BIOCIDES FOR EUROPE

Experiences of the BPR

...an Industry perspective

5th PCD Industry Symposium on Biocidal Products
29 May 2025 | Celbridge
Boris Van Berlo

Membership

FOR TWENTY-TWENTYTHREE

Company Members

Trade Association Members

National Federation Members

WHO WE ARE

Biocides for Europe, formerly known as EBPF (European Biocidal Products Forum), is a Sector Group of Cefic, the European Chemical Industry Council representing the biocides industry in Europe.

WHAT WE DO

We represent the European biocides industry to Authorities such as the European Commission, ECHA and national Competent Authorities.

Biocides for Europe also provides a forum to establish common positions to inform ongoing debates with authorities and other stakeholders at the regulatory, technical and scientific level.

CONTACT

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Visit our homepage on the web at
www.biocidesforeurope.org

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FOR EUROPE

A sector group of Cefic

European Chemical Industry Council - Cefic aisbl
EU Transparency Register n° 64879142323-90

1. Art. 95(5) BPR data protection expiry

2. Product authorization after AS approval

1. Art. 95(5) BPR data protection expiry

2. Product authorization after AS approval

Data protection?

What is it?

The temporary right of the owner of a test or study report **to prevent it being used for the benefit of another applicant without suitable cost sharing**

Why is it important?

Allows companies making significant **investments in data to support the safety and efficacy of (active) substances** to have a limited period of protection to make a **return on their investments**

- Prevents free riding
- Supports level playing field

Data protection under the BPR

Protection period for the data shall start when they are submitted for the first time

Data protected under Art. 60 or for which the protection period under Art. 60 has expired shall not be protected again

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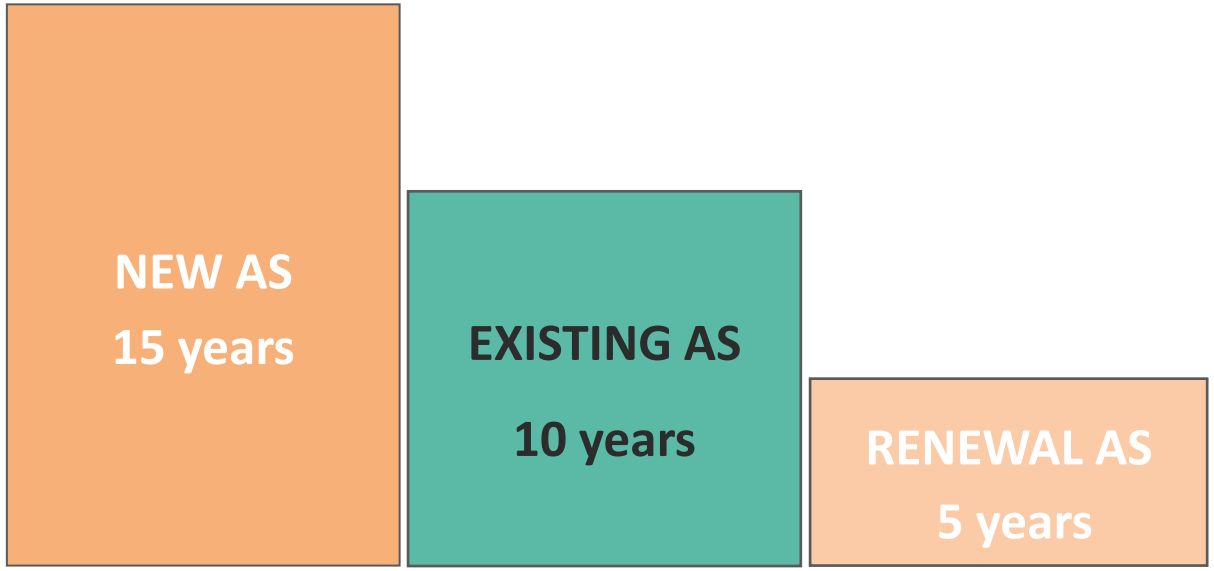
Data protected under Art. 60 or for which the protection period under Art. 60 has expired shall not be protected again

Protection period for the submitted data shall end X years from the first day of the month following the date of adoption of a decision

In accordance with Art. 9 or Art. 14(4) as relevant (approval or renewal)



Data protection under the BPR

Article 60 (2)

The protection period for data submitted with a view to the approval of an **existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision** in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

Data protection under the BPR

Article 60 (2)

The protection period for data submitted with a view to the approval of an **existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision** in accordance with Article 9 on the approval of the relevant active substance for the particular product-type.

Article 95 (5)

By way of **derogation from Article 60, all data protection periods** for active substance/product-type combinations listed in Annex II to Regulation (EC) No 1451/2007, but for which a decision on inclusion in Annex I to Directive 98/8/EC was not taken before 1 September 2013, **shall end on 31 December 2025**.

Data protection under the BPR

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Other regulations

Plant Protection Products Regulation (EC) 1107/2009

Test and study reports -> data protection* of **10 years from the date of first authorisation** (13 years for low-risk plant protection products)

REACH (EC) 1907/2006

Study summaries and robust study summaries submitted in the framework of a registration -> **12 years data protection from the date of the submission**

No hard-stop
Equal and fair treatment of all players for any new data generated and submitted at any time!

*Data protection = "the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant"

Data protection hard-stop

Initial intention of the legislator

Art. 60(2): 10 years data protection from first day of the month following the date of adoption of a decision on the approval of the active substance

Art. 89(1): end RP = 14/05/**2014**

Art. 95(1): derogation from *Art. 60(2)*, data protection all not yet approved RP AS ends = 31/12/**2025**

BPR Initial Text
Directive 2009/107/EC

Data protection hard-stop - historical error

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BPR Initial Text
Directive 2009/107/EC

BPR Amendment (2013 & 2014)

Art. 60(2): 10 years data protection from first day of the month following the date of adoption of a decision on the approval of the active substance

Art. 89(1): end RP = 31/12/**2024**

Art. 95(5): derogation from *Art. 60(2)*, data protection all not yet approved RP AS ends = 31/12/**2025**

BPR Consolidated Text
Regulation (EU) No 736/2013
Regulation (EU) No 334/2014

Data protection hard-stop - historical error leading to mismatch

Initial intention of the legislator

Art. 60(2): 10 years data protection from first day of the month following the date of adoption of a decision on the approval of the active substance

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BPR Consolidated Text
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Recent extension RP (2024)

Art. 60(2): 10 years data protection from first day of the month following the date of adoption of a decision on the approval of the active substance

Art. 89(1): end RP = 31/12/**2030**

Art. 95(5): derogation from *Art. 60(2)*, data protection all not yet approved RP AS ends = 31/12/**2025**

3rd extension RP

Data protection and the Review Programme - the intention

Data protection hard-stop in December 2025
If Review Programme finalised by 2014 as intended in the initial BPR text

Data protection and the Review Programme - the intention

Data protection hard-stop in December 2025
If Review Programme finalised by 2014 as intended in the initial BPR text

> 10 years between both end-dates
All existing active substances
would benefit from foreseen
10 years data protection
according to Art. 60 BPR

Data protection and the Review Programme - the reality

Data protection hard-stop in December 2025

Review Programme not finalised in 2014 - extended to 2024 - still not finalised

Data protection and the Review Programme - the reality

Data protection hard-stop in December 2025

Review Programme not finalised in 2014 - extended to 2024 - still not finalised

< to << 10 years between both end-dates

Only 27% existing active substances*

has benefitted from foreseen

10 years data protection

according to Art. 60 BPR

Cefic sector group

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*At end of 2015, 10 years before the Art. 95(5) data protection hard-stop, only 27% of Review Programme was finalised

Data protection and the Review Programme - the reality

Data protection hard-stop in December 2025

Review Programme not finalised in 2024 - extended to 2030 - only 50% finalised

Data protection and the Review Programme - the reality

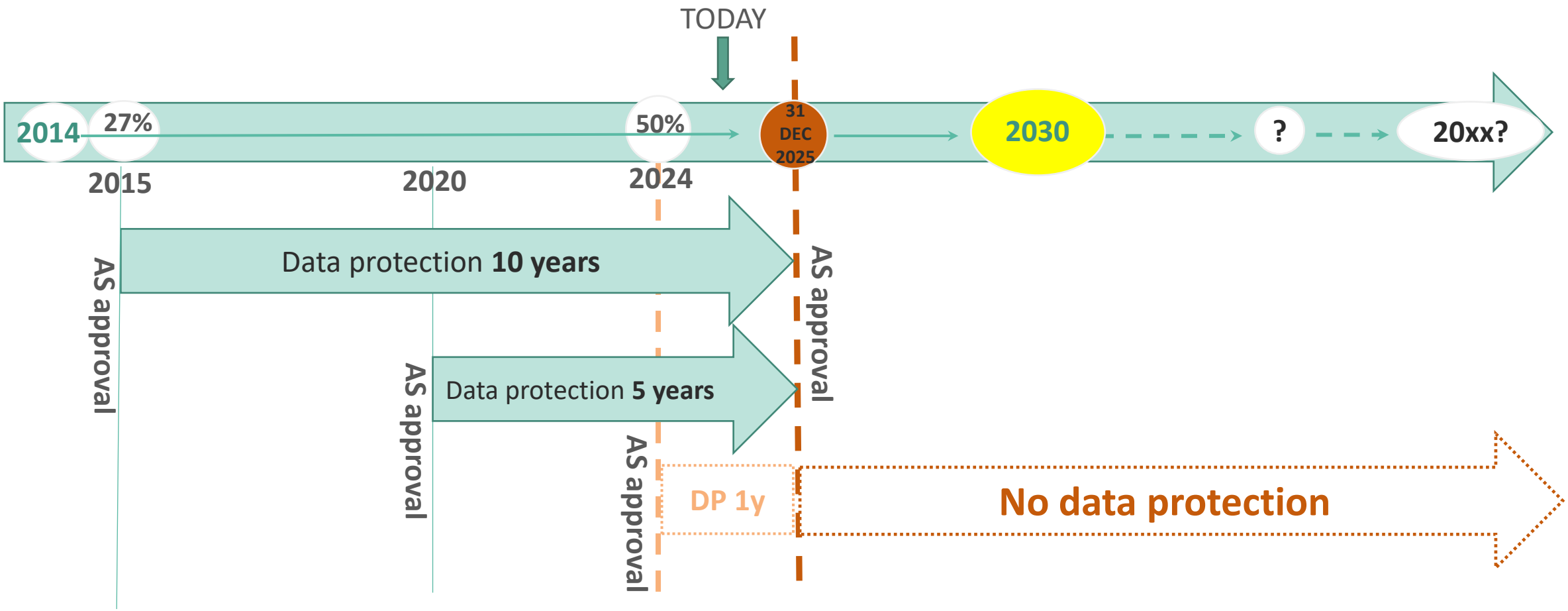
Data protection hard-stop in December 2025
Review Programme not finalised in 2024 - extended to 2030 - only 50% finalised

Moving goalposts

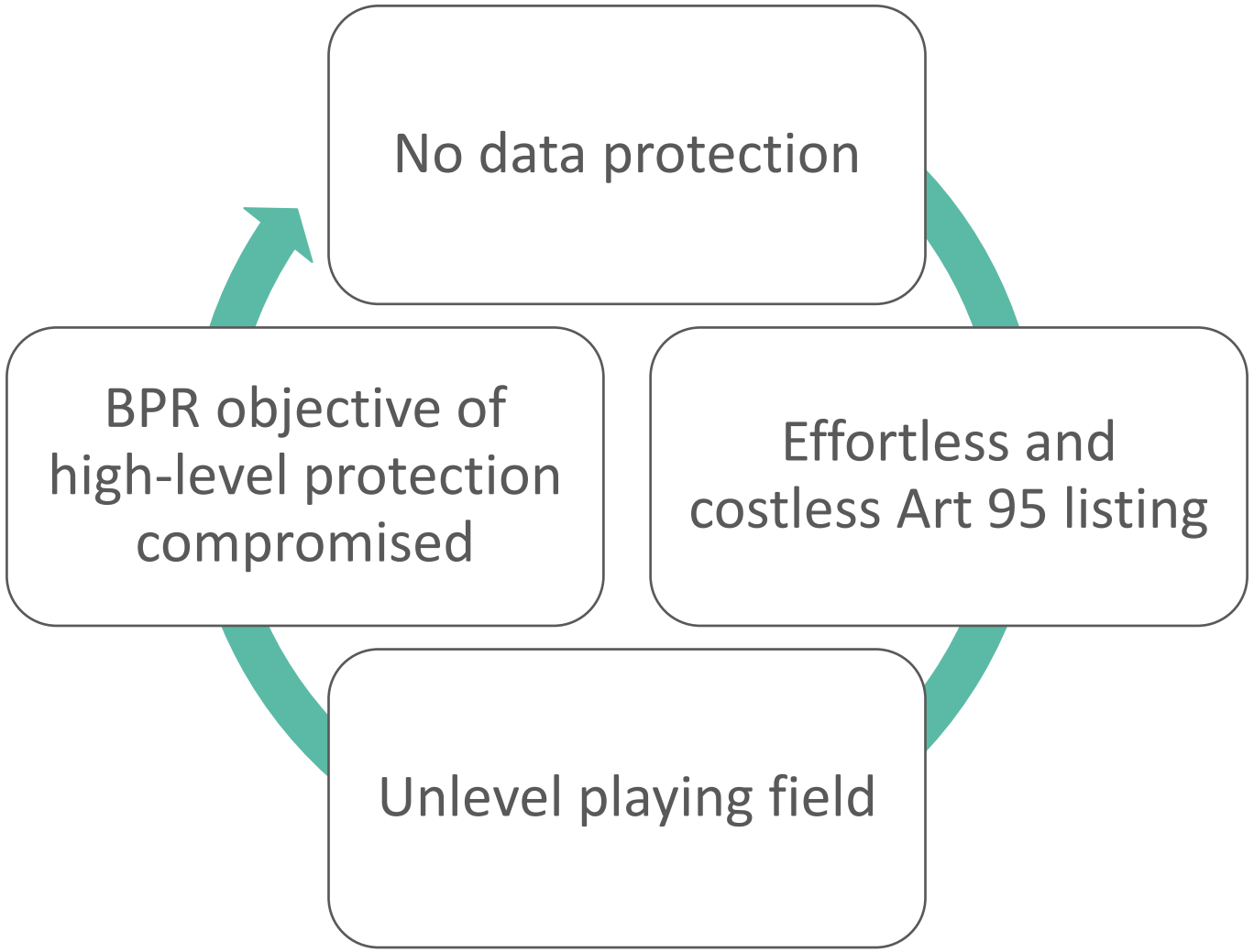
High number of requests for new data that will not benefit from any data protection at all

(including ED data, but not exclusively)

Data protection and the Review Programme - the reality



Consequences



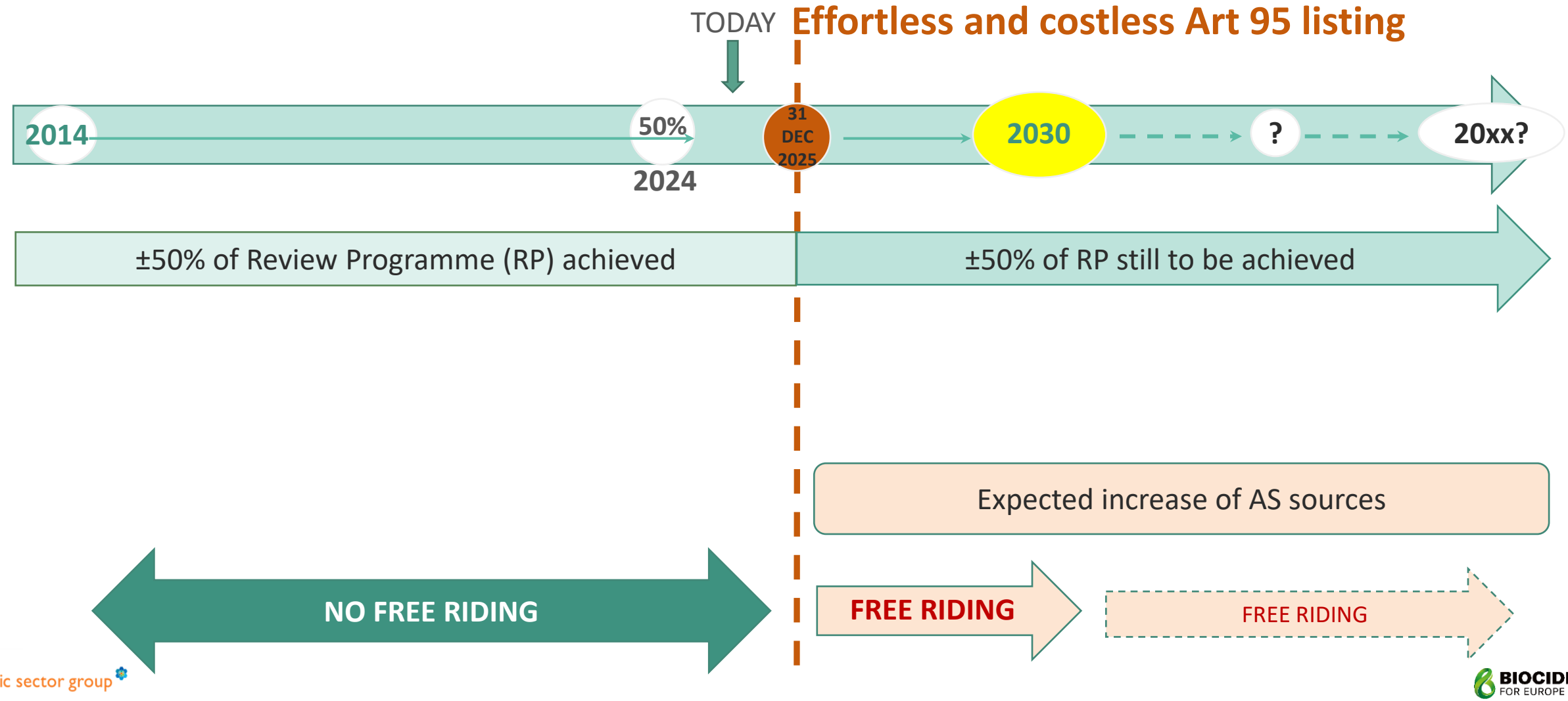
Article 95 listing after 2025

Effortless and costless Article 95 listing

Article 95 (1)

…A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ('the substance supplier') or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ('the product supplier'), may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a **reference to a complete substance dossier for which all data protection periods have expired**…

Free riding re-introduced



Cefic sector group

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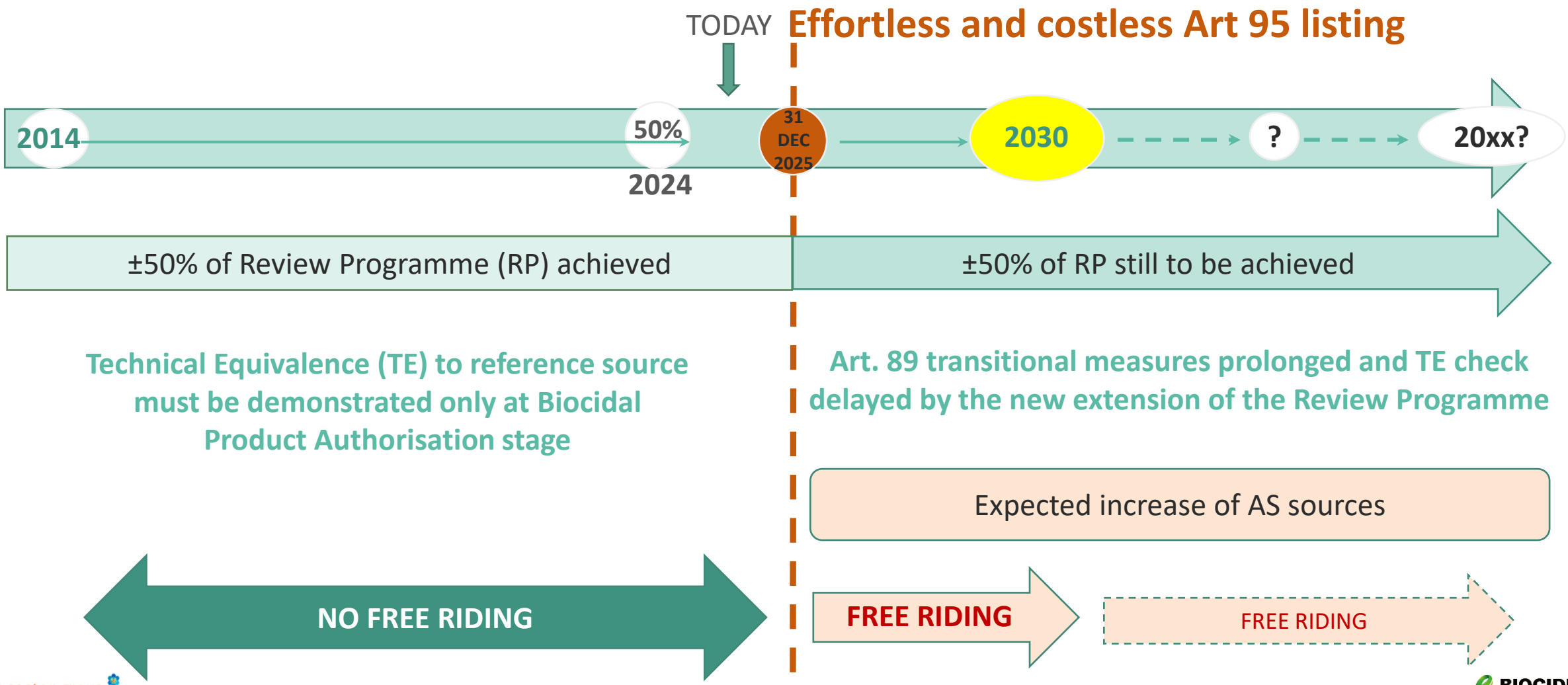
Safety goal BPR compromised



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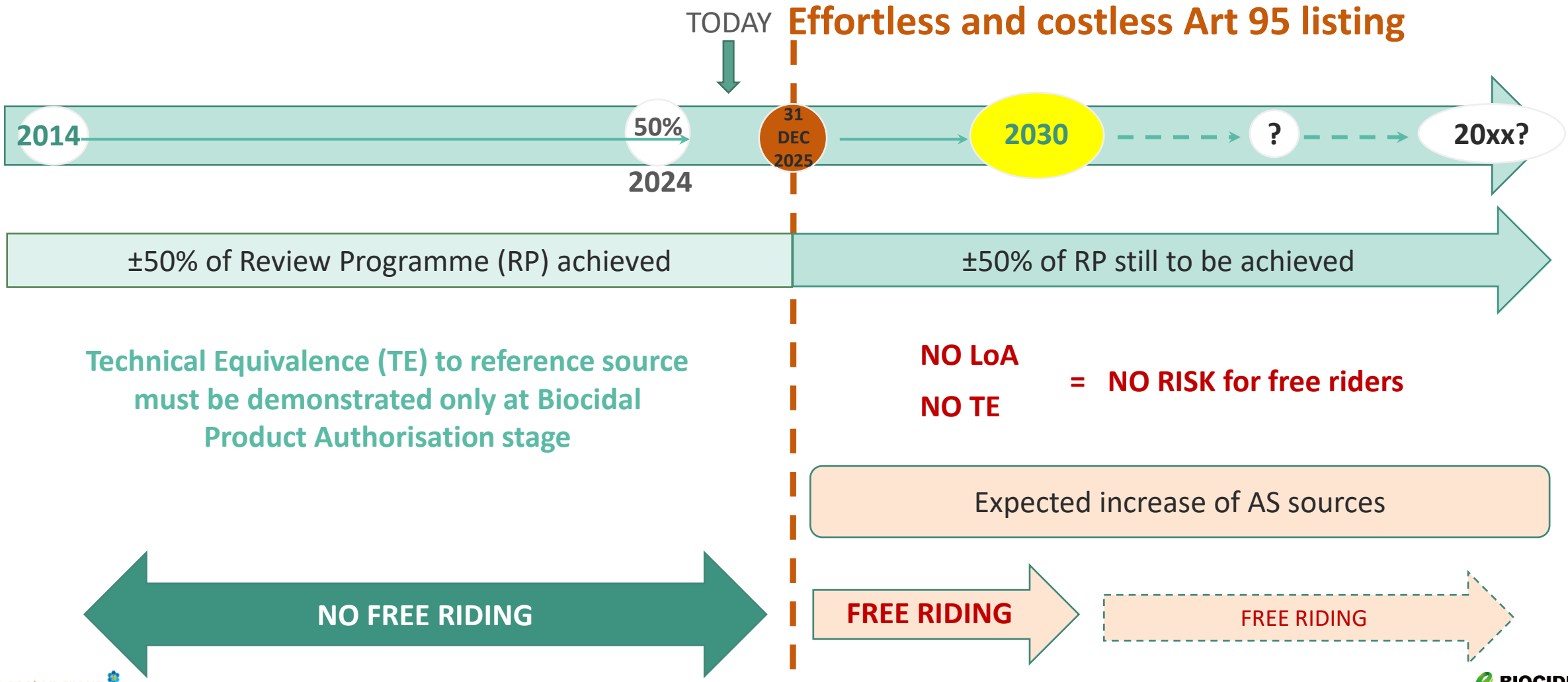

Objectives of the BPR

Safety

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment…

Level playing field

(58) A level playing field should be established as quickly as possible on the market for existing active substances…

Objectives of the BPR

~~Safety~~

(3) The purpose of this Regulation is to improve the free movement of biocidal products within the Union while ensuring a high level of protection of both human and animal health and the environment…

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(58) A level playing field should be established as quickly as possible on the market for existing active substances…

Objectives of the BPR

~~Safety~~

Uncompliant sources
Unknown (level of) impurities
TE delayed due to RP delays

protection of both human and animal health and the environment…

Level playing field

(58) A level playing field should be established as quickly as possible on the market for existing active substances…

Objectives of the BPR

~~Safety~~

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Unknown (level of) impurities
TE delayed due to RP delays

protection of both human and animal health and the environment…

~~Level playing field~~

(58) A level playing field should be established as quickly as possible on the market for existing active substances

Objectives of the BPR

~~Safety~~

Uncompliant sources
Unknown (level of) impurities
TE delayed due to RP delays

protection of both human and animal health and the environment…

~~Level playing field~~

Re-introduction of free-riding
Harms BPR compliant companies
Facilitates unfair competition

"Cry wolf" or exaggeration…?

- Free riding existed under BPD
- Back in 2014, *"a MS reported that according to a recent survey of their market, **90% of biocidal products placed on their market contain an active substance**, the manufacturer of which is **not listed in accordance with Article 95**"**
- Third parties approached our members for LoA but no continuation due to the cost of it
- Third parties approached our members for LoA but no continuation due to no chemical similarity
- In consortia, participants leave the consortium due to the impending investments in studies (e.g. ED) that with the current situation will not benefit from any data protection - This could result in substances not being supported anymore

**CA58 Nov2014-Minutes-agreed At CA59 March2015-Doc.2* - agenda point 5.12. Article 95 and phasing out of non-compliant products

"Cry wolf" or exaggeration…?

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…no, it is a genuine concern!

Cefic sector group

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*CA58 Nov2014-Minutes-agreed At CA59 March2015-Doc.2 - agenda point 5.12. Article 95 and phasing out of non-compliant products

CORRECTION NEEDED

No hard-stop on 31/12/2025

Realignment with RP extension 31/12/2030

Extend data protection till 31/12/2031

Existing (old) data

Data included at the submission of the AS/PT dossier (typically 2004-2008)

only for NEW DATA

Data generated under the BPR due to:

- continuously changing/new guidance
- Regulation (EU) 2017/2100 on ED
- BPR Annexes amendments
- redefinition of ASs
- …

ACTION NEEDED

Authorities to understand better the importance of data protection and acknowledge the severity of this issue

Equal and fair treatment of all players for any new data generated and submitted under the BPR

No hard-stop on 31/12/2025

Work together to solve this unfair situation

MSs & IND to convince COM to use the most appropriate legal and regulatory tool to ensure BPR studies have data protection matching the extended length of the Review Programme… as it was initially intended

Take home messages

Dangers:	• Safety concern - high level of protection jeopardized • Free riding on the horizon • Unfair treatment leading to loss of active substances
What can you do?	• Raise this issue with your Competent Authority • Raise data protection issue with COM • Support proposal to extend data protection expiry

1. Art. 95(5) BPR data protection expiry

2. Product authorization after AS approval

Review Programme still ongoing…

…in the meantime, till the AS approval date of a certain AS/PT combination:

National Procedures in Transition Period

- Procedures different in every MS
- Requirements different in every MS
- Obligations different in every MS

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…in the meantime, till the AS approval date of a certain AS/PT combination:

National Procedures in Transition Period

- Procedures different in every MS
- Requirements different in every MS
- Obligations different in every MS

From the AS approval date onwards

- Only BPR authorisation procedures for that AS/PT combination
- Applications need to be made before AS approval date to stay on the market during evaluation!

Authorisation of Biocidal Products

General tips for applicants

Start to prepare well in advance of approval date!

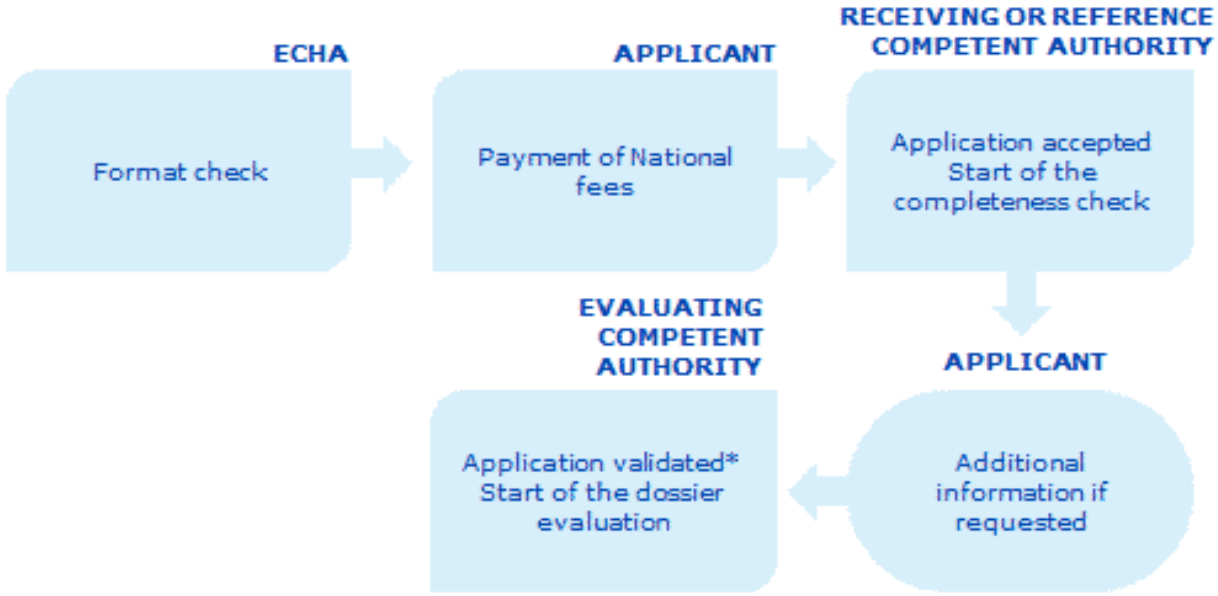
- Find eCA/refMS and get written confirmation of their commitment to act as such
- Request pre-submission meeting(s) with eCA/refMS
- Get external help if necessary
- Consciously choose your preferred Biocidal Product (BP) application-type
- Build your dossier using all relevant ECHA IT Tools & templates
- Be aware of all requirements & most recent applicable guidance
- Stay in contact/communicate with your eCA/refMS

Authorisation of Biocidal Products

National Authorisation (NA) - Art. 29-31 BPR

If you are only interested in one single local market

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d



This schematic and all others on BPR process-flows courtesy of ECHA

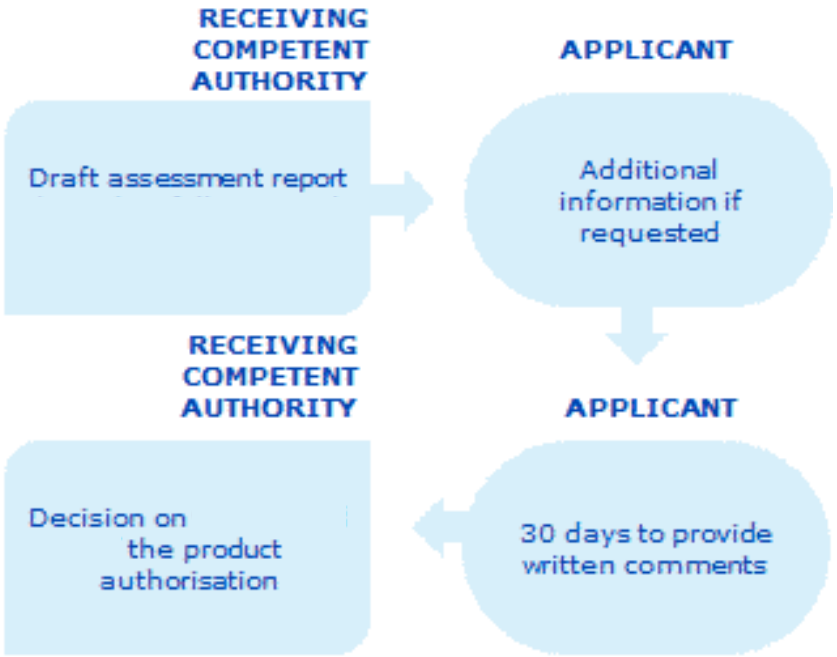
Authorisation of Biocidal Products

National Authorisation (NA) - Art. 29-31 BPR

If you are only interested in one single local market

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d
- Evaluation: 365d + 180d stop the clock
- Including 30d commenting period applicant on draft PAR
- Finalisation: grant/refuse authorization

Single product or Biocidal Product Family



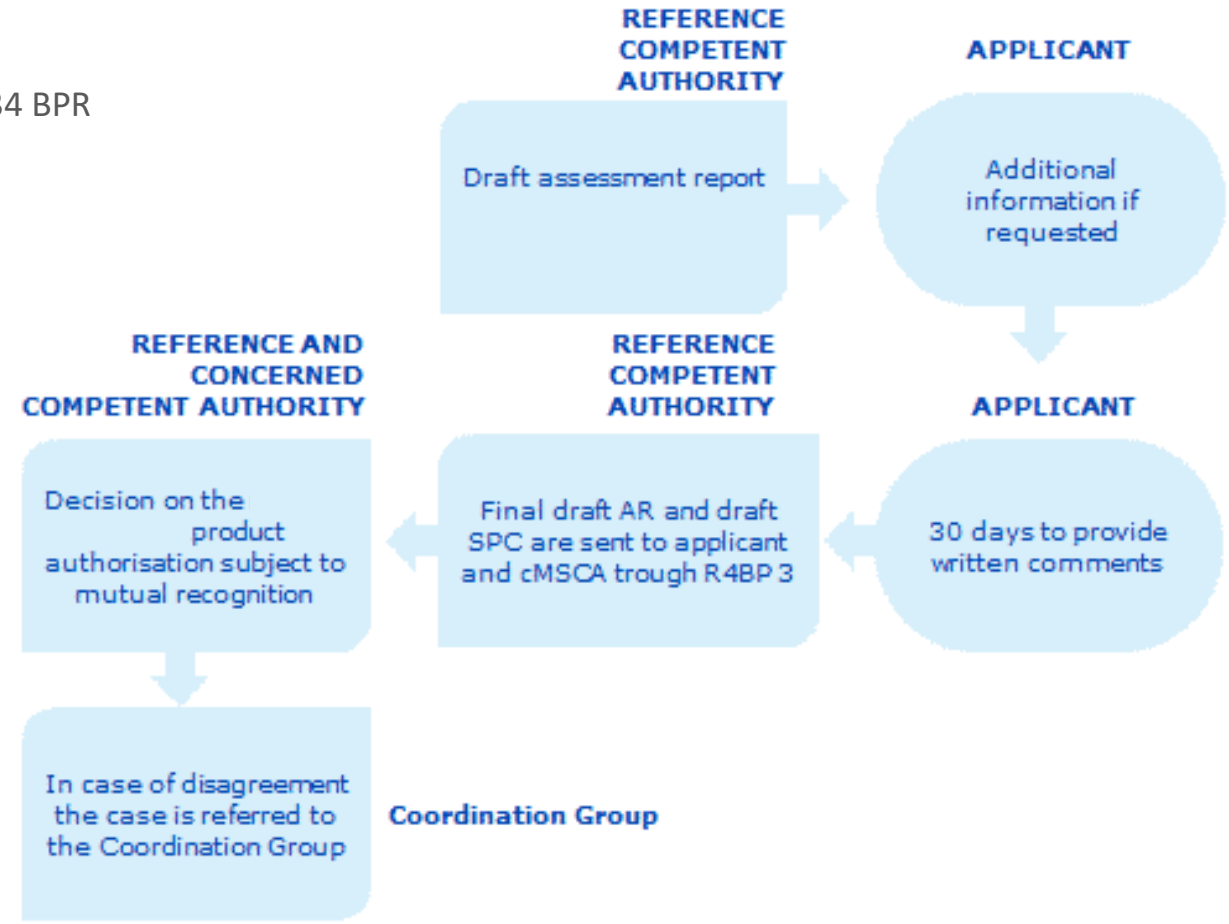
Authorisation of Biocidal Products

Mutual Recognition in Parallel (MRP) - Art. 34 BPR

If you are interested in several markets

Submitted at same time as NA

- Payment: 30 days
- Validation: 30d + *90d stop the clock* + 30d
- Evaluation: 365d + 180d stop the clock
- Including 30d commenting period applicant on draft PAR



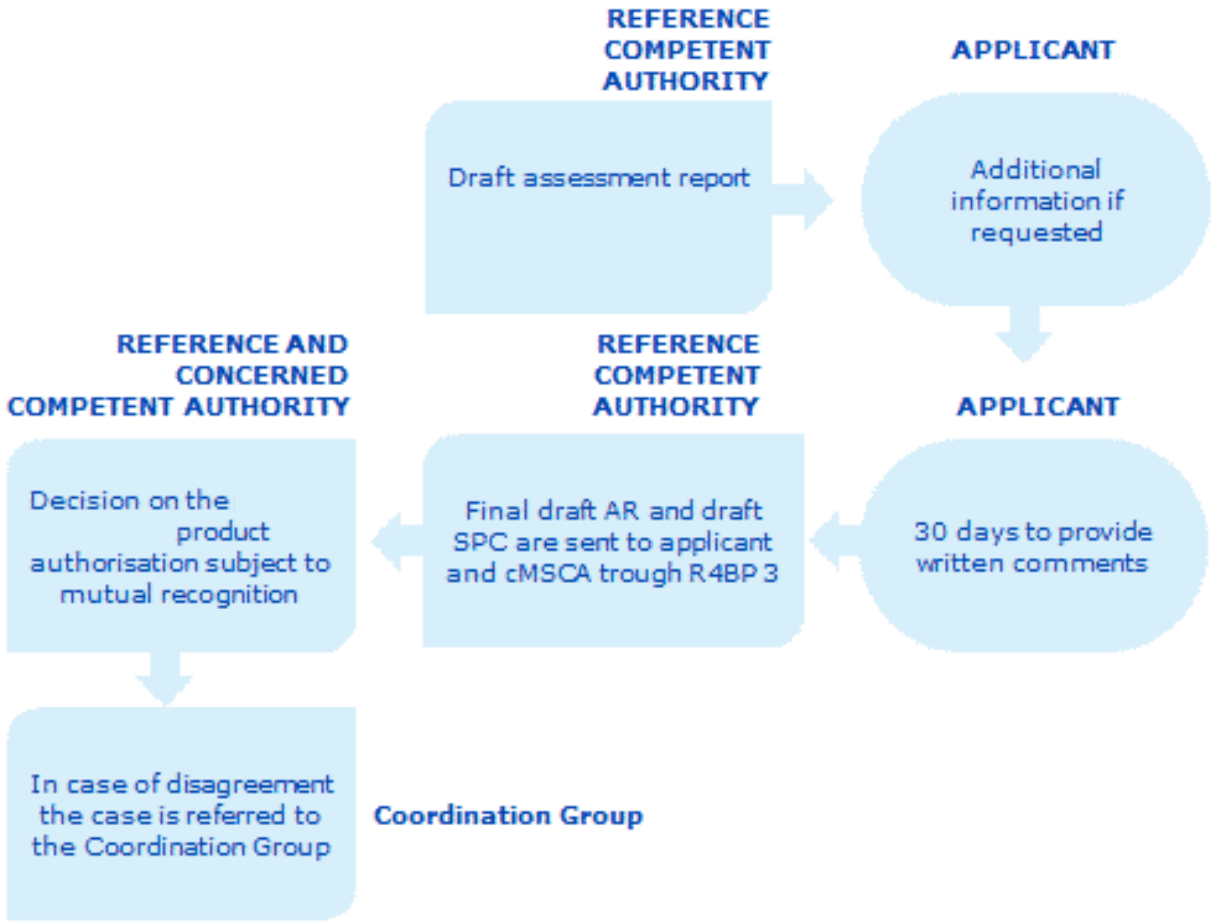
Authorisation of Biocidal Products

Mutual Recognition in Parallel (MRP)

If you are interested in several markets

Mutual Recognition Phase (90d)

- 1st step: 40d cMS commenting period
- 2nd step: 50d bilateral exchange
- If agreement on PAR & SPC: 30d to grant authorisation
- If no agreement on PAR & SPC: submission of referral to Coordination Group (CG)



Authorisation of Biocidal Products

Mutual Recognition in Parallel (MRP)

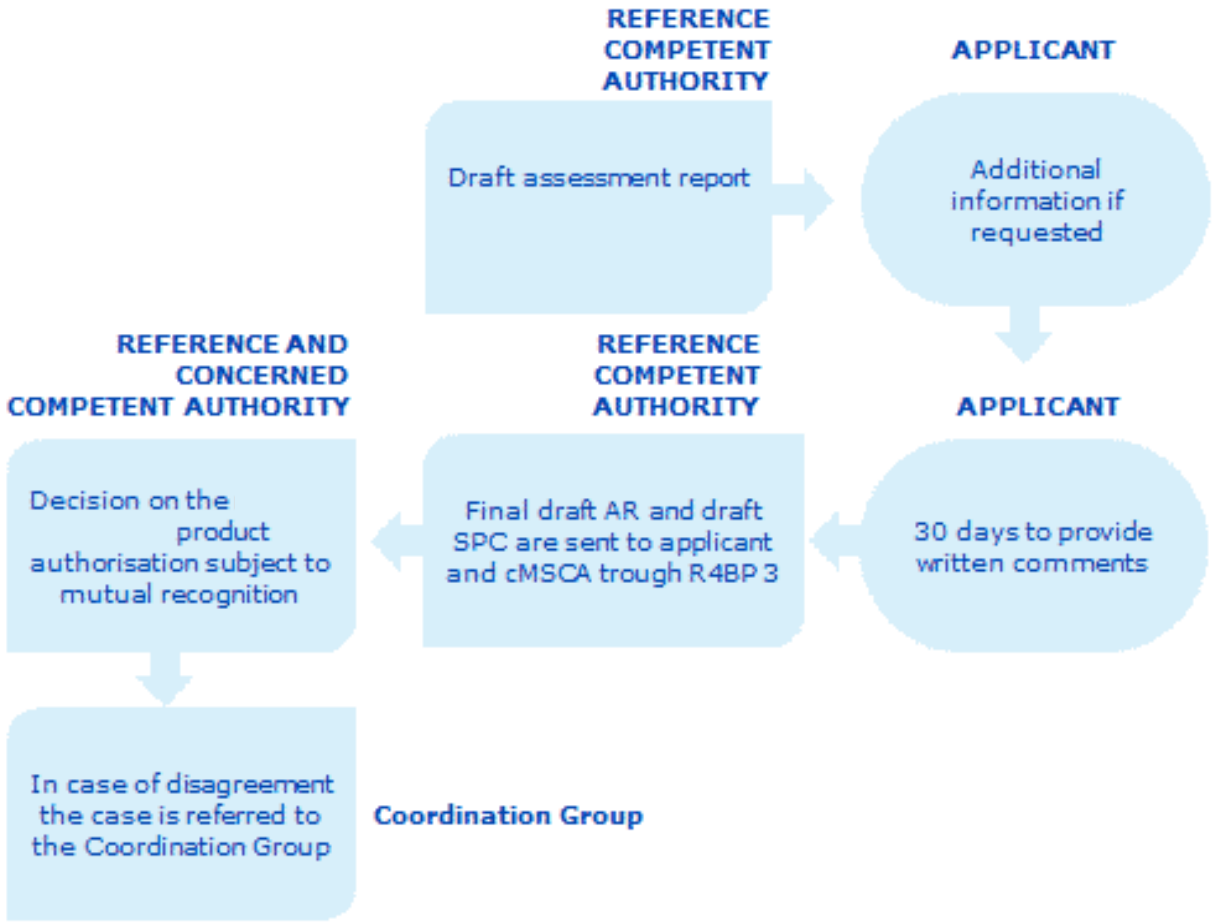
If you are interested in several markets

CG Referral Procedure (60d) - Art. 35-36 BPR

- Discussion in CG (during meeting, teleconference or written procedure)
- Applicant should be heard
- If agreement after 60d: finalisation by granting/refusing authorisation
- If no agreement: referral of disagreement to COM according to Art. 36 BPR

COM to adopt decision (implementing act)

Possibility to ask ECHA opinion according to Art. 38 BPR



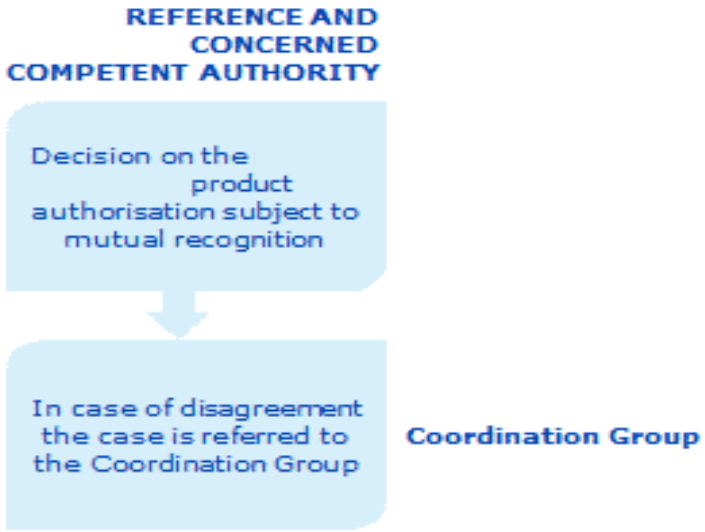
Authorisation of Biocidal Products

Mutual Recognition in Sequence (MRS) - Art. 33 BPR

If already existing NA in a MS and you are interested in additional market(s)

Submitted at any time

- Payment: 30 days
- Validation: 30d
- Mutual recognition phase: 90d
- Procedure similar to MRP



Authorisation of Biocidal Products

Union Authorisation (UA) - Art. 41-46 BPR

If you are interested in whole EU market or substantial amount of markets

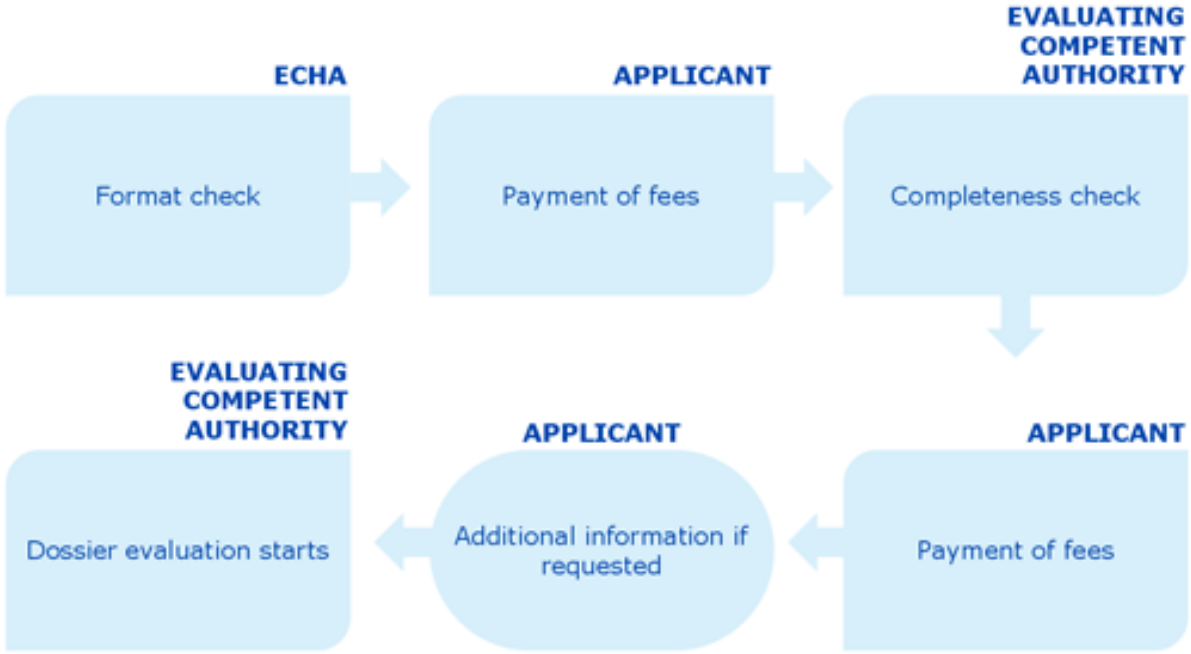
- Decision by COM (implementing act) after BPC peer-review & BPC opinion
- For BP with similar conditions of use across the EU *(soon new guidance + template for applicants!)*
- Highly recommended to perform ECHA pre-submission application for UA *(adaptations expected!)*
- Not for BP containing AS meeting exclusion criteria
- Not for BP of PT 14, 15, 17, 20 & 21
- Had sequential start-up: last phase 1 January 2020, so now available for all other PTs
- Fee for ECHA (submission + annual fee) & fee for eCA
- Possible for single product or for Biocidal Product Family

Authorisation of Biocidal Products

Union Authorisation (UA)

If you are interested in whole EU market or substantial amount of markets

- Payment ECHA: 30d
- Acceptance ECHA
- Validation eCA: 30d + 90d stop the clock + 30d
- Payment eCA: 30d (part of validation)
- Acceptance eCA

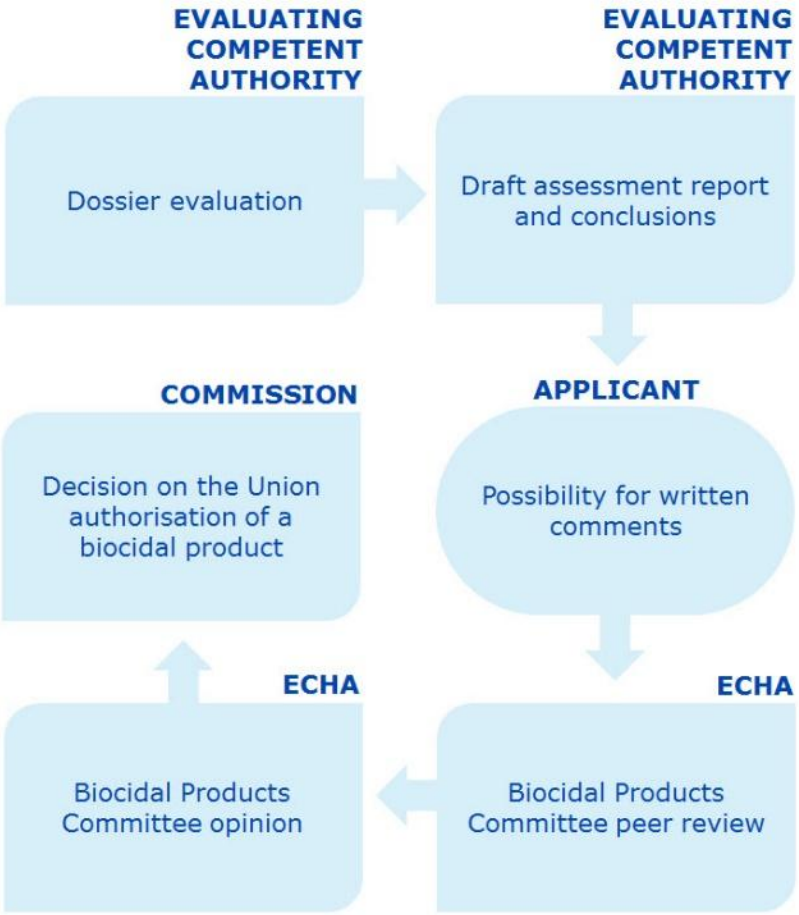


Authorisation of Biocidal Products

Union Authorisation (UA)

If you are interested in whole EU market or substantial amount of markets

- Evaluation eCA: 365d + 180d stop the clock
- Including 30d commenting period applicant
- eCA submits draft PAR & SPC to ECHA
- Peer-review process: 180d
- WG discussion possible
- BPC opinion mandatory

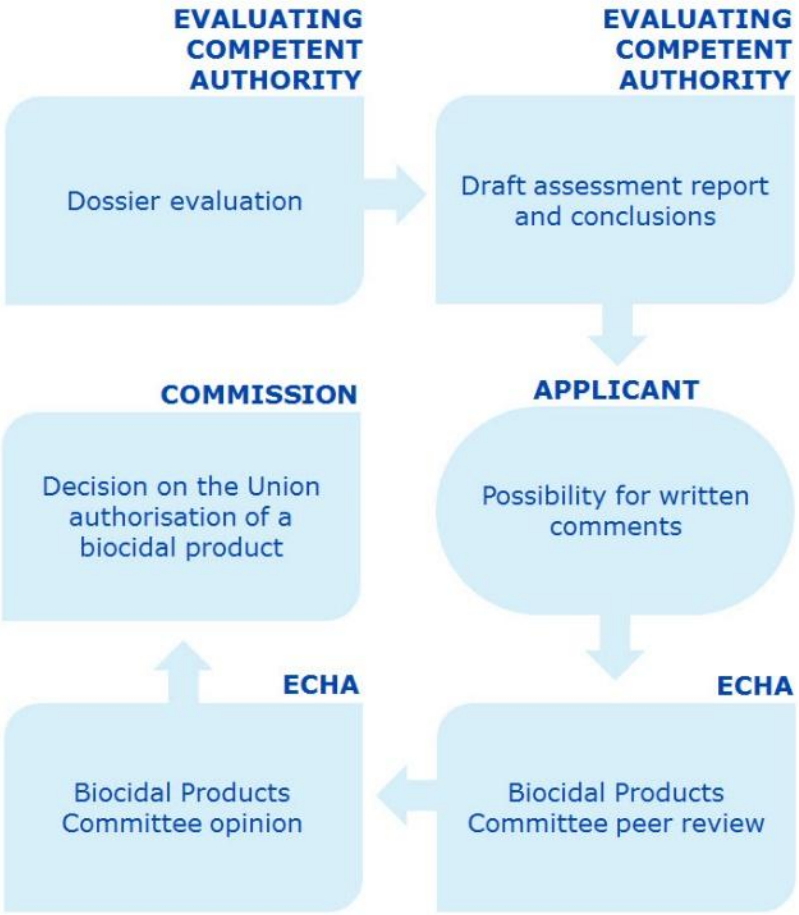


Authorisation of Biocidal Products

Union Authorisation (UA)

If you are interested in whole EU market or substantial amount of markets

- ECHA submits BPC opinion & final PAR to COM
- SPC translation in all official languages of EU: 30d
- If UA granted: COM to adopt implementing regulation
- If UA not granted: COM to adopt implementing decision



Authorisation of Biocidal Products

Simplified Authorisation (NA) - Art. 25-27 BPR

To encourage the use of less harmful BPs

BP to comply with all these conditions:

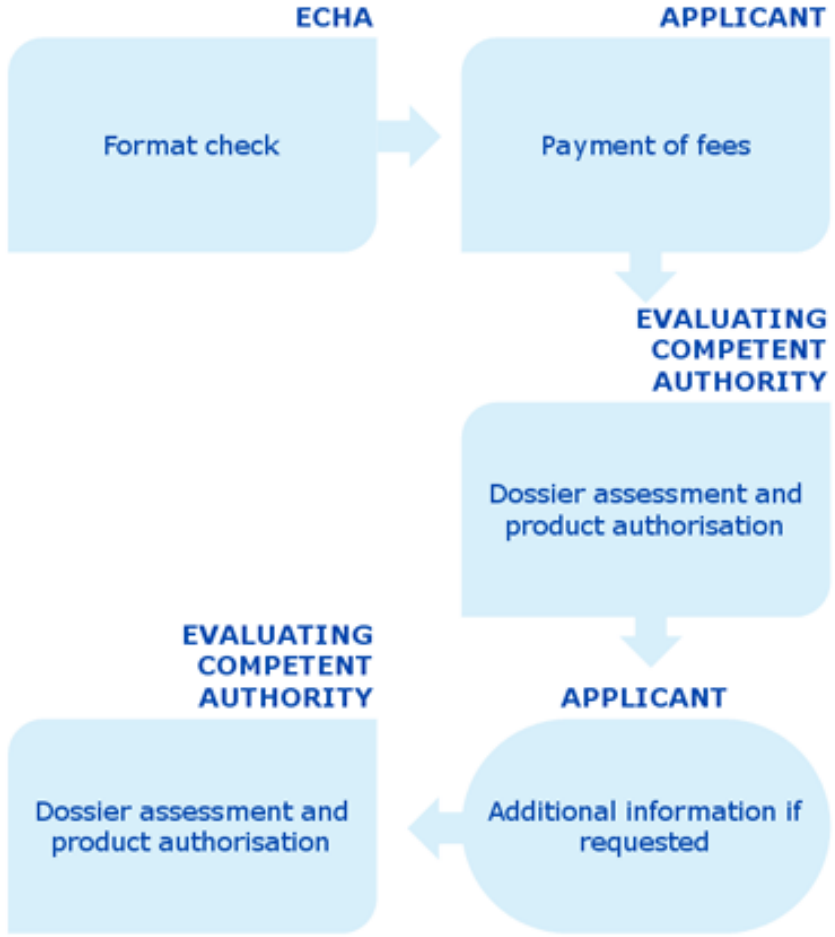
- AS on Annex I BPR (& comply to specified restrictions)
- Not containing substances of concern (SoC)
- Not containing nanomaterials
- Demonstrate sufficient level of efficacy
- Not requiring any personal protective equipment (PPE) for intended use & handling

Authorisation of Biocidal Products

Simplified Authorisation (NA)

Procedure similar to NA

- Shorter timelines
  - Payment: 30d
  - Evaluation: 90d + 90d stop the clock + 90d
  - Finalisation: grant/refuse authorization
- Different/lower data requirements
- Can be made available on MS markets without need for MR
  - Notification 30 days before placing BP on MS market



Authorisation of Biocidal Products

Same Biocidal Products Authorisation (SBP)

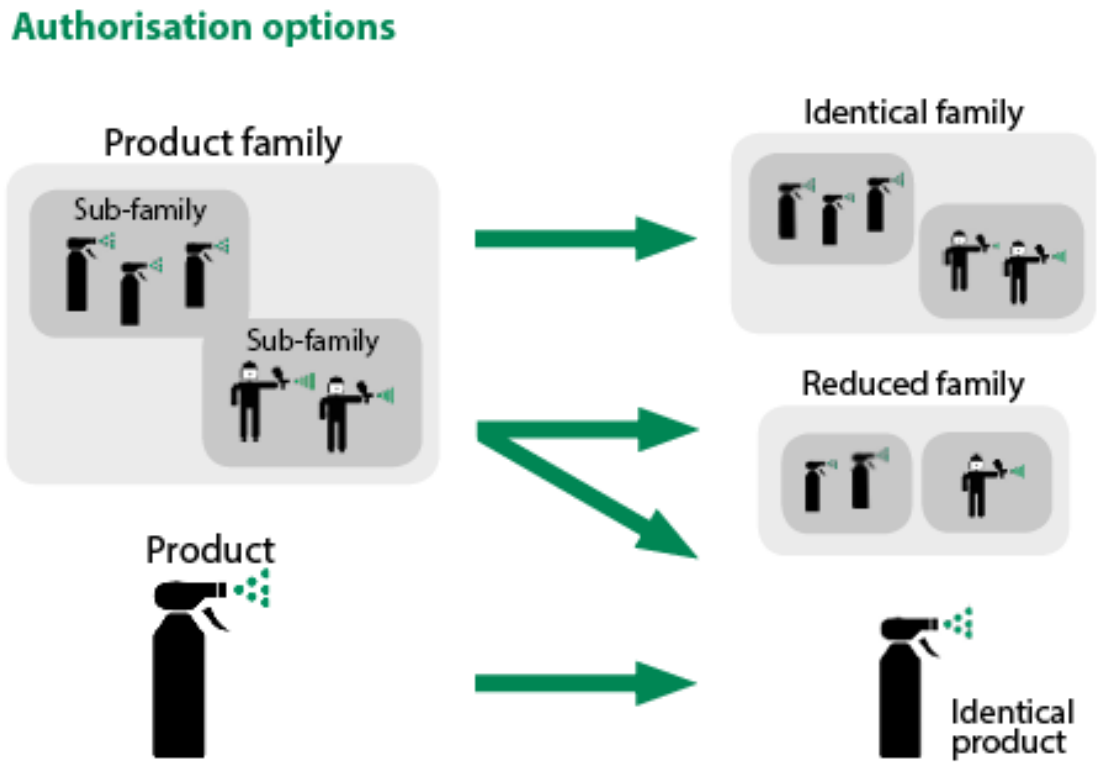
Regulation (EU) 414/2013

amended by Regulation (EU) 2016/1802

currently under new amendment *(expected soon)*

- For identical products
- For identical Biocidal Product Families
- To reduced authorisation
- To reduced market (UA → NA)

Same Biocidal Product has always different authorisation number than reference product



Authorisation of Biocidal Products

Same Biocidal Product of NA

Reference product has been authorised by NA or is subject of authorisation application

- Adapted data requirements

- eCA validation: 30d
  - Check that differences between same product and reference product is only info which can be subject of an administrative change ((EU) No 354/2013)

- eCA to grant/refuse authorisation: 60d
  - Either from validation
  - Either from adoption decision concerning the reference product

Authorisation of Biocidal Products

Same Biocidal Product of NA

Reference product has been authorised by NA or is subject of authorisation application

- Adapted data requirements
- eCA validation: 30d
  - Check that differences between same product and reference product is only info which can be subject of an administrative change ((EU) No 354/2013)
- eCA to grant/refuse authorisation: 60d
  - Either from validation
  - Either from adoption decision concerning the reference product

Same Biocidal Product of UA

Reference product has been authorised by UA or is subject of authorisation application

- Adapted data requirements
- ECHA validation: 30d
  - Check that differences between same product and reference product is only info which can be subject of an administrative change ((EU) No 354/2013)
- ECHA to prepare opinion and send to COM: 30d
  - Either from validation
  - Either from date submission opinion on reference product

Interesting ways to access the market

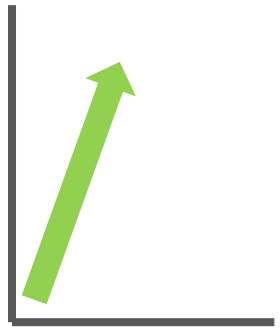
Biocidal Product Family

Union Authorisation

Same Biocidal Products

Interesting ways to access the market

Biocidal Product Family

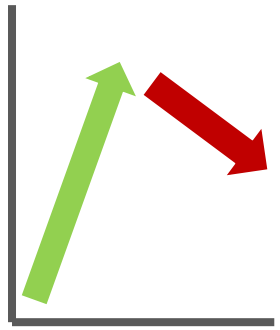


Union Authorisation

Same Biocidal Products

Interesting ways to access the market

Biocidal Product Family



Revision BPF concept
New guidance

Union Authorisation

Same Biocidal Products

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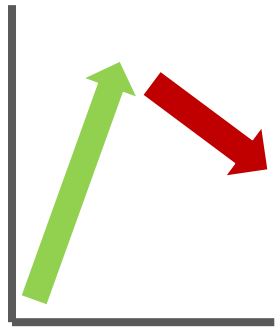
Biocidal Product Family



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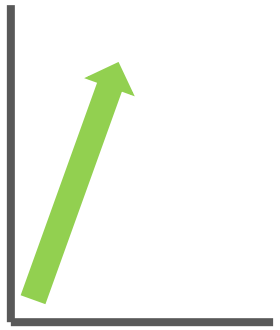

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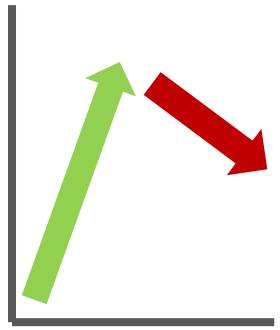

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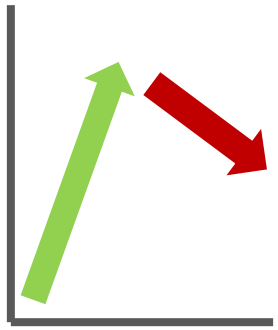

Uncertainty
Unpredictability
? Higher ECHA fees ?
? New procedure
similar conditions of use ?

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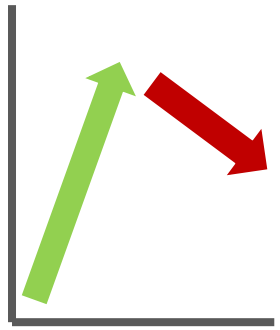

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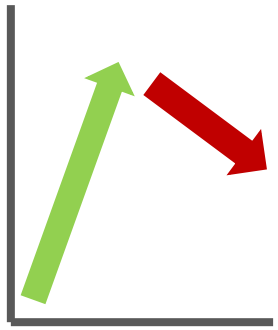

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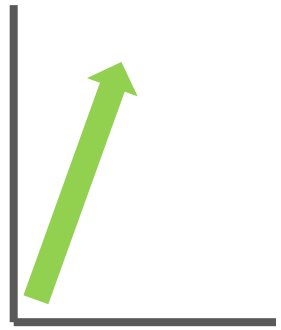

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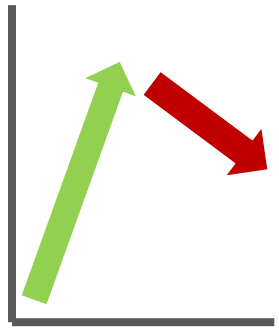

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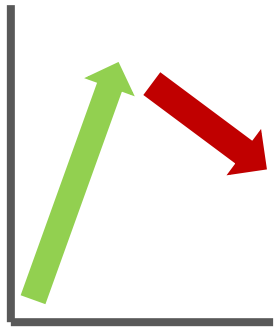

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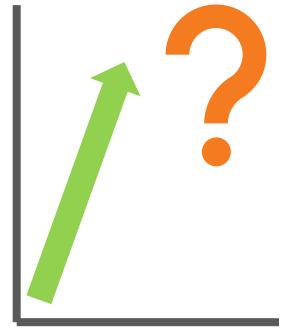

Ongoing amendment
SBP Regulation

Take home messages

Start to prepare well in advance of approval date!

- Get external help if necessary
- In particular for SMEs: explore authorisation through SBP or as part of a Biocidal Product Family
- Explore if your AS supplier can assist you
- Explore if a product consortium exists for your type of products
- If it does not exist, consider setting-up a product consortium with some peers

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Be aware

- Not easy to find an eCA for your UA or a refMS for your NA!
- Everything goes smoother with a complete and high quality dossier!

Start to prepare well in advance of approval date!

BIOCIDES
FOR EUROPE

Thank You

Contact:
biocides@cefic.be