Ctgb experiences with BPR applications

Cindy van der Meer

Account manager Biocides

Teamleader ServiceDesk & Project Support

ctgb

Contents

Ctgb

- Organisation

Product applications under the BPR

- National and Union applications

Union applications

- Procedure
- Costs
- Processing times

Ctgb

Board for the authorization of plant protection products and biocides

2 units: Biocides
Plant Protection Products

Independent body

Biocides team:

- 10 dossier managers
  - 2 solely work on administrative applications
- 6 APCP experts
- 6 EFF experts
- 7 HH experts
- 6 ENV experts

Servicedesk, Legal, Communication, Policy

Ctgb

The task of the Ctgb is to assess whether ppp and biocidal products are safe for humans, animals and the environment and efficacious in accordance with criteria laid down in legislation

NL-legislation: Law on pesticides since 1962

EU-legislation: Biocidal Product Regulation since 2013

Regulation of biocides

- All biocidal products regulated
  - Active substance(s) approved for relevant PT: BPR
  - Active substance(s) still under review for relevant PT: NL-legislation

- Access to Dutch market only with authorisation of Ctgb

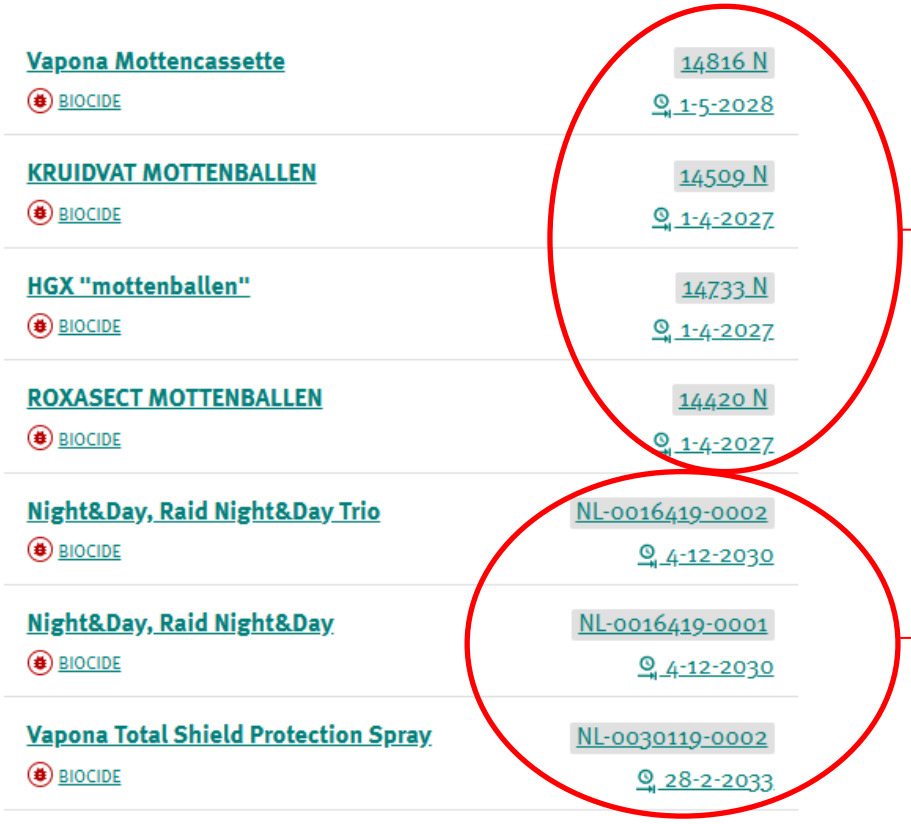
- Database of authorised products https://toelatingen.ctgb.nl/nl/authorisations






Database

https://toelatingen.ctgb.nl/nl/authorisations



NL transitional law

BPR

ctgb

Contents

Ctgb

- Organisation

Product applications under the BPR

- National and Union applications

Union applications

- Procedure
- Costs
- Processing times

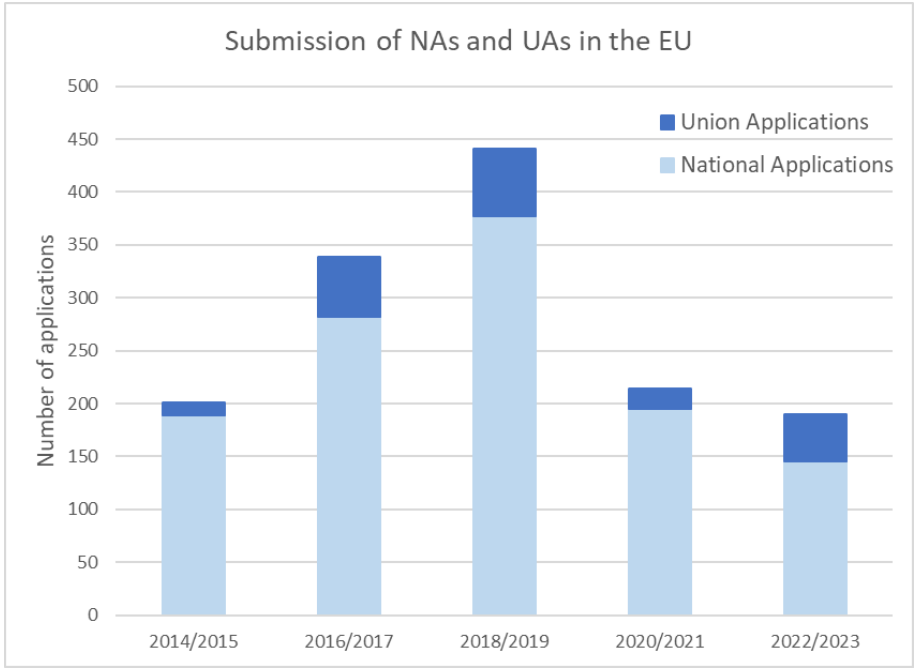
Product authorisation under BPR

Two main routes:

- Union authorisation
  - Products that have similar conditions of use across the union
  - PT 14-15-17-20-21 excluded
  - Authorisations are issued by the commission
  - Products can be placed on the market throughout the union

- National authorisation combined with mutual recognitions
  - All product types
  - Authorisations are issued by the individual member states
  - Products can be placed on the market of member states where an authorisation is obtained

UAs and NAs in EU



- Total number of product applications is mainly driven by active substances approved
- Proportion of UAs 14%

Ctgb as evaluating authority (eCA)

Completed or In progress 2014-2023	Total in EU	NL as eCA
National Applications	1235	94
Union Applications	197	66

- Ctgb is eCA of 1/3 of the total number of UAs (!)
- In 2018 measurements were taken to reduce influx at Ctgb
- Ctgb has a great deal of experiences with UAs

Contents

Ctgb

- Organisation

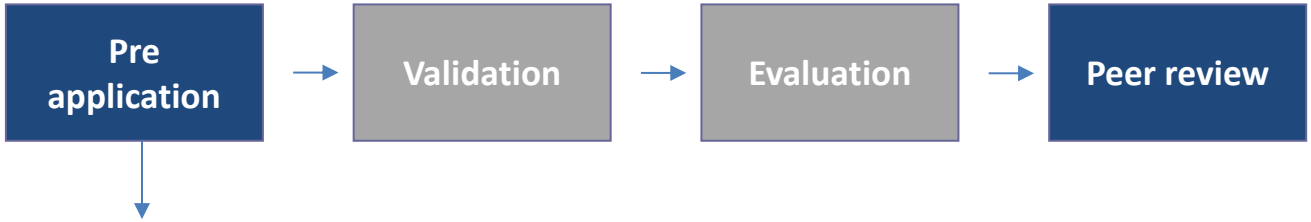
Product applications under the BPR

- National and Union applications

Union applications

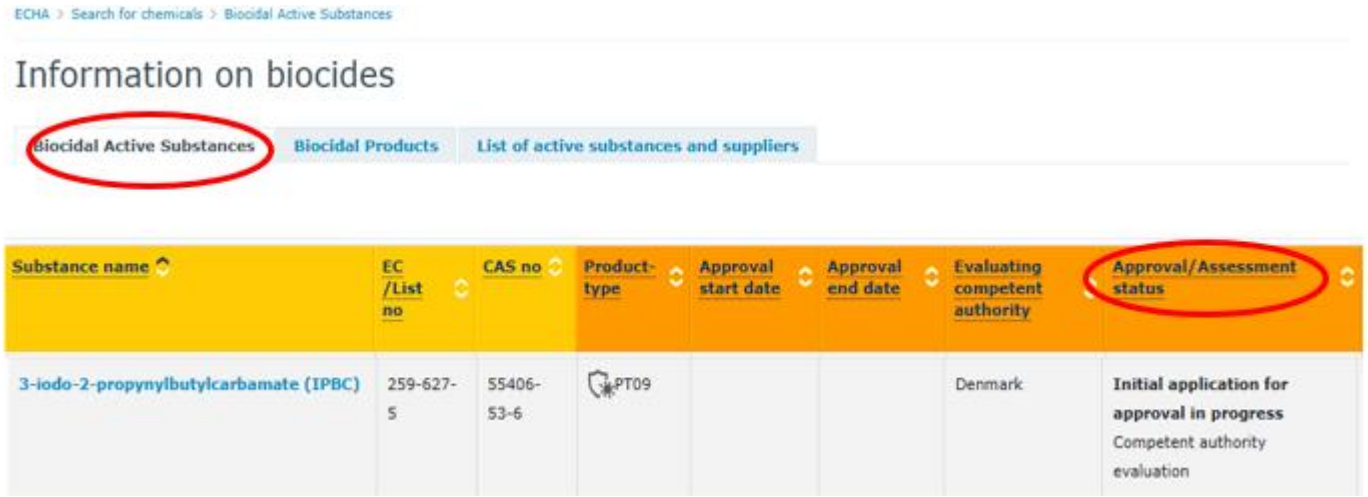
- Procedure
- Costs
- Processing times

Procedure of UAs



- Keep track of evaluation progress of actives substances
- Start early with dossier preparation
- Find an eCA

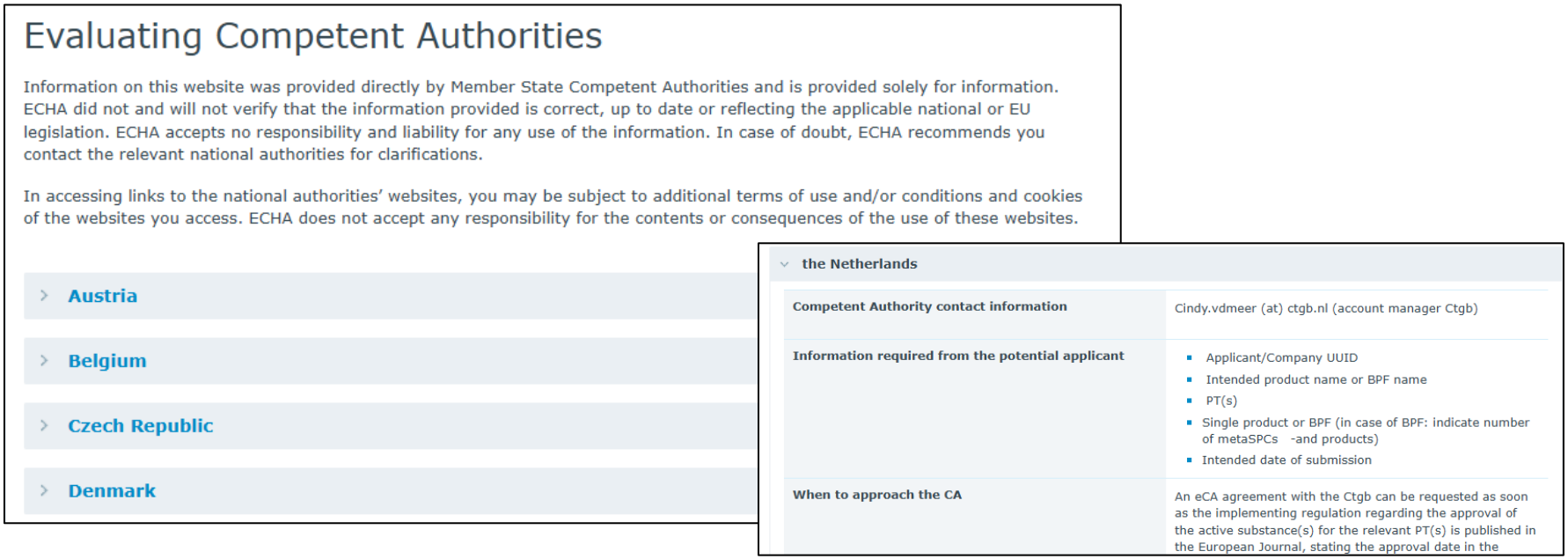
https://echa.europa.eu/nl/regulations/biocidal-products-regulation/understanding-bpr



Finding an eCA

- Finding an eCA can be challenging
  - Only 13 out of 27 MS accept UAs as eCA
  - Many MSCAs are overloaded

https://echa.europa.eu/nl/evaluating-competent-authorities-for-union-authorisation



Evaluating Competent Authorities

Information on this website was provided directly by Member State Competent Authorities and is provided solely for information. ECHA did not and will not verify that the information provided is correct, up to date or reflecting the applicable national or EU legislation. ECHA accepts no responsibility and liability for any use of the information. In case of doubt, ECHA recommends you contact the relevant national authorities for clarifications.

In accessing links to the national authorities' websites, you may be subject to additional terms of use and/or conditions and cookies of the websites you access. ECHA does not accept any responsibility for the contents or consequences of the use of these websites.

- Austria
- Belgium
- Czech Republic
- Denmark

the Netherlands

Competent Authority contact information	Cindy.vdmeer (at) ctgb.nl (account manager Ctgb)
Information required from the potential applicant	▪ Applicant/Company UUID ▪ Intended product name or BPF name ▪ PT(s) ▪ Single product or BPF (in case of BPF: indicate number of metaSPCs -and products) ▪ Intended date of submission
When to approach the CA	An eCA agreement with the Ctgb can be requested as soon as the implementing regulation regarding the approval of the active substance(s) for the relevant PT(s) is published in the European Journal, stating the approval date in the

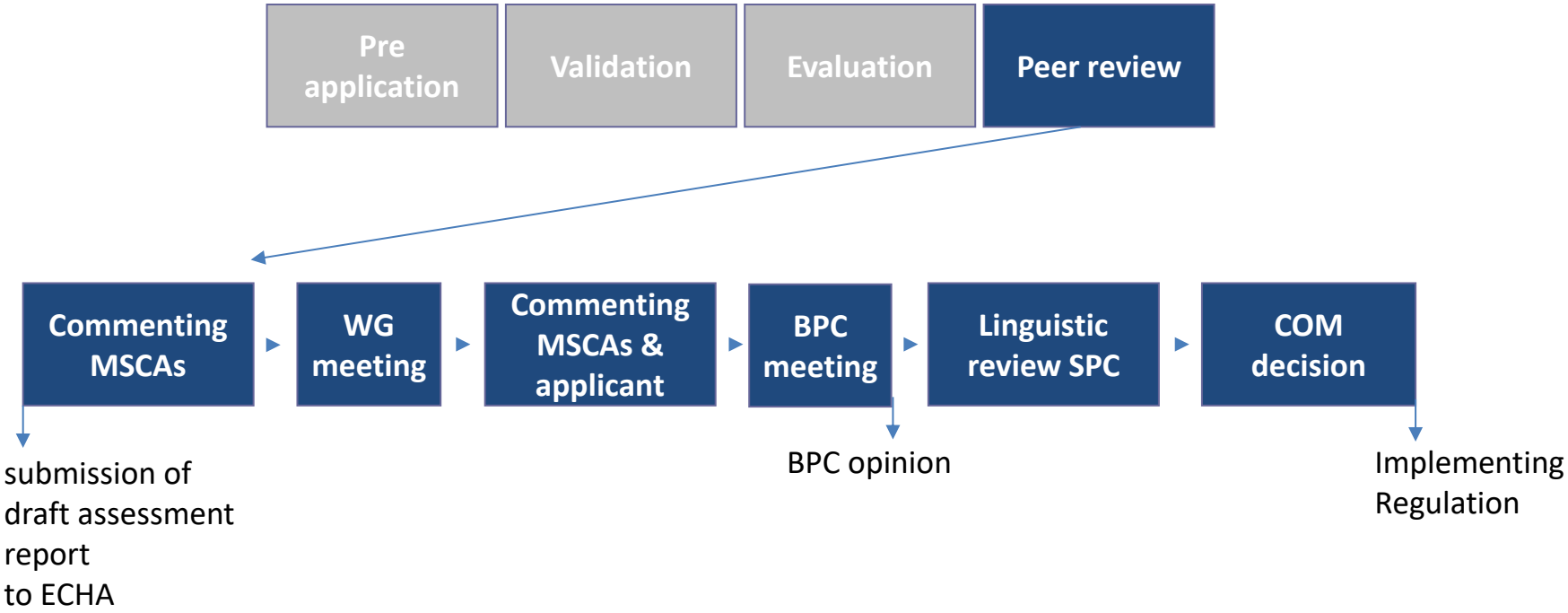
Pre-submission meeting

- UA pre-submission services of Ctgb
  - Only when Ctgb will be eCA
  - Contact ServiceDesk@ctgb.nl
  - Meeting with experts and dossier manager of Ctgb

- UA pre-submission services of ECHA:
  - Consultation of MSs whether products are deemed eligible for UA
    - Within the scope of the BPR?
    - PTs correctly assigned
    - Conditions of use similar?
  - Pre-submission meeting (R4BP code: UP-APP)

ctgb

Peer review of UAs



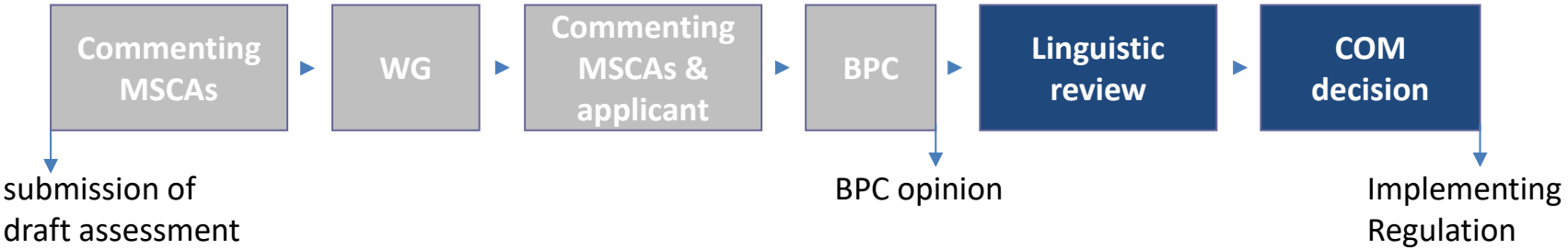
- Peer review phase has many consecutive steps
- Takes 1-2 years
- Steps are coordinated by ECHA
- Timelines are fixed in process flows

Process flow

UA WP step	TASK		Process flow 52
1	Submission	Start	04 December 2023
		End	22 March 2024
6	Commenting phase	Start	15 April 2024
		End	26 April 2024
7	RCOM	Start	#N/A
		End	#N/A
7	Trilateral Discussions	Start	29 April 2024
		End	17 May 2024
8	Disagreeing in closing a point	Start	20 May 2024
		End	24 May 2024
15	**WG Meeting**	**Start**	**10 June 2024**
		End	**21 June 2024**
24	Commenting WG Minutes	Start	09 July 2024
		End	30 July 2024
28, 31	Preparation of updated CAR/PAR, draft SPC and BPC opinion by eCA and submission by eCA to ECHA	Start	24 June 2024
		End	05 August 2024
32	ECHA–eCA consultation on updated CAR/PAR, draft SPC and BPC opinion and submission by ECHA to BPC	Start	06 August 2024
		End	12 August 2024
35	Commenting BPC on updated CAR/PAR, draft SPC and BPC opinion	Start	14 August 2024
37	**BPC Meeting**		
39	Final Opinion		
40, 42	Final CAR & IUCLID/Doc III - Final PAR & SPC		
41	Confidentiality check (applicant)		
44	Non-confidential documents		

- Tight timelines, strictly managed
- No possibility for ‘pause’
- No possibility for submission of additional data at this stage
- Uses, metas or products may drop out in this final phase

Linguistic review



- BPC opinion refers to SPC in English language
- SPC translations in all EU languages should be provided within 10 days

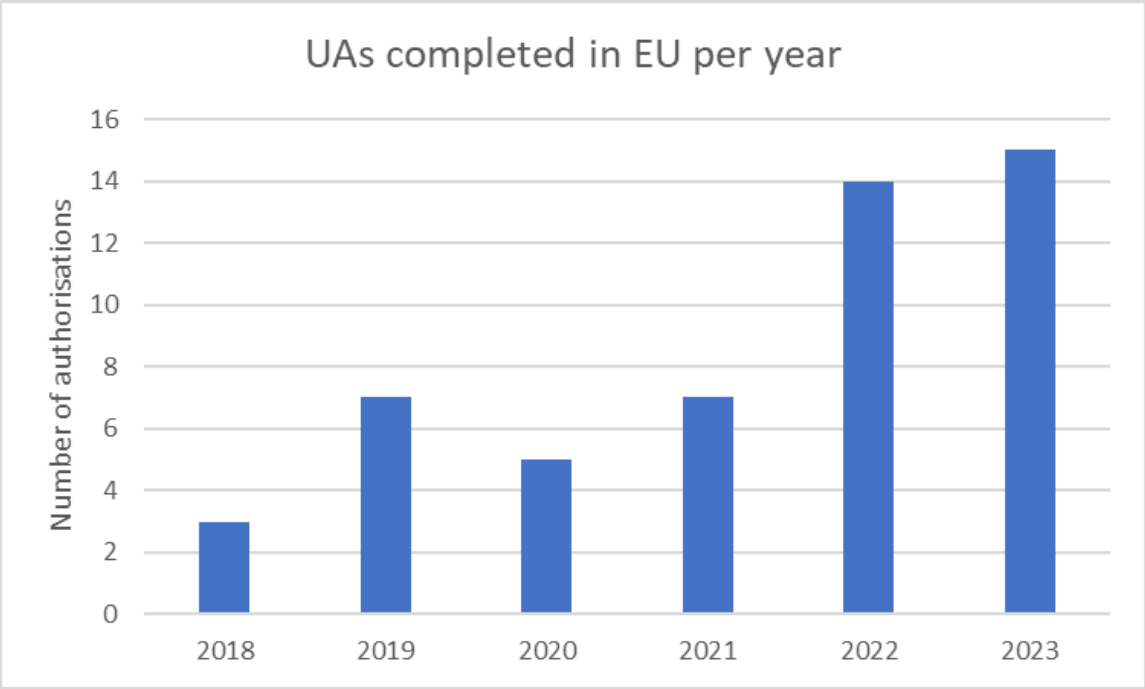
(Also MSs in which products will not be marketed)

- MSs check the proposed SPCs in their own language
- All communications via R4BP, intensive process

https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee

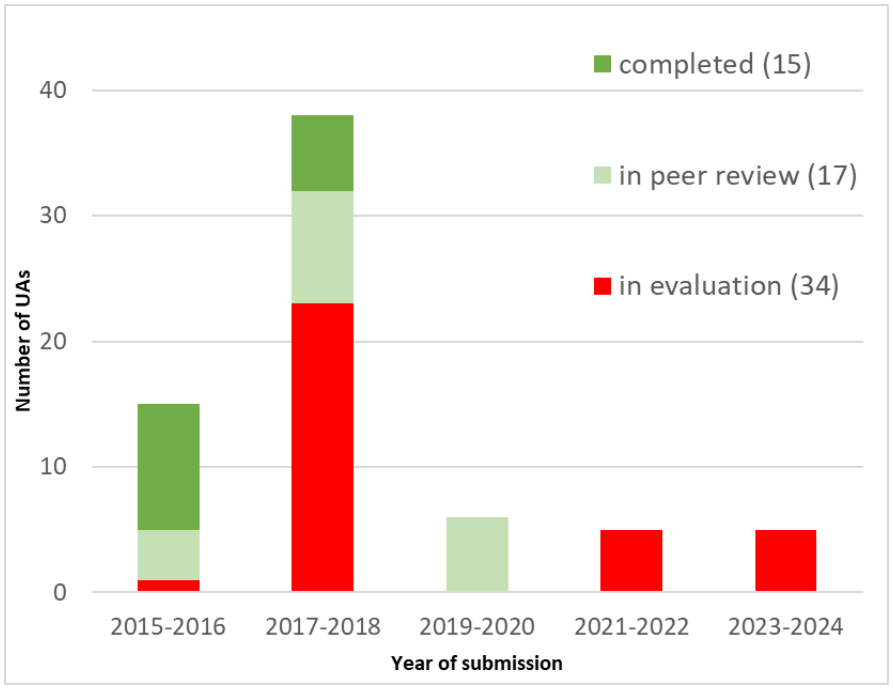
Linguistic review of the translations of the summary of product characteristics (SPC) for Union authorisation applications and for major changes applications of Union authorisation

Completion of UAs



- 1-8-2024: in total 57 UAs completed
- >30 UAs via Same Biocidal Products procedure
- 424 products authorised (5% of total)

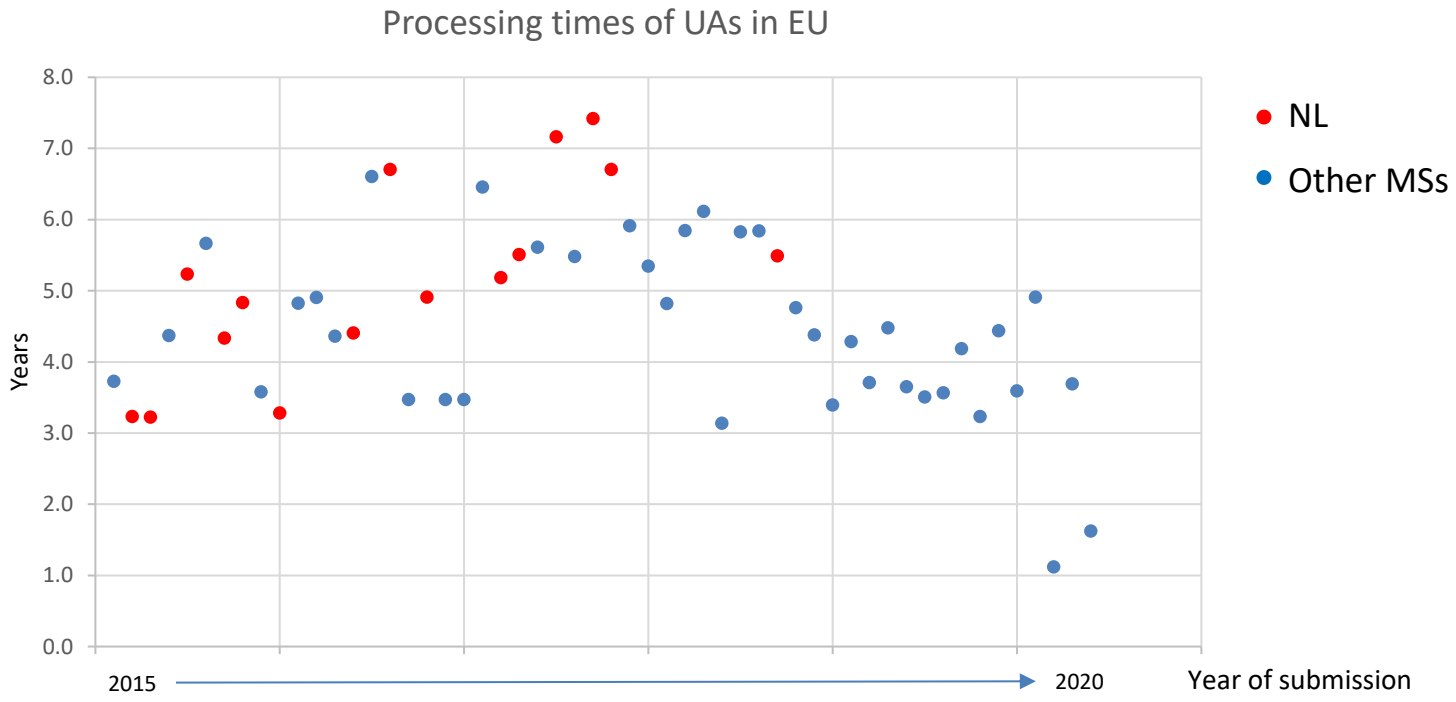
Progress UAs at Ctgb



- Ctgb has a large backlog of UAs submitted in 2017-2018
  - Large biocidal product families with low similarity between products
  - Many PTs and uses
  - Splitting of families / consortia

- Measurements to reduce influx at Ctgb from 2018

Processing times for UAs



- BPR timelines (3y) exceeded
- On average 4 - 5 years to obtain a Union authorisation
- Generally, UA processing times are longer than for NAs
  (but in some MS it can take a long time to obtain authorisation by mutual recognition)

Costs for UA

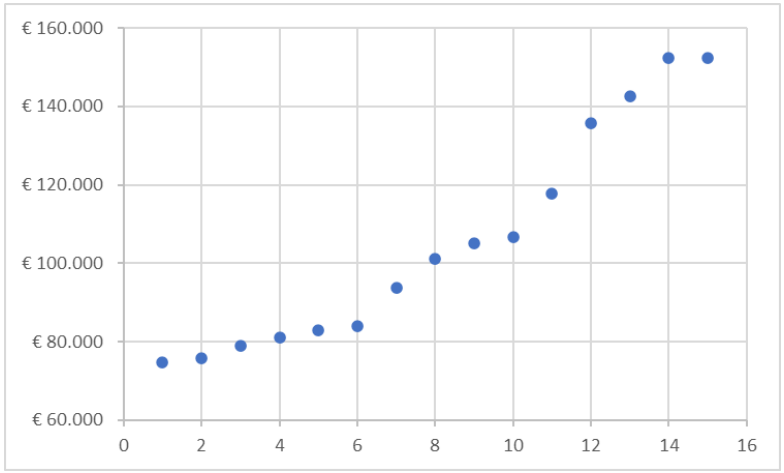
- ECHA: fixed fees: IR(EU) 564/2013
- Amendments because of inflation
  - Application fee UA
    - Single product: 95k / Biocidal Product Family: 180k
  - Annual fee UA
    - Single product: 12k / Biocidal Product Family: 24k
  - Fee reduction for micro/small/medium enterprises

- Ctgb: Tariff decree: www.ctgb.nl
- UA fee is based on the actual costs incurred
  - Based on the number of hours worked on a specific application
  - Payment in advance
  - No annual fee for Union Authorisations at Ctgb

ctgb

Costs for UA at the Ctgb

Costs for 15 UAs completed at Ctgb 2018-2024:



- Average costs of UAs at Ctgb: EUR 110k
- Hourly tariff Ctgb in 2025: 196 euro

Main factors:

- Family or single product
- Similarity between products of BPF
- Number of metas, PTs, uses
- Quality of PAR/SPC
- Guidance available / correctly applied?
- Co-formulants: ED / SOCs?

- Similar products already authorised?
- Harmonisation between MSCAs

Summary UAs

- Access to the EU market with one application
- For products that have similar conditions of use
- Peer review (incl. linguistic review) phase is challenging
  - Process flows with tight deadlines
  - Data submission is closed at this stage
- High costs and long processing times
- Good preparation in collaboration with eCA (and consultants) is essential

Thank you!

Cindy.vdmeer@ctgb.nl

ctgb