Industry perspective of the BPR Regulation (EU) No 528/2012

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Kerona Scientific Ltd.
12th March 2020
Kerona Scientific Ltd.

- Regulatory consultancy
- Founded 2014
- HQ Ireland (Skerries)
- Office in Madrid, Spain
- Worldwide client base
- PPP, biocide, PB clients
- Multilingual multidisciplinary team
- www.kerona.ie
Dr. Irene McGrath

• Over 26 years managing Regulatory Departments in industry and working as a consultant for the regulation of plant protection products, biocides, plant biostimulants and fertilisers in the EU
• B.Sc. Analytical Science, Ph.D. Chemistry
• Diploma in Project Management
• Founded Kerona Scientific Ltd in 2014
• Email: irene@kerona.ie
Our biocide projects

- Representation with the MSCA
- Notifications in Ireland and other EU MS, registration in Turkey
- Study commissioning
- Additional product types (PT) for existing AS at EU level
- Complete BPR dossiers (IUCLID, product assessment report (PAR), SPC, R4BP3 submission)
- Risk assessments (human health, environment, ED assessment, higher tier risk mitigation)
- Biocidal Product Family (BPF) dossiers
- Task force representation
- Main product types (PT) 1-5, 7-9, 14/18/19
- Technical equivalence under the BPR
- Chemical and microbial AS
Main areas to be discussed

- Industry obligations under the BPR:
  - Knowing the status of your AS at EU level
  - BPR submission deadlines
- Data requirements for BP authorisation under the BPR
- Data sharing: Article 95/Letters of access
- Biocidal Product Families (BPF)
- Same biocidal products (SBP)
- Union authorisation
- Simplified authorisation (Annex I substances)
- Endocrine disruption (ED assessment)
EU Status of an AS

- AS is always approved in relation to one or more PTs
- **Existing AS**: on EU market on 14 May 2000 as an AS of a BP
- **New AS**: not on the market on 14 May 2000 as an AS of a BP
- Very few New AS: applications triggered by industry
- Existing AS: safety is evaluated via the Review Programme
- While AS is in review programme (pending an inclusion/non inclusion decision), BP can be marketed via national rules during the ‘transitional period’
- AS approval date is the data submission deadline for BP re-authorisation dossiers
BPs – transitional measures

• For BPs already authorised, the authorisation is still valid under the BPR until its expiry date or unless cancelled
• Many existing AS’s still under evaluation in the Review Programme - will continue until at least 2024, until all AS evaluated
• BPs containing AS’s under evaluation in the Review Programme can continue to be marketed in the EU according to MS national rules (varies by MS) provided Art. 95 requirements are met (‘transitional period’) 
• Once the AS is included in the approved list at EU level for a certain PT, an application for authorisation of the BP of that PT must be submitted
Review of existing AS

[Indicative Timeline]

2000 2002 2007 2010

Identification → Notification → Dossier Submission → Review Programme

AS no longer supported
## Time limits for evaluation of existing AS/PT’s – Annex III of the Review Programme Regulation

<table>
<thead>
<tr>
<th>Priority list</th>
<th>Product-types</th>
<th>Evaluation (submit assessment report)</th>
<th>Start BPC opinion</th>
<th>Progress (% evaluations finalised)</th>
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<tbody>
<tr>
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<td>1, 2</td>
<td>31/12/2018</td>
<td>31/3/2019</td>
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<td>6, 13</td>
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<td>7, 9, 10</td>
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<td>11, 12, 15, 17, 20, 22</td>
<td>31/12/2022</td>
<td>30/9/2023</td>
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</table>
Status of the Review Programme

• 253 AS/PT combinations finalised
• 474 combinations ongoing
• As of Feb 2020, 35% of programme completed
• Completion deadline: end 2024
• 95 decisions per year now needed to meet the deadline
  – Only 52 in the last three years!
• Drop in delivery of BPC opinions
• Delays from applicants & MS:
  – Redefined in-situ active substances – increased work programme
  – Assessment of endocrine disruptors – new criteria since Jun 2018
Sample timelines – chlorine based disinfectants

- AS’s: NaClO, Cl₂, Ca(ClO)₂
- In situ generated AS – e.g. active chlorine released from calcium hypochlorite
- Two of the top three biocides based on production
- Task force/consortia set up with many companies taking part
- Three separate AS dossiers submitted under the BPR
- Supporting PT 1, 2, 3, 4, 5 (11 and 12)
- Dossiers submitted in 2007
- Final CA decision PT 1-5 in 2017, approval date 1/01/2019
- Final authorisations due in 2020 (PT 1 – 5)
- PT 11, 12 still under review
Case study - Sample AS approval – Chlorocresol (CMK) for PT13

• Biocidal Products Committee (BPC) meeting minutes 13-14 April 2016 – The BPC adopted by consensus the opinions for the approval of this AS/PT combination – see minutes published on ECHA website
• BPC opinion dated 13/04/2016 - published on ECHA website
• Assessment report dated April 2016 published on ECHA website
• **Date of approval in the implementing Regulation - 1 May 2018 for PT13**
• Product authorisation dossiers for chlorocresol containing BPs of PT 13 had to be submitted by 1 May 2018
Timeline - BP dossier preparation

T – 2y
- Decide which product(s) you are supporting
- Conduct data gap analysis, start ambient shelf-life study
- Consider consortia formation early
- Consider BPF strategy - efficacy/phys-chem testing

T – 1y
- Get access to the active substance (LoA or other)
- Preliminary risk assessments – based on actual use
- Discuss approach with eMS
- Create a draft PAR, IUCLID file, SPC

T – 6m
- If using UA, deadline ECHA pre-submission (similar use)

T – 1m
- Submit your dossier and payment

T
- AS approval date = BP dossier submission deadline

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# Data requirements for BP

## Data point | Title
--- | ---
1 | Applicant
2 | Identity of the biocidal product
3 | Physical, chemical & technical properties
4 | Physical hazards
5 | Methods of detection & identification
6 | Effectiveness against target organisms
7 | Intended use & exposure
8 | Toxicological profile for humans & animals
9 | Ecotoxicological studies
10 | Environmental fate & behaviour
11 | Measures to protect humans & environment
12 | Classification, labelling & packaging
13 | Evaluation & summary

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**Product identity and detection**
## Data requirements for BP

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<thead>
<tr>
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<td>Applicant</td>
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<td>2</td>
<td>Identity of the biocidal product</td>
</tr>
<tr>
<td>3</td>
<td><strong>Physical, chemical &amp; technical properties</strong></td>
</tr>
<tr>
<td>4</td>
<td><strong>Physical hazards</strong></td>
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<td>6</td>
<td><strong>Effectiveness against target organisms</strong></td>
</tr>
<tr>
<td>7</td>
<td>Intended use &amp; exposure</td>
</tr>
<tr>
<td>8</td>
<td><strong>Toxicological profile for humans &amp; animals</strong></td>
</tr>
<tr>
<td>9</td>
<td><strong>Ecotoxicological studies</strong></td>
</tr>
<tr>
<td>10</td>
<td><strong>Environmental fate &amp; behaviour</strong></td>
</tr>
<tr>
<td>11</td>
<td>Measures to protect humans &amp; environment</td>
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<tr>
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<td>Classification, labelling &amp; packaging</td>
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<tr>
<td>13</td>
<td>Evaluation &amp; summary</td>
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**Product end-points**

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# Data requirements for BP

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<td>Identity of the biocidal product</td>
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<td>13</td>
<td>Evaluation &amp; summary</td>
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</table>

**Product assessment and use**

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Access to protected data

• AS data is required for BP authorisation – LoA can cover this

• Letter of access gives the competent authorities permission to use data from one applicant for the benefit of another applicant

• LoA doesn’t automatically provide a copy of the data to the applicant

• Each LoA is negotiated individually
Article 95 list

- List of relevant substances and the respective substance and product suppliers - The list of ‘accepted sources’ of AS’s that can be used in BP’s
- To ‘ensure the equal treatment of persons placing AS on the market’
- ECHA is responsible for publication of the list
- BP cannot be made available on the market unless either the substance supplier or the product supplier is included in the Article 95 list for the relevant product type
- AS must be sourced from companies on the list

<table>
<thead>
<tr>
<th>Active Substance Name</th>
<th>EC number</th>
<th>CAS number</th>
<th>PT</th>
<th>Entity Name</th>
<th>Country</th>
<th>Supplier Type</th>
<th>Inclusion Reason</th>
<th>Inclusion Date</th>
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<tbody>
<tr>
<td>(3S,52,7E)-9,10-secocholesta-5,7,10(19)-triien-3-ol (Cholecalciferol)</td>
<td>200-673-2</td>
<td>67-97-0</td>
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<td>BASF Agro B.V. Arnhem (NL) Freienbach Branch</td>
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<td>(3S,52,7E)-9,10-secocholesta-5,7,10(19)-triien-3-ol (Cholecalciferol)</td>
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<td>67-97-0</td>
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<td>Aerovon Insect Control GmbH</td>
<td>Germany</td>
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<td>(9Z,12E)-tetradeca-9, 12-dien-1-y acetate</td>
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<td>benzothiazol-2-ylthio(methyl thiocyanate (TCMTB)</td>
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<td>11364-17-0</td>
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<td>Laboratorios Miret, S.A.</td>
<td>Spain</td>
<td>Substance Supplier</td>
<td>Art.95 submission</td>
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Technical equivalence

- Article 95 is not automatically linked to Technical Equivalence - they are different procedures
- Article 95 is necessary to use an AS in a product, while technical equivalence refers to the source of AS used in the BP
- Technical equivalence to a reference source is only possible for an approved AS
- Important at the level of product authorisation – often overlooked
Issues with BP dossiers

• Lack of data (especially storage stability, shelf-life – 2 years)
• Efficacy testing – check label claims and species controlled
• Biocidal Product Family (BPF) – splitting of a product range
• Failing risk assessments
  – some BP have limited options for refinement in the exposure scenarios
  – need for higher tier data or risk mitigation measures
• MSCA availability
  – Notice period
  – Pre-submission meeting?
• Data access/Article 95
• Need for foresight and planning
Biocidal product family (BPF)

A group of biocidal products with:

• Same AS
• Similar uses
• Similar composition within specified variations so that
  • Level of risk is not increased
  • Efficacy of the product is not reduced

All products in BPF covered by one authorisation

Useful if many similar formulations with similar uses in the portfolio, and for product ranges that differ in e.g. AS concentration, colour/scent

Reduced administrative cost per product and burden in dossier management
Biocidal product family

BPs in family are defined by well-structured SPC (summary of product characteristics)

Meta-SPC: 3 levels of information

1. **Family**: General information that applies to all products
2. **Meta**: Formulation type, authorised uses, risk management measures and hazard and precautionary statements common to the products
3. **Product**: specific information at the product level
BPF - guidance

- Note for Guidance on Implementing the BPF concept issued 2014
- New Note for Guidance: CA-July19-Doc4.2-Final
- Clarification of concept of similarity
- Addresses:
  - Best practice in pre-submission meeting
  - Assessment of similarity in BPF by applicants
  - Splitting of families for ongoing applications
- Once BPF established then draw up testing plan
  - Efficacy testing – lowest conc. in the meta grouping
  - Phys-chem – review each BP to determine testing
Union authorisation (UA)

- Authorisation is given by the Commission
- Access to entire EU market via single authorisation
- BPs with ‘similar conditions of use across the Union’
- Not applicable to AS meeting the exclusion criteria
- Expensive: €80,000 ECHA fee per product (€150,000 per family) + MS fees (varies by MS) + annual fee of €10,000 (€20,000 per family)
- Fee reductions possible for SMEs
- Phased introduction by PT:

<table>
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<tr>
<th>Product types</th>
<th>Introduction of UA</th>
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<td>1, 3, 4, 5, 18, 19</td>
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<tr>
<td>7, 8, 9, 10, 11, 12, 16, 22</td>
<td>From 1 January 2020</td>
</tr>
</tbody>
</table>
Same Biocidal Product (SBP)

• Defined in Commission Implementing Regulation (EU) No 414/2013:
  – “... a product ... which is identical to another single BP, BPF, or individual product of a BPF which has been authorised or registered in accordance with Directive 98/8/EC... or Regulation (EU) No 528/2012, or for which an application for such authorisation has been submitted (the ‘related reference product’ (RRP))”

• Official MS procedure for the authorisation of back-to-back products and marketing authorisations (letter of access must be obtained from authorisation holder of the RRP)

• Can apply for authorisation of a SBP where an identical BP (RRP) is already authorised or is under evaluation

• UA applications often include SBP
Same Biocidal Product (SBP)

• Provision for SBP authorisation on a member of a BPF or the whole family
• As long as the formulations are the same, allows ‘same products’ to be formulated independently by individual companies
• Allows ‘same product’ companies to obtain non-active ingredients from alternative sources to those used by the lead
• Allows ‘same product’ companies to obtain AS from alternative sources to those used by the lead as long as they are included on the Article 95 list
• Fees for UA of a SBP - €2,000; fees also payable to eCA
Simplified authorisation

• ‘To encourage the use of products with a more favourable environmental or human or animal health profile, it is appropriate to provide for simplified authorisation procedures for such biocidal products’

• Product authorisation criteria
  – AS in Annex I
  – No substances of concern or nanomaterials in product
  – Product is sufficiently effective
  – No PPE is required for handling/use

• Authorisation procedure:
  – Application made to ECHA
  – One MS will evaluate
  – Product can be placed on market in all MSs – notify with no need for MR
## Annex I categories

<table>
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<th>Category</th>
<th>Description</th>
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<td>1</td>
<td>Food additives (Reg. (EC) No. 1333/2008)</td>
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<td>Substances included in Annex IV of REACH</td>
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<td>3</td>
<td>Weak acids</td>
</tr>
<tr>
<td>4</td>
<td>Traditionally used substances of natural origin</td>
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<tr>
<td>5</td>
<td>Pheromones</td>
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<td>6</td>
<td>Substances included in Annex I or IA to the BPD</td>
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<tr>
<td>7</td>
<td>Other</td>
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Exclusion & substitution criteria

Exclusion criteria:

• Carcinogens, mutagens and reprotoxic substances (1A or 1B)
• Endocrine disruptors
• Persistent, bioaccumulative and toxic (PBT)
• Very persistent and very bioaccumulative (vPvB)

Substitution criteria:

• Based on intrinsic hazardous properties in combination with the use and potential exposure
Endocrine disruptors

• Commission Delegated Regulation (EU) No 2017/2100
  – Scientific criteria for determining endocrine-disrupting properties pursuant to the BPR
  – Applicable from 07/06/2018

• Joint action by ECHA and EFSA
• Guidance document published 7/6/2018 EFSA Journal 2018;16(6):5311
ED criteria

• Based on 2002 WHO/IPCS definition of an ED

- Shows an adverse effect
- Endocrine mode of action
- Adverse effect is a consequence of the endocrine mode of action
Assessment of ED

- All available relevant scientific data must be considered when determining ED properties
- Weight of evidence (WoE) approach for assessment of the data
- Strategy described in guidance document:
  - Gather all relevant information
  - Assemble and assess lines of evidence for endocrine activity and adversity
  - Initial analysis of the evidence
  - Mode of Action (MoA) analysis
  - Overall conclusion on the ED criteria
- Excel template for reporting the available relevant information
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**Treasured articles**

- ‘Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products’

- Treated articles do not need authorisation unless they have a primary biocidal function

  - *Primary biocidal function vs. additional function:*

    - Biocidal product = Antibacterial wipes
    - Treated article = Socks with antibacterial function
In-situ generated AS

• AS generated from one or more precursors at the place of use
• Approval process involves the evaluation of the generated AS and the precursor(s) in the context of each product type

Examples:
Active chlorine generated from sodium chloride by electrolysis
Monochloramine generated from ammonia and a chlorine source
Peracetic acid generated from TAED and sodium percarbonate
Differences to REACH

• BPR considers products and AS (REACH - substances only)
• Under the BPR, every AS and BP is banned unless regulators give permission for marketing/use (in REACH only selected SVHC are banned unless authorised)
• Every BPR dossier is evaluated
• High regulatory cost of the BPR
  – No ‘fast-track’ system e.g. special consideration for low risk substances (e.g. microbials)
  – Adding additional PT
• Data requirements not tonnage dependent
  – Huge impact on SMEs
  – Discourages innovation - disincentive
ECHA Guidance on BPR

Biocidal Products Regulation guidance structure

VOL. I
Identity, phys-chem, analytical methodology

PART A+B+C
Information requirements + Assessment + Evaluation

VOL. II
Efficacy

PART A
Information requirements

PART B+C
Assessment + Evaluation

VOL. III
Human Health

VOL. IV
Environment

VOL. V
Specific guidance

Active substances and suppliers (Art 95 list)
Disinfection By-Products
Endocrine disruptors
Micro-organisms
Technical equivalence

Guiding you through the Regulatory Maze
Useful Publications

BPR VADEMECUM
2020
4th Edition
updated January 2020

Biocidal Products Regulation (EU) No 528/2012
and BPR User Guide

CLP Desktop Companion

Guiding you through the Regulatory Maze
### Free webinar

**An introduction to technical equivalence under the BPR**  
13 May 2020

### Biocides series

- **An overview of the BPR (Regulation (EU) No.528/2012**  
  20 May 2020

- **Data requirements for biocidal products under the BPR**  
  27 May 2020

- **Human health data requirements and risk assessment under the BPR**  
  3 Jun 2020

- **Environmental risk assessment under the BPR**  
  10 Jun 2020
Thank you – any questions?

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Guiding you through the regulatory maze