



Fee Overview under the BPR

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**Product Defense for REACH and Biocides 2015
Steptoe**



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Introduction

Focus on Biocide Product Authorisation Fee



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Content

1. EU Report on the Fees
2. Industry perspective
3. Some comparisons
4. Conclusions



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Report on the Fees

- **EU CA-March15-Doc.7.2.**
- Areas of focus
 - Fees for the evaluation of a.s. per PT and per additional PT;
 - Fees for the authorisation of a BP and of a BP Family;
 - Fees for the mutual recognition of an authorisation for a BP and for a BP Family
 - The annual Fee;
 - Existing measures supporting SMEs in this process



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Report on the Fees

- **EU CA-March15-Doc.7.2.**
- Areas of focus
 - Highlight average indicative fee amounts
 - Not included:
any top-up fee that a wide majority of MSCAs apply to their basic fee



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Report on the Fees

- Fees for Biocide Product Authorization
 1. More than half of the MSs (16) have established the Fee < 20 000 € **9MSs / 16**
 2. Whilst 10 have set it above 20 000 €, among which 6 have set it above 40 000 €

BUT

A large group of MSs: process of adoption/reviewing relevant legislation (12 MSs / 28)



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Report on the Fees

- Fees for Mutual recognition of BP Authorization
 1. In 19 MSs MR Fee < 5000 € with an average of approx. 4000 €
7MSs / 19
 2. In 10 MSs, MR Fee > 5000 €, among which 4 MSs set it > 10 000 €
2MSs / 10

BUT

A large group of MSs: process of adoption/reviewing relevant legislation (12 MSs / 28)



Report on the Fees

- BP Family
 - BPF fee are generally higher as single BP authorization
- Annual Fee
 - 9 MSs are requesting Annual Fees (at the moment) between 100 and 500 € **3 MSs / 9**
 - Average \approx 280 € (2 MSs > 1000 €)
 - ECHA: 10.000 € (PA) / 20.000€ (BPF)
- Support measures for SMEs
 - Only 7 MSs (fee reduction (3) but also other measures)



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Report on the Fees

- Final comments from the report
 - Specific fee regulation still has not been adopted in some MS, hence requirements under Article 80(2) of the BPR have not been fully implemented in all MSs
 - Cost of BP National Authorization via MR of BPs *is not significantly different* from those of applying for Union Authorization
 - Similar conclusions can be drawn for annual fees

However, uncertainty that companies supporting products authorized by the Union might be forced to pay both the ECHA and MS' annual fees



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Industry perspective

- What did we face when collecting information on fee?
 - Information not always available on official websites
 - Help desks not responding
 - Different languages
 - Different currencies
 - Different fee structures



Industry Fee Overview



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Industry perspective

- Biocide product Authorisation + Mutual recognition

National Authorization

Average

Biocide Product (2015) 1 a.s. – 1 PT – 1 User Group	~ 41 000 €*
BP – Mutual Recognition (2015) 1 a.s. – 1 PT – 1 User Group	~ 6 000 €*
Total / BP (PA + MR) (2015)	214 000 €**

* Basis for calculation: 16 MSs where Fees have been updated + NO + CH

** Basis for calculation: 28 MSs + NO + CH



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Industry perspective

- Biocide product Union Authorization

National Authorization

Average

Biocide Product Union Authorization <i>Commission Implementing Regulation (EU) No 564/2013</i>	80.000 €*
Biocide Product Union Authorization Evaluation MS Fee	~ 60 000 €*
Total / BP (ECHA + MS) (2014)	140 000€

* Basis for calculation: 12 MSs where Fees have been updated + NO



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Industry perspective

- Biocide Product Family

National Authorization	Average
Biocide Product Family (2015) First Authorization 1 a.s. – 1 PT – 1 User Group	~ 75 000 €* ~ 9 000 €* 336 000 €**
Biocide Product Family (2015) Mutual Recognition 1 a.s. – 1 PT – 1 User Group	
Total / BPF (A+MR) (2015)	

vs **214 000 €** for a single BP

* Basis for calculation: 16 MSs where Fees have been updated + NO + CH

** Basis for calculation: 28 MSs + NO + CH



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Industry perspective

- Additional fees – Top-up fees

	Median
Biocide Product - RMS Additional a.s. 7 Countries	≈ 3300
Biocide Product - RMS Additional PT 12 Countries	≈ 5000
Biocide Product - RMS Additional user group 9 Countries	≈ 4500
Biocide Product - MR Additional a.s. 8 Countries	≈ 2500
Biocide Product - MR Additional PT 11 Countries	≈ 3500
Biocide Product - MR Additional user group 10 Countries	≈ 3200



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Industry perspective

- Biocide Product : Basic fee + additional fees

Biocide Product (2015) Authorization sought for all over Europe+NO+CH PT8 – 1 st Authorization + MRs 3 active substances 3 user groups (Industrial-Professional-Amateur)	Basic fee + 2x add a.s. fee + 2 x add. User group RMS ~ 41.000 + 6600 + 9000 MSs (29 countries) ~ 29x6.000+8x5.000+10x6.400
Total	334 600 €*

* Basis for calculation: 28 MSs + NO + CH



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Industry perspective

- Biocidal product: Administrative change

National Authorization	Average
Biocide Product (2014) Administrative change RMS	~ 500 €*
Biocide Product (2014) Administrative change Mutual Recognition	~ 500 €*
Total / administrative change (2014)	15 000 €**

* Basis for calculation: 12 MSs where Fees have been updated + NO + CH

** Basis for calculation: 28 MSs + NO + CH



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Some comparisons

- BP : Fee BPR (2015) vs Fee BPD (2010)

Biocide Product Fee / BPR / (2014)
28 EU MSs + NO + CH

~ **214 000 €***

Biocide Product Fee / BPD / (2010)
28 EU MSs + NO + CH

~ **100 000 €***

X 2



Some comparisons

- Authorization + MR vs Union Authorization

BP /BPR (2014) First Authorization + MR	214 000 €
BP /BPR (2014) Union Authorization	140 000 €

Basis for calculation: 28 MSs + NO + CH

- Union Authorization (Article 42)
 - Phase-in approach
 - Exclusion for BP containing a.s. falling under Article 5 and those of product-types 14, 15, 17, 20 and 21



Some comparisons

- BP : Difference between MS fees

	Average
Biocide Product Fee BPR / 2015 <i>Finland FIN</i>	96 000 €
Biocide Product Fee BPR / 2015 <i>Belgium BE</i>	15 000 €

~ **X 6**



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Some comparisons

- BP : Evaluating Member State fee -
First authorisation vs Union Authorization

Average

Biocide Product Fee / First Authorization BPR / 2015 28 EU MSs + NO + CH	~ 41.000 €
Biocide Product Fee / Union Authorization - eMS BPR / 2014 28 EU MSs + NO + CH	~ 60.000€

~ X 1.5



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Some comparisons

- BP Fee vs Plant Protection Product Fee

Biocide Product Fee / BPR / (2015) 28 EU MSs + NO + CH	~ 214 000 €
PPP Fee / PPPR/ (2010) 28 EU MSs + NO + CH <i>(information received by ECPA)</i>	~ 185 000 €

BUT

Biocide market vs PPP market: **3.5 X lower**
(source: market survey)



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Conclusions

- ▶ Fee have drastically increased under the BPR
- ▶ Fee will highly impact the Biocide business
- ▶ All the actors of the supply chain will be impacted
- ▶ Biocide sector is in transition - Fewer variability in terms of products
- ▶ Disproportion with other markets (PPP)



Conclusions

What is needed?

- ▶ Revision of the Fee Regulation (January 2015) should consider the impact for our Industry
→ Status?
- ▶ Same when MSs review their fee legislation
- ▶ More SMEs measures (ECHA + MS levels)
- ▶ Reasonable Annual Fee (mainly in case of cumulative MS fees and ECHA fee for UA)



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Conclusions

What is needed?

HARMONISATION

▶ PA/MR

- ? differences between MS
- ? fee update on which basis – recommendations?
- ? MS in adoption/review process → fee increase very likely

▶ Top-up fees

- ? Intention to add top-up fees?
- ? Big impact on industry



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Thank you



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