



Update on pre-submission administrative check pilot, guidance and events

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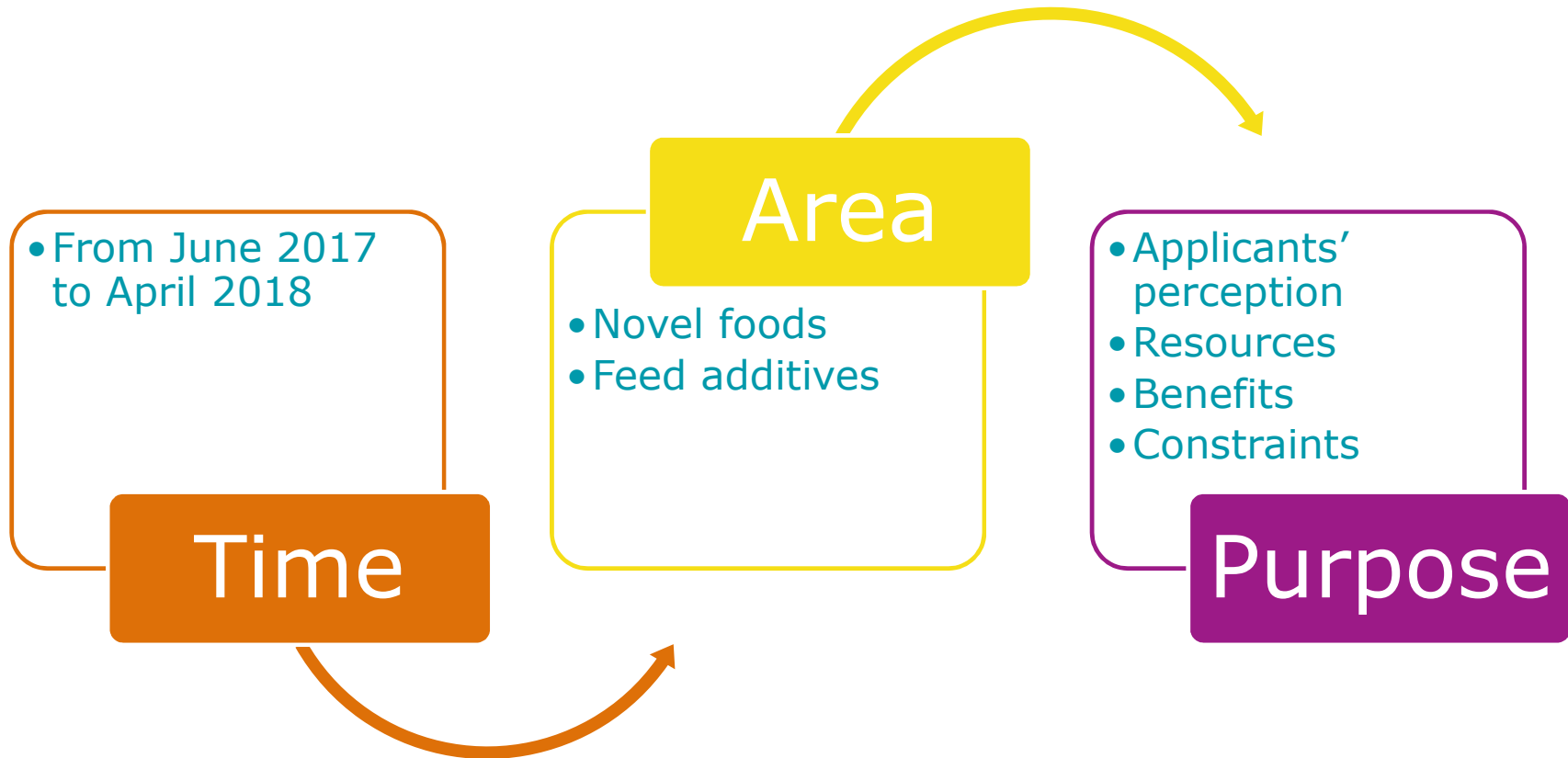
13 June 2018

CONTENT OF THIS PRESENTATION

- **Pre-submission administrative check of draft dossiers (Pilot)**
- **Update on guidance documents and events**

PILOT: Pre-submission administrative check of draft dossiers

PRE-SUBMISSION ADMINISTRATIVE CHECK



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

APPLICANTS' FEEDBACK

SMEs **confirmed** that:

- The teleconference was **useful**
- The **support** provided by the EFSA staff before the teleconference was **helpful**
- **EFSA staff** carefully explained how to improve the dossier and **addressed all questions** raised during the teleconference
- Applicant felt supported by EFSA in the preparation of the dossier



All companies consulted would **recommend this service** to other SMEs

Update on guidance documents and events

GUIDANCE DOCUMENTS UPDATES

AREA	GUIDANCE
FEED	<ul style="list-style-type: none"> • Guidance on the identity, characterisation and conditions of use of feed additives (implementation: 1 May 2018) (EFSA-Q-2016-00823) • Guidance on the assessment of the safety of feed additives for the target species (implementation: 1 May 2018) (EFSA-Q-2016-00553) • Guidance on the assessment of the safety of feed additives for the consumer (implementation: 1 May 2018) (EFSA-Q-2016-00822) <ul style="list-style-type: none"> • Feed Additive Consumer Exposure (FACE) calculator • Guidance on the characterisation of microorganisms used as feed additives or as production organisms (implementation: 1 Sep 2018) (EFSA-Q-2017-00211) • Guidance on the assessment of the efficacy of feed additives (impl.: 1 Sep 2018) (EFSA-Q-2017-00246)
GMO	<ul style="list-style-type: none"> • Mandate to develop a technical note to the applicants on, and checking of, the quality of the methodology, analysis and reporting covering full sequencing and insertion site analysis of the genetically modified event, and generational stability and integrity (EFSA-Q-2017-00706) • Explanatory note on Next Generation Sequencing (NGS) (EFSA-Q-2017-00440) • Explanatory note to guidance on the measurement of protein levels newly expressed in genetically modified plants (EFSA-Q-2016-00231)
NUTRI	<ul style="list-style-type: none"> • Update of NDA Panel guidance on the scientific requirements for health claims related to physical performance (EFSA-Q-2018-00243)
BIOCONTAM	<ul style="list-style-type: none"> • Request for an update of the EFSA scientific opinion on guidance on methodological principles and scientific methods to be taken into account when establishing Reference Point Action (RPAs) for non-allow pharmacologically active substances present in food of animal origin (EFSA-Q-2018-00114)

GUIDANCE DOCUMENTS UPDATES

AREA	GUIDANCE
PESTICIDES	<ul style="list-style-type: none"> • Art. 31: EFSA guidance on testing and interpretation of comparative inter-species in-vitro metabolism (EFSA-Q-2018-00444) • Update of the EFSA guidance on the assessment of the exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA-Q-2018-00274) • Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments (EFSA-Q-2017-00620) • EFSA Guidance document on risk assessment for birds and mammals from plant protection products (EFSA-Q-2017-00555) • Guidance of EFSA on completing risk assessment for active substances of plant protection products that have isomers and for transformation products of active substances that may have isomers (EFSA-Q-2017-00113) • Guidance of EFSA on risk assessment for amphibians and reptiles (EFSA-Q-2011-00987) • EFSA Guidance on non-target terrestrial plants (EFSA-Q-2011-00983) • Guidance of EFSA on in-soil risk assessment (EFSA-Q-2011-00980) • Guidance of EFSA on risk assessment for non-target arthropods (EFSA-Q-2011-00976) • Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009 (EFSA-Q-2016-00825)
AHAW	<ul style="list-style-type: none"> • Revision of guidance of the assessment criteria for studies evaluating the effectiveness of stunning interventions regarding animal protection at the time of killing (EFSA-Q-2017-00711)

EVENTS

UPCOMING WEBINAR

■ **Guidance document on safety of feed additives for target animals - What is new?**

15th of June from 10 to 11 am

Registration on [EFSA website](#)

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](#)
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