LAEG questions to DG SANTE legislative officers (3 March 2020)

General Food Law

1. Access to data – data protection: how will the fundamental right of data privacy of individuals be safeguarded in the context of disclosure of non-vertebrate studies?

2. Personal data protection (general): We are concerned by the fact that the names of authors of regulatory studies are made accessible to the public (e.g. publication in the website of agencies). Would the Commission agree that regulations 2016/679 and 2018/1725 prohibit disclosure of personal data contained in regulatory dossiers, with the exception of very limited circumstances (e.g. Article 39e GFL)?

3. Confidentiality claims: submitting detailed justifications for confidentiality claims will not be an easy task. What is the Commission view on this issue? Is the Commission planning to draft a guidance document with EFSA in order to spell out the content and level of detail of confidentiality claims?

4. Notification of studies: if commissioned studies could potentially be used in a EU regulatory process but a final decision is not yet made (e.g. studies with global perspective for which it is not yet clear if they will be submitted in the EU), will applicants only have to notify them when the definite decision on the use has been taken?

5. What would be the duration of the two consultation periods provided by Article 32c? Can the feedbacks received during these consultations delay the time frame set out in Regulation 1107/2009 (particularly in situations with high political pressure, e.g. by requesting additional studies)?

6. Verification studies, Article 32d: what is DG SANTE interpretation of "exceptional circumstances of serious controversies or conflicting results"? Could the Commission provide a concrete example of past situations that would fall within these exceptional circumstances?

7. We are one year away from the application of the revised GFL and the deadline to implement all new provisions is very ambitious. Only two technical groups have been set up by EFSA and it appears difficult to get all implementation measures ready for March 2021. What would be the solution in case of delay?

8. The GFL allows public access to the entire content of dossiers available to EFSA in food safety matters. There is a significant risk that such dossiers will be downloaded and used outside the EU by parties operating without the agreement of the dossier owner. Does the Commission support the idea that access to full study reports should be done study by study with no possibility to download complete dossiers? What other safeguards does the Commission/EFSA envisage to prevent misuse?