CIPAC Guideline How to conduct a CIPAC collaborative trial

1. Duties of the collaborative trial coordinator

- Contact the Secretary of CIPAC to clarify open issues

- Provide a draft info sheet incl.:

  - The contact person.

  - A method description containing the essential parameters of the method incl. the required equipment.

  - The time frame of the trial.

  - The max number of possible participants.

  - In cases that special equipment is required, the conductor of the trial should consider to provide this equipment to the participants.

  - The declaration of the samples sent out is clearly and correct (the samples itself as well as the cover letter).

  To minimise problems with the customs when sending out the samples CIPAC will provide an example containing information that could be used.

  This proposal contains amongst others a confirmation note:

  - *substance is intended for laboratory use only*
  - *that the substance is not intended for further commercial distribution of the substances*
  - *that there will be no release into the environment*
  - *all residual amounts of substance not needed in the laboratory experiments will either be disposed as chemical in accordance with national regulations by a professional company or sent back to sponsor*

  Furthermore, the following is also helpful to minimise potential problems:

  - *Container labelling & Package labelling*

  Containers and the shipment packages have to be labelled correctly with the correct pictograms according to GHS and Dangerous Goods Transportation (IATA, RID, ADR, IMDG).

  - *Material Safety Data Sheet*

  A material safety data sheet should be included in the package.

  - *Pro forma invoice*

  The shipment papers should include a proforma invoice that indicates a low cost value for the contents of the package (e.g. invoice from your company to

our company stating that 20 Euro (or comparable low amount of money) will be charged for the containers).

- At the end of the trial, the participants will be informed concerning the results and the code used for its laboratory. *This should be done three to four weeks before the CIPAC meeting.*

It should be noted that CIPAC (strongly) recommend to conduct a small scale trial (around four participants) to reveal problems/difficulties or need for clarification before the full scale trial.

However, this is just a recommendation and not mandatory.

In case help is needed to acquire laboratories for the small scale trial, either CIPAC or one of the regional CIPAC PACs (CHIPAC, DAPA, DAPF, ESPAC or JAPAC) can be contacted.

2. Duties of CIPAC

- Double check with the conductor of the trial whether all essential information are available

- Making the info sheet available to the interest public (via CIAPAC website and e-mail distribution list)

- Selection of participants in the case of full scale trials. This will be done by the following procedure:

  - *drawing of lots*
  - *In the first round one participant of each region will be drawn*
  - *Proposal for the regions: America (North, Latin, South); Europe, Asia, Africa/Oceania*
  - *In the second round all notified possible participants are put in one pot and the remaining number of participants will be drawn*
  - *CIPAC informs the conductor of the trial, the participants as well as the lab that were not selected*

The procedure should start four weeks after the CIPAC information sheet has been sent out and finalised within five days

3. Duties of the participants

- Able to perform the required analysis (e.g. availability of the equipment incl. the described column)

- Follow the method description. The aim of the trial is to validate the method!

Of course recommendations to improve the method are welcomed, but these should be done separately from the method validation.

Considerable deviation from the original method could lead to the situation that because of the changes, the results cannot be considered for the assessment of the method that should be tested in the collaborative trial.

However, any deviation from the original method described has to be documented and justified. *This is important for the coordinator of the trial to judge whether this is an acceptable deviation or the deviation is so essential that the respective results cannot be considered in the assessment of the results.*

- Who wants to participate in a trial indicates this to CIPAC via cipac-trial@...and in “cc” to the respective the contact person (company) given in the info sheet

The application should include the explicit address where the samples have to be sent.