

EU Transparency Regulation

An Industry Perspective

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CropLife Europe Supports Transparency

The Transparency Commitment



05 THE GATEWAY TO MORE SAFETY DATA

CropLife International member companies are among the world's leading developers of crop protection solutions which enable farmers to produce food for a growing world in a safe and environmentally sustainable way. While the product authorization process is the essential assurance to farmers and consumers that crop protection products meet the highest standards for safety, efficacy and quality, the effective transparency of safety data can further enhance public confidence in the process. That's why in March 2018 CropLife International and its member companies launched their transparency commitment to make more safety-related data publicly available.

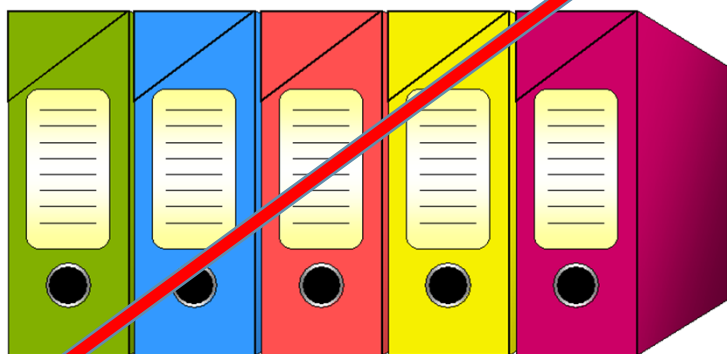
Risk Communications

- Croplife Europe covers some of the most misunderstood sectors relative to perceived risks and benefits
- The Regulation's requirement for '*General Plan for Risk Communication*' to (among other objectives) '*foster public understanding of the risk analysis [...] to enhance confidence in its outcome*' is highly welcome

EFSA published '[Technical assistance in the field of risk communication](#)' in January 2021, a literature review of risk communication concepts and practices

Online Submissions

A 20-year old dream !



IUCLID 6.5 PORTAL

Early EFSA Involvement

■ A welcome development ...

- ... provided not limited to rules and procedures
- ... provided that applicants, EFSA and (co)RMS scientific experts can exchange in pre-submission interactions

■ Should reduce late review surprises



Notification of Studies

- Concept: the applicant declares, reports and submits what it conducts
 - Core principle of transparency
- Notifying requires significant procedural and organizational changes within applicants' systems
- Will require increased anticipation and advanced preparation of regulatory dossiers
- Very strict admissibility assessment. Mismatches may lead to loss of approval

Dossiers Public Disclosure

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- Dossiers to be made available for public consultation shortly after submission:
 - Core provision of the regulation
 - Concerns entire content, ‘studies’ and ‘non-studies’, whether addressing safety or not
 - Watermarks possible and names hidden on non-confidential version of dossiers
 - Applicants must anticipate increased public scrutiny at that stage

Confidentiality

- CBI (confidential business information): types of information that can be claimed confidential similar to current system...
- ... But claims must be made, justified, reviewed and approved by EFSA (renewals) or Rapporteur Member State (crop protection active substances)
- ... And criteria must cumulatively be met:
 - Not already publicly available and acquired legally
 - Disclosure must be demonstrated to cause 'significant harm'
 - >5% of applicant's turnover (rebuttable presumption)
 - Document must be less than 5-year old (rebuttable presumption)

Conclusions



A paradigm shifting legislation – Achieving its positive potential depends on practical implementation





Thank You!

