Regulation on the making available and use of biocidal products (BPR) and Wood Preservation

WEI Meeting
Brussels, Belgium
30th March 2017
I – State of implementation of BPR, overall progress

II – Status of Wood preservatives PT08: approvals of AS, authorisation of BP

III – PT08: start of renewal of approvals of AS
I – State of implementation of BPR, overall progress
Application of the BPR

- Regulation (EU) No 528/2012 (BPR) adopted 5 years ago, entered into application on 1st September 2013

- Compared to Directive 98/8/EC, evolutions:
  - New procedures:
    AS approval procedures, National authorisation / mutual recognition procedures, Union authorisation (PT08 in 2020), Applications to ECHA for technical equivalence (art. 53), Applications to ECHA for registration on the AS suppliers list (art. 95), etc.
  - New principles:
    Exclusion (C/M/R, PBT/vPvB, ED) / substitution of active substances, comparative assessment of biocidal products, treatment and Labelling provisions of treated articles (art. 58), mandatory data sharing of data on vertebrates (art. 62), etc.
Obligations

- For all parties involved: Industry, Member States, Commission, ECHA
- For Industry:
  - Compliance with basic provisions of the BPR (e.g.: AS in the review programme, transitional measures/systems in Member States, need for BPR authorisation, procedures, etc.)
  - Compliance with the sources of active substances contained in BPs, list of suppliers of AS (art. 95)
  - Provisions on R&D (art. 56)
  - Compliance with treatment or incorporation in Treated Articles of AS supported in EU (art. 58 + transitional measures 94)
  - Compliance with labelling of Treated Articles *when needed* (art. 58)
  - Authorisation holder:
    - Classification & Labelling (art. 69)
    - Information of any adverse effect (art. 47)
    - Holding a register during the validity of the authorisation + 10 years after the end of validity (art. 68)
    - Quality compliance for manufacturers (art. 65)
    - Notification for poisoning surveillance (art. 73), etc.
Implementing legislation

✓ Regulation on changes to product authorisation: Reg. (EU) No 354/2013 of 18th April 2013
✓ Regulation on authorisation of same biocidal products: Reg. (EU) No 414/2013 of 6th May 2013
✓ Regulation on fees to ECHA: Reg. (EU) No 564/2013 of 18th June 2013
✓ Regulation on the extension of duration of review programme to 2024: Reg. (EU) No 736/2013 of 17th May 2013
✓ Regulation on the modification on data requirements (proof of technical equivalence in BP applications): Reg. (EU) No 837/2013 of 25th June 2013
✓ Regulation on the procedures for the renewal of authorisations by mutual recognition: Reg. (EU) No 492/2014 of 7th March 2014
Policy definition

- A lot of positions, procedures, approaches agreed in CA meetings

"Finalised documents" : [https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a](https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a)
Commission guidance

- Guidance documents on various topics, for instance:
  - *Document on biocidal product families (last update March 2016):*
    https://circabc.europa.eu/w/browse/3a0f9434-a4aa-4cdf-9be3-7c60b784a6de
  - *Guidance on treated articles (November 2014 version):*
    https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22
  - *Document on comparative assessment (May 2015 version):*
    https://circabc.europa.eu/w/browse/c309ae58-bdd7-421d-a678-8d8ac361d4e0
  - *Guidance on similar conditions of use, for the Union authorisation:*
    https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e
• **Practical Guide on BPR: Special Series on Data Sharing (April 2015 version):**
  - *Introduction to the BPR and SME considerations*
  - *Data Sharing*
  - *Letter of access*
  - *Consortia*

Focus : Treated articles (Chap. XIII, art. 58)

**Objective:** Ensure protection of health and the environment in EU, ensure better competition between treated articles that are treated in EU and those treated outside EU, better information of customers/consumers

- **Definition of "treated articles"** (e.g. treated wood):
  - Substance, mixture or article (according to REACH definitions)
  - Treated with or intentionally incorporating biocidal products

- **Allowed on the market only** if all the active substances contained in the BP are approved for the relevant product type or included in Annex I to the BPR, and it complies with relevant conditions of approval of the AS

- **Guidance on Treated articles "CA-Sept13-Doc 5.1.e (Rev1) - treated articles guidance.doc", borderline BPs/TA (revision 2014):**
  - [https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22](https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22)
Labelling of certain treated articles

- **Required if**
  - Case 1: Claim is made regarding **biocidal properties of the article** (e.g. wood protected against attacks of insects etc.)
  - or
  - Case 2: Conditions of **AS approval** so requires

- **Information to be provided in the national language:**
  1. Statement that article incorporates biocides
  2. Biocidal property of the article (e.g. wood protected against attacks of insects, etc.)
  3. Name of all active substances and all nanomaterials (e.g. treated with [name of AS], incorporate [name of nano] as a nanomaterial, etc.)
  4. Instructions for use to protect man and environment, where appropriate (e.g. to protect the environment, the wood cannot be used for outdoor constructions, etc...)

- **Outside these 2 cases:** Instructions for use to protect man and environment where appropriate (see point 4 above)

- **Obligation for suppliers to give some information at the request of a consumer within 45 days** (i.e. similar to provisions in Article 33(2) of REACH)
Application

- **Provisions applicable since 1st September 2013, in particular concerning labelling provisions**

- **Transitional provision between 2013-2017 on active substances allowed (see Art. 94)**
  - **As from 1st March 2017:**
    Only treated wood with active substances approved, included in Annex I or under evaluation on 1st September 2016 can be placed on the EU market (i.e. first supply, what is already in the chain of distribution can continue to be supplied)

- **Information on the ECHA website**
II – Status of Wood preservatives

PT08: approvals of AS, authorisation of BP
Progress on the review programme of existing active substances

- Objective: around 620 evaluations to finalised by 2024 for all PTs (disinfectants, preservatives, pest control, others)
- March 2017: 33% of finalised evaluations (i.e. decisions adopted)

→ 95% for PT08 wood preservative active substances
PT08 Actives substances

- Most PT08 active substances have been reviewed and a decision on the approval has been taken.

- Only a 2 wood preservative active substances remain under assessment/peer review:
  - Didecylpolyoxethylammonium borate, CAS No 214710-34-6 (eCA= EL)
  - N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine, CAS No 2372-82-9 (eCA = PT)

- Progression of the whole review programme:
  - Document "CA-March17-Doc.5.1 - Progress of the RP of AS_rev1"

https://circabc.europa.eu/w/browse/2bf86ab4-a8e3-4bac-9747-25ed9aec3060
# PT08 Approved actives substances

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<th>Name of AS</th>
<th>Year of decision</th>
<th>No</th>
<th>Initial duration of approval (in years)</th>
<th>Date of approval</th>
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<td>Coco alkyltrimethylammonium chloride (ATMAC/TMAC)</td>
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Additional information on the review programme

- Information on ECHA website (assessment reports, approval/non approval decisions etc.):
  

PT08 product authorisation stage

- Possibility for:
  - National authorisation
  - Mutual recognition in parallel
  - Mutual recognition in sequence
  - Union Authorisation may be granted as from 2020
  - (Simplified authorisation procedure if AS in Annex I)

+ Changes, same biocidal products…

→ Most applications: Mutual recognition in parallel, as existing products need to be authorised on the market of several Member States


- In addition, it can be granted for:
  - Single biocidal product
  - Biocidal product family (same AS, similar composition, similar uses, similar risk and efficacy)
    - E.g. family of different colours of a wood preservative formulation
Overview on BP authorisation:
CA-March17-Doc.4.7 - executive report on product authorisation.docx
https://circabc.europa.eu/w/browse/e448e653-c3ea-41fb-a27c-baa7a06b39ee

Number of authorised products in the EU according to the BPD/BPR by product type

The numbers cover all active product authorisations. Assets that have multiple product types are counted multiple times in the report.
Specific case: AS meeting the exclusion criteria

**Objective:** Forbid the making available on the market of BP with AS meeting the exclusion (and substitution) criteria, to promote substitution and innovation

- Art 10(1)(a): substances that meet the exclusion criteria (CMR 1A/1B, PBT/vPvB, Endocrine disrupters), but which are nevertheless approved due to the derogations established under article 5(2), or which were/are approved under the principles of directive 98/8 (in particular substance for which the draft report from the MS were submitted before 1st September 2013)
  - For PT08: Creosote, Disodium tetraborate, Disodium octaborate tetrahydrate, Boric acid, Boric oxide, cyproconazole, propiconazole (recent proposal for classification R1B)

- It shall be noted that products shall normally not be authorised:
  - Products shall only be authorised in the Member State(s) in which at least one of the conditions for derogation to exclusion mentioned in Article 5(2) is met:
    - Negligible risks, no exposure of human/animal/environment (e.g.: closed systems)
    - Essential for public or environmental health reasons
    - Disproportionate negative impact on Society compared to the risks of using the substance/product

- Applicants are excepted to submit additional information to defend their application to allow the evaluation to be made under point 10 of Annex VI of the BPR
  - E.g. for creosote, an analysis regarding the technical and economic feasibility of substitution considering the specific situation of each of the MS where an application is made
PT08 product authorisation stage: Comparative assessment

**Objective:** Forbid or restrict the making available on the market of BP with AS candidate for substitution, to promote substitution and innovation

- Active substances in red and in orange (slide 16):
  - **Candidates for substitution**
    List: [https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d](https://circabc.europa.eu/w/browse/e379dc27-a2cc-46c2-8fbb-46c89d84b73d)

- Products containing candidates for substitution are subject to a comparative assessment before authorisation and at the renewal
  **Prohibition or restriction if:**
  - Alternatives
    - Present significantly lower risk
    - Are sufficiently effective, and
    - Present no significant economic or practical disadvantage, and
  - Chemical diversity adequate to minimise resistance

**Guidance:** [https://circabc.europa.eu/w/browse/c309ae58-bdd7-421d-a678-8d8ac361d4e0](https://circabc.europa.eu/w/browse/c309ae58-bdd7-421d-a678-8d8ac361d4e0)
Conclusion on Exclusion/ Substitution provisions

→ Strong incentives to substitute
III  – PT08: Start of renewal of approvals of AS
Start of the renewal of approval process

- For the first PT08 AS which were approved under Directive 98/8/EC

- Deadline for the submission of applications for:
  - 2016: Creosote
  - 2017: Sulfuryl fluoride, Dichlofluanid
  - 2018: Thiaclorpid, Chlothianidin, Etofenprox, Propiconazole, Tebuconazole, Thiametoxam, IPBC, K-HDO, Thiabendazole
  - 2019, 2020....

- Substance under exclusion and substitution: higher scrutiny for the renewal

- Additional guidance on renewal (under finalisation):
  CA-March17-Doc.5.4 - AS renewals 2016-2020.doc
  https://circabc.europa.eu/w/browse/e448e653-c3ea-41fb-a27c-baa7a06b39ee
AS under exclusion (in red)

- **Approval should not be renewed** unless one of the conditions of Art 5(2) is met

- **Applicants** shall provide evidence in the application:
  - Thoroughly investigate whether one of the conditions set out in Article 5(2) is met, for which precise use(s) within the relevant product-type. These elements should be included in the application for renewal, as well as during the public consultation phases for transparency to third parties.

  - For each of those uses referred above that he considers meeting the conditions set out in Article 5(2), propose appropriate risks mitigation measures to ensure that exposure of humans and environment is minimised.
AS under **exclusion** (in red)

- Importance of **public consultations** during the examination:
  - Performed by ECHA during the BPC review: to gather information on **alternatives or absence of alternatives**
    

  - Performed by ECHA on behalf of COM after the BPC opinion: to gather information whether the conditions of article 5(2) for **derogation to exclusion are met or not met**

  ➞ Must be followed closely by the sector

  ➞ Sector and stakeholders are asked to provide useful information (alternatives or absence of alternatives AND for which precise uses) and justifications

  ➞ Information collected are used by Authorities for the decision making process
AS under exclusion (in red)

- If conditions of Article 5(2) for derogation are **not** demonstrated
  - Ban, no renewal possible.
  - Wood preservative products must be removed from the EU market
  - Treated articles can no longer be placed on the EU market.

- If conditions of Article 5(2) for derogation are demonstrated
  - Renewal may be possible for a maximum period of 7 years (instead of 15 years for "normal" substances)
  - Strict conditions and restrictions
  - Renewal of BP autorisation may be possible in relevant Member States for 5 years (applications must be submitted)
  - Treated articles must be compliant with conditions set in the approval
  - **Need for Industry to invest in R&D on chemical and non-chemical alternatives**
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<tr>
<th>Name of AS</th>
<th>Initial duration of approval (in years)</th>
<th>Expiry date of approval</th>
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Conclusion
- Significant progress on PT08 products over the past years

- **Wood preservatives AS:**
  - 2 active substances still under review
  - Start of the renewal of approval of PT08 active substances

- Starting in 2020 of Union authorisations

→ BPR: fully operational on wood preservatives
Thank you for your attention

For further information:

Commission website:

https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b
(Sante-Biocides@ec.europa.eu)

ECHA website & Helpdesk on Biocides: