

## Biocides & Transparency

**Biocide Europe 2018**

**Darren Abrahams**

**27 November 2018**

1. BPR rules & ECHA's Dissemination Policy
2. Wider rules on access & lessons from Glyphosate
3. Implication for Biocides of [Proposal](#) on transparency and sustainability of EU risk assessment in the food chain (EFSA) &

# 1. BPR rules & ECHA's Dissemination Policy

- From time of adoption of Implementing Regulation approving AS – “up to date” info (**no confidentiality claims**):
  - ISO **name** and IUPAC **nomenclature** (where available)
  - name in EINECS (if applicable)
  - **CLP + exclusion criteria** information (met or not)
  - **physicochemical endpoints** and data on pathways and environmental fate and behaviour
  - **result of each toxicological and ecotoxicological study**
  - acceptable exposure level or predicted no-effect concentration (under Annex VI BPR common principles);
  - guidance on **safe use** provided (Annexes II & III BPR)
  - **analytical methods** (Sections 5.2 and 5.3 of Title 1, and Section 4.2 of Title 2 of Annex II).

# 1. BPR rules & ECHA's Dissemination Policy

- From time of adoption of Implementing Regulation approving AS – “up to date” info (**unless valid confidentiality claim**):
  - degree of purity of the AS and **identity of impurities** and/or additives of AS **known to be hazardous** (if essential to classification and labelling)
  - **study summaries** or **robust study summaries** of studies submitted to support AS approval
  - other **information** contained **in SDS**
  - AS **trade name(s)**
  - AS **assessment report**

# 1. BPR rules & ECHA's Dissemination Policy

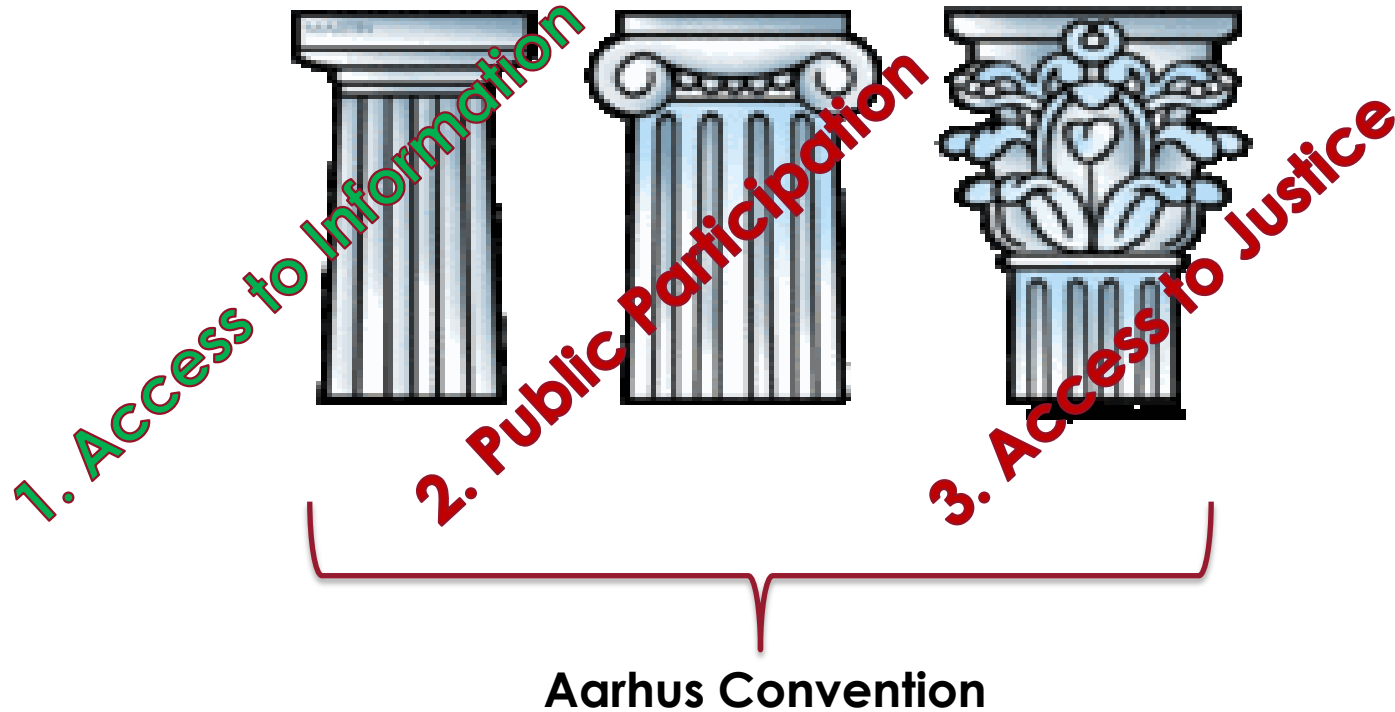
- From the date on which a **biocidal product** is authorised – “up to date” info”:

No confidentiality claims	Unless valid confidentiality claim
<ul style="list-style-type: none"><li>• <b>terms and conditions</b> of the authorisation</li></ul>	<ul style="list-style-type: none"><li>• <b>study summaries</b>, or <b>robust study summaries</b>, of studies submitted to support the BP authorization</li></ul>
<ul style="list-style-type: none"><li>• summary of the biocidal product characteristics (<b>SPC</b>)</li></ul>	<ul style="list-style-type: none"><li>• BP assessment report (“<b>PAR</b>”)</li></ul>
<ul style="list-style-type: none"><li>• <b>analytical methods</b> (Sections 5.2 and 5.3 of Title 1, and Section 5.2 of Title 2 of Annex III)</li></ul>	

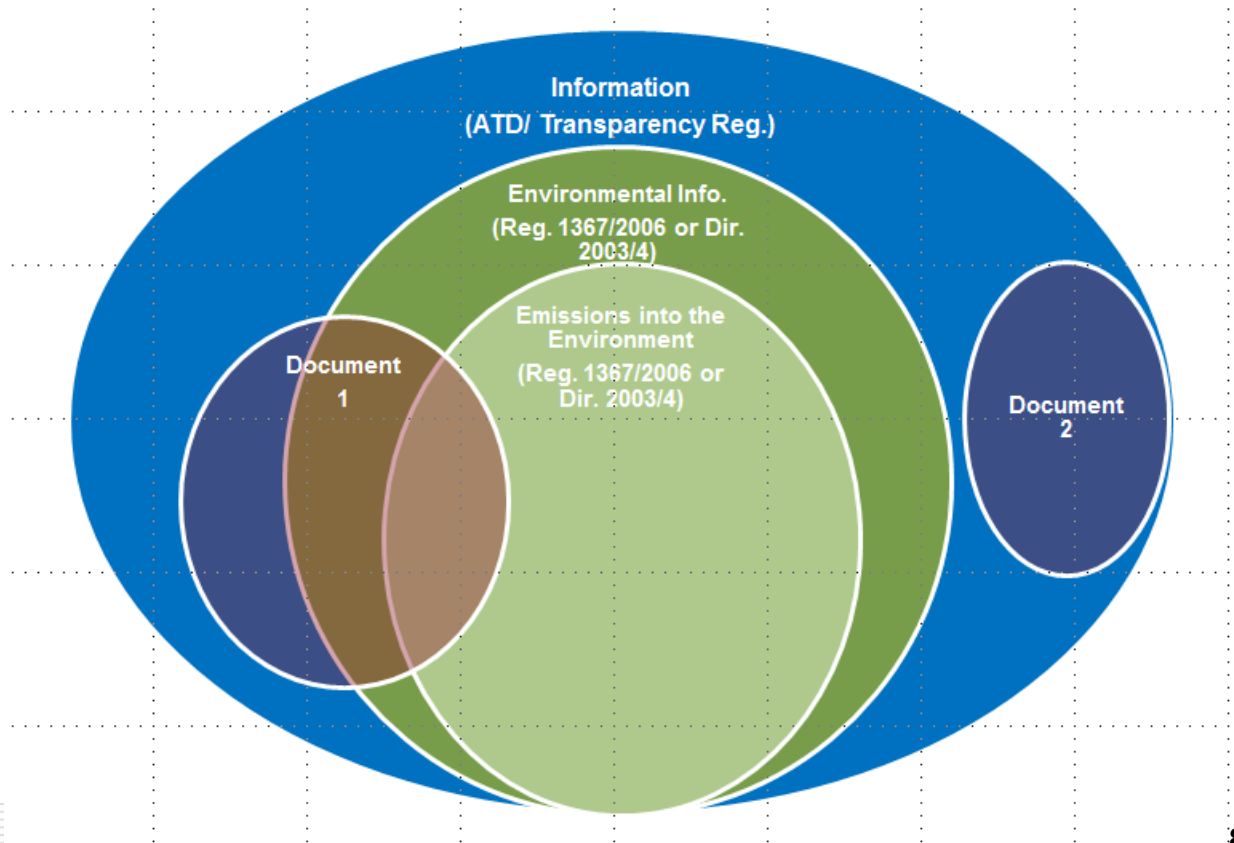
- **No Comparative tools or product factsheets mandated by BPR.**

## Wider rules on access to information & the lessons from Glyphosate

## 2. Wider rules on access & lessons from Glyphosate

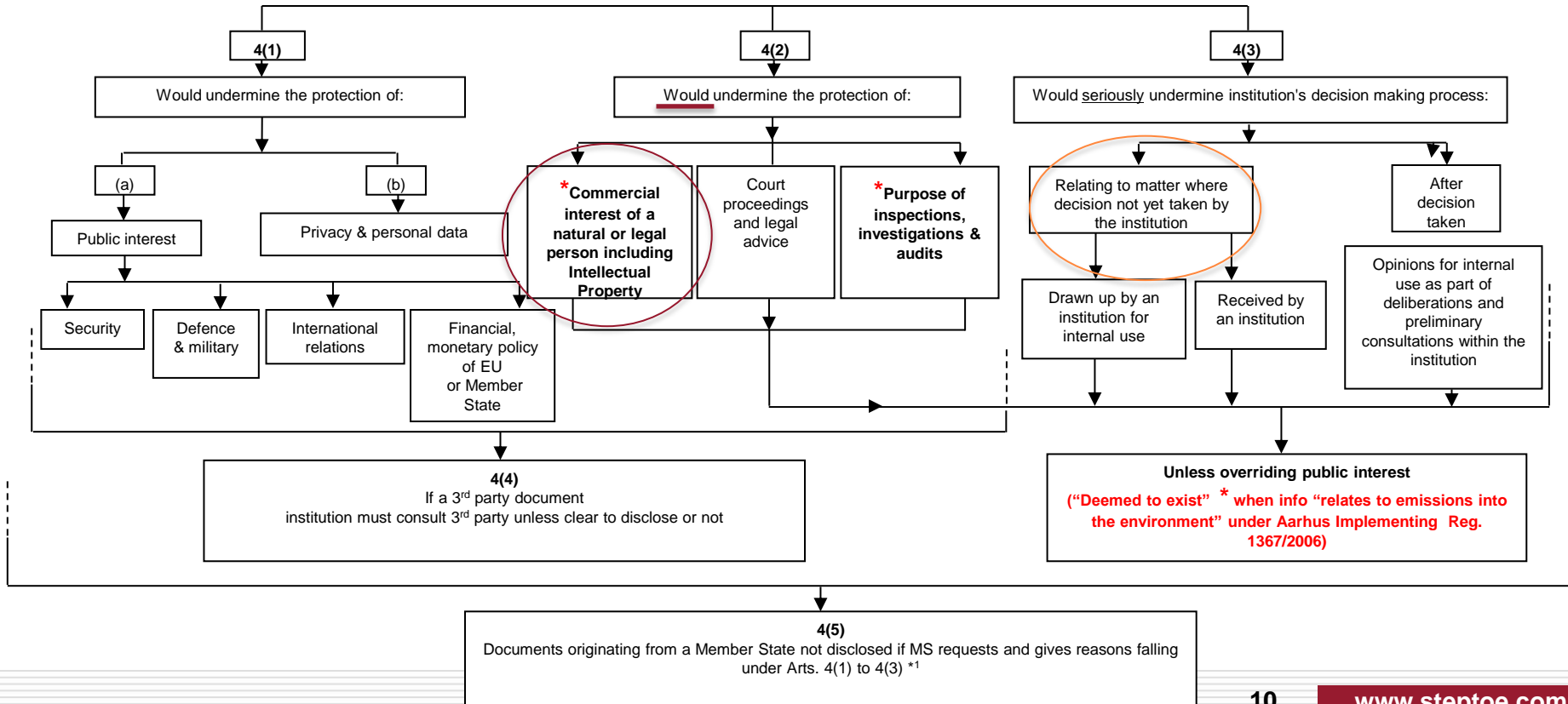


# Different types of information & different rules





# Exceptions to disclosure ATD/Transparency Reg (EC) 1049/2001



# T-545/11 RENV - Greenpeace and PAN Europe v Commission

Commission **refused access to part of DAR issued by German rapporteur on glyphosate under PPPD** based on protection of commercial interests:

1. data which concerns "**the identification and the quantity of various impurities present in the active substance** notified by each of the operators which took part in the procedure for the inclusion of glyphosate in Annex I of Directive 91/414" (non-relevant impurities);
2. "**the analytical profile of batches tested**": "information **concerning the quantity of all the impurities present** in the various lots and the minimum, median and maximum quantity of each of those impurities..." set out, for each operator; and
3. "**the composition of plant protection products developed by the operators** which applied for the inclusion of glyphosate in Annex I to Directive 91/414...the **exact quantities**, per kilogramme or per litre, **of the active substance and of adjuvants used** in their manufacture [of which were]...indicated..."

# T-545/11 RENV - Greenpeace and PAN Europe v Commission

- **Striking case because this kind of information is explicitly protected in PPPR:** “normally be deemed to undermine the protection of the commercial interests...:
- Same type of presumptions in BPR, Art. 66(2):
  - details of the **full composition** of a biocidal **product**
  - the **precise tonnage** of the active substance or biocidal product manufactured or made available on the market
  - **links** between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product
  - names and addresses of **persons involved in testing on vertebrates**

In related case C-442/14 (“Imidacloprid”), the Court held, the “**presumption**” is only an **effective barrier** to disclosure of information on emissions into the environment **when no request for information has been made** under (the Access to Environmental Information Directive)!

# T-545/11 RENV - Greenpeace and PAN Europe v Commission

- **21 November, Gen. Court held that requested information does not constitute information on “emissions into the environment”.**
  - It only “at the very most, has a link to emissions into the environment”
  - Fundamentally, accepted that “Glyphosate is not intended to be released into the environment as such”.
  - There might be information on “emissions into the environment”, “only at the stage of the national authorisation”.
  - Consequence of 2 stage system (with TE requirement).

An indication of what is to come for Biocides?

**Proposal on transparency and sustainability of EU risk assessment in the food chain (EFSA)**

# Transparency proposal: why now?

1. Part of the Commission response to **the European Citizens' Initiative** "*Ban glyphosate and protect people and the environment from toxic pesticides*".
2. Complaint that transparency varies depending upon the different sectoral rules – need for **harmonisation**.
3. Commission conclusion that "*transparency and accountability of the studies EFSA uses to assess risks could not be achieved without opening up those studies and the data they use to the public*".
4. **Risk communication** not considered effective enough.

# CBI Claims: new burden of proof (reversal)

**GENERALLY confidential treatment would be claimed**, based upon “verifiable justification” that disclosure would “significantly harm the interests concerned”:

- the **method and other technical and industrial specifications** relating to that method, **used to manufacture** or produce the subject matter of the request for a scientific output, including a scientific opinion;
- **commercial links** between a producer or importer and the applicant or the authorisation holder, where applicable;
- **commercial information** revealing sourcing, market shares or business strategy of the applicant; and
- **quantitative composition** of the subject matter of the request for a scientific output, including a scientific opinion.

*For each of the eight pieces of SPECIFIC existing EU sectoral legislation, the proposal lists additional information which EFSA “may also” treat as confidential based upon the same “verifiable justification.”*

Article 39(2)

# CBI Claims: standard of proof (highest in EU transparency regimes)

“verifiable justification” that disclosure would “significantly harm the interests concerned”

- **ATD today: disclosure** “would undermine the protection of commercial interests”.
- **EU GM Food and Feed today:** “disclosure might significantly harm its competitive position” .
- **PPPR:** “provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests...”



# Timing of disclosure (faster than anywhere else)

EFSA would be required to “...make public without delay...:

(c) scientific data, studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion...

(d) the information on which its scientific outputs, including scientific opinions are based....

Information submitted would be disclosable as soon as it is submitted to EFSA - subject only to procedure for CBI claims (in the worst case, take as little as 12 weeks). **Contrast with ATD rules for ongoing decisions.**

# Adequate control of disclosed information?

## No agreement to terms of use?

“... shall be made public on a dedicated section of the Authority’s website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format.”

## To avoid misuse/commercial use:

“not be considered as an explicit or implicit permission or license for the relevant data and information and their content to be used, reproduced, or otherwise exploited and its use by third parties shall not engage the responsibility of the European Union.”

# Adequate remedies?

## If unhappy with a decision on disclosure:

- Court of Justice: as under ATD Regulation.
- No automatic suspensive effect.
- No BoA

# Take home messages

- The push for transparency is relentless.
- CBI is under scrutiny in EU in the courts and through (parallel) legislation.
- The latest front for product defence? Have a strategy for your BP Authorizations.
- Initiatives in PPPs may spread...come BPR review.

\*\*\*

# Darren Abrahams



[dabrahams@steptoe.com](mailto:dabrahams@steptoe.com)

*“he is very knowledgeable and experienced in his field - a very good communicator who is responsive and strategically savvy.” Chambers Europe 2018*

- **English barrister, Avocat at the Brussels Bar**, partner resident in Brussels
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defense of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.