State of play and experiences regarding the biocidal product dossiers

in Belgian and European procedures

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BE

Legal basis

Main RD

4 APRIL 2019. - Koninklijk besluit betreffende het op de markt aanbieden en het gebruiken van biociden

http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&table_name=wet&cn=2019040431

4 AVRIL 2019. - Arrêté royal relatif à la mise à disposition sur le marché et à l'utilisation des produits biocides

http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2019040431&table_name=loi

PS: The previous RD (8 May 2014) was cancelled at the same time (= In force 3/5/2019)

BE

Legal basis

Related RD

13 NOVEMBER 2011. - Koninklijk besluit tot vaststelling van de retributies en bijdragen verschuldigd aan het Begrotingsfonds voor de grondstoffen en de producten

https://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2011111309&table_name=wet

13 NOVEMBRE 2011. - Arrêté royal fixant les rétributions et cotisations dues au Fonds budgétaire des matières premières et des produits

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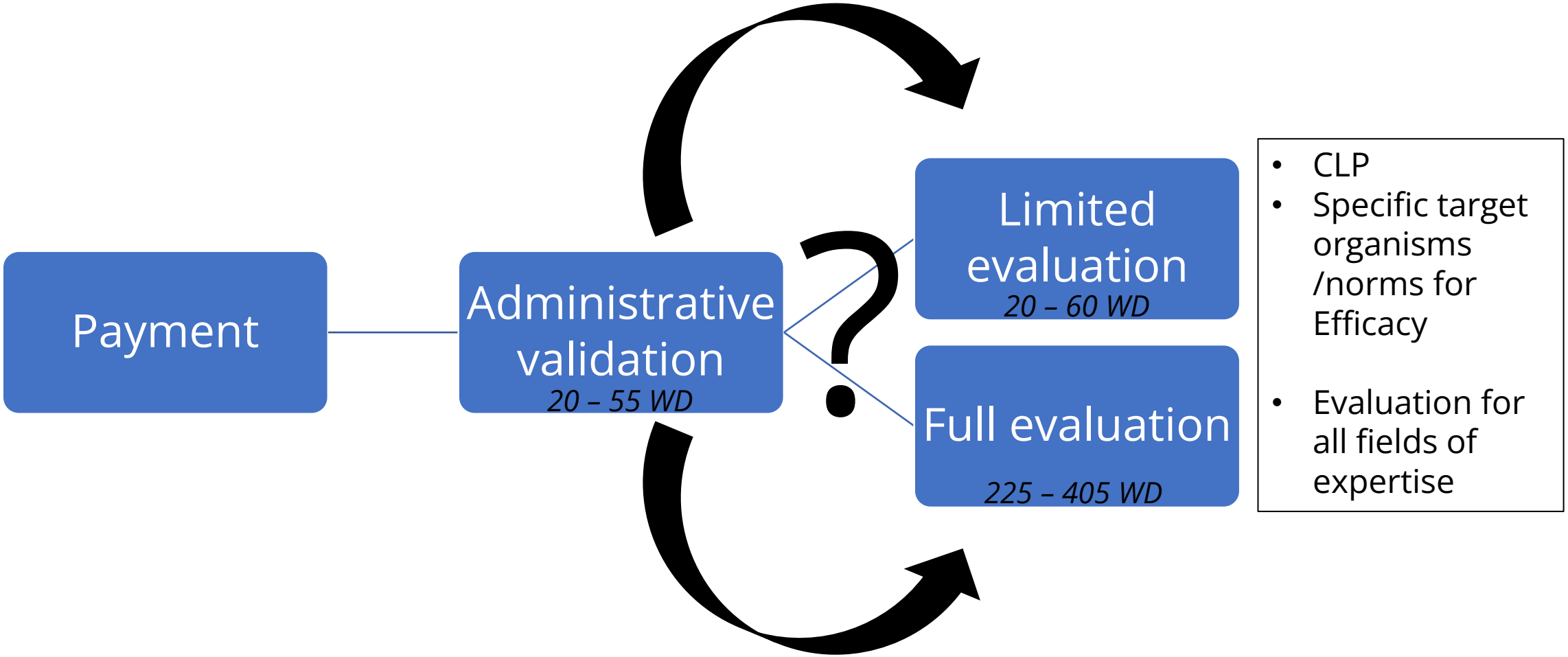
BE

Registration procedure



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Limited vs. Full evaluation

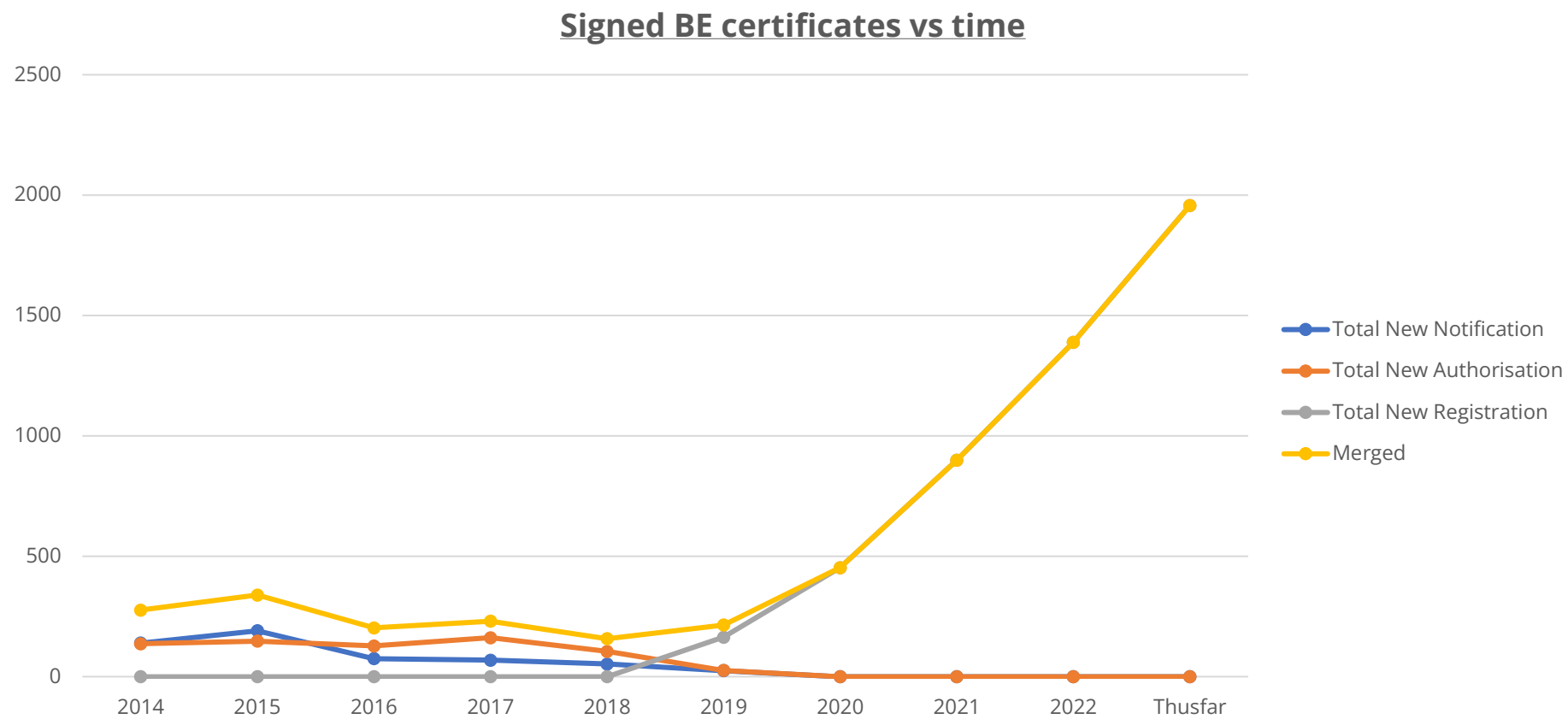
As per RD 4/4/2019, possible (and thus not limitative) indications can be:

- *1° history of the biocide involved, for example a negative advise;*
- *2° a substantiated complaint against the biocide concerned, against a very similar biocide or against a group of biocides to which the biocide in question belongs;*
- *3° an incompatibility between the classification and labeling and the intended use;*
- *4° scientific literature data, a report from the poison control center or a designation from another Member State that may indicate a potential danger to humans or the environment of the biocide concerned or of a substance that it contains;*
- *5° scientific literature data, a report from the poison control center or a designation from another member state that demonstrate an objectified microbial resistance.*

BE

Experiences

Note: Data up to 3/8/2023

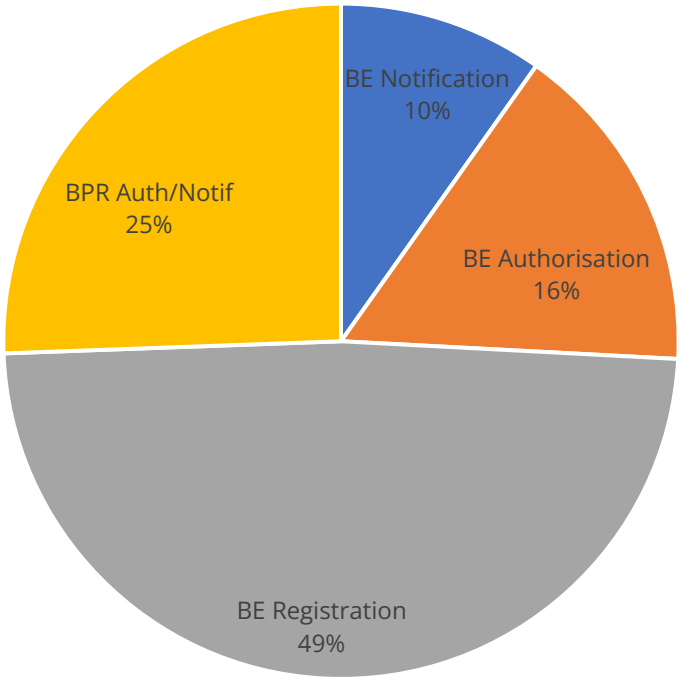


Experiences

BE

Note: Data up to 3/8/2023

BE market by type of certificate



BE

Experiences

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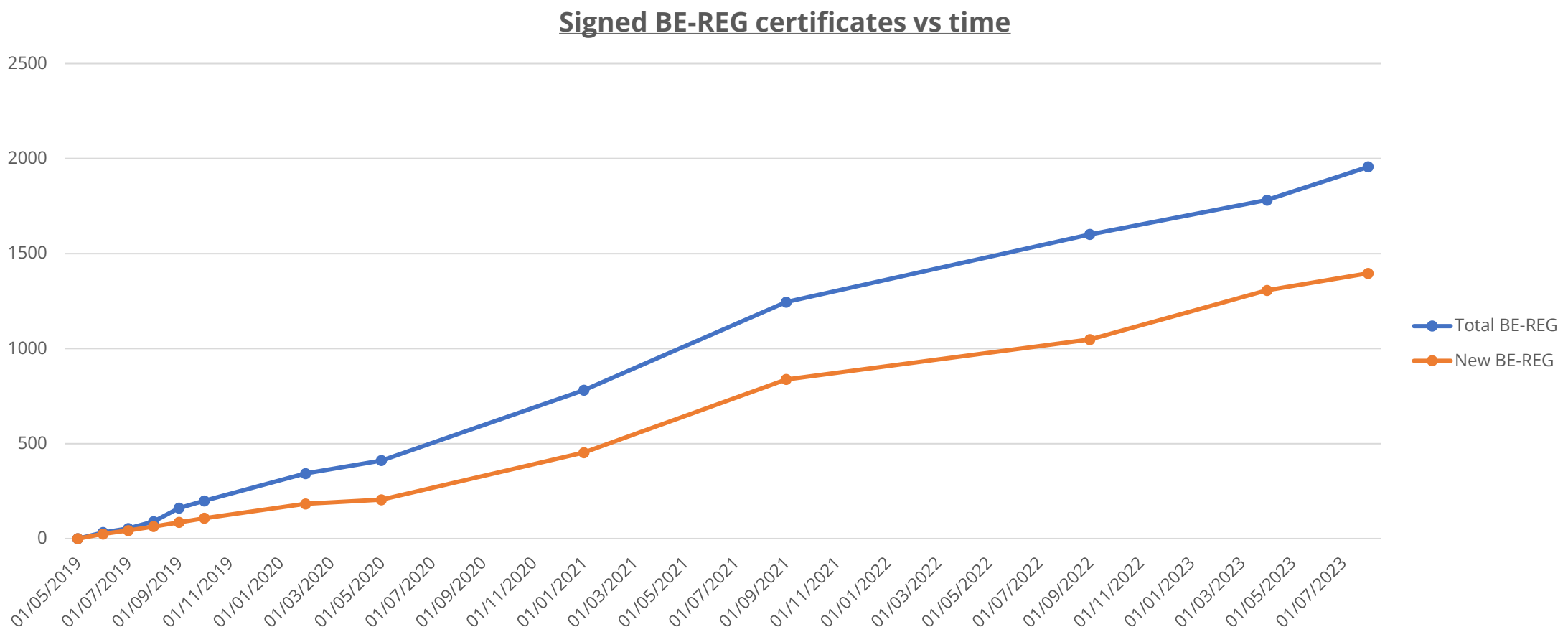

Experiences

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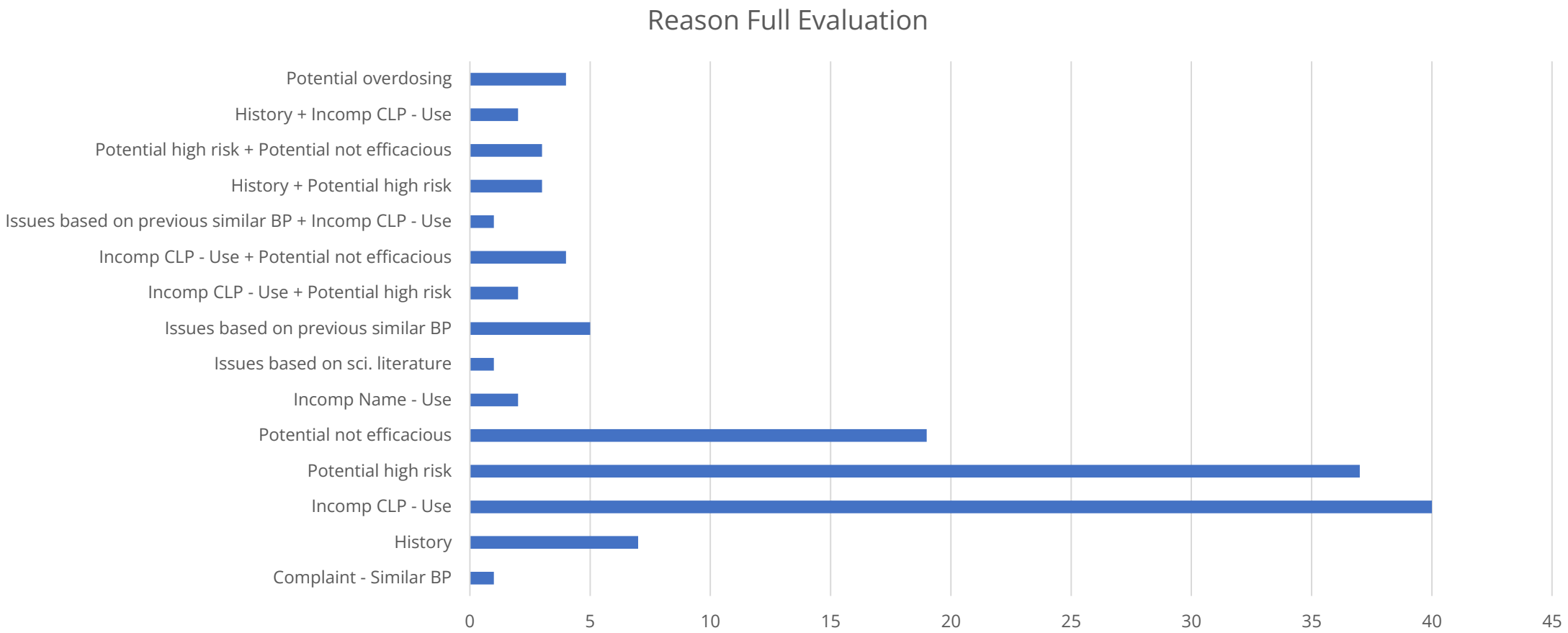

Experiences

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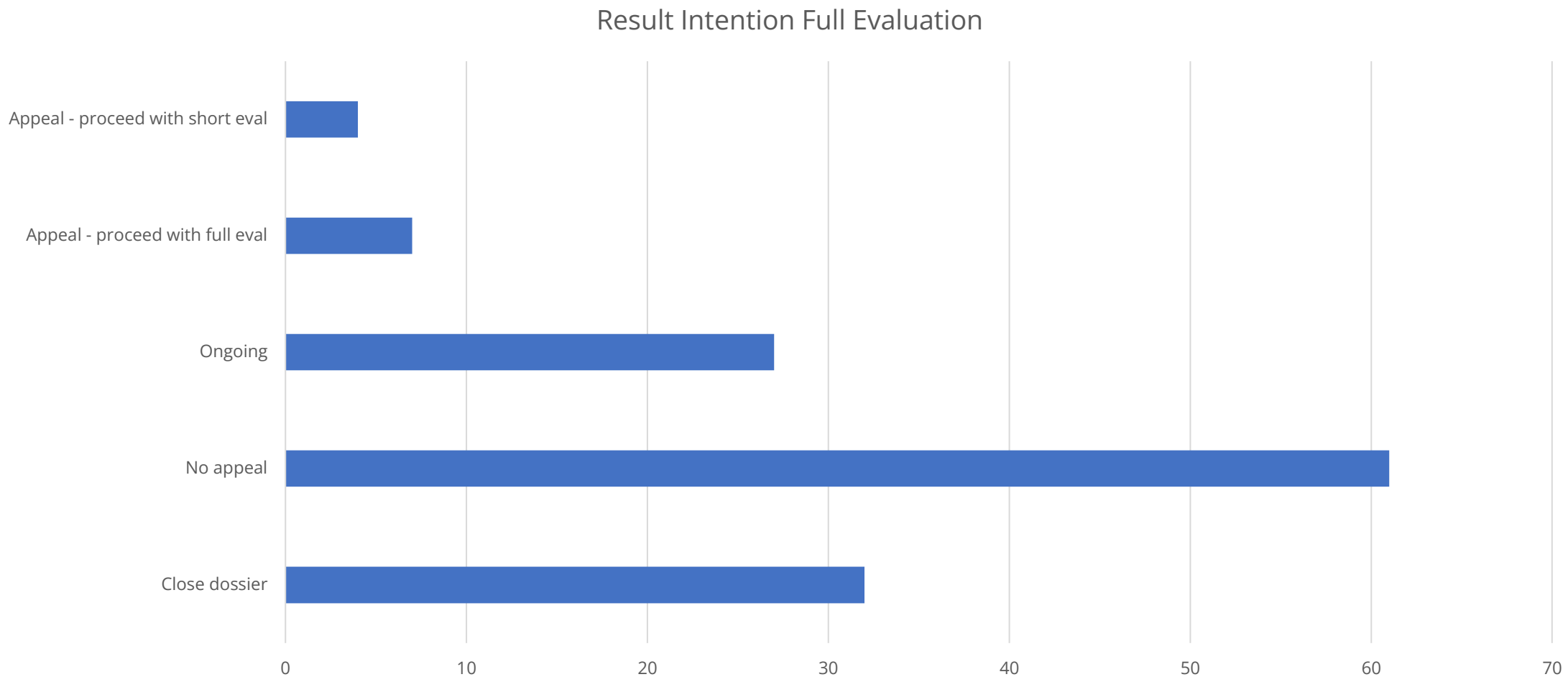

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Transitional biocides – impact due to extension of the *Review Programme*

BE

Review programme

- Legal basis
  - Article 89(1) - Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22/5/2012 concerning the making available on the market and use of biocidal products
  - Commission Delegated Regulation (EU) No 1062/2014 of 4/8/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council

Transitional biocides – impact due to extension of the *Review Programme*

BE

Review programme

- Goal
  - (Non-)approval of all the existing biocidal active substances/PT-combinations by 2010, later 2014, then 2024.
    - Existing active substances: Biocidal active substances which were on the market before the BPD entered into force (14/5/2000)
    - New biocidal active substances: Biocidal active substances which were not on the market before the BPD entered into force (14/5/2000)
  - Discussion ongoing at CA-level (COM incl.) on requirement for further extension
    - Proposed new deadline 31/12/2030

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- Amendments to legal basis (pending publication)
  - Royal Decree of 4/4/2019 concerning the making available on the market and use of biocidal products
    - Instating the possibility to renew/prolong BE registrations (Art. 15/1), incl. appeal possibility (Art. 17)
    - Amending the provision to renew/prolong still valid BE notifications and authorisations, previously granted under RD 8/5/2014, in order to harmonize with the new Art. 15/1 (Art. 43 §2)

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- Amendments to legal basis (pending publication)
  - Royal Decree of 13/11/2011 establishing the fees and contributions payable to the Budget Fund for Raw Materials and Products
    - Establishing a fee for a dossier for the renewal/prolongation of still valid BE notifications and authorisations, previously granted under RD 8/5/2014 (Annex III)
  - Royal Decree of 9/12/2021 establishing an Advisory Committee on Biocides[…]
    - Empowering the Committee to give advise on renewals/prolongations, provided that a full evaluation was performed on the dossier

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- Impact analysis
  - ± 2000 dossiers for renewal/prolongation of transitional biocides are expected
    - (~3400 products authorized according to BPR/registered in BE)
    - Unknown number will be selected for full evaluation, taking longer for dossier evaluation
    - Renewal/prolongation process may not jeopardize the capacity of BE CA to grant new registrations and/or other changes to existing products, nor to meet its expectations at EU-level under BPR

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- Impact analysis
  - Legally foreseen deadline for submission of renewal/prolongation dossiers (6 months prior to end date of authorisation) will not be sufficient to manage all dossiers and perform all evaluations in due time
  - Delays in dossier management and/or evaluation risk causing disruption within the market

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- BE CA's actions
  - Recruiting additional employees, specifically for the renewal/prolongation process in 2024
  - Trying to anticipate and spread workload on its scientific personnel
  - Timely communication to IND to call upon their active participation/assistance with the renewal/prolongation process

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- Requested IND actions
  - Timely and thorough dossier preparation, based on requirements in Annex I of RD 4/4/2019
  - (Voluntary) early submission
  - Active communication/participation during the dossier management

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- (Voluntary) early submission
  - **Only applicable to**:
    - Transitional products (~auth. number formats: "**BE-REG-**XXXXX", "**NOTIF**XXXX", "XXX**B**") which are;
    - still valid today and have an end date authorisation ≤ 31/12/2024;
    - and will not be entitled to a BPR Art.89(2) extension prior to 1/1/2025 (~when product is part of a BPR-dossier)

*Take home message

Transitional biocides – impact due to extension of the *Review Programme*

BE

Plan of action regarding transitional biocides in BE

- (Voluntary) early submission
  - Proposed timeline for submission:
    - By 1/12/2023: All dossiers for renewal/prolongation for products meeting the "**NOTIF**XXXX"-format or having an auth. number BE-REG-00800 or higher.
    - By 1/3/2024: All dossiers for renewal/prolongation for products meeting the "XXX**B**"-format or having an auth. number BE-REG-00799 or lower.

*Take home message

Transitional biocides – impact due to extension of the *Review Programme*

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Renewal or prolongation? What to choose?

- Prolongation when the product, since its last renewal (if applicable), has not yet been authorized/registered for a 10-year period. Else, renewal.
  - Example 1: Product registered on 1/2/2021 and valid until 31/12/2024
    - **Prolongation** to be submitted, since not yet on the market for a 10-year period.
  - Example 2: Product authorized on 1/2/2002, renewed in 2012, renewed in 2022, and valid until 31/12/2024
    - **Prolongation** to be submitted, since not yet on the market for a 10-year period since its last renewal
  - Example 3: Product authorized on 1/4/2004, renewed in 2014, and valid until 31/12/2024
    - **Renewal** to be submitted, since on the market for a 10-year period since its last renewal

*Take home message

Transitional biocides – impact due to extension of the *Review Programme*

BE

Renewal or prolongation? What to choose?

- How to check when your product was last renewed?
  - You can check when your product was renewed by consulting the signing history, located at the end of the certificate (above the (e-)signature), on your latest certificate. Look for the word “hernieuwing” (NL) or “renouvellement” (FR).

Transitional biocides – impact due to extension of the *Review Programme*

BE

Our common goal throughout the upcoming renewal/prolongation process:

To avoid disruptions within the market, whilst continuing to ensure a high level of protection of human and animal health and the environment

Join the Effort

BE

Thank you for your attention!

Further information

Belgian Biocides website

www.biocide.be

EU

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    - Families
    - Renewals
    - MRP v/s MRS
    - General
- Questions?

EU

General introduction

- BPR 528/2012 entered into force 10 years ago, on 1/9/2013
- Experience and guidances have increased over the years
- However, complexity of the BPR and its procedures increases too
- Various challenges for all parties involved
- Prioritisation

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Workload overview

- All NA-APP, UA-APP, SA-APP and renewals that were submitted from 2012 until 2020 are closed, with one exception

- Status of ongoing dossiers:

Submission year	# dossier	Status	Remarks
2018	1	On hold	Assessment reopened for an article 75(1)(g) procedure
2021	6	2 near completion 4 on hold	4 on hold → PT14 renewals waiting for the finalisation of the AVKs comparative assessment
2022	17	Ongoing	-
2023	7	Ongoing	Waiting for 7 dossiers not yet submitted

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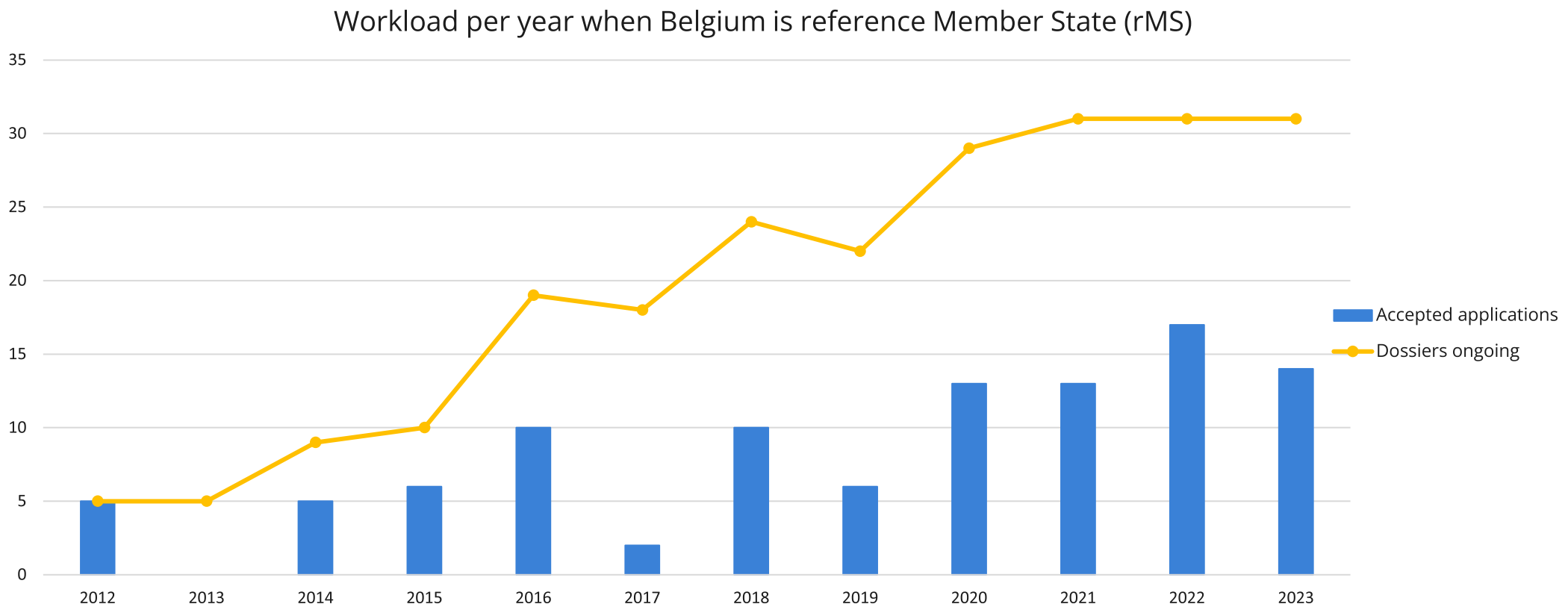
Workload overview

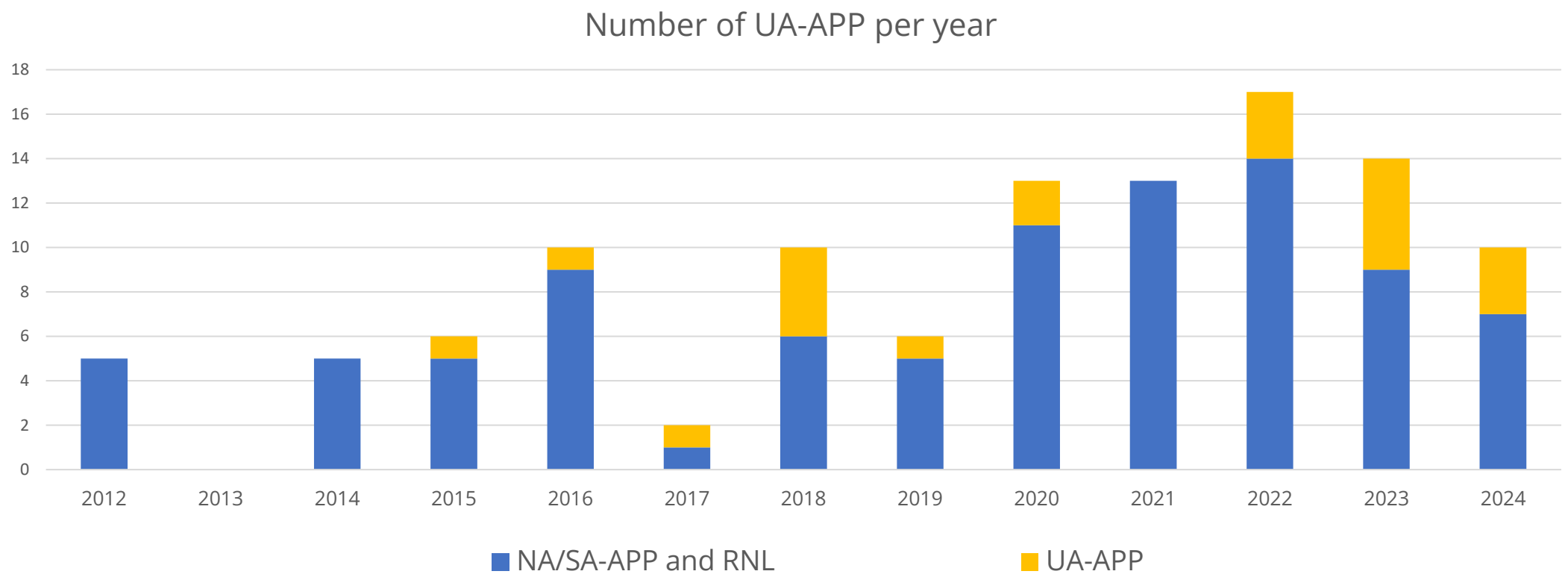
NA-APP, UA-APP, SA-APP and renewals only



Experiences

Union authorisations

The number of UA-APP we can manage per year is limited



Experiences

Union authorisations

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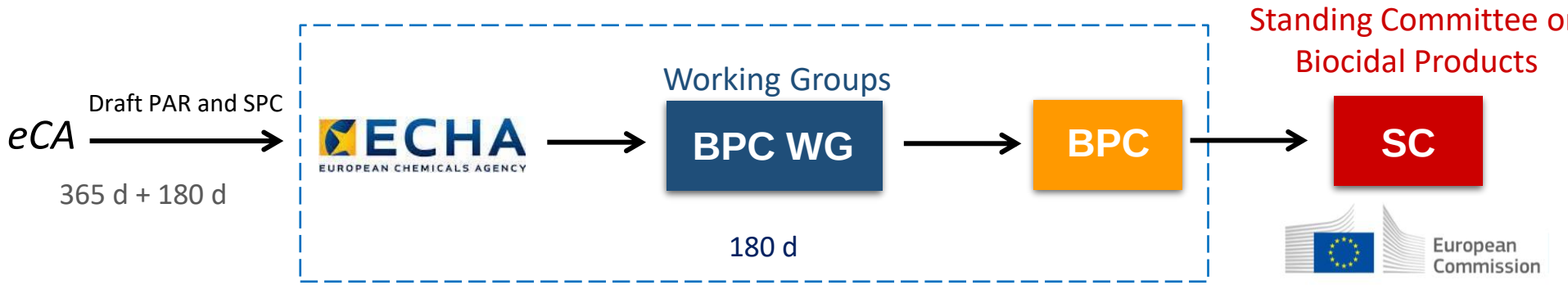
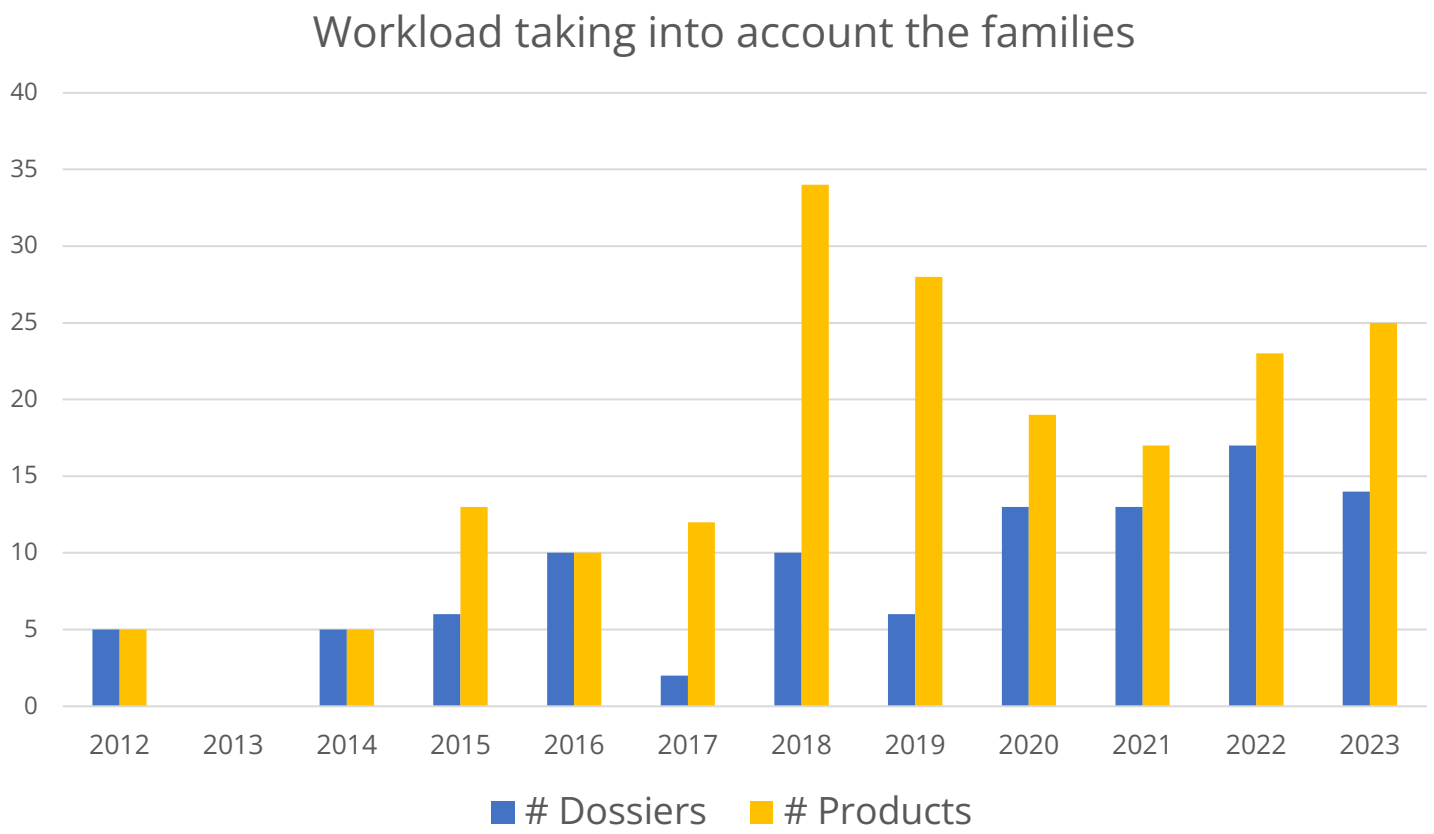


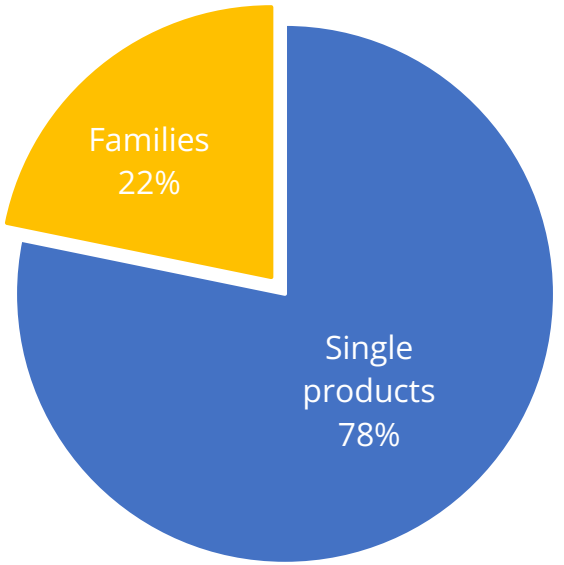
- Peer-review phase longer and with more steps compared to NA-APP, with possibility of going back to previous steps
- The authority competent to deliver the authorisation is the European Commission
- There is no timeline defined after the BPC has sent its Opinion to the Commission
- The authorisation is delivered on the whole EU market as from the validity date in the implementing decision published at the Official Journal of the EU

Experiences

Families

EU





Experiences

Families

- The guidance implementing the concept of biocidal product families is applicable to new applications submitted as of 1/10/2019
  - CA-July19-Doc 4.2

- The guidance specifies further the definitions of a family from the Article 3(1)(s) of the BPR:
  (i) Similar uses
  (ii) Same active substances
  (iii)Similar composition with specified variations
  (iv)Similar levels of risk and efficacy

Experiences

Families

- The families not complying with the guidance need to be split

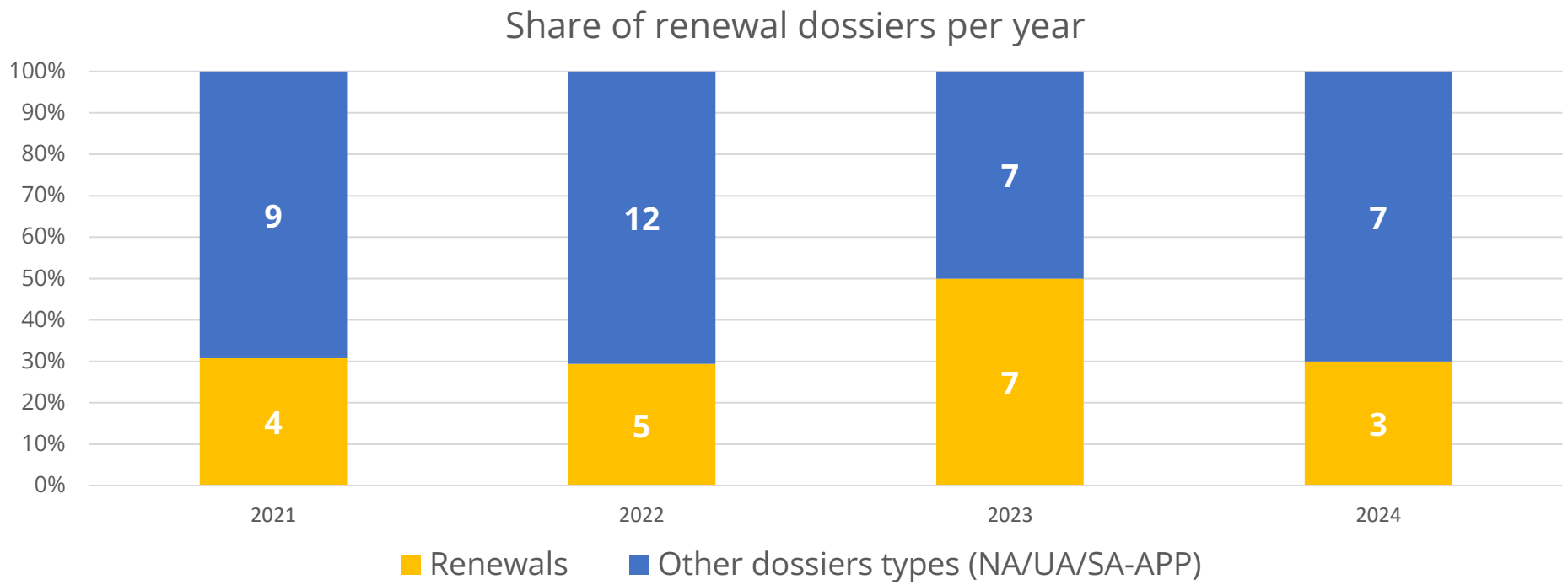
- The families containing authorisations under article 19(1) and article 19(5) also need to be split → Different levels of risk and efficacy → Document CG-57-2023-05

- How to split? → Document CG-30-2018-05
  - The initial application continues only with compliant products
  - The products that cannot stay in the family will still benefit from the transitional period (article 89 if the BPR)
  - One or more new application(s) should be submitted to address the part of the original family that is no longer covered by the initial application

Experiences

Renewals

- The share of renewals per year is currently between 30% and 50% of our workload as rMS
- The number of products to be renewed is inevitably increasing



Experiences

Renewals

EU

- Full v/s light evaluation
  - Article 31(5) of the BPR: *« the receiving competent authority shall […] decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary »*

- Evaluation phase: full evaluation = 365 days; light evaluation = 180 days

- The vast majority of the first renewal dossiers we are evaluating are full evaluation:
  - Endocrine disruptors not assessed
  - New guidances (for example Efficacy guidance for PT19)

Experiences

Renewals

EU

A separate regulation covers the renewal subject to mutual recognition: (EU) No 492/2014

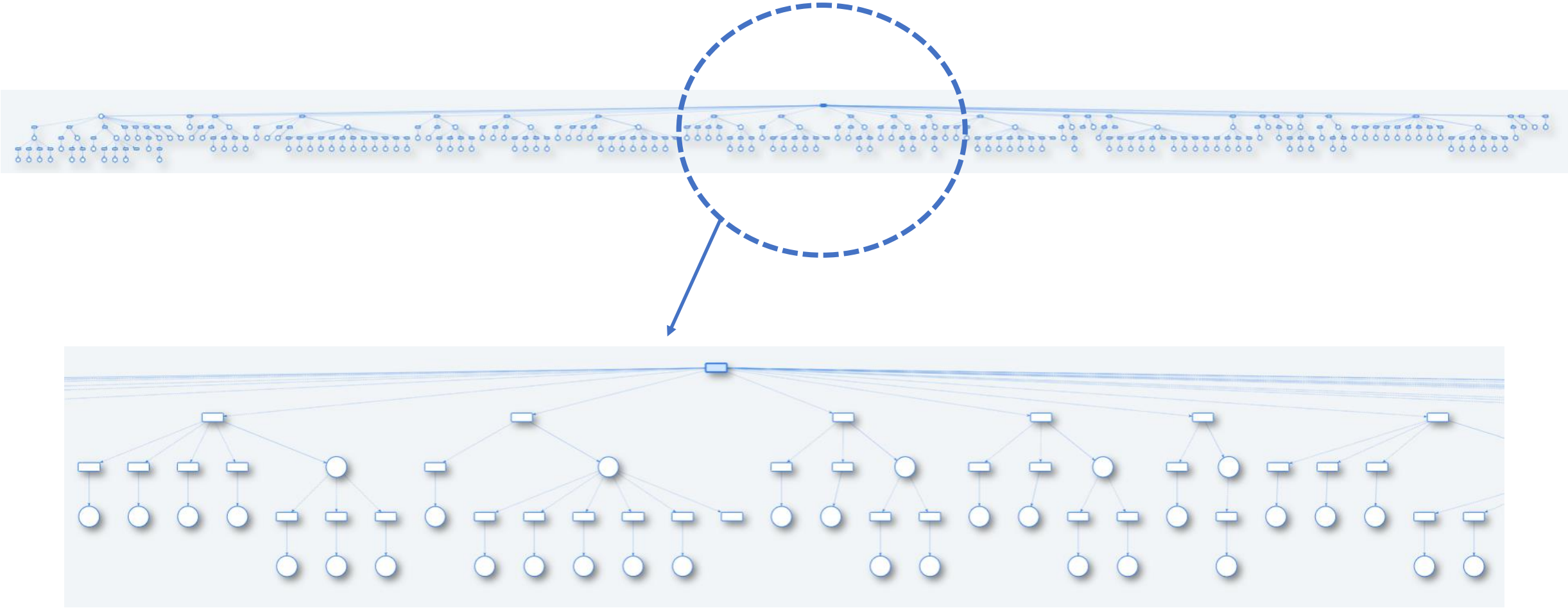
The complexity of the procedures of the BPR created very complex links between authorisations

- Mutual recognitions
- Mutual recognition from mutual recognition
- Same biocidal products not from the NA-APP
- Changes in same biocidal products but not in the reference product
- Changes not applicable for all the concerned Member-States

Experiences

Renewals

EU



Experiences

Renewals

EU

- Challenges to figure out the links and what needs to be renewed
- Challenges in terms of workload
- Technical difficulties to group the applications in R4BP3

→ Complete the supporting document thoroughly

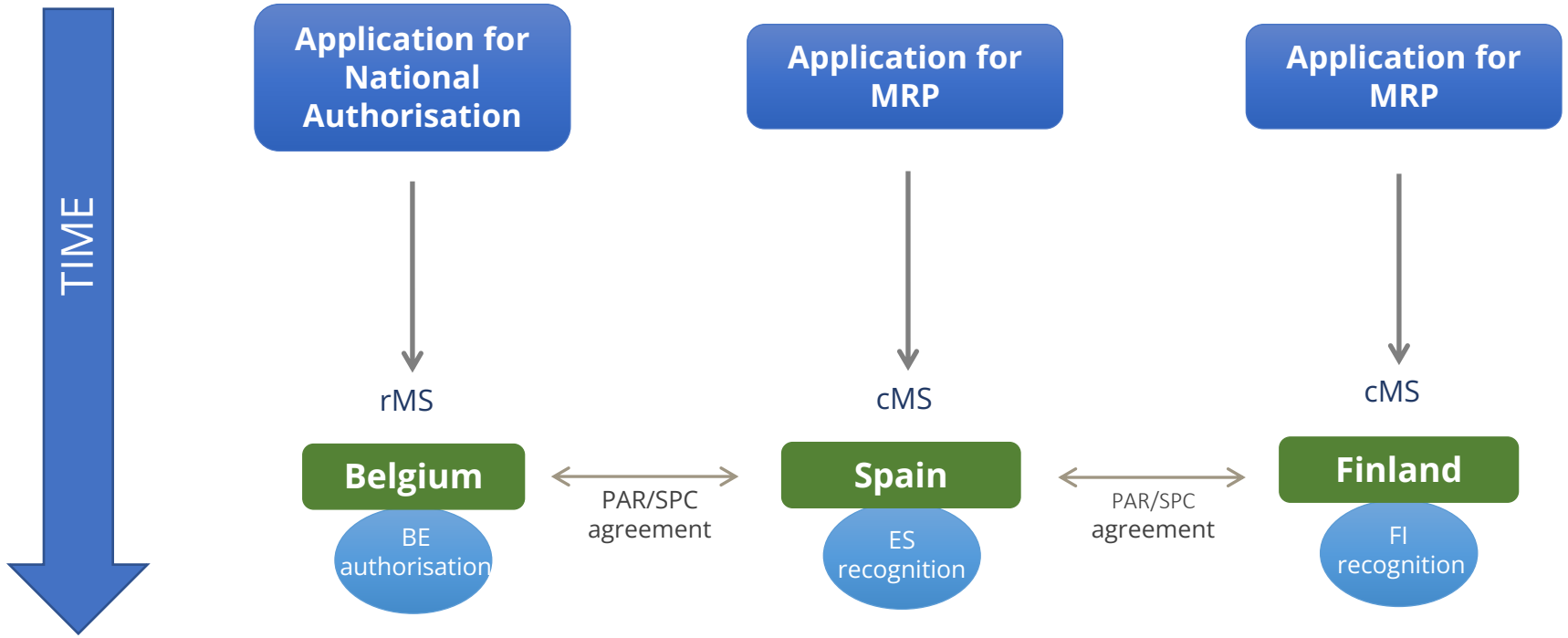
→ Respect of the principle of same biocidal products

→ Limit the changes only applicable to one market area

Experiences

Mutual recognition in parallel v/s in sequence

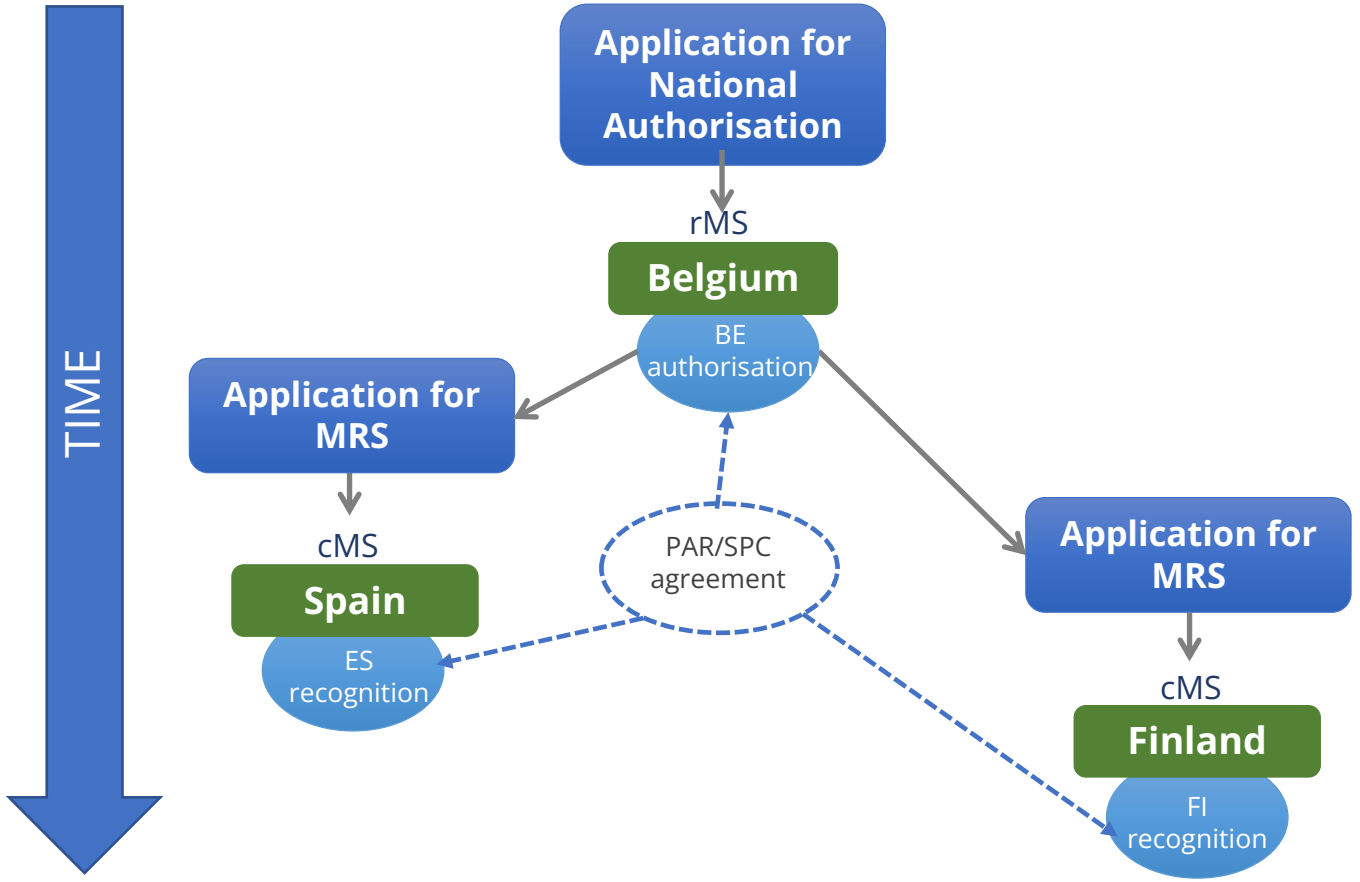
Procedure for mutual recognition in parallel (NA-MRP; article 34 of the BPR)



Experiences

Mutual recognition in parallel v/s in sequence

Procedure for mutual recognition in sequence (NA-MRS; article 33 of the BPR)



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Experiences

Mutual recognition in parallel v/s in sequence

- Any changes in the Summary of Product Characteristics (SPC) triggers a referral to the coordination group to allow the consultation of all the concerned Member-States
- High workload for the applicant and the reference Member State
- Risk of significant modifications or non-authorisations decision even though the product has been on the market for some time
- Synchronisation of several MRS not always possible

→ Advice to use the procedure of mutual recognition in parallel whenever possible

→ When several MRS are sought, inform the reference Member State before the submission and submit all dossiers at the same time

Experiences

General

EU

Crucial points for the good progress of a dossier

- The presubmission meeting
- The dossier must be complete at the submission
- Continuous and transparent communication
- Respect of the procedures and the deadlines
- Keep up-to-date with new guidances or procedures

Experiences

General

EU

- ECHA is working on a tool to have an overview of the ECHA guiding documents for stakeholders and Member States

- Highlight on some recent documents:
  - Guiding principles on handling information provided by the applicant during NA/SA-APP and UA-APP processes
  - Updated or new working procedures for UA processes (UA-APP, UA-MAC and UA-MIC), all available on ECHA BPC's webpage
  - Management of new information on Active Substance submitted for a product authorisation application (CG public documents)
  - Shelf-life setting, alignment of the practices with the actual requirements of the BPR
  - Post-authorisation conditions, revision of the existing documents for NA/SA-APP and UA-APP
  - Streamline process for the renewal of PT8 products containing Propiconazole (CA-March23-Doc.4.11)

EU

Thank you for your attention

Further information

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www.biocide.be