Steptoe

# Update on the EU's Biocidal Products Regulation

*What is happening and what to watch*

## *The Twelfth Antimicrobial Workshop*

**Darren Abrahams & Seth Goldberg**

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# Darren Abrahams

***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.

# Seth Goldberg

*sgoldberg@steptoe.com*

- Partner in Steptoe's Washington office
- Has practiced environmental law and litigation for 36 years
- Has focused on antimicrobials and other pesticides for over 30 years.
- Also represents clients on a range of chemical regulatory issues before multiple federal and state regulatory agencies.
- He regularly handles hearings and appeals before trial and appellate courts and administrative agencies

# Topics for today

1. **BPR refresher and status update**

2. **Focus on current and likely flashpoints:**
   a) Data Sharing – issue spotting
   b) CLP Classification & BPR Exclusion Criteria
   c) Technical equivalence.

3. **Take home messages**

# 1. BPR Refresher & Status Update

# BPR Main Principles: Helicopter View

- **Purpose of legislation:**
  - single market in biocidal products (harmonised regulation of sale and use in EU)
  - human, animal and environmental safety

- **What it covers:**
  - approval (and renewal) of 'active substances' (review programme ends 31 Dec. 2024 or not…?)
  - authorisation (and renewal) of biocidal products (formulated products containing active substance)
  - data sharing and data protection re substance and product dossiers
  - labelling requirements
  - new role of ECHA ("BPC" - Biocidal Products Committee)
  - appeal from relevant ECHA decisions (on data sharing, non-acceptance of applications, etc.)
  - central biocide registry: R4BP
  - enforcement coordination

# BPR Main Principles: Helicopter View

- **'Biocidal products':**
  - BPR expands scope of biocidal products (subject to authorisation) to expressly include:
    - biocidal products generated 'in-situ' from non-biocidal substances/mixtures
    - certain products treated with/incorporating biocidal products ('treated articles' with a 'primary biocidal function')
  - approval of actives in imported treated articles (without primary biocidal effect); so important even if you are not a "biocides" business.

- **BPR replaces BPD:**
  - repealed Biocidal Products Directive 1998/8 from 1 September 2013 (continuing transitional relevance: incomplete BPD active approvals and product authorisations)

# BPR Main Principles: Scope (1)

| | BPD | BPR |
|---|---|---|
| Active substance | A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms. | A substance or a microorganism that has an action on or against harmful organisms. |
| Biocidal product | Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, **intended to** destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. | Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or **generating** one or more active substances**, with the intention of** destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organism by any means other than mere physical or mechanical action.<br><br>**A treated article that has a primary biocidal function shall be considered a biocidal product.** |
| Treated article | None | Any substance, mixture or article which has been treated with, or **intentionally** incorporates, one or more **biocidal products**. |

# BPR Main Principles: Scope (2)

**Biocidal Product Types**

| Group 1* Disinfectants | Group 2 Preservatives | Group 3 Pest Control | Group 4 Other biocides |
|---|---|---|---|
| ▪ *PT1*: Human hygiene<br>▪ *PT2*: Disinfectants and algaecides not intended for direct application to humans or animals<br>▪ *PT3*: Veterinary hygiene<br>▪ *PT4*: Food and feed area<br>▪ *PT5*: Drinking water | ▪ *PT6*: Preservatives for products during storage<br>▪ *PT7*: Film preservatives<br>▪ *PT8*: Wood preservatives<br>▪ *PT9*: Fiber, leather, rubber and polymerized materials preservatives<br>▪ *PT10*: Construction materials preservatives<br>▪ *PT11*: Preservatives for liquid-cooling and processing systems<br>▪ *PT12*: Slimicides<br>▪ *PT13*: Working or cutting fluid preservatives | ▪ *PT14*: Rodenticides<br>▪ *PT15*: Avicides<br>▪ *PT16*: Molluscides, vermicides, and products to control other invertebrates<br>▪ *PT17*: Piscicides<br>▪ *PT18*: Insecticides, acaricides, and products to control other arthropods<br>▪ *PT19*: Repellants and attractants<br>▪ *PT20*: Control of other vertebrates (previously PT23) | ▪ ~~*PT20*: Preservatives for food or feedstocks*~~<br>▪ *PT21*: Antifouling products<br>▪ *PT22*: Embalming and taxidermist fluids |
| ** Excludes cleaning products that are not intended to have a biocidal effect, including washing liquid, powder and similar products.* | | | ** Because now covered by specific EU legislation* |

# BPR Main Principles: Key Features (1)

- **Core structures continue under BPR**:
  - pre-market authorisation regime, with two levels:
    - approval for active substance (EU level), authorisation of biocidal product (national or EU)
  - positive 'Union' list of active substances
    - specific active substance/product type combinations with Risk Management Measures/use conditions
  - distinction between 'existing active substances' (on market in biocidal products other than for R&D on 14.5.2000) and 'new active substances' (not on14.5.2000)

- **Commission programme for review of existing active substances:**
  - industry previously notified substances for review by deadline
  - 'participants' (data holders) submitted application/joint dossier supporting inclusion
  - letter of access to dossier required by non-participants for BPR product authorisation
  - …and now also for inclusion on approved source list from September 2015 ("Art 95 list") – no more spot market.

# BPR Main Principles: Key Features (2)

- **More streamlined AS review process**
  - chosen CA within 365 days of validation (or longer where further info required)
  - sends assessment report and conclusions to ECHA, taking account written comments from applicant during 30 day consultation period
  - ECHA prepare and submit approval opinion to Commission within 270 days of receiving evaluation conclusions from CA
  - will apply to AS for which draft CA assessment report has been issued after 01.09.2013
- **Mandatory data sharing** with all active substance suppliers (Article 95)
- **Exclusion** (AS) (applied under BPD for Annex IA only)
  - active substances that meet the criteria for CMR (1A or 1B), PBT or ED (REACH criteria)
  - unless negligible risk under realistic worst case conditions of use; or, essential; or, disproportionate negative impact on society (socio-economic analysis) → substitution
- **Substitution** (BPs)
  - e.g. sensitiser, 2 of PBT criteria, significant proportion of impurities or non-active isomers
  - public consultation 60 days (opportunity for interested 3rd parties)
  - approval not exceeding 7 years

# BPR Main Principles: Key Features (3)

- **New (more efficient) product authorisation procedures**…
  - Commission estimates EUR 2.7 billion cost savings over 10 years

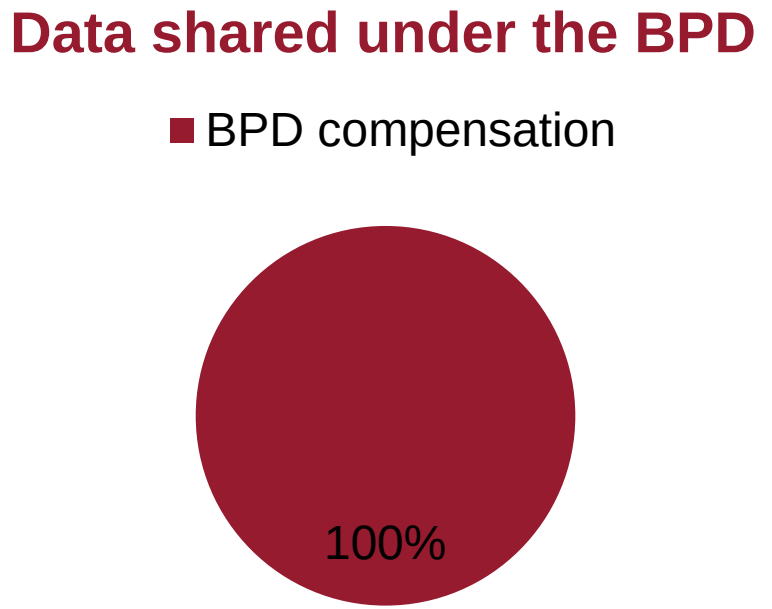
- **Union authorisation** phased in by PT until January 1, 2020
  - single procedure for Union wide market access
  - not available for certain product types or products containing excluded actives

- **Simplified product authorisation** (low risk, Annex I, not nano)

- **Mutual recognition** of product authorisation:
  - 'in parallel' with first authorisation (time efficient)
  - dedicated procedures for Commission to resolve MS deadlock
  - not required for Union and simplified authorisation (but notification, similar conditions of use across Union)

## 2(a) Data Sharing – Issue Spotting

# Data sharing for free under the BPR?



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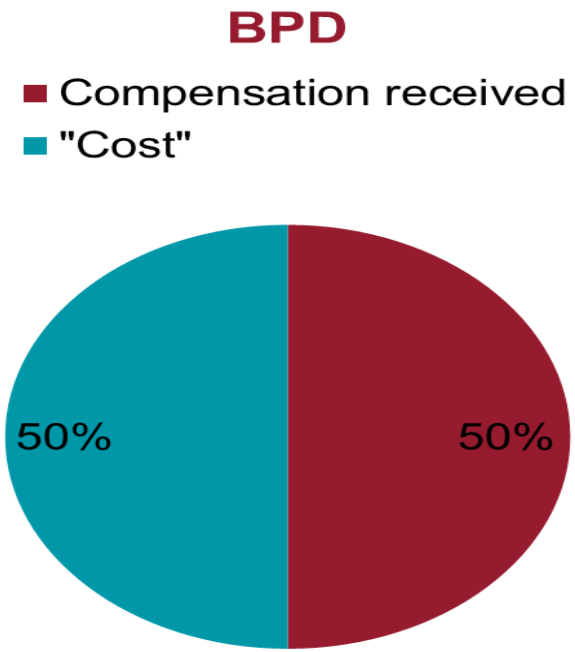


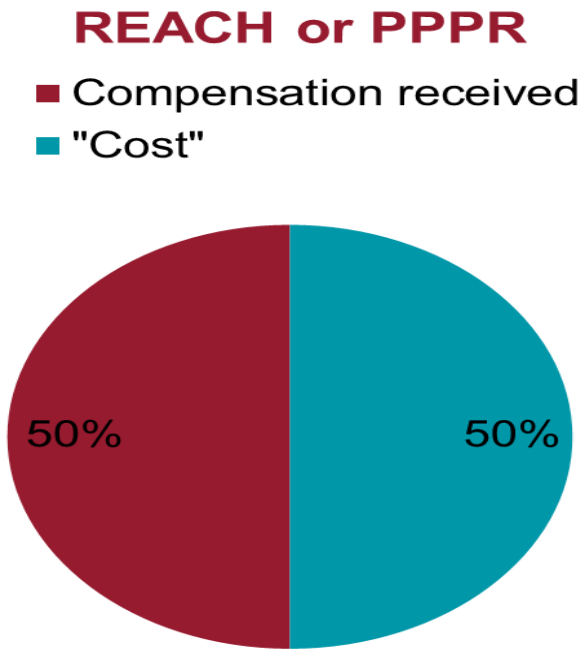

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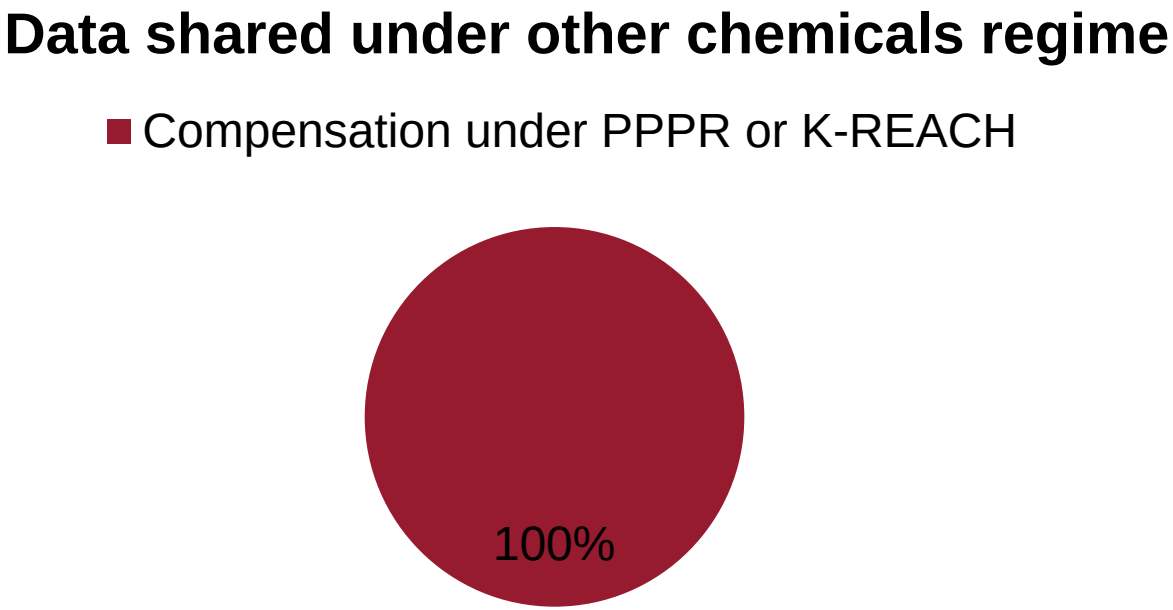


# Relevance of data accessor already holding a study for the relevant endpoint?

**Can data accessor still invoke mandatory data sharing when it already has a study?**

**Can the data owner refuse to share in these circumstances?**

# Relevance of data accessor already holding a study for the relevant endpoint?

Remember: a Prospective Applicant only has to pay

> "*to share only in the costs of information that it is **required** to submit for the purposes of this Regulation*" (Article 63(4)).

# Can a pre-payment be insufficient?

**Does ECHA have to consider the amount of the pre-payment?**

# Can a pre-payment be insufficient?

Remember: The requirements for ECHA granting access are:

> *"…that the **prospective applicant** demonstrates that every effort has been made to reach an agreement and that the prospective applicant **has paid the data owner a share** of the costs incurred…" (Article 63(3))*

- *What a about "low-balling"?*

  *"The **data owner** shall **not refuse to accept any payment offered** pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court…" (Article 63(3))*

- *Is the encouragement in ECHA's special series on Data Sharing guidance correct?*

# Focus on current and likely flashpoints

**2(b) Exclusion Criteria & Classification**

# BPR Exclusion Criteria

**1. Subject to paragraph 2, the following active substances shall not be approved:**

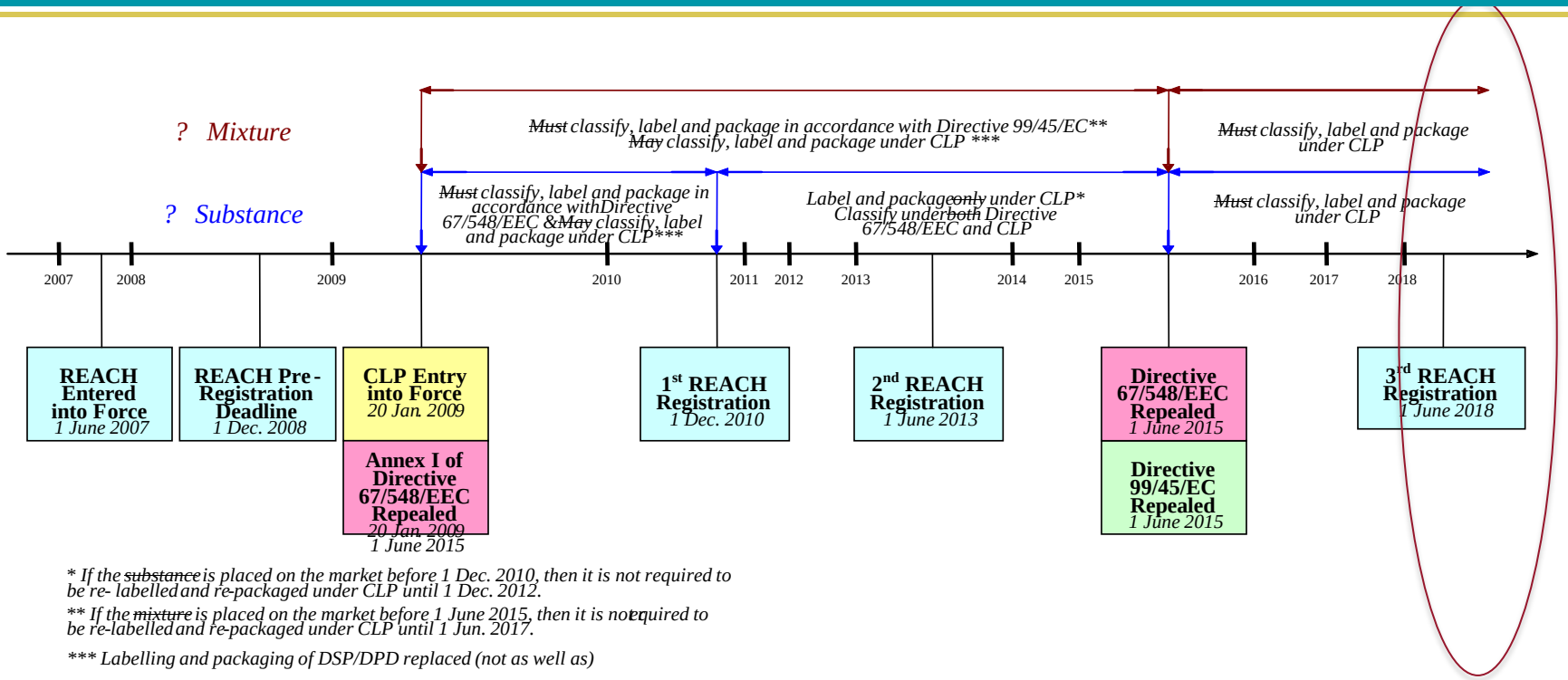
**(a) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, carcinogen category 1A or 1B;**

**(b) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, mutagen category 1A or 1B;**

**(c) active substances which have been classified in accordance with Regulation (EC) No 1272/2008 as, or which meet the criteria to be classified as, toxic for reproduction category 1A or 1B;**

**(d) active substances which…are considered as having endocrine-disrupting properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(1) of Regulation (EC) No 1907/2006 as having endocrine disrupting properties;**

# CLP Overview




** If the ~~substance~~ is placed on the market before 1 Dec. 2010, then it is not required to be re- labelled and re-packaged under CLP until 1 Dec. 2012.*

*** If the ~~mixture~~ is placed on the market before 1 June 2015, then it is not required to be re-labelled and re-packaged under CLP until 1 Jun. 2017.*

**** Labelling and packaging of DSP/DPD replaced (not as well as)*

# Procedure for establishing harmonized classification and labelling (CLH)

Note: Dossier by MSCA only possibility for PPP or BP active substances

Substances normally subject to CLH (Article 36 CLP)

- Respiratory sensitiser 1
- CMR 1A; 1B or 2
- PPP or biocidal active substances
- Other substances if justified

Proposal for inclusion may be submitted to ECHA:

- By a MSCA where the product is made available on the market (Art. 37(1))
- By a manufacturer, importer or downstream user of a substance in the absence of any previous CLH (Art. 37(2))

Note: if a manufacturer, importer, or downstream user submits a proposal for a substance not normally subject to CLH, it pays a fee to ECHA

or

CLH dossier submitted to ECHA → Public consultation (45 days) → Possibility for submitting party to respond to public consultation → RAC forms an opinion on proposal

Max. 18 months of RAC's receipt of proposal

Proposal and RAC opinion submitted to Commission → ATP legal text drafted by DG GROW (ENTR) on the basis of RAC opinions of previous calendar year → Commission inter-service consultation → REACH Committee opinion → Regulatory procedure with scrutiny → Inclusion of CLH in Annex VI entry through ATP Regulation

Indicative timeframe of 3 to 9 months

**KEY**

**MSCA**: Member State Competent Authority
**CLH**: Harmonized classification and labelling
**ECHA**: European Chemicals Agency
**RAC**: Risk Assessment Committee of ECHA
**ATP**: Adaptation to Technical Progress
**EP**: European Parliament

# Classification Procedures & Legal Challenges

- **Consider <u>which</u> stages are apt for legal advocacy and which may <u>also</u> be susceptible to legal challenge:**
  - MSCA submits CLH proposal (admin. conduct review by national courts + ECJ)
  - ECHA launching of public consultation
  - RAC opinion (Case T-311/06, *FMC Chemical SPRL v EFSA*)
  - REACH Committee opinion
  - ATP Regulation (Direct annulment action)

  **Issues of "legal effects" and "ripeness" to be considered.**

- **Companies have to prepare legal arguments and legal strategy early**
  - Use legal arguments during preliminary stages before adoption
  - Be prepared to use legal arguments in court actions
  - Introduce court actions timely, when justified and when useful

# Use of General Principles of EU law on Classification

- **General Principles of EU law ultimately apply before and after a challengeable decision is adopted**:
  - duty "*to **examine carefully and impartially** all the relevant elements of the individual case*"
  - must verify "***whether the evidence relied on is factually accurate**, reliable and consistent but also whether that evidence **contains all the information** which must be taken into account in order to assess a complex situation and **whether it is capable of substantiating the conclusions drawn from it***"
  - "*[take] **into account of all the relevant factors and circumstan**ces of the situation the act was intended to regulate*"
  - **non-retroactivity** - cannot anticipate a legal regime/thresholds which does not yet apply. If not done - puts final decision in peril.

**Good decision-making is a benefit to all stakeholders.**

# Focus on current and likely flashpoints

**2(c) Technical Equivalence**

# TE: what is it and when is it needed?

- *" **'technical equivalence' means similarity,** as regards the chemical composition and hazard profile, of a substance produced either from **a source different to the reference source, or from the reference source but following a change to the manufacturing process** and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54".* **Article 3(1)(w):**

- *"the chemical identity, quantity and technical equivalence of active substances … determined according to the relevant **requirements in Annexes…III**"*

  **conditions for granting an authorization, Article 19(1)(c)**

- "*Where the biocidal product contains an active substance that has been **manufactured in locations or according to processes or from starting materials other than those of the active substance evaluated for the purpose of approval pursuant to Article 9** of this Regulation, evidence has to be provided that technical equivalence has been established in accordance with Article 54 of this Regulation or has been established, following an evaluation having started before 1 September 2013, by a competent authority designated in accordance with Article 26 of Directive 98/8/EC."* **Annex III para. 2.5**

# TE: what is it and when is it needed?

- Practical Guide on Data Sharing under the Biocidal Products Regulation (EU):

  *"Technical equivalence is a requirement for a product authorisation application but is not a requirement for an application under Article 95 of the BPR and is not a legal pre-requisite for data sharing under Article 62 and Article 63 of the BPR".*

- Not to be confused with ECHA "Chemical Similarity Check Service":

  *"The chemical similarity check differs from the technical equivalence assessment under Article 54 of the BPR because a decision on the approval of the active substance has not yet been adopted and, therefore, the official reference source of the active substance is not yet established."*

  *BoA decision in case A-014-2016 (7 March 2018):*

  *"...establishing chemical similarity is not a requirement for applications under Article 95..."*

- Achievable for review programme participants but what about Art.95 list alternative suppliers?

# Technical equivalence and effective remedies

***"Time and tide wait for no man"***

- *"Following a decision to approve a particular active substance for a specific product-type, Member States shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation* ***within three years of the date of approval****". (Art 89(3) BPR)*

- *In practice:*
  - *official reference specification of AS first indicated in BPC opinion*
  - *date of adoption of AS approval i.e. published in OJEU (typically +/- 6 months)*
  - *auth. Application (****including technical equivalence decision****) must be submitted* ***before effective date of approval*** *(typically +/- 14 – 18 months after date of adoption )*

**+/- 24 month authorisation window**

- *BoA cases typically take +/- 12 – 18 month from notice of appeal to decision.*

***BoA suspends ECHA decision & also the submission deadline?***

# Role of national courts in data sharing

**After the BoA**

**&**

**Where no dispute**

# Can a pre-payment be insufficient?

After the BoA: Proportionate share assessment or better to settle?

Where no dispute: The use of BPR principles to reopen agreements?

# Take home messages