1st MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

APPLICATIONS DESK UNIT

Held on 3rd December 2020 via web-meeting

(Agreed on 3rd December 2020)

Participants

- Working Group Members:

  Rob Jaspers, Mercedes Garcia, Pirkko Puranen, Vitor Silvino Nogueira, Guido Jacobs

- Hearing Experts[1]:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  APDESK Unit: Karine Lheureux, Murielle Borg, Constanza Miranda, Catalina Manieu, Nikola Burelli, Patricia Romero and Claudia Parisi

  FEED UNIT: Gloria López-Gálvez

  GMO UNIT: Silvia Federici, Anna Lanzoni and Nikoletta Papadopoulou

  FIP UNIT: Natalia Kovalkovicova and Alexandros Lioupis

  NUTRI UNIT: Wolfgang Gelbmann

  PRES UNIT: José Oriol Magrans Soria

- Others:

  Not Applicable

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf.

1. Welcome and apologies for absence

EFSA welcomed the participants.

2. Adoption of agenda

Change proposed was to move up section 'Format of meetings' from point 4.5 to 4.2. All the participants agreed, and the agenda was adopted.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s)

4.1. EFSA provided an overview of its mission and organization, including the way how it addresses and carries out food safety risk assessments. More specific details were provided on the work done by the Applications Desk Unit, and how the applications for market authorisation of regulated products are handled from reception to validation.

EFSA presented the Good Laboratory Practice (GLP) activities and structure in the last four years of implementation with the aim of enhancing GLP compliance check of studies in dossiers during suitability/completeness check and risk assessment. Activities such as: GLP Annual Audit Programme; development of the GLP verification checklist; creation of the GLP Task Force at EFSA, creation of the GLP Working Group and the establishment of collaboration with EC DG GROW, Monitoring authorities from Member States (MS), ECHA, EMA and SANTE F.

EFSA presented what are the expectations from the GLP Working Group: to support scientific units assessing GLP studies and to provide advice and training on GLP matters to the specific units and EFSA staff.

The experts of the working group provided a brief introduction on their career background.

4.2. Format of the meetings: EFSA proposed the technical agenda for the future WG meetings, administrative aspects, frequency and duration of the meetings, the way of sharing documents with the experts and the output documents to be delivered.

4.3. GLP in Genetically Modified Organisms (GMO) applications: EFSA provided an overview of the regulatory framework for GMO applications as regards the quality standards required for studies supporting GMO applications. Discussions were held on the interpretation of the regulation; on the definition of 'study' and 'toxicological study'; on criteria to assess GLP compliance; on other quality standards as ISO; on GLP compliance of facilities and on the role of MS as monitoring authorities of GLP facilities. Further discussion is needed.

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4.4. EFSA and the experts discussed about a GMO application where a self-declaration of GLP compliance is provided for the studies. Experts provided advise and suggested to request further clarifications to the applicant.

A second case was presented of a newly received application, where a study is requested to be eligible for the derogation of article 5 of Regulation 503/2013. Further clarifications will be requested to the applicant.

4.5. Verification of GLP status of studies – GLP checklist

Two weeks before the WG meeting, the experts were requested to apply the new GLP checklist, developed by the GLP Task Force for the second phase pilot, on five studies from different food sectors, that were claimed to be studies performed under GLP principles. The experts provided detailed feedback and views in writing and also comments and suggestions for the improvement of the checklist during the meeting.

5. Any Other Business

None.

6. Next meeting(s)

Four meetings are proposed for 2021, with a frequency of one meeting every three months. Dates will be defined in January 2021.