CropLife Europe – Implementation of the Transparency Regulation for GMOs applications

***Ad hoc* meeting EFSA – GMO applicants**

23 June 2021

Active involvement of CropLife Europe members

- EFSA Technical Group NOS
- EFSA Technical Group IUCLID
- Advisory Group on food chain and animal and plant health
- EFSA Sounding Board
- Industry Roundtable with EFSA
- EFSA training programme (webinars)

Content

- General key principle
- Notification of studies
- Validation process
- Renewal Applications
- E-submission Food Chain Platform
- Conclusions

General key principle

- No impact of Transparency Regulation on the data package to support GM applications in the EU

Notification of studies

- **Key principles**
  - Notification of studies (NoS) in support of EU applications *prior* to the start of those studies
  - Technical issues accessing the EFSA NoS Database count as *valid justification* if any delay in NoS

- Generation of regulatory data is ***complex***: requires coordination with several expert teams; follows quality standards; needs to cover global data requirements.

Validation process

- Pre-submission phase: Notification of studies in the EFSA database
- Submission phase: Submission of the Application including study reports via E-submission Food Chain Platform
  - *How and which information linked to notification of studies EFSA assesses for validation purposes?*
  - *What criteria will be used to consider justifications as valid? Will EFSA request clarifications in case a justification is unclear?*
  - *Could EFSA explain the steps in case of discrepancies?*

Renewal Applications

- Additional documents or studies performed by or on behalf of the applicant (*and not intended for the EU*) do not qualify for the notification process

E-submission Food Chain Platform

- **For GM dossier,** Part II – Scientific Info divided in more than 50 parts
- **Many different files for the Scientific Info main text**
  - Increase the potential for errors
  - Challenging to have an overview of the application
- **Information from one report or reference would be split across different parts**
  - Multiple uploads of the same study report/reference
  - Increased workload both for applicants and EFSA

E-submission Food Chain Platform

- Applicants should be allowed to include all information under one high level section and avoid further subdivision

  – *When will the e-submission platform be interconnected with the EFSA.connect portal?*

Conclusions

- CLE expects that the implementation of the Transparency Regulation will result in more efficient EFSA risk assessment processes and predictable timelines