Opportunities for evolving towards a transparent and efficient implementation of the Transparency Regulation

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INTRODUCTION

Bayer supports transparency throughout the risk assessment of its products. A company-specific process was initiated in 2017, granting public access to safety-relevant studies used by regulatory authorities to authorise Plant Protection Products (PPPs), and later extended to those used for Genetically Modified (GM) crop risk assessment. The objectives of this initiative at Bayer are therefore similar to those of the subsequently established 2019 EU Transparency Regulation: increase the transparency of the EU risk assessment in the food chain and strengthen the reliability, objectivity and independence of the studies commissioned by industry and assessed by the European Food Safety Authority (EFSA) to increase the EU citizens' trust in EU food systems. The new Regulation impacts eight food domains overseen by EFSA and of interest to Bayer are GM crops, PPPs and Food Supplements. While the overall objective of the Regulation is supported by Bayer, it provides a high degree of complexity and uncertainty for technology developers that may result in significant delays in the risk assessment that can negatively impact access to innovations and new technologies for farmers and consumers.

METHODOLOGY

We developed an overview laying out the different new elements brought by the Transparency Regulation and how these were implemented by EFSA, following the published Practical Arrangement documents and accompanying information. Furthermore, we assessed potential opportunities arising from the Regulation as well as the practical challenges posed by its implementation for technology developers due to the complexity of regulatory data generation as well as other factors such as the existing differences in global regulatory data requirements. Lastly, the assessment provides insights into how Bayer is developing internal systems designed to ensure full compliance with all the new elements of the Regulation.

RESULTS

Our assessment demonstrates that, while the general objectives of the Transparency Regulation are in line with those of Bayer's transparency initiative initiated in 2017, its implementation can create practical challenges for technology developers. Key challenges were identified with the implementation of the requirement of study notifications, for which the technology developer has to notify, in an EFSA database, each study that supports the application prior to the study start date. Each notified study has to be provided in full upon submission of the application. In the event of non-compliance, justification needs to be provided to EFSA. Regulatory data generation is complex and supports submissions to regulatory agencies of several countries, each of whom have different data requirements. Even though Bayer adapted its internal processes to enable study notifications in compliance with the Regulation, the challenges relating to conflicting submission requirements and timing across the globe may lead to unavoidable compliance challenges with the new requirements for reasons not related to transparency. This can significantly impact the commercialisation of new technologies.

DISCUSSION

If a technology developer is not compliant with the new requirements brought by the Transparency Regulation, even due to reasons not related to transparency, this may lead to procedural consequences, and can be extremely impactful considering the already lengthy timelines of the EU regulatory process, resulting in significant delays in the risk assessment that can limit access to innovations and new technologies for farmers and consumers. While the importance of transparency in the risk assessment is acknowledged and supported by Bayer, this should be done in an efficient and pragmatic manner using processes that enable a consistent dialogue between all stakeholders involved. The elements of such processes that enable a transparent approach should apply equally to all stakeholders, consider the reality, specifics and complexity of regulatory data generation, and guarantee that penalties are only applied when the requirements are not followed for reasons related to transparency.