientific aspects - Safety

Safety for the environment

- To consider the modifications introduced in the current guidance

4. Scientific aspects - Efficacy

No modifications to the existing guidance are foreseen

Efficacy only required for:

- coccidiostats and histomonostats
- modifications of the conditions of use that may have an impact on the efficacy

4. Means to provide evidence

- **Literature searches**
  - should be performed and reported as described in the guidance on the safety for the target species
  - need to include in the guidance:
    i. the key aspects of the literature search;
    ii. clarifications on how to report the results (submission of the .RIS file);
    iii. detailed requirements regarding the search strategy and keywords

4. Means to provide evidence

- **New studies**
  - possibility to demonstrate the safety (and/or efficacy) of the additive with new studies, instead or along with the literature searches
  - modification on the conditions of use (e.g., higher or lower use levels, new target species, new uses) might require new studies

Discussion

5. November info-session

5. Scope

Strategic objective 1 ‘prioritise public and stakeholder engagement in the process of scientific assessment’

Strategic objective 4 ‘prepare for future risk assessment challenges’

5. Scope

Allow a direct dialogue between the parties involved to

- Develop guidance documents that are fit for purpose
- Facilitate the practical implementation of the new guidance documents

5. New guidance documents

Identity and Characterisation

Characterisation of Microorganisms

Safety for the Target species

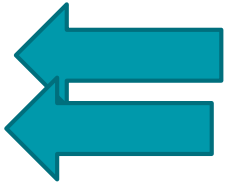
Safety for the Consumer

Safety for the User

Safety for the Environment

Efficacy

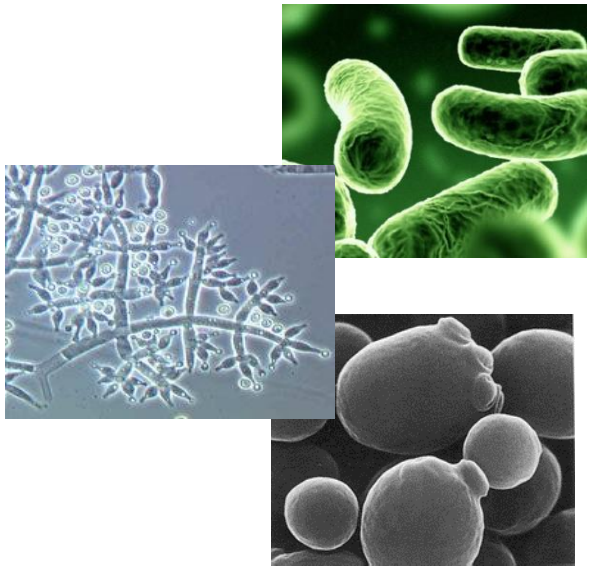
Renewal



5. EFSA's proposals

Updated Guidance documents on

- Microbial characterisation
- Environmental risk assessment
- Efficacy



5. EFSA's proposal – cont..

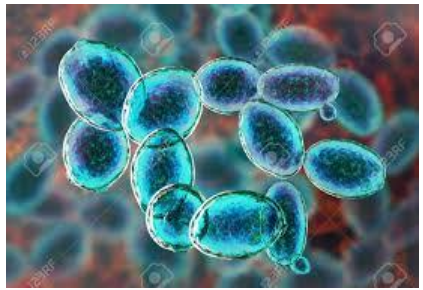
Prepared in collaboration with stakeholders

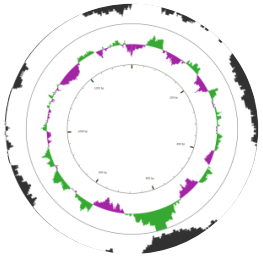
- Main changes
- Rational
- Different perspectives
- Collection of feedback

On-going activities

6. On-going activities

Microorganisms





- WGS note
- Antimycotic susceptibility
- *Enterococcus faecium* virulence factors

Discussion