5.1.2.e Woo **PhD.**

Subject: FW: GLP studies
Attachments: Ares(2017)3994840.pdf; 20170823_Second statement for commission glyphosate.pdf; D(2017)2384.pdf

From:
Sent: 31 January 2019 16:26
To:
Cc: EFSA Press
Subject: GLP studies

1. Is there any obligation under GLP for an applicant seeking an authorisation (or renewal) to submit all studies performed as part of a dossier? submit a dossier?

   Under Good Laboratory Practice, there is not such requirement. However this very topic is being currently discussed at political level in the context of the European Commission proposal to amdend the EU General Food Law.

2. Is there a register where EFSA and/or other EU regulatory bodies can access all the studies performed by an applicant as part of a dossier?

   As per above, at the moment this is not foreseen by the EU legislation.

3. If not, isn't there a risk that only the 'useful' GLP studies (the ones servinmg the interest of the applicant) are included in the dossier by the applicant?

   The provisions setting data requirements for an active substance are quite detailed and publicly available for consultation (Regulation EU 283/2013; Regulation EU 284/2013). For an applicant dossier to be complete all the requirements have to be met. In other words all the studies that are requested need to be submitted. A list of test methods and guidance documents is available here

4. I attach a 2002 study about the dermal absorption of glyphosate, carried out by the research institute TNO. The study report mentions technical difficulties relating 'recovery'. This GLP study was not submitted by the manufacturers as part of the glyphosate risk assessment in 2002 and 2015. **Question:** Had it been submitted, would EFSA have had an interest in it?

   We replied to a European Commission's request (sent to both EFSA and ECHA) related to an in vitro TNO study on rat skin with the same title as the one you shared. Please see attached relevant documentation (European Commission request and EFSA and ECHA public responses).