MONITORING REPORT AUTHORISATIONS OF BIOCIDAL PRODUCTS.

The European Chemicals Agency (hereinafter "ECHA") has compiled the data for this report based on records reported by Member States in the Register for Biocidal Products (R4BP3) and the applicable legal deadlines set out in the Biocidal Products Regulation. The report aims to give a reasonably accurate insight into the delays in the application process, however ECHA cannot and does not guarantee the information is fully accurate. For example, there may be cases of late reporting in R4BP3 which would falsely indicate a delay in the corresponding application process.

1. BACKGROUND AND PURPOSE OF THE DOCUMENT.

The purpose of this document is to give an overview of the delays in products authorisations in the EU. Member States are invited to reflect on the figures provided and to share their conclusion on them, with aa view to improve the functioning of the system.

This report provides an overview of the delays in all applications submitted from 01/01/2010 until 20/08/2020 (included) for 5 case types:

- NA-APP (Application for National Authorisation),
- NA-MRP (Mutual Recognition in parallel),
- NA-MRS (Mutual recognition in sequence),
- SA-APP (Application for Simplified Authorisation) and
- UA-APP (Application for Union Authorisation).

Delays are represented in the graphs in percentage, the number of cases delayed/on time are represented in the graphs as numbers.

The total number of authorisations (total workload per MSs is also provided).

Before and after 3.10:

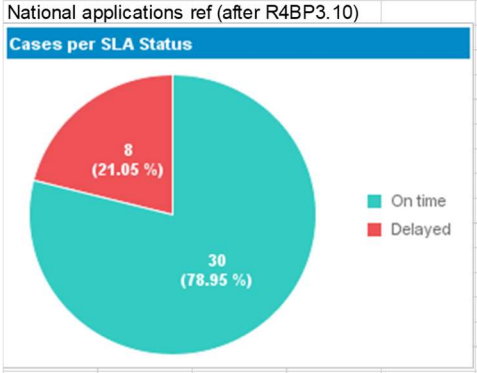
- Please note that in October 2017 a new release of R4BP 3 (version 3.10) changed the way grouped applications for NA-APP and NA-MRP were implemented, introducing further steps to accommodate the Agreement on SPC/PAR after submission of the draft SPC/PAR by the eCA and a potential referral. That is reported in this document dividing NA-MRPs into MRPs "before 3.10" and "after 3.10" to indicate the increased number of steps of the latter.

- Regarding NA-APPs, this is reflected in the fact that submissions for NA-APP "reference" might contain further steps than the past ones due to the fact that they are following the new route. This does not exclude that there might be reference NA-APPs with the old setting, since already in the past it was possible to apply for a reference case.

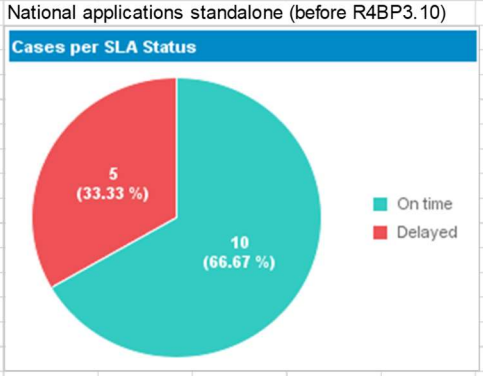
2. DELAYS BY MEMBER STATE- DELAYS IN ALL APPLICATIONS SUBMITTED FROM 01/01/2010 UNTIL 20/08/2020.

2.1. Belgium

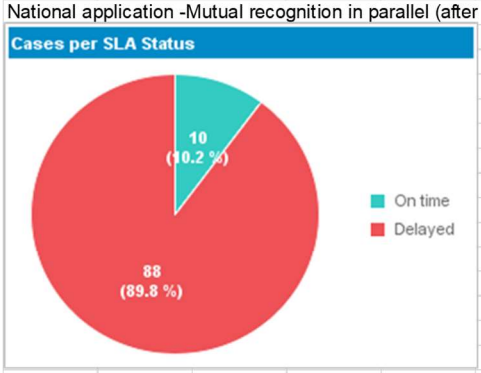
National applications ref (after R4BP3.10)



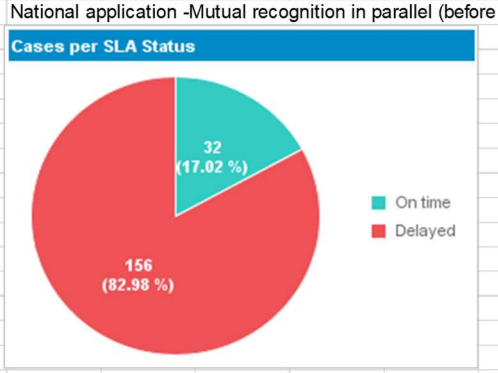
National applications standalone (before R4BP3.10)



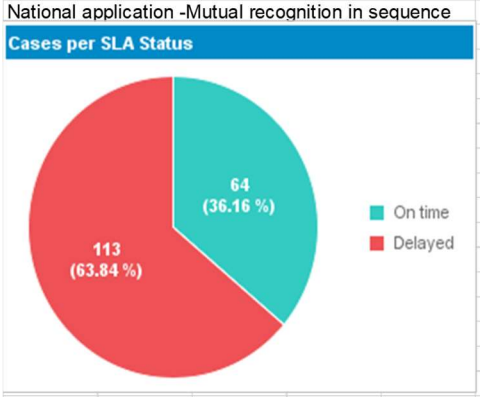
National application -Mutual recognition in parallel (after R4BP3.10)



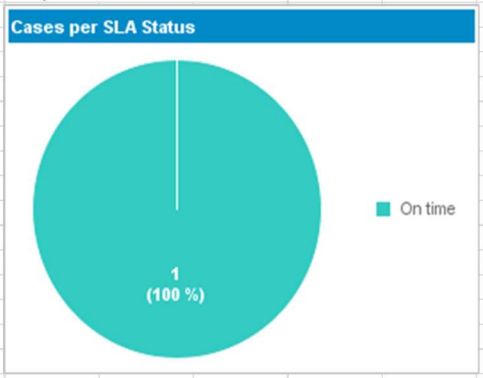
National application -Mutual recognition in parallel (before R4BP3.10)



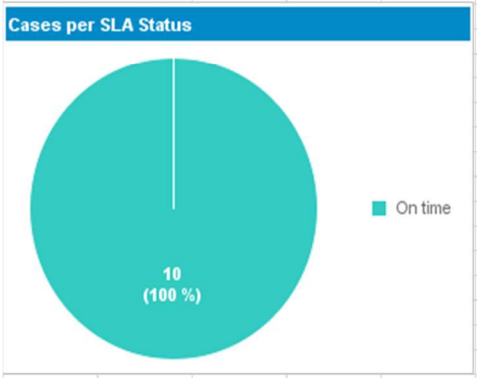
National application -Mutual recognition in sequence



Simplified authorisations

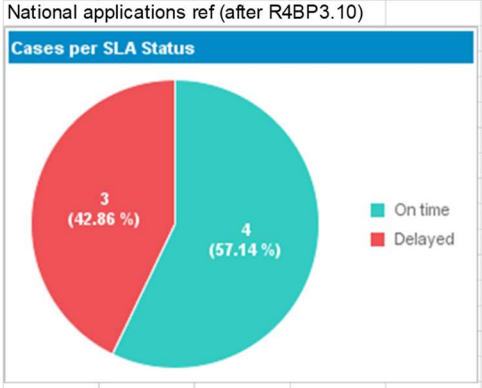


Union Authorisations

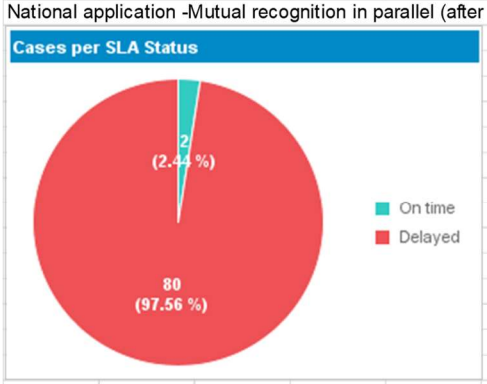


2.2. Bulgaria

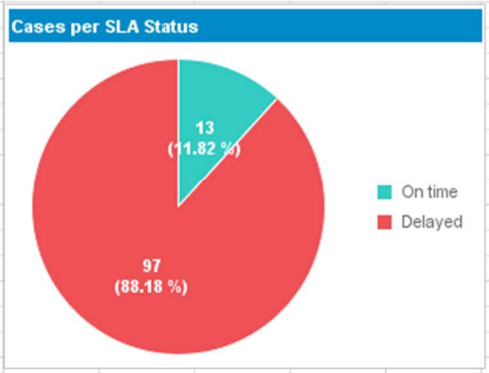
National applications ref (after R4BP3.10)



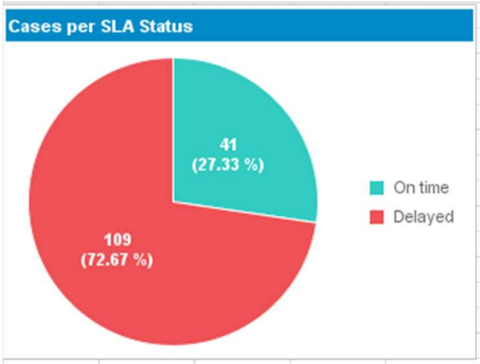
National application -Mutual recognition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10)

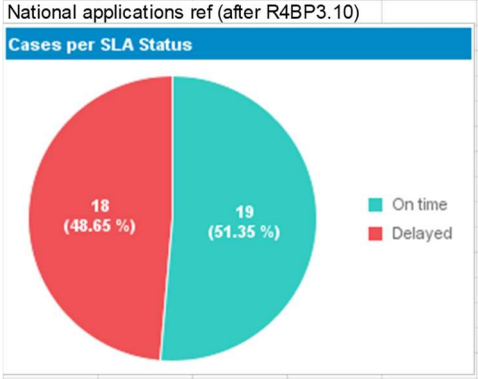


National application -Mutual recognition in sequence

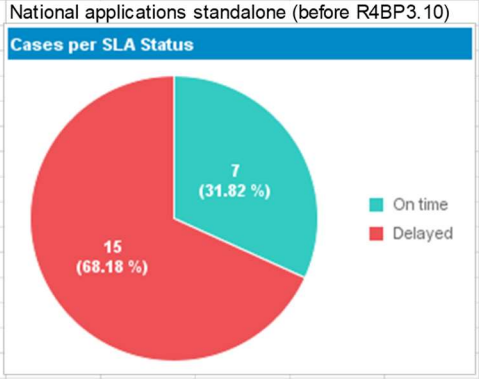


2.3. Check Republic

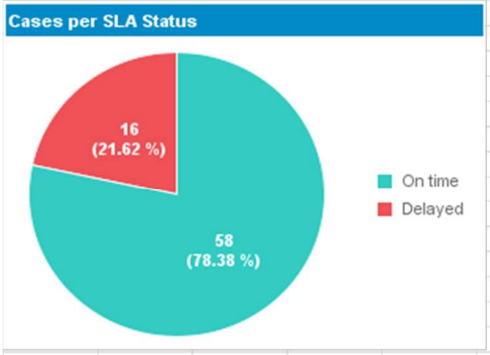
National applications ref (after R4BP3.10)



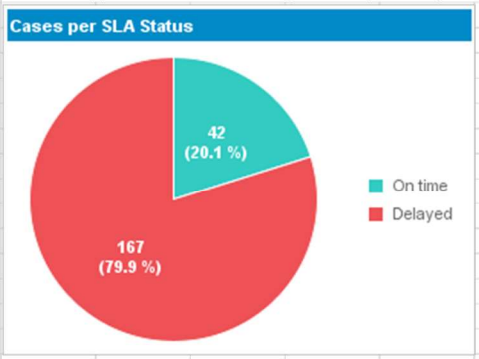
National applications standalone (before R4BP3.10)



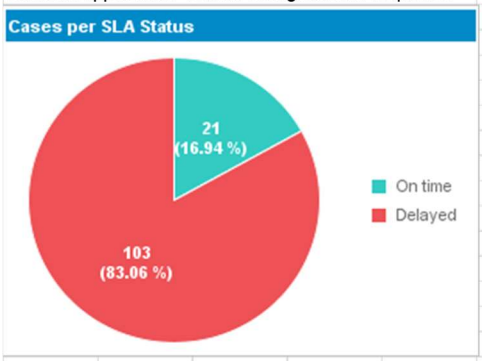
National application -Mutual recognition in parallel (after R4BP3.10)



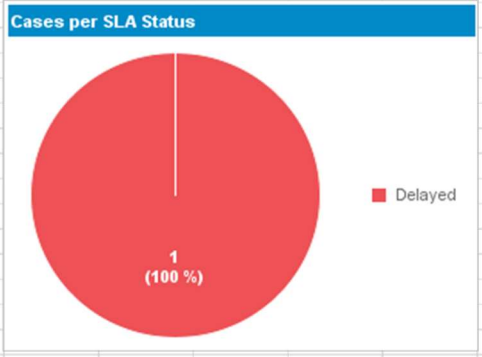
National application -Mutual recognition in parallel (before R4BP3.10)



National application -Mutual recognition in sequence

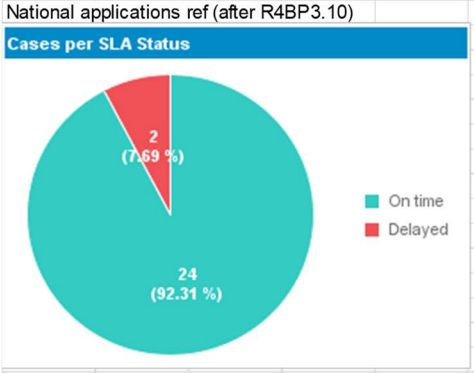


Union Authorisations

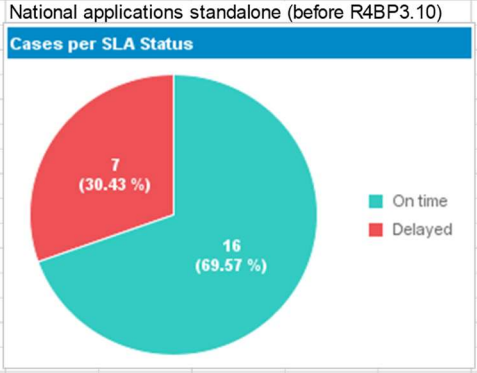


2.4. Denmark

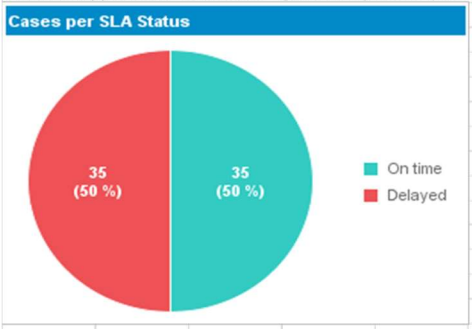
National applications ref (after R4BP3.10)



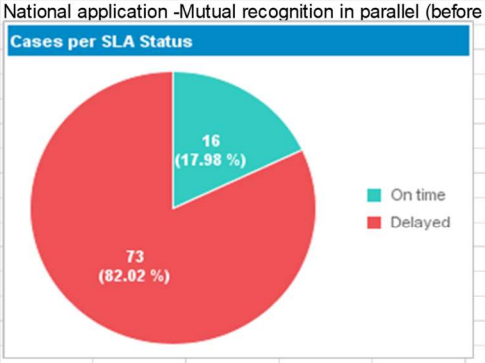
National applications standalone (before R4BP3.10)



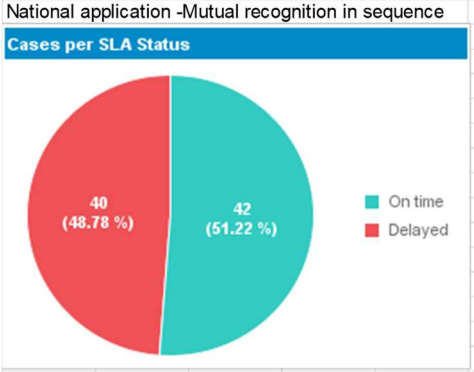
National application -Mutual recognition in parallel (after R4BP3.10)



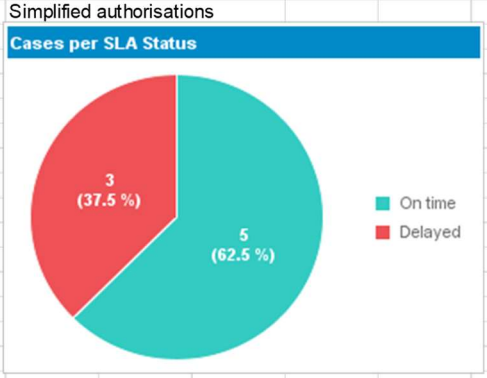
National application -Mutual recognition in parallel (before R4BP3.10)



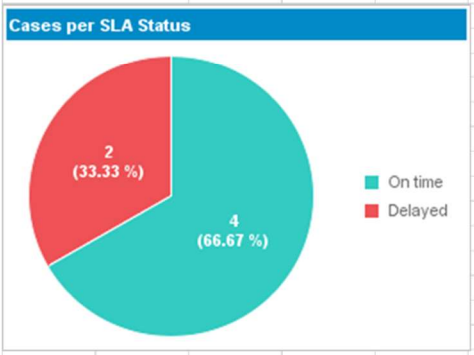
National application -Mutual recognition in sequence



Simplified authorisations

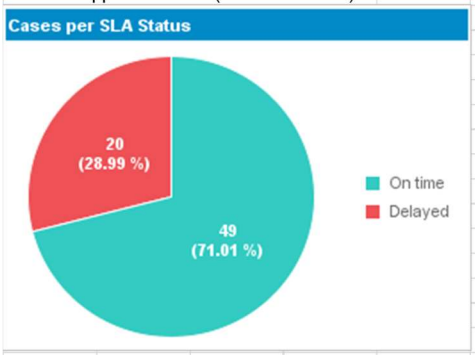


Union Authorisations

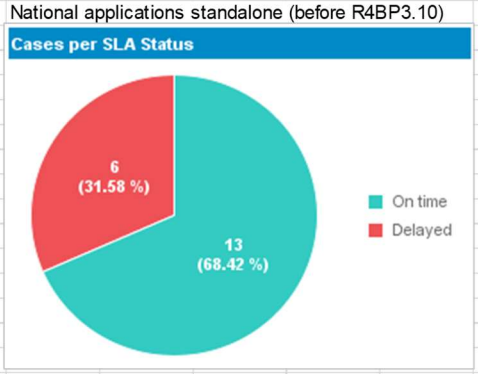


2.5. Germany

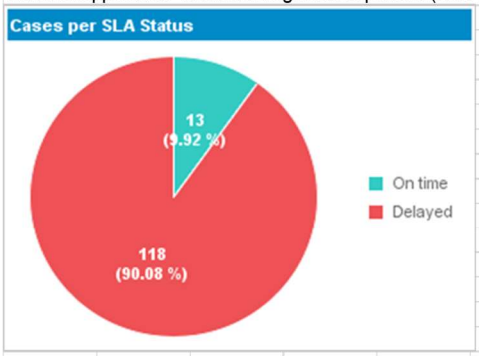
National applications ref (after R4BP3.10)



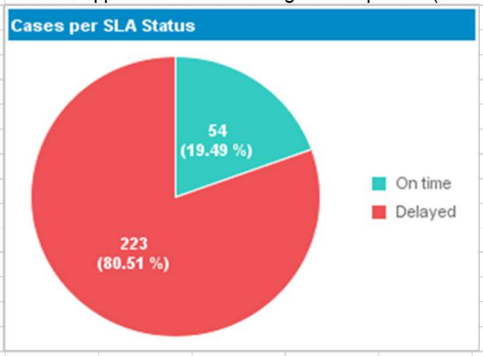
National applications standalone (before R4BP3.10)



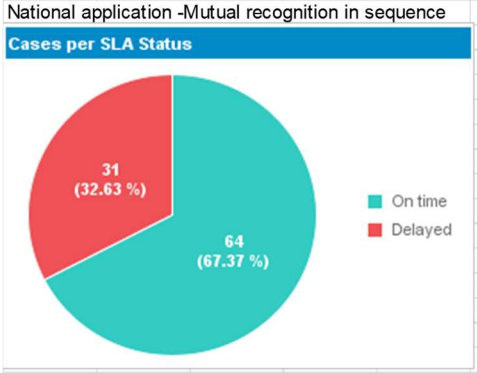
National application -Mutual recognition in parallel (after R4BP3.10)



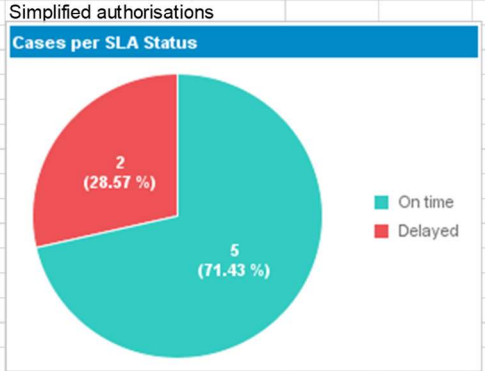
National application -Mutual recognition in parallel (before R4BP3.10)



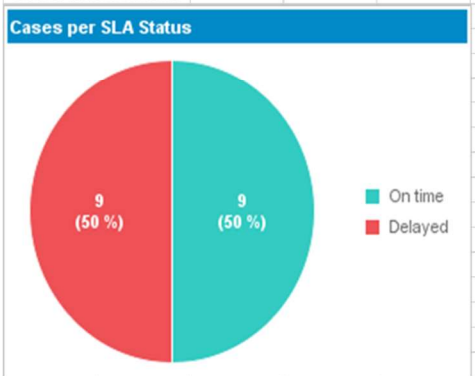
National application -Mutual recognition in sequence



Simplified authorisations

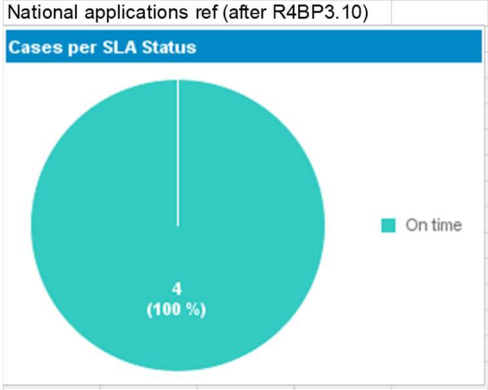


Union Authorisations

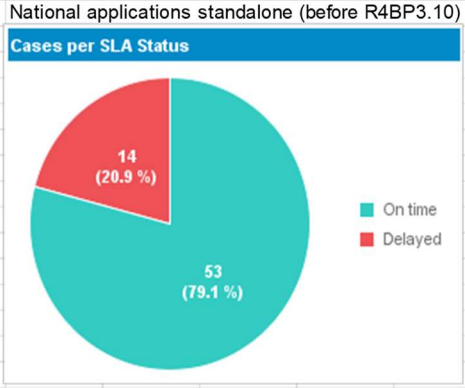


2.6. Estonia

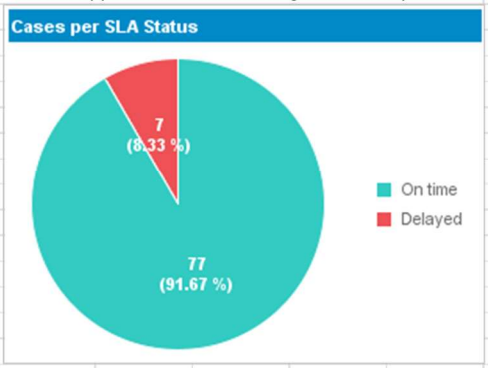
National applications ref (after R4BP3.10)



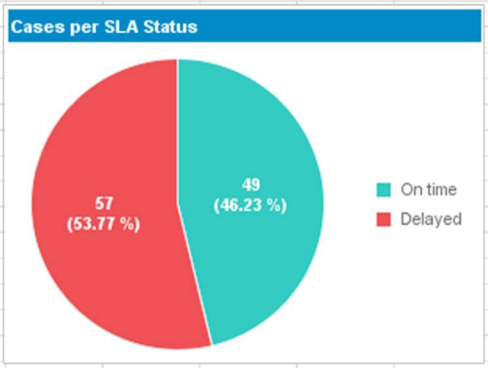
National applications standalone (before R4BP3.10)



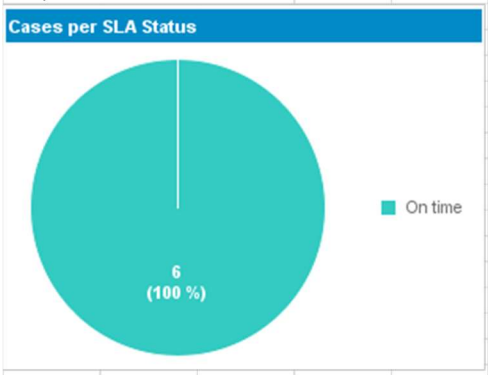
National application -Mutual recognition in sequence



National application -Mutual recognition in parallel (before R4BP3.10.)

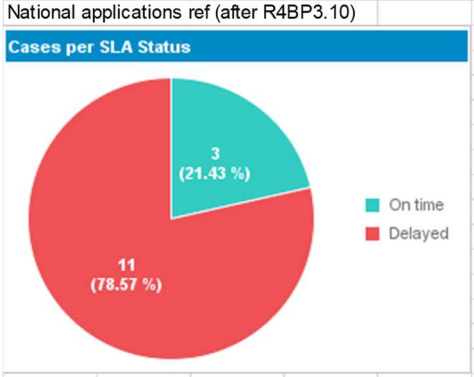


Simplified authorisations

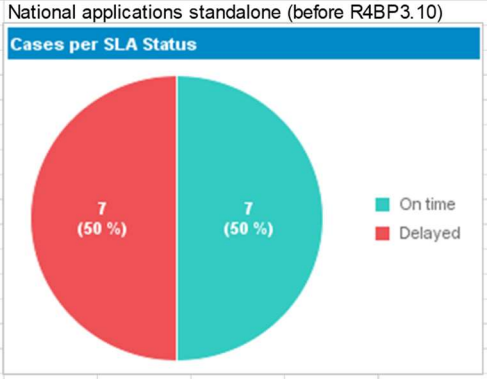


2.7. Ireland

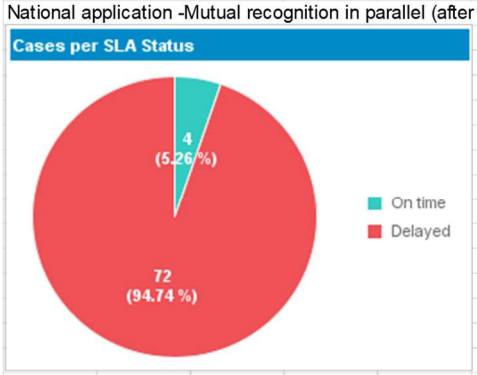
National applications ref (after R4BP3.10)



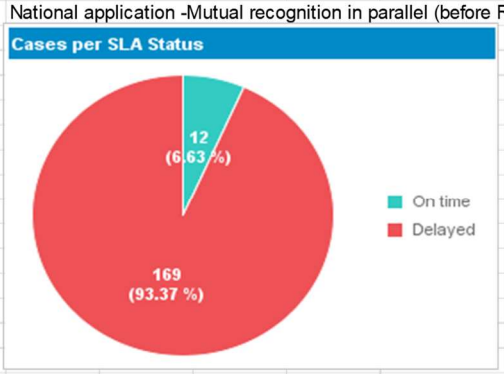
National applications standalone (before R4BP3.10)



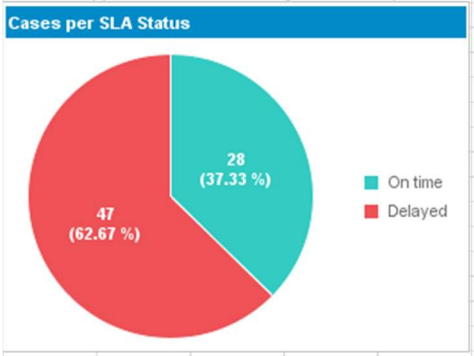
National application -Mutual recognition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

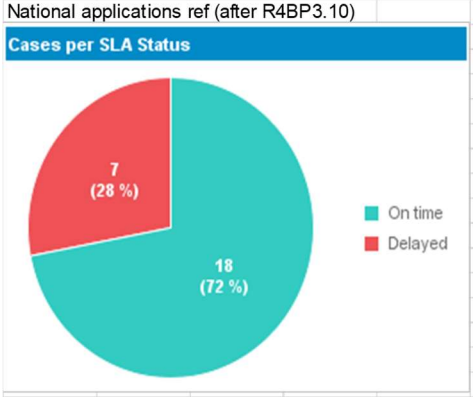


National application -Mutual recognition in sequence

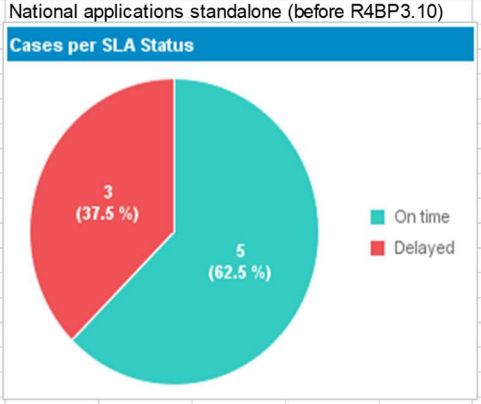


2.8. Greece

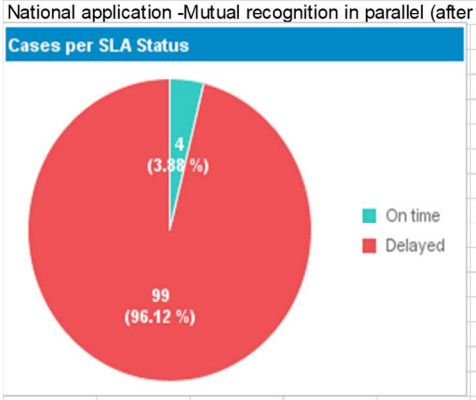
National applications ref (after R4BP3.10)



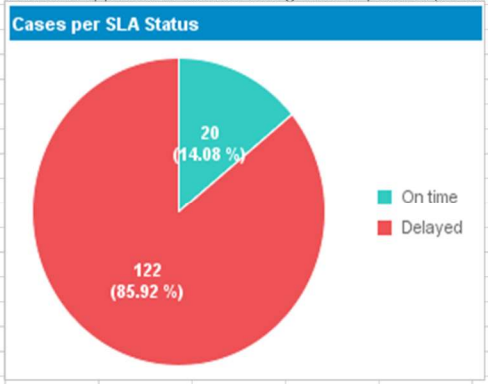
National applications standalone (before R4BP3.10)



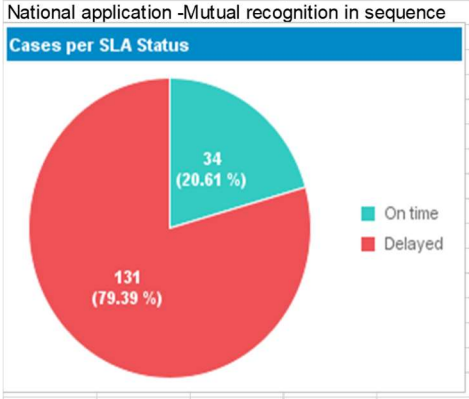
National application -Mutual recognition in parallel (after R4BP3.10)



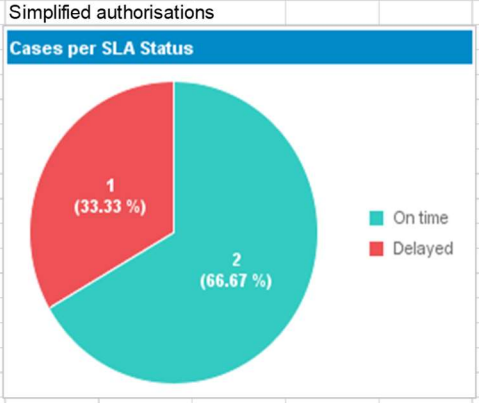
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

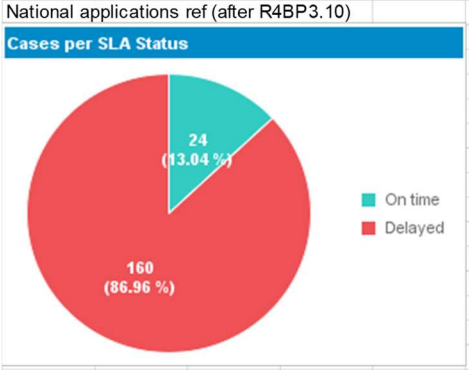


Simplified authorisations

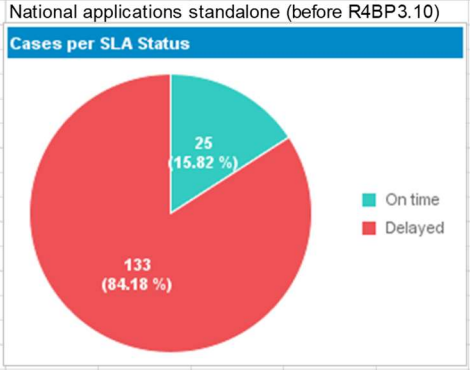


2.9. Spain

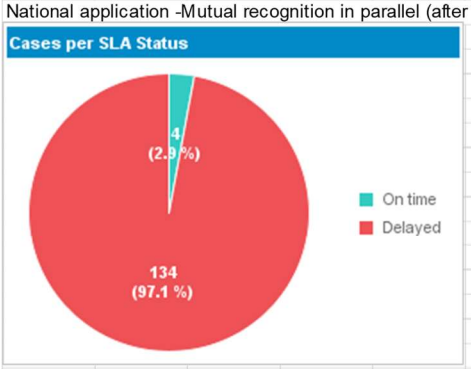
National applications ref (after R4BP3.10)



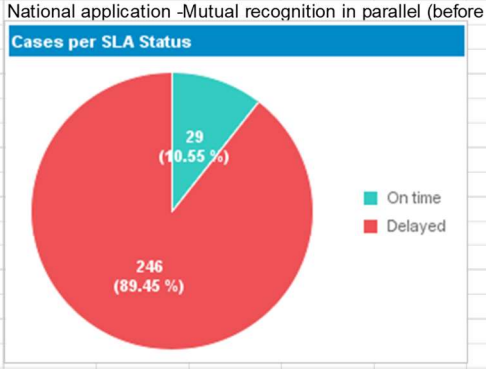
National applications standalone (before R4BP3.10)



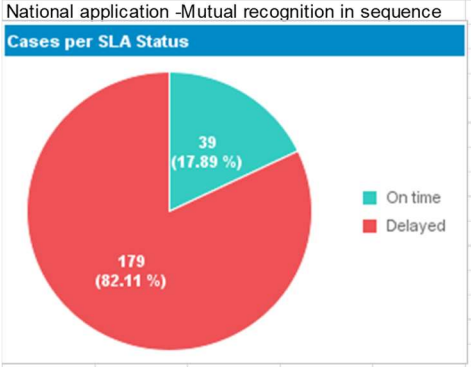
National application -Mutual recognition in parallel (after R4BP3.10)



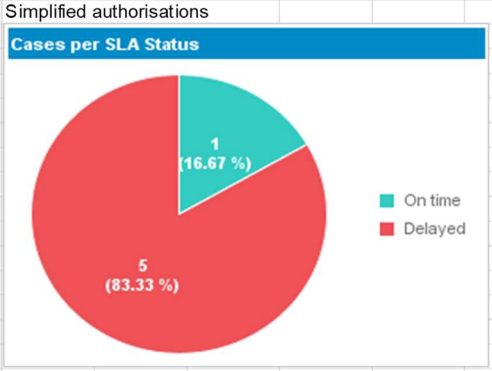
National application -Mutual recognition in parallel (before R4BP3.10.)



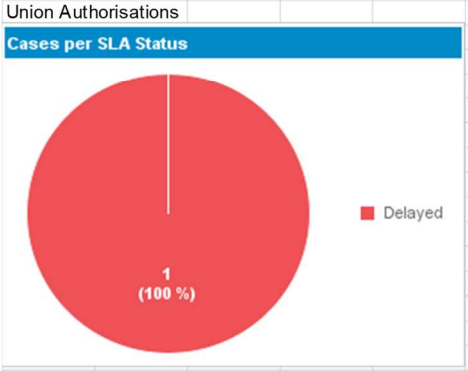
National application -Mutual recognition in sequence



Simplified authorisations

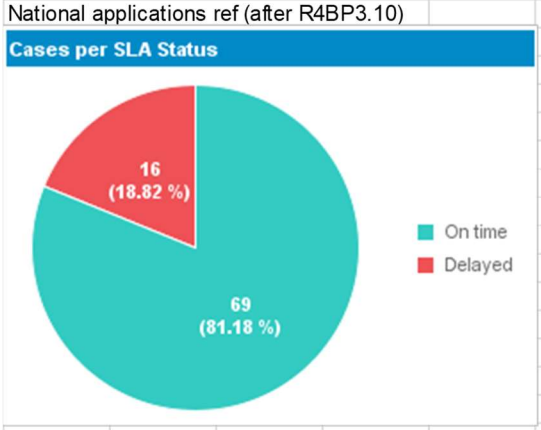


Union Authorisations

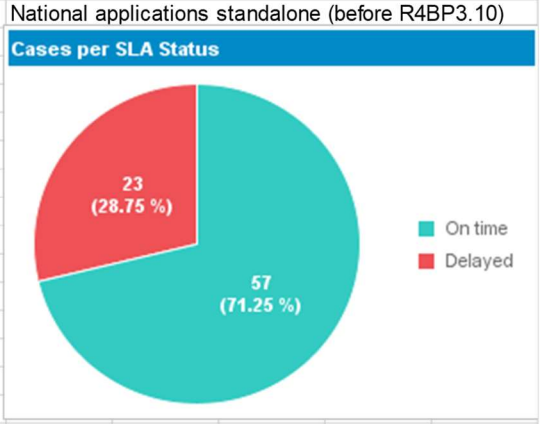


2.10. France

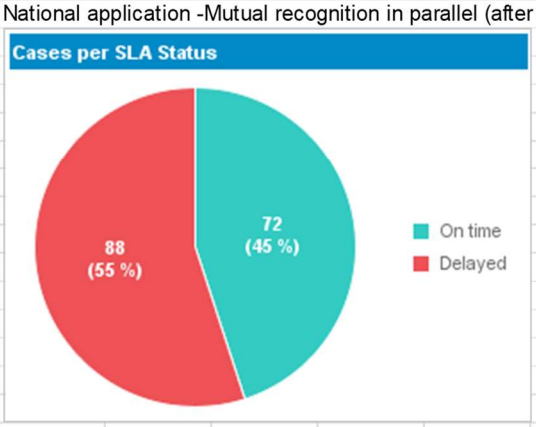
National applications ref (after R4BP3.10)



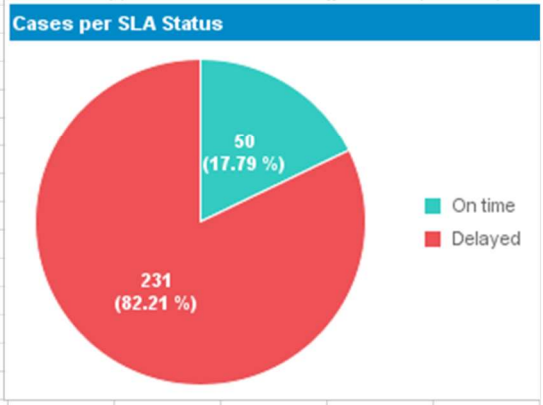
National applications standalone (before R4BP3.10)



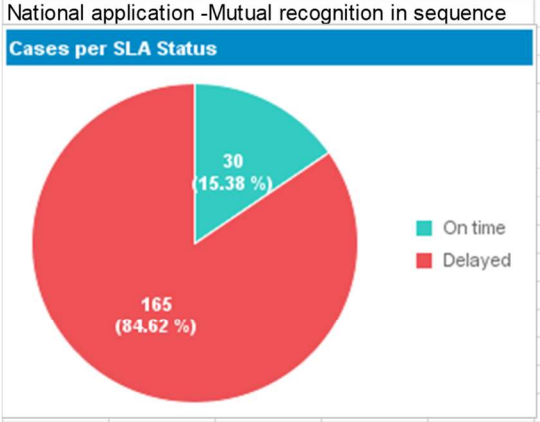
National application -Mutual recognition in parallel (after R4BP3.10)



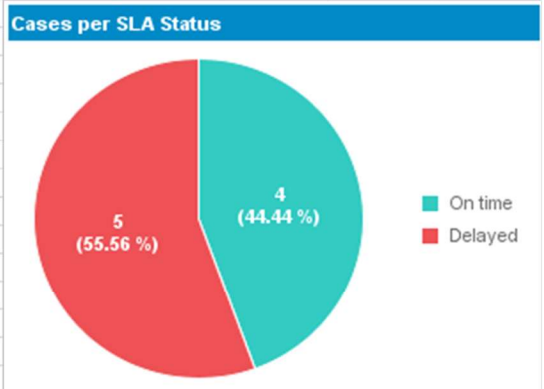
National application -Mutual recognition in parallel (befo



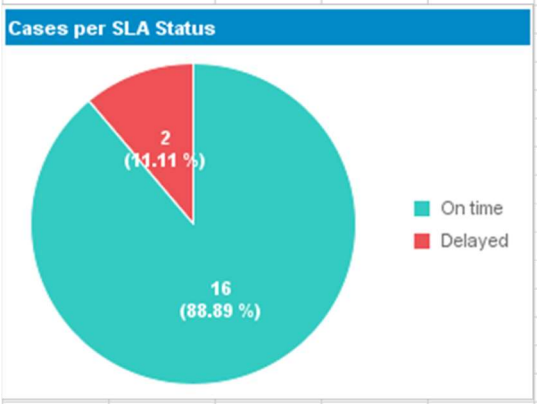
National application -Mutual recognition in sequence



Simplified authorisations

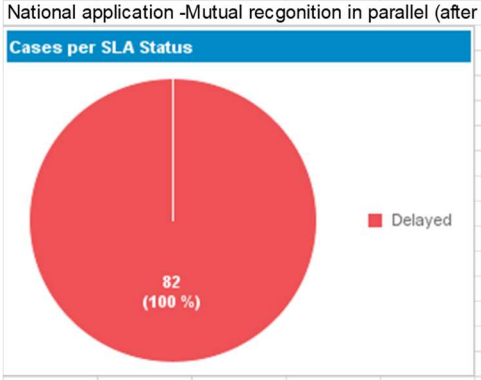


Union Authorisations

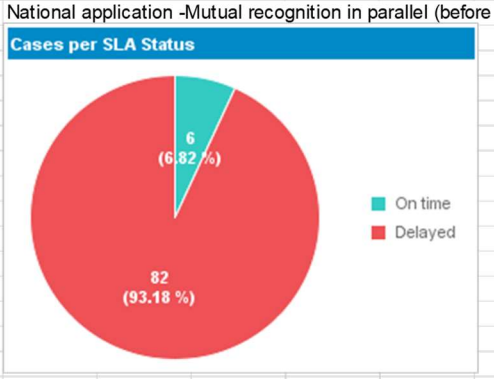


2.11. Croatia

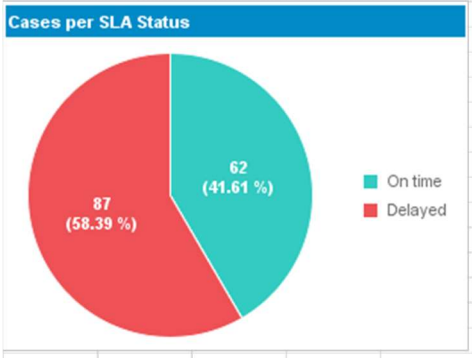
National application -Mutual recgonition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

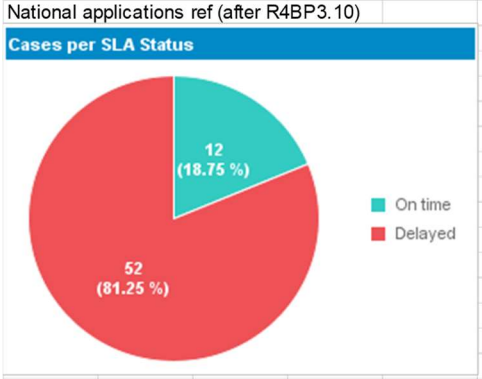


National application -Mutual recognition in sequence

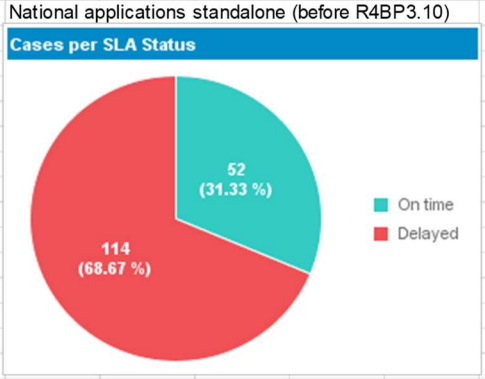


2.12. Italy

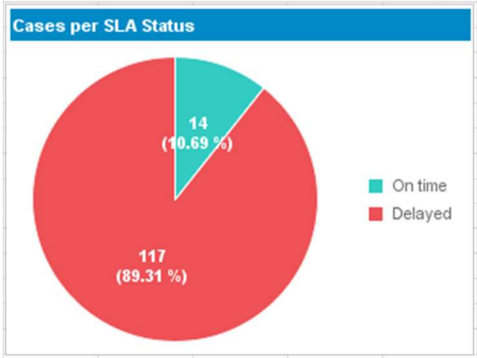
National applications ref (after R4BP3.10)



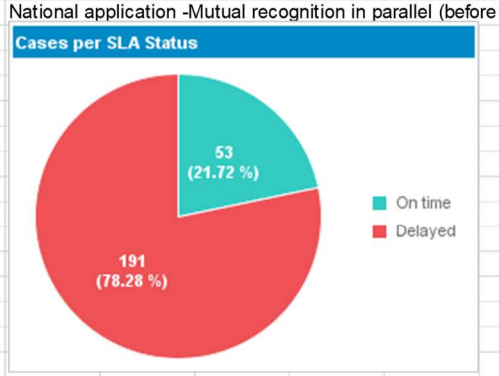
National applications standalone (before R4BP3.10)



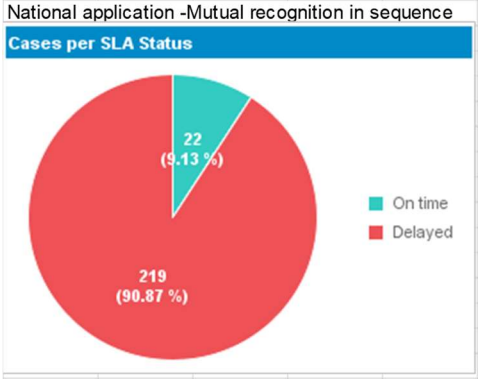
National application -Mutual recognition in parallel (after R4BP3.10)



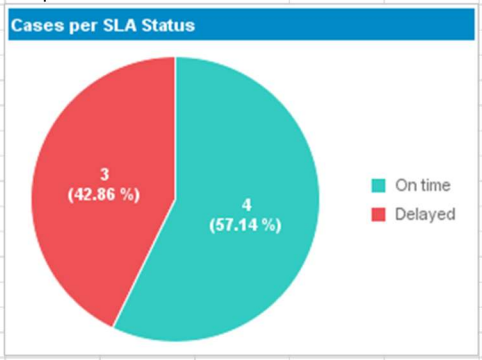
National application -Mutual recognition in parallel (before R4BP3.10)



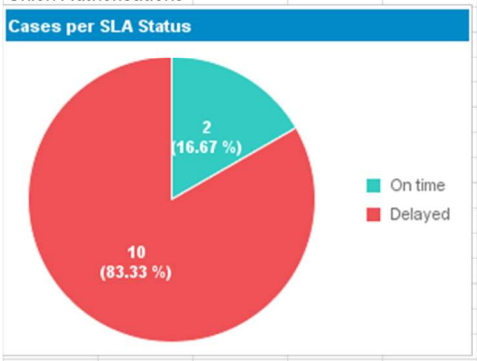
National application -Mutual recognition in sequence



Simplified authorisations

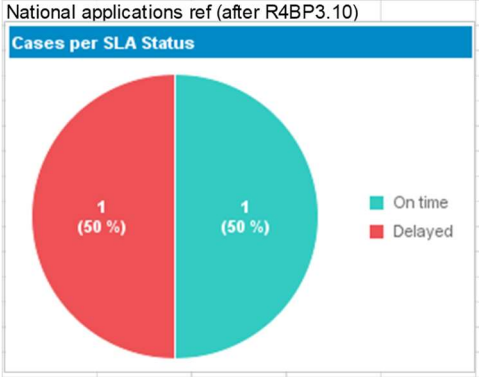


Union Authorisations

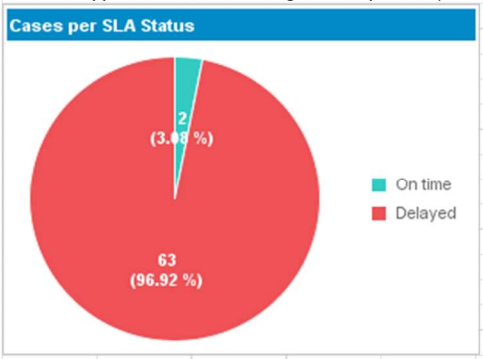


2.13. Cyprus

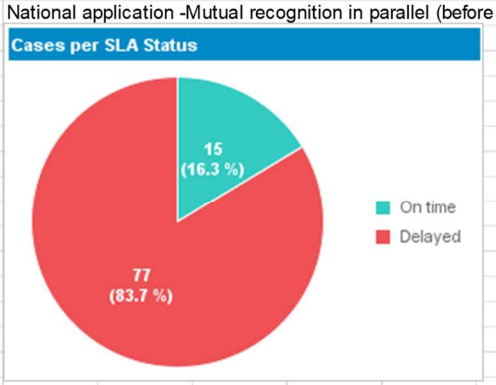
National applications ref (after R4BP3.10)



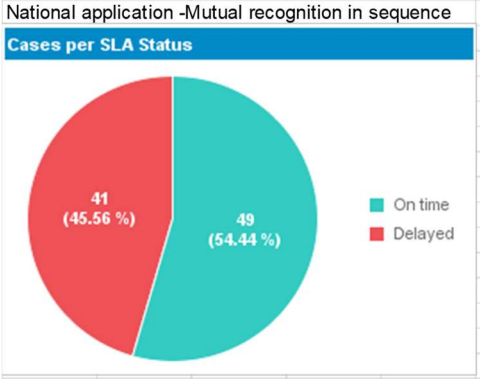
National application -Mutual recognition in parallel (after R4BP3.10)



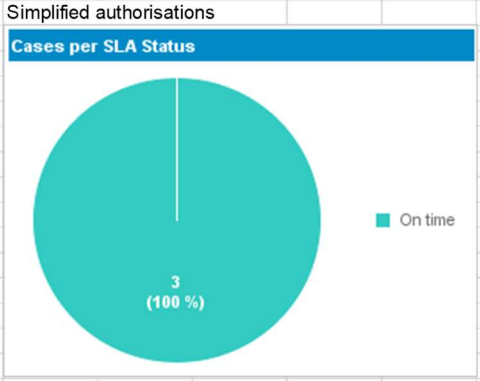
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

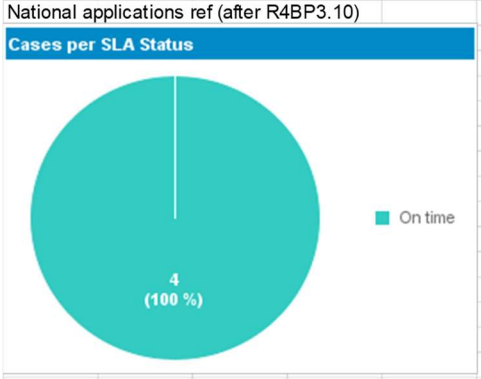


Simplified authorisations

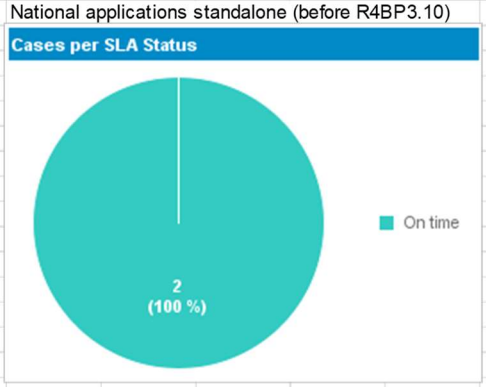


2.14. Latvia

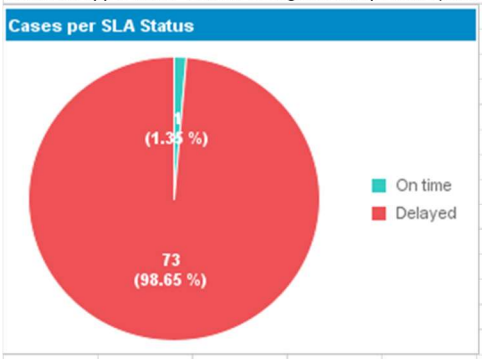
National applications ref (after R4BP3.10)



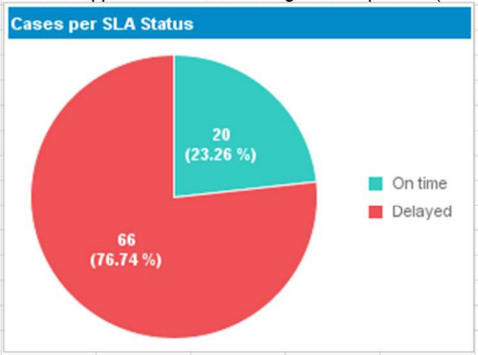
National applications standalone (before R4BP3.10)



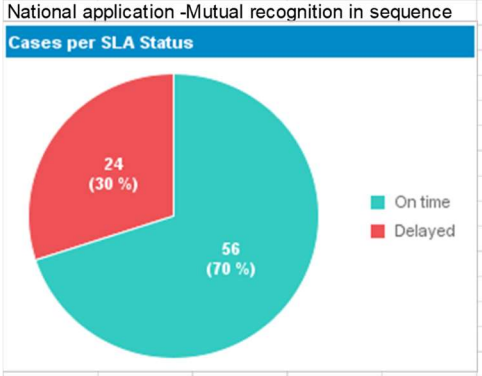
National application -Mutual recognition in parallel (after R4BP3.10)



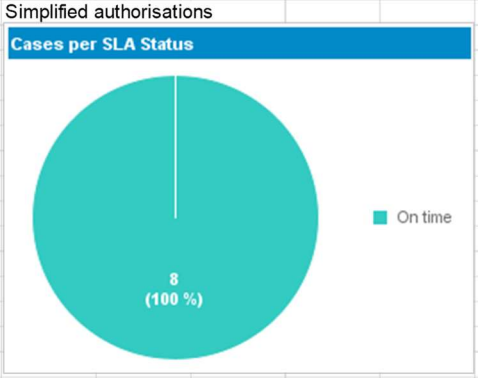
National application -Mutual recognition in parallel (before R4BP3.10)



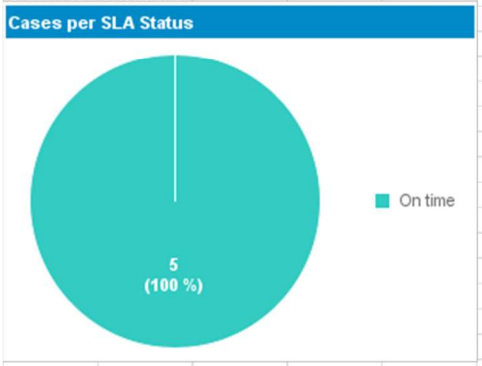
National application -Mutual recognition in sequence



Simplified authorisations

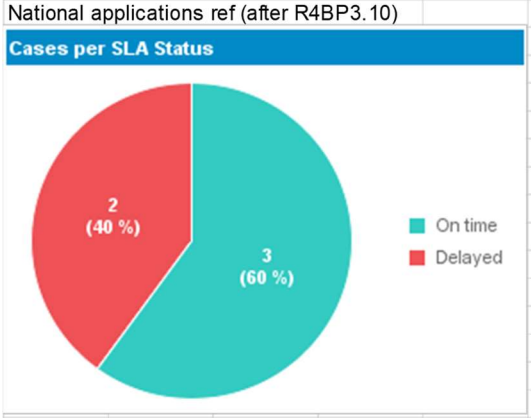


Union Authorisations

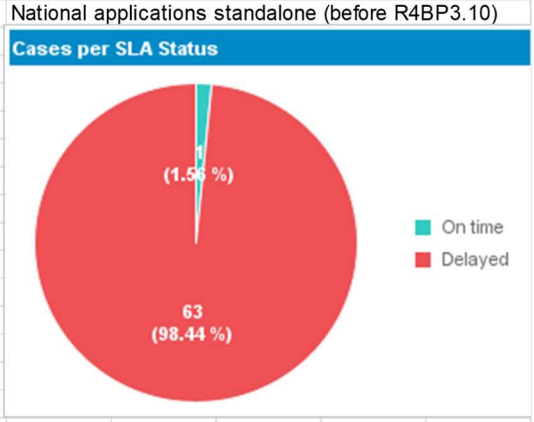


2.15. Lithuania

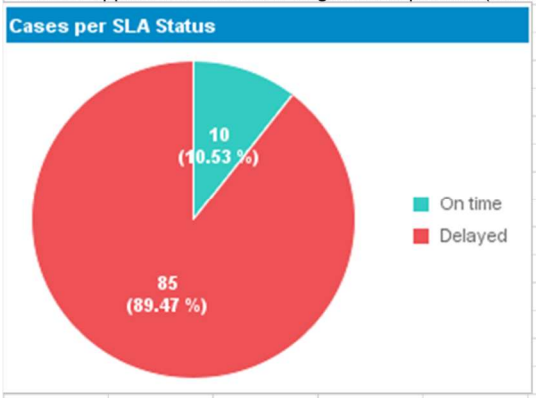
National applications ref (after R4BP3.10)



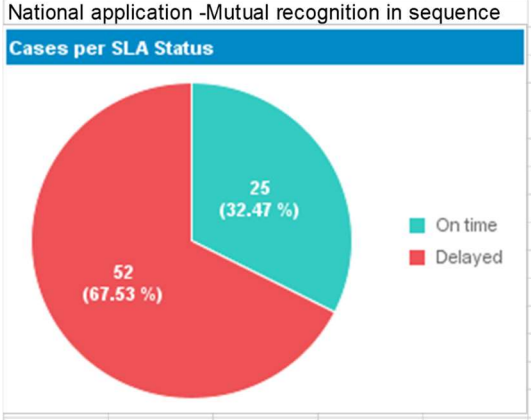
National applications standalone (before R4BP3.10)



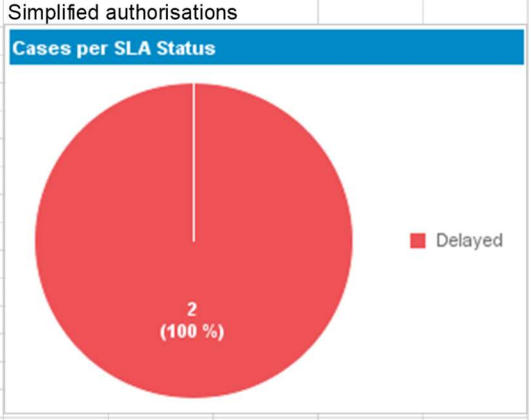
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

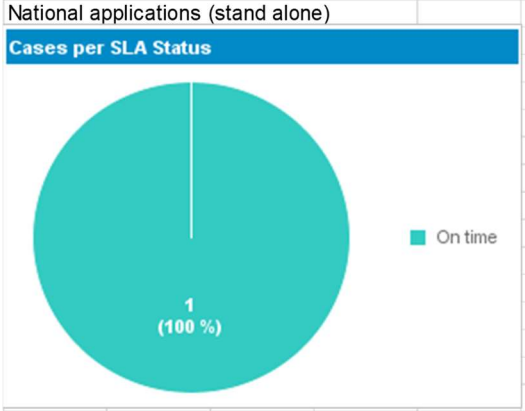


Simplified authorisations

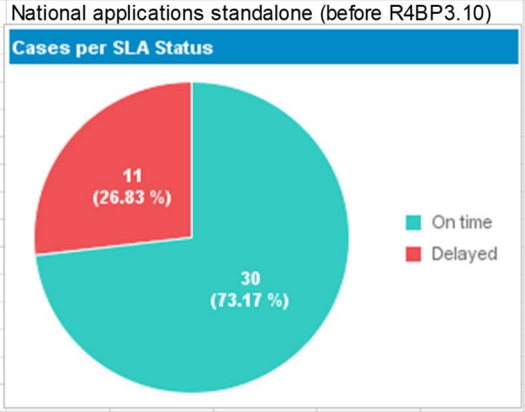


2.16. Luxembourg

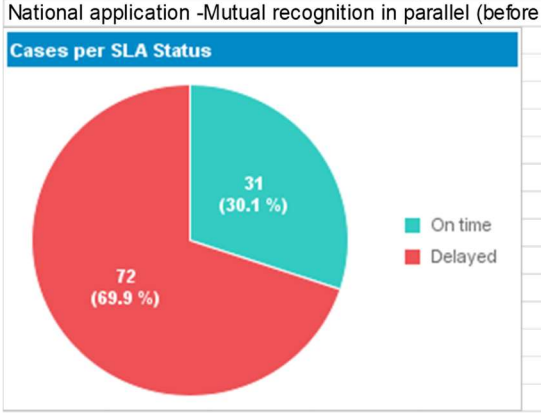
National applications (stand alone)



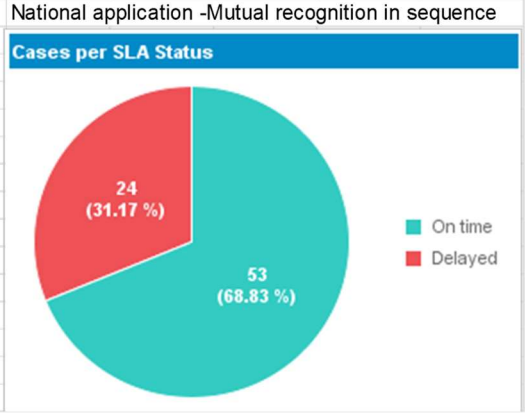
National applications standalone (before R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

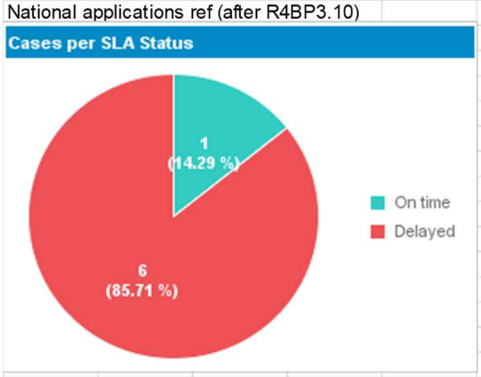


National application -Mutual recognition in sequence

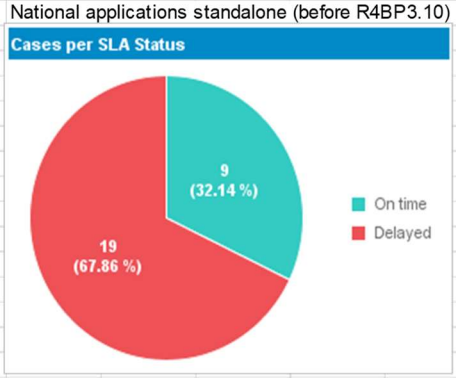


2.17. Hungary

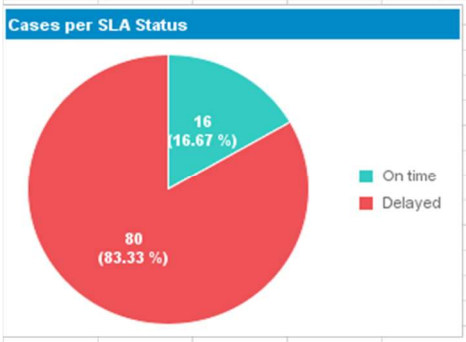
National applications ref (after R4BP3.10)



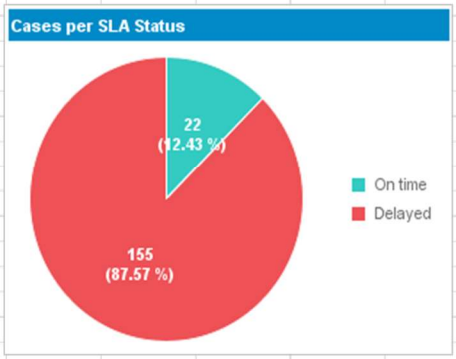
National applications standalone (before R4BP3.10)



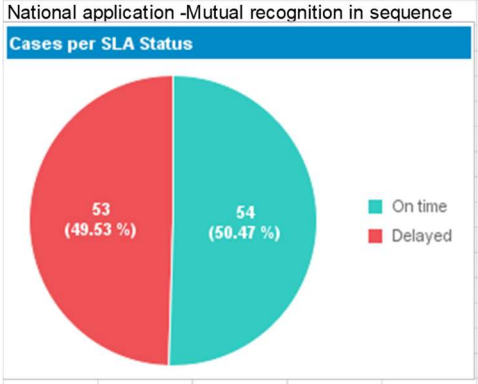
National application -Mutual recognition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

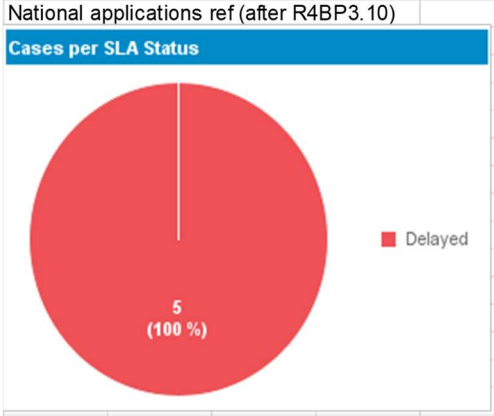


National application -Mutual recognition in sequence

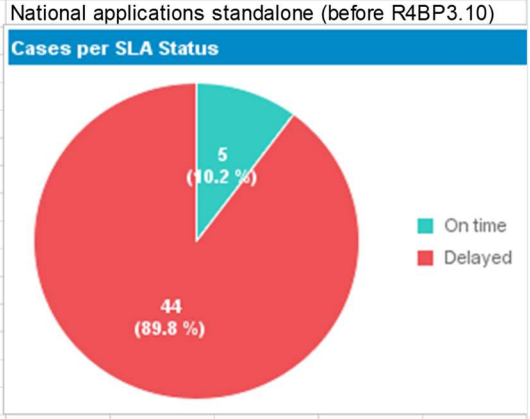


2.18. Malta

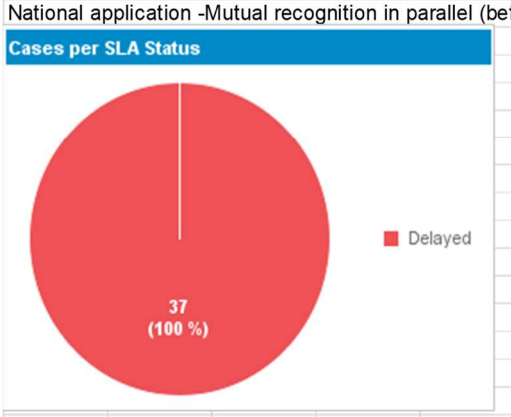
National applications ref (after R4BP3.10)



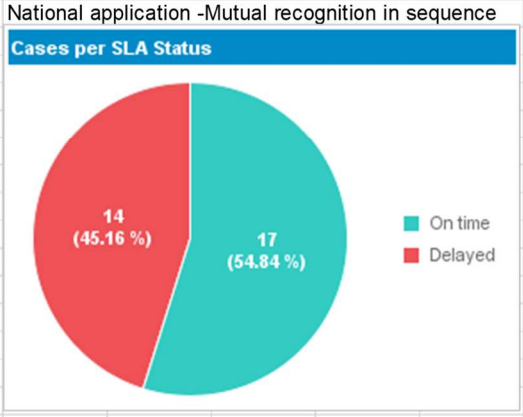
National applications standalone (before R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

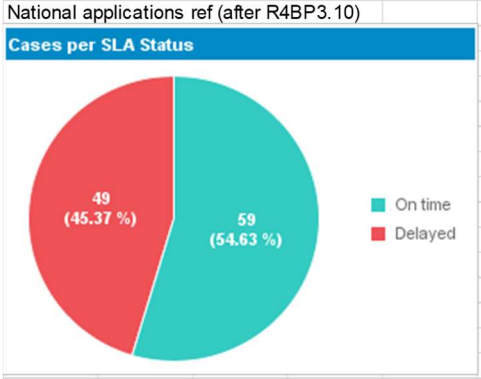


National application -Mutual recognition in sequence

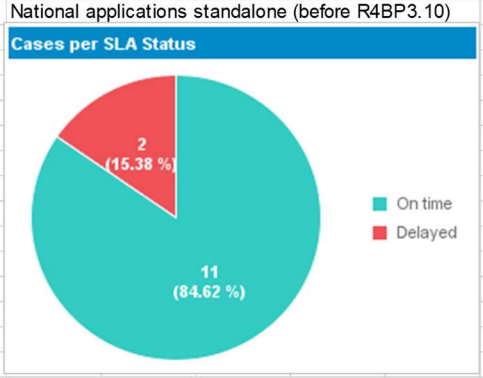


2.19. Netherlands

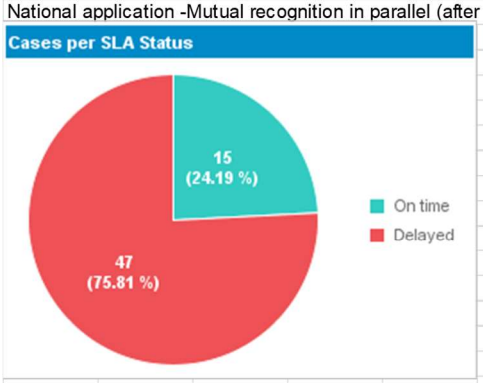
National applications ref (after R4BP3.10)



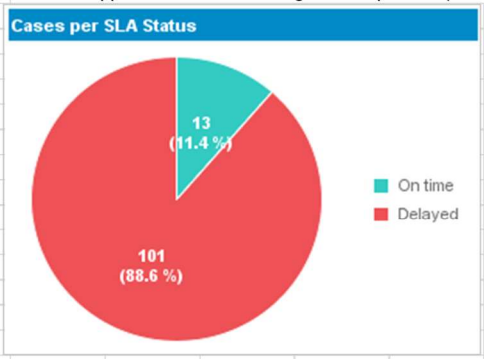
National applications standalone (before R4BP3.10)



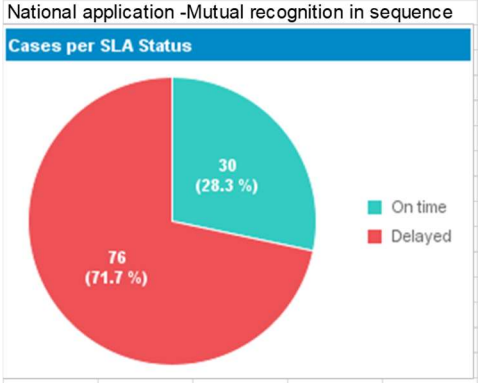
National application -Mutual recognition in parallel (after R4BP3.10)



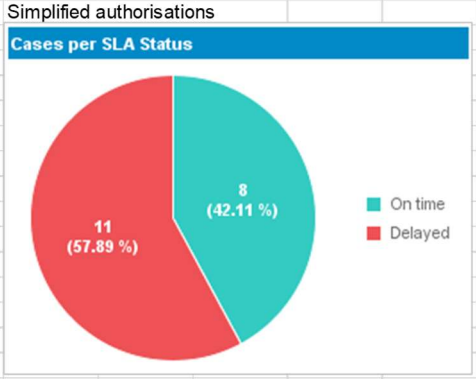
National application -Mutual recognition in parallel (before R4BP3.10.)



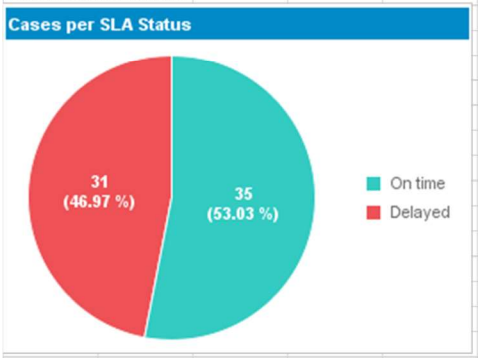
National application -Mutual recognition in sequence



Simplified authorisations

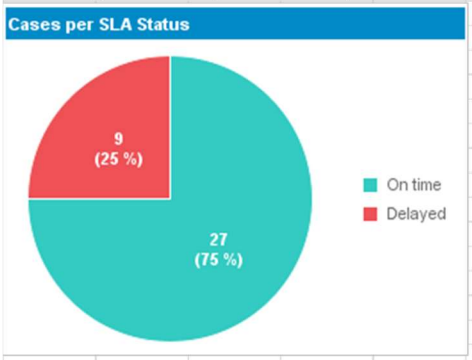


Union Authorisations

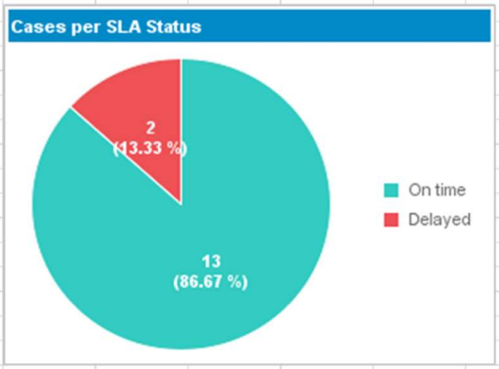


2.20. Austria

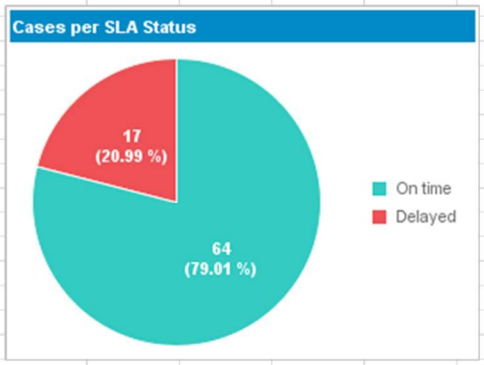
National applications ref (after R4BP3.10)



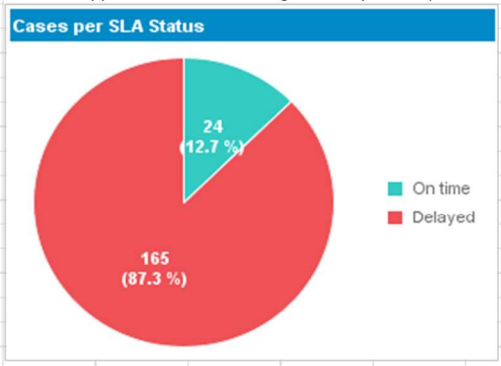
National applications standalone (before R4BP3.10)



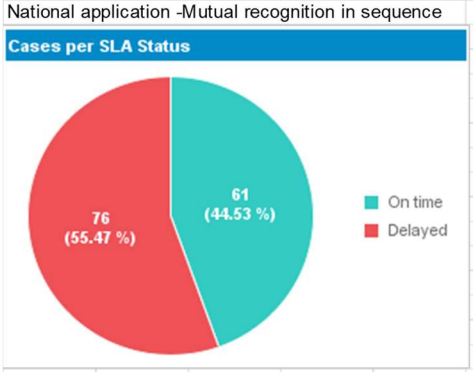
National application -Mutual recognition in parallel (after R4BP3.10)



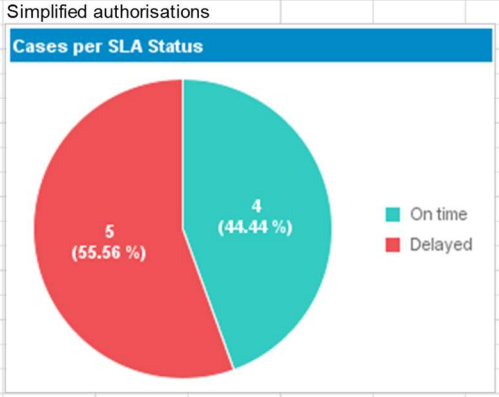
National application -Mutual recognition in parallel (before R4BP3.10.)



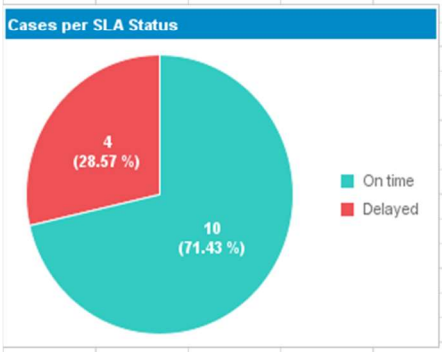
National application -Mutual recognition in sequence



Simplified authorisations

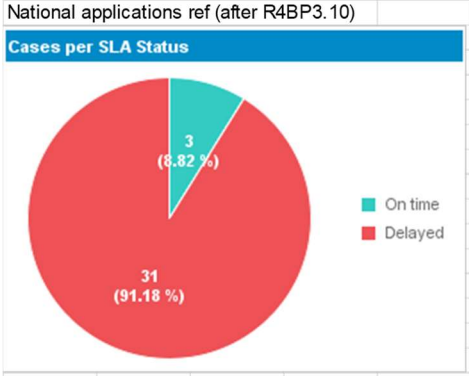


Union Authorisations

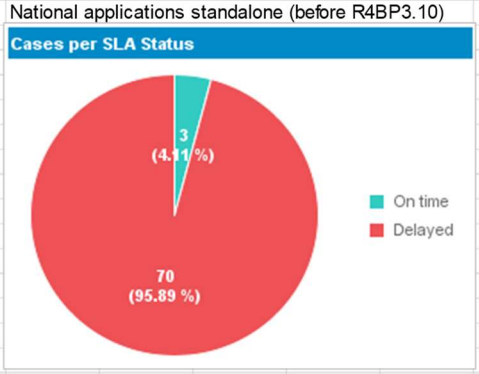


2.21. Poland

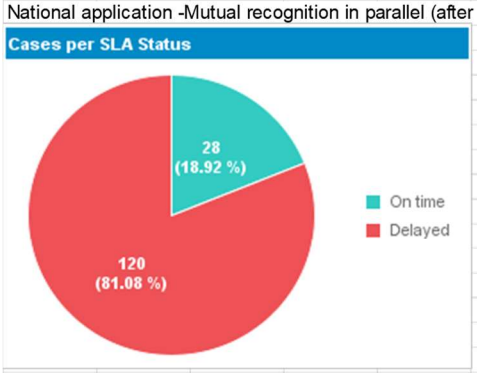
National applications ref (after R4BP3.10)



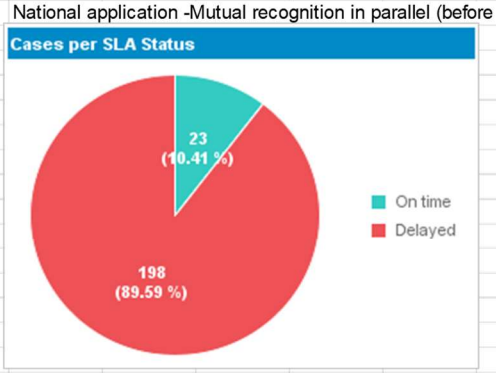
National applications standalone (before R4BP3.10)



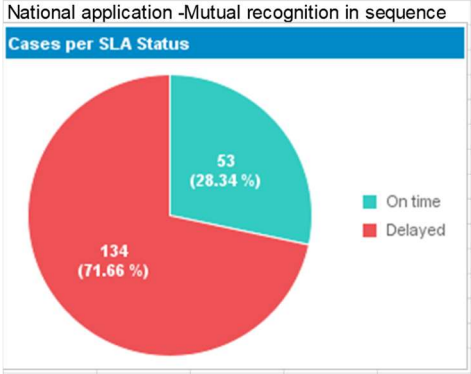
National application -Mutual recognition in parallel (after R4BP3.10)



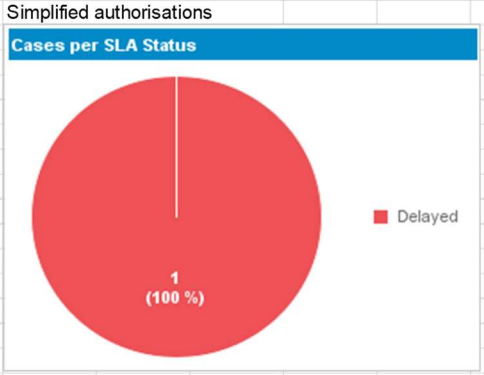
National application -Mutual recognition in parallel (before R4BP3.10.)



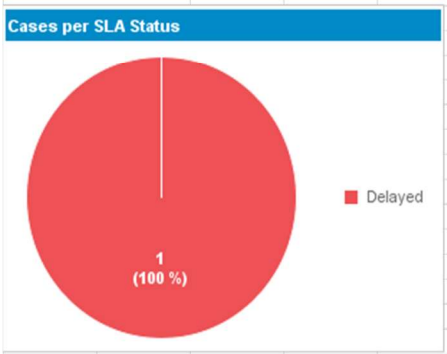
National application -Mutual recognition in sequence



Simplified authorisations

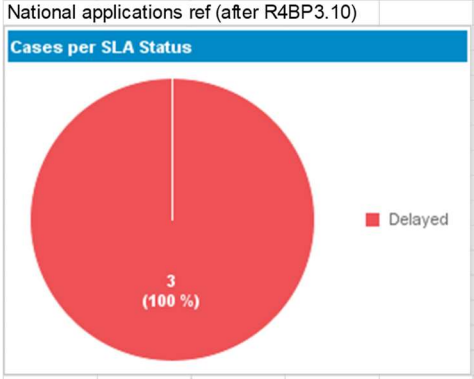


Union Authorisations

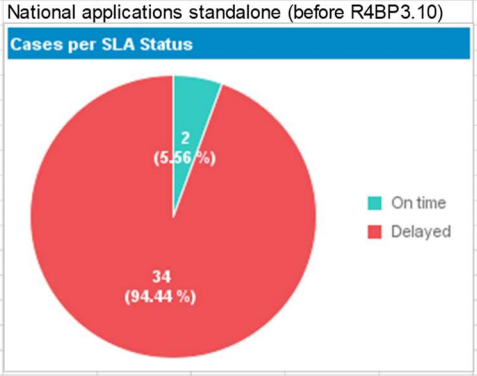


2.22. Portugal

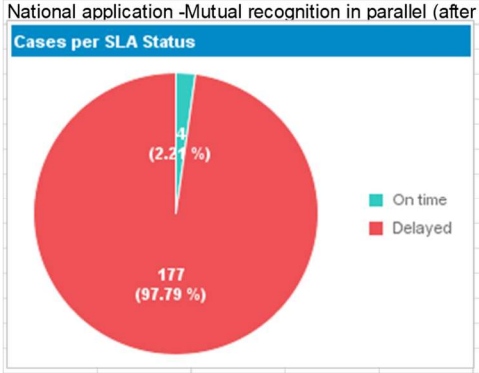
National applications ref (after R4BP3.10)



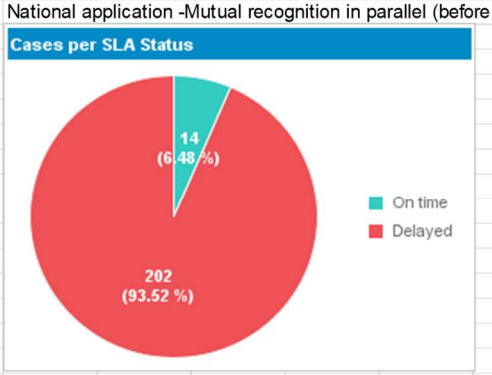
National applications standalone (before R4BP3.10)



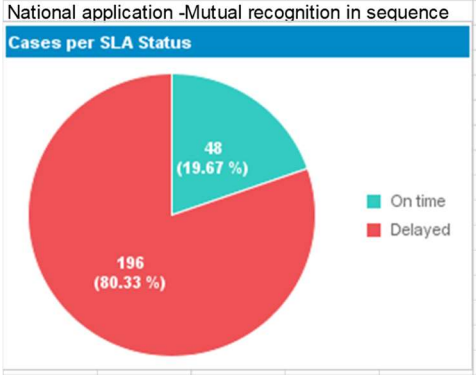
National application -Mutual recognition in parallel (after R4BP3.10)



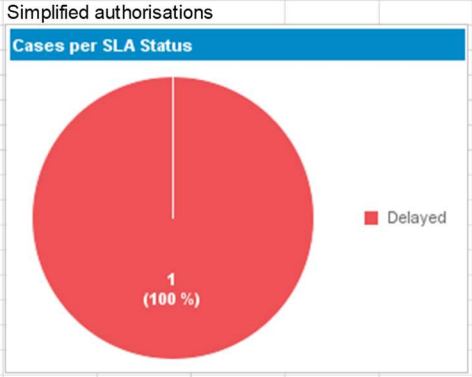
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

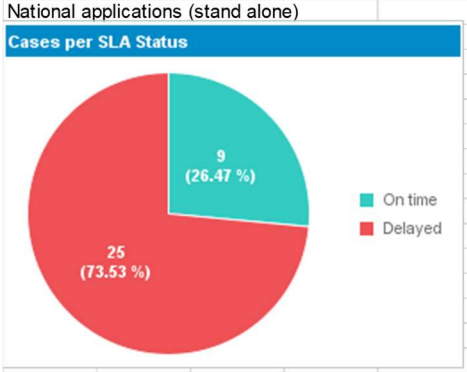


Simplified authorisations

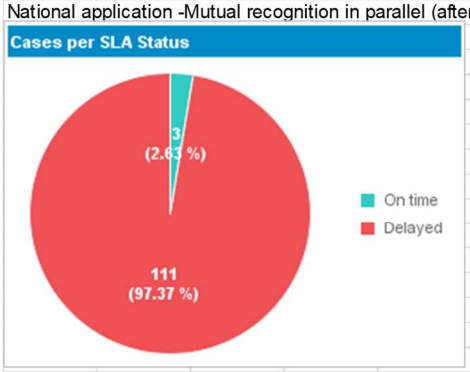


2.23. Romania

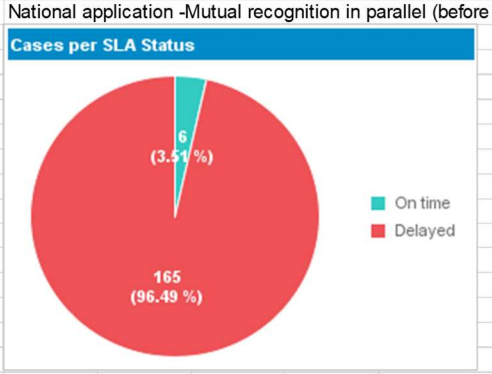
National applications (stand alone)



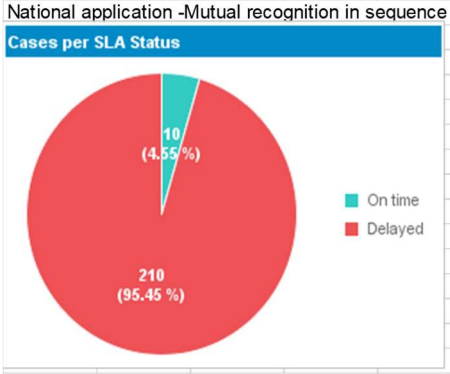
National application -Mutual recognition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10)

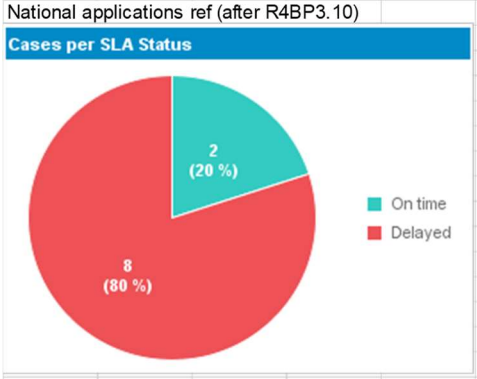


National application -Mutual recognition in sequence

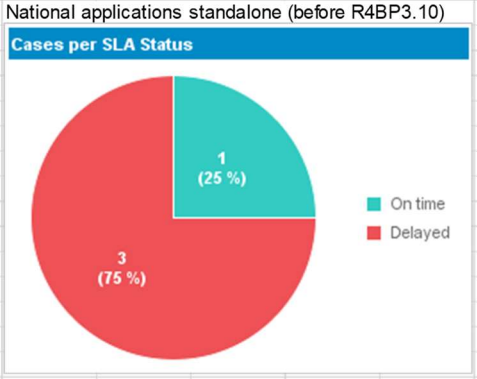


2.24. Slovenia

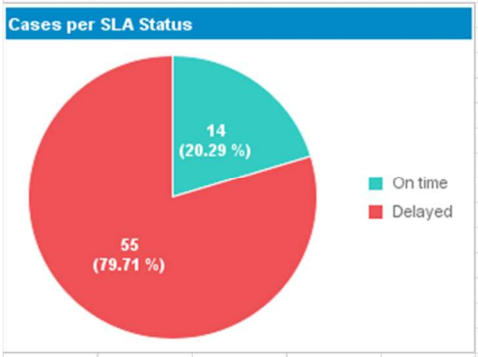
National applications ref (after R4BP3.10)



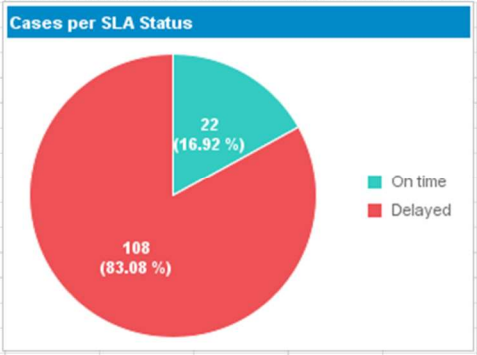
National applications standalone (before R4BP3.10)



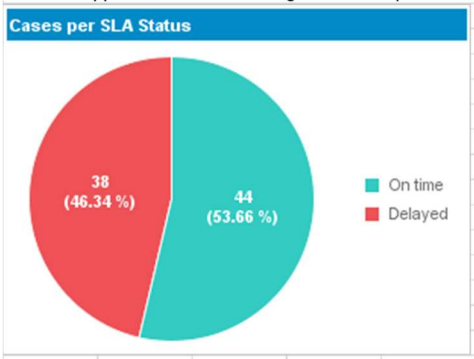
National application -Mutual recognition in parallel (after R4BP3.10)



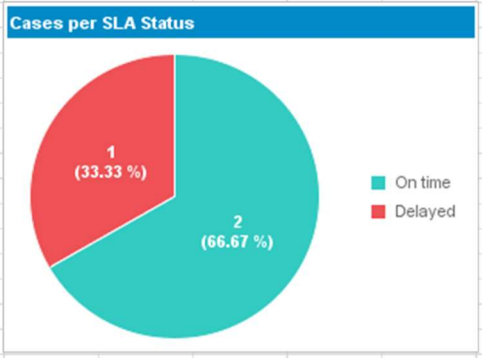
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

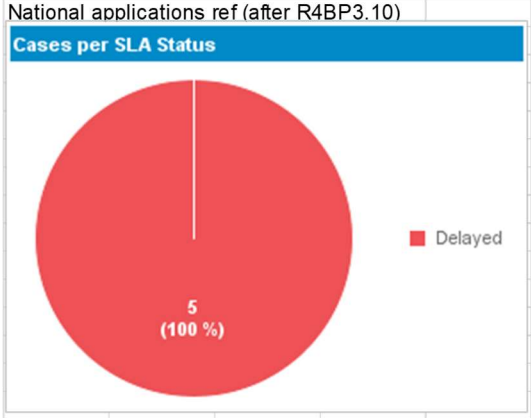


Union Authorisations

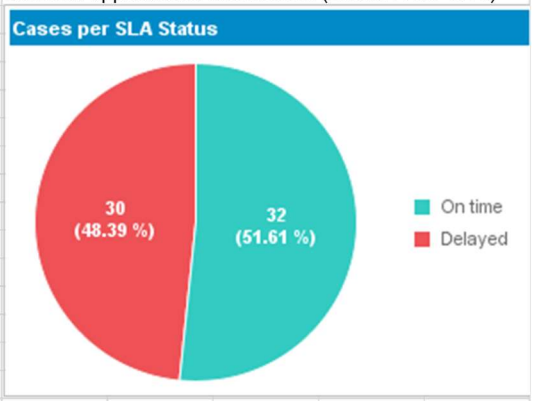


2.25. Slovakia

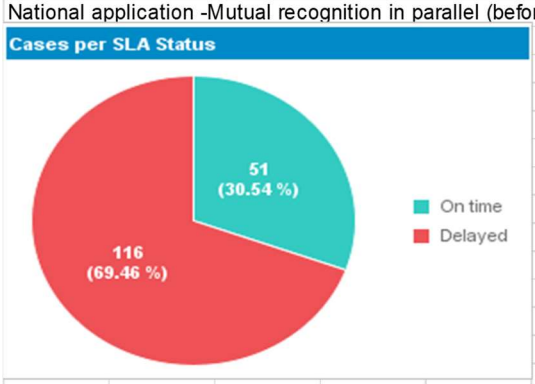
National applications ref (after R4BP3.10)



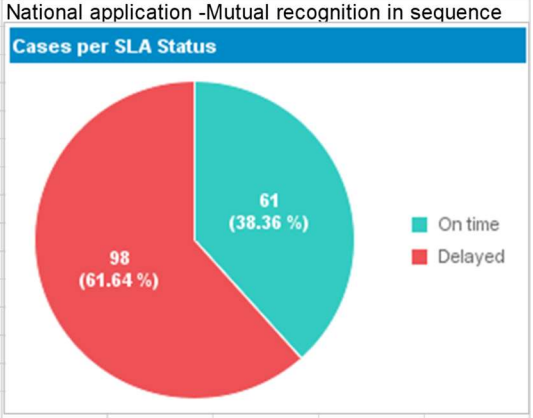
National applications standalone (before R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

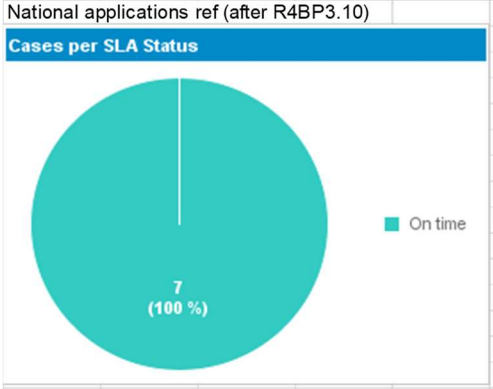


National application -Mutual recognition in sequence

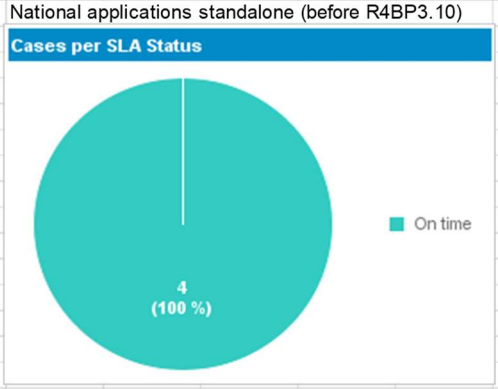


2.26. Finland.

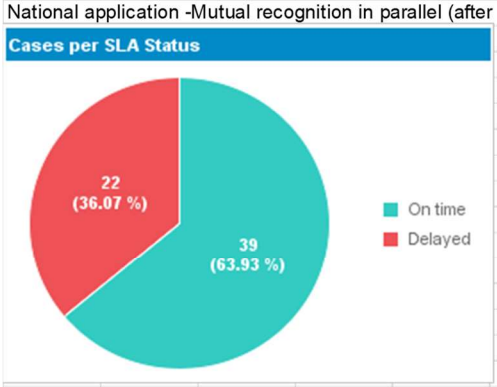
National applications ref (after R4BP3.10)



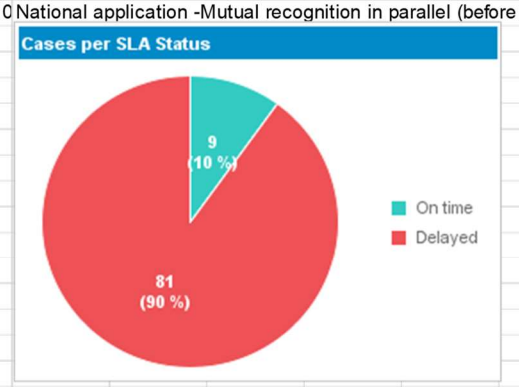
National applications standalone (before R4BP3.10)



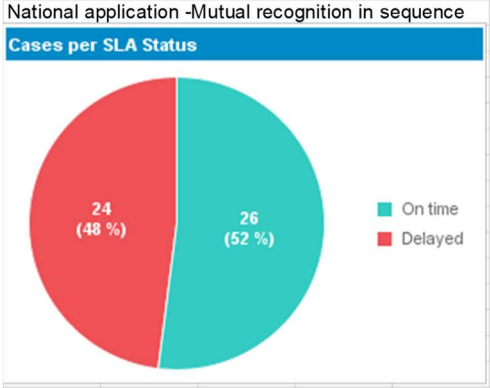
National application -Mutual recognition in parallel (after R4BP3.10



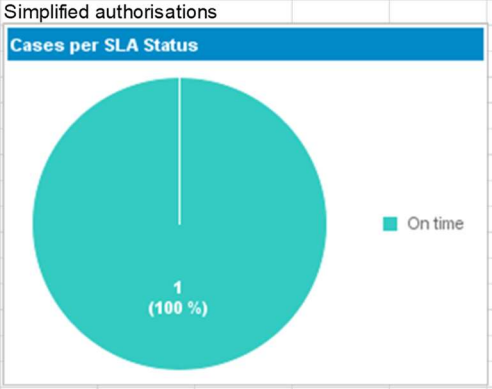
National application -Mutual recognition in parallel (before R4BP3.10)



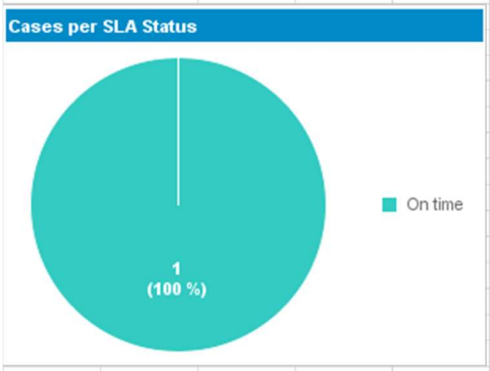
National application -Mutual recognition in sequence



Simplified authorisations

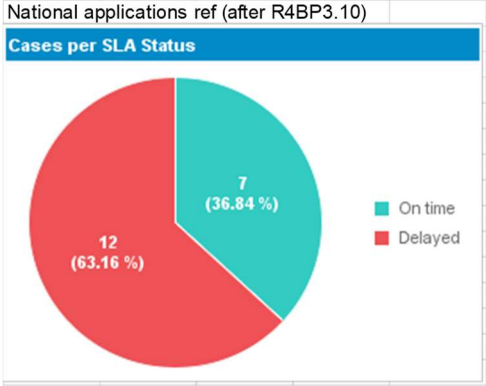


Union Authorisations

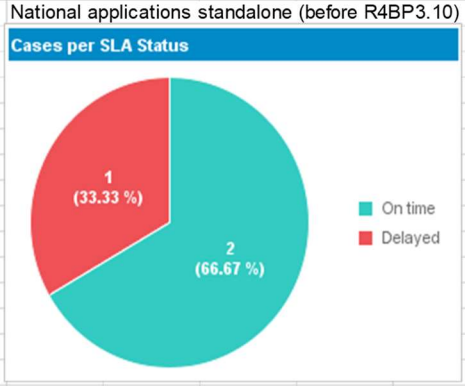


2.27. Sweden

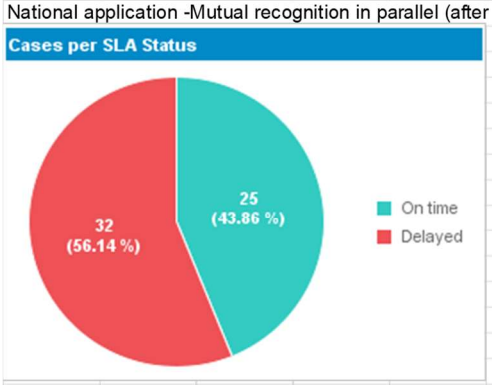
National applications ref (after R4BP3.10)



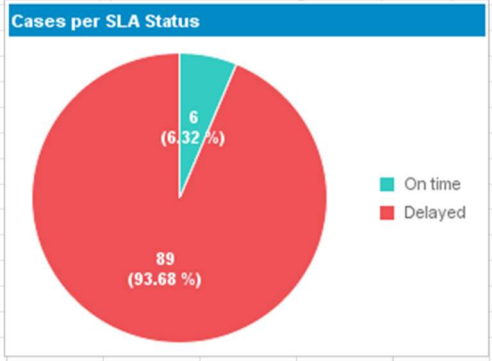
National applications standalone (before R4BP3.10)



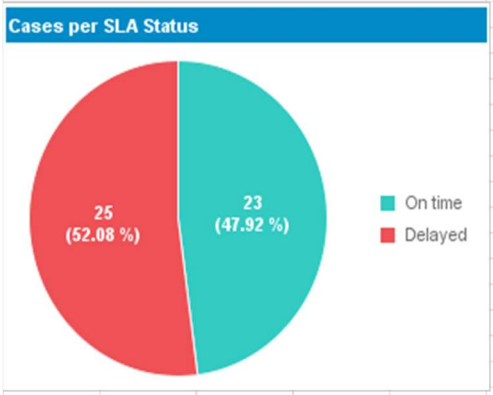
National application -Mutual recognition in parallel (after R4BP3.10



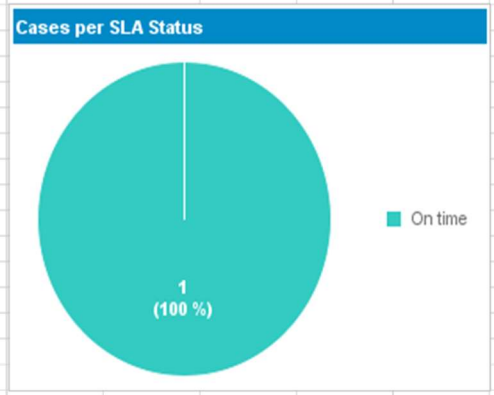
National application -Mutual recognition in parallel (before R4BP3.10.)



National application -Mutual recognition in sequence

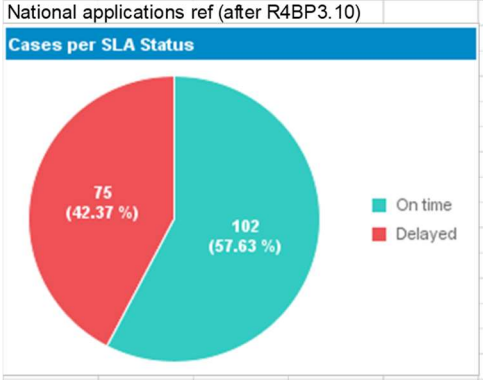


Union Authorisations

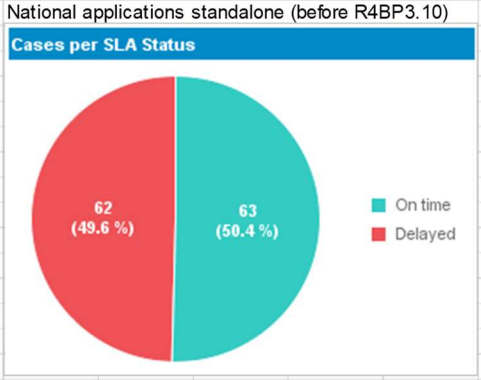


2.28. United Kingdom

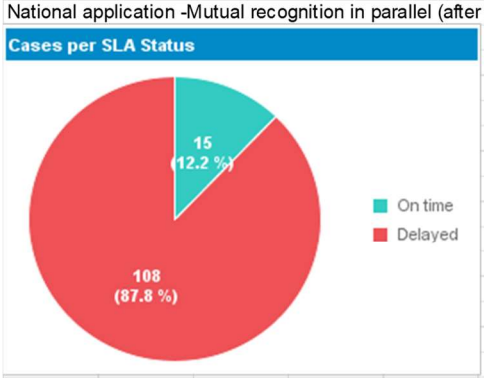
National applications ref (after R4BP3.10)



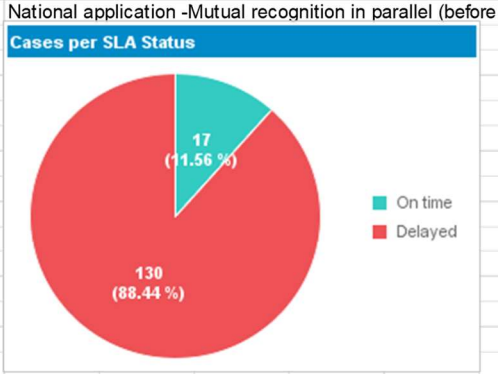
National applications standalone (before R4BP3.10)



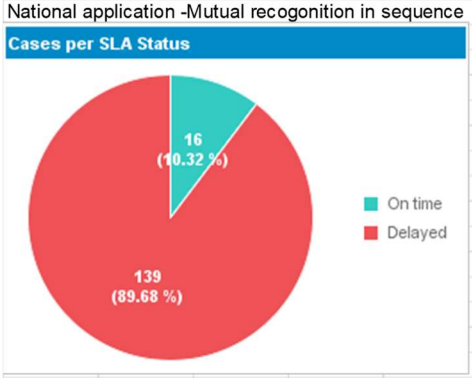
National application -Mutual recognition in parallel (after R4BP3.10)



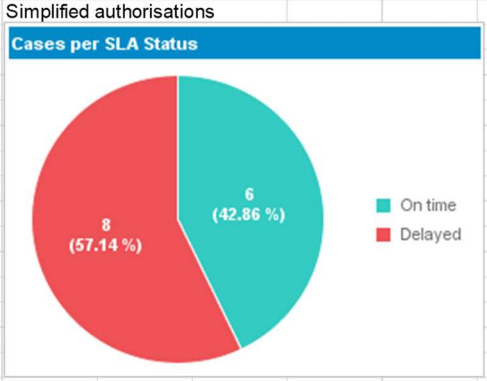
National application -Mutual recognition in parallel (before R4BP3.10.)



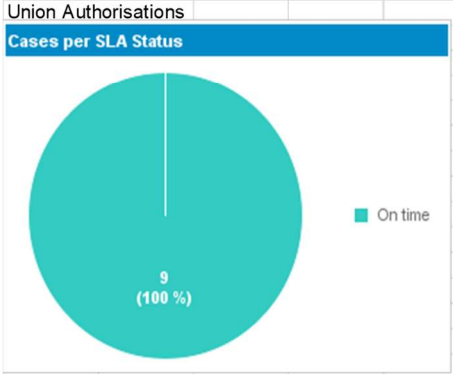
National application -Mutual recogonition in sequence



Simplified authorisations

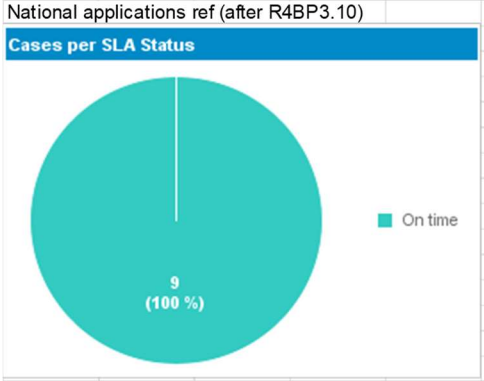


Union Authorisations

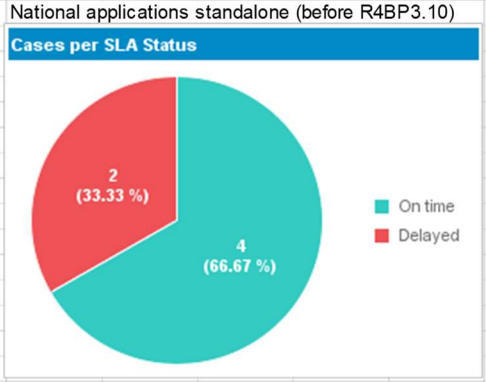


2.29. Norway

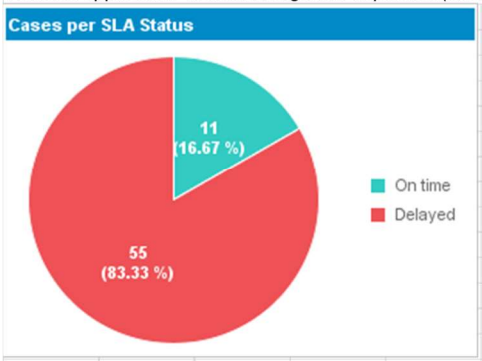
National applications ref (after R4BP3.10)



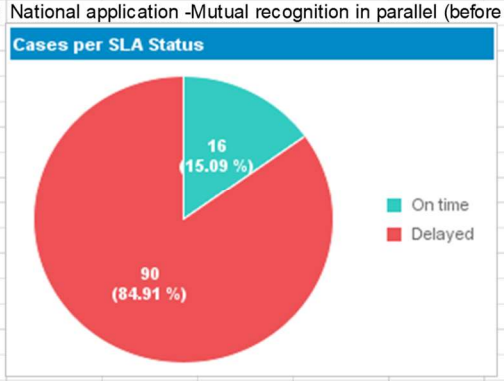
National applications standalone (before R4BP3.10)



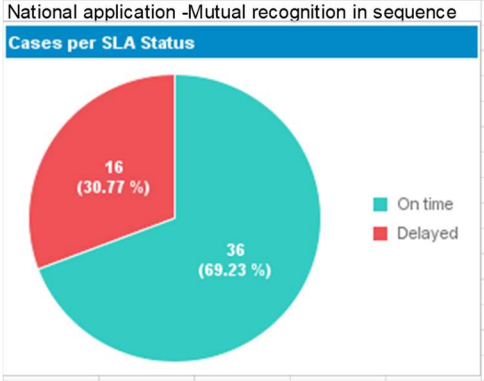
National application -Mutual recognition in parallel (after R4BP3.10)



National application -Mutual recognition in parallel (before R4BP3.10.)

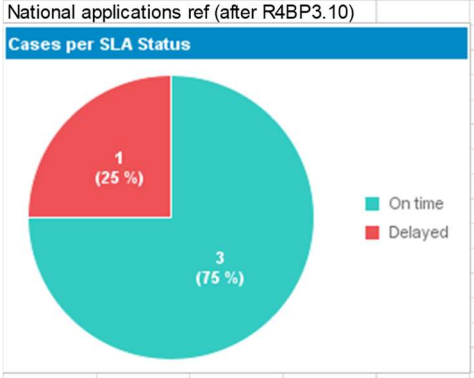


National application -Mutual recognition in sequence

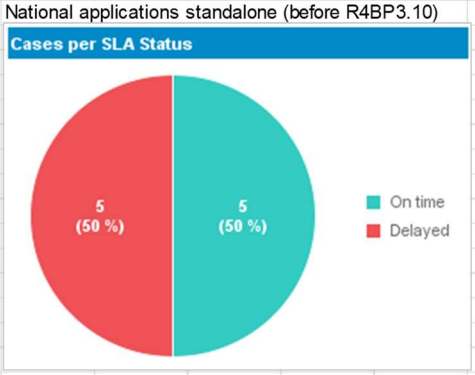


2.30. Switzerland

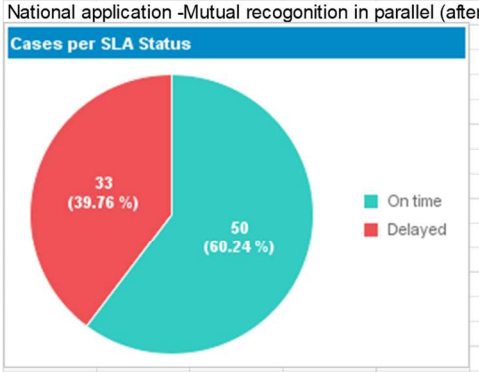
National applications ref (after R4BP3.10)



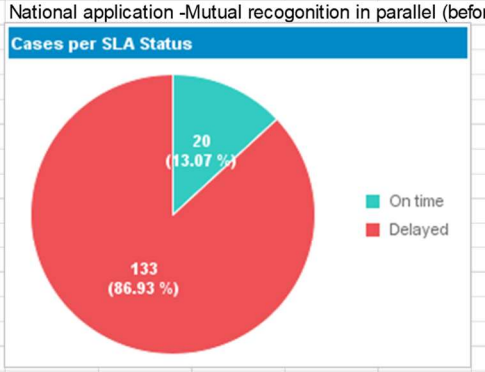
National applications standalone (before R4BP3.10)



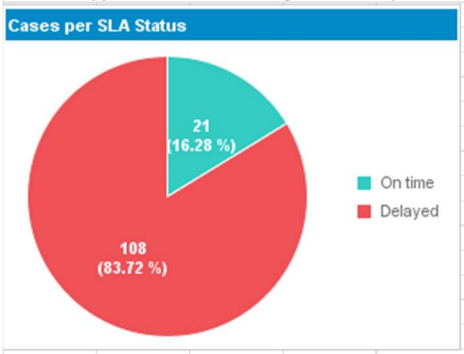
National application -Mutual recogonition in parallel (after R4BP3.10)



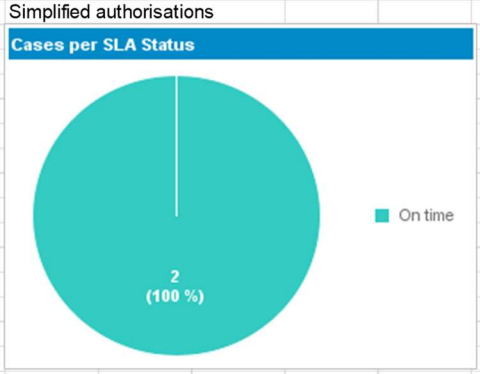
National application -Mutual recogonition in parallel (before R4BP3.10.)



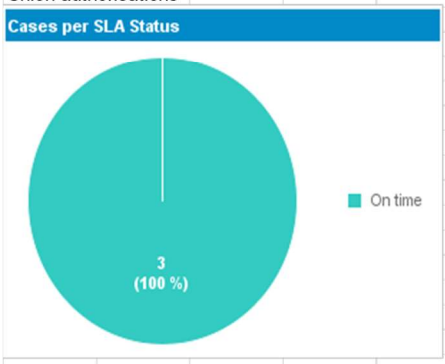
National application -Mutual recognition in sequence



Simplified authorisations



Union authorisations



3. DELAYS BY MEMBER STATE AND PROCEDURE.

% cases delay (data R4BP3, jan2010-aug2020)							
Member State	**NA (ref)**	**NA (standalone)**	**MRP (after R4BP3.10)**	**MRP (before R4BP3.10**	**MRS**	**SA**	**UA**
Belgium	21%	33%	**90%**	**83%**	64%	0%	0%
Bulgaria		43%	**98%**	**88%**	73%		
Czechia	49%	68%	**22%**	**80%**	83%		100%
Denmark	8%	30%	**50%**	**82%**	49%	38%	33%
Germany	29%	32%	**90%**	**81%**	33%	29%	50%
Estonia	0%		**21%**	**54%**	8%	0%	
Ireland	79%	50%	**95%**	**93%**	63%		
Greece	28%	38%	**96%**	**86%**	79%	33%	
Spain	87%	84%	**97%**	**89%**	82%	83%	100%
France	19%	29%	**55%**	**82%**	85%	56%	11%
Croatia	100%		**93%**		58%		
Italy	87%	69%	**89%**	**78%**	91%	43%	83%
Cyprus	50%	97%	**84%**	**46%**		0%	
Latvia	0%	0%	**99%**	**77%**	30%		0%
Lituania		40%	**98%**	**89%**	68%		
Luxembourg		0%	**27%**	**70%**	31%		
Hungary	86%	68%	**83%**	**88%**	50%		
Malta	100%		**90%**	**100%**	45%		
Netherlands	45%	15%	**76%**	**89%**	72%	58%	47%
Austria	25%	13%	**21%**	**87%**	55%	56%	29%
Poland	91%	96%	**81%**	**90%**	72%	100%	100%
Portugal	100%	94%	**98%**	**93%**	80%	100%	
Romania	74%		**97%**	**96%**	95%		
Slovenia	80%	75%	**74%**	**83%**	46%		33%
Slovakia	100%		**48%**	**69%**	62%		
Finland	0%	0%	**36%**	**90%**	48%	0%	0%
Sweden	63%	33%	56%	**94%**	52%		0%
U.K.	42%	50%	**88%**	**88%**	90%	57%	0%
Norway	0%	33%	**83%**	**85%**	69%		
Switzerland	25%	50%	**40%**	**90%**	88%	0%	0%
Average	*51%*	*46%*	***72%***	***83%***	*63%*	*41%*	*37%*

NA-National authorisation
MRP- Mutual recognition in paralel
MRS-Mutual recognition in sequence
SA-Simpliefied authorisations
UA-Union authorisations

4. DELAYS BY PROCEDURE AND STAGE (ALL MEMBER STATES):

National authorisations (reference)

	Delayed	On time
Authorised biocidal product	2	4
Bussiness Rules Check	194	790
ECHA Acceptance	35	
MSCA Evaluate and Decide	302	358
Evaluate and Draft PAR & SPC	44	170
MSCA Acceptance	686	90
Referral to Coordination Group (for MRP after 3.10)	2	
MSCA Validation	403	449

National authorisations (standalone)

	Delayed	On time
Bussiness Rules Check	92	529
ECHA Acceptance	12	
MSCA Evaluate and Decide	304	320
MSCA Acceptance	423	80
MSCA Validation	191	219

National authorisaations-Mutual recognition in parallel (after R4BP 3.10)

	Delayed	On time
Authorised biocidal product	64	6
Agree on SPC	25	45
Bussiness Rules Check		2726
ECHA Acceptance	453	2273
MSCA Acceptance	2224	347
MSCA Validation	1	1

National authorisaations-Mutual recognition in parallel (before R4BP 3.10)

	Delayed	On time
Authorised biocidal product		15
Agree on SPC	4	11
Bussiness Rules Check	542	3045
ECHA Acceptance	943	2585
MSCA Evaluate and Decide	1870	1468
MSCA Acceptance	2433	299
MSCA Validation	1511	687

National authorisations-Mutual recognition in sequence

	Delayed	On time
Bussiness Rules Check	269	2476
ECHA Acceptance	460	2258
MSCA Evaluate and Decide	1736	1702
MSCA Acceptance	1645	529
MSCA Validation	809	1349

Simplified authorisations

	Delayed	On time
Bussiness Rules Check	21	103
ECHA Acceptance	1	
MSCA Evaluate and Decide	34	61
MSCA Acceptance	60	38
MSCA Validation	10	4

Union Authorisations

	Delayed	On time
Bussiness Rules Check	154	124
Commission Decision	20	4
ECHA Acceptance	35	142
MSCA Evaluation	34	113
ECHA opinion	12	18
MSCA Validation	130	82

5. NUMBER OF CASES BY MEMBER STATE (01/01/2010-20/08/2020).

Name	Cases (#)	On-time (#)	Delayed (#)
Spain	980	122	858
Italy	865	159	706
France	828	298	530
United Kingdom	750	228	522
Portugal	681	68	613
Poland	665	110	555
Germany	616	207	409
Romania	539	28	511
Belgium	527	157	370
Netherlands	488	171	317
Austria	481	203	278
Czech Republic	467	147	320
Greece	446	83	363
Hungary	415	102	313
Slovakia	393	144	249
Switzerland	384	104	280
Ireland	360	54	306
Bulgaria	349	60	289
Croatia	319	68	251
Denmark	304	142	162
Slovenia	298	85	213
Estonia	267	189	78
Latvia	259	96	163
Cyprus	252	70	182
Lithuania	243	39	204
Norway	239	76	163
Sweden	223	64	159
Luxembourg	222	115	107
Finland	214	87	127
Malta	122	22	100
Iceland	51	9	42

6. MAIN CONCLUSIONS:

- Differing situations between MSs on percentage of delays and workload.
- 17 MSs with high percentage of delays on almost all the procedures.
- Member States with higher percentage on delays are also the ones that have processed more applications.
- Worst average (all MSs) delays figures are on mutual recognition in parallel. Improvement over time (before and after R4BP3.10.).
- Best average (all MSs) delay figures are for Union Authorisations.
- Main delays in almost all the procedures in acceptance stage of the dossier.