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: <u>https://classified.circabc.europa.eu/ui/welcome</u>, for:

- 1. 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.
- 2. 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)
- 3. Any other relevant data transfers related to food additives, food enzymes and food flavourings*

* Except for applications for food additives, food enzymes and food flavourings under the Common Authorisation Procedure laid down in Regulation (EC) No 1331/2008, which shall be submitted through the electronic submission system: <u>E-Submission Food Chain Platform</u>.

STEP 1 - E-mail communication

The interested party (hereinafter referred to as the 'the data provider') shall first notify, via the e-mail, the Commission services of their interest to submit the data of a certain type (e.g. data in reply to DG SANTE calls for data) 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 data submission related to the food additive re-evaluation, the data provider 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:

- <u>SANTE-E2-Additives@ec.europa.eu</u>
- <u>SANTE-E2-ENZYMES@ec.europa.eu</u>
- <u>SANTE-E2FLAVOURINGS@ec.europa.eu</u>

In case the data provider does not have the EU login user id they are requested to follow the

instructions available on our website

Regarding *CIRCABC*, if the data provider does not know how to access and use such platform, information is provided in a <u>video on our website</u>.

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

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

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

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

STEP 3 - Commission's invitation for data submission

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

Data to be submitted:

For the data submission related to the food additive re-evaluation, the data provider 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 <u>https://ec.europa.eu/food/safety/food improvement agents/additives/reevaluation</u> <u>en)</u> describes the general approach followed by the Commission services.

STEP 4 - Data submission and confirmation by the data provider

The data provider uploads the data into the indicated folder.

If the data provider does not know how to upload documents in *CIRCABC*, information is provided in a <u>video on our website</u>.

Once the data provider 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 data provider, that the data have been uploaded into the relevant folder in *CIRCABC*.

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 data provider 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 data provider at the time when the complete submission is confirmed by the data provider.

STEP 6 - Additional data to be submitted

When additional data, related to the data already submitted, need to be provided, the data provider (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 data provider and the Commission.