Overview of the BPR and Authorisation procedures

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I – Overview: key elements of the BPR and on-going tasks for the implementation

II – Main procedures for the authorisation of BPs

III – Focus on the list of suppliers of AS (Art. 95)
I – Overview: Key elements of the BPR
Biocides Regulation

- Regulation (EU) 528/2012 (BPR) : entered into application on 1st September 2013
  → Lastly amended by Regulation No 334/2014 of 11 March 2014

- A lot of provisions are now applicable:
  - Use of the various procedures for new applications
    - AS approval procedures
    - National authorisation / mutual recognition procedures
    - Possibilities to apply for Union authorisation for PT1, 3, 4, 5, 18, 19 (art. 42)
    - Possibilities to apply for a authorization via a simplified authorisation procedure (art. 26)
    - Possibilities for parallel trade (art 53)
    - Applications to ECHA for technical equivalence (art. 54)
    - Applications to ECHA for registration on the AS suppliers list (art. 95)
    - Etc.
Application of the BPR

- New principles:
  - Exclusion / substitution of active substances (Art. 5 / 10)
  - Comparative assessment of biocidal products containing AS meeting the substitution criteria (Art. 23)
  - Nanomaterials excluded if not explicitly covered in the approvals of AS
  - Labelling provisions of treated articles (Art. 58)
  - Mandatory data sharing of data on vertebrates (Art. 62)
  - Mandatory data sharing of all toxicological and environmental data for the sake of the listing on the AS supplier list of ECHA (art. 95)
  - Data protection periods (Art. 60)
  - Evolution of scope and transitional provisions (Art. 93):
  - Role of ECHA in the biocides framework
  - Etc.
Obligations

For all parties involved: Industry, Member States, Commission, ECHA

For Industry:

- Compliance with "basic" provisions of the BPR (ex: AS in the review programme, transitional measures/systems in Member States, if no BPR authorisation when needed no making available on the market possible etc.)
- Compliance with the procedures (timing for submitting application, additional data, fee payments etc…)
- As from 1st Sept. 2015, making available on the market possible only if the source of AS is on ECHA's list (art. 95)
- Provisions on R&D (art. 56)
- Compliance with treatment or incorporation of AS supported in EU in Treated Articles (art. 58 + transitional measures 94)
- Compliance with labelling of Treated Articles when needed (art. 58, no transitional measures)
- Authorisation holder of BPR authorisations:
  - 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 of BPs (art. 65)
  - Notification for poisoning surveillance (art. 73), etc.
Transitional period

To achieve the objectives of the Regulation

On the big picture, probably until 2024? : when the last BP on the EU market is authorised according to the harmonised EU regulation, and no more subject to the national systems of MSs

"Transitional" provisions (Article 89 to 95), mostly to :
- manage the review programme of AS and transition to BPR authorisations
- manage the change of scope on BPs from the BPD to BPR (mainly on in-situ generation), and allow a transition for concerned AS and BPs
- manage the change of scope on Treated articles (TA) from the BPD to BPR
- manage the transition for the compliance of the source of AS, to ensure that all BPs made available on the EU market are compliant as from 1st Sept 2015
Implementation

- A lot of work on-going at EU level in order to implement the BPR and continue the construction of the biocides framework
- 42 tasks foreseen directly in the BPR (delegated/implementing acts, guidelines)
- Coordination COM/ECHA, involvement of MS and IND
- Some tasks with COM as leader, other with ECHA as leader

Overview:
https://circabc.europa.eu/w/browse/7c9f6736-1cb1-451f-8ed1-d2bcfcaaa870
(see CA-Sept13-Doc.5.1.a - Preparatory actions.pdf)
Implementing legislation

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

✓ Regulation 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: under formal process of adoption, publication around May 2014

✓ Regulation on the organisation of the review programme of active substances (to replace Reg. (EU) 1451/2007): under discussion, for adoption by 2nd semester of 2014

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Commission guidance

Work on guidance documents or proposals on various topics:

- *Proposal of management of nanomaterials:*
  
  https://circabc.europa.eu/w/browse/f2d79b34-2f5a-4bb4-97e8-b982c9def765

- *Guidance on fees payable to Member States:*
  
  https://circabc.europa.eu/w/browse/b5c900a2-ef66-4a46-996d-00d5a29aee9a

- *Guidance on similar conditions of use, for the Union authorisation:*
  
  https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e

- *Guidance on treated articles:*
  
  https://circabc.europa.eu/w/browse/e1adf8de-0ad6-4484-84ec-80704391a038

- *Document on comparative assessment:*
  
  https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcafe7e

- *Other Guidance under discussion:*
  
  - Borderline between biocidal products and cosmetics:
    
    https://circabc.europa.eu/w/browse/6283ad7a-7416-4b83-a201-92ba58224222
  
  - In situ generation:
    
    https://circabc.europa.eu/w/browse/7f81cf6d-a333-441a-ab96-324c8d9de8a0

etc.
Organisation of the biocides framework

- Organisation of the evaluation of existing active substances, in order to meet the objective of finishing the review programme by the end of 2024:
  
  https://circabc.europa.eu/w/browse/661e8fca-9353-47da-a031-c1341d6aa335

Organisation: CA-Feb13-Doc.8.3, CA-Sept13-Doc.8.3-Final

Principles for approval: CA-March14-Doc.4.1-Final

Adoption of decision on the approval of active substances after evaluation since the beginning of the review programme

| Year     | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | Total |
|----------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|     |
| 2006     |   |   |   |   |   | 1 |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    | 1   |
| 2007     |   |   |   |   |   | 2 |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    | 3   |
| 2008     |   |   |   |   |   | 8 |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    | 10  |
| 2009     |   |   |   |   |   | 7 |   |   |   | 6  | 3  |    |    |    |    |    |    |    |    |    |    |    | 16  |
| 2010     |   |   |   |   |   | 1 |   |   |   | 1  | 3  | 5  | 1  |    |    |    |    |    |    |    |    |    |    | 11  |
| 2011     |   |   |   |   |   | 4 |   |   |   |    | 0  | 6  | 2  |    |    |    |    |    |    |    |    |    |    |    | 12  |
| 2012     |   |   | 2 |   |   |   |   |   |   |    | 1  | 6  | 2  |    |    |    |    |    |    |    |    |    |    |    | 17  |
| 2013     | 1 | 1 | 2 | 1 | 1 | 1 | 4 | 1 | 1 |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 19  |
| 2014 (on-going) |   | 2 | 3 | 1 | 1 | 1 | 1 | 1 | 1 |    |    |    |    |    |    |    |    |    |    |    |    | 18  |

Decisions are taken on around 16% of dossiers in the review programme

Objective: as from 2014, at least 50 decisions per year on the approval of existing active substances
Organisation of the biocides framework

... while continuing the progression of the authorisation phase of BPs for the harmonisation of the EU market:

Evolution of the number of product authorisations granted in the EU according to the BPD/BPR from February 2012 to May 2014
On-going / Future works

- **On-going:**
  - ECHA: some guidance documents, continuous development of the R4PB
  - COM: discussions on MRLs, update of the borderline guidance biocides/cosmetics, study on sustainable use, study on RMM on rodenticides, guidance on comparative assessment etc…
  - Specific tasks on:
    - Nanomaterials
    - In situ-generation
    - Guidance on data sharing, LoA, and consortium

- **Main priorities in the coming years:**
  - Finish the review programme of active substances
  - Authorisation of biocidal products, process of MR and Union authorisation
Short term keys dates for Industry

- **1st September 2015**: All products *made available on the market* must contain a source of AS listed on ECHA list under Art. 95

- **1st September 2016**: Deadline to submit applications to support AS of BP which were not in the scope of the BPD but are now in the scope of the BPR
  - If no submission, no *making available on the market* of BPs possible on 1st March 2017
  - Need to follow closely the review of the substances to ensure compliance

- **1st September 2016**: Deadline to submit applications to support existing AS used in TA (if not yet supported in imported TA, existing AS that are used outside EU)
  - If no submission, no *placing on the market* of TA possible on 1st March 2017
  - Need to follow closely the review of the substances to ensure compliance
II – Main procedures for the authorisation of BPs
Authorisation of BPs

- A key element of the regulatory framework

- Conditions for granting an authorisation (see art. 19 of BPR)
  → A product is authorised if it has proven efficacy, and it has demonstrated no unacceptable risk for human health, animal health (non-target organisms) and the environment

- Authorisation can be given for a maximum period of 10 years

- Authorisation can be given for a single product or a biocidal product family (+ same BP/BPF)

- National authorisations (via single national authorisation, mutual recognition in sequence or in parallel) or Union authorisations
Main prerequisites

- AS approved for appropriate PTs

- Full technical data package (LoA, studies, risks assessment etc.)

- Proof of Technical Equivalence of the source(s) of active substances used in the product

- Application ready to be submitted
- Deadline for existing products: latest date of approval of the ASs used in the product
Key tools

- **The Register for Biocidal Product (R4BP)**: all applications in relation with the BPR must be submitted via the R4BP, public data base of approved active substances and authorised products

- **Applications for authorisation**: on-line forms to be filled up, and contains the technical data and assessment of the product in an IUCLID format, as well as a *proposed* Summary of the biocidal Product Characteristics (SPC)

- **Assessment report**: contains the summary of the hazard, risks and efficacy assessment, which motivates a decision of authorisation or non-authorisation

- **The authorisation decision**: which indicate the terms and conditions of the authorisation for placing on the market, and includes the *validated* SPC
- The Register for Biocidal Product (R4BP - «v3»)
The Summary of the biocidal Product Characteristics (SPC)


1. Administrative information

1.1. Trade name of the product

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Country (if relevant)</th>
</tr>
</thead>
</table>

1.2. Authorisation holder

<table>
<thead>
<tr>
<th>Name and address of the authorisation holder</th>
<th>Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of the authorisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expiry date of the authorisation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.3. Manufacturer(s) of the product

<table>
<thead>
<tr>
<th>Name of manufacturer</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Address of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Location of manufacturing sites</td>
<td></td>
</tr>
</tbody>
</table>

1.4. Manufacturer(s) of the active substance(s)

<table>
<thead>
<tr>
<th>Active substance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Address of manufacturer</td>
<td></td>
</tr>
<tr>
<td>Location of manufacturing sites</td>
<td></td>
</tr>
</tbody>
</table>

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

<table>
<thead>
<tr>
<th>Common name</th>
<th>TUPAC name</th>
<th>Function</th>
<th>CAS number</th>
<th>EC number</th>
<th>Content (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Active substance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-active substance1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 In case the product would have more than one name, all names can be provided in this field, if the other elements of the SPC are identical. Otherwise additional SPCs would have to be provided (one SPC per name).
2 Non-active substances, of which knowledge is essential for proper use of the product. In the SPC(s) in the application the applicant shall indicate all the active function(s), e.g. solvent, dispersant, preservative, pigment.
Key procedural steps

Once an application is submitted in the R4BP:

- **Acceptance phase (30 days)**: for payment of the fee
- **Validation phase (30 days)**: to check the completeness and quality of the application (use the correct format, use the correct procedure, did not forget major information etc.)
  - Possibility of submission of additional information requested by the evaluating CA - “eCA” - (90 days max + 30 days for verification by eCA)
- **Evaluation phase (365 days)**: to assess the product
  - Possibility of suspension for submission of additional information requested by the eCA (180 days max)
- **Decision phase**: authorisation or non-authorisation of the product
Authorisation of BPs:
Single National Authorisation (Chap. VI)

• **Use of the procedure**: when a company wants to place its product on the market of only one MS (for the moment?)

• **Persons involved**: applicant, the MS

• The product can only be placed and made available on the market of this MS, and use in this MS
Authorisation of BPs: Procedure for Mutual Recognition (Chap. VII)

- **Use of the procedure**: when a company wants to place its product on the market of several MS.

- **Persons involved**: applicant, the reference MS (i.e. perform the technical assessment), the concerned MS(s), and possibly the Commission and ECHA.

- **Two possible procedures of mutual recognition**
  - **in sequence**: when the product is already authorised UNDER THE BPR in at least one MS (i.e. previously authorised via single national authorisation procedure, or via mutual recognition in parallel), or
  - **in parallel**: when the product is not yet authorised UNDER THE BPR in any MS, the assessment will be done by a reference MS.

- **After reception of the (draft) authorisation decision (including the SPC) and the assessment report**: 90 days for Member States to agree between them.

- **Unresolved disagreements** referred to co-ordination group of Member States and, ultimately, Commission, possibly based on ECHA opinion.
Authorisation of BPs: Procedure for Mutual Recognition (Chap. VII)

- **Derogation** to mutual recognition possible in some cases
- **Grounds:**
  - Protection environment and human, animal health, national treasures of artistic, historical or archaeological value
  - Public policy or public security
  - Target organism not present in harmful quantities, or
  - In particular products containing substances meeting the exclusion or substitution criteria
- **Procedure**
  - Member State to seek agreement with applicant (60 days)
  - If no agreement, then Commission decides
Authorisation of BPs: Union authorisation (Chap. VIII) – What?

Objective: Facilitate the making available on the EU market of BP with similar conditions of use, simplify procedures for economic operators targeting a lot of MS market, reduce the overall administrative burden

- Authorisation given by the EU Commission, valid across EU (if not restricted)

- Use of the procedure: when a company wants to place its product on the market of several MS and possibly the entire EU market, and ensure the highest harmonisation

- Persons involved: applicant, ECHA, the reference MS (i.e. perform the technical assessment), all other MSs, and eventually the Commission

- Excluded:
  - Products containing substances fulfilling the exclusion criteria
  - Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)
  - Antifouling products (PT 21)
Union authorisation (Chap. VIII) – When?

Phase-in period for possible granting of authorisation, decided for workability of the measure

- From 1 September 2013: products containing new active substances (whatever the PT, except those excluded) or products within PTs 1, 3, 4, 5, 18 and 19;
- From 1 January 2017: PTs 2, 6 and 13;
- From 1 January 2020: the remaining possible PTs (7, 8, 9, 10, 11, 12, 16, 22).

→ Commission will make a report by 31 December 2017 to Council and Parliament
Union authorisation (Chap. VIII) – How?

- Pre-application to ECHA, in order to verify the eligibility to the Union authorisation procedure (i.e. verification of similar condition of use).
- Guidance on similar conditions of use (minor modifications to be made in the document):
  https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e
- Application submitted to ECHA, and accepted by ECHA
- Application validated and evaluated by Evaluating Competent Authority chosen by applicant: 1 year
- Peer-review by ECHA in the Biocidal Products Committee, ECHA opinion: 9 months
- Commission decision authorising the product on the entire EU market

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Authorisation of BPs :
Comparative assessment of BPs (art.23)

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

- Consequence of substitution of AS: comparative assessment of BP containing these ASs
- Made during the assessment of the authorisation of the BP or the renewal of authorisation, either at MS or EU level
- Products containing candidates for substitution will not be authorised if:
  - Alternatives
    - Present significantly lower risk
    - Are sufficiently effective, and
    - Present no significant economic or practical disadvantage, and
  - Chemical diversity adequate to minimise resistance
- Possible derogation for MS to perform a comparative assessment for a maximum of 4 years in order to gain experience

→ Authorisation of BP for a maximum of 5 years
Authorisation of BPs:
Simplified procedure for authorisation for some BP (Chap. V)

Objective: Facilitate the making available on the market of products with lower concern/better profiles with regard to health and environment

- For products with:
  - As all listed in Annex I of the BPR
  - Contain no substance of concern, and no nanomaterials
  - Sufficient efficacy
  - No need to wear PPE

- Consequence for product authorisation
  - Faster procedure: evaluation in 90 days by the MS
  - Once an authorisation is given by one MS, the product can be made available on the market of all MS after notification

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III – Focus on the list of suppliers of AS (Art. 95)
Provisions for alternative suppliers of AS – cost sharing (art 95)

Objective: Level playing field for interested persons on active substances (mostly suppliers of AS), avoid monopolistic situations and enhance free competition

- As from 1st September 2015, only biocidal products containing suppliers of active substances registered can be made available on the market

- List of suppliers made by ECHA, publicly available on its website since 1st September 2013, and regularly updated: http://echa.europa.eu/information-on-chemicals/active-substance-suppliers

- This provision applies to all biocidal products (whether they are placed on the market under the transitional rules of MS, or subject to a BPR authorisation)
Focus on Art. 95 : What to do

- **WHAT** : Submit an application of registration to ECHA, which includes :
  - Either a **letter of access to the data (LoA)** currently under assessment for the AS, or the data which already led to the approval of the AS
  - Or, a complete dossier with all data on the AS (Annex II of BPR), similar to the one currently under assessment for the AS, or the data which already led to the approval of the AS
  - Or, a reference to a complete dossier, whose data are not protected anymore (the 1st protection of data will end on 2018 for the 1st active substance approved – sulfuryl fluoride – but in practise, the data protection will fall in 2025 for most of the existing active substances)

- **Encouraged way to fulfil this duty : use letter of access (LoA)**

To this specific end :
- Mandatory data sharing extended to all tox and ecotox data (including e-fate studies), including data not made via tests on vertebrates
- Data sharing compensation mechanism (art. 63)
- Persons obtaining these LoA can use them or share them to obtain product authorisations (ex: a supplier of AS will share them with its clients, in order that they can obtain their product authorisation)
Focus on Art. 95: What to do

By WHO:

- Logically, person responsible for the *placing on the market* of an active substance on the EU market (i.e. 1st supply of an AS on the EU territory):
  - Producer of an AS, importer of an AS
  - Importer of a biocidal product (i.e. it contains a source of AS introduced *de facto* on the EU market)

→ Indeed, these are the persons who take the 1st benefit of the current support of these active substance in the review programme by participants

- Participants in the review programme are automatically listed
Focus on Art. 95: What to do

- **HOW**: submission via the Register for biocidal products (R4BP)
  

- **WHEN**: submission possible since 1st September 2013

- **To be done ASAP**
Focus on Art. 95: Anyway…

... Obligation of Result:

As from 1st September 2015, only biocidal products containing sources of active substances registered and listed by ECHA can be *made available on the market* (i.e. all supply banned for other biocidal products)

ECHA Guidance document:

Conclusion
BPR : same spirit as BPD, but new tool and new measures to better fulfil the objectives of the overall framework on biocides

Most BP on the EU market will be authorised according to the BPR standards, various possible procedures

Entry into application on 1st September 2013 :
  ➢ A lot of work on-going at EU level for the implementation of the BPR
  ➢ Many challenges for both COM/ECHA/MSs and IND

On track for target 2024 : end of review programme, final stage for full harmonisation of the EU market
Thank you for your attention

For further information:

Commission website:
http://ec.europa.eu/environment/biocides/
https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b
ENV-Biocides@ec.europa.eu

ECHA website & Helpdesk on Biocides: