

Written communication from ERM received on 25 February 2020

- **With no specific reference to Regulation 396/2005 (MRL), will the provisions of the new GFL Regulation apply to any MRL applications?**
From a reading of the legislation, it would appear that the GFL provisions do not apply when the studies are only used for an MRL application. It would however be useful to have this confirmed, in particular related to the following related questions:
 - Will studies only used for MRL applications need to be notified under Article 32b?
 - In relation to Article 32b, will applications for import tolerances (related to use outside the EU) be treated in the same way as applications for MRLs (related to a crop use in the EU)?
 - Will the confidentiality provisions of Article 39 apply to MRL applications?
- **For the notification of studies under Article 32b, we understand that there will be no requirement to notify studies that have been completed before 27th March 2021 (where they will be submitted with an application after that date). Could you confirm that understanding?**
- **For the notification of studies under Article 32b, is there a requirement that studies that are on-going on 27th March 2021 be notified to the database?**
- **For the notification of studies under Article 32b, there is a requirement to notify "starting and planned completion dates". What are the expectations in terms of the accuracy of the date?** The exact starting dates of studies may change at short notice (e.g. could be postponed by a few days/weeks – for various reasons). Given this uncertainty, it would be helpful to include a range in the notified starting and completion dates (e.g. a specific week or month and not a specific day). Can you confirm that this will be acceptable?
- **For the notification of studies under Article 32b, will the EFSA database provide a system whereby all interested parties would be aware of a particular notification?** With a requirement that business operators (para 2) and laboratories (para 3) notify a study, having separate notifications for each study will create confusion for notifiers and EFSA. It would be useful for the database to 'connect' with the other party when the first notification is made – and the second party can then confirm the data. Having such a system will also reduce the risk of double notifications.
- **Also under Article 32b, how will the database manage a situation where a study is owned by multiple companies?** For reasons of transparency, all the owners of the data should be notified of, or have access to, the notification that has been made and consideration should be given to develop a system that is transparent to all data owners.
- **For the notification of studies under Article 32b, when will the structure of the database be communicated to stakeholders?** In order to allow preparation by 'notifiers' to ensure that notifications are properly registered and to improve coordination between the notifying parties, early communication on the functioning of the database would be helpful.
- **Article 39a sets out which information an applicant may request to be treated as confidential. Can you confirm that this provision applies only to the data that have been physically included in the actual application?**
For renewal applications under Regulation 1107/2009, it is our understanding this

provision will not apply to previously submitted data that is relied upon to support the application; it will apply only to data actually included in the application. Could you please confirm that understanding?