



federal public service  
**HEALTH, FOOD CHAIN SAFETY  
AND ENVIRONMENT**

# Experiences with BP dossiers

BE and EU procedures

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  - ▶ Legal basis
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# 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](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](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2019040431&table_name=loi)

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

# Legal basis

► Related RD - modified:

27 FEBRUARI 2019. - Koninklijk besluit tot wijziging van het koninklijk besluit van 13 november 2011 tot vaststelling van de retributies en bijdragen verschuldigd aan het Begrotingsfonds voor de grondstoffen en de producten

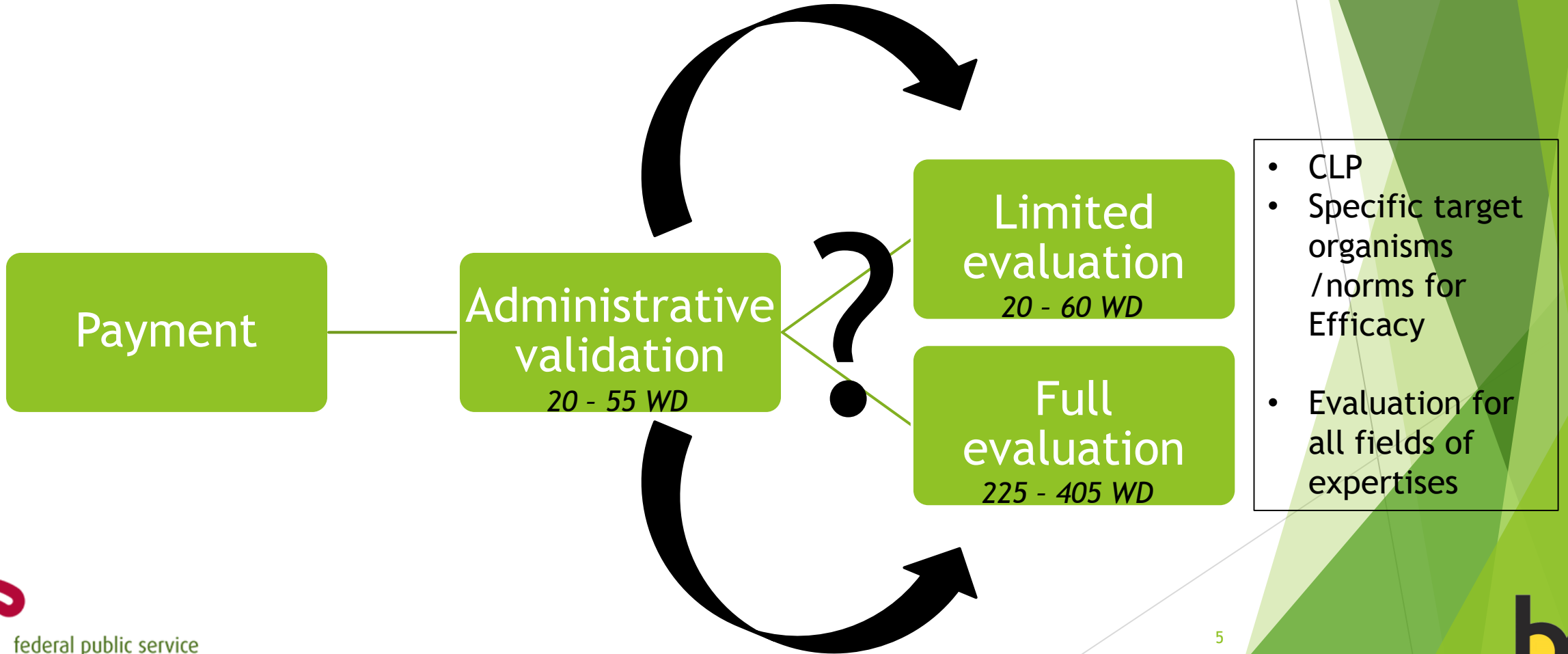
[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=nl&la=N&cn=2011111309&table\\_name=wet](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2011111309&table_name=wet)

27 FEVRIER 2019. - Arrêté royal modifiant l'arrêté royal du 13 novembre 2011 fixant les rétributions et cotisations dues au Fonds budgétaire des matières premières et des produits

[http://www.ejustice.just.fgov.be/cgi\\_loi/change\\_lg.pl?language=fr&la=F&cn=2011111309&table\\_name=loi](http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2011111309&table_name=loi)

*PS: Mostly renaming « authorisation/notification » => « registration » and other related changes*

# Registration procedure

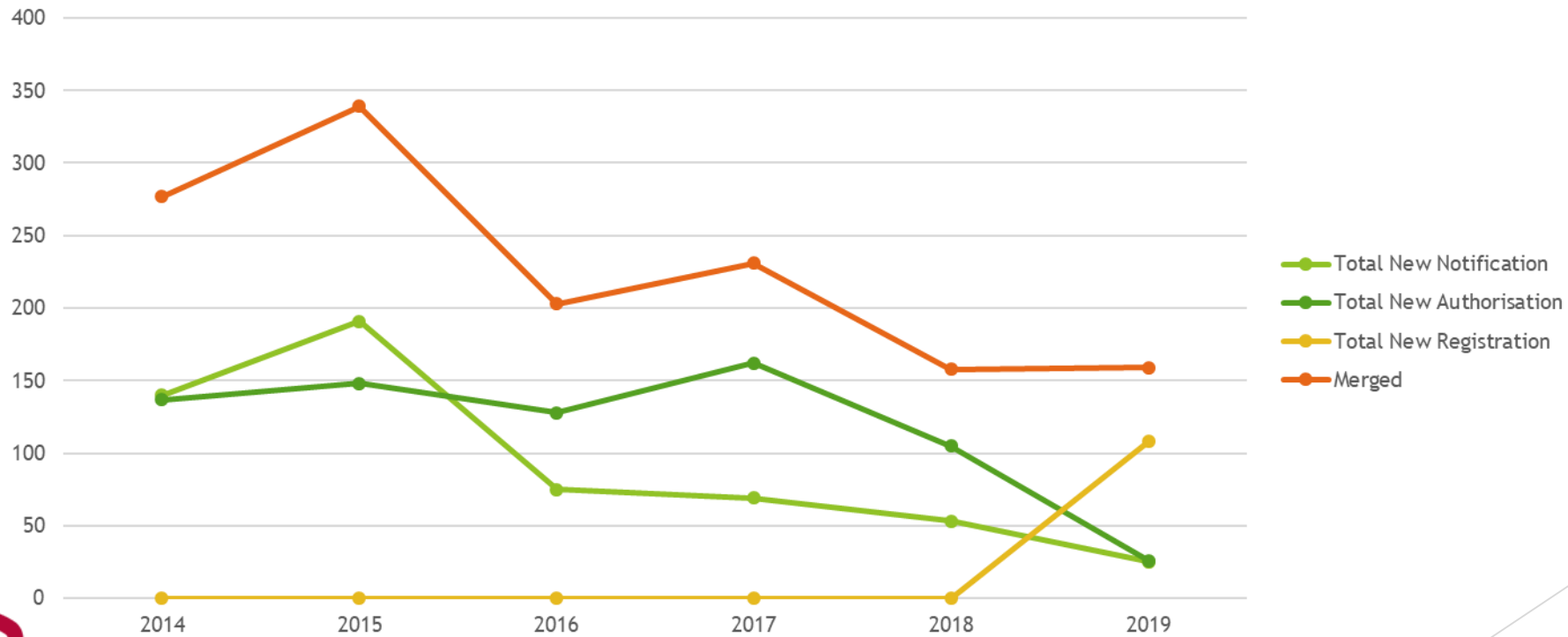


# Limited vs. Full evaluation

- ▶ As per RD 04/04/2019, 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.*

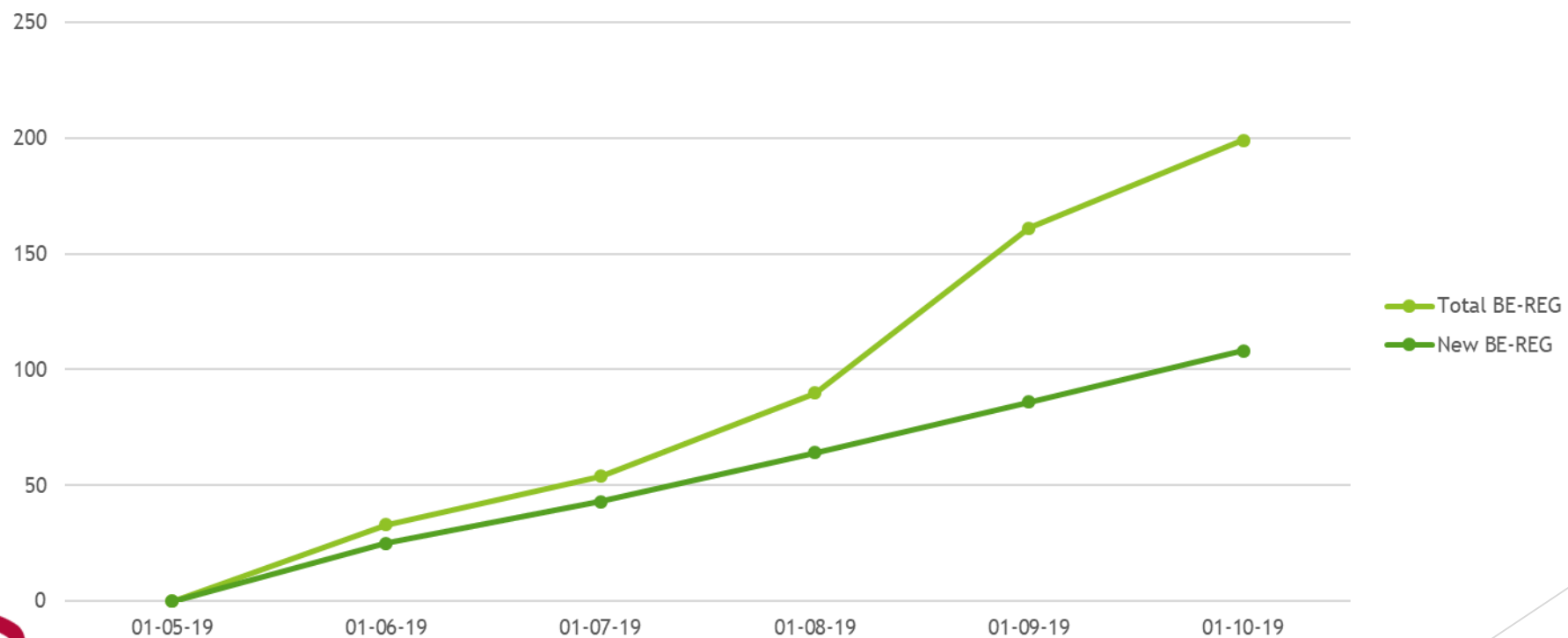
# First experiences

Signed BE certificates vs time



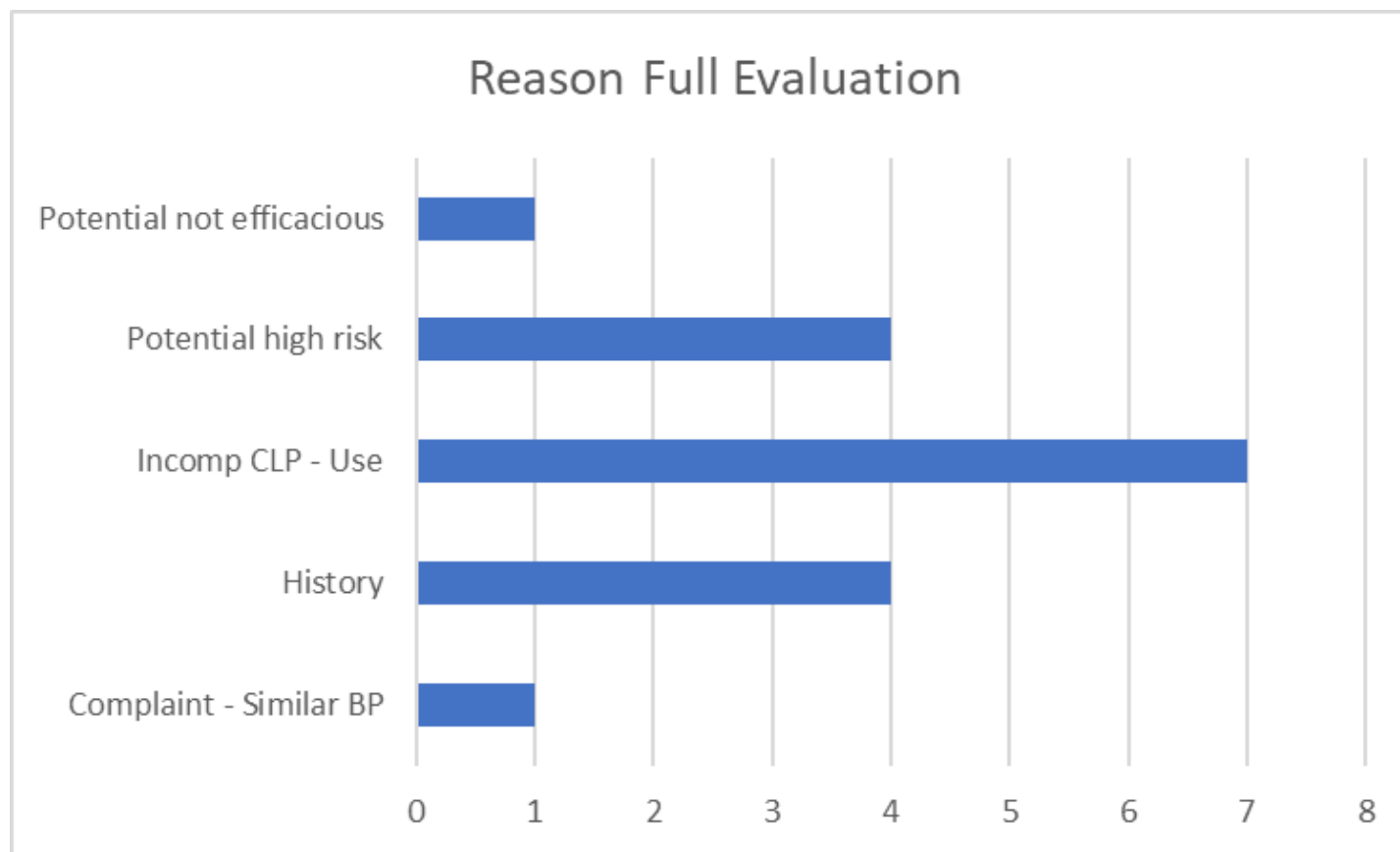
# First experiences

Signed BE-REG certificates vs time

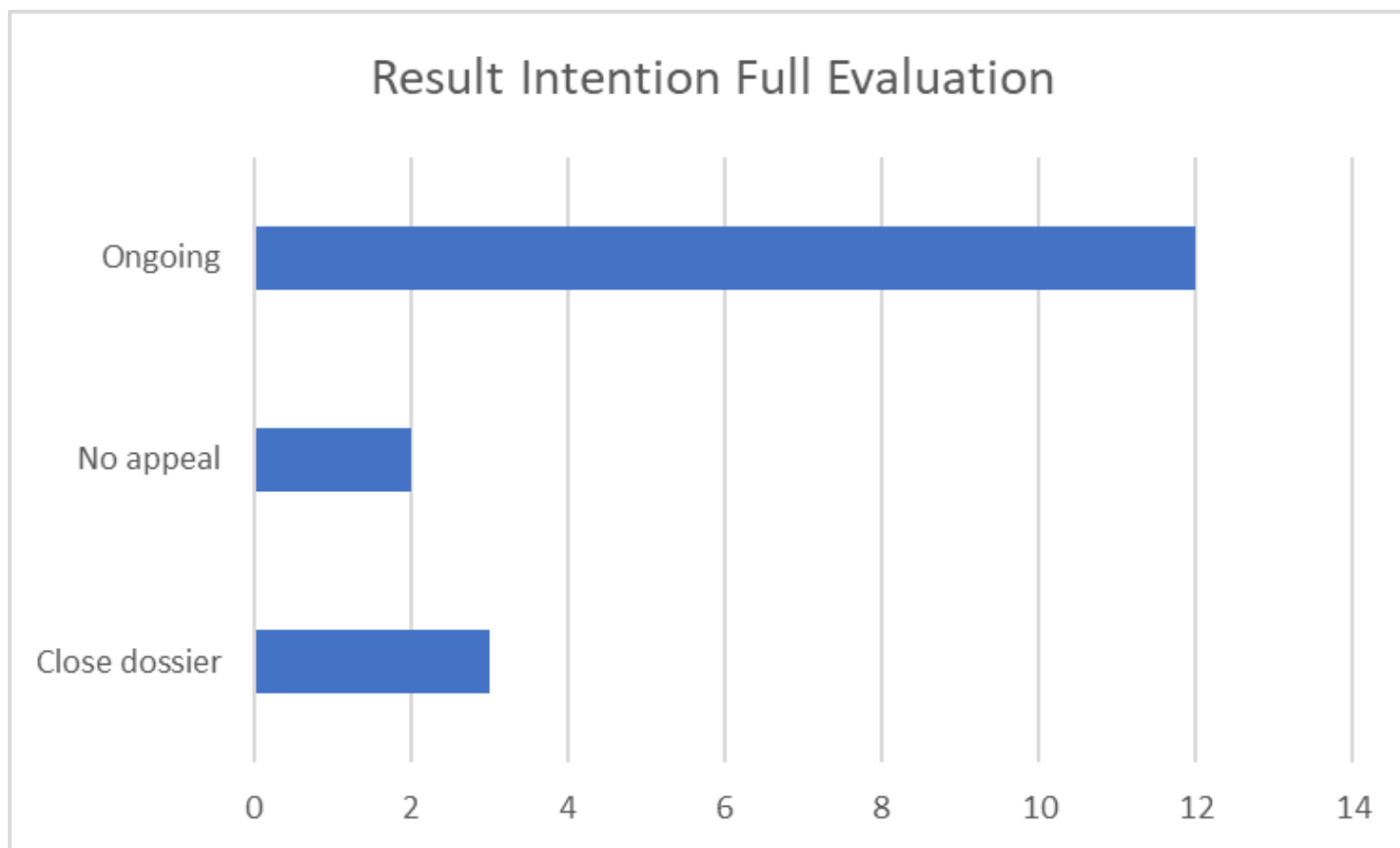




# First experiences



# First experiences



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- ▶ **EU procedure**
  - ▶ General introduction
  - ▶ Main product authorisation procedures
  - ▶ First experiences
- ▶ **Questions?**

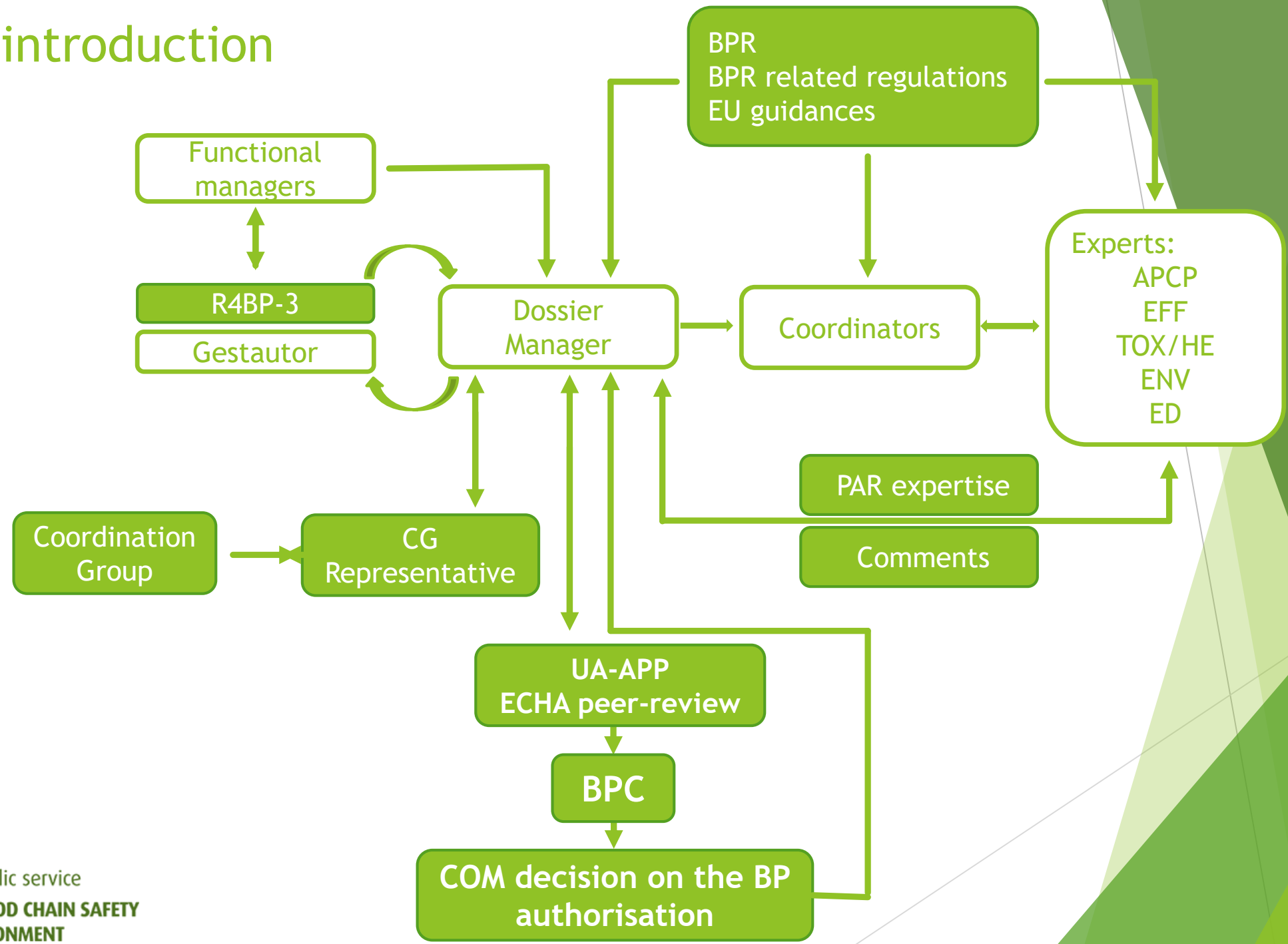
# General introduction

- ▶ BPR 528/2012 entered into force on September 1<sup>st</sup>, 2013
- ▶ BPR and EU related regulations
- ▶ EU guidances
  - Authorisation granted by the rMS or the EC
  - For single biocidal products or product families
  - Strict deadlines

# General introduction

- ▶ EU biocidal product authorisations:
  - NA-APP
  - UA-APP
  - SA-APP
  - NA-MAC, NA-MIC,...
  - NA-MRP/MRS
- ▶ EU procedures:
  - Referrals (Art.35)

# General introduction



# General introduction

- ▶ Request from future applicant if BE does agree to act as rMS/eCA
- ▶ Assignment of:
  - Dossier manager (contact point, follow-up R4BP-3, PAR & SPC, Gestautor,..)
  - Experts: APCP, EFF, TOX/HE, ENV, ED
- ▶ Pre-submission meeting (1500 €, deductible)
- ▶ Identification of the product during transitional period (Art.89)

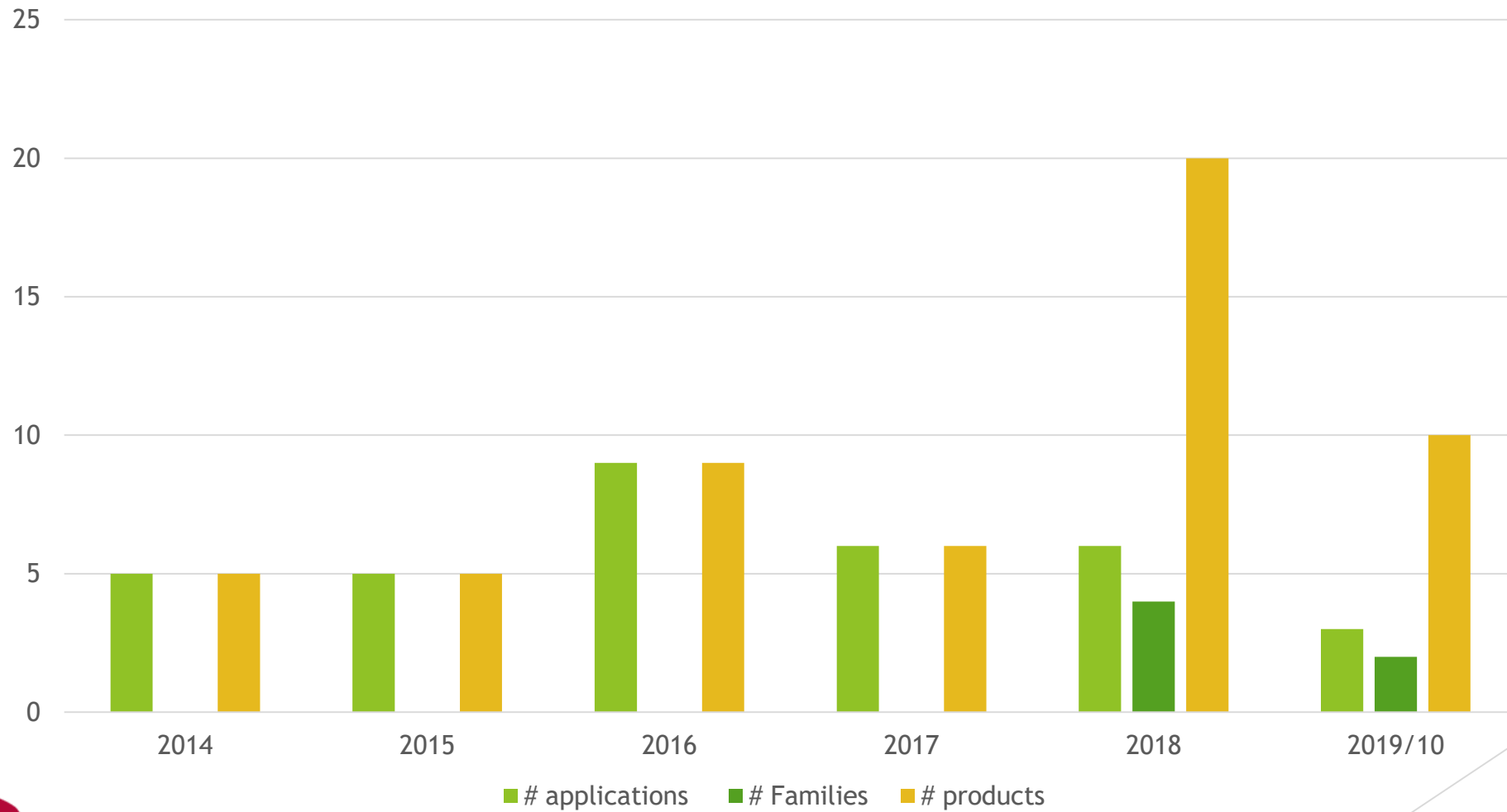
# EU product applications

- ▶ NA-APP
- ▶ UA-APP
- ▶ SA-APP & SN-NOT
- ▶ NA-MAC & NA-MIC
- ▶ NA-MRP & NA-MRS



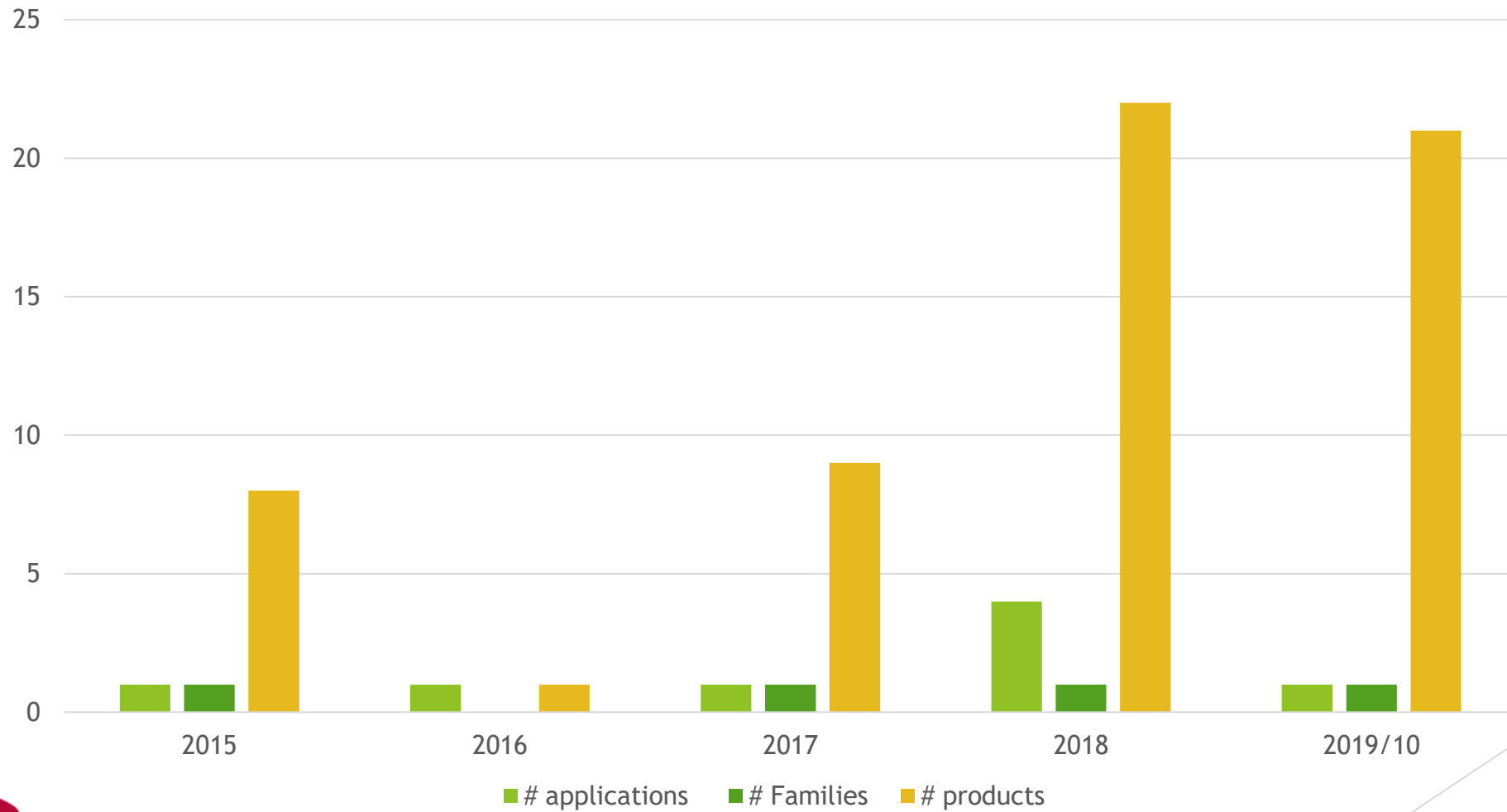
Submission year	# dossiers	Status	Remarks
2014	5	5 closed	
2015	5	5 closed 4 in finalisation	Delay due to lack of guidance PT19, waiting EU decision
2016	9	8 closed 1 in progress	
2017	6	5 closed 1 in progress	
2018	6	6 in progress	
2019	3	3 in progress	

# NA-APP



Submission year	# dossiers	Status
2015	1	BPC opinion
2016	1	In progress
2017	1	In progress
2018	4	In progress
2019	1	In progress

# UA-APP



# SA-APP & SN-NOT

	SA-APP	SN-NOT
2015	0	4
2016	0	4
2017	0	6
2018	0	11
2019	1	7

## NA-MAC

Submission year	# dossiers	Remarks
2015	5	4 eCA
2016	10	0 eCA
2017	10	1 eCA
2018	7	0 eCA
2019/10	4	2 eCA

## NA-MIC

Submission year	# dossiers	Remarks
2014	2	1 eCA
2015	8	0 eCA
2016	7	0 eCA
2017	8	4 eCA
2018	6	2 eCA
2019	12	0 eCA

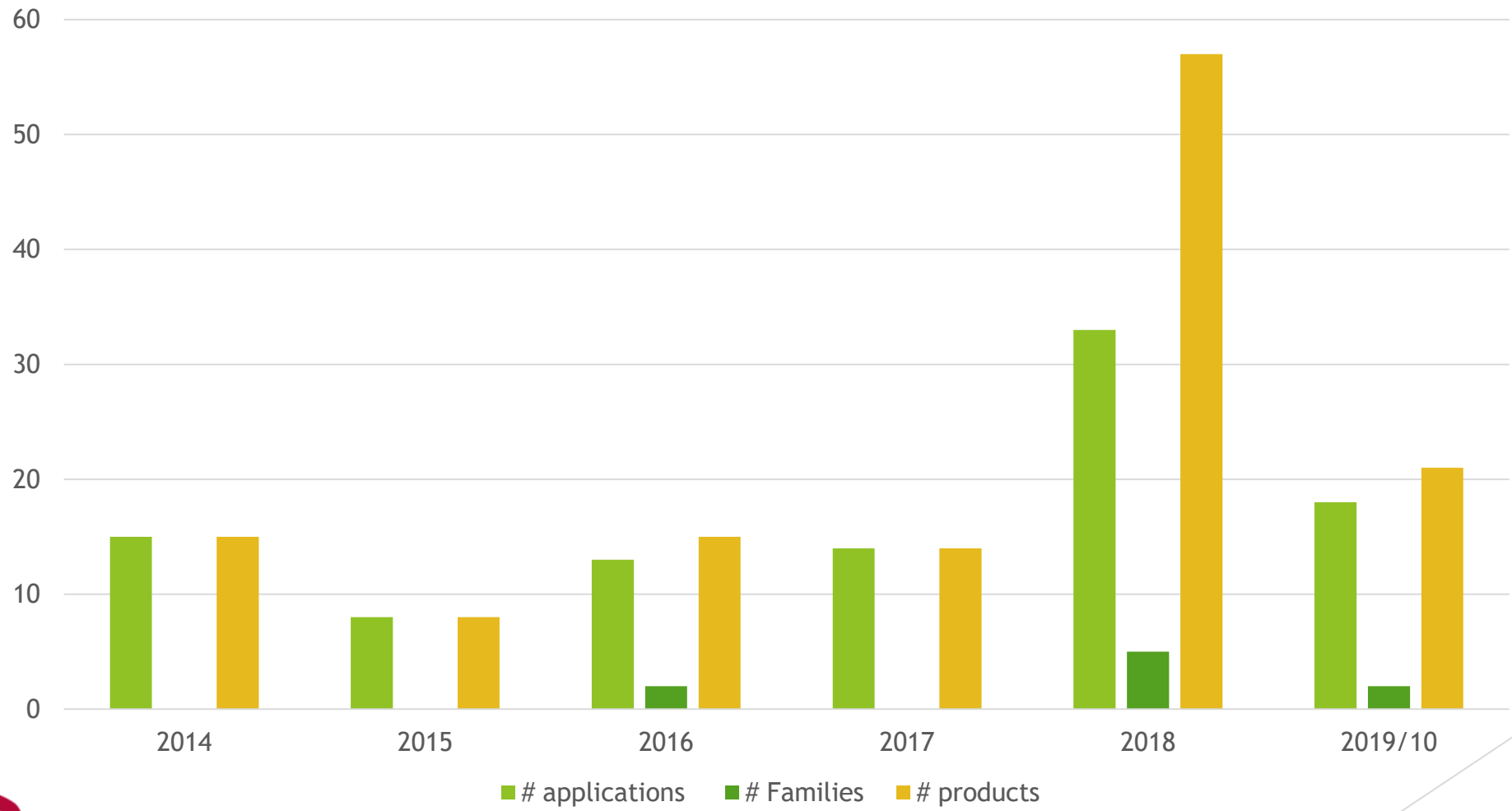
## NA-MRP

Submission year	# dossiers	Status
01/09/2013	7	7 closed
2014	9	8 closed
2015	52	28 closed
2016	47	24 closed
2017	61	16 closed
2018	44	8 closed
2019	15	1 closed

## NA-MRS

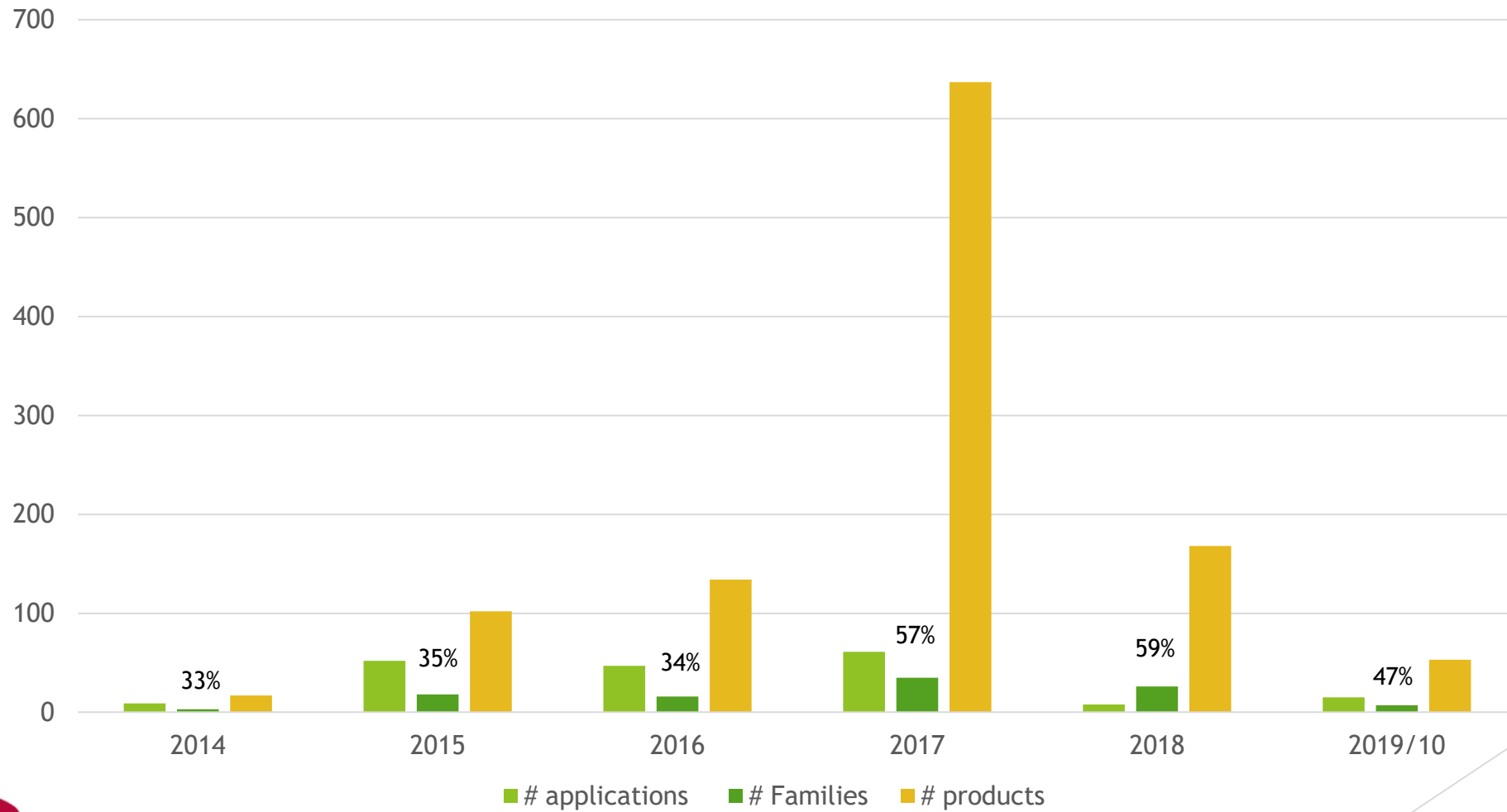
Submission year	# dossiers	Status
01/09/2013	3	3 closed
2014	15	15 closed
2015	8	8 closed
2016	13	13 closed
2017	14	14 closed
2018	33	29 closed
2019	18	3 closed

# NA-MRS





# NA-MRP



# Referrals

## ▶ Art. 35-38 of the BPR

- MPR - MRS (art. 35-38): Where any cMS considers that a biocidal product assessed by the rMS does not meet the conditions laid down in Art.19.
- Simplified authorisation (art. 27): Where a cMS considers that a biocidal product authorised in accordance with Art. 26 has not been notified or labelled in accordance with paragraph 1 of this Article or does not meet the requirements of Art. 25.

## ▶ BPR compliance

- GC-22-2017-23 “Submission of referrals to the CG under Article 27(2) of the BPR”
- “Resolving disagreements on mutual recognition: working procedure for the Coordination Group (CG)” (Revision 13, version of 13 Mai 2019)
- Template “Referral of a disagreement by the concerned Member State under Article 35 of Regulation (EU) No 528/2012”
- Manual “How to run BPR processes with R4BP3 in MS CA”

# Referrals (Art.35) - CG

		BE eCA	Closed Consensus	Under discussion	Art.36
2013	2		2		0
2014	6		4		2
2015	9		8		1
2016	16		16		0
2017	52	2	47		4
2018	56	2	55		1
2019/10	28	3	23	1	3

# First experiences

- ▶ Challenging regulation:
  - new procedures
  - new implementing regulations
  - IT tools
- ▶ Effort to assist the applicant:
  - Helpdesk
  - Pre-submission meeting
  - Transparent communication with applicant during evaluation
- ▶ Active participation in EU meetings → knowledge transfer

# Thank you for your attention

**Any Questions...  
Just Ask!**



For further information

Belgian Biocides website

[www.biocide.be](http://www.biocide.be)