Written communication from Sounding Board member

Communication from the Association of Veterinary Consultants (AVC) on behalf of the Practitioners Associations stakeholder category sent to TransparencyRegulationImplementation@efsa.europa.eu on 20/07/2020

Modifications, Article 13 of Reg 1831/2003:

Modifications are not mentioned in the Regulation - will the requirement of notification of studies also apply? Will the modification dossier also made public?

-What happens if a company decides to withdraw an application - are the notifications deleted from the EFSA database? Including those coming from CROs?

-For renewals, how long will it take EFSA to provide feedback on study design?

-Will the option to consult EFSA about study design be available for new applications?

-Will EFSA's opinion be influenced by the number of studies notified for a feed additive (e.g. 9 efficacy studies notified: 3 of them with positive results, 2 of them with negative results and 4 inconclusive). Will EFSA conclude negatively in such a case? (Until now EFSA FEEDAP accept that not all efficacy studies may give a positive outcome, but evidence of the potential for efficacy is required. On the other hand EFSA for efficacy of nutrition & health claims take a "weight of evidence" approach.)

-According to Article 32b, point 7 The Authority shall make public the notified information only in cases where it received a corresponding application or notification and after the Authority has decided on the disclosure of the accompanying studies in accordance with Articles 38 to 39e.
The article above states that the notified information will be released to the public 1) after the application is considered valid and b) after the authority decides on confidentiality. However, according to some information shared before, it seems that the study notifications will be released before the confidentiality assessment - could EFSA please clarify?

-Can EFSA detail what information will be released to the public under the definition of study design? I.e. will you release the full study protocol? or maybe just the information required in article 32b + total number of animals + Nº and type of treatments + endpoints to measure…?