A Practical Introduction to the BPR: Overview

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Partner

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Pre-Conference Workshop
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3. Role of:
   - ECHA
   - Commission
   - Member States
A Brief Introduction of Steptoe
Steptoe: Footprint

- Palo Alto
- Century City
- Los Angeles
- Phoenix
- Chicago
- New York
- Washington, DC
- Rockville*
- London
- Brussels
- Beijing

*Complex Litigation & Discovery Center
Steptoe: Principal Practice Areas

**Regulation, Enforcement & Public Policy**
- Antitrust & Competition
- Energy
- Environment & Life Sciences (Incl. Food & Food Contact)
- Government Affairs & Public Policy
- Government Investigations & Enforcement
- Government Contracts
- International Regulation & Compliance
- International Trade & Investment
- Telecom, Internet & Media
- Transportation

**Commercial Litigation & Arbitration**
- Intellectual Property
- Insurance
- Professional Liability
- ERISA, Labor & Employment
- Complex Commercial Disputes

**Transactions & Tax**
- Tax
- Corporate / Securities
- Property
Steptoe - Overview

- International law firm focused on regulatory issues and litigation
- Over 500 professionals
- Chemical Regulation, Environment and Life Sciences practice is a core focus
  - Largest practice in Brussels, widely recognized for accomplishments
  - Well known in Washington for antimicrobials, pesticides and environmental litigation
  - Unique practice in Beijing focused on regulatory evolution to facilitate market access
- Team includes lawyers, scientists, regulatory and technical advisors
EU Chemicals - Litigation

- Before the EU courts
  - First successful action before the EU General Court – annulment of European Commission Regulation imposing restrictions on the use of Cd and Cd compounds in specific plastics
  - Two successful appeals before the European Court of Justice
  - Three pending actions
  - Supporting the European Commission and ECHA

- Before the ECHA Board of Appeal
  - Two successful appeals
  - Many pending appeals

- Before national courts
  - Successful action against the Member State’s competence to act in the framework of EU legislation
Key Contacts

- **Darren Abrahams**, partner and English barrister
  - Practice focused on EU regulatory requirements and the related commercial issues in the environment, chemicals, and life sciences area
  - Well-known for (1) litigation work before the Court of Justice of the EU and the EU General Court in the chemicals regulation (REACH & agrochemicals) and environmental areas and (2) product defense & product approvals work (biocides, agrochemicals, and biotechnology (GMOs))

- **Ruxandra Cana**, partner
  - Expertise in litigious matters involving chemicals in the EU. She has represented clients in more than 25 litigation matters in cases before the EU General Court, the EU Court of Justice or the Board of Appeal of the European Chemicals Agency, or national courts
  - Widely-known REACH expert in Europe

- **Dr. Anna Gergely**, director EHS Regulatory
  - Widely-recognized combined scientific knowledge and regulatory experience in the chemicals and life sciences areas
  - Well-known for nanotechnology expertise when implemented in applications falling under REACH, biocides, cosmetics, food and food contact applications

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Key Contacts

- **Jim Searles**, partner
  - Advises on international trade law, EU market access/regulatory compliance
  - Long experience with EU chemicals law, notably concerning marketing restrictions and REACH compliance; litigation experience before EU Courts and BoA of ECHA

- **Craig Simpson**, Senior European Legal Advisor and UK qualified solicitor
  - Has more than 14 years of experience advising multinational companies and trade associations on EU regulatory compliance and related commercial issues in the food, chemical regulation, and life sciences areas
  - Core food areas include the regulatory status of ingredients, food contact materials, labelling and packaging and nutrition and health claims, particularly in the context of functional foods and food supplements

- **Indiana de Seze**, senior associate
  - Focuses predominantly on the regulation of chemicals through the REACH, biocides, and plant protection products regimes, and other applications of chemicals requiring regulatory clearance or pre-market authorizations
  - Has significant litigation experience. She represents clients before the EU and national courts, and the BoA of ECHA
Key Contacts

 **Eléonore Mullier**, associate
  - Advises on regulatory compliance & litigation (EU and national courts, and the BoA of ECHA) in the field of environmental law at both EU and national levels
  - Focuses on chemical and product regulations (REACH, CLP, biocides, plant protection products), climate change, and waste

 **Blandine Gayral**, paralegal
  - Focuses on EU chemicals regulation (biocides, agrochemicals, and REACH), working closely with the European Commission (EC) and national competent authorities in the EU
  - European Commission experience with drafting EU chemicals regulation (e.g. Fertilizers Regulation proposal, the Biocidal Product Regulation)

 **Michel Michaux**, technical advisor (chemical engineer)
  - Previously worked for the European Chemical Industry Council (Cefic)
  - Focuses on management of consortia set up for pesticide, biocide, and REACH registrations that cover in excess of 150 substances; set up and managed the Cefic Biocides Forum and consortia of companies jointly registering biocidal active substances; co-author of RIP 3-4 on data sharing, which served as a basis for ECHA’s Guidance on Data Sharing
BPR Main Principles
BPR Main Principles: Evolution

- **REACH Regulation 1907/2006**
  - Date of entry into force: 26-Jul-91
- **Biocidal Products Directive 98/8**
  - Date of entry into force: 14-May-98
- **Plant Protection Products Directive 91/414**
  - Date of entry into force: 1-Jun-07
- **Plant Protection Products Regulation 1107/2009**
  - Date of entry into force: 14-Dec-09
- **Biocidal Products Regulation 528/2012**
  - Date of entry into force: 1-Sep-13

Date of entry into force
BPR Main Principles: Supplementary Measures

1. Regulation on changes to product authorisation: Reg. (EU) No 354/2013 of 18th April 2013


4. Regulation on the extension of duration of review programme to 2024: Reg. (EU) No 736/2013 of 17th May 2013

5. Regulation on the modification on data requirements (proof of technical equivalence in BP applications): Reg. (EU) No 837/2013 of 25th June 2013


### BPR Main Principles: Scope (1)

<table>
<thead>
<tr>
<th>BPD</th>
<th>BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Active substance</strong></td>
<td>A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.</td>
</tr>
<tr>
<td><strong>Biocidal product</strong></td>
<td>Any substance or a microorganism that has an action on or against harmful organisms.</td>
</tr>
<tr>
<td><strong>Treated article</strong></td>
<td>None</td>
</tr>
</tbody>
</table>

**BPD**

- **Active substance**: A substance or microorganism including a virus or a fungus having general or specific action on or against harmful organisms.

**BPR**

- **Active substance**: A substance or a microorganism having general or specific 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.

- **Treated article**: None

- **Treated article**: Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.
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’ (substance/microorganism in the product with controlling effect on target organism)
- authorisation (and renewal) of biocidal products (containing active substance)
- data sharing and data protection re substance and product dossiers, at approval and authorisation stages
- labelling requirements
- new role of ECHA (“BPC” - Biocidal Products Committee)
- appeal from some (not all) ECHA decisions
- central biocide registry: R4BP
- enforcement
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)
## Biocidal Product Types

<table>
<thead>
<tr>
<th>Group 1* Disinfectants</th>
<th>Group 2 Preservatives</th>
<th>Group 3 Pest Control</th>
<th>Group 4 Other biocides</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PT1</strong>: Human hygiene</td>
<td><strong>PT6</strong>: Preservatives for products during storage</td>
<td><strong>PT14</strong>: Rodenticides</td>
<td><strong>PT20</strong>: Preservatives for food or feedstocks*</td>
</tr>
<tr>
<td><strong>PT2</strong>: Disinfectants and algacides not intended for direct application to humans or animals</td>
<td><strong>PT7</strong>: Film preservatives</td>
<td><strong>PT15</strong>: Avicides</td>
<td><strong>PT21</strong>: Antifouling products</td>
</tr>
<tr>
<td><strong>PT3</strong>: Veterinary hygiene</td>
<td><strong>PT8</strong>: Wood preservatives</td>
<td><strong>PT16</strong>: Molluscsides, vermicides, and products to control other invertebrates</td>
<td><strong>PT22</strong>: Embalming and taxidermist fluids</td>
</tr>
<tr>
<td><strong>PT4</strong>: Food and feed area</td>
<td><strong>PT9</strong>: Fiber, leather, rubber and polymerized materials preservatives</td>
<td><strong>PT17</strong>: Piscicides</td>
<td></td>
</tr>
<tr>
<td><strong>PT5</strong>: Drinking water</td>
<td><strong>PT10</strong>: Construction materials preservatives</td>
<td><strong>PT18</strong>: Insecticides, acaricides, and products to control other arthropods</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PT11</strong>: Preservatives for liquid-cooling and processing systems</td>
<td><strong>PT19</strong>: Repellants and attractants</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PT12</strong>: Slimicides</td>
<td><strong>PT20</strong>: Control of other vertebrates (previously PT23)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>PT13</strong>: Working or cutting fluid preservatives</td>
<td></td>
<td>- Because now covered by specific EU legislation</td>
</tr>
</tbody>
</table>

* Excludes cleaning products that are not intended to have a biocidal effect, including washing liquid, powder and similar products.

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**BPR Main Principles: Scope (2)**
Biocidal products (« BP ») containing existing active substances (« AS ») which have been / are being evaluated can remain on the national market (if BP application submitted before the AS approval date) (Article 89 § 2 to 4)

- BP authorisations dossiers not yet evaluated remain subject to the BPD [but see Articles 5(1) and 10 of the BPR] (Article 91)
  - To be BPR labelled once they get their BPR authorisation
  - BP authorisations / registrations delivered prior to that date remain valid until their expiration date but are subject to the BPR

Approval of an AS for a product-type (« PT »)
- Deadline for submission of application for associated BP (including MR) (Article 89 § 2)
  - Authorisation refused
  - Application rejected
  - No application submitted for BP after approval of last AS
  - Conditions attached to the authorisation making it necessary to change a BP

180 days Prohibition on the market

12 months Use of stocks

18 months Use of stocks

Prohibition on the market of a BP consisting of, containing or generating an AS for which the AS supplier or the BP supplier is not listed in the BPR, except if all AS listed in Annex I (Article 95)

Prohibition on the market of BP consisting of, containing or generating an AS for which no dossier has been submitted by 1 Sept 2016 (Article 94)

Prohibition on the market of TA containing AS that are neither under the review programme / nor authorised / for which no application has been filed by 1 Sept, 2016 (Article 94)
BPR Main Principles: Basic features

- **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 on 14.5.2000)

- **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)
    - addresses non-participant ‘free rider’ issue pending Commission inclusion decision
BPR Main Principles: Basic features

- **More streamlined AS review process**
  - Applies 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)

- **Nanomaterials**

- **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** (AS)
  - e.g. exclusion criteria, respo. 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 & identified as such in Union list of approved AS
BPR Main Principles: Basic features

- **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)
BPR Main Principles: Basic features

- **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)

- **Market Access without authorisation**: parallel trade permit
  - product sold in other MS and identical to that already sold on relevant MS market
Role of ECHA, Commission & Member States
Role of ECHA

ECHA has three main roles:

1. Advisory
2. Decision-Making
3. Coordination/Support

Substantial impact on your rights and obligations
Role of ECHA: Advisory on AS

- **Approval/Renewal Opinion by European Biocidal Products Committee on CA evaluation** [Art. 8(4) and 14(3)], includes identification of candidates for substitution [Art. 10(2)]

- **Other Scientific/Technical Opinions on request from Commission** for AS Review of Approval [Art. 15(2)]

- **Opinion on inclusion in Annex I** (AS for products subject to simplified procedure) [Art. 28]
Role of ECHA: BPC

Structure of the BPC and its Working Groups

**Biocidal Products Committee**
Chair: Erik van de Plassche

**Permanent Working groups**
- **Efficacy**
  Chair: Ann Thuander
- **Analytical methods**
  **Physical-chemical properties (APCP)**
  Chair: Bernard Krebs
- **Human health**
  Chair: Antero Alraksinen
- **Environment**
  Chair: Heike Schimmelpfennig

**Ad hoc Working groups**
- **Human exposure**
  Chair: Chiara Peccorini
- **Assessment of residue transfer to food**
  Chair: Laura Ruggeri
- **Environmental exposure**
  Chair: Heike Schimmelpfennig
Ambitious plan of circa 50 active substance/product type combinations approved or not approved per year (see Annex III of Reg. (EU) No 1062/2014):

<table>
<thead>
<tr>
<th>Priority</th>
<th>Existing active substances for product types</th>
<th>eCA has to submit assessment report to ECHA by</th>
<th>The BPC* must start to prepare its opinion (for submission to Commission) by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st priority list</td>
<td>8, 14, 16, 18, 19, 21</td>
<td>31/12/2015</td>
<td>31/03/2016</td>
</tr>
<tr>
<td>2nd priority list</td>
<td>3, 4, 5</td>
<td>31/12/2016</td>
<td>31/03/2017</td>
</tr>
<tr>
<td>3rd priority list</td>
<td>1, 2</td>
<td>31/12/2018</td>
<td>31/03/2019</td>
</tr>
<tr>
<td>4th priority list</td>
<td>6, 13</td>
<td>31/12/2018</td>
<td>31/03/2020</td>
</tr>
<tr>
<td>5th priority list</td>
<td>7, 9, 10</td>
<td>31/12/2020</td>
<td>31/03/2021</td>
</tr>
<tr>
<td>6th priority list</td>
<td>11, 12, 15, 17, 20 and 22</td>
<td>31/12/2022</td>
<td>31/09/2023</td>
</tr>
</tbody>
</table>

* The Agency shall submit the opinion to the Commission within 270 days of the start of the preparation.
Role of ECHA: Advisory on Product

- Opinions on request from Commission for Mutual Recognition (where disagreements not resolved in Coordination Group) [Art 38(1)]

- Opinion on Union Authorisation [Art. 44(3)] and on Renewal [Art. 46(3)]

- Opinion on amendment or cancellation [Art. 47(2)]
ECHA: Advisory Role Challengeable?

Advisory function is important BUT not everything is challengeable (even if the Opinion is wrong, public and financially damaging):

‘It is settled case-law that only measures the legal effects of which are binding on the applicant and capable of affecting his interests by bringing about a distinct change in his legal position are acts or decisions against which proceedings for annulment may be brought.

As regards, specifically, acts or decisions drawn up in a procedure involving several stages, only measures definitively laying down the position of the institution on the conclusion of that procedure are, in principle, measures against which proceedings for annulment may be brought. It follows that preliminary measures or measures of a purely preparatory nature are not measures against which proceedings for annulment may be brought.’

(Case T-311/06, FMC Chemical SPRL v EFSA, para. 43)
ECHA: Advisory Role Challengeable?

However, even if Opinions are not challengeable, when they form the basis for subsequent Commission decisions, substantive flaws may vitiate the final decision.

This is a reason for legal issues to be taken seriously before a final decision. Why wait for it to become 'ripe'/delay?

Not in anyone’s interest to build up a pipeline of weak decisions awaiting review.
ECHA: Advisory Role Challengeable?

General Principles of EU law ultimately apply:

- duty 'to examine carefully and impartially all the relevant elements of the individual case' (Case C-126/90 Technische Universität München, para. 14);

- 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' (Case C-12/03 P, Tetra Laval, para. 39)

- '[take] into account of all the relevant factors and circumstances of the situation the act was intended to regulate' (Case T-96/10 Rütgers Germany GmbH and Others v ECHA, para. 100)

- Non-retroactivity – Opinions cannot anticipate a legal regime/thresholds which does not yet apply.

If not done – puts final decision in peril.
## ECHA Decision-Making: BoA Remedies

<table>
<thead>
<tr>
<th>Fees∞</th>
<th>Data Sharing</th>
<th>Technical Equivalence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Validation of AS applications</strong> - rejection of application for non payment of fees within 30 days (Art 7.(2))</td>
<td>Mandatory where parties don’t agree (Art 63(3))</td>
<td>Decision on technical equivalence (Art 54.(4))</td>
</tr>
<tr>
<td><strong>Renewal of AS applications</strong> - rejection of application for non payment of fees within 30 days (Art 13.(3))</td>
<td>Referral to unprotected data when technically equivalent (Art 64(1))</td>
<td>Rejection of application where further information requested for technical equivalence but not provided so rejected (Art 54.(5))</td>
</tr>
<tr>
<td><strong>Validation of Union Authorisation</strong> - rejection of application for non payment of fees within 30 days (Art 43.(2))</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Renewal of Union Authorisation</strong> - rejection of application for non payment of fees within 30 days (Art 45.(3))</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Rejection of application for Technical Equivalence for non payment of fees within 30 days</strong> (Art 54.(3))</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

∞▲ Same remedy for fees non-payments and/or failure to provide requested information under Reg. (EU) 613/2013, Reg. (EU) 564/2013 (also on SME status) and Reg. (EU) 354/2013.
ECHA Decision-Making: CJEU Remedies

ATD

- Free-standing right to challenge **ECHA decisions** on access to documents (under Regulation (EC) 1049/2001) before **General Court**. Consider applicability of Article 4 **exceptions** including commercial interests of a natural or legal person, including intellectual property. **Access to document is useful in itself**, and useful in any later appeal.

- Alternative right to complain to **Ombudsman**.

Dissemination & Confidentiality Claims

- Also a potential remedy before the General Court if representations on disclosure unsuccessful.

Remember that ECHA (like the Commission) is potentially subject to non-contractual liability for damage caused.
Member State Authorities: Binding Decisions

- Binding decisions (essentially administrative) by MS such as:
  - validation decisions on product dossiers, requests for further data and final decision (should be challengeable under administrative law principles)
  - technical equivalence
  - disclosure of sensitive information
  - granting of parallel trade permits

- MS do not act in a legal vacuum because they are part of a 'European' procedure under the BPR.

- The same legal principles should be part of your dialogue (before having to consider national courts and ECJ Preliminary Reference).
## Role of ECHA & Others in authorisation procedures (I)

<table>
<thead>
<tr>
<th></th>
<th>1. NATIONAL BIOCIDAL PRODUCT AUTHORIZATION</th>
<th>2. PRODUCT MUTUAL RECOGNITION IN PARALLEL</th>
<th>3. PRODUCT MUTUAL RECOGNITION IN SEQUENCE</th>
<th>4. UNION AUTHORIZATION OF BIOCIDAL PRODUCTS</th>
<th>5. SIMPLIFIED BIOCIDAL PRODUCT AUTHORIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAXIMUM APPROVAL PERIOD (YEARS)</strong></td>
<td>10 (5 if contains candidate for substitution)</td>
<td>10</td>
<td>10</td>
<td>10 (5 if contains candidate for substitution)</td>
<td>10 (5 if contains candidate for substitution)</td>
</tr>
<tr>
<td><strong>CONTENTS OF APPLICATION</strong></td>
<td>-Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
<td>To chosen evaluating CA (reference MS)</td>
<td>Translation of national authorization granted in reference MS into relevant official languages</td>
<td>-Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
<td>-Summary of product characteristics (potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td>-Summary of product characteristics in appropriate language(s)</td>
<td>-As for national or simplified product authorization, as appropriate</td>
<td>-Summary of product characteristics</td>
<td>-Summary of product characteristics</td>
<td>-Summary of product characteristics</td>
</tr>
<tr>
<td></td>
<td>-Confirmation that not applied to other CA</td>
<td>-List of other MSs where national authorization sought</td>
<td>in MS required languages</td>
<td>in appropriate language(s)</td>
<td>(potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td>To other MSs where national authorization sought</td>
<td>-Identity of reference MS and other MSs where national authorization sought</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Summary of product characteristics in MS required languages</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>APPLICATION SUBMITTED TO</strong></td>
<td>Chosen CA where want to market product</td>
<td>Simultaneously to reference MS and other MSs concerned (see above)</td>
<td>Each CA of countries (other than reference MS) where want to market</td>
<td>ECHA, with confirmation of which CA has agreed to evaluate</td>
<td>ECHA, with confirmation of evaluating CA</td>
</tr>
<tr>
<td></td>
<td>Application accepted on receipt of fee within 30 days of informing applicant</td>
<td>Application accepted if fee received within 30 days of informing applicant</td>
<td>Application accepted if receives fee within 30 days of informing applicant</td>
<td>Application accepted on receipt of fee within 30 days of informing applicant</td>
<td>Application accepted if fee received within 30 days of informing applicant</td>
</tr>
<tr>
<td><strong>VALIDATION BY</strong></td>
<td>Chosen CA within 30 days of acceptance</td>
<td>Evaluating CA (reference MS) within 30 days of its acceptance</td>
<td>Each CA within 30 days of its acceptance</td>
<td>Chosen CA within 30 days of ECHA acceptance subject to payment of CA fee</td>
<td>No formal validation stage</td>
</tr>
<tr>
<td></td>
<td>Decline to evaluate if same product/use already subject of authorization application with another authority</td>
<td>Applicant to provide missing information normally within max 90 days</td>
<td></td>
<td>Applicant to provide missing information normally within max 90 days</td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
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</tbody>
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Maximum approval period (years)

<table>
<thead>
<tr>
<th></th>
<th>10 (5 if contains candidate for substitution)</th>
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</tr>
</thead>
</table>

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Contents of application

- Dossier/LoA for product and each active (potential data waiver/adaptation)
- Summary of product characteristics in appropriate language(s)
- Confirmation that not applied to other CA
- To chosen evaluating CA (reference MS)
- As for national or simplified product authorization, as appropriate
- List of other MSs where national authorization sought
- To other MSs where national authorization sought
- Identity of reference MS and other MSs where national authorization sought
- Summary of product characteristics in MS required languages

Application submitted to

- Chosen CA where want to market product
  - Application accepted on receipt of fee within 30 days of informing applicant

Validation by

- Chosen CA within 30 days of acceptance
  - Decline to evaluate if same product/use already subject of authorization application with another authority
  - Applicant to provide missing information normally within max 90 days

---

ECHA, with confirmation of which CA has agreed to evaluate

Application accepted on receipt of fee within 30 days of informing applicant

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ECHA, with confirmation of evaluating CA

Application accepted if fee received within 30 days of informing applicant

---

No formal validation stage

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### Role of ECHA & Others in authorisation procedures (II)

<table>
<thead>
<tr>
<th></th>
<th>1. NATIONAL BIOCIDAL PRODUCT AUTHORIZATION</th>
<th>2. PRODUCT MUTUAL RECOGNITION IN PARALLEL</th>
<th>3. PRODUCT MUTUAL RECOGNITION IN SEQUENCE</th>
<th>4. UNION AUTHORIZATION OF BIOCIDAL PRODUCTS</th>
<th>5. SIMPLIFIED BIOCIDAL PRODUCT AUTHORIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EVALUATION BY</strong></td>
<td>Chosen CA within 365 days of validation</td>
<td>Evaluating CA (&quot;reference MS&quot;) within 365 days of validation</td>
<td>CAs agree summary of product characteristics within 90 days of validation and record agreement in Register for Biocidal Products</td>
<td>Chosen CA within 365 days of validation of application</td>
<td>Reduced evaluation by chosen CA (&quot;verification of eligibility&quot; for simplified authorization) within 90 days of accepting application (or longer where further information required)</td>
</tr>
<tr>
<td></td>
<td>Applicant to provide missing information within normally max 180 days (during which 365 timer is suspended)</td>
<td>Same coordination and resolution procedures as per &quot;In Sequence&quot;</td>
<td>Same coordination and resolution procedure if MS objection that safety authorization conditions not met</td>
<td>Applicant to provide missing information within normally max 180 days</td>
<td>Applicant to provide missing information within normally max 90 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Drafts assessment report, conclusions and reasons for granting or refusing authorization</td>
<td>Drafts assessment report, conclusions and reasons for granting or refusing authorization</td>
<td>Applicant written comments on evaluation conclusions during 30 day period</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Send assessment report and summary of product characteristics to other MSs and applicant</td>
<td>Send assessment report and summary of product characteristics to other MSs and applicant</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other MSs CAs to agree summary of biocidal product characteristics within 90 days of receipt of report and record agreement in Register for Biocidal Products</td>
<td>Other MSs CAs to agree summary of biocidal product characteristics within 90 days of receipt of report and record agreement in Register for Biocidal Products</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reference MS to enter report and summary and any conditions on marketing and use in Register</td>
<td>Reference MS to enter report and summary and any conditions on marketing and use in Register</td>
<td>Reference MS to enter report and summary of biocidal product characteristics</td>
<td>Reference MS to enter report and summary of biocidal product characteristics</td>
</tr>
<tr>
<td><strong>APPROVAL/NON-APPROVAL</strong></td>
<td>Chosen CA: - drafts assessment report with conclusions and reasons for granting or refusing authorization; - send electronic copy to applicant requesting comments within 30 days; - finalizes report taking account of conclusions.</td>
<td>All relevant MSs to authorize biocidal product within 30 days of agreement on summary and in conformity with summary</td>
<td>Each CA to authorize biocidal product within 30 days of agreement on summary and in conformity with summary</td>
<td>Commission authorization approval Regulation or non-approval decision on receipt of ECHA opinion</td>
<td>Provided eligible, chosen CA must authorize within 90 days of submission of additional information requested by applicant</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If absence of agreement between all CAs, those CAs agreeing to summary may authorize product</td>
<td>In absence of agreement between all CAs, CAs agreeing to summary may authorize product</td>
<td>Commission can require conditions particular to certain MS territory or exclude a certain territory on MS derogation request</td>
<td></td>
</tr>
<tr>
<td><strong>TIMELINE (DAYS)</strong></td>
<td>725</td>
<td>845</td>
<td>905 (725 + 180)</td>
<td>935</td>
<td>300</td>
</tr>
</tbody>
</table>

*(Assumes that (i) each time period is used in full, (ii) periods for additional information are always required, (iii) the Coordination Group, where applicable, is able to resolve differences without requiring the Examination Procedure in Article 35, and (iv) that each stage follows on immediately from that preceding it.)*
And now for the small print…

dabrahams@steptoe.com
A Practical Introduction to the BPR:
Overview of interlinks with other legislation

Darren Abrahams, Partner
& Indiana de Seze, Senior Associate

Biocides Europe 2015 - 18th Annual European Conference
Pre-Conference Workshop
24 November 2015
Content

1. BPR and other regulatory regimes
2. Focus on BPR and REACH
3. CLP
4. Focus on BPR and Plant Protection Products
5. Sustainable Use
The BPR and other regulatory regimes
Outside scope

(a) food or feed used as repellents or attractants (PT 19);

(b) biocidal products when used as (food) processing aids within the meaning of Regulation (EC) No 1831/2003 and Regulation (EC) No 1333/2008

(c) BPs on own or in a treated article where necessary for Defence (in specific cases on an individual MS basis).
Exemptions for non biocidal uses

- Article 2(2) BPR

Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall not apply to biocidal products or treated articles that are within the scope of the following instruments:


Exemptions for non biocidal uses

(d) Regulation (EC) No 1831/2003 – feed additives;


(f) Regulation (EC) No 1333/2008 - authorisation procedure for food additives, food enzymes and food flavourings;

(g) Regulation (EC) No 1334/2008 - flavourings and certain food ingredients with flavouring properties for use in and on foods;

(h) Regulation (EC) No 767/2009 - placing on the market and use of feed

(i) Regulation (EC) No 1107/2009 - placing of plant protection products on the market;


Exemptions for non biocidal uses

- Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments and is intended to be used for purposes not covered by those instruments, BPR shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments.

- Regulation 1935/2004 - food contact materials: no longer exempted (were exempted under BPD). PT 4 redefined to cover FCM.
Overlaps in scope

Article 2(3) BPR:

Subject to any explicit provision to the contrary in this Regulation or other Union legislation, this Regulation shall be without prejudice to the following instruments:

(a) classification, packaging and labelling; misleading and comparative advertising;

(b) protection of workers at work;

(c) water intended for human consumption;

(e) persistent organic pollutants, industrial emissions, export of chemicals, substances that deplete the ozone layer

(f) REACH

(g) protection of animals used for scientific purposes

(h) sustainable use of pesticides

(i) waste
Focus on the BPR and REACH
Limits of Relief from REACH

- **Article 15(2) REACH**
  - “Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC...or in Commission Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title”.

- **Limited Scope**:
  - Article 15(2) only concerns Registration.
  - REACH's provisions on Authorisation exclude substances used in biocides but Authorisation obligations still apply to biocidal substances when used in other applications (Art. 56(4)(b)). Dossier must be submitted, including information exceeding the requirements for the specific tonnage registration.
Limits of Relief from REACH

- **Dual Uses:**
  - Strictly read Art. 15(2) means any dual use by same legal entity renders **total tonnage** subject to REACH registration. (But ECHA's Guidance...)
  - Guidance on Registration envisages splitting tonnages:
    - “If a manufacturer or importer manufactures or imports the substance for biocidal and non-biocidal uses, it will have to submit a registration for the **quantities** of the substance used in non-biocidal products.” (section 2.2.4.1)

- **Art. 29 SIEF obligations** remain for non biocidal uses:
  - all producers of biocidal substances obliged to participate and **subject to mandatory data sharing**.

- **Article 57 BPR extension** of deemed registration:
  - for AS manufactured or imported for use in biocidal products authorised for placing on the market under:
    - Art. 27 simplified procedure for low risk actives
    - Art. 55 **essential uses** for public health/env. protection
    - Art. 56 R&D
REACH Influence on BPR

- REACH-like models and REACH reference points abound in the BPR:
  - ECHA progressively involved in AS evaluations.
  - Phased-in Union authorisation for certain PTs
  - Biocidal products eligible for simplified authorisation procedures (Annex I) initially based on REACH Annex IV among other sources
  - BoA appeal mechanism
  - 'substances of Concern” (non-AS) defined by reference *inter alia* to those which meets the criteria for being a PBT or vPvB in accordance with Annex XIII of REACH
  - Key REACH article 3 definitions adopted (though in some cases confusing – “articles” (REACH) versus “treated articles” (BPR)
REACH Influence on BPR

- **REACH-like models and REACH reference points abound in the BPR:**
  - Art. 5, AS **exclusion criteria** include:
    - being identified in accordance with Arts. 57(f) and 59(1) of REACH as having endocrine disrupting properties;
    - meeting the criteria for being PBT or vPvB according to Annex XIII of REACH

  - Art. 10, AS **candidates for substitution** criteria include:
    - meeting **two** of the criteria for being PBT in accordance with Annex XIII of REACH

  - BP may not be authorised for use by general public if **inter alia**:
    - it consists of, contains or generates a substance that meets the criteria for being PBT or vPvB in accordance with Annex XIII to REACH

  - **REACH Data Sharing Guidance** identified as a reference point for determining sharing in a “fair, transparent and non-discriminatory” manner. (But not fit for purpose.)
Clear REACH – BPR Differences

- But the BPR is not “REACH for Biocides”:

<table>
<thead>
<tr>
<th>REACH</th>
<th>BPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tonnage threshold data requirements</td>
<td>One size fits all data package</td>
</tr>
<tr>
<td>SIEFS may be from 10 to 10,000 participants per SIEF</td>
<td>Generally less than 10 participants per substance (normally 2-5)</td>
</tr>
<tr>
<td>5% + of dossiers will be evaluated</td>
<td>All substance and product dossiers evaluated</td>
</tr>
<tr>
<td>Only hazardous substances subject to Authorisation</td>
<td>All products authorized</td>
</tr>
</tbody>
</table>
Focus on CLP
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.

Label and packaging only under CLP*

Classify under both Directive 67/548/EEC and CLP

Must classify, label and package in accordance with Directive 67/548/EEC & May classify, label and package under CLP***

Label and package only under CLP*

Must classify, label and package in accordance with Directive 99/45/EC**

May classify, label and package under CLP***

Must classify, label and package under CLP

REACH Entered into Force 1 June 2007

REACH Pre-Registration Deadline 1 Dec. 2008

CLP Entry into Force 20 Jan. 2009


1st REACH Registration 1 Dec. 2010

2nd REACH Registration 1 June 2013

3rd REACH Registration 1 June 2018


* 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 Jan. 2017.

*** Labelling and packaging of DSP/DPD replaced (not as well as)
CLP – BPR Interface

- It’s not just the label!
- ECHA Introductory Guidance on the CLP Regulation:

Many provisions of CLP are closely linked to provisions under the REACH Regulation and other Union legislation. The most relevant links to REACH, to Regulation (EU) No 528/2012 on biocidal products (Biocidal Product Regulation or BPR) and to Regulation (EC) No 1107/2009 on plant protection products (Plant Protection Product Regulation or PPPR) are briefly explained…

Substances that are active substances in the meaning of the PPPR or BPR are normally subject to harmonised classification and labelling … i.e. all hazard classifications and labelling elements will be harmonised. This is a difference to other substances where only the classification and labelling elements for CMRs and respiratory sensitisers will normally be harmonised while other classifications and the related labelling elements will only be harmonised on a case-by-case basis if justification is provided demonstrating the need for such action at Union level (CLP Article 36(2))…
Procedure for establishing harmonized classification and labelling (CLH)
Article 37 Regulation (EC) No. 1272/2008 (CLP)¹

**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))

**Inclusion of CLH in Annex VI entry through ATP Regulation**

**Possibility for submitting party to respond to public consultation**

**Max. 18 months of RAC’s receipt of proposal**

**RAC forms an opinion on proposal**

**Commission inter-service consultation**

**ATP legal text drafted by DG GROW (ENTR) on the basis of RAC opinions of previous calendar year**

**Proposal and RAC opinion submitted to Commission**

**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

¹ See also ECHA “Guidance on the preparation of dossiers for harmonized classification and labelling” (August 2014)
² Must be in format specified in second paragraph of Art. 37(2)
Focus on the BPR and the Plant Protection Products Regulation
Commonalities BPR/PPPR

- Active substance approval at EU level
- Plant protection product at national level (no EU level for PPP)
- Existence of regime-specific data protection and data sharing rules
- AS Candidates for substitution and comparative assessment of products
- Mutual recognition for products
- Low risk active substances
Main differences PPPR over BPR

- No involvement of ECHA or the Board of Appeal in PPPR
- No R4BP platform
- No EU product authorisations
- Zonal evaluation process
- Data protection duration detached from approval duration
- Scope of and remedies to data sharing
Consistency issues between BPR/PPPR

- AS evaluation undertaken by potentially different competent authorities/Member States: different outcomes?

- ECHA may ensure consistency of processes but not for PPPR

- Handling of confidential business information and disclosure of information:
  - Art 66(3) BPR provides, among others, disclosure of
    (b) precise tonnage of BP
    (g) a summary of the results of the tests required pursuant to Article 20 to establish the product’s efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;
  - PPPR provides disclosure of
    Art 10: AS summary dossier
    Art 16: contents of application for AS approval renewal
Sustainable use of biocides

- Article 18 BPR makes it an obligation to draw report by 18 July 2015 on sustainable use of biocides and how the BPR is contributing to this objective.

- Report was drafted and communicated to the Council and Parliament timely with following conclusions:
  - The first priority for most Member States is the completion of the work programme – no additional measures will be adopted for now.
  - A roadmap of actions is described in the report, which include the shortening of the duration of the BPR authorisations and enhanced labelling provisions and downstream user information.
Roadmap of actions, including:

- ensuring that once active substances are approved, product authorisations are granted, amended or cancelled within three years;

- benefiting from the legislative tools available, in particular, by closely following the developments of the best available techniques reference documents (BREFs), developed under the EU’s integrated pollution prevention and control regime, that can be relevant for biocidal products;

- defining the objectives of monitoring their use, what would need to be collected and how. This is likely to be done via Echa's registry for biocidal products (R4BP 3);

- discussing labelling requirements to allow specific statements for biocidal products, with a better profile for the environment or public health;

- encouraging the use of smart tags or quick response codes on biocidal product labels to provide further information on the product's properties, the instructions for, and elements to consider before, use; and

- supporting the development of standards by the European Committee for Standardization (CEN) that could contribute to sustainable use and professional practices (pest control is one example).
Questions?

dabraham@steptoe.com
A Practical Introduction to the BPR: Costs, data protection and data sharing provisions

Darren Abrahams
Partner

Biocides Europe 2015 - 18th Annual European Conference
Pre-Conference Workshop
24 November 2015

This presentation is indicative only and is not a substitute for comprehensive legal advice.
Data Costs: Market levelling – finally?

- REACH created a “watershed” moment requiring Pre-Registration of phase in substances in order to maintain lawful market access until the applicable Registration deadline. Created an individual right per legal entity (manufacturer, importer, OR).

- In contrast, BPD created a free-rider problem:
  - During the BPD transitional period, Member States may apply their national rules for placing biocidal products on the market. Free-riders may continue to place existing active substances on the market until the inclusion of the existing active substance into Annex I/IA to the BPD. So companies who had invested € millions in the review programme had the same market access as those who had spent nothing (“1st free rider problem”).

- Under BPR Data owners have lost exclusive use but should now be able to exclude "free-riders" - Article 95 list of active substances and suppliers. Equally, those who have joined the list should have the same market access rights. The purpose of this list is to “ensure the equal treatment of persons placing active substances on the market” (recital 8, BPR).
Data Costs - Approach to the market

- Stated objectives:
  - create a "level playing field...as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of a fair compensation of the costs borne by data owners" (Recital 58)
  - "minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products" (Recital 57)

- Open season for competitors accessing data since 1 Sept, 2013. New data sharing and compensation rules for all data submitted under BPD and BPR applied immediately.
Data Costs - Data Sharing

- Mandatory data sharing more extensive than REACH and PPPR. Not just data involving tests on vertebrates.

- For **existing AS data** mandatory data sharing not limited to vertebrate animals but also under Art. 95(3):
  - "to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates". (i.e. Exhaustive list of Existing Active Substances to be examined under the Review Programme/ New Work Programme Regulation)

- Unlike REACH where a joint dossier is the norm, every "Alternative Supplier" must calculate whether it is better to:
  - "cherry pick" from the dossier (using own data where already owned)
  - "buy in" completely (Fees Regulation encourages a complete buy in)
Data Costs - Data Sharing

- As an exception to the rules on existing AS data, mandatory data sharing not applicable to AS "listed in Annex I in categories 1 to 5 and 7 or to biocidal products containing only such substances":
  - Substances authorised as food additives according to Regulation (EC) No 1333/2008
  - Weak acids
  - Traditionally used substances of natural origin
  - Substances included in Annex IV to REACH Regulation
  - Pheromones
  - Others

(NB: Commission Implementing Regulation (EU) No 88/2014 on Article 95(6) procedure for amending Annex I)
## Sharing of Existing Data: Overlap & Differences

<table>
<thead>
<tr>
<th></th>
<th><strong>REACH</strong> (Art. 30 Phase-In Substances)</th>
<th><strong>BPR</strong> (Art. 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STANDARD (AND BURDEN)</strong></td>
<td>“Every effort” to ensure that the costs of sharing the information is determined in a “fair, transparent and non-discriminatory way” (burden on both parties)</td>
<td>“Every effort” to reach an agreement. Compensation determined in a “fair, transparent and non-discriminatory manner” OR parties may agree to submit matter to binding arbitration (burden on both parties)</td>
</tr>
<tr>
<td><strong>SUBJECT TO SHARING</strong></td>
<td>Study involving tests on vertebrate animals</td>
<td>Tests or studies on vertebrates. Plus all tox., ecotox., env. fate and behaviour studies (for Art. 95 list)</td>
</tr>
<tr>
<td><strong>PROCESS TRIGGERED BY</strong></td>
<td>SIEF participant</td>
<td>Prospective applicant</td>
</tr>
<tr>
<td><strong>DECISION MAKER</strong></td>
<td>ECHA</td>
<td>ECHA</td>
</tr>
<tr>
<td><strong>TIMELINES</strong></td>
<td>No earlier than 1 month after request of proof of costs</td>
<td>No earlier than 1 month after name of data owner provided + 60 day maximum for ECHA decision (Prospective applicant must have paid a share of costs before Decision)</td>
</tr>
<tr>
<td><strong>SUB-LICENSEING?</strong></td>
<td>No (Legal entity specific unless otherwise agreed)</td>
<td>No (Exception under Article 95 to an applicant for authorization in its supply chain)</td>
</tr>
<tr>
<td><strong>COMPENSATION PRINCIPLES</strong></td>
<td>Costs shared equally</td>
<td>Proportionate share of the cost</td>
</tr>
<tr>
<td><strong>COMPENSATION PROCEDURE (ABSENT AGREEMENT)</strong></td>
<td>Data owner may enforce € claim through MS Courts</td>
<td>MS Courts decide on proportionate share</td>
</tr>
<tr>
<td><strong>REMEDIES AGAINST DECISION</strong></td>
<td>BoA + General Court</td>
<td>BoA + General Court</td>
</tr>
</tbody>
</table>
Data Sharing Rules: Sharing of What?

- Data protection is distinct from confidentiality:
  - Public information can be subject to data protection
  - Secret information may not be subject to data protection
- No necessary link between data protection and confidentiality
- No definition of 'data protection' in the BPR (as under the BPD and REACH). All protected data submitted for BPD/BPR purposes. What is submitted is not limited to studies alone. Clear intention to ensure nothing slips between the gaps:

  ‘With a view to ensuring that all proprietary information submitted in support of the approval of an active substance or the authorisation of a biocidal product is protected from the moment of its submission and to prevent situations where some information is without protection, the data protection periods should also apply to information submitted for the purposes of Directive 98/8/EC.’ (Recital 55)
Data Sharing Rules: What Can Be Protected?

- Data requirements are those for:
  - Existing and new AS data (Annex II and Article 6)
  - Existing and new BP data (Annex III and Article 20)

  submitted for BPD/BPR purposes.
Data Sharing Rules: Protection Periods

- All data protection periods start from when data under BPD or BPR is submitted for the first time. No cumulative protection periods once they have expired. (Arts. 60 and 95)

<table>
<thead>
<tr>
<th>ACTIVE SUBSTANCE (AS)</th>
<th>BIOCIDAL PRODUCT (BP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval of a NEW AS</td>
<td>BP with a NEW AS</td>
</tr>
<tr>
<td>15 years</td>
<td>15 years</td>
</tr>
<tr>
<td>from the first day of</td>
<td>from the first day of</td>
</tr>
<tr>
<td>the month following</td>
<td>the month following</td>
</tr>
<tr>
<td>the date of adoption</td>
<td>the first decision</td>
</tr>
<tr>
<td>of AS approval decision (i.e. adoption of Implementing Regulation)</td>
<td>to authorize a BP</td>
</tr>
<tr>
<td>of each AS/product-type combination</td>
<td>(either by a MS authority or by the Commission, Union authorization)</td>
</tr>
</tbody>
</table>

| Approval of an EXISTING AS | BP with ONLY EXISTING AS |
| 10 years | 10 years |
| from the first day of the month following the date of adoption of AS approval of each AS/product-type combination | from the first day of the month following the first decision taken to authorize a BP |

If AS (product-type combination) is not already approved before Sept. 1, 2013, all data protection periods for AS (product-type combination) still under review remain until a (longstop of) December 31, 2025.

| RENEWAL/REVIEW of an AS approval | RENEWAL/AMENDEMENT OF BP AUTHORIZATION |
| 5 years | 5 years |
| from the first day of the month following the decision on renewal/review of an AS | from the first day of the month following the decision on the renewal/amendment of a BP authorization |
Data Sharing Rules: LoA or Hard Copy?

- **Art. 62(2):**

  - ‘Where the data acquired under those tests or studies are still protected… the prospective applicant:
    
    (a) shall, in the case of data involving tests on vertebrates; and
    
    (b) may, in the case of data not involving tests on vertebrates, request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.’

  Ambiguity will be used to argue that hard copies are required.
Data Sharing Rules: LoAs "With Legs"

Data Owner

LoA or Forced Sharing

Substance Supplier or Product Supplier

included in the list

SS or PS "entitled to allow applicants to make reference". [Art. 95(4)]

Applicant for authorisation of a BP 1

Applicant for authorisation of a BP 2

Applicant for authorisation of a BP 3

Applicant for authorisation of a BP 4

Third Party

Sub-licence to customer in own supply chain.
List of Active Substances and Suppliers: Article 95

- Since 1 Sept. 2015 those who (i) do not have access to a "complete substance dossier" and (ii) therefore have not been included on the list of approved sources drawn up by ECHA should be excluded from the market:
  - Biocidal products "consisting of, containing or generating a relevant substance...shall not be made available [i.e. "any supply"] on the market or used unless either the substance supplier or the product supplier is included in the list...for the product-type(s) to which the product belongs".

- Data Submitters: of a "complete dossier" under the Review Programme Regulation (Participants) or Supporters of New AS or "third party" AS dossiers submitted along with a Product authorisation, will also be included in list

- "Substance supplier": "who manufactures [in EU] or imports [into EU] a relevant substance, on its own or in biocidal products"

- "Product supplier": "who manufactures [in EU] or makes available on the market a biocidal product consisting of, containing or generating that relevant substance"

- Any one company may fulfill multiple roles

- However, ECHA allows non-EU suppliers to be on the list via an EU-established representative (see press release ECHA/NA/14/36).
Approved Sources List: Article 95

- **Data Submitters**: of a "complete dossier" under the **Review Programme Regulation (RP Participants)** or Supporters of New AS or "third party" AS dossiers submitted along with a Product authorisation, are also be included in list.

---

**ECHA**

**Entity Name**: LANXESS Deutschland GmbH

<table>
<thead>
<tr>
<th>Product Type:</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Germany</td>
</tr>
<tr>
<td>Supplier Type</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td>Inclusion Reason</td>
<td>RP Participant</td>
</tr>
<tr>
<td>Inclusion Date</td>
<td>24-Sep-14</td>
</tr>
</tbody>
</table>

**Ethanol**

<table>
<thead>
<tr>
<th>Product Type:</th>
<th>1</th>
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<tr>
<td>EC: 200-578-6</td>
<td>CAS: 64-17-5</td>
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<tr>
<th>Supplier Type</th>
<th>Inclusion Reason</th>
<th>Inclusion Date</th>
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<tr>
<td>Accuron Biozide GmbH</td>
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<td>30-Jan-15</td>
</tr>
<tr>
<td>Alcogroup</td>
<td>Substance Supplier</td>
<td>28-Aug-15</td>
</tr>
<tr>
<td>Alcohols Montplet S.A.</td>
<td>Substance &amp; Product Supplier</td>
<td>25-Aug-15</td>
</tr>
<tr>
<td>Alcohols Oliva SA</td>
<td>Substance Supplier</td>
<td>29-Jul-15</td>
</tr>
<tr>
<td>Alcosuisse</td>
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<td>27-Aug-15</td>
</tr>
<tr>
<td>Allia Plc</td>
<td>Substance &amp; Product Supplier</td>
<td>10-Sep-15</td>
</tr>
<tr>
<td>AVT Abfall- und Verpackungstechnik GmbH</td>
<td>Substance Supplier</td>
<td>30-Jan-15</td>
</tr>
<tr>
<td>Azucarera Montero S.A.</td>
<td>Substance &amp; Product Supplier</td>
<td>23-Sep-15</td>
</tr>
<tr>
<td>B. Braun Melsungen AG</td>
<td>Substance Supplier</td>
<td>24-Sep-14</td>
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<tr>
<td>BCD Chemie GmbH</td>
<td>Substance Supplier</td>
<td>31-Aug-15</td>
</tr>
<tr>
<td>Berkel AHK Alkoholhandel GmbH &amp; KG</td>
<td>Substance Supplier</td>
<td>17-Jul-15</td>
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<td>Bemmer Oy</td>
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<td>BODE Chemie GmbH</td>
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<td>Borregaard AS</td>
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<tr>
<td>Brauns-Heitmann GmbH Co. KG</td>
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<td>Brenntag GmbH</td>
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<td>BruggemannAlcohol Heilbronn GmbH</td>
<td>Substance Supplier</td>
<td>08-Jul-15</td>
</tr>
</tbody>
</table>
Approved Sources List: Article 95

- **Data Submitters**: of a "complete dossier" under the Review Programme Regulation (RP Participants) or Supporters of New AS or "third party" AS dossiers submitted along with a Product authorisation, are also be included in list.

<table>
<thead>
<tr>
<th>L-(+)-lactic acid</th>
<th>EC: 201-196-2</th>
<th>CAS: 79-33-4</th>
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<tr>
<td>Purac Bioquimica sa</td>
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<tr>
<th>(9Z,12E)-tetradeca-9, 12-dien-1-yl acetate</th>
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<tr>
<td>Aeroxon Insect Control GmbH</td>
<td>Germany</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td>Gea srl</td>
<td>Italy</td>
<td>Product Supplier</td>
</tr>
</tbody>
</table>
Approved Sources List: Article 95

- Agreement ATD 44/2014 between ECHA and European Commission allows non-EU Representatives

### Symclosene

<table>
<thead>
<tr>
<th>Product Type</th>
<th>EC: 201-782-8</th>
<th>CAS: 87-90-1</th>
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<tr>
<td>3V Sigma SpA</td>
<td>Italy</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td>BAYROL Deutschland GmbH</td>
<td>Germany</td>
<td>Product Supplier</td>
</tr>
<tr>
<td>Bayrol Deutschland GmbH</td>
<td>Germany</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td>Bengbu Jingxian Hongfa Europe Ltd (Acting for Bengbu Jingxian Hongfa Chemical Co. Ltd.)</td>
<td>Ireland</td>
<td>Substance Supplier</td>
</tr>
<tr>
<td>CEHTRA UK Ltd</td>
<td>United Kingdom</td>
<td>Substance Supplier</td>
</tr>
</tbody>
</table>

### Didecyldimethylammonium chloride (DDAC (C8-10))

| Product Type | EC: 270-331-5 | CAS: 68424-95-3 |
|--------------|---------------|----------------|---|
| Lonza Cologne GmbH | Germany | Substance Supplier | RP Participant | 24-Sep-14 |
| Mason Europe Limited c/o Technology Sciences (Europe) Ltd. | United Kingdom | Substance Supplier | RP Participant | 24-Sep-14 |
| Representative to be appointed for Consumer Specialty Products Association (CSPA) (United States) | United Kingdom | Substance Supplier | RP Participant | 24-Sep-14 |
| Representative to be appointed for Mason Chemical Company (United States) | United Kingdom | Substance Supplier | RP Participant | 24-Sep-14 |
| Stepan Europe | France | Substance Supplier | RP Participant | 24-Sep-14 |
Issues For Private Parties
Listed Companies

- You are the only lawful source for the active substances/PT combinations for which you are listed in biocidal products.

- If you are not the direct source to a DU customer, expect to receive requests for confirmation that you are the source of an AS used in a biocidal product.

- Unless there is effective enforcement against non-compliant market actors, the value of your investment and of having given up exclusive use of data is seriously undermined.

- Private “enforcement” of Article 95 becomes essential.

- Supply chains are often complex (both yours and your competitors). This may be (mis-)used to obfuscate the compliance status of biocidal products.

- It is not enough to identify the manufacture of an AS by a non-listed company because the Article 95(2) rule applies to the biocidal products which are “made available”.
Consortia

- Companies have cooperated to build the expensive BPD/BPR dossiers, pooling resources. In order to protect that investment they will have to cooperate again (as they may be doing for product dossiers, post-AS approval).

- Whilst individual companies (especially when the only listed source) may find private enforcement simpler to undertake, groups have to operate in a way which avoids competition/antitrust law pitfalls.

- When you think you have identified a non-lawful source, you will want to make sure that another member of the Consortium is not the 100% lawful source:
  1. Gather data on tonnages of AS supplied to suspect non-listed company by Consortia members (without sharing exact numbers with other members i.e. through a trustee or “black box”) and produce aggregate tonnage for the whole consortium.
  2. Try to gather data on tonnages of AS in biocidal products placed on the market by suspect non-listed company. If available, can be used to carry out an indicative comparison against 1. (If not available, this is a matter to be checked by nat. enforcement authorities).
Pending List Companies

- ECHA has facilitated your commercial position by showing the world that you aspire to being a lawful source. The market is clearly watching.

- Anomaly: after the 1 September deadline this list is still maintained and updated.

- The list creates no rights or legitimate expectations. A final decision still has to be made.

- Your AS “shall not be made available” - any supply. No phase out in the BPR - immediate effect.

- Will need a strategy to respond to customer inquiries. Expect that commercial terms will have to be vigorously negotiated given your market position.

- Source from a listed company as a “stop gap” lawful solution (must be 100%)?
Companies Not Yet On The Pending List

- The same considerations apply as for Pending List companies – no legal distinction.
- Listing needs to be achieved before product can be made available.
- No difference if you are a new supplier or existing who has not managed to be included on the list.
- Position is not helped by delays at the ECHA assessment stage.
Enforcement Policy & Challenges

- Outside “private” enforcement (supply chain policing and informing of customers and enforcement authorities), EU MSs have a free-standing obligation to enforce. Failure to do so would:
  - be a breach of their Treaty obligations
  - expose them to potential infringement proceedings by Commission
  - raise prospect of fines for non-compliance with a Court condemnation of failure to enforce

- Honeymoon periods have been discussed by MSs openly!

- Note for Guidance CA – Sept15- Doc.9.1. outlines “proposal for a structure at EU level for enforcement, controls and monitoring” – a report (after fact finding) is envisaged for 2018!

- A BPR Enforcement Group (“BEG”) to meet 2-4 times/yr. Its 14 objectives include:
  - developing and establishing enforcement strategy at European level
  - proposing, prioritizing and organizing common enforcement projects
  - liaising with industry and stakeholders
Supply Chain Options:
To Be or Not to Be on the Article 95 List
Supply Chain Scenarios: Commodity Active

AS Substance Supplier **not** on Article 95

Product Supplier
**Must** be on the Article 95 list

BP1  BP 2  BP 3  BP 4

*Free choice of TE supplier*
Supply Chain Scenarios: Standard

AS Substance Supplier on Article 95

Product Supplier
Need not be on the Article 95 list

BP1  BP 2  BP 3  BP 4

Tie between regulatory and commercial relationships!
Supply Chain Scenarios: Mixed

AS Substance Supplier 2
not on Article 95

AS Substance Supplier
1 on Article 95

Product Supplier
Only needs to be on the Article 95 list for AS Sup. 2
(or another non-listed source)

BP1  BP 2  BP 3  BP 4

Commercial leverage remains
Lessons Drawn from ECHA Data Sharing Dispute Decisions

- Every effort:
  - By both parties: clear requests (opt-out), clear & proactive replies
  - Fact-based: no *a posteriori* explanation – every documented exchange counts
  - Examination of negotiations having taken place between prospective registrant’s request and dispute initiation (indication of 6-12 months, 12 days premature)
  - Timeliness: start of negotiations, duration of negotiations, pace of negotiations
  - Responsiveness: number of days count, no holidays
  - One attempt and mere assertions (*e.g.* excessively high price, other substance LoAs are less costly) are insufficient – constructive contributions
Lessons Drawn from ECHA Data Sharing Dispute Decisions

Examples of criteria assessments by ECHA

- **Fairness:**
  - Lead registrant’s proposal to accept instalments to take into account SME status counted as effort
  - SME status must be substantiated to justify reductions sought
  - Decisions to refund previous registrants seen as effort
  - Equal sharing “not manifestly unfair” (proof of costs still required)
  - Pay only data required to be submitted (own data, tonnage band)

- **Transparency:**
  - List of studies and breakdown of costs (within one month) = first step
  - Cost sharing mechanism
  - Proof of past expenses
  - Future costs not hypothetical
  - Number and capacity of parties (not name)
Lessons Drawn from ECHA Data Sharing Dispute Decisions

- **Non-discrimination:**
  - Same price irrespective of tonnage band/data requirements
  - Price increase depending on registration date

- **Procedural aspects:**
  - Duty to inquire if there is alternative data in SIEF only prior to testing
  - DSD must be initiated prior to submission of dossier
  - Submission of an incomplete dossier (by reason of DSD) does not affect the right to manufacture or import a substance
  - Parties invited to continue negotiating:
    - If favourable to claimant, on the price and terms of access to non vertebrate data
    - If unfavourable to claimant, to find agreement
  - Very few appeals
Lessons from the BoA (cont’d)

DATA SHARING TERMS

- BoA confirmed that ECHA:
  - Should not assess if the “actual and precise cost of a letter of access is reasonable or justified” (as in Data Sharing Q&A)
  - May make an assessment of whether each of the parties made “every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way”

- BoA takes a holistic approach to “every effort” test without separating the three subcomponents:
  - A fact/case driven analysis as to whether every effort is taken based on the “arguments presented during the data sharing negotiations between the parties” (word for word)
  - Only communications between the parties during data sharing negotiations are examined (confirms ECHA practice on DSD, published in August 2014)
Negotiation Process

- **Essential to set in place standard:**
  - Data sharing agreements
  - Negotiation protocols
  - Cost calculation spreadsheets/baseline data
to allow for rapid responses.

- **Typical stages in process:**
  - Confidentiality Agreement (vanilla or pre-empting negotiations)
  - Agreement on what is sought (list)
  - Delegation of entire process to binding arbitration
  - Exchanges on principles for compensation
  - Review of numbers
  - Review of draft agreement
  - Face to face negotiation
  - Offer to pay
Compensation

Indicative list of issues to consider in negotiations:

- **Scope of rights**
  - Citation or ownership?
  - Geographical spread (EU, EEA, EFTA, EU + US etc?)
  - Purpose (BPR only? BPR + PPP, REACH?)

- **Cost**
  - Distinction between costs & commercial data value
  - Dossier costs versus raw data costs
  - Actual cost (+ inflation) or replacement cost?
  - Management costs (actual or fixed/variable percentage)
  - Risk premium (compare REACH and BPR risk, and nature of study)?
  - Loss of opportunity?
  - Early market access premium?
Compensation

Indicative list of issues to consider in negotiations:

- Dynamic cost formula or static?
  - Reimbursement mechanism for overpaying?
  - Claw-back for underpaying and updates?
  - EU only considerations or discounts for other jurisdictions?

- Other
  - Are you being asked for commercial information not required by BPR (use of black box trustees)?
  - Bundling?
  - Tying data access to supply contracts?
  - Lump sum penalties for change of supplier? Royalty systems to incentivise loyalty to suppliers?
Questions?

dabrahams@steptoe.com
A Practical Introduction to the BPR: Available guidance

Darren Abrahams, Partner
& Indiana de Seze, Senior Associate
Content

1. Formerly Manual of Decisions
2. Extensive guidelines and papers available on Commission’s platform
3. Harmonisation and binding decisions
4. Biocides Enforcement Group
Manual of Decisions

- Now repealed, the Manual of Decision was compiled under BPD with the list of questions and answers received by the European Commission and the competent authorities of the Member states

  https://circabc.europa.eu/d/a/workspace/SpacesStore/d0155521-069e-4e8c-91cc-126006d32a83/Manual%20of%20decisions%20(obsolete%20as%20of%2001.10.2015)

- Rule of consensus: some Member States had “comments”

- Settlement of status of so-called “borderline” products, such as cosmetic products or PPP, or articles.

- Issues:
  - Many internal inconsistencies or flaws in logic because questions were answered as they came
  - No binding nature of MoD: MS could adopt different approaches: no harmonised view
  - Rendered obsolete by BPR in view of the entry in the scope of previously non scope products, such as treated articles, precursors to in-situ generated active substances, etc.
Manual of Decisions

- Repealed officially on 23 October 2015. Companies who, on the basis of the MoD, considered their product to be excluded from the scope of the biocides legislation can contact their national helpdesk to check whether the status has changed.
  - If the product could now fall under the new Biocidal Products Regulation, companies can submit a declaration of interest to notify to ECHA until 30 October 2016 (see Art. 15(a) of Rev Programme Reg).
  - The Commission will then assess and provide ECHA with a list of notifiable active substance/product-type combinations. Companies will have six months from publication by ECHA to notify their intention to submit an application to get their active substance/product-type combination included in the Review Programme.
  - Full application for approval must be submitted within two years.

- The corresponding biocidal products will benefit from transitional measures: it will be possible to make them available on the market and use them in accordance with national laws, until the Commission decides on the approval of the active substance/product-type combination.
Current guidance

- At Competent Authority meetings, a number of issues are discussed from the perspective of the applicability and the enforcement of the BPR.
- Papers are discussed and agreed by themes: no codification or compilation available.
- Several stages are published on public platform: 
  [https://circabc.europa.eu](https://circabc.europa.eu) > Health and Food Safety > Biocides > Library
- Examples of papers agreed at CA meeting:
  - CA-Nov14-Doc.5.8 - Final.rev2 - Implementing the new BPF concept.doc
  - CA-Sept15-Doc.6.2 - Final - Masterbatches.docx
  - CA-Sept15-Doc.4.3 - Final - Article 95 implementation and enforcement - In situ.doc
  - CA-Sept13-Doc 5.1.e (Rev1) - treated articles guidance.doc
New source of guidance on biocides: ECHA

- ECHA now publishes technical and other guidance

<table>
<thead>
<tr>
<th>Volume I Identity/phys-chemical/analytical methodology</th>
<th>Volume II Efficacy</th>
<th>Volume III Human health</th>
<th>Volume IV Environment</th>
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<tr>
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<td>Part B Under development</td>
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<tr>
<td>Part C Under development</td>
<td>Under development</td>
<td>Under development</td>
<td>Under development</td>
</tr>
</tbody>
</table>

**Volume V Specific Guidance**

- Active substances and suppliers (Article 95 list) | Guidance
- Technical equivalence | Guidance
- Micro-organisms | Guidance
Problem with guidance

- Guidance is by definition non binding on any other person than its author
- Affects the legal situation of a person by creating rights
- When guidance is revised: when does it apply?
- What when it contradicts the legal text?

- Example: Article 95 applies to “persons established within the Union who manufacture or import a relevant substance”. The applicable guidance (http://echa.europa.eu/documents/10162/15623299/biocides_guidance_active_substance_suppliers_en.pdf) extends to non EU manufacturers also.

- What if guidance is overturned by case law of the EU courts?
  - Söll case redefined biocidal products to cover “even products which act only by indirect means on the target harmful organisms, so long as they contain one or more active substances provoking a chemical or biological action which forms an integral part of a causal chain, the objective of which is to produce an inhibiting effect in relation to those organisms” Case C-420/10: Judgment of the Court (Third Chamber) of 1 March 2012 (reference for a preliminary ruling: Landgericht Hamburg – Germany - Söll GmbH v Tetra GmbH)
Problem with guidance

**Thor Germany** (1 August 2013)

- Confirms applicability of Legal Certainty requirements. Whilst it is the **duty of every company to know the obligations imposed on them, rules should be clear and precise**, so that individuals may be able to ascertain unequivocally what their rights and obligations are and may take steps accordingly.

- **Guidance** that even a diligent and prudent registrant exercising a reasonable level of due care could have misunderstood failed this requirement - led to annulment of a decision.

*Legal certainty does not permit a ‘we all know what it is supposed to say’ approach* to interpretation and enforcement of the BPR. This does not exclude a sincere purposive/teleological reading of the BPR (but it has to be well founded rather than just asserted).
Problem with guidance

*N.V. Elektriciteits Netherlands* (10 October 2011)

- Confirms obligation to keep guidance up to date and that any changes are communicated in a clear and accurate manner to those affected by it.

- Guidance does not constitute a source of law, which would be comparable to legislation but if published, can nevertheless bind the administrative body in question. Where ECHA has decided to publish guidance its conduct can be confined by such guidance. This flows from the creation of a legitimate expectation, legal certainty and equal treatment/non-discrimination.
Harmonisation through binding decisions

- Article 3(3) BPR allows Commission to adopt decisions on specific cases

  The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard in particular to Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, and whether a specific product or group of products is a biocidal product or a treated article or neither. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3)

- Applicable throughout EU: level playing field

- Can be challenged before General Court in Luxembourg: no suspensive effect
Harmonisation through binding decisions


- Commission Implementing Decision (EU) 2015/646 of 23 April 2015 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on bacterial cultures intended to reduce organic solids and to be placed on the market for that purpose.
BEG

- MSCAs and Commission agreed mid-November on set up of Biocides Enforcement Group, separate from ECHA’s enforcement forum.
- They may be reconciled after 2 or 3 years
- BEG may help in harmonising enforcement approaches to issues which are the subject matter of non-binding guidance or no guidance
Look here

• Commission website on biocides:
  • http://ec.europa.eu/environment/biocides/

• CIRCABC public space on biocides:
  • https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

• ECHA website & Helpdesk on Biocides:
  • http://echa.europa.eu/regulations/biocidal-products-regulation

• Steptoe Biocides News & Briefs:
  • http://www.steptoe.com/biocides-news-and-briefs
Questions?

dabrahams@steptoe.com