SME PERSPECTIVE:
HOW TO BEST APPLY RESOUCES FOR DEALING WITH THE BPR

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I-Tech - an SME in the biocides business

- Global operating bio-tech company listed on Nasdaq First North (ITECH)
- Headquartered at AstraZeneca Gothenburg in BioVentureHub
- University spin-off – founded around a scientific innovation
- Innovation - active substance in PT21
- Spent many years on R&D and regulatory – industrial and commercial focus from 2014 and onwards

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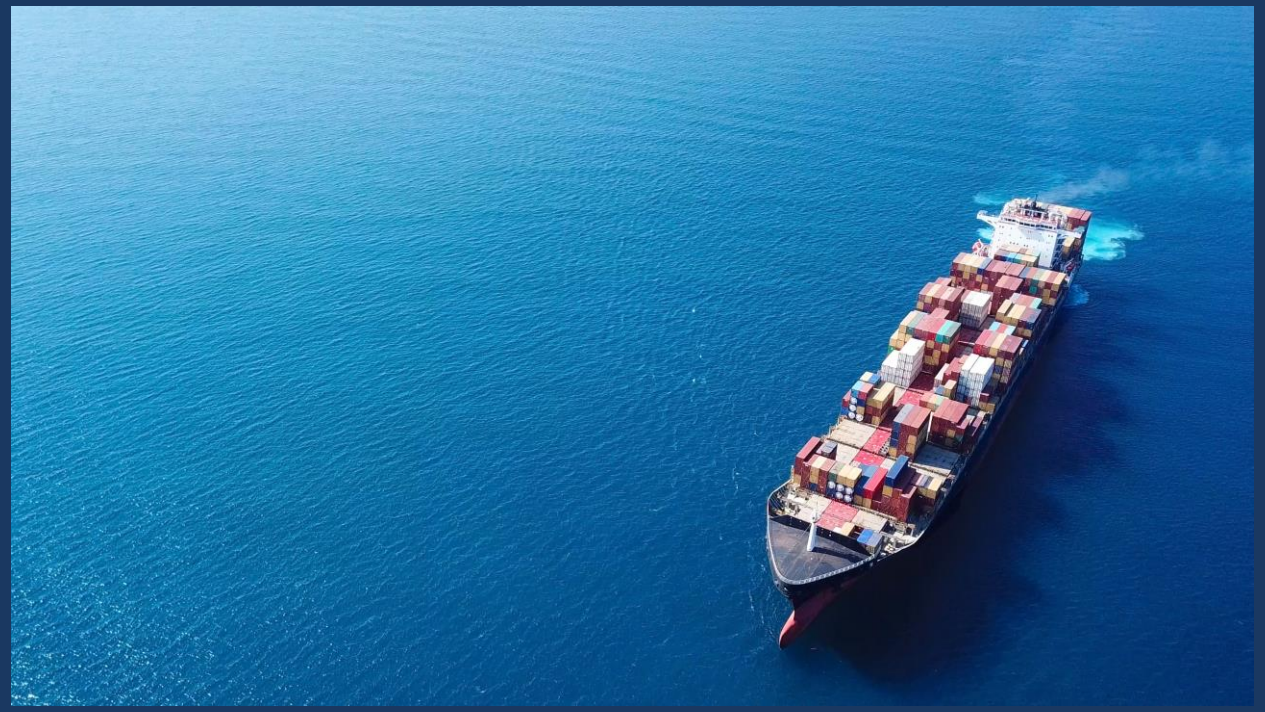
First BPR approval – a long journey to the market

- New active substance
- BPD to BPR
- New criteria
- Changes and compromises



Lessons learnt

- Do you have resources to support your substance?

- It will take more time than you planned for
- The target might move
- More data will be needed at some stage
- The outcome might not be the expected

After approval - post-approval requierments

- AS approved – resources still needed?
- Full scale production
- Technical equivalence
- Analytical methods
- Maximum Residue Level?

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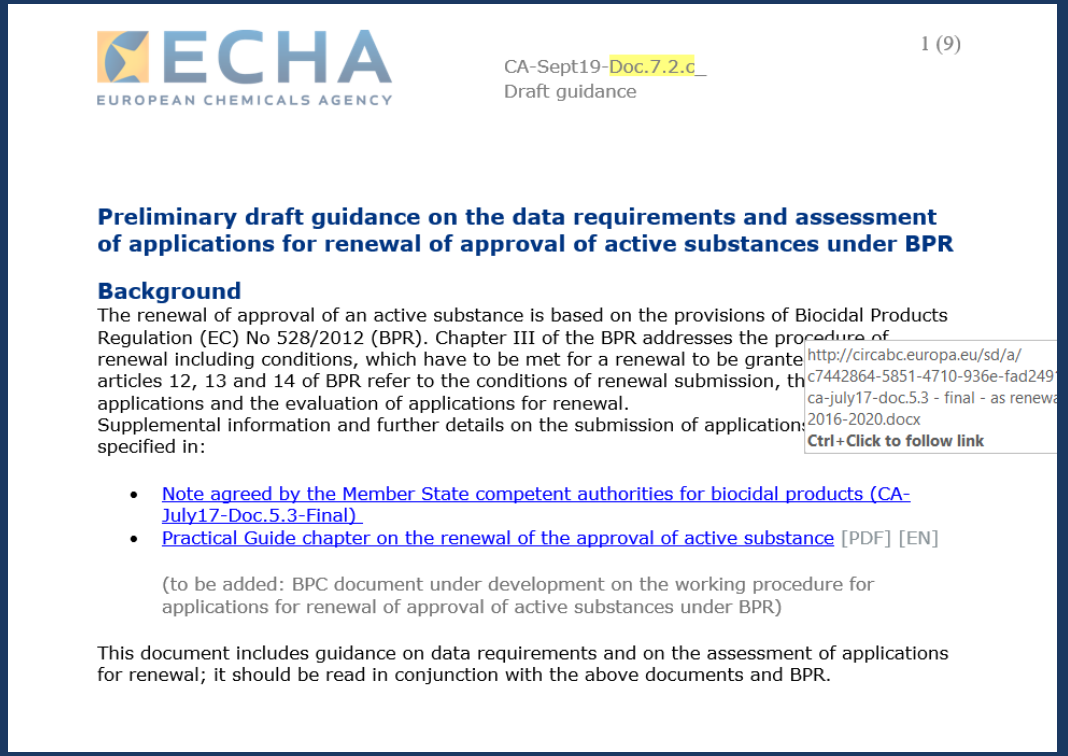
Product approvals and new uncertainties

- Many questions left from active substance approval to product authorization
- Evaluation and authorization delayed
- Still nothing approved for some product types

Re-registration time

- Soon time to initiate renewal
- New evaluating member state?
- Reduced or full evaluation?
- New data requirements
- Endocrine disruption assessment – enough information available?



ECHA
EUROPEAN CHEMICALS AGENCY

CA-Sept19-Doc.7.2.c_
Draft guidance

1 (9)

Preliminary draft guidance on the data requirements and assessment of applications for renewal of approval of active substances under BPR

Background

The renewal of approval of an active substance is based on the provisions of Biocidal Products Regulation (EC) No 528/2012 (BPR). Chapter III of the BPR addresses the procedure of renewal including conditions, which have to be met for a renewal to be granted. Articles 12, 13 and 14 of BPR refer to the conditions of renewal submission, the applications and the evaluation of applications for renewal.
Supplemental information and further details on the submission of applications specified in:

http://circabc.europa.eu/sd/a/c7442864-5851-4710-936e-fad249... ca-july17-doc.5.3 - final - as renewa... 2016-2020.docx
Ctrl+Click to follow link

- Note agreed by the Member State competent authorities for biocidal products (CA-July17-Doc.5.3-Final)
- Practical Guide chapter on the renewal of the approval of active substance [PDF] [EN]

(to be added: BPC document under development on the working procedure for applications for renewal of approval of active substances under BPR)

This document includes guidance on data requirements and on the assessment of applications for renewal; it should be read in conjunction with the above documents and BPR.

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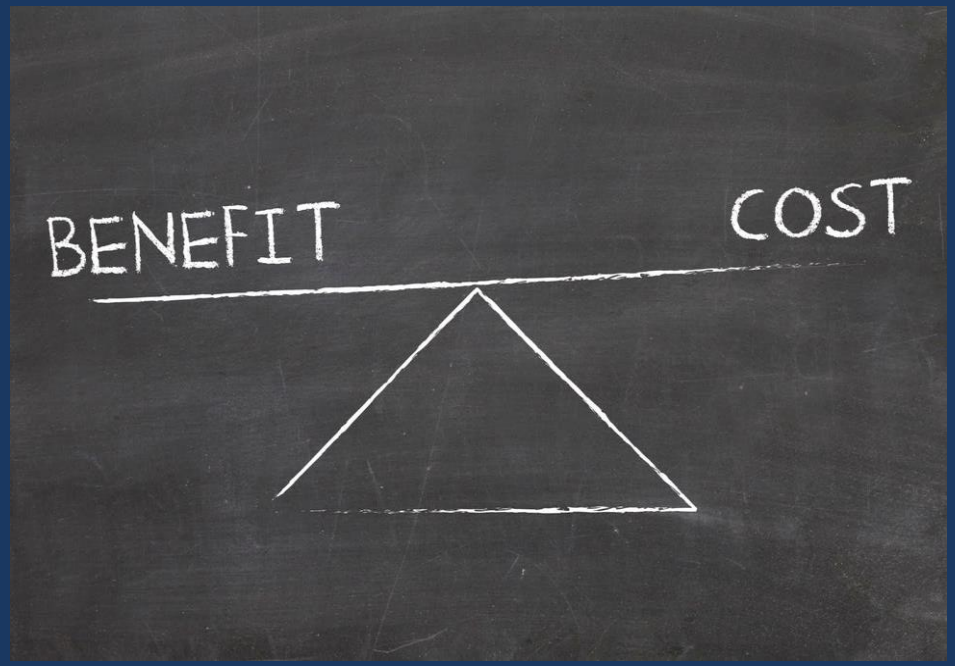
Business aspects of BPR

- Cost for first approval
- Cost to maintain approval
- Still no products on the market
- Importance and size of the EU market?
- Benefits with BPR approval besides market?



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THANK YOU!

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