# EU Transparency – Hurdles Still to Come

CLE Conference 08/03/2023

# Transparency is Critical

- Wider society: building trust & accountability
- Review of regulator decisions: important for regulatory evolution and challenge by stakeholders
- Equality of treatment between applicants and equivalent scenarios
- Supports decision making by industry, understanding precedents
- Good policy making: choices for the future can only be made where the relevant facts are known

# Transparency Mechanisms

## Proactive Disclosure

- Sector specific legislation:
  - Transparency Regulation – 2019/1381
    - Notification of studies
    - Proactive publication
    - Confidentiality requests
- Some implementation "outsourced" to soft law measures – EFSA's "*Practical Arrangements*"
- Company voluntary initiatives

## Reactive Disclosure

- Horizontal legislation:
  - Access Regulation 1049/2001
  - Aarhus Regulation 1367/2006
- National transparency legislation
- Typical threshold requirements:
  - Specific request required, limited volume
- Aarhus Convention also relevant for some requests in under national legislation

**Common to both regimes – the need to consider the relevance and availability of exceptions (e.g. confidential business information) and relationship to other rights (e.g. GDPR)**

# Transparency Mechanisms – Factors to Consider

- **Interrelationships between proactive & reactive regimes:**
  - Partially a response to the anticipated numbers of reactive requests?
  - Potential for differential application of relevant tests and different results, in particular the scope of exemptions – despite some cross reference
  - Also compare to the operations of other regimes, e.g. EMA. Fragmentation?

- **Difficulties with proactive disclosure – simple in theory but resource intensive in practice:**
  - EFSA Practical Arrangements and operational difficulties with implementation and claims for confidentiality & protection of personal data
  - Importance of flexibility. Solvable… but with significant effort?
  - Practical Arrangements cannot overwrite other substantive requirements. Delegation principles involved, and Arrangements expressly required to be "*in accordance with this Regulation and other relevant Union law*"

# Core Concepts for Implementation – Scope of CBI Exemption

Reactive Scope – Aarhus

*Hautala* – available unless the **purpose** of the information is to assess emissions into the environment

Why was the information submitted? What use did the regulator make of it?

Proactive Scope - GFL

Available for limited subset of information; but not if that information is "*relevant to the assessment of safety*"

syngenta

## Core Concepts for Implementation – Scope of CBI Exemption

- Who decides the "purpose" of the information or if it is "relevant to the assessment of safety" and more importantly, how?
  - Who: Significant caseload and need to consider arguments by information owner. Resource constraints…
  - How: Need to ensure decisions are harmonised and taken on a principled and reproducible basis, and in accordance with the relevant law. Avoid conflict between reactive/proactive tests, but within the law.
- Examples – inert coformulants – water? Other formulation details not considered as part of the safety assessment?
- Potential for further conflict, e.g. GDPR requirements
- Further litigation eventually necessary to seek clarity?

## Core Concepts for Implementation – Equal Treatment

- Need to apply principles consistently – neutral to applicant and content
  - e.g. “me too” product dossiers
  - No legal basis for differential application of reactive publication and the *Hautala* test; the safety assessment of all products is within scope
  - All products are assessed on their own merits
- Choices regarding scope and process should be workable for all scenarios
- Temptation to argue that situations are somehow different, possibly to reduce significant workload due to application of principles

## Further Implications to Consider

- **Data protection** – simply because a study is now transparent, no automatic right to use that study "*for the benefit*" of another applicant.
  - Regardless of whether obtained under transparency or other means (e.g. Regulation 2020/1740)
    - e.g. relevant product authorisations are automatically extended when a new AI submission passes a renewal completeness check. The information in that renewal dossier has indeed then been used "*for the benefit"* of the other applicant, including in relation to extending its product authorisations. If the data is still protected, this should be considered an infringement.

- **Transparency during the decision making process itself** – NGO litigation to use reactive transparency requests to reveal MS positions of during approval procedures
    - Will also be relevant in other situations – e.g. expert meetings

# Questions & Discussion