

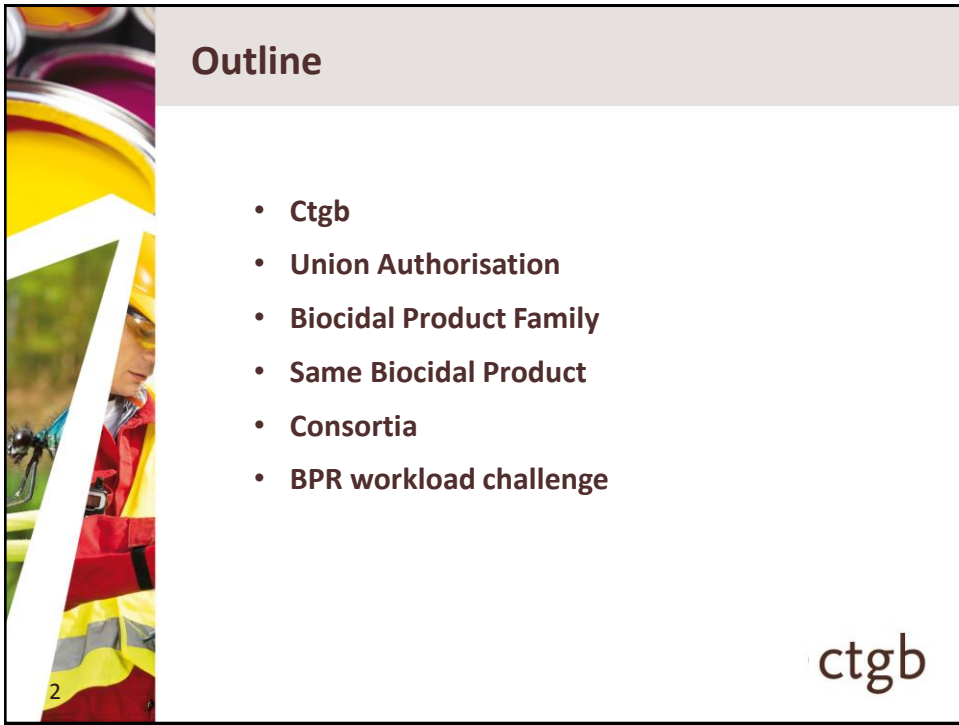


BPR update:
Union Authorisation, Families and
Same Biocidal Product

Marcel Hulsman
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Brussels, 24 November 2016

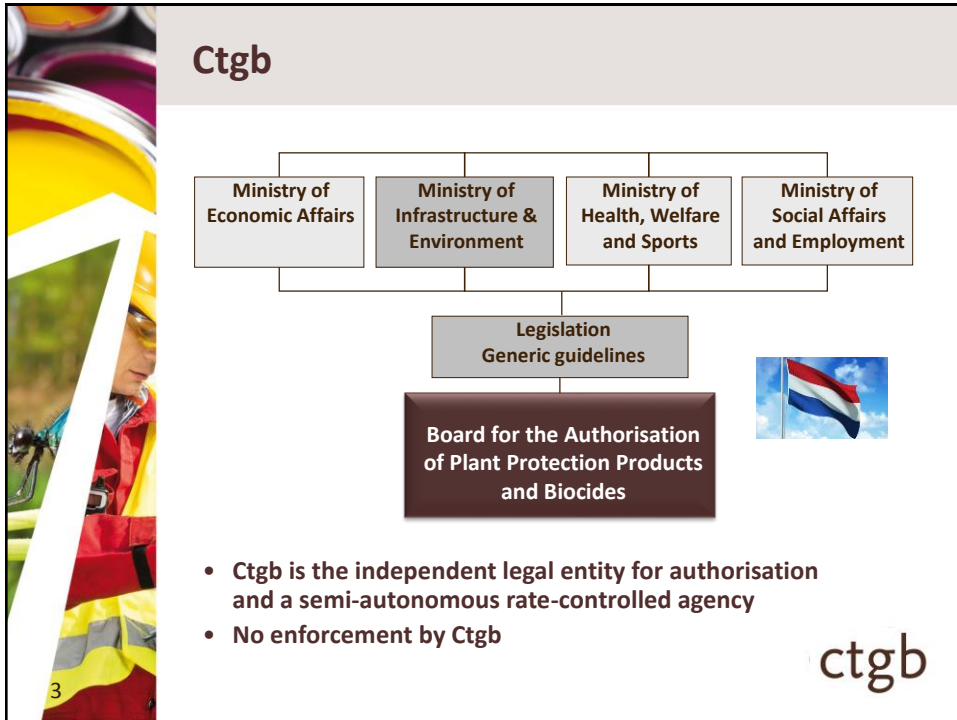
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Outline

- **Ctgb**
- **Union Authorisation**
- **Biocidal Product Family**
- **Same Biocidal Product**
- **Consortia**
- **BPR workload challenge**

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Positioning of Ctgb

- Independent governmental authority
- Mandate:
 - To decide upon authorisations (biocides as well as PPPs) based on assessment of applications
 - Advice to the minister on general policy issues
- Board and director are appointed by the minister
- Budget and annual report need the consent of the minister
- Apart from that: independent



Facts about the Secretariat

- Hourly fee € 124,- (2016)
- Budget: ca. € 16.800.000
- 65% income based on fees for applications
- 15% based on a yearly fixed fee per authorised product
- 20% paid by government related to requests for advice from ministries, EU-peer review process and legal procedures

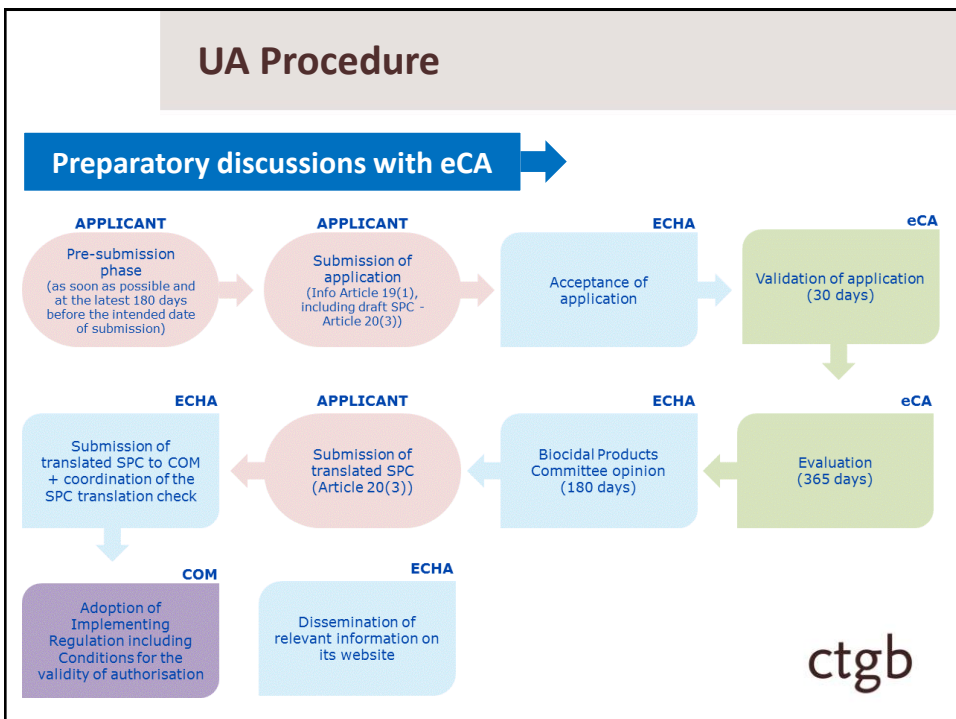



Union Authorisation (UA)

- Authorisation granted by the European Commission, valid on the entire Union market
- For single biocidal products or product families
- Excluded:
 - Products containing substances fulfilling the exclusion criteria (Article 5 of BPR)
 - Products to control rodents, birds, fish, and other vertebrates (PTs 14, 15, 17 and 20)
 - Antifouling products (PT 21)




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Union vs National procedures

UA	NA + Mutual recognitions
<ul style="list-style-type: none"> • Apply at ECHA, select eCA • Validation within 30 days • 12 month for evaluation 	<ul style="list-style-type: none"> • Apply at eCA and CMSs • Validation within 30 days • 12 month for evaluation
<ul style="list-style-type: none"> • Peer review (~6 mo) 	<ul style="list-style-type: none"> • Peer review by CMSs (~3 mo)
<ul style="list-style-type: none"> • Authorisation granted by COM 	<ul style="list-style-type: none"> • Authorisation granted by eCA and CMSs involved
<ul style="list-style-type: none"> • Products are allowed in EU 	<ul style="list-style-type: none"> • Products are allowed in eCA and CMSs



First experiences

Union Authorisation: new concept

- Evaluation phase similar to NA
- No evaluation finalised yet
- No experience on peer review phase


Most UA applications are Biocidal Product Families

- Complexity determined by BPF structure

Consult your eCA and ECHA well in advance


- Discuss the BPF structure

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Biocidal Product Family

- An authorisation can be granted for a single product or for a biocidal product family
- *Implementing the new concept of BPFs (CA-Nov14-Doc.5.8 rev3)*
- A family consists of products with
 - Same active substance(s)
 - Similar composition within specified variations
 - Similar uses
 - Similar levels of risk and efficacy
- Strict conditions
- Reduces costs for registration
- Easy to add new family members post-authorisation



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BPF Guidance

Be aware of ongoing discussions (CA, CG)

Example:

- *“Similar uses*
- **Similar uses** for products belonging to a BPF have to be understood as **different uses** within the PT(s) to which the BPF belongs.
- Therefore, provided that the risk and efficacy assessment provides a positive outcome, products belonging to a BPF can include different:
 - User categories.
 - Target organisms (e.g. rats and mice or ticks and fleas).
 - Application methods (e.g. spraying and brushing).
 - Applications rates and frequency.
 - Fields of use (e.g. indoor or outdoor).”

Implementing the new concept of BPFs
([CA-Nov14-Doc.5.8 rev3](#))

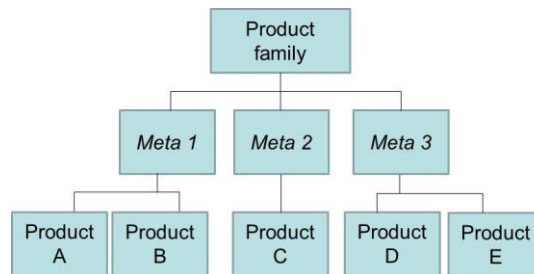
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Family: 3 levels

1. General family
2. Meta families (*meta* SPC)
 - Grouping the products within the family
3. Individual products (product SPC)



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Building BPF strategy

Subdivision in meta families

- Based on identical shelf life and C&L
- All possible new products should fit within the range of the *meta* family and be efficacious
- Efficacy testing for all products in family?
 - prevent repetition
 - possible new products should be covered
- Test one or more 'worst case' products
 - lowest/highest concentration of AS
 - most difficult conditions
 - provide justification for 'worst case'

Best Case
Normal Case
Worst Case

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Example 1: Multiple Active Substances

Disinfectant BPF	BP1	BP2	Meta SPC
AS 1	10%	5%	5% - 10%
AS 2	2%	8%	2% - 8%
Target organisms	Bacteria	Bacteria	Bacteria
	Yeasts	Yeasts	Yeasts

- Consider the whole potential range of (new) products within *meta* SPC
- Maximum risk and minimum level of efficacy
- Worst case scenario?
 - Efficacy: 5% AS1 + 2% AS2
 - Risk: 10% AS1 + 8% AS2
- or split into 2 *meta* SPCs

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Example 2: Co-formulants

Disinfectant BPF	BP1	BP2	BP3
Gel formulation			
AS	A%	A%	A%
Viscosity	20.000	24.000	22.000
Thickener A	3%	0%	1%
Thickener B	0%	1%	0,5%

- BP1 and BP2 in one *meta* SPC?
 - Post-authorisation notifications of new products
 - All possible new products should fit within the range of the *meta* family and be efficacious

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Example 2: Co-formulants

Disinfectant BPF Gel formulation	BP1	BP2	BP3
AS	A%	A%	A%
Viscosity	20.000	24.000	22.000
Thickener A	3%	0%	1%
Thickener B	0%	1%	0,5%

- BP1 and BP2 in one *meta* SPC?
 - All possible new products should fit within the range of the *meta* family and be efficacious
- “Worst case” new product BP4 in the same *meta* SPC?
 - Thickener A: 3% + Thickener B: 1%

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Example 2: Co-formulants

Disinfectant BPF Gel formulation	BP1	BP2	BP3
AS	A%	A%	A%
Viscosity	20.000	24.000	22.000
Thickener A	3%	0%	1%
Thickener B	0%	1%	0,5%

- BP1 and BP2 in one *meta* SPC?
 - All possible new products should fit within the range of the *meta* family and be efficacious
- “Worst case” new product BP5 in the same *meta* SPC?
 - Thickener A: 0% + Thickener B: 0%

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Meta SPC considerations

Broad ranges, few *meta* SPCs

- + Less data required
- + Broad range of (new) products possible
- Difficult to find a worst-case


Limited ranges, more *meta* SPCs

- + Easier to find worst-case
- Requires more data
- Less flexibility in (future) product range

Consider “simplification” of composition:

- Beware of large number of substances
- Reduce number of components with equal function:
e.g. buffers, acids
- Avoid concentration: 0% in *meta* SPC

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Grouping of co-formulants

Draft proposal Coordination Group (Nov 2016)

- To avoid excessive splitting of *meta* SPCs
- Should be allowed to group co-formulants

Co-formulants within a certain functional group

- Same hazard and safety statements
- Same functionality
- Same impact on risk
- Same impact on efficacy

Comments of MSs (Dec 2016)
Commission -> new Q&A added to BPF Guidance

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Example 2: Co-formulants (new*)

Disinfectant BPF Gel formulation	BP1	BP2	BP3
AS	A%	A%	A%
Viscosity	20.000	24.000	22.000
Thickener A	3%	0%	1%
Thickener B	0%	1%	0,5%

Meta SPC:

- Thickener to provide viscosity range 20.000 to 24.000
- Thickener concentration range 1% to 3%

Composed of Thickener A, Thickener B or combination of both

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Same Biocidal Product 1



Regulation (EU) 414/2013


- An authorisation is sought for a product that is identical to an authorised product (= the reference product)

SBP


- Private label companies
- LoA to all data supporting the reference product
- Authorisation holder: Private label company
- Different Authorisation number
- Limited application costs

UA → UA NA → NA BPF → BPF

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Same Biocidal Product 2



Regulation (EU) 1802/2016



- of 11 October 2016
- Amending Regulation (EU) 414/2013

New options to respond to the needs of companies (SMEs)


SBP

- From BPF to single product
- From Union Authorisation to National Authorisation

UA BPF → NA single product

Consortia



Consortia for Active Substances

Consortia for Products


- Companies (SMEs) working together
- Initiatives by consultants


Benefits

- Save effort by sharing expertise
- Share costs for dossier preparation and testing
- Share (application) costs to ECHA and MSs

UA and BPF particularly suitable for cooperation

Same Biocidal Product!





BPR Workload challenge 1

“Major” Active Substances approved:

2015 Iodine

2016 Permethrin
Propan-2-ol
Glutaraldehyde


2017 Hydrogen peroxide
C(M)IT/MIT
Peracetic acid

Applications	2014	2015	2016 to date	2017 to date
EU: NA + UA	50	240	220	
NL: UA	-	6	8	23*

*: notifications

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BPR Workload challenge 2

Commission Report on the BPR fee model

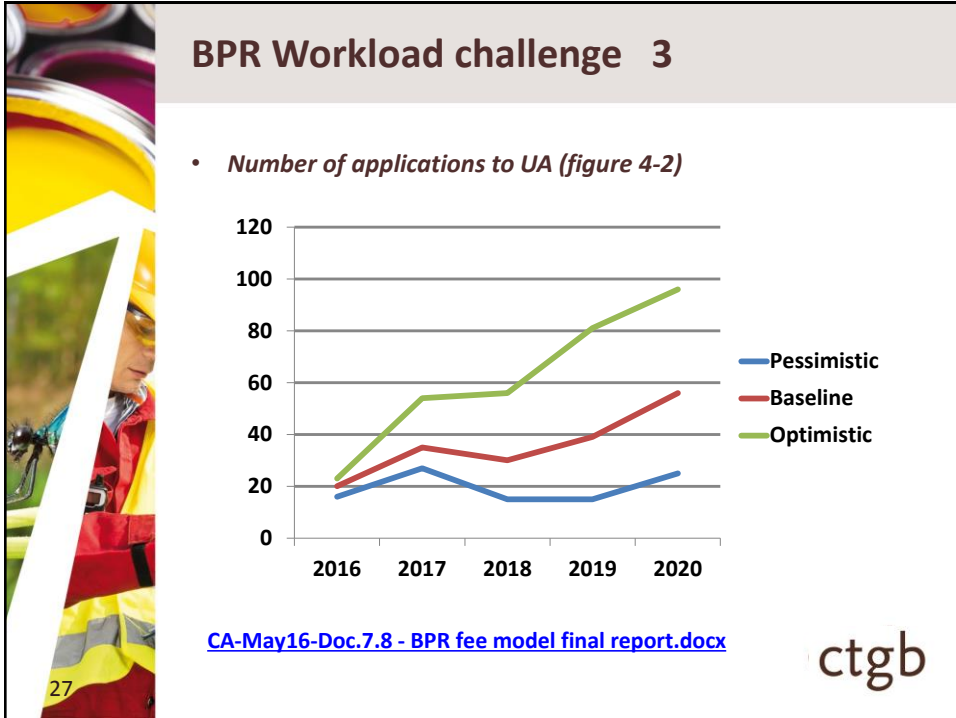
- Summary of the estimates of the number of applications for Union Authorisations (table 4-7)*

	2016	2017	2018	2019	2020	Total
Pessimistic	16	27	15	15	25	98
Baseline	20	35	30	39	56	180
Optimistic	23	54	56	81	96	310

[CA-May16-Doc.7.8 - BPR fee model final report.docx](#)

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Concluding remarks

Union Authorisation and BPF

- New concepts providing flexibility
- No evaluation finalised yet
- No experience on peer review phase

Most UA applications are BPFs

- Complexity determined by BPF structure
- Explain and justify your choices
- Keep it simple!

SME

- Consider joining a consortium or apply via SBP

Keep up-to-date

- New Regulations, Amendments, Guidance

Consult your eCA pre-submission

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Thank you for your attention

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