

Written communication from Cyton Biosciences Ltd - a knoell company

Communication from Cyton Biosciences Ltd - a knoell company sent to TransparencyRegulationImplementation@efsa.europa.eu on 21/09/2020

- Regulation (EU) 1381/2019 (Transparency Regulation) will be implemented in March 2021; laboratories and applicants will need to notify EFSA about their planned studies before these start.
For applications such as renewal applications, where the preparation of studies does not apply, which are the implications of this Regulation on these applications?

- The assumption is the dossier will continue to have a confidential section and EFSA will still publish a public opinion, as before the implementation of this Regulation.
Does this new Regulation directly apply to renewal applications?