# SUPPORTING APPLICANTS IN THE AREA OF REGULATED PRODUCTS (REPRO)

## Outcome of interactive group exercises

## *37th Meeting of the Focal Point Network*

**Hotel Crowne Plaza Bratislava**
**Bratislava, Slovak Republik, 3-4 October 2018**

efsa
European Food Safety Authority

**LEGEND:**
*In **bold** the most voted items*
*In green what is under assessment/development*

# GROUP EXERCISE 1: CATALOGUE OF SERVICES

| | OUTOCOME OF BRIANSTORMING | WHAT AVAILABLE OR NEW INFORMATION? WHERE? |
|---|---|---|
| 1 | **Overview of process and guidance for pre-submission** | • Who does what in the applications process (flow)?<br>• Risk management vs Risk assessment infographic<br>• *(Video under investigation)* |
| 2 | **Completeness check: clarifications, missing information, duration** | • Workflows of application for each REPRO area: e.g. for Feed additives<br>• Administrative guidance for the processing of applications for regulated products<br>• Amministrative guidance per area also clarifying timing e.g. feed additives<br>• Catalogue of services for opportunity of interecation at various steps of application process<br>• Ask APDESK web form |
| 3 | **Guidance documents, technical guidelines, detailed data requirements** | • For each scientific area of Application section there is a subpage called: 'Regulation and guidance' where all regulation, administrative and scientific guidance and data requirements are listed (e.g. for FCM)<br>• Ask APDESK web form<br>• *(Pesticides update under development)* |
| 4 | Guidance documents detailing the procedure for preparation and submission of application | • Administrative guidance per area (see above)<br>• Ask APDESK web form |
| 5 | Scientific workshops / conferences | Event calendar accessible from EFSA website and also directly from the Applications section |
| 6 | Publication output | EFSA website > Publication session > EFSA Journal |
| 7 | Technical guidance document. List of scientific evidence, scientific opinion issue. Technical meetings | • For each scientific area of Application section there is a subpage called: 'Regulation and guidance' where all regulation, administrative and scientific guidance and data requirements are listed (e.g. for FCM)<br>• Ask APDESK web form |
| 8 | EFSA guidance document. Application desk unit available during submission | • 'Regulation and guidance' web page for each scientific area<br>• Ask APDESK web form<br>• Catalogue of services *(update under development)*<br>• Administrative guidance for the processing of applications for regulated products *(update under development)* |
| 9 | Info sessions | • Event calendar accessible from EFSA website and directly from the Applications section<br>• *(New topics for webinars under assessment)* |

***LEGEND:***
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# GROUP EXERCISE 2: APPLICATION WEB SECTION

| | OUTOCOME OF BRIANSTORMING | WHAT AVAILABLE OR NEW INFORMATION? WHERE? |
|---|---|---|
| 1 | **Infographic of whole process - Interactive decision tree style, with timeline** | • Who does what in the applications process (flow)?<br>• Risk management vs Risk assessment infographic<br>• For each scientific REPRO area workflows of application flow are available: e.g. for Feed additives<br>• *(New products under assessment)* |
| 2 | **First steps for applicants** | • Administrative guidance for the processing of applications for regulated products<br>• Catalogue of services for opportunity of interecation at various steps of application process<br>• Amministrative guidance per area also clarify timing e.g. of feed additives<br>• For each scientific REPRO area workflows of application flow are available: e.g. for Feed additives<br>• *(New products to support applicants under assessment)* |
| 3 | **Application for dummies** | *(Applications for dummies under assessment)* |
| 4 | Make the infographic as the 1st interface | |
| 5 | Individual tracking of the status of your dossier | • Register of questions database accessible directly from Applications section<br>• Ask APDESK web form<br>• *(IT tool for tracking of application: e-submission system under assessment)* |
| 6 | Indication of the phase / stage with approximate end of stage / status | • Register of questions database accessible directly from Applications section<br>• Formal letters sent to the applicant throughout the application process<br>• Ask APDESK web form<br>• *(IT tool for tracking of application: e-submission system under assessment)* |
| 7 | Where to go in the web to start an application | Applications section. For each scientific area general workflow, Regulation and guidance, FAQs, Tools webpages pages are available |
| 8 | Templates popping up from infographic | |

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# GROUP EXERCISE 3: SME

| | OUTOCOME OF BRIANSTORMING | WHAT AVAILABLE OR NEW INFORMATION? WHERE? |
|---|---|---|
| **1** | FAQ section on national FP websites which will provide link to EFSA dedicated website | • Link to Applications section or dedicated scientific areas sub pages |
| **2** | What is the problem we are trying to solve? Visibility? Where to start? Do they know if they need to submit an application at all? To whom? – National Authority? EFSA? | • Link to Applications section and dedicated scientific areas sub pages<br>• *(SME targeted initiatives under assessment)* |
| **3** | Process: how to do it? Who to speak to? Know what is needed for a good application | • Link to Applications section<br>• Ask APDESK web form<br>• Catalogue of services for opportunity of interecation at various steps of application process<br>• *(Ad hoc activities & SME targeted initiatives under assessment)* |
| **4** | How to get the info / evidence needed? | • Link to Applications section<br>• Ask APDESK web form<br>• Catalogue of services for opportunity of interecation at various steps of application process<br>• *(SME targeted initiatives under assessment)* |
| **5** | SME won't have capability for trials, tests, where to get reliable help? | |
| **6** | Good advice to avoid SME's paying things that are not needed, don't provide | |
| **7** | Use FP network to ask for info from other countries | |
| **8** | Translation of fact sheets / guidelines into national languages | *(Ad hoc products under assessment)* |
| **9** | EFSA to produce decision tree in order for the applicant to find out whether their products must be authorised or not | *(Ad hoc products/activities & SME office under assessment)* |

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