Navigating transitional issues under the BPR and the role of ECHA

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Outline

- BPR transitional provisions concerning:
  - evaluation of active substance dossiers and complete and incomplete BPD product authorisation applications
  - biocidal products authorised under national transitional regimes containing existing actives awaiting approval
  - new types of biocidal products not in the scope of the BPD
  - active listing requirements concerning treated articles which are not biocidal products
  - requirement for BPR compliant labelling (Article 69 and 58)
  - new active substance data requirements.

- Issues where BPR silent and/or where clarification needed

- ECHA’s new responsibilities under BPR

- Latest information on ECHA fees re BPR
Themes re transitional periods

- Recurrent factors determining applicable transitional periods:
  - type of product (biocidal product, treated article, active)?
  - product already on the market on the 1 September 2013 (BPR application date)?
  - product authorisation or active approval (treated articles) submitted by BPR specified deadline?
  - existing stock disposal and use periods?
Status of national transitional product authorisations (Article 89)

- Article 89(2) similar to Article 16(1) BPD
  - products containing existing actives awaiting approval for relevant product type can remain on national market until the approval or non-approval decision
  - depends on individual MS system

- In case of existing active approval:
  - can remain on market until MS decides on product authorisation (‘within 2 years of date of active approval’)
    • where BPR authorisation application submitted prior to active approval date
    • no marketing gap if authorisation granted
  - authorisation refused/application rejected = prohibited on market 180 days after decision/365 days for disposal and use of existing stocks
  - no ability to submit authorisation application post active approval date (new products)?
Status of national transitional product authorisations (Article 89)

- 2 years enough time to process authorisation application?
- no authorisation application submitted prior to active approval date = product prohibited on market 180 days after date of active approval /365 days for disposal and use of existing stocks

- In case of existing active non-approval:
  - marketing permitted until 12 months from non-approval decision

- Subject to active manufacturer or importer being on published source list (Article 95)

- Extension of duration of existing actives review past May 2014 anticipated: specific Commission measures.
Evaluation of active substances (Article 90)

- Phased in role of ECHA Biocidals Products Committee - evaluation coordination and facilitation through organisational and technical support to MSs and Commission:
  - from 1 September 2013: for new active dossiers submitted post September 1, 2012
  - from 1 January 2014: for earlier submitted incomplete new and existing active BPD dossiers (‘historical dossiers’ majority)

- Active dossiers where Member State evaluation incomplete at 1 September 2013 completed according to BPR:
  - applicant able to submit further information to address new BPR requirements

- Significant exclusion or substitution implications:
  - excluded actives (CMR, PBT, vPvB, endocrine disruptors)
    - approved only exceptionally and, if so, for 5 years maximum
Evaluation of active substances (Article 90)

- candidates for substitution (excluded substances, respiratory sensitisers, low ADI/AOEL, specific exposure concerns)
  - ECHA opinion on candidate approval/renewal considers and consults on substitutes
  - maximum 7 years approval/renewal

- New nanomaterials requirement:
  - not covered by active approval unless specified
  - separate risk assessment requirement for products containing

- Commission may review active approval at any time when significant safety concerns (cancellation or amendment)

- ‘Every effort shall be made to avoid causing delays to the review programme…’
Transitional procedures – biocidal products (Article 91-93)

- Evaluation of biocidal product authorisation applications submitted under BPD completed according to BPD (Article 91), BUT:
  - more expansive BPR authorisation conditions (Article 19) apply if excluded active (for example, vulnerable groups such as pregnant women and children)
  - BPR comparative assessment procedure applies if product contains candidate active
  - applicant able to submit further information relevant to application of new provisions
  - incomplete registrations (low risk product) post 1 September 2013?

- Biocidal products already authorised/registered under BPD remain on market until authorisation expiry/cancellation BUT subject to BPR from September 1, 2013 (Article 92):
  - which provisions?
    - comply with supplementary Article 19 conditions when amend existing authorisations?
    - BPR labelling applies immediately?
Transitional procedures – biocidal products (Article 91-93)

- Biocidal products not in scope of BPD (some in situ products, treated articles with a primary biocidal function etc.) (Article 93):
  - specific longer transitional periods (reflect first time obligation) only where already on market
  - remain on market until product authorisation decision, provided authorisation application submitted by September 1, 2017
  - placing on market permitted until 180 days after any decision refusing authorisation
  - if no authorisation application, marketing permitted until 180 days after 1 September 2017
  - disposal and use of existing stocks until later of (i) 365 days from authorisation refusal decision or (ii) 12 months + 180 days after 1 September 2017
  - products not already on market on 1 September permitted only after authorised — arbitrary distinction depending on date of placing on market?
    • reliance on Article 89(2)?
Transitional procedures – Treated articles (which are not biocidal products) (Article 94)

- Treated articles without primary biocidal function (actives treated with or incorporated must be on Union List or in Annex I (Article 58(2)):
  - transitional period only if already on market
  - effective ban on new treated articles until active(s) approved
  - different provisions regarding *existing* or *new* actives with which treated article treated or incorporates
  - new actives:
    - may continue to be marketed until relevant active approval decision, provided approval application submitted by September 1, 2016
    - if no approval application submitted, prohibited from September 1, 2016
    - placing on market permitted until 180 days after any active non-approval decision
  - existing actives:
    - may continue to be marketed until relevant active approval decision (application already submitted under existing actives review)
    - placing on market permitted until 180 days after any active non-approval decision or, if later, by 1 September 2016
  - no disposal or use of existing stocks provision? (Article 52 limited to biocidal products)
Transitional measures: new active data access requirements (Article 95)

- Persons (EU M/Is) placing active substance on EU market (as such or in biocidal products) (‘relevant persons’):
  - submit to ECHA active dossier, LoA (ECHA may force data sharing) or a reference to dossier for which data protection periods have expired
  - from September 1, 2015: marketing prohibition on products for which M/I of contained active product or product importer not on published source list (existing stocks disposal and use until 1 September 2016)
  - level playing field for those placing actives on market - end to free riding non-participants in existing active review

- Not applicable to:
  - most BPR Annex I low risk actives
  - actives in treated articles without primary biocidal function (only biocidal products)
Transitional measures: new active data access requirements (Article 95)

- List includes:
  - relevant persons having submitted Article 95 dossier, LoA or reference under Article 95
  - (automatically) participants supporting relevant existing active under the existing active substances review
  - automatic inclusion of relevant persons who have submitted active dossiers/LoAs under BPD/BPR requirements other than review (supporting new actives)?

- Parties other than M/I of actives or importer of product to submit?
  - downstream product formulator with a letter of access if supplier not listed?

- Right of grantee of letter of access to permit applicants for authorisation of a biocidal product containing active to refer to letter for purposes of application (supply chain specific?)

- Listing distinct from technical equivalence: listed ≠ Annex I/Union list approved
Transitional periods for new BPR labelling requirements

- When is relabelling according to new BPR labelling requirements (Art 69: authorisation holder details, nano materials/Article 58 treated articles) necessary?

- Biocidal products within scope of BPD:
  - not already BPD authorised (authorised under national schemes) as of 1 September 2013: only on placing on market post BPR authorisation (Article 69 obligations are imposed on BPR ‘authorisation holders’)?
  - already BPD authorised and on the market: from 1 September 2013 (literal reading of Article 92(2))

- Biocidal products outside scope of BPD:
  - only on placing on the market post BPR authorisation (no obligation to BPR relabel products already on market during transitional period pending BPR authorisation?)
Transitional periods for new BPR labelling requirements

- Treated articles without a primary biocidal function:
  - only on placing on the market post approval of relevant actives (no obligation to BPR relabel articles already on market during transitional period pending active(s) approval)?

- Where existing products remain on the market post authorisation or active approval, as appropriate:
  - need to relabel only future supplies placed on market, or also existing BPD labelled stocks already on the market?
# ECHA role in product authorisation and active approval (I)

<table>
<thead>
<tr>
<th></th>
<th><strong>ACTIVE SUBSTANCE APPROVAL FOR SPECIFIED PT</strong></th>
<th><strong>NATIONAL BIOCIDAL PRODUCT AUTHORISATION</strong></th>
<th><strong>Simplified Biocidal Product Authorisation</strong></th>
<th><strong>Product Mutual Recognition in Sequence</strong></th>
<th><strong>Product Mutual Recognition in Parallel</strong></th>
<th><strong>Union Authorisation of Biocidal Products</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAXIMUM APPROVAL PERIOD (YEARS)</strong></td>
<td>10 (5 if contains candidate for substitution)</td>
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</tr>
<tr>
<td><strong>CONTENTS OF APPLICATION</strong></td>
<td>Dossier for active and representative biocidal product (potential data waiver/adaptation)</td>
<td>- Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
<td>- Summary of product characteristics in appropriate language(s)</td>
<td>Translation of national authorisation granted in reference MS into relevant official languages</td>
<td>To chosen evaluating CA ('reference MS'):</td>
<td>- Dossier/LoA for product and each active (potential data waiver/adaptation)</td>
</tr>
<tr>
<td></td>
<td>Support for exceptional approval of excluded substances</td>
<td>- Summary of product characteristics in appropriate language(s)</td>
<td>- Efficacy data (potential data waiver/adaptation)</td>
<td>- Information evidencing eligible for simplified procedure in appropriate language(s)</td>
<td>- As for national or simplified product authorisation, as appropriate</td>
<td>- Summary of product characteristics</td>
</tr>
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<td></td>
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<td>- Confirmation that not applied to other CA</td>
<td></td>
<td>- Confirmation that not applied to other CA</td>
<td>- List of other MSs where national authorisation sought</td>
<td>- Confirmation of similar conditions of use across Union in appropriate language(s)</td>
</tr>
<tr>
<td><strong>APPLICATION SUBMITTED TO</strong></td>
<td>ECHA, with confirmation of evaluating CA</td>
<td>Chosen CA where want to market product</td>
<td>ECHA, with confirmation of evaluating CA</td>
<td>Each CA of countries (other than reference MS) where want to market</td>
<td>Simultaneously to reference MS and other MSs concerned (see above)</td>
<td>ECHA, with confirmation of which CA has agreed to evaluate</td>
</tr>
<tr>
<td></td>
<td>Application accepted on receipt of fee within 30 days of informing applicant</td>
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</tr>
<tr>
<td><strong>VALIDATION BY</strong></td>
<td>Chosen CA within 30 days of ECHA acceptance</td>
<td>Chosen CA within 30 days of acceptance</td>
<td>No formal validation stage</td>
<td>Each CA within 30 days of its acceptance</td>
<td>Evaluating CA ('reference MS') within 30 days of its acceptance</td>
<td>Chosen CA within 30 days of ECHA acceptance subject to payment of CA fee</td>
</tr>
<tr>
<td></td>
<td>Applicant to provide missing information within normally max 90 days</td>
<td>Decline to evaluate if same product/use already subject of authorisation application with another authority</td>
<td>Applicant to provide missing information normally within max 90 days</td>
<td></td>
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# ECHA role in product authorisation and active approval (II)

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<tr>
<th><strong>Active Substance Approval for Specified PT</strong></th>
<th><strong>National Biocidal Product Authorisation</strong></th>
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<tr>
<td><strong>EVALUATION</strong></td>
<td>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</td>
<td>Chosen CA within 365 days of validation (or longer where further info required) Applicant to provide missing information within normally max 180 days</td>
<td>Reduced evaluation by chosen CA (&quot;verification of eligibility&quot; for simplified authorisation) within 90 days of accepting application (or longer where further information required) Applicant to provide missing information within normally max 90 days</td>
<td>CAs agree summary of product characteristics within 90 days of validation and record agreement in Register for Biocidal Products Coordination group (including applicant) and Commission resolution procedure if MS objection that safety authorisation conditions not met Commission resolution procedure (including applicant) for mutual recognition derogation (public policy, public security, protection of environment, etc.)</td>
<td>Evaluating CA (&quot;reference MS&quot;) within 365 days of validation Same coordination and resolution procedures as per &quot;in sequence&quot; Drafts assessment report, conclusions and reasons for granting or refusing authorisation Send assessment report and summary of product characteristics to other MSs and applicant 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 Reference MS to enter report and summary and any conditions on marketing and use in Register Chosen CA within 365 days of validation of application Applicant to provide missing information within normally max 180 days Applicant written comments on evaluation conclusions during 30 day period Chosen CA send assessment report and conclusions to ECHA, taking into account applicant comments ECHA prepare and submit to Commission opinion on authorisation of product within 180 days of receipt (including any conditions on marketing or use)</td>
</tr>
<tr>
<td><strong>APPROVAL/NON-APPROVAL</strong></td>
<td>Commission adopt approval Regulation or non-approval decision Approved substances in public Union list of authorised active substances</td>
<td>Chosen CA: - drafts assessment report with conclusions and reasons for granting or refusing authorisation; - send electronic copy to applicant requesting comments within 30 days; - finalises report taking account of conclusions.</td>
<td>Provided eligible, chosen CA must authorise within 90 days of acceptance of application or of submission of additional information requested by applicant</td>
<td>Each CA to authorise biocidal product within 30 days of agreement on summary and in conformity with summary In absence of agreement between all CAs, CAs agreeing to summary may authorise product</td>
<td>All relevant MSs to authorise biocidal product within 30 days of agreement on summary and in conformity with summary If absence of agreement between all CAs, those CAs agreeing to summary may authorise product</td>
</tr>
</tbody>
</table>
ECHA role in BPR procedures (I)

- Approval of active substance:
  - initial receipt and acceptance of applicant approval dossier
  - European Biocidal Products Committee prepares opinion on CA evaluation – basis for Commission decision
  - opinion includes identification of candidates for substitution
  - existing active applications under BPR from 1 January 2014 (replace DG JRC)

- BPR product authorisations:
  - Union authorisation (union wide, avoids national + mutual recognition need)
    • similar ECHA procedural role as for active approval
    • phased in for different PTs between 1 September 2013 and 1 January 2020 to permit development of ECHA capacity/experience
  - Simplified authorisation
    • initial receipt and acceptance only, prior to reduced CA evaluation
  - Mutual Recognition
    • provide Commission with technical/scientific opinion where MR disagreements not resolved in Coordination Group
ECHA role in BPR procedures (II)

- **Technical Equivalence:**
  - is your active the same as Union list (BPD Annex I) approved (reference) active?
  - when needed?
    - where active source other than applicant for BPD Annex I inclusion
    - where same source but change in manufacturing process or location
  - application to ECHA with fee and relevant info
  - ECHA two tier procedure:
    - Tier 1 analytical data assessment
    - Tier 2 hazard profile (phys-chem and ecotox data) assessment only if no Tier 1 equivalence found
    - decision within 90 days

- **Active Data Access (Article 95):**
  - receives active dossier, LoA or dossier reference
  - publishes source list
ECHA role in BPR procedures (III)

- Data sharing compensation:
  - includes permitting applicant to refer to data in absence of parties’ agreement (Article 63(3))

- Maintain Register for Biocidal Products:
  - exchange of information between CAs, ECHA, Commission and applicants including applications
ECHA fees under BPR

- Article 80 BPR: anticipated Commission specification of ECHA fees concerning BPR responsibilities:
  - includes Union authorisation, technical equivalence, source list applications, appeals
  - one fee per applicant for joint active approval
  - SME reductions
  - ‘in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived’ (Art. 80(2)(e))
    - use of fees to deter/encourage: carrot or stick
    - reimbursement of substitutable actives (for excluded active) approval application fee
    - increased fees for approval of active candidates for substitution
    - no SME reduced fee for products containing candidate actives
    - appeal fee reimbursed where appeal well founded
    - partial fee refund if rejected during validation or withdrawn after submission
Craig Simpson

- UK qualified solicitor and senior associate in Steptoe’s Brussels office
- Practice focuses on EU regulatory requirements and related commercial issues in the life sciences field and EU competition law
- Clients include leading multinational companies and trade associations operating at both European and international levels
- Regularly lectures and publishes on matters affecting the life sciences industries
- Consistently recommended as a leading practitioner in the Global Counsel Which Lawyer? Yearbook for EU Life Sciences