Guidance for online data submission on Food Improvement Agents via CIRCABC Sante-Cad-In Group

Due to the COVID-19 outbreak and in order to allow the business continuity of the Commission’s services, this user guide has been developed. CIRCABC Sante-Cad-In Group will allow the interested parties to upload the data and the Commission to take the necessary follow-up steps including, when appropriate, to share the data with the European Food Safety Authority.

The objective of this user guide is to facilitate the submission of the data through an electronic platform ‘CIRCABC’, available at: https://classified.circabc.europa.eu/ui/welcome, for:


2. Data submitted as a reply to DG SANTE calls for data as regards the follow up to the EFSA’s scientific opinions on the re-evaluation of the safety of permitted food additives.

3. Submissions to DG SANTE of scientific data concerning existing flavouring substances under evaluation identified with footnotes 1 to 4 in column 8 of the Union list of Flavourings (Annex I of Regulation (EC) 1334/2008 on flavourings)

4. Any other relevant data transfers related to food additives, food enzymes and food flavourings.

STEP 1 - E-mail communication

The interested party (hereinafter referred to as the ‘applicant’) shall first notify, via the e-mail, the Commission services of their interest to submit the data of a certain type (e.g. an application) and shall provide the EU log-in user id or the e-mail address that they used in order to obtain the EU log-in.

For applications, the applicant shall enclose in the e-mail, the accompanying letter – i.e. see Annex to Regulation (EU) No 234/2011 and a public summary of the application.

For data submission related to the food additive re-evaluation, the applicant shall clearly identify in the email to which call for data the submission replies.

The e-mail must be sent to one of the following functional mailboxes, depending on whether it relates to additives, enzymes or flavourings:

- SANTE-E2-Additives@ec.europa.eu
- SANTE-E2-ENZYMES@ec.europa.eu
- SANTE-E2-FLAVOURINGS@ec.europa.eu
In case the applicant does not have the *EU login user id* they are requested to follow the instructions available on our website.

Regarding *CIRCABC*, if the applicant does not know how to access and use such platform, information is provided in a [video on our website](#).

**STEP 2 - SANTE-CAD-IN account and folder creation**

Upon the e-mail request by the applicant (see step 1), the Commission will create a specific folder where the applicant will upload the data.

The applicant is granted access via their EU login account to this folder.

The folder will be accessible only to the applicant, the Commission services and, when appropriate, EFSA.

**STEP 3 - Commission’s invitation for dossier submission**

The Commission invites, via the e-mail, the applicant to submit the data (e.g. a dossier) and indicates the folder (via a hyperlink in the e-mail) that the applicant will use to upload the data.

**Data to be submitted:**

To prepare an application (dossier) for food additives, enzymes and flavourings, the applicant shall follow the *Practical guidance for applicants* (available at [https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en](https://ec.europa.eu/food/safety/food_improvement_agents/common_auth_proc_guid_en)), as regards the type of requested information and data that are to be included. The document also describes the various stages of the authorisation procedure.

For the data submission related to the food additive re-evaluation, the applicant shall follow the instructions in the *relevant call for data*. The document *Approach for the follow-up of EFSA’s scientific opinions on the re-evaluation of the safety of permitted food additives* (available at [https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en](https://ec.europa.eu/food/safety/food_improvement_agents/additives/re-evaluation_en)) describes the general approach followed by the Commission services.

**STEP 4 - Data submission and confirmation by the applicant**

The applicant uploads the data into the indicated folder.

If the applicant does not know how to upload documents in *CIRCABC*, information is provided in a [video on our website](#).

Once the applicant has uploaded all documents in *CIRCABC*, they must send an e-mail to the functional mailbox (used in step 1) confirming that they have completed the submission.
**STEP 5 - Commission’s confirmation of data receipt**

The Commission confirms, via the e-mail to the applicant, that the data have been uploaded into the relevant folder in *CIRCA BC*.

Afterwards the Commission shall:

1. Create a new folder in the SANTE-CAD-IN Group and copy the submitted data to the new folder. The applicant shall not have any access rights to the new folder.

2. Use this new folder for the necessary follow-up steps, including, when appropriate, data sharing with EFSA.

The creation of the new folder is necessary so that the Commission works only with the data as submitted by the applicant at the time when the complete submission is confirmed by the applicant.

**STEP 6 - Additional data to be submitted**

When additional data, related to the data already submitted, need to be provided, the applicant (or the Commission services respectively) shall inform about this via the e-mail.

The additional data can be sent via the e-mail or uploaded in the original SANTE-CAD-IN Group folder, as agreed between the applicant and the Commission.