

Pilot phase June – December 2017

Description of the new support initiative “Pre-submission administrative check teleconference of draft dossiers prepared by small and medium-sized enterprises (SMEs)”

Service name	Pre-submission administrative check teleconference of draft dossiers prepared by small and medium-sized enterprises (SMEs)
Unit in charge	Application Desk Unit (APDESK)
Service available from	Pilot phase: June-December 2017
Description	The pre-submission administrative check for SMEs is a teleconference organised between EFSA staff and an individual SME, to provide administrative and procedural support on draft dossiers in two areas of the regulated product (REPRO) Department [feed additives and novel foods (excluding traditional foods)]
Scope	<p>The pre-submission administrative check teleconference for SMEs is organised in order to provide:</p> <ol style="list-style-type: none"> preliminary feedback on the format and administrative completeness of the applications to be submitted; increase quality of applications submitted to EFSA; provide dedicated support to SMEs in the area of regulated products <p>The scientific aspects of the draft dossiers will not be discussed. Consequently, questions and advice on scientific aspects of the draft dossier are outside the scope of the support initiative</p>
Participants	<ul style="list-style-type: none"> EFSA APDESK staff SMEs European Commission representative (on an <i>ad hoc</i> basis)
Duration	1 hour and 30 minutes
Outcome	EFSA APDESK staff sends an e-mail to all participants certifying that the teleconference took place indicating the date, the duration and a short summary of the discussion to ensure mutual understanding.
Who can request the service	A SME which is preparing an application for feed additives or novel foods (excluding traditional foods) and which can demonstrate its SME status assessment ¹
When to request the service	Indicatively from 3 to 6 months before the official submission of the application
How to request the service	SME sends an email to: smeoffice@efsa.europa.eu Instructions on how to prepare for the teleconference will be provided at that time
Staff in charge	APDESK staff: Email: smeoffice@efsa.europa.eu

¹ http://ec.europa.eu/growth/tools-databases/SME-Wizard/smeq.do:SME_SESSION_ID=b-ufL00HyHxVTyXVy_HnIJZ62XmAcO6ExIwf2leHwuiFIh2i6iDW!1056756400?execution=e1s1