

Administrative and procedural issues

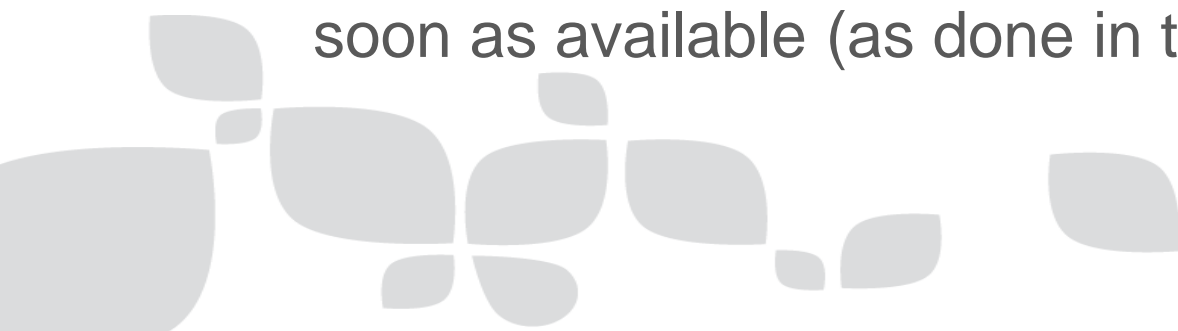
Ad hoc meeting EFSA – GMO applicants
5-6 October 2023

Company experience with E-SFC platform

- Familiarity with the new system is increasing and less technical issues are identified.

Remaining technical issues

- The system allows only for one set of questions to be handled at the same time.
 - Proposal: It should be possible for EFSA to send any new questions as soon as available (as done in the past e.g. the clock remains stopped)



Company experience with E-SFC platform



Remaining technical issues

- **In case of a clarification question, relevant sections of the application are sometimes locked and cannot be used for answering the question.**
 - Proposal: All relevant sections should be unlocked in case of EFSA questions

- **When submitting the application, the system generates a list of errors that needs to be corrected for valid submission. However, the list shows only the first 3 errors.**
 - Proposal: All errors should be visible at the same time



Company experience with E-SFC platform



Remaining technical issues

- As regards the confidentiality assessment, the system does not allow to reflect EFSA's draft confidentiality decision (partial acceptance or rejection, missing draft decision) which creates confusion.
- In some instances, E-SFC does not allow to enter the unique identifier of stacked events.



Company experience with E-SFC platform



Suggestions for improvement

- In view of the agreed format of uploading sections in Part II, when sending questions, the relevant higher level of a specific section should be unlocked as well as sections where Annexes, References, Appendices are supposed to be uploaded.
- The withdraw button is too prominent.
 - Proposal: a smaller button and an additional tick would be useful to avoid accidentally withdrawing the application
- Some study types in the dropdown list are duplicated.



Company experience with E-SFC platform



Suggestions for improvement

- Please consider the given day (and not specific time) when establishing a deadline for the response.
- Timely confidentiality assessment as in some cases it has not been completed after more than 35 weeks from validity and it delays the launch of the public consultation.
- To refer to study reports, please consider using study report numbers instead of study author names when sending questions. This would reduce time for preparation of submission packages by reducing unnecessary confidentiality claim requests.

Company experience with E-SFC platform



Clarification questions:

- *How to deal with sets of questions that have different deadlines (within the same request)?*
- *If the application structure in E-SFC will not be changed in the short term, is there a pragmatic way to fill in the sections that are not used (currently, for all of those sections, applicants need to tick “not applicable” and then provide a justification)?*



Company experience with E-SFC platform



Clarification questions:

- *How is EFSA using the completeness check list (Appendix A) and other Appendices? Are they still useful and needed?*



Thank you

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