AUTHORISATION OF BIOCIDAL PRODUCTS UNDER THE BIOCIDAL PRODUCTS REGULATION

ASIAN-EUROPEAN BIOCIDES REGULATORY SUMMIT,
01/02 SEPTEMBER 2014, SINGAPORE

Dr. Hans-Josef Leusch, SCC GmbH, Bad Kreuznach
Transitional phase and transitional measures
BPR authorisation processes for biocidal products
Criteria for selection of the suitable process
Fees
Dossier preparation steps
What can the applicant do to smoothen the evaluation and the decision process?
Technicalities (IUCLID, R4BP)
Article 17 (1) BPR: „Biocidal products shall not be made available on the market or used unless authorised in accordance with this regulation.“

- Products based on new active substances: Article 17 (1) fully applies.
- Products based on existing biocidal substances: transitional measures apply (Article 89 of BPR).
TRANSITIONAL MEASURES (ARTICLE 89 BPR) (1)

“A Member State may continue to apply its national system or practice of making biocidal products available on the market,

- if the active substances have been or are being evaluated under Regulation No 1451/2007
- as long as the active substances have not been approved or withdrawn.

Important: An application for product authorisation - and if relevant applications for MR - must be submitted not later than the date of approval of the last active substance contained in a given product.
TRANSITIONAL MEASURES
(ARTICLE 89 BPR) (2)

◆ In case no submission is made by the date of approval
  
  – the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance
  
  – disposal and use of existing stocks may continue until 365 days after the date of approval of the active substance.

◆ In case of rejection or of negative decision: same time lines apply.
PT 14, 8: product dossiers according to BPD/BPR mostly submitted
PT 18, 19: BPD/BPR dossiers submitted for part of existing products
Other PTs: only very few BPD/BPR dossiers submitted so far
Submission of BPR product dossiers is expected to stretch out to:
- XII 2018: PT 18, 19, 21
- XII 2019: PT 3, 4, 5
- XII 2021: PT 1, 2
- XII 2022: PT 6, 13
- XII 2023: PT 7, 9, 10
- VI 2026: PT 11, 12, 15, 17, 22, 23

Many PT14 and PT 8 products will be re-authorised before the last products will be authorised the first time.
WHICH ACTIVE SUBSTANCES WILL BE APPROVED NEXT?

Check ECHA website for latest version of the BPC work programme:
„About us/Who we are/Biocidal Products Committee/Commitee work programme for BPC“

1. Introduction

This document presents the work programme of the BPC constituting the rolling agenda for the WG and BPC meetings for the year 2014 and the meetings in 2015. The current version contains the status as of 30 July 2014. This document lists the scheduled active substance product type (PT) combinations for which the evaluating Competent Authority (eCA) confirmed to the SECR to prepare the relevant documents in time.
WHICH ACTIVE SUBSTANCES WILL BE APPROVED NEXT? (2)

Date of BPC meeting + 2 years
= expected date of approval of active substance
= deadline for submission of BPR product dossiers based on this active

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT</th>
<th>eCA</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coated copper flake</td>
<td>21</td>
<td>FR</td>
<td>Review Programme; CAR submitted after EiO.</td>
</tr>
<tr>
<td>Cuprous oxide</td>
<td>21</td>
<td>FR</td>
<td>Review Programme; CAR submitted after EiO.</td>
</tr>
<tr>
<td>Carbendazim</td>
<td>7, 9, 10</td>
<td>DE</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
</tbody>
</table>

**Working Group, 14-18 September 2015**

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT, eCA</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMK</td>
<td>1, 2, 3, 6, 9, 13</td>
<td>Review Programme; PT13 CAR submitted before EiO; other PTs after EiO</td>
</tr>
</tbody>
</table>

**BPC, 29 September-1 October 2015**

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT</th>
<th>eCA</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Icandine</td>
<td>19</td>
<td>DK</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>2, 3</td>
<td>DE</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
</tbody>
</table>

**Working Group, 23-27 November 2015**

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT</th>
<th>eCA</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEM 5772</td>
<td>2, 7, 9</td>
<td>ES</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
<tr>
<td>BIT</td>
<td>2, 6, 9, 10, 11, 12, 13</td>
<td>ES</td>
<td>Review Programme; CAR submitted after EiO. Early WG discussion during eCA evaluation</td>
</tr>
<tr>
<td>NaClO₄</td>
<td>1, 2, 3, 4, 5, 11, 12</td>
<td>IT</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
<tr>
<td>CaClO₄</td>
<td>2, 3, 4, 5, 11</td>
<td>IT</td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
<tr>
<td>Cl₂</td>
<td>IT</td>
<td></td>
<td>Review Programme; CAR submitted before EiO.</td>
</tr>
</tbody>
</table>

**BPC, 8-10 December 2015**

<table>
<thead>
<tr>
<th>Active substance</th>
<th>PT</th>
<th>eCA</th>
<th>Submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMK</td>
<td>1, 2, 3, 69, 13</td>
<td>FR</td>
<td>Review Programme; PT13 CAR submitted before EiO; other PTs after EiO</td>
</tr>
</tbody>
</table>
Transitional phase and transitional measures

BPR authorisation processes for biocidal products

Criteria for selection of the suitable process

Fees

Dossier preparation steps

What can the applicant do to smoothen the evaluation and the decision process?

Technicalities (IUCLID, R4BP)
AUTHORIZATION PROCESSES FOR BIOCIDAL PRODUCTS UNDER THE BPR

- National authorisation
  - National authorisation (Article 29 BPR)
  - Mutual recognition in parallel (Article 34 BPR)
  - Mutual recognition in sequence (Article 33 BPR)

- Union authorisation (UA) (Articles 41-44 BPR)

- Simplified authorisation (Article 26 BPR)*

- Authorisation of same biocidal products (Regulation No 414/2013)

* not addressed in this presentation
CONDITIONS FOR GRANTING AN AUTHORIZATION (ARTICLE 19)

- Active substance has been approved for relevant PT and specified conditions are met.
- Product is sufficiently effective.
- Product has no unacceptable effects on
  - target organisms (resistance, unnecessary pain for vertebrates)
  - the health of humans
  - the environment.
- Analytical methods are available according to requirements.
- PC properties of product are acceptable for appropriate use and transport, etc.
NATIONAL AUTHORISATION: SUBMISSION OF APPLICATION

- For authorisation in **only one** EU Member State. Can be recognized by other Member States: mutual recognition in sequence or in parallel.

- Submit (thought R4BP) to the receiving competent authority:
  - IUCLID dossier
  - Primary supporting documents*
    - Draft summary of products characteristics (SPC)
    - A decision on technical equivalence when source different from reference source
    - LoA for active substance or ‘permission to refer’ from ECHA
  - Additional supporting document*
    - ‘Statement for national authorisation application’

*to be attached to section 13 of IUCLID dossier
After payment of fees and validation of the application, the receiving competent authority **evaluates the dossier within 365 days** and decides whether to grant an authorization.

If the active substance is a candidate for substitution, the receiving competent authority performs a **comparative assessment as part of the evaluation**.

Upon request by the receiving competent authority, the applicant can **post-submit missing information** during the validation phase (time limit normally 90 days) or during the evaluation phase (suspension of the 365-day period for normally not more than 180 days).

**Applicant can comment** on the draft product assessment report (PAR): Receiving competent authority shall take due account of the comments when finalizing its assessment.
MUTUAL RECOGNITION IN PARALLEL: SUBMISSION OF APPLICATION

- Apply for national authorisation in reference Member State and simultaneously for mutual recognition in parallel in concerned MS

- Submit (through R4BP) to the reference Member State:
  - IUCLID dossier
  - Primary supporting documents: same as for national authorisation
  - Additional supporting document:
    - ‘List of all the Member States where a national authorization and its mutual recognition is sought’

- Submit to the concerned MS:
  - Reference number (number assigned by R4BP)
  - Primary supporting documents
    - Draft SPC (in official languages requested by concerned Member States)
    - Letters of access to the product and/or the active substance dossiers
  - Additional supporting document
    - “List of all the Member States where a national authorization and its mutual recognition is sought”
MUTUAL RECOGNITION IN PARALLEL EVALUATION OF APPLICATION

- Applicant to pay fees
- Reference MS to validate application
- Reference MS to evaluate dossier within 365 days: assessment report and draft SPC
- Concerned MS to agree on SPC within 90 days and to record agreement in R4BP
- Concerned MS to authorise the biocidal product within 30 days of agreement
- In case no agreement is reached, each MS is free to authorise the product according to SPC.
MUTUAL RECOGNITION IN SEQUENCE: SUBMISSION OF APPLICATION

- Applicable if the product is already authorized in one Member State and the applicant seeks to have this authorization recognized in one or more additional Member States

- Submit (R4BP) to the competent authorities of each Member State:
  - Reference number (number assigned by R4BP to the initial NA asset) to start the application
  - Primary supporting documents
    - Summary of the products characteristics (with attached national authorisation)
    - Translation of the national authorisation into the languages of the Member States concerned
    - Letters of access to the product and/or the active substance dossiers
After payment of fees and validation of application, the Member States concerned shall – within 90 days - agree on the summary of products characteristics and shall record their agreement in R4BP.

Within 30 days of reaching agreement, each Member State concerned shall authorize the product in conformity with the agreed SPC.

Duration of mutual recognition process: ca. 5 months
HANDLING OF OBJECTIONS TO MUTUAL RECOGNITION (ARTICLES 35/36 BPR)

- Objections of concerned MS to MR are referred to and discussed in the coordination group.
- If no agreement within 60 days, COM is involved.
- ECHA may be asked by COM for an opinion on scientific and technical aspects.
- Final decision by COM (implementing act)
- Member States to follow decision within 30 days
UNION AUTHORIZATION (1)
WHAT IS IT?

- New concept and an alternative to applying for national authorization and mutual recognition
- Granted by EU COM and valid in all EU MS (unless otherwise specified)
- Only for products with similar conditions of use in all EU MS
- Not for products which contain active substances meeting any of the exclusion criteria
- Not for products in PT 14 (rodenticides), PT15 (avicides), PT17 (piscicides), PT20 (control of other vertebrates), PT 21 (antifouling products)
- Applicant needs confirmation from MS that MS agrees to take over the role of eCA.
The Union authorisation may be **granted**: 

<table>
<thead>
<tr>
<th>From 1 September 2013</th>
<th>From 1 January 2017</th>
<th>From 1 January 2020*</th>
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<tbody>
<tr>
<td>PT 1, 3, 4, 5, 18, 19</td>
<td>PT 2, 6, 13</td>
<td>PT 7, 9, 10, 11, 12, 16, 22</td>
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<tr>
<td>BP containing one or more new actives</td>
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*all remaining PTs
UNION AUTHORIZATION (3)
VERIFICATION OF SIMILAR USE CONDITIONS
ACROSS THE EU

❖ Applicant pre-submission: at the latest 6 months before submission of their application for UA, applicants shall submit the draft SPC to ECHA.

❖ ECHA shall notify Member States and COM.

❖ Member States and COM shall verify that
  a) product has similar conditions of use across the EU
  b) product falls within the scope of the BPR
  c) appropriate PT has been assigned.

❖ If disagreement, matter to be discussed further. Upon request of a MS, COM can decide in accordance with Article 3.3 BPR.

❖ ECHA to inform the applicant of the conclusions of the pre-submission consultation within 180 days of the submission of the SPC

❖ Applicant to include confirmation of similar use conditions in his application for product authorization.
Files to be submitted through R4BP:

- IUCLID dossier

- Primary supporting documents
  - Draft SPC in one of the official languages of the EU accepted by the eCA
  - Letter of access
  - Decision on Technical equivalence
  - Letter of access or ‘permission to refer’ from ECHA

- Additional supporting documents
  - Letter from the eCA stating agreement to evaluate the application
  - Written confirmation of: a) product has similar conditions of use across the Union, b) falls within the scope of the BPR and c) correct PT has been attributed
UNION AUTHORISATION (5): ASSESSMENT OF APPLICATION

- **Evaluation of application by eCA within 365 days;** product assessment report (PAR) with conclusions and draft SPC are sent to ECHA.
- The applicant can comment on draft CAR and post-submit missing information (only upon request by eCA).
- **ECHA to provide COM with opinion within 180 days.** Working procedure: next slide
- Within **30 days** of submission of opinion, **ECHA to send SPC in all official EU languages to COM** (preparation by applicant, check by ECHA)
- **COM grants Union authorisation** by adopting an implementing regulation (in case of not granting UA: implementing decision).
- **COM can decide to deviate from same use conditions upon request of a Member State.**
### Union authorisation applications: working procedure for the Biocidal Products Committee (BPC)

(AGreed on 10 October 2013 at BPC-3)

#### Timelines for the steps in the peer review process for Union authorisation including one WG discussion

<table>
<thead>
<tr>
<th>Task</th>
<th>Process flow 5</th>
<th>Process flow 6</th>
<th>Process flow 7</th>
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<tr>
<td>Commenting period (28 days)</td>
<td>Start 29 Aug 2014</td>
<td>End 26 Sep 2014</td>
<td>Start 7 Nov 2014</td>
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<tr>
<td>Commenting WG minutes (14-21 days)</td>
<td>Start 1 Dec 2014</td>
<td>End 15 Dec 2014</td>
<td>Start 2 Feb 2015</td>
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<tr>
<td>eCA updates the PAR (21 days before BPC)</td>
<td>Start 21 Nov 2014</td>
<td>End 13 Jan 2015</td>
<td>Start 23 Jan 2015</td>
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**Note:** Start and End dates for each task are provided as an example. The actual dates may vary depending on the specific applications and decisions made within the Biocidal Products Committee (BPC).
AUTHORISATION OF SAME BIOCIDAL PRODUCT

- Regulation (EU) No 414/2013
- Authorisation procedure for a product (the 'same product') which is identical to a product (the 'reference product') which is already authorised according to BPD/BPR or for which an application has been submitted.
- Possible differences: information subject to administrative changes (trade names, authorisation holder, etc.)
- Application through R4BP to:
  - Competent authority having granted or being requested to grant authorisation of the reference product (in case of national authorisation)
  - ECHA (in case of UA)
- Reference and same product obtain different authorisation numbers (separate authorisations).
- R4BP shows link between reference product and same product
- Same product can be changed according to Regulation (EU) No 354/2013 independently from reference product.
Additional trade names

- One product (one authorisation number) can have different trade names*
- Different names can be used by applicant or by his clients (marketing reasons / private labels)
- Authorisation holder/ authorisation number must always be on the product label.

Same products authorisation:

- Authorisation of same product is independent from the authorisation of the reference product. -> Different product names and different authorisation numbers

*to be applied for in SPC and in national supporting documents
Transitional phase and transitional measures
- BPR authorisation processes for biocidal products
- **Criteria for selection of the suitable process**
- Fees
- Dossier preparation steps
- What can the applicant do to smoothen the evaluation and the decision process?
- Technicalities (IUCLID, R4BP)
## Authorisation Procedures: Criteria for Selection

<table>
<thead>
<tr>
<th>Authorisation procedures</th>
<th>Reasons for selection</th>
</tr>
</thead>
</table>
| National authorisation            | For authorisation in just one MS  
Basis for MR (in sequence and in parallel)                                                                                                                                                                           |
| Mutual recognition in sequence    | For authorisation in additional MS where the product is not yet available on the market according to national rules. Product can only be sold after mutual recognition has been granted.                                           |
| Mutual recognition in parallel    | For authorisation in additional MS where the product is already available on the market according to national rules. The product can be sold during the assessment of the application.                                      |
| Union authorisation (UA)          | If it is intended that the product shall be made available on the market in all or many EU MSs:  
• UA is expected to simplify procedures and thus to reduce administrative burden for the applicant.  
• The BPC working procedure is expected to provide for a harmonised assessment.                                                                                                                                   |
| Same products authorisation       | Offers substance suppliers the possibility to support their clients (formulators) in product authorisation. For example, a substance supplier may apply for authorisation of a reference product / product family. He would issue letters of access to his clients, who could then apply for same-products authorisation. |
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### ECHA fees according to „ECHA fee regulation“

Commission Implementing Regulation (EU) No 564/2013

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Fee (EUR) per product</th>
<th>Fee (EUR) per product family</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granting of Union authorisation (UA)</td>
<td>80 000</td>
<td>150 000</td>
</tr>
<tr>
<td>Granting of UA if product is identical to representative product</td>
<td>40 000</td>
<td>-</td>
</tr>
<tr>
<td>Additional fee for comparative assessment</td>
<td>40 000</td>
<td>60 000</td>
</tr>
<tr>
<td>Union authorization of a same biocidal product</td>
<td>2000</td>
<td>Not indicated</td>
</tr>
<tr>
<td>Annual fee for biocidal products / families authorized by the Union</td>
<td>10 000</td>
<td>20 000</td>
</tr>
<tr>
<td>Mutual recognition submission fee per MS where MR is sought</td>
<td>700</td>
<td>700</td>
</tr>
<tr>
<td>Fee reduction for SME established in the Union (except where product contains a candidate for substitution)</td>
<td>10, 20, 30 % (for medium-sized, small and micro enterprises)</td>
<td></td>
</tr>
<tr>
<td>The national fees of the eCA come on top.</td>
<td>See national fee regulations</td>
<td></td>
</tr>
</tbody>
</table>
Fees in some EU MS according to national fee regulations

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Product</td>
<td>Product family</td>
<td>Product</td>
</tr>
<tr>
<td>Germany</td>
<td>50 000</td>
<td>75 000</td>
<td>15 500</td>
</tr>
<tr>
<td>Denmark</td>
<td>23 000</td>
<td>38 000</td>
<td>10 000</td>
</tr>
<tr>
<td>Netherlands</td>
<td>18 500*</td>
<td>22 000*</td>
<td>6555</td>
</tr>
<tr>
<td>Sweden</td>
<td>33 000</td>
<td>66 000</td>
<td>13 000</td>
</tr>
<tr>
<td>UK</td>
<td>Work on biocidal products is charged out at a rate of £393 per day.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*advance payment only; actual costs will be booked on hourly rate basis.
CONTENT

- Transitional phase and transitional measures
- BPR authorisation processes for biocidal products
- Criteria for selection of the suitable process
- Fees
- **Dossier preparation steps**
- What can the applicant do to smoothen the evaluation and the decision process?
- Technicalities (IUCLID, R4BP)
DOSSIER PREPARATION STEPS (1)

Steps before publication of assessment report

- Define the relevant uses of your products
- Identify substances of concern
  (substitution possible?)
- Check storage stability and efficacy of your products
  (check available data or run tests!)
- Adjustment of product composition and product portfolio
- Definition of product families if suitable
- Identification of available relevant product studies:
  (e.g. storage stability, PC properties, efficacy, dermal absorption, leaching…)
DOSSIER PREPARATION STEPS (2)

Steps after publication of assessment report

- Read assessment report carefully:
  - Are your relevant uses covered by the assessment report (AR)?
  - Does the AR highlight critical issues to be assessed at product level?
- Perform preliminary risk assessments: are your uses safe?
  (Try to obtain ERA and HHRA, i.e. Doc IIB/C of CAR)
- Perform data gap analysis and identify need for new studies.
- Select reference MS / eCA and check their availability
- Pre-submission meeting: on the basis of your precise analysis and precise questions
- Perform missing studies and write the dossier: can partly be done in parallel
- Before you submit the dossier, check national requirements.
  (additional supporting documents, submission of hardcopies on top of IUCLID)
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WHAT CAN THE APPLICANT DO?

- Try to fix a pre-submission meeting early.
- Be well prepared: present your precise analysis of critical issues and discuss them openly.
- Don’t wait for the evaluating authority to identify problems during the assessment which you are already aware of long before dossier submission!
- You may ask your reference MS to check critical issues even before dossier submission with concerned MS.
- Provide clear assessments in your dossiers.
- After submission, check your R4BP account frequently. Be prepared to address questions and requests at short notice.
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Technicalities (IUCLID, R4BP)
THE DOSSIER FORMAT HAS CHANGED

Before 1 September 2013
  – Dossier preparation in Word format
  – Submission of dossiers in paper format and on CD

Since 1 September 2013:
  – Dossier preparation in IUCLID
  – Submission of dossiers through R4BP
WHAT IS IUCLID?

- International Uniform Chemical Information Database
- Software programme used to enter, store, maintain and exchange data on substances, mixtures and micro-organisms, including biocidal active substances and products
- Format required by Article 79 BPR for the preparation of dossiers on active substances and biocidal products.
- Can be downloaded free of charge from the IUCLID website. (http://iuclid.eu).
- Data is entered and stored in IUCLID in editable datasets.
- The data can be exported from IUCLID into a non-editable file called a dossier (.i5z file).
SECTION TREE FOR A BIOCIDAL PRODUCT DOSSIER

- Section numbering according to Annex II/III BPR
- Red section symbols: core data
- Green section symbols: additional data
- Not yet included: templates for microorganisms
TEMPLATE FOR AN ENDPOINT STUDY RECORD

- Relevant data has to be filled in for a
  - Study
  - Literature reference
  - Waiver

- Different types of fields:
  - Free text
  - Drop-down
  - Repeatable blocks
The dossier creation wizard is launched.
WHAT IS R4BP?

- **Register for Biocidal Products**
- IT system established and maintained by ECHA
- Used for the submission of dossiers and exchange of information between industry and authority users
- Consists of two independent interfaces, one for industry users and one for the authority users (ECHA, MSCAs and COM).
- A IUCLID dossier can be uploaded into R4BP and submitted through R4BP to the authorities.
- The industry interface allows industry users to:
  - Submit applications
  - Review data
  - Download documents (e.g. invoices)
  - View the status of submitted applications and payments
  - Complete tasks assigned by authority user
  - Receive the final decisions / outcome concerning an application.
WHERE TO FIND R4BP

Asian-European Biocides Regulatory Summit 01/02
Sept. 2014 Singapore
SUBMISSION OF DOSSIERS IN R4BP3

Please select one of the following application types to submit your application.
You may select one application each time.

Submit application for:
- Approval of active substance
- Inclusion in the Article 95 (active substance suppliers) list
- National authorisation

BEFORE YOU SUBMIT:
- Before you submit your application, please consult the submission manuals and supporting documents to make sure your application contains all the data requirements for an application (Regulation 528/2012). You can find further information in:
  - Guidance documents
  - Biocides Submission Manuals
- Please contact the ECHA Helpdesk if you have any questions regarding the submission process.
After submission, the application can only be amended on request of the evaluating authority.

The authorities assign tasks in R4BP (e.g. to submit additional information).

Deadlines for compliance with tasks may be short.

→ regularly check your R4BP account in order not to miss any deadline!
THANK YOU FOR YOUR KIND ATTENTION

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