



## ANNEX 1 - LIST OF MAIN CHANGES INTRODUCED IN THE UPDATED VERSION OF 28 AUGUST 2023 OF THE QUESTIONS AND ANSWERS ON THE EFSA PRACTICAL ARRANGEMENTS' DOCUMENT

Front page	A new sentence on the temporal applicability of the updated version is added.
PART B	
Question 4	The sentence referring to studies performed for development purposes is removed, while the concept is further elaborated in Question 34. A new paragraph is included to clarify which analytical measurements are exempted from notification of study obligations as of the date of the publication of the updated version of the Q&A document. A sentence is also added to clarify that method validation studies are not considered to fall within the study definition.
Question 6	The number of additional contacts that can be added to an account is increased (from two to six, or more in certain cases) with regard to the registration of entities in the Connect.EFSA platform.
Question 11	It is specified that background information should be provided when requesting general pre-submission advice.
Question 14	It is clarified that a closer support may be given to SMEs, by providing the answer to the general pre-submission advice preferably in a meeting.
Question 15	A sentence is added to indicate that EFSA can request for a clarification before deciding on the acceptability of a general pre-submission advice request.
Question 19	Information is added to clarify which parts of a general pre-submission advice request is not subject to proactive disclosure.
Question 22b	A new question is added to clarify what is meant by an intended study.
Question 28b	A new question is added to clarify in which circumstances the pre-submission activities related to a renewal pre-submission advice can be interrupted by EFSA.
Question 32	The former answer is removed as the question relates to a situation which can no longer arise.
Question 34	A sentence is added to clarify which studies cannot be considered being conducted for research purposes only, in the context of notification of study obligations. Information is added to clarify at which stage the notification of study obligations would apply for applications that have been submitted in the context of Regulation (EC) No 1107/2009.
Question 35	Information is added to complement the information on the co-notification process to reflect the behaviour of the system.
Question 37	A sentence is added to clarify which type of documentary evidence is expected to be provided in case of studies that were initially performed for other purposes than for the European Union market and that have been notified with delay.

The main changes are highlighted in the document with a grey shading. Minor and editorial changes are not listed above.