9th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

FRONT-DESK AND WORKFORCE PLANNING UNIT

22 November 2023
09:00-13:00
MEETING MINUTES – Agreed on 11 December 2023

Location: Webconference

Attendees:

- **Working Group Members**:

  Rob Jaspers (Chair), Constanza Miranda, Pirkko Puranen, Vitor Silvino Nogueira

- **Hearing Experts[1]:**

  Tamara Coja (AGES, coordinator of the GLP grant)

- **European Commission**:

  André Kleensang (Representative from EC DG SANTE F4)

- **EFSA:**

  FDP: Bénédicte Vagenende, Sara De Berardis, Silivia Federici, Laura Paltrinieri, Claudia Parisi and Ellen Van Haver
  FIP: Natalia Kovalkovicova
  NIF: Michele Ardizzone, Wolfgang Gelbmann, Grammatikou Paschalina, Pietro Piffanelli
  PREV: José Oriol Magrans Soria

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the EFSA GLP Task Force member Joana Firmino (FEEDCO). Tamara Coja was invited for agenda item V.IV only.

II. Adoption of the agenda

The agenda was adopted without changes.

III. 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

[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

[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

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.

IV. Agreement of the minutes of the 8th Working Group meeting

The minutes of the 8th GLP Working Group meeting were agreed by written procedure on 21 June 2023[4].

V. Scientific topics for discussion

V.I Follow-up actions from 8th WG meeting

The FDP Unit informed the WG about the request for an ad hoc study audit[5] of a 90-day feeding study that was performed in a test facility but removed from the compliance monitoring programme by the respective GLP monitoring authority shortly after the starting date of the study. The relevant monitoring authority confirmed that the outcome of the study audit is expected by the end of 2023.

The NIF Unit presented the outcome of two ad hoc study audits for an *in vitro* micronucleus test and a 90-day toxicity study as a part of a Novel Food application following the identification of multiple errors in the study reports questioning the validity of the studies (see second point of V.II of the 7th GLP WG minutes). The audits performed by the national GLP Monitoring Authority confirmed several deviations from GLP principles and concluded that both studies were non-GLP compliant. The NIF Unit has asked the applicant to take appropriate actions and to provide a GLP compliant study.

V.II GMO checklist for 90-day toxicity feeding studies

The NIF Unit presented the checklist of the GMO food & feed safety WG (see point VI of the 141st GMO WG minutes[6]). This checklist compiles the requirements of the Implementing Regulation 503/2013[7], OECD TG 408[8], EFSA SC Guidance 2011[9] and EFSA 2014[10] for assessing a 90-day toxicity study included in GMO applications, but also lists the minimum required information to be present in a study report for assessing the reliability of the diet when GLP was claimed for the whole study except for the dietary preparation phase.

Following previous discussions and comments from the GLP WG, the WG experts endorsed the GMO checklist for 90-day toxicity feeding studies.

The NIF Unit will proceed with proposing to GMO applicants to integrate the checklist alongside the submission of a 90-day toxicity feeding study in GMO applications.

[4] https://www.efsa.europa.eu/sites/default/files/wgs/applications-desk/wg-good-laboratory-practices.pdf
[5] according to EFSA's GLP Standard Operating Procedure (part II of SOP_S_022)
[6] https://www.efsa.europa.eu/sites/default/files/2022-01/wg-applications-foodfeed-2018-2024.pdf
[7] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32013R0503
[8] OECD (Organisation for Economic Co-operation and Development), 1998. OECD Guideline for the testing of chemicals - Test No. 408: Repeated Dose 90-Day Oral Toxicity Study in Rodents. OECD Publishing, Paris.
[9] EFSA Scientific Committee, 2011. EFSA guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. EFSA Journal 2011;9(12):2438, 21 pp. https://doi.org/10.2903/j.efsa.2011.2438
[10] EFSA (European Food Safety Authority), 2014. Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for GMO risk assessment. EFSA Journal 2014;12(10):3871, 25 pp. https://doi.org/10.2903/j.efsa.2014.3871

V.III Selection of GLP studies for audit purposes (SOP_S_022)

The FDP Unit presented the revised draft of EFSA's GLP Standard Operating Procedure SOP_S_022[11] for the selection of GLP claimed studies for audit purposes, either for launching EFSA's Annual audit programme or in case of an ad hoc study audit triggered by GLP-related concerns. The FDP Unit will proceed with consulting the relevant stakeholders before finalising the draft and for having the 2024 Annual Audit Programme launched according to the revised procedure.

V.IV GLP grant – second deliverable

The beneficiary of the GLP grant GP/EFSA/FDP/2022/02 (Refining the methodology for verifying the GLP compliance of studies submitted within an application for regulated products) gave an overview of the GLP findings of studies that were assessed since the last WG meeting. Some further refinements to the GLP compliance checklist were discussed with the WG.

V.V Question/Issues presented by the Units

There were no new issues raised by the EFSA Units.

VI. Any other business

The Commission informed the WG about their fact-finding missions performed in 2023 and upcoming missions.

Pirkko Puranen informed the WG that this was her last meeting as GLP WG member. The Chair thanked her for her commitment to the GLP WG activities. The FDP Unit will discuss her replacement with the WG Chair along the selection of new WG experts.

VII. Next Meeting

The FDP Unit will send the WG experts new WG meeting dates for 2024.

[11] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-022_S.pdf

8th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

FRONT-DESK AND WORKFORCE PLANNING UNIT

6-7 June 2023
14:00-18:00 (6 June) / 09:00-13:00 (7 June)
MEETING MINUTES – Agreed on 21 June 2023

Location: hybrid meeting: EFSA - Parma/Webconference

Attendees:

- **Working Group Members**:

  Rob Jaspers (Chair), Constanza Miranda, Pirkko Puranen, Vitor Silvino Nogueira

- **Hearing Experts[1]:**

  Tamara Coja (AGES, coordinator of the GLP grant)

- **European Commission**:

  André Kleensang (Representative from EC DG SANTE F4)

- **EFSA:**

  FDP: Bénédicte Vagenende, Laura Paltrinieri and Ellen Van Haver
  FIP: Natalia Kovalkovicova
  NIF: Piffanelli Pietro, Grammatikou Paschalina

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the following EFSA GLP Task Force members: Joana Firmino (FEEDCO), Wolfgang Gelbmann (NIF) and José Oriol Magrans Soria (PREV). Natalia Kovalkovicova could not participate on 7 June and Tamara Coja was invited for agenda item 5.2.1 only.

II. Adoption of the agenda

The agenda was adopted without changes.

III. 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.

[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

[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

IV. Agreement of the minutes of the 7th Working Group meeting

The minutes of the 7th GLP Working Group meeting were agreed by written procedure on 21 February 2023[4].

V. Scientific topics for discussion

V.I Follow-up actions from 7th WG meeting

1) Repeated dose 90-day oral dietary studies (general discussion)

Following the discussions at the last WG meeting on repeated dose dietary 90-day oral toxicity studies, for which GLP was claimed for the whole study except for the diet formulation, EFSA has reached out to other receiving authorities and GLP monitoring authorities to ask for their views on the acceptability of the GLP claim of such studies.

Generally, from the feedback received from authorities located outside the European Union, it was understood that these studies are either not required for GMO applications or not performed in their country. For applications for the authorisation of GMOs in the European Union, the Regulation (EU) No 503/2013 requires the submission of 90-day feeding studies in rodents with whole genetically modified food/feed. It is additionally required that toxicologically studies shall be conducted in facilities which comply with the (a) requirements of Directive 2004/10/EC; or (b) OECD GLP Principles, if carried out outside the Union.

The NIF Unit gave an overview of repeated dose dietary 90-day oral toxicity studies that have been included in GMO applications received by EFSA. For the majority of cases, those studies were performed in facilities located outside the EU and for which it is indicated in the GLP compliance statement that the part of the study on dietary preparation was excluded from GLP. Only for few studies the diet preparation phase was performed in accordance with GLP.

The NIF Unit informed that EFSA is requesting the applicant for additional evidence to ensure that the test item was properly mixed into the diet but also indicated that the Unit would benefit from additional guidelines for assessing the reliability of the data in 90-day studies of which the dietary preparation phase is excluded from GLP. The GLP WG will support the NIF Unit in drafting such a verification checklist, but also indicated that for new studies, submitted in future, applicants should endeavour to perform the whole study under GLP, including the diet preparation.

2) 90-day feeding study performed in testing facility that has been removed from the GLP compliance monitoring programme

For a 90-day feeding study that was part of a GMO application and that was discussed at the last GLP WG meeting (see first point of V.II of the 7th GLP WG minutes), the GLP WG confirmed that EFSA will need to ask for a GLP study audit given that the test facility at which the study was performed has been removed from the compliance monitoring programme by the respective GLP monitoring authority shortly after the starting date of the study. The NIF Unit will proceed with launching the request for an ad hoc study audit according to EFSA's GLP Standard Operating Procedure (part II of SOP_S_022[5]).

[4] https://www.efsa.europa.eu/sites/default/files/wgs/applications-desk/wg-good-laboratory-practices.pdf
[5] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-022_S.pdf

3) Follow-up on NF ad hoc study audits for an *in vitro* micronucleus test and a 90-day toxicity study

The GLP WG was informed about two study audits that EFSA has requested following the discussions at the last WG meeting (see second point of V.II of the 7th GLP WG minutes). EFSA is yet waiting for the outcome of the study audits that have been performed by the respective GLP monitoring authority.

V.II GLP grant – first deliverable

The beneficiary of the GLP grant GP/EFSA/FDP/2022/02 (Refining the methodology for verifying the GLP compliance of studies submitted within an application for regulated products), presented the scope and the structure of the newly developed GLP compliance checklist, and gave an overview of the first results after having applied the checklist on 200 studies.

Following the presentation, the FDP Unit provided the experts with 8 case-studies to try-out the GLP verification checklist and in this way to collect the feedback on their experience of verifying the GLP compliance of a study when completing this checklist. The results and the feedback from the GLP WG will be shared with the GLP grant beneficiary in view of the next refinement of the GLP checklist.

V.III Question/Issues presented by the Units

There were no new issues raised by the EFSA Units.

V.IV EFSA Annual Audit Programme

The FDP Unit informed the GLP WG about the study audit reports that have been received in the context of EFSA's 2022 Annual Audit Programme, and the launch of this year programme beginning of May 2023. The FDP Unit also discussed with the GLP WG the selection process of studies for audit purposes as foreseen by EFSA's GLP Standard Operating Procedure SOP_S_022 and possible amendments to be made in view of having this SOP revised by the end of this year.

V.V Updates on Fact-Finding missions

The Commission informed the WG about their fact-finding missions performed in 2022 and 2023.

VI. Any other business

There was no any other business.

VII. Next Meeting

The next meeting will be held on 22 November 2023 (AM) via web conference.

7th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

FRONT-DESK AND WORKFORCE PLANNING UNIT

1st February 2023
14:00-18:00
MEETING MINUTES – Agreed on 21 February 2023

Location: Audio-Web

Attendees:

- **Working Group Members**:

  Rob Jaspers (Chair), Pirkko Puranen, Vitor Silvino Nogueira

- **European Commission**:

  André Kleensang (Representative from EC DG SANTE F4)

- **EFSA:**

  FDP: Bénédicte Vagenende and Ellen Van Haver
  FEEDCO: Joanna Firmino
  FIP: Natalia Kovalkovicova
  NIF: Piffanelli Pietro, Wolfgang Gelbmann
  PREV: José Oriol Magrans Soria

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from working group (WG) member Constanza Miranda and Commission representative Joanna Warnel.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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.

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

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

IV. Agreement of the minutes of the 6th Working Group meeting

The minutes of the 6th GLP Working Group meeting were agreed by written procedure on 4 October 2022[3].

V. Scientific topics for discussion

V.I Follow-up actions from 6th WG meeting

The NIF Unit presented the follow-up to the discussions at the last WG meeting when some GLP issues were identified for toxicological and non-toxicological studies as part of a GMO application. For the repeated dose dietary 90-day oral toxicity study, for which GLP was claimed for the whole study, except for the diet formulation, the GMO sub-WG on Toxicology (GMO Food and Feed) checked that in the Study Report the Study Director clearly acknowledged that the "diet formulation" step was not GLP compliant. The GMO sub-WG on Toxicology carried out a detailed assessment of the information provided for the test/control materials and diet used in 90-day toxicity studies including homogeneity and stability of the formulated diet. Furthermore, the GMO sub-tox WG Experts are aware that the diet preparation phases are commonly outsourced to non-GLP sites (e.g. to a feed manufacturer) following quality standards in place for the feed production sector. The GLP WG indicated that other quality standards [i.e. ISO9001, ISO9002] are, however, not equivalent to GLP, and when such a critical study phase is excluded from GLP by the Study Director, such a design may jeopardise the GLP status of the whole study. The GLP WG suggested to investigate whether other kind of evidence might support the reliability of diet preparation (for example, on the quantitative analysis of diet samples and presentation of its results in the study report).

For the protein characterisation studies, following the discussions at the last WG meeting, the applicant was asked why the purification step of the protein was not conducted according to GLP. The applicant clarified that the purification activity was part of the test substance synthesis activity which preceded the GLP study. The applicant subsequently amended the study reports to make this clear. The GLP WG indicated that in such case the purification step cannot be verified against GLP and the GMO risk assessors will need to assess whether this information is necessary for accepting the other parts of the studies. With regard to the amended study reports, if the exclusion of the purification step was initially foreseen in the study plan, there might not have been a need for amending the reports. However, the GLP WG noted that the exclusion of the purification step from GLP should have been indicated in the GLP compliance statement, and that was also not stated in the amended study reports.

The NIF Unit will bring these elements to the attention of the respective GMO WGs for further consideration.

V.II Questions/Issues presented by the Units

The NIF Unit presented possible GLP issues for a repeated dose 90-day toxicity study in rats with whole food/feed as part of a GMO application. Besides the fact that also for this study the diet preparation phase was excluded from GLP (see point V.I above), the study report describes two different GM crop events, one of which is not subject of the GMO application. From a GLP point of view this is acceptable, as long as a clear division between the two events is made and this is well explained in the study report. The NIF Unit also raised the question about the reliability of translated documents included in the study report (for instance the GLP compliance statement that

[3] https://www.efsa.europa.eu/sites/default/files/wgs/applications-desk/wg-good-laboratory-practices.pdf

was originally not in English language). The GLP WG clarified that this is acceptable given that a separate statement on the correctness of the translation was included in the report and signed by the Study Director.

Regarding the diet preparation phase being excluded from GLP, the NIF Unit will ask the applicant to clarify why this step of the study was excluded from GLP, and how the Study Director ensured that the diet preparation was performed according to adequate quality standards to guarantee the appropriateness of the diets according to the scope of the study. In addition, the applicant will be asked if additional analyses were performed on the feed samples to provide evidence that the test item was properly mixed into the diet.

The NIF Unit presented issues in the study reports of toxicity studies as part of a Novel Food application. It concerns reported unrealistic values and errors in a repeated dose 90-day toxicity study for several parameters and some identical results in an *in vitro* micronucleus test for the testing with and without metabolic activation, questioning the quality and validity of those studies. Both studies were performed in the same test facility. The NIF Unit has asked the applicant for clarification about these multiple errors, especially with regards to the statistical analyses of the results of the 90-day study and their assessment. The GLP WG considered that the large number of errors also questions the validity of the other (statistically not significant different and apparently realistic) results of the 90-day study, when considering that even obviously wrong and unrealistic figures were not spotted, discussed and/or corrected by the Study Director. In addition, for the repeated dose 90-day toxicity study it was noted that a part of the analysis (about one element of the formulation and which is the scope of the application) was not done under GLP, neither was that study phase inspected by Quality Assurance (QA). The sentence in the QA statement indicating that the study report reflects the raw data is also questionable. The GLP WG advised the NIF Unit to ask for a GLP study audit for these studies before the claims of GLP compliance can be accepted.

VI. Any other business

VI.I EC/SANTE F4 Fact Finding missions

The Commission informed the WG about their fact-finding missions (FFM) performed in 2022 and about their FFM plans for 2023.

VI.II Awarded GLP grant

The FDP Unit informed the GLP WG about the grant GP/EFSA/FDP/2022/02 (Refining the methodology for verifying the GLP compliance of studies submitted within an application for regulated products) that was awarded to a consortium consisting of the Austrian Agency for Health and Food Safety and the Greek Benaki Phytopathological Institute. The grant has a duration of 18 months and will end in June 2024.

VI.III 2022 Annual Audit Programme

The FDP Unit informed the GLP WG about EFSA's Annual Audit Programme that was launched in April 2022 and for which EFSA started to receive the first audit reports from the national monitoring authorities.

VI.IV Declaration of Interest (DoI) portal

The GLP WG experts were informed about the new DoI Portal for updating their declaration of interests where applicable.

VII. Next Meeting

The next meeting is scheduled for 6-7 June 2023.

6th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

FRONT-DESK AND WORKFORCE PLANNING UNIT

Held on 14 September 2022 via web-meeting

(Agreed on 4 October 2022)

Participants

- Working Group Members:
  Rob Jaspers (Chair of the WG), Constanza Miranda, Pirkko Puranen, Vitor Silvino Nogueira
- European Commission:
  André Kleensang (Representative from EC DG SANTE F)
- EFSA:

FDP:	Daniela di Feliciantonio, Oscar Gonzalez, Catalina Manieu, Bénédicte Vagenende and Ellen Van Haver
FIP:	Natalia Kovalkovicova
NIF:	Michele Ardizzone (for agenda point 5.2); Pietro Piffanelli
PREV:	José Oriol Magrans Soria

1. Welcome and apologies for absence

The Chair welcomed the participants. The Chair informed the working group (WG) about the resignation of the WG members (Guido Jacobs and Mercedes García González) as a recent change in their professional situation was raising a conflict of interest. The WG thanks them for their commitment and contribution to the WG activities. Two new EFSA staff members were introduced, Joanna Firmino as FEEDCO representative of EFSA's internal Task Force (replacing Frank Verdonck) and Oscar Gonzalez who recently joined the FDP Unit.

Apologies were received from the Commission representative Joanna Warnel and from EFSA staff members Joanna Firmino (FEEDCO) and Francesca Volpi (LA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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. Agreement of the minutes of the 5th Working Group meeting

The minutes[3] of the 5th WG meeting (held on 2 March 2022) were agreed by written procedure.

5. Scientific topics for discussion

5.1 Follow-up actions from 5th WG meeting

Following the discussions at the last WG meeting about identified GLP issues for a molecular characterisation study as part of a GMO application, the applicant was asked to clarify the significant time lag between the dates of completion of the respective Review Draft Report and of the Review Final Report of a GLP claimed study. The applicant indicated that the study and the data presented in the report were initially signed without the GLP formality. The applicant proceeded with the procedure of the compliance with the OECD GLP principles following EFSA's initial request stipulating that, according to Regulation (EU) No 503/2013, studies, other than toxicological studies shall comply with the GLP principles laid down in Directive 2004/10/EC or be conducted by organisations accredited under the relevant ISO standard. The WG indicated that it is not a GLP compliance issue to have a significant time delay between the experimental study completion and the report finalisation. However, a GLP compliant study would need to be conducted under GLP as from the start and to be laid down in the study plan. The assessor/receiving authority is not reviewing the study plan as such but EFSA will need to check the GLP compliance status of the final study report.

The proposed changes made to the EFSA GLP verification check list were discussed. Additional identifiers for non-chemical substances were added for verifying the information on the test and reference items in GMO molecular characterisation or protein characterisation studies. The WG suggested to list the elements on biological (GM plants and microorganisms) substances separately from those on chemical substances. The EFSA GLP verification check list should however remain practical and not become too long, also because it should not be considered as an exhaustive list.

5.2 Feedback on the application of the EFSA GLP verification checklist on GMO applications

The FDP Unit presented the approach taken for verifying the GLP compliance status of studies submitted as part of an GMO application. During the completeness check, the FDP Unit is completing the EFSA GLP verification checklist that concerns the verification of (1) the GLP compliance status of the test facility, (2) the information present in the study report with regard to personnel involved in the study and the dates of the study, (3) the GLP compliance statement, and (4) the Quality Assurance statements. For toxicological studies, special attention is paid in verifying the GLP compliance status of the test facility as, according to Regulation (EU) No 503/2013, toxicological studies shall be

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[3] https://www.efsa.europa.eu/sites/default/files/wgs/applications-desk/wg-good-laboratory-practices.pdf

conducted in facilities which comply with the (a) requirements of Directive 2004/10/EC; or (b) OECD GLP Principles, if carried out outside the Union. Where applicable, the FDP Unit contacts the national Monitoring Authority when the information on the test facility is not in accordance with the information available in the OECD Annual Overviews. The NIF Unit proceeds with verifying the remaining questions of the GLP checklist for concluding on the overall GLP compliance status of the studies.

The GLP checklists that were completed for the toxicological and non-toxicological studies submitted as part of a GMO application, were shared with the GLP WG. For the two protein characterisation studies, it was indicated in the reports that the purification of the plant protein was not conducted according to GLP. However, this was not stated in the GLP compliance statement. The NIF Unit will ask the applicant to clarify why the purification step was excluded from GLP. For the toxicological study (repeated dose 90-day oral toxicity study - dietary), GLP was claimed for the whole (multisite) study, except for the diet preparation. The WG noted that Quality Assurance was present during the diet preparation phases, however it is not explained why this part was excluded from GLP. From a GLP inspection point of view this is a critical phase of the study and no sufficient evidence has been provided about the homogeneity and stability of the diet, neither on how the Study Director was ensured that the diet preparation was performed according to established protocols. The WG advised the NIF Unit to pay special attention to the description of the diet composition and feeding scheme in the study report during the risk assessment phase and to ask the applicant for additional information where applicable. It was also noted that in addition to the study report on the repeated dose 90-day oral toxicity study, the applicant had provided an additional report with supplementary information on this study. However, this report didn't contain additional information on the diet. According to the WG experts this report providing supplementary information on the 90-day study should be a part of the main study report. The NIF Unit indicated that reports with supplementary information are often provided separately and that this point on how to report on studies could be addressed in the next update of the GMO guidance documents.

5.3 Questions/Issues presented by the Units

The FIP Unit presented the question that was received in the context of the update of the Scientific Guidance on food flavourings following its publication for public consultation[4]. The specific question that concerned GLP is whether a BMD analysis performed in the context of toxicity studies and the applied software need to be carried out under GLP. The requestor also asked for clarification on the way of reporting: what kind of spreadsheets are expected and if they need to be built into the reports or to be submitted as stand-alone sheets.

The WG indicated that EFSA will need to firstly clarify whether the BMD analysis is a part of the study or not. In case the data for performing the BMD analysis can be retrieved from the study report and be performed by the applicant after the study has been completed, in that case the BMD analysis could be considered to be performed outside the context of GLP and be provided as a document separately from the toxicity study report. However, if EFSA considers this as a part of the study and to be performed by the testing facility, validation of the software under GLP will be needed in accordance with the OECD Advisory document N° 17 on GLP application of GLP principles to computerised systems[5].

6. Any Other Business

6.1. Fact-finding missions

The Commission informed the WG about their recent and planned fact-finding missions for 2022.

[4] https://www.efsa.europa.eu/sites/default/files/2022-06/scientific-guidance-on-flavourings-draft.pdf

[5] https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)13&doclanguage=en

6.2. Selection of WG experts

The WG discussed the need for strengthening the GLP WG with one or two experts following the resignation of two experts from the GLP WG. Besides expertise in GLP, the WG considered it an asset for having an expert with experience in other quality standards (i.e. ISO accreditation) and/or with experience in both risk assessment and GLP inspections. FDP will proceed with the experts' selection according to EFSA's established procedures.

6.3. Grant GP/EFSA/FDP/2022/02

The experts were informed about the GLP call for proposal "Refining the methodology for verifying the GLP compliance of studies submitted within an application for regulated products" as published on the EFSA website.

7. Next meeting(s)

The next meeting is scheduled for 30 November 2022 by teleconference.

APPLICATIONS DESK UNIT

5th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

Front-Desk and Workforce Planning (FDP) UNIT

Held on 2 March 2022 via web-meeting

(Agreed on 22 March 2022)

Participants

- Working Group Members:

  Mercedes García González, Guido Jacobs, Rob Jaspers (Chair), Constanza Miranda, Vitor Silvino Nogueira and Pirkko Puranen

- Hearing Experts[1]:

  Not Applicable

- European Commission:

  Andre Kleensang and Joanna Warnel (DG SANTE F)

- EFSA:

FDP	Daniela di Feliciantonio, Catalina Manieu, Bénédicte Vagenende, Ellen Van Haver
FEEDCO	Frank Verdonck
FIP	Natalia Kovalkovicova
NIF	Piffanelli Pietro, Wolfgang Gelbmann
PREV	José Oriol Magrans Soria

1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA informed the working group (WG) about EFSA's reorganised units[2] as of January 2022 and about new members joining the EFSA's GLP internal Task Force following EFSA's reorganisation.

[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.

[2] https://www.efsa.europa.eu/sites/default/files/assets/orgchart.pdf

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2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[3] and the Decision of the Executive Director on Competing Interest Management[4], 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.

One expert, Guido Jacobs, declared orally a recent change under 'Employment' to be reported in the Annual Declaration of Interest (ADoI). With regard to this meeting, the interest declared by Guido Jacobs was assessed. In accordance with EFSA's Policy on Independence[3] and the Decision of the Executive Director on Competing Interest Management[4], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned. The expert will proceed in updating its ADoI accordingly.

4. Agreement of the minutes of the 4th Working Group meeting

The minutes[5] of the 4th WG meeting (held on 29 November 2021) were agreed by written procedure.

5. Scientific topics for discussion

5.1. Pending actions from the 4th WG meeting

The follow-up on the verification of GLP compliance of randomly selected studies that were discussed at the 4th WG meeting are addressed under agenda points 5.3 & 5.4.

5.2. Questions/issues presented by the Scientific Units

The NIF Unit brought two GMO applications to the attention of the GLP WG for their advice on GLP-related issues. For the first GMO application, a more than 4-years delay was noted between the dates of the experimental study completion and the report finalisation while verifying the GLP compliance and QA claims for two study reports. Even if this time-delay is not a GLP compliance issue, other possible GLP issues were identified in the study report which would need to be clarified with the applicant: the absence of a unique study number, amendments or deviations (which could have reflected the reasons for the time-delay) are not reported, instead a new report seems to be issued (there can only be one study report for each study, including possible amendments from the original study plan). The WG also indicated that a study audit could be requested to determine the GLP status of the study considering the identified GLP issues.

The second GMO application that was discussed is currently in stop-the-clock following a request from EFSA for additional information that was raised during the risk-assessment phase. The NIF Unit was informed by the applicant that the GLP audit inspection for renewing the GLP certification status of the test facility, where the applicant is carrying out the new study that was requested by EFSA, was

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[5] https://www.efsa.europa.eu/sites/default/files/wgs/applications-desk/wg-good-laboratory-practices.pdf

postponed due to the Covid-pandemic situation. The applicant asked EFSA which implications this would have on the GLP compliance status of the study. For this particular case, where the test facility has been removed from the GLP monitoring program due to Covid-pandemic-related delays, the WG indicated that a study audit could be requested once the study has been finalised and submitted to EFSA.

5.3. Follow-up on the verification of GLP compliance of randomly selected studies through the checklist

The FDP Unit informed the WG about the follow-up of GLP issues that the experts had identified at the 4th WG meeting[4] while applying the verification GLP checklist on 5 randomly selected studies. No follow-up was needed for the study of the Pesticides' application as no GLP issues were then identified. For the studies as part of the Feed Additives' and Food Contact Materials' applications, the respective FEEDCO and FIP Unit representatives had verified the GLP findings within their Unit and for both cases the conclusion was that the identified GLP-findings didn't impact the reliability and the scientific outcome of these studies. For the Food Additives' application[6], the study in question was carried out at two test sites, one of which was not appearing in the OECD Annual overviews. EFSA contacted the monitoring authority of the country where the study was performed and it was clarified that both test sites had been inspected for the respective area of expertise withing the period when the study was carried out, and thus confirming the GLP claim of the study. The GLP issues identified for the GMO study will be discussed at the next GMO Food and Feed WG meeting (mid-March).

One of the GLP-issues identified that were recurrent for these and previous case studies concerned the information on the stability and homogeneity of the test item. The WG indicated that this information should be available to the study director before carrying out the study. There is no obligation to perform stability studies by the same facility as where the toxicity study is carried out, but in case e.g., the stability of the test item in the solvent was not tested at the facility itself, the study director should indicate in the test report where this information was obtained from and report on the impact on the study outcome for not having performed this analysis in a GLP environment, if applicable. Risk assessors have to judge whether the study was carried out with a test item for which all the necessary information is available (either in the report itself or elsewhere in the dossier).

5.4. GLP verification check list

Further improvements to the verification check list were discussed along the GLP findings indicated under agenda items 5.2 & 5.3. Additional instructions were defined to enable the completion of the checklist in a consistent way among different GLP assessors and a list of concluding sentences corresponding to the type of identified GLP-findings was added for concluding on the GLP claim of the study.

6. Any Other Business

An update was given by DG SANTE F on the fact-finding missions, including the last mission that was completed in February 2022 in a laboratory accredited to ISO standard 17025.

7. Next meeting(s)

The next meeting is scheduled for 8 June 2022 by teleconference.

[6] this study was wrongly assigned to be a Novel Food application in the minutes of the 4th GLP WG meeting.

APPLICATIONS DESK UNIT

4th MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

APPLICATIONS DESK UNIT

Held on 29th November 2021 via web-meeting

(Agreed on 15th December 2021)

Participants

- Working Group Members:

  Mercedes García González, Guido Jacobs, Rob Jaspers (Chair of the WG), Constanza Miranda Vega, Vitor Silvino Nogueira and Pirkko Puranen

  Apologies: Pirkko Puranen

- Hearing Experts[1]:

  Not Applicable

- European Commission:

  André Kleensang and Joanna Warnel (DG SANTE F)

- EFSA:

APDESK:	Daniela di Feliciantonio, Karine Lheureux (Head of the APDESK Unit), Catalina Manieu and Stefania Mori
FIP Unit:	Natalia Kovalkovicova and Ellen Van Haver
GMO Unit :	Pietro Piffanelli and Anna Lanzoni
LA Unit:	Francesca Volpi
PRES/PREV Unit:	Bénédicte Vagenende
REPRO Department:	Alessandra Giarola

  Apologies were received from: Gloria López-Gálvez, Judit Fernández, Wolfgang Gelbmann, 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.

The Chair welcomed new representatives of EFSA who will support the Working Group (WG) GLP from next year:

- Bénédicte Vagenende, appointed as the Head of a new Front-Desk&Workforce Planning (FDP) Unit from January2022,
- Ellen Van Haver, senior scientific officer joining FDP Unit from January 2022, and taking over the tasks from Judit Fernandez during her absence,
- Pietro Piffanelli, replacing Anna Lanzoni in representing GMO Unit.

The termination of the role of Karine Lheureux in the support of this WG was announced to WG members. Karine Lheureux is appointed as the Head of a new Risk Assessment Logistics (RAL) Unit from January 2022.

2. Adoption of agenda

The agenda was adopted without changes.

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. One expert, Mercedes García González, declared orally a recent change under 'Employment' to be reported in the Annual Declaration of Interest (ADoI). 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.

3.1. Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

With regard to this meeting, the interest declared by Ms Mercedes Garcíaa was assessed. In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], and taking into account the specific matters discussed at the meeting in question, the interest declared was not deemed to represent a Conflict of Interest for the expert concerned. The expert will proceed in updating the ADoI accordingly.

4. Scientific topic(s)

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

4.1. Feedback from experts on GLP checklist on randomly selected studies:

- EFSA selected randomly 5 studies from applications for regulated products currently submitted in EFSA in the following sub-areas: Pesticides, Feed Additives, GMO, Novel Food, Food contact materials. The studies were revised by the WG experts applying the EFSA verification GLP checklist.
- The WG discussed the applicability of the EFSA verification GLP checklist in practice and proposed some improvements to the checklist.

4.2.Outsourcing project on GLP activities

- **EFSA updated the WG on the progress of the outsourcing project under elaboration, including the GLP verification for studies submitted to EFSA via the developed EFSA verification GLP checklist and the audit programme. A** discussion on the scope, duration, and expected starting date were taken place.

4.3.Update from EC/SANTE/F Fact-Finding missions

- An update was given by DG SANTE F on the fact-finding missions in laboratories and testing facilities conducting studies and tests underpinning regulated product applications that were submitted to EFSA after 27th March 2021. In 2021 two missions were carried out in laboratories accredited to ISO standard 17025. All fact-finding missions should be completed on 28 March 2025.

5. Any Other Business

The WG GLP meetings 2022 calendar was not discussed due to lack of time. EFSA will propose dates for the meetings in 2022 as soon as possible. In future EFSA will try to distribute documents for discussion at least 14 days before a meeting.

6. Next meeting(s)

APDESK will share the proposed dates for four meetings in 2022.

APPLICATIONS DESK UNIT

3rd MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

APPLICATIONS DESK UNIT

Held on 11th October 2021 via web-meeting

(Agreed on 22nd October 2021)

Participants

- Working Group Members:

  Mercedes García González, Guido Jacobs, Rob Jaspers (Chair of the WG), Constanza Miranda, Vitor Silvino Nogueira and Pirkko Puranen.

- Hearing Experts[1]:

  Not Applicable

- European Commission:

  André Kleensang and Joanna Warnel (DG SANTE F); Frank Swartenbroux and Agnieszka Anna Turek (DG SANTE)

- EFSA:

APDESK:	Daniela di Feliciantonio, Judit Fernández, Karine Lheureux (Head of the APDESK Unit), Catalina Manieu and Stefania Mori
FEED:	Jordi Tarrés-Call
FIP:	Natalia Kovalkovicova and Gloria López-Gálvez
GMO:	Anna Lanzoni
LA:	Francesca Volpi
NUTRI:	Wolfgang Gelbmann
PRES/PREV:	José Oriol Magrans Soria
REPRO:	Alessandra Giarola and Tom Meyvis

- 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. The chair welcomed a new WG member Constanza Miranda.

2. Adoption of agenda

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. The pending actions from the previous WG meeting were discussed.

- The previous WG report was adopted with no comments.
- Proposed improvements of the EFSA GLP checklist were presented and discussed to include the use of OECD annual overviews in assessment. Proposed amendments were agreed.

4.2. Two scientific Units presented questions/issues for discussion and EFSA presented an outsourcing project:

4.2.1. FEED Unit:

- Three ecotoxicity studies were presented to the WG.
- Discussion took place and the experts concluded that the issues presented were of scientific nature and not strictly related to GLP. The consequences of excluding the chemical analyses from GLP should have been considered as a major GLP compliance issue affecting the reliability of the whole study.
- As far as possible, the use of the verification EFSA GLP checklist was recommended for future cases.

4.2.2. GMO Unit:

- GMO presented the outcome of the additional verification of the quality standards for studies other than toxicity studies.
- With regards to the verification of the quality of such studies provided in line with GLP principles, EU Reg 503/2013 requires that studies other than toxicity studies shall comply with GLP as laid down in Directive 2004/10/EC. This Directive requires Member States to verify GLP compliance of test facilities conducting GLP studies (see Art. 1 and 3). Based on

[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

this requirement GLP compliance inspections and study audits can be requested even when test facilities have never been inspected such as, for example, in so-called 'GLP-light' cases. A dedicated EFSA GLP checklist was also discussed for such studies.

- Discussion on ISO standards also took place. Extension of the remit of the WG to cover other quality standards was proposed.
- Finally, aspects related to quality standard implementation, areas to work on internally are: raw data (definition, management); completeness of information; deviations.

ACTIONS:

- GMO Unit and EC to follow-up on next steps as regards GLP implementation aspects.
- GMO Unit and EC and to discuss the way in which the text of Reg 503/2013 regarding 'accredited under the relevant ISO standard' should be interpreted.
- EFSA to consider extending the remit of the Working group to other quality standards of relevance for EFSA (ISO standards).

4.3. Outsourcing project on GLP activities:

- EFSA presented a project to outsource some GLP activities —including the GLP verification for studies submitted to EFSA via the developed EFSA GLP checklist and the audit programme — due to the high volume of studies received.
- Discussion on the prioritisation of these studies and the time needed to conduct the tasks took place.

ACTION: EFSA to follow-up to refine the project specifications and feedback on the next WG.

5. Any Other Business

An update was given by DG SANTE F on the fact-finding missions. Studies submitted after 27th March 2021 are considered for fact-finding missions. In 2021 one mission was completed, a second mission is planned.

6. Next meeting(s)

Next meeting is proposed by the end of 2021. It will be held as Audio-Web meeting.

APPLICATIONS DESK UNIT

2nd MEETING OF THE WORKING GROUP ON GOOD LABORATORY PRACTICE

APPLICATIONS DESK UNIT

Held on 25th March 2021 via web-meeting

(Agreed on 25th March 2021)

Participants

- Working Group Members:

  Mercedes Garcia González, Rob Jaspers (Chair of the WG), Guido Jacobs, Vitor Silvino Nogueira and Pirkko Puranen,

- Hearing Experts[1]:

  Not Applicable

- European Commission:

  Joanna Warnel

- EFSA:

  APDESK UNIT: Murielle Borg, Catalina Manieu, Nikola Burelli, Patricia Romero Fernandez and Claudia Parisi

  FEED UNIT: Gloria Lopez Galvez

  GMO UNIT: Anna Lanzoni

  FIP UNIT: Natalia Kovalkovicova

  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. Apologies were received from Karine Lheureux (APDESK).

2. Adoption of agenda

The agenda was adopted. Point 4.3 was omitted since no questions were received from the EC for this meeting.

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. The pending actions from the previous WG meeting were discussed.

- Proposed improvements of the GLP check list were presented and discussed. Proposed amendments are agreed.
- Identification of the GLP status of a test facility: to consult the OECD GLP annual report data base (access restricted).
- Practical cases can be considered for next meeting, also in relation to the use of the OECD data base to check the GLP status of the test facilities.

ACTION: to explore access of EFSA assessors to the OECD GLP annual report database.

4.2. Two scientific Units presented questions/issues for discussion

4.2.1. FIP Unit:

- GLP Laboratories outside the EU: see above in relation to the OECD GLP annual report database
- Practical example of a repeated dose 90-day oral toxicity study included in a published opinion (EFSA CEP Panel, 2020)[4].
- Conclusion on the Repeated dose 90-day oral toxicity study. WG concluded that the issues raised on the study are mainly scientific with respect to the interpretation of the study but some potential GLP issues cannot be ruled out.

[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] https://www.efsa.europa.eu/en/supporting/pub/en-1948

4.2.2. GMO Unit:

- Proposal of a Draft "non-GLP check list" for non-toxicological studies – Quality of scientific information in GMO application dossiers: requirements and verification. A draft document was shared before the meeting and comments have been made by WG experts. The comments were discussed with the WG.

ACTIONS: Document will be updated considering the comments. GMO unit will prepare some examples for next meeting.

4.3. The item was deleted from the agenda (see point 2 above)

5. Any Other Business

An update was given on the annual DG Growth Meeting on GLP held on 17-18.02.2021.

DG SANTE F updated on the fact finding mission.

6. Next meeting(s)

Next meeting will be in the trimester April to June 2021; date is to be decided. It will be held as Web meeting.

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.