EUROPEAN COMMISSION
HEALTH & FOOD SAFETY DIRECTORATE-GENERAL

Directorate E – Food and feed safety, innovation
Pesticides and Biocides

09 September 2022

Report on the compliance with the legal deadlines set out in the Regulation (EC) No 1107/2009 concerning the authorisation of plant protection products reported by Member States and Norway for the years 2017, 2018, 2019 and 2020

Important notice:

The data underlying this working document was reported by Member States and Norway in two questionnaires carried out in 2019 and 2021. This working document aims to give an overview on the performance of the authorisation processes and all conclusions are drawn from the data provided by the participating countries.

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Contents

1. BACKGROUND AND PURPOSE OF THE DOCUMENT

The purpose of this document is to give an overview of the performance of Member States competent authorities in complying with the deadlines set for product authorisations in Regulation (EC) No 1107/2009[1], based on data provided by Member States for the periods:

- 1 January 2017 to 31 December 2019 (**1st survey)**
- 1 January 2020 to 31 December 2020 (**2nd survey)**

The first survey was received by **29 countries** (28 Member States including United Kingdom and Norway) and the second survey by **28 countries** (27 Member States -without United Kingdom -and Norway). It is intended to repeat the survey regularly in order to monitor trends in compliance with the legal deadlines.

The surveys concerned the following procedures for product authorisation under Regulation (EC) No 1107/2009:

Member States acting as a zonal rapporteur MS

- Authorisation of a plant protection product
- Authorisation of a plant protection product for minor uses
- Authorisation of a plant protection product containing a low risk substance
- Authorisation of a plant protection product containing a substance that is a candidate for substitution
- Renewal of an authorisation of plant protection products

Member States acting as a concerned MS

- Authorisation of a plant protection product
- Authorisation of a plant protection product for minor uses
- Authorisation of a plant protection product containing a low risk substance
- Authorisation of a plant protection product containing a substance that is a candidate for substitution
- Renewal of an authorisation of plant protection products

Others

- Mutual recognition of an authorisation from a reference MS
- Granting of a parallel trade permit

This document also provides an overview of the information provided by countries on the:

- Challenges faced by countries to complete the authorisation procedures for plant protection products within the applicable deadline
- Actions suggested by countries to improve completion of the authorisation procedures for plant protection products within the applicable deadline.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1107-20210327

2. NUMBER OF PLANT PROTECTION PRODUCTS AUTHORISED IN EACH MEMBER STATE

In the first survey, Member States provided information of the **total number of plant protection products authorised** in each country **in 2017, 2018 and 2019**. The numbers reported were mostly actual numbers, though for Romania only an estimation was possible. In this survey, Member States did not distinguish between the different types of authorisation procedures.

The summary of this data is presented in Table 1.

Table 1: *Total number of plant protection products authorised in each country in 2017, 2018 and 2019 ordered from the highest to the lowest. UK was included in the survey.*

2017	
UK	3362
ES	2125
PL	2012
FR	1976
CZ	1613
BE	1499
NL	941
DE	*818*
CY	774
DK	579
LU	545
SI	529
FI	462
LT	396
LV	382
SE	355
EE	344
PT	255
MT	197
RO	110
HR	78
HU	75
NOR	16

2018	
UK	3342
PL	2224
ES	2149
FR	2016
CZ	1478
BE	1458
NL	1000
DE	*872*
CY	848
DK	605
LU	586
SI	539
FI	464
LV	439
LT	427
EE	374
SE	369
PT	249
MT	229
RO	114
HR	62
HU	57
NOR	**17**

2019	
UK	3245
PL	2387
ES	2146
FR	1810
CZ	1502
BE	1498
NL	1045
CY	*821*
LU	571
DK	548
SI	529
FI	467
LV	451
EE	433
LT	429
SE	376
MT	266
PT	250
RO	123
HU	85
HR	57
NOR	6
DE	/

In the second survey, Member States provided information of the **number of plant protection products authorised in each country only during 2020**. Member States distinguished between the different types of authorisation procedures.

The summary of this data is presented in Table 2.

Table 2: *Plant protection products authorised in each country only during 2020 according to the different procedures allowed by the legislation EC (No) 1107/2009 ordered from the highest amount to the lowest.*

Authorisation of PPPs as ZRMS		Renewal of authorisation of PPPs as ZRMS		Authorisation of PPPs as CMS		Renewal of authorisation of PPPs as CMS		Mutual recognition of an authorisation from a Reference MS		Granting of a parallel trade permit		Applications for amendements for existing authorisations	
EL	83	**IT**	19	**PT**	86	**PL**	28	**RO**	71	**DE**	437	**EL**	999
DE	65	**EL**	15	**BE**	78	**CZ**	24	**DE**	63	**ES**	436	**PL**	992
FR	52	**ES**	11	**ES**	61	**AT**	16	**CY**	61	**PL**	142	**PT**	573
IT	38	**FR**	10	**AT**	35	**BE**	13	**MT**	58	**FR**	101	**LU**	376
PL	25	**SE**	9	**CZ**	35	**ES**	13	**PL**	53	**SK**	94	**SI**	333
ES	20	**DE**	7	**HU**	35	**BG**	12	**SK**	52	**CY**	92	**HR**	285
AT	15	**AT**	5	**HR**	34	**HU**	12	**EL**	49	**CZ**	49	**CZ**	197
CZ	15	**PT**	5	**EL**	34	**DE**	11	**BG**	45	**BE**	43	**EE**	194
MT	12	**CZ**	4	**SK**	33	**EL**	11	**PT**	44	**FI**	36	**BE**	179
NL	11	**LT**	3	**PL**	32	**IE**	9	**LU**	36	**HU**	31	**BG**	140
BE	5	**DK**	2	**BG**	30	**FI**	8	**IT**	35	**PT**	19	**CY**	98
SE	5	**HU**	2	**DE**	24	**EE**	5	**HU**	34	**AT**	18	**HU**	81
DK	3	**PL**	2	**SI**	24	**PT**	5	**SI**	32	**LT**	15	**NL**	60
LV	3	**BE**	1	**RO**	22	**SK**	5	**HR**	31	**EL**	13	**AT**	55
SI	3	**BG**	1	**EE**	18	**LV**	4	**CZ**	30	**LU**	12	**IE**	40
LT	2	**EE**	1	**NL**	16	**FR**	3	**IE**	30	**SE**	12	**LT**	30
HR	1	**IE**	1	**FR**	12	**LU**	3	**ES**	29	**MT**	12	**RO**	14
HU	1	**LV**	1	**FI**	9	**NL**	3	**LT**	26	**BG**	9	**FR**	10
SK	1	**NL**	1	**LT**	9	**SI**	2	**SE**	22	**NL**	9	**DK**	8
BG	0	**SI**	1	**IT**	7	**SE**	2	**AT**	21	**IE**	5	**FI**	6
FI	0	**HR**	0	**DK**	5	**HR**	1	**BE**	21	**SI**	5	**SK**	6
IE	0	**FI**	0	**SE**	5	**LT**	1	**LV**	19	**HR**	4	**ES**	3
NO	0	**MT**	0	**IE**	4	**RO**	1	**FI**	18	**DK**	4	**NO**	1
PT	0	**NO**	0	**LV**	4	**DK**	0	**FR**	11	**LV**	4	**LV**	0
CY	/	**SK**	0	**MT**	1	**MT**	0	**NL**	9	**IT**	2	**SE**	0
EE	/	**CY**	/	**NO**	0	**NO**	0	**NO**	9	**RO**	1	**DE**	/
LU	/	**LU**	/	**CY**	/	**CY**	/	**DK**	7	**EE**	0	**IT**	/
RO	/	**RO**	/	**LU**	/	**IT**	/	**EE**	4	**NO**	0	**MT**	/

AVERAGE TIMING THAT COUNTRIES TOOK TO FINALISE THE DECISIONS OF THE REGULATORY PROCEDURES

The surveys collected information on the minimum, average and maximum timing that countries took to finalise the decisions of the regulatory procedures. The information provided from **subchapters 3.1. – 3.4** reflects **only the average timing.**

3.1 MEMBER STATES ACTING AS A ZONAL RAPPORTEUR MS

3.1.1 Authorisation of a plant protection product - (legal deadline 12 to 18 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **20 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product was **19 months.**

The **longest time** indicated by one country was **45 months** (see Figure 1).

Among the 20 countries that replied, **10 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 1 for detailed information.

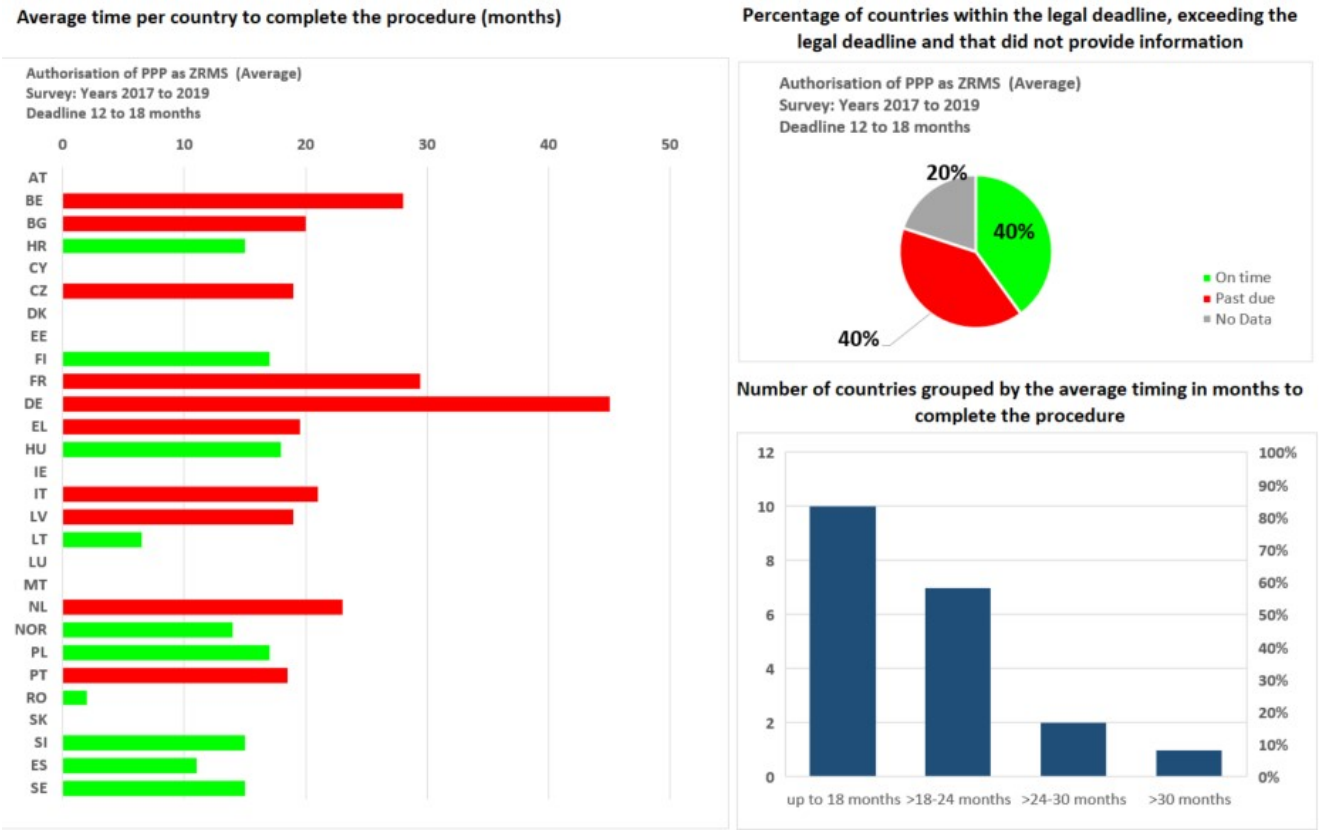


***Figure 1**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the authorisation of a plant protection product (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product (bottom right).*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

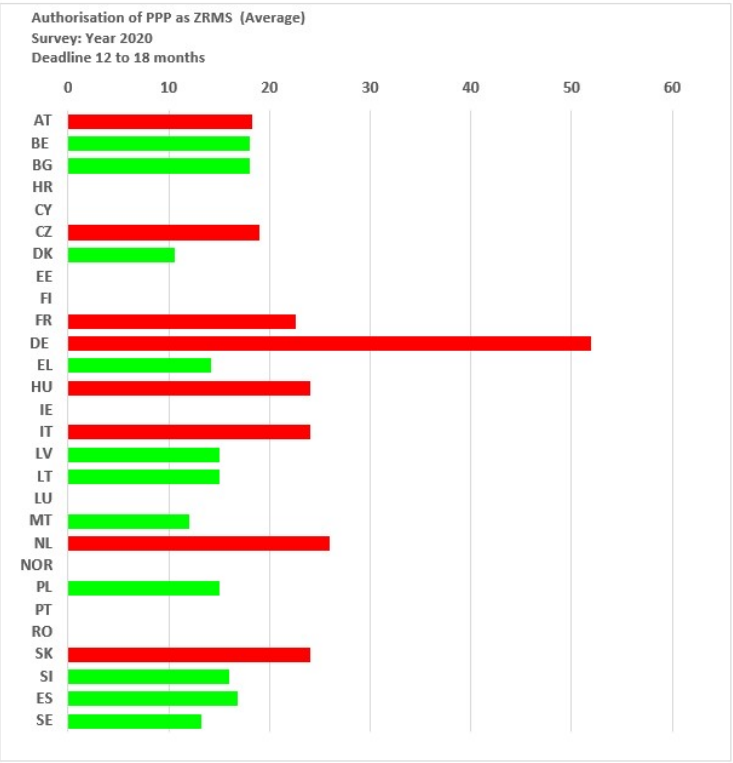
A total of **19 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product was **20 months.**

The **longest time** indicated by one country was **52 months** (see Figure 2).

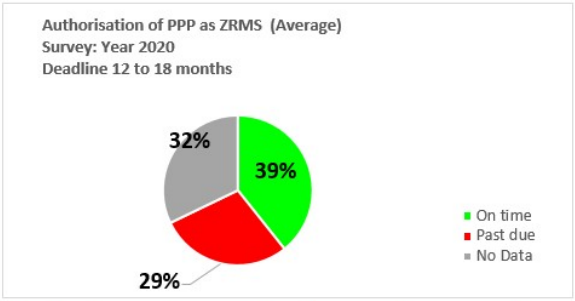
Among the 19 countries that replied, **11 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 2 for detailed information.

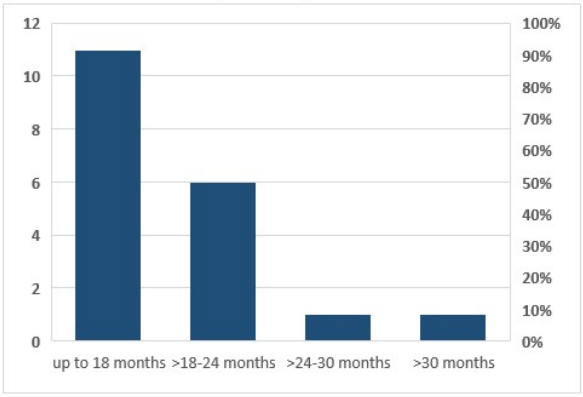
Average time in months per country to complete the procedure



Compliance with the legal deadline



Number of countries grouped by the average time in months to complete the procedure



Authorisation of PPPs as ZRMS																											
EL	DE	FR	IT	PL	ES	AT	CZ	MT	NL	BE	SE	DK	LV	SI	LT	HR	HU	SK	BG	FI	IE	NO	PT	CY	EE	LU	RO
83	65	52	38	25	20	15	15	12	11	5	5	3	3	3	2	1	1	1	0	0	0	0	0	/	/	/	/

***Figure 2**: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product (bottom right).*

The table below the graphs indicates the number (from the highest to lowest) of authorisations of plant protection products that were granted by each Member State between 1 January 2020 to 31 December 2020.

3.1.2 Authorisation of a plant protection product for minor uses - (legal deadline 12 to 18 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **18 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product for minor uses was **7 months.**

The **longest time** indicated by one country was **27 months** (see Figure 3).

Among the 18 countries that replied, **16 countries** were able to finalise decisions on applications for the authorisation of a plant protection product for minor uses **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 3 for detailed information.

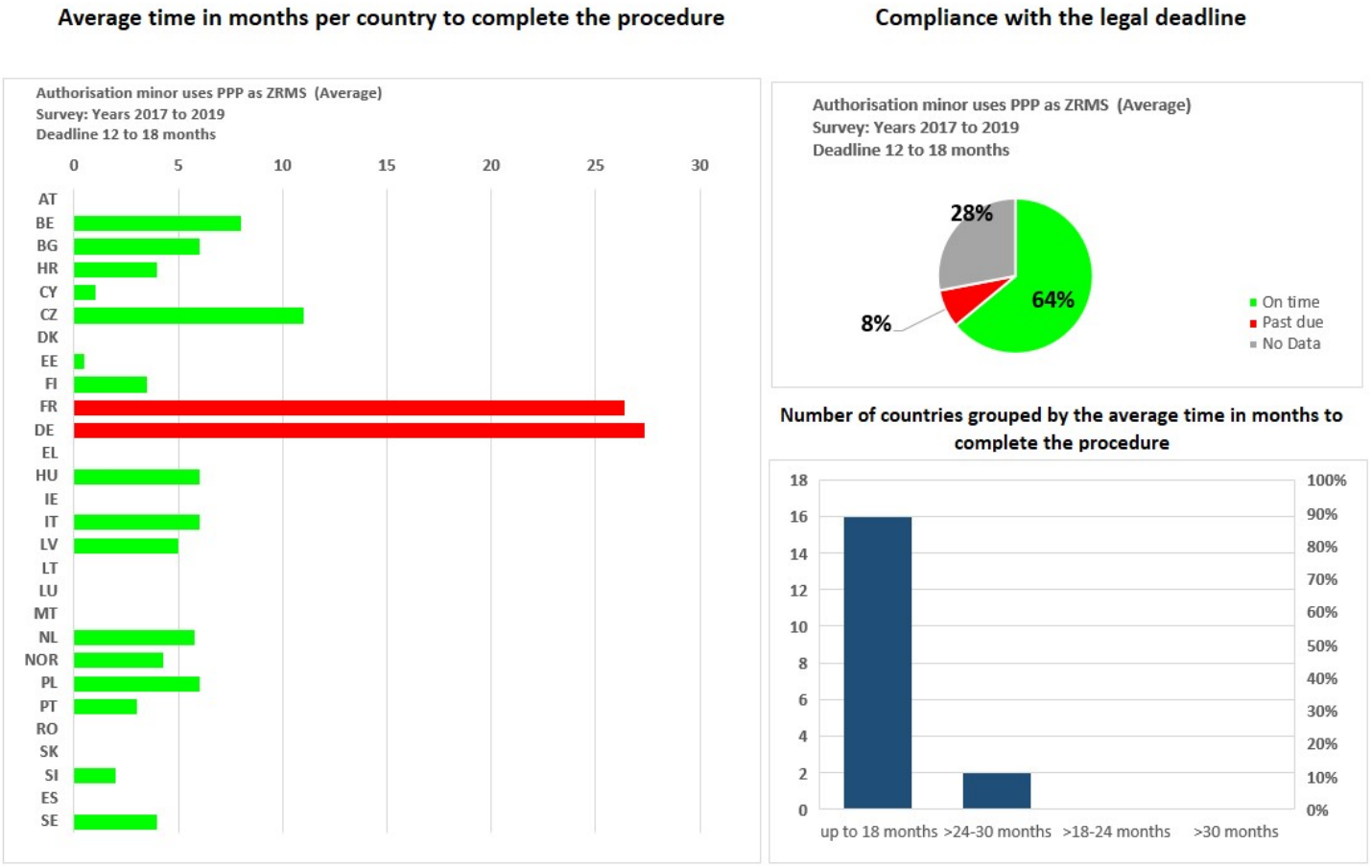


***Figure 3**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the authorisation of a plant protection product for minor uses (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product for minor uses (bottom right)*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **7 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product for minor uses was **12 months.**

The **longest time** indicated by one country was **22 months** (see Figure 4).

Among the 7 countries that replied, **6 countries** were able to finalise decisions on applications for the authorisation of a plant protection product for minor uses **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 4 for detailed information.

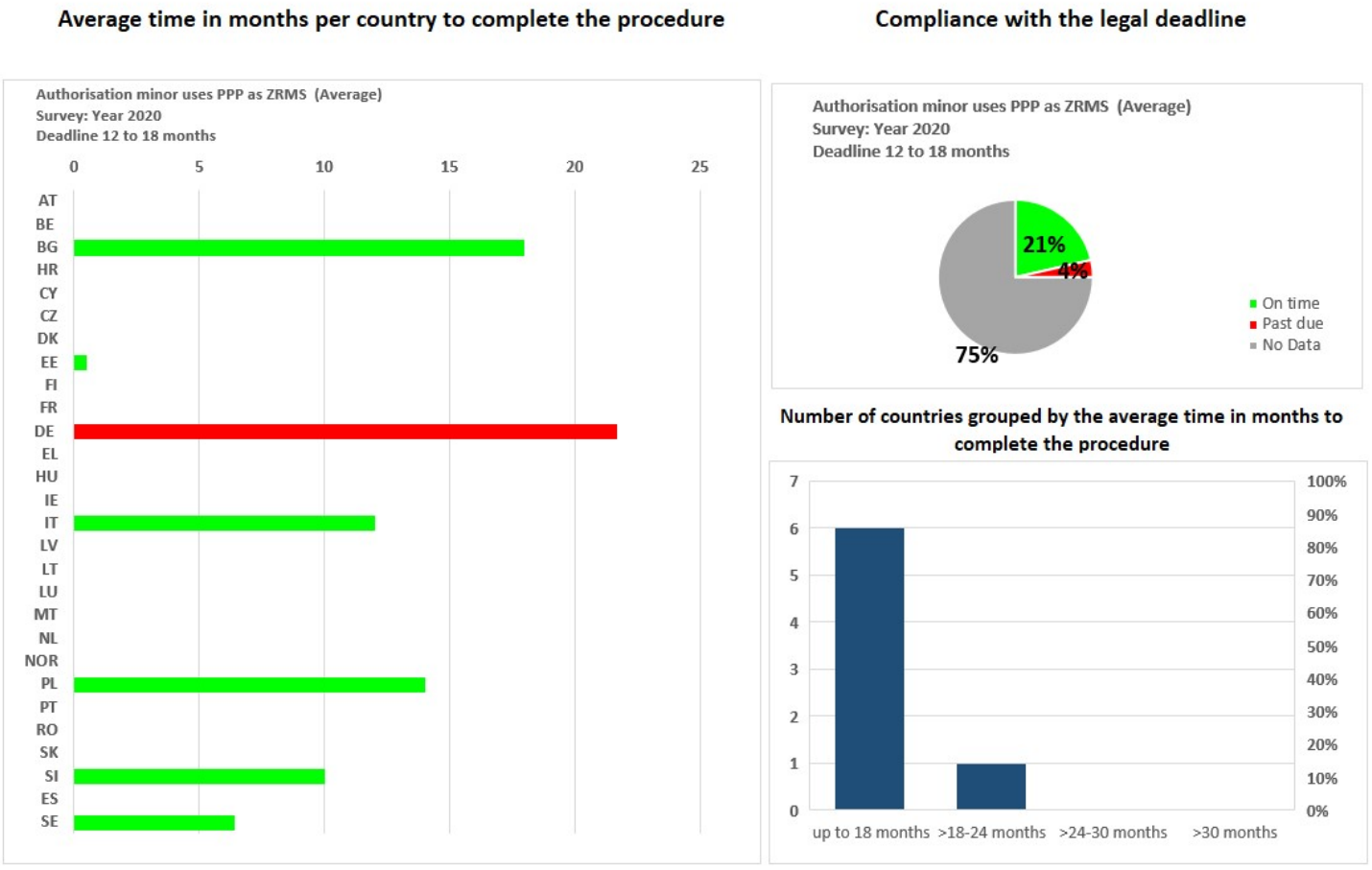


Figure 4: *Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product for minor uses (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product for minor uses (bottom right).*

3.1.3 Authorisation of a plant protection product containing a low risk substance - (legal deadline 4 to 10 months[2])

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **10 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product containing a low risk substance was **7 months.**

The **longest time** indicated by one country was **23 months** (see Figure 5).

Among the 10 countries that replied, **7 countries** were able to finalise decisions on applications for the authorisation of a plant protection product containing a low risk substance **within the legal deadline** of 4 to 10 months (green coloured).

See Figure 5 for detailed information.

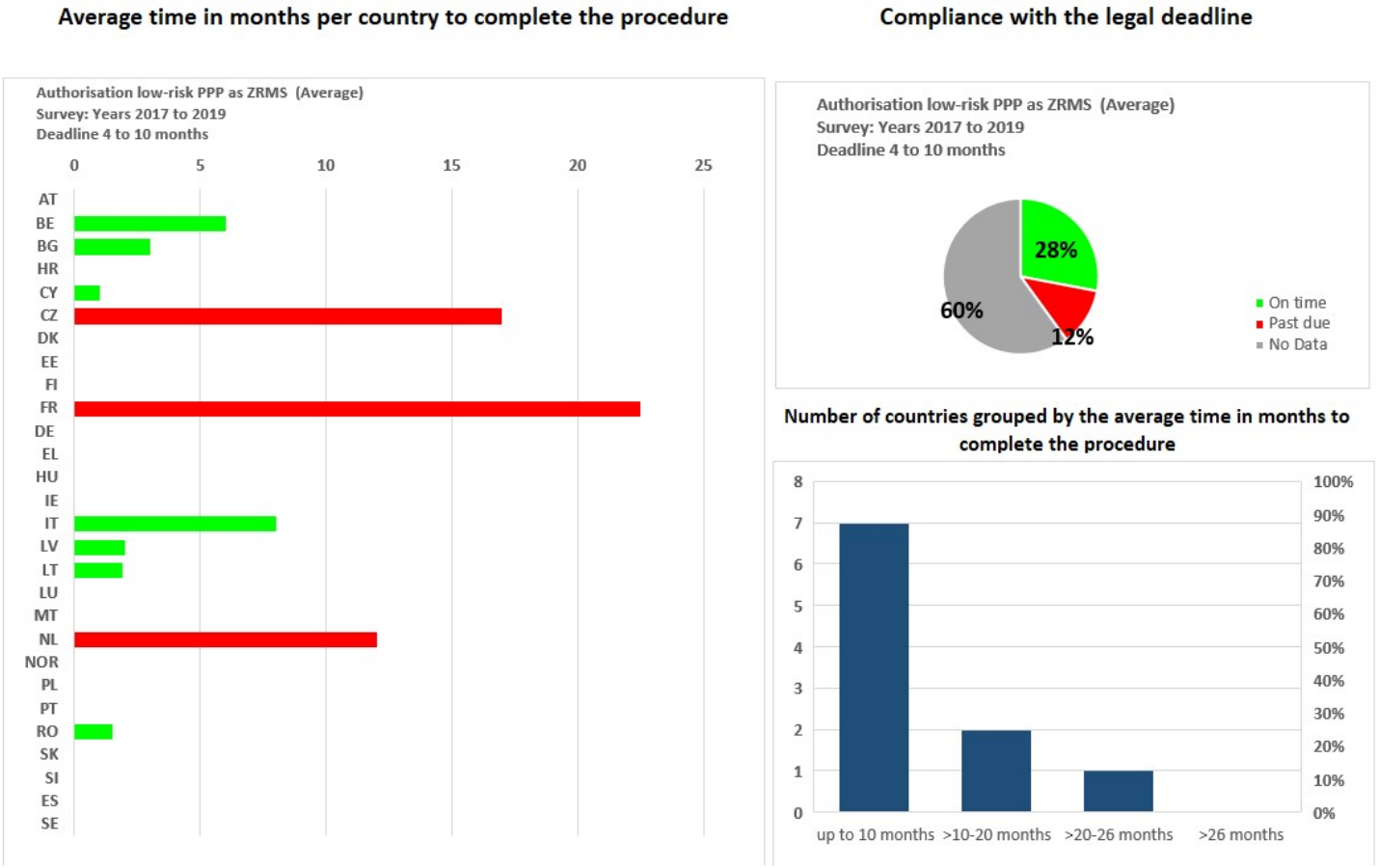


***Figure 5**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the authorisation of a plant protection product containing a low risk substance (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a low risk substance (bottom right).*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

[2] See Article 47(3) of the Regulation (EC) No 1107/2009 for the placing on the market of plant protection products.

A total of **5 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product containing a low risk substance was **12 months.**

The **longest time** indicated by one country was **16 months** (see Figure 6).

Among the 5 countries that replied, **3 countries** were able to finalise decisions on applications for the authorisation of a plant protection product containing a low risk substance **within the legal deadline** of 4 to 10 months (green coloured).

See Figure 6 for detailed information.

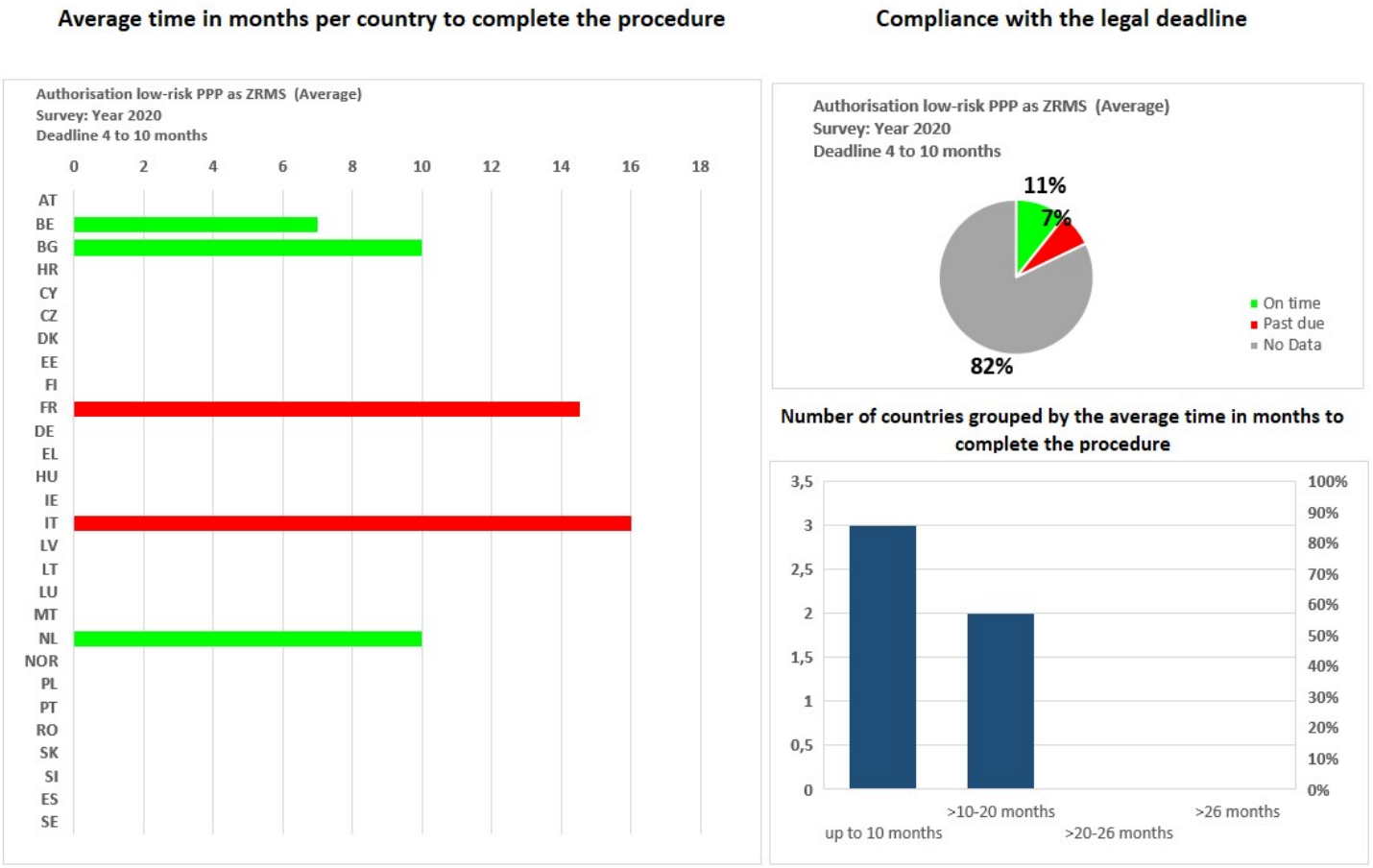


***Figure 6**: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product containing a low risk substance (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a low risk substance (bottom right).*

3.1.4 Authorisation of a plant protection product containing a substance that is a candidate for substitution - (legal deadline 12 to18 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **7 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution was **15 months.**

The **longest time** indicated by one country was **27 months** (see Figure 7).

Among the 7 countries that replied, **5 countries** were able to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 7 for detailed information.

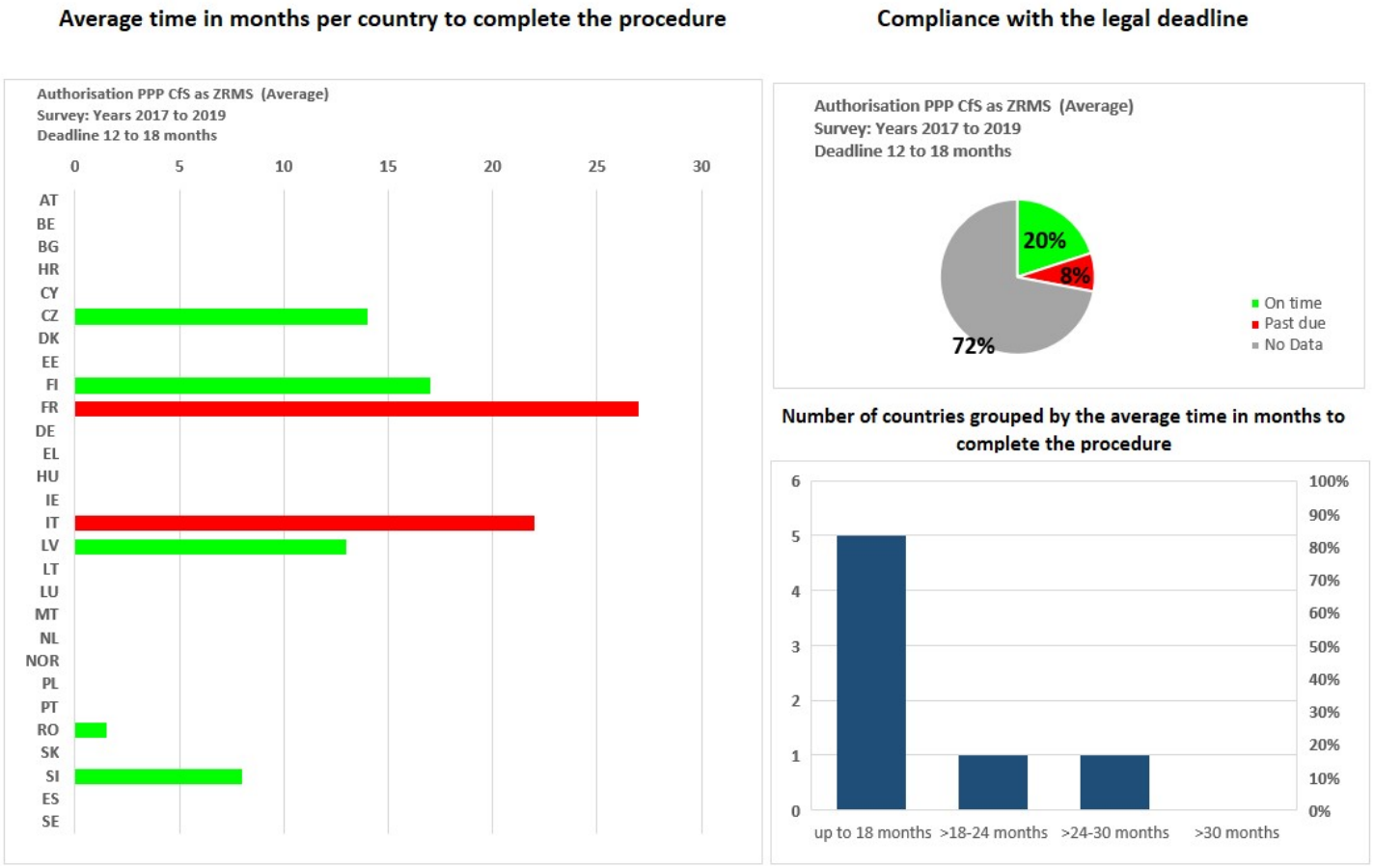


***Figure 7**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (bottom right).*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **10 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for was **20 months.**

The **longest time** indicated by one country was **32 months** (see Figure 8).

Among the 10 countries that replied, **5 countries** were able to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution **within the legal deadline** of 12 to 18 months (green coloured).

See Figure 8 for detailed information.

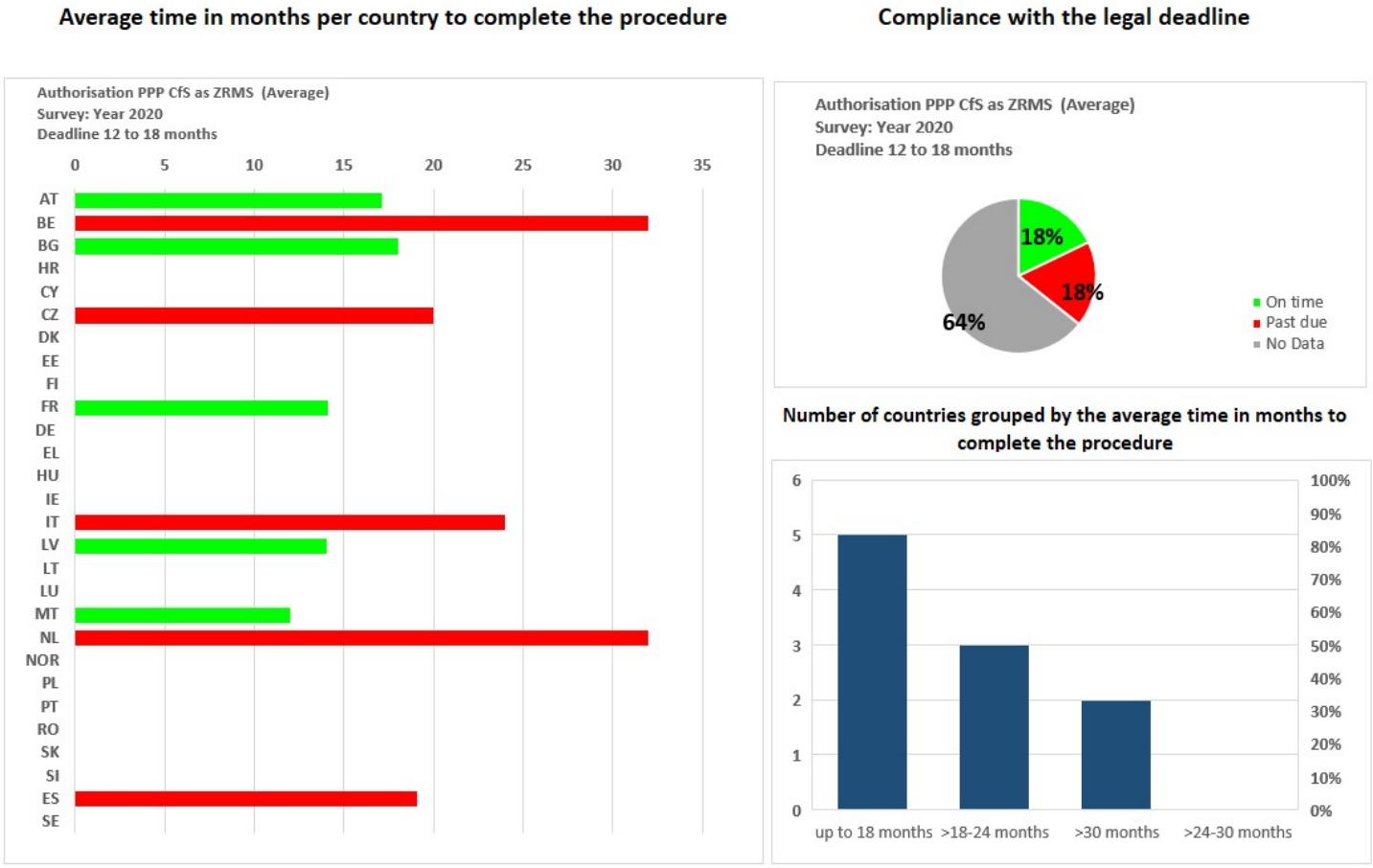


Figure 8: *Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (bottom right).*

3.1.5 Renewal of an authorisation of plant protection products - (legal deadline 12 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **15 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the renewal of an authorisation of a plant protection product was **21 months.**

The **longest time** indicated by one country was **46 months** (see Figure X).

Among the 15 countries that replied, **2 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 12 months (green coloured).

See Figure 9 for detailed information.

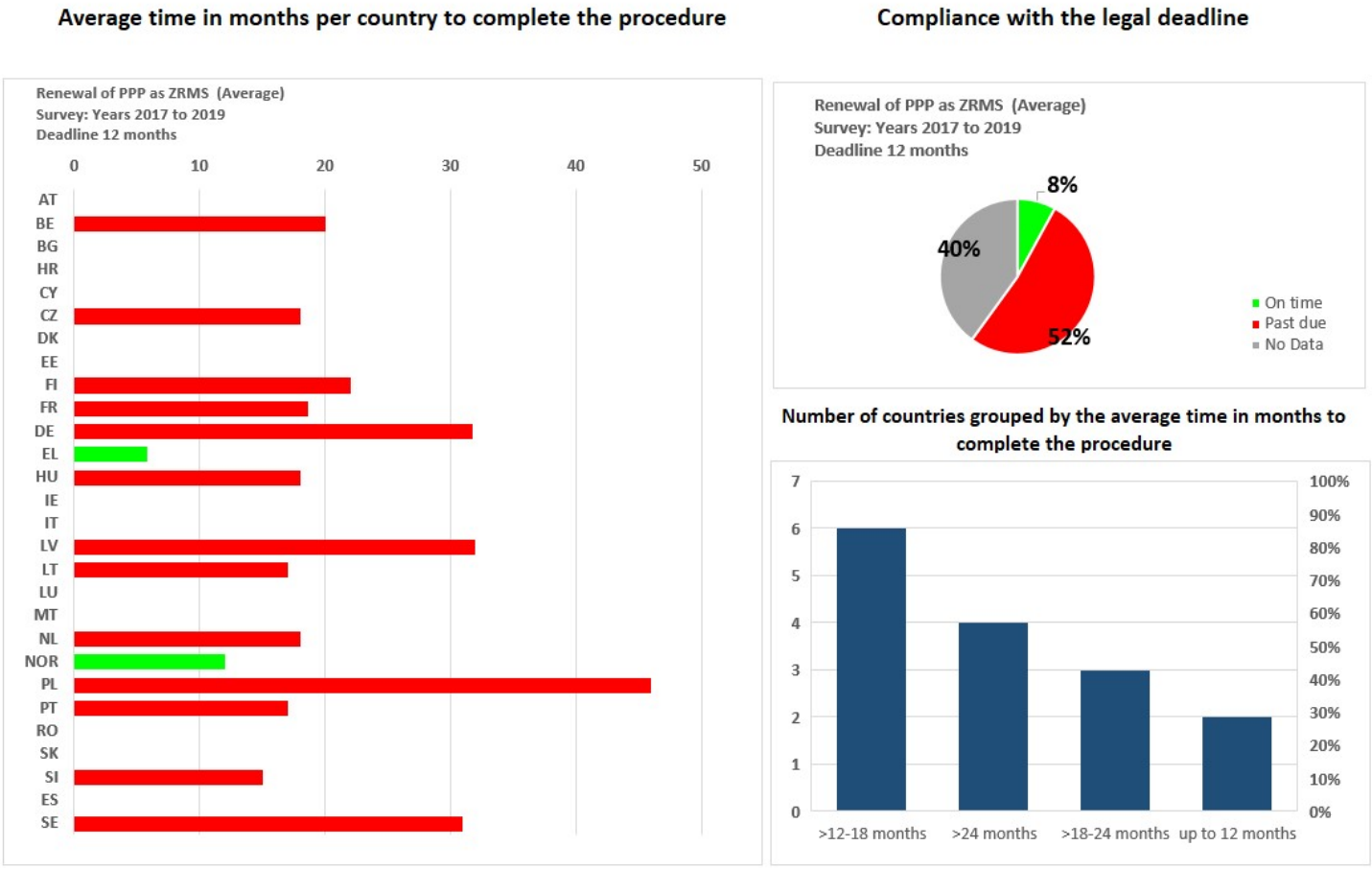


***Figure 9**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the renewal of an authorisation of a plant protection product (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the renewal of an authorisation of a plant protection product (bottom right)*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

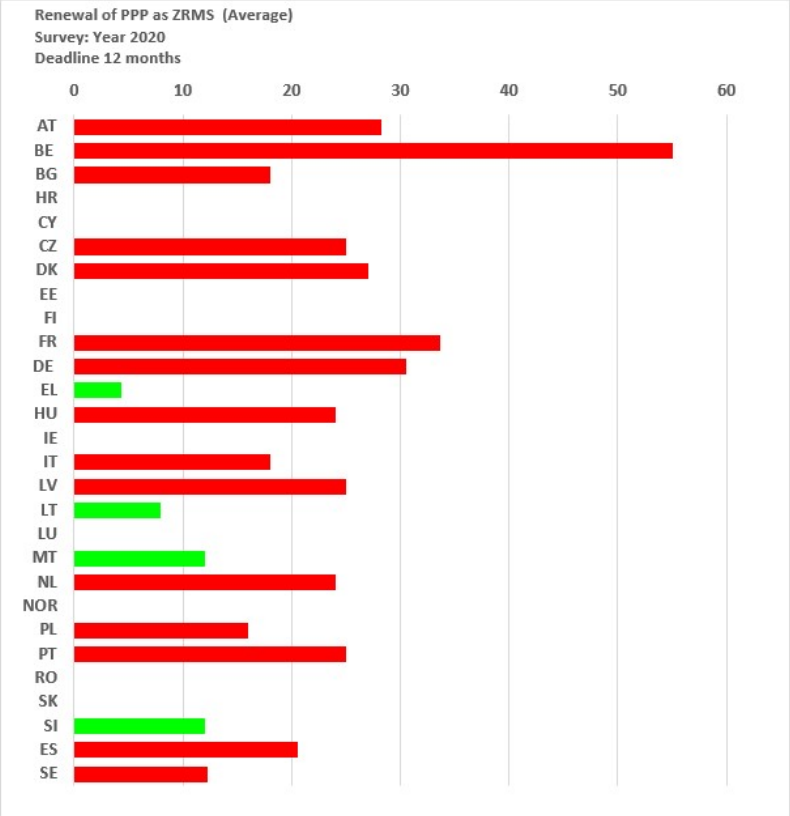
A total of **19 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the renewal of an authorisation of a plant protection product was **22 months.**

The **longest time** indicated by one country was **55 months** (see Figure 10).

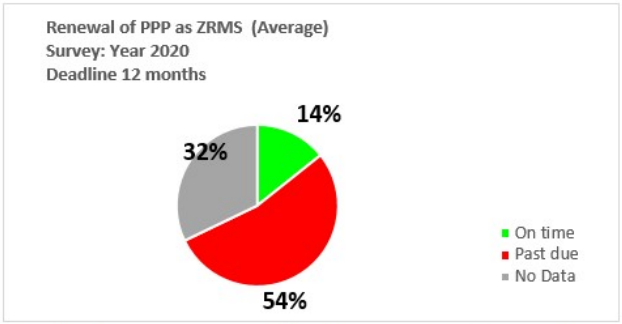
Among the 19 countries that replied, **4 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 12 (green coloured).

See Figure 10 for detailed information.

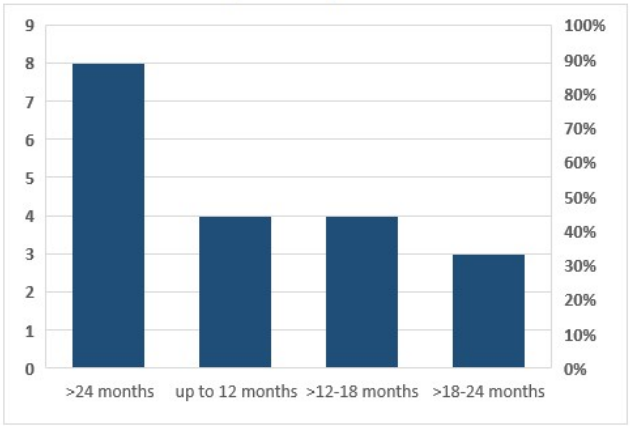
Average time in months per country to complete the procedure



Compliance with the legal deadline



Number of countries grouped by the average time in months to complete the procedure



Renewal of authorisation of PPPs as ZRMS																										
IT	EL	ES	FR	SE	DE	AT	PT	CZ	LT	DK	HU	PL	BE	BG	EE	IE	LV	NL	SI	HR	FI	MT	NO	SK	CY	LU	RO
19	15	11	10	9	7	5	5	4	3	2	2	2	1	1	1	1	1	1	1	0	0	0	0	0	/	/	/

Figure 10*Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the renewal of an authorisation of a plant protection product (left), compliance with the legal deadline of 12 to 18 months (top right), and number of countries grouped by the average timing in months to complete the renewal of authorisation of a plant protection product (bottom right).*

The table below the graphs indicates the number (from the highest to lowest) of the renewals of an authorisation of plant protection products that were granted by each Member State between 1 January 2020 to 31 December 2020.

3.2 MEMBER STATES ACTING AS A CONCERNED MS

3.2.1 Authorisation of a plant protection product - (legal deadline 4 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **20 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product was **10 months.**

The **longest time** indicated by one country was **42 months** (see Figure 11).

Among the 20 countries that replied, **6 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 4 months (green coloured).

See Figure 11 for detailed information.

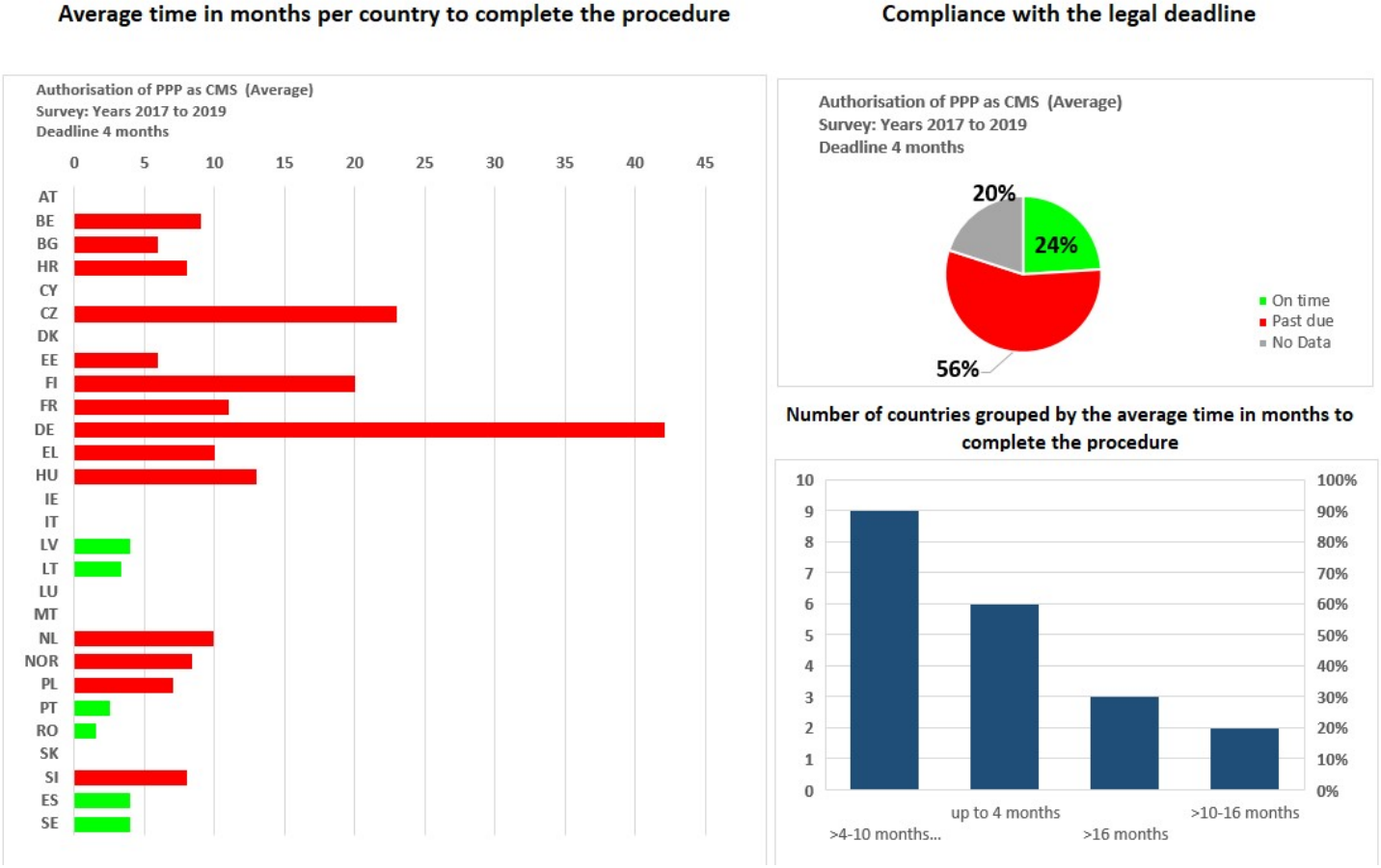


***Figure 11**: Between 1 January 2017 to 31 December 2019: Average time in months per country to complete the authorisation of a plant protection product (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product (bottom right).*

- ***2nd survey: from 1 January 2020 to 31 December 2020***

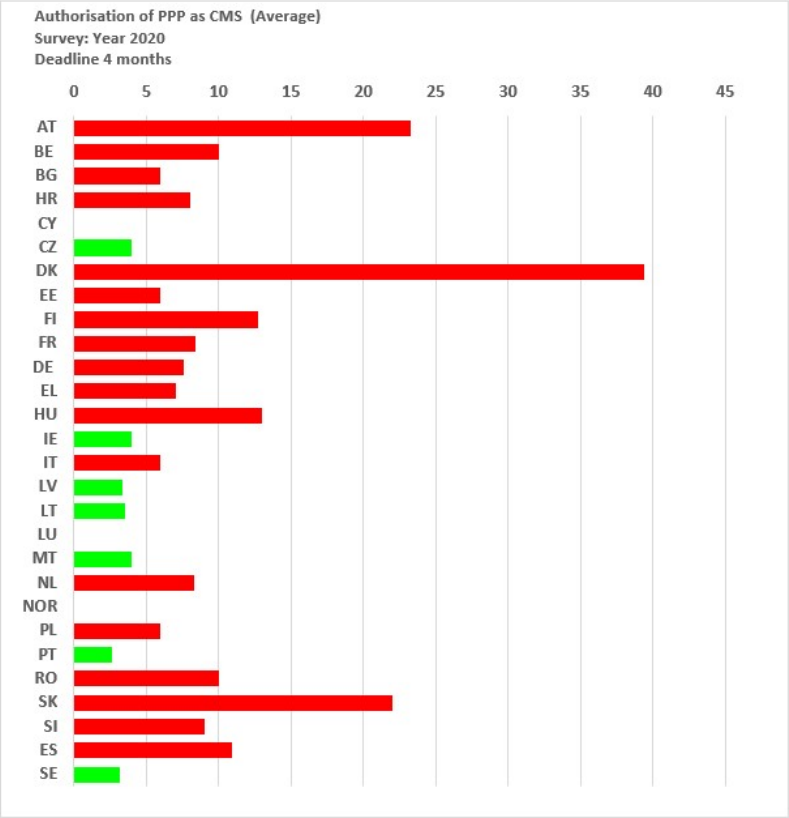
A total of **25 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product was **10 months.**

The **longest time** indicated by one country was **39 months** (see Figure 12).

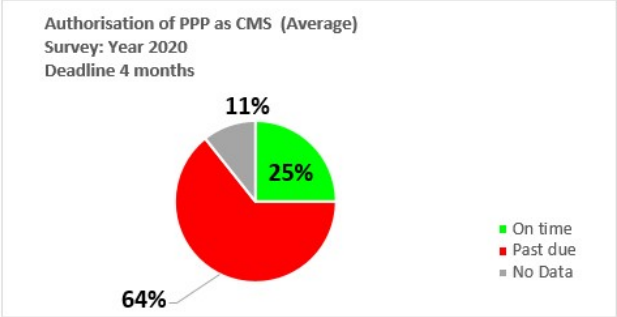
Among the 25 countries that replied, **7 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 4 months (green coloured).

See Figure 12 for detailed information.

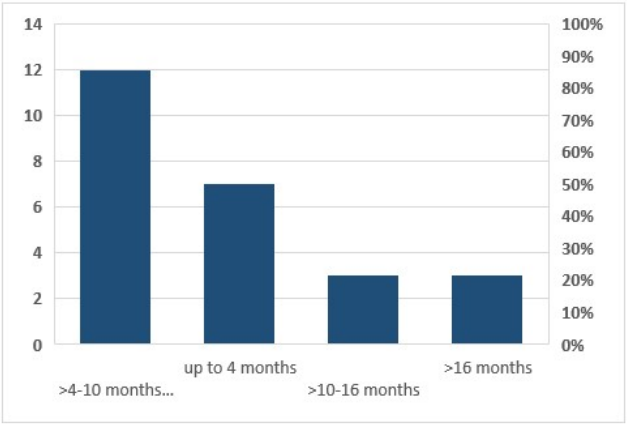
Average time in months per country to complete the procedure



Compliance with the legal deadline



Number of countries grouped by the average time in months to complete the procedure



Authorisation of PPPs as CMS																										
PT	BE	ES	AT	CZ	HU	HR	EL	SK	PL	BG	DE	SI	RO	EE	NL	FR	FI	LT	IT	DK	SE	IE	LV	MT	NO	CY	LU
86	78	61	35	35	35	34	34	33	32	30	24	24	22	18	16	12	9	9	7	5	5	4	4	1	0	/	/

Figure 12: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product (bottom right).

The table below the graphs indicates the number (from the highest to lowest) of authorisations of plant protection products that were granted by each Member State between 1 January 2020 to 31 December 2020.

3.2.2 Authorisation of a plant protection product for minor uses - (legal deadline 4 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

Regarding the time taken to finalise decisions on applications for the authorisation of a plant protection product for minor uses**,** no information was reported by any of the 29 countries.

- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **10 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product for minor uses was **5 months.**

The **longest time** indicated by one country was **9 months** (see Figure 13).

Among the 10 countries that replied, **3 countries** were able to finalise decisions on applications for the authorisation of a plant protection product for minor uses **within the legal deadline** of 4 months (green coloured).

See Figure 13 for detailed information.

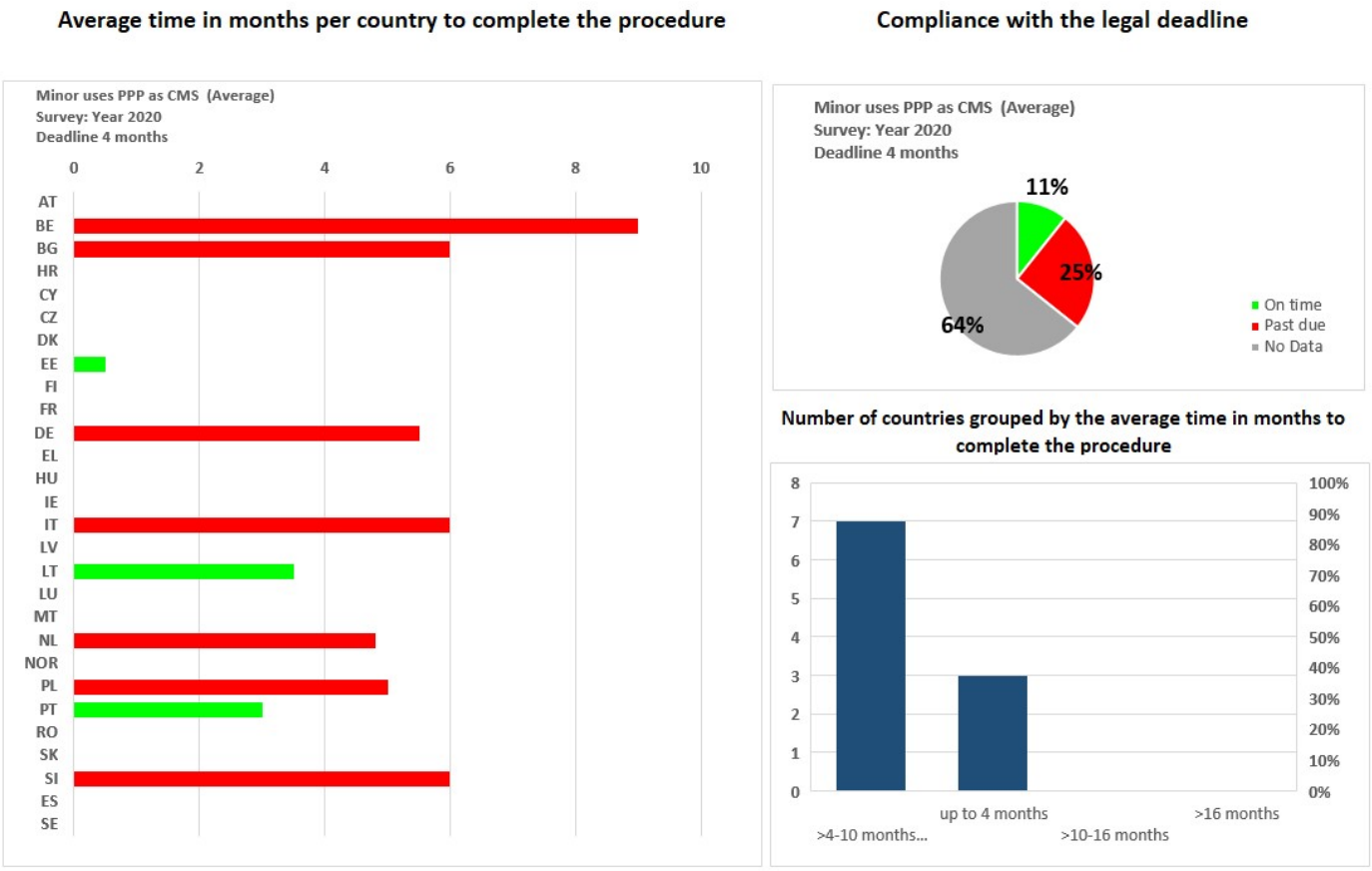


Figure 13*: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product for minor uses (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product for minor uses (bottom right).*

3.2.3 Authorisation of a plant protection product containing a low risk substance - (legal deadline 4 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

Regarding the time taken to finalise decisions on applications for the authorisation of a plant protection product containing a low risk substance**,** no information was reported by any of the 29 countries.

- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **6 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection was **8 months.**

The **longest time** indicated by one country was **19 months** (see Figure 14).

Among the 6 countries that replied, **2 countries** were able to finalise decisions on applications for the authorisation of a plant protection product **within the legal deadline** of 4 months (green coloured).

See Figure 14 for detailed information.

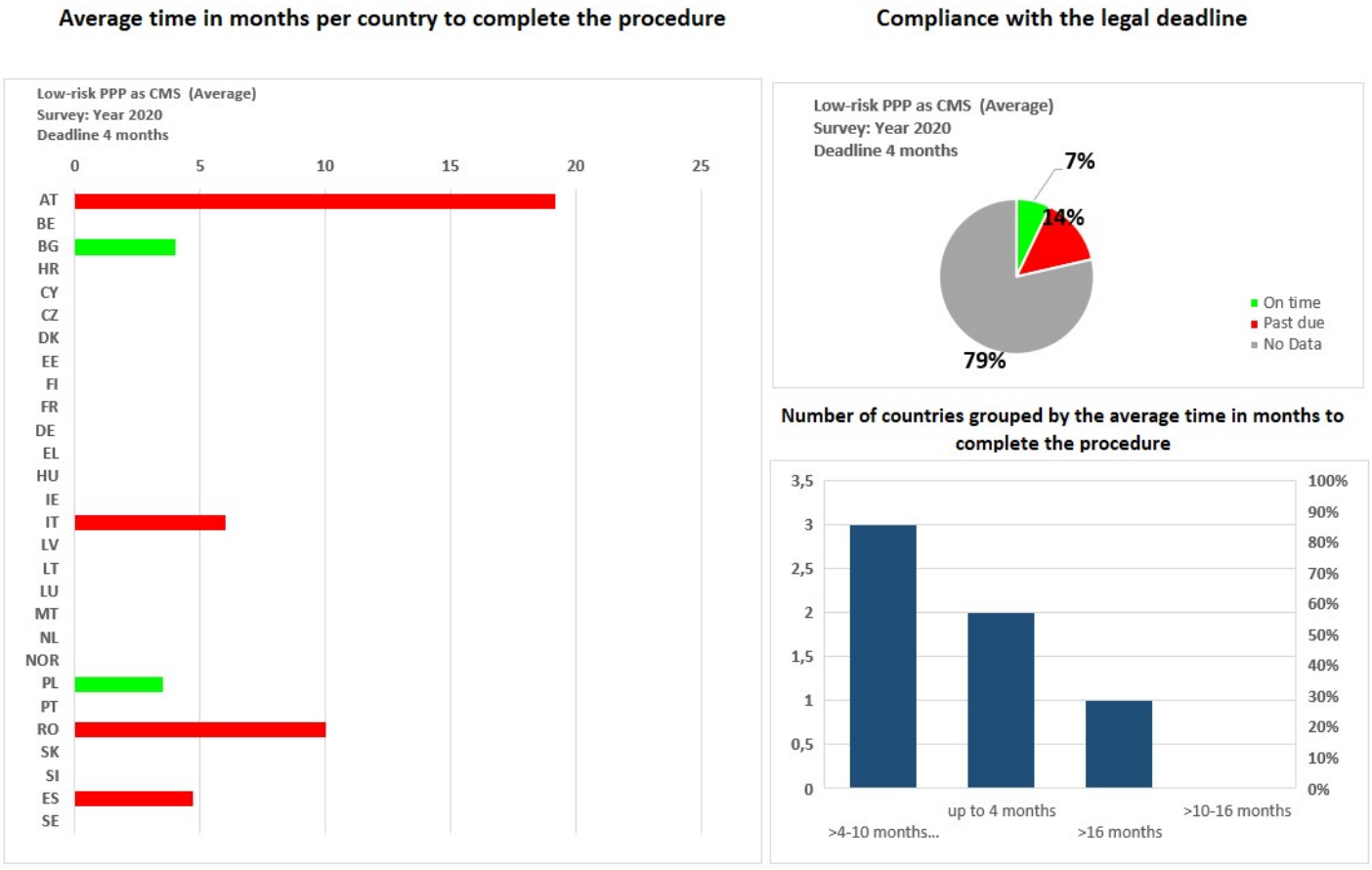


Figure 14: *Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product containing a low risk substance (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a low risk substance (bottom right).*

3.2.4 Authorisation of a plant protection product containing a substance that is a candidate for substitution - (legal deadline 4 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

Regarding the time taken to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution, no information was reported by any of the 29 countries.

- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **14 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution was **10 months.**

The **longest time** indicated by one country was **30 months** (see Figure 15).

Among the 14 countries that replied, **3 countries** were able to finalise decisions on applications for the authorisation of a plant protection product containing a substance that is a candidate for substitution **within the legal deadline** of 4 months (green coloured).

See Figure 15 for detailed information.

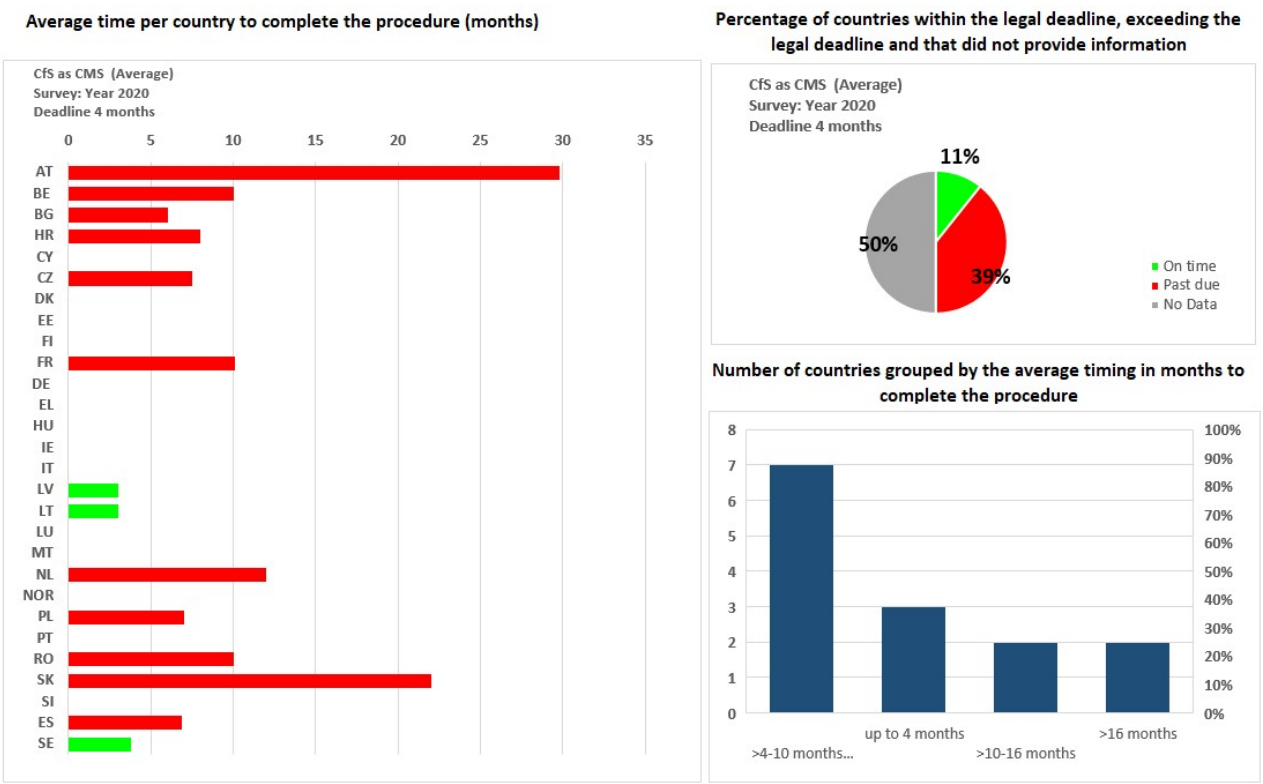


***Figure 15**: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the authorisation of a plant protection product containing a substance that is a candidate for substitution (bottom right).*

3.2.5 Renewal of an authorisation of plant protection products when acting as concerned MS - (legal deadline 4 months)

- ***1st survey: from 1 January 2017 to 31 December 2019***

Regarding the time taken to finalise decisions on applications for the renewal of an authorisation of a plant protection product, only **one country** out of the 29 countries involved **provided information**. During this period, the **average** time taken by the country to finalise this procedure was **15 months.**

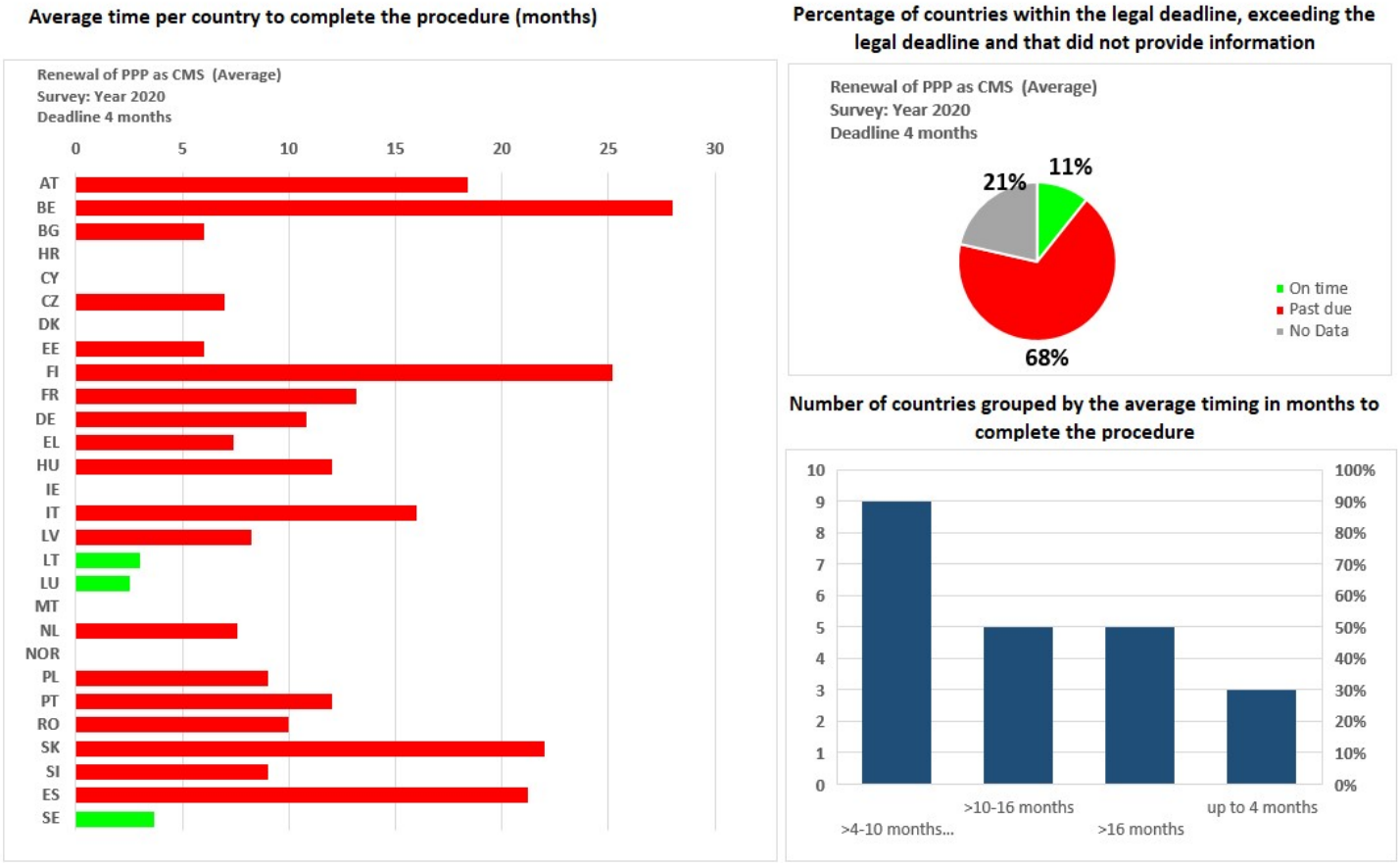
- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **22 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to finalise decisions on applications for the renewal of an authorisation of a plant protection product was **12 months.**

The **longest time** indicated by one country was **28 months** (see Figure 16).

Among the 22 countries that replied, **3 countries** were able to finalise decisions on applications for the renewal of an authorisation of a plant protection product **within the legal deadline** of 4 months (green coloured).

See Figure 16 for detailed information.



Renewal of authorisation of PPPs as CMS																									
PL	CZ	AT	BE	ES	BG	HU	DE	EL	IE	FI	EE	PT	SK	LV	FR	LU	NL	SI	SE	HR	LT	RO	DK	MT	NO	CY	IT
28	24	16	13	13	12	12	11	11	9	8	5	5	5	4	3	3	3	2	2	1	1	1	0	0	0	/	/

Figure 16*: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the renewal of an authorisation of a plant protection product (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the renewal of an authorisation of a plant protection product (bottom right).*

The table below the graphs indicates the number (from the highest to lowest) of renewals of an authorisation of plant protection products that were granted by each Member State between 1 January 2020 to 31 December 2020.

3.3 MUTUAL RECOGNITION OF AN AUTHORISATION FROM A REFERENCE MS - (LEGAL DEADLINE 4 MONTHS)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **23 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to mutually recognise an authorisation of a plant protection product from a reference MS was **7 months.**

The **longest time** indicated by one country was **16 months** (see Figure 17).

Among the 23 countries that replied, **5 countries** were able to mutually recognise an authorisation of a plant protection product from a reference MS **within the legal deadline** of 4 months (green coloured).

See Figure 17 for detailed information.

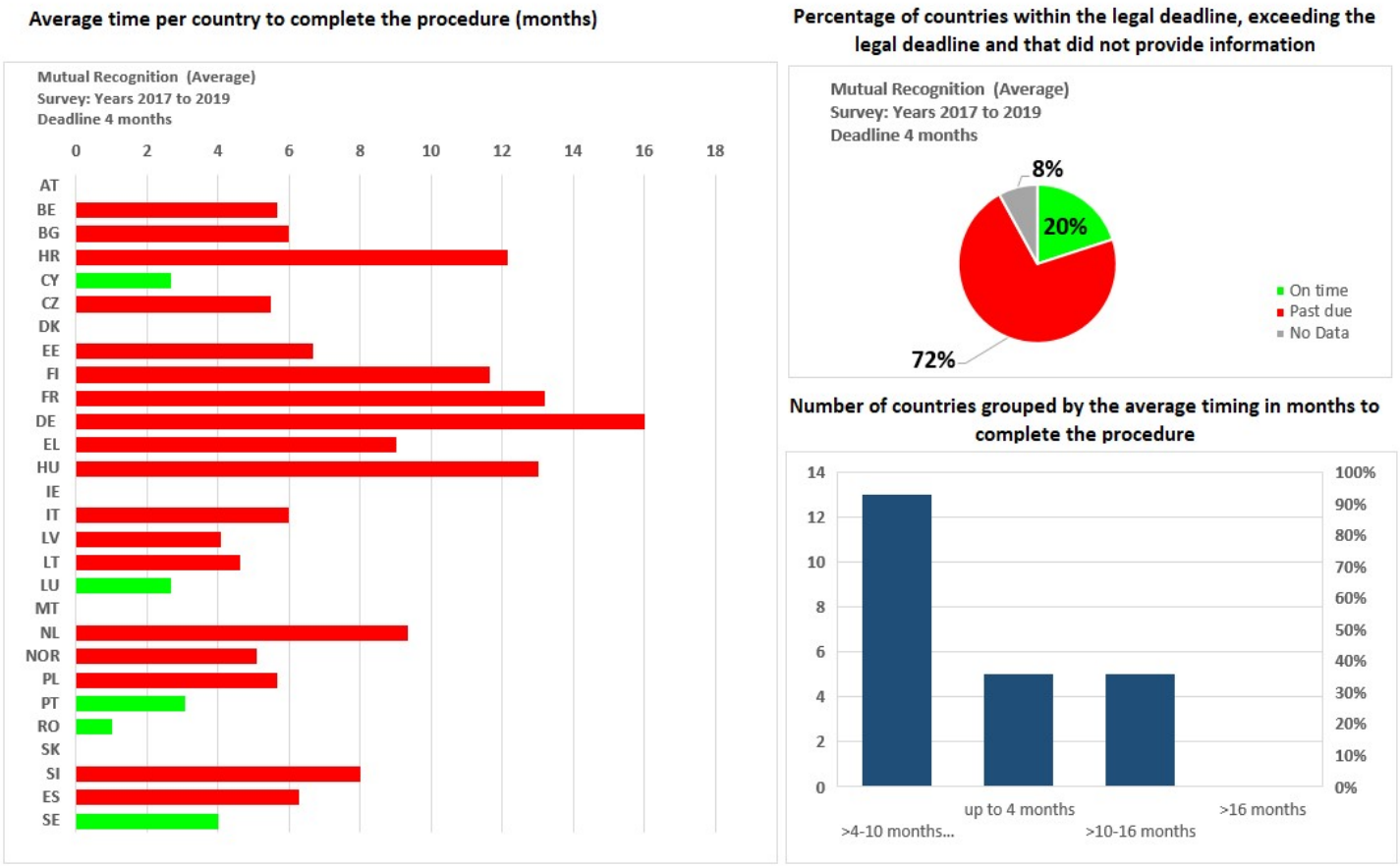


***Figure 17**: Between 1 January 2017 to 31 December 2019: Average time in months per country to mutually recognize an authorisation of a plant protection product from a reference MS (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to mutually recognize an authorisation of a plant protection product from a reference MS (bottom right).*

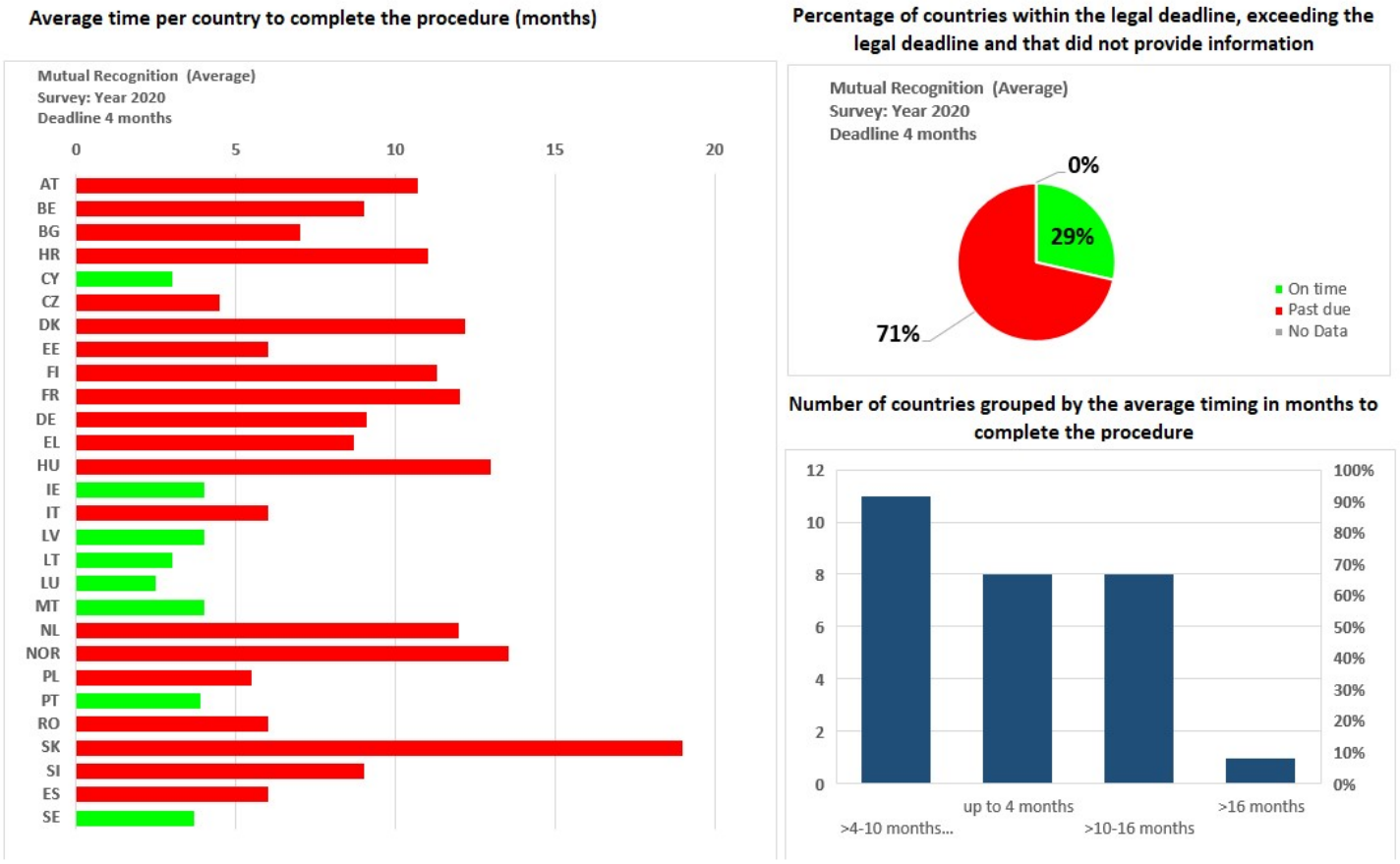
- ***2nd survey: from 1 January 2020 to 31 December 2020***

All the 28 countries involved **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to complete the mutual recognition of an authorisation of a plant protection product from a reference MS was **8 months.**

The **longest time** indicated by one country was **19 months** (see Figure 18).

Among the 28 countries that replied, **8 countries** were able to complete the mutual recognition of an authorisation of a plant protection product from a reference MS **within the legal deadline** of 4 months (green coloured).

See Figure 18 for detailed information.



Mutual recognition of an authorisation from a Reference MS																									
RO	DE	CY	MT	PL	SK	EL	BG	PT	LU	IT	HU	SI	HR	CZ	IE	ES	LT	SE	AT	BE	LV	FI	FR	NL	NO	DK	EE
71	63	61	58	53	52	49	45	44	36	35	34	32	31	30	30	29	26	22	21	21	19	18	11	9	9	7	4

***Figure 18**: Between 1 January 2020 to 31 December 2020: Average time in months per country to complete the mutual recognition of an authorisation of a plant protection product from a reference MS (left), compliance with the legal deadline of 4 months (top right), and number of countries grouped by the average timing in months to complete the mutual recognition of an authorisation of a plant protection product from a reference MS (bottom right).*

The table below the graphs indicates the number (from the highest to lowest) of authorisations of plant protection products mutually recgonised by each Reference Member State between 1 January 2020 to 31 December 2020.

3.4 GRANTING OF A PARALLEL TRADE PERMIT MS - (LEGAL DEADLINE 45 DAYS)

- ***1st survey: from 1 January 2017 to 31 December 2019***

A total of **19 countries** out of 29 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to grant a parallel trade permit was **60 days.**

The **longest time** indicated by one country was **180 days** (see Figure 19).

Among the 19 countries that replied, **9 countries** were able to grant a parallel trade permit **within the legal deadline** of 45 days (green coloured).

See Figure 19 for detailed information.

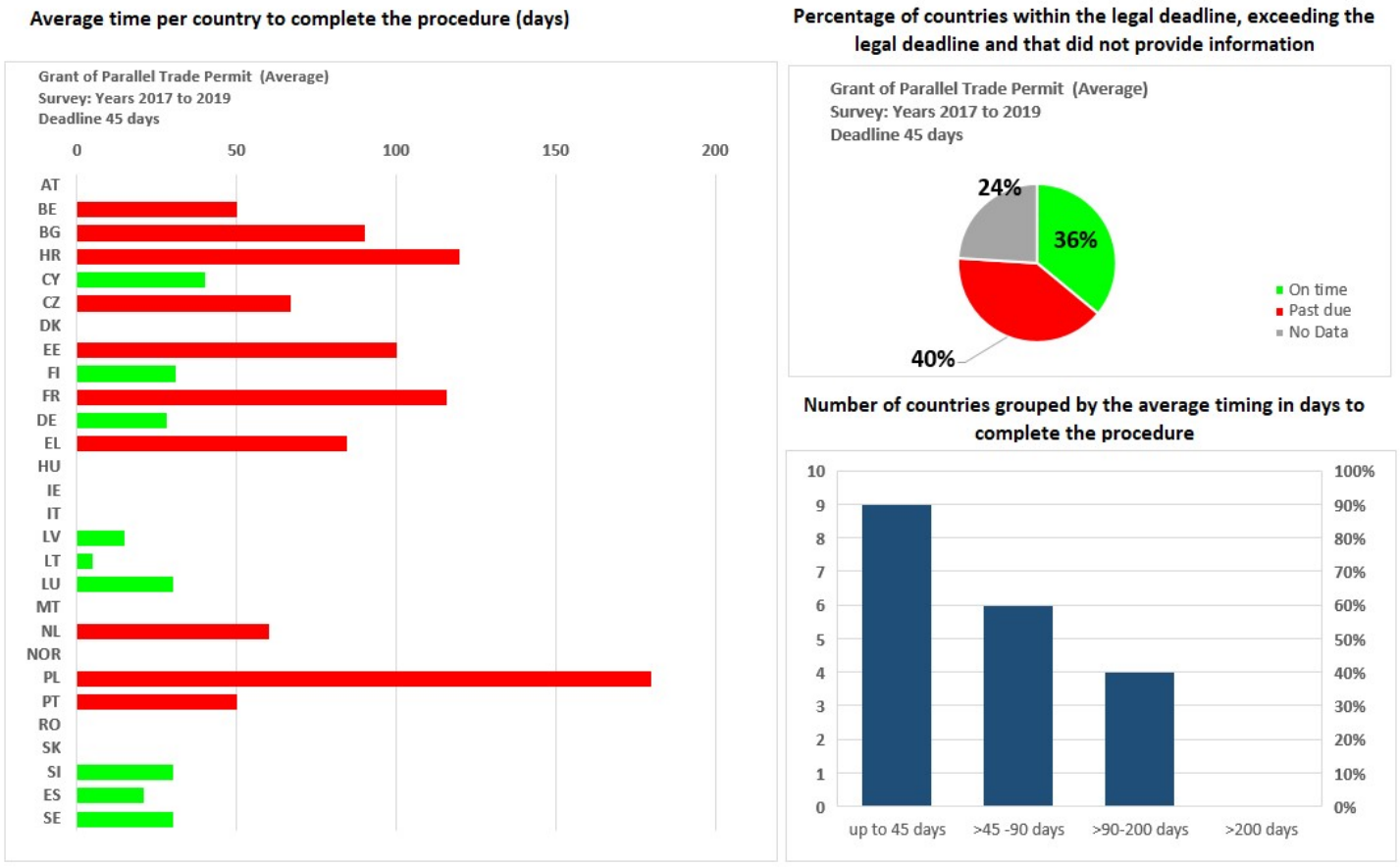


Figure 19: *Between 1 January 2017 to 31 December 2019: Average time in months per country to grant a parallel trade permit (left), compliance with the legal deadline of 45 days (top right), and number of countries grouped by the average timing in months to grant a parallel trade permit (bottom right).*

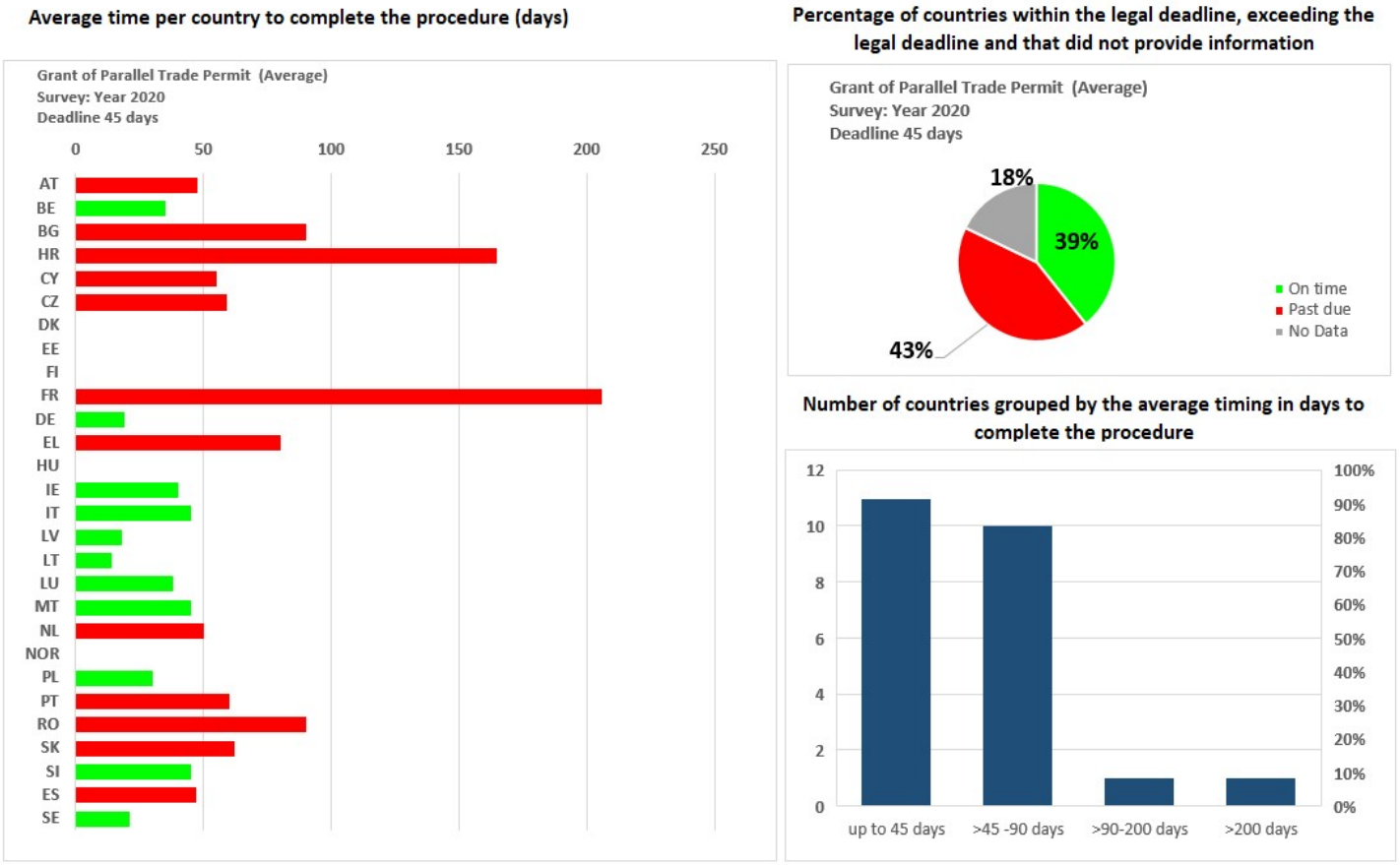
- ***2nd survey: from 1 January 2020 to 31 December 2020***

A total of **23 countries** out of 28 **provided information** on the timeline that they took to finalise this procedure. During this period, the **average** time taken by the countries to grant a parallel trade permit was **59 days.**

The **longest time** indicated by one country was **206 days** (see Figure 20).

Among the 23 countries that replied, **11 countries** were able to grant a parallel trade permit **within the legal deadline** of 45 days (green coloured).

See Figure 20 for detailed information.



Granting of a parallel trade permit																											
DE	**ES**	**PL**	**FR**	**SK**	**CY**	**CZ**	**BE**	**FI**	**HU**	**PT**	**AT**	**LT**	**EL**	**LU**	**SE**	**MT**	**BG**	**NL**	**IE**	**SI**	**HR**	**DK**	**LV**	**IT**	**RO**	**EE**	**NO**
437	436	142	101	94	92	49	43	36	31	19	18	15	13	12	12	12	9	9	5	5	4	4	4	2	1	0	0

Figure 20: *Between 1 January 2020 to 31 December 2020: Average time in months per country to grant a parallel trade permit (left), compliance with the legal deadline of 45 days (top right), and number of countries grouped by the average timing in months to complete the granting of a parallel trade permit (bottom right).*

The table below the graphs indicates the number (from the highest to lowest) of parallel trade permits that were granted by each Member State between 1 January 2020 to 31 December 2020.

4. CHALLENGES FACED BY COUNTRIES TO COMPLETE THE AUTHORISATION PROCEDURES FOR PLANT PROTECTION PRODUCTS WITHIN THE APPLICABLE DEADLINE

According to the answers provided in response to the survey, Member States cannot comply with the legal deadlines set out in Regulation (EC) No 1007/2009 since the total amount of applications received at national level is usually very high and there is insufficient staff available to process them. National authorities also claimed that the quality of dossiers submitted is often very poor.

Regarding the risk assessment process in the Member States, the obstacles to complete the work within the legal deadlines are:

- Burden created by significant administrative and technical requirements when conducting the assessment for product authorisations in combination with a lack of human resources to perform the assessments.
- The data gaps or issues that could not be finalised as listed in the EFSA Conclusions on the active substance(s) contained in the plant protection products, the need for amendments, extension of the timelines because of the request of additional information to the applicants, and the updates on the Guidance Documents.

In terms of planning, Member States stated that the authorisation procedures are affected by an unpredictability factor that may bring delays, e.g. procedures that require more evaluation capacity than anticipated, unpredictability when certain capacity is needed because of delays in active substance renewal or unpredictable start of evaluations when acting as concerned Member State (due to delays in the assessment by the zonal Member State).

In 2020, most Member States also explained that the processes were delayed because of the impact of the COVID- 19 pandemic.

5. ACTIONS SUGGESTED BY COUNTRIES TO IMPROVE COMPLETION OF THE AUTHORISATION PROCEDURES FOR PLANT PROTECTION PRODUCTS WITHIN THE APPLICABLE DEADLINE

To comply with the applicable legal deadlines, Member States suggested several actions in the surveys:

Regarding the application process, many Member States raised the need to improve the quality of the dossiers submitted by applicants. To do that, some Member States proposed to organise pre-submission meetings between applicants and national authorities to explain and clarify the existing data requirements while improving the collaboration between these actors. Some other Member States suggested creating a national electronic system for the submission of applications.

In general, many Member States consider that the administrative burden of the assessment process needs to be reduced.

In addition, and contrary to what was stated in the previous section, some Member States would like to have updated and/or new Guidance Documents.

Among Member States and in particular small Member States there is a consensus, that trainings (e.g. BTSFs[3], courses/webinars on new guidance documents, PPPAMS[4] and IUCLID[5]) are needed to increase the expertise for the authorization process.

Finally, -if there would not be any political or financial constraints- most of the Member States would immediately increase the number of staff involved in authorisation processes.

Annex II includes all the information reported by the countries in the survey.

[3] Better Training for Safer Food (BTSF) BTSF is a European Commission training initiative to improve the knowledge and implementation of EU rules covering food and feed law, animal health and welfare, as well as rules on plant health and plant protection products– https://ec.europa.eu/food/horizontal-topics/official-controls-and-enforcement/legislation-official-controls/better-training_en

[4] The Plant Protection Products Application Management System (PPPAMS) was developed by the European Commission to enable industry users to create applications for Plant Protection Products (PPP) and submit these to EU countries for evaluation. EU countries then manage these applications within the system, concluding with authorisation of the PPP or refusal of the application. See https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products/pppams_en

[5] International Uniform Chemical Information Database (IUCLID) - https://iuclid6.echa.europa.eu/

ANNEX I: AVERAGE TIME FOR COMLPETING THE PROCEDURES (2017-2019 AND 2020)

– Average time for completing the procedures (1 January 2017 to 31 December 2019)

Measure	Deadline	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	NOR	PL	PT	RO	SK	SI	ES	SE	# MS response	On Time %	Average	Maximum
Active Substance Evaluation as RMS	TBC		15,0								17,3										15									2	0%	16	17
Authorisation of PPP as ZRMS	12 to 18 months		28,0	20,0	15,0		19,0			17,0	29,4	45,0	19,5	18,0		21,0	19,0	6,5			23,0	14,0	17,0	18,5	2,0		15,0	11,0	15,0	20	50%	19	45
Authorisation minor uses PPP as ZRMS	12 to 18 months		8,0	6,0	4,0	1,0	11,0		0,5	3,5	26,4	27,3		6,0		6,0	5,0				5,8	4,3	6,0	3,0			2,0		4,0	18	89%	7	27
Authorisation low-risk PPP as ZRMS	4 to 10 months		6,0	3,0		1,0	17,0				22,5					8,0	2,0	1,9			12,0				1,5					10	70%	7	23
Authorisation PPP CfS as ZRMS	12 to 18 months						14,0			17,0	27,0					22,0	13,0								1,5		8,0			7	71%	15	27
Renewal of PPP as ZRMS	12 months		20,0				18,0			22,0	18,6	31,8	5,8	18,0			32,0	17,0			18,0	12,0	46,0	17,0			15,0		31,0	15	13%	21	46
Authorisation of PPP as CMS	4 months		9,0	6,0	8,0		23,0		6,0	20,0	11,0	42,1	10,0	13,0			4,0	3,3			9,9	8,4	7,0	2,5	1,5		8,0	4,0	4,0	20	30%	10	42
Minor uses PPP as CMS	4 months																													0			0
Low-risk PPP as CMS	4 months																													0			0
CfS as CMS	4 months																													0			0
Renewal of PPP as CMS	4 months												14,8																	1	0%	15	15
Mutual Recognition	4 months		5,7	6,0	12,2	2,7	5,5		6,7	11,6	13,2	16,0	9,0	13,0		6,0	4,1	4,6	2,7		9,3	5,1	5,7	3,1	1,0		8,0	6,3	4,0	23	22%	7	16
Grant of Parallel Trade Permit	45 days		50,0	90,0	120,0	40,0	67,0		100,0	31,0	116,0	28,0	84,4				15,0	5,0	30,0		60,0		180,0	50,3			30,0	21,0	30,0	19	47%	60	180

# of responses MS	0	8	6	5	4	8	0	4	7	9	6	6	5	0	5	8	6	2	0	7	5	6	6	5	0	7	4	6				
# on-time	0	2	2	2	4	2	0	1	4	0	1	1	2	0	2	5	4	2	0	1	3	2	3	5	0	4	3	5				
% timeliness by MS		25%	33%	40%	100%	25%		25%	57%	0%	17%	17%	40%		40%	63%	67%	100%		14%	60%	33%	50%	100%		57%	75%	83%				

Legend
On time
Past due
No Data

Average time for completing the procedures (1 January 2020 to 31 December 2020)

Measure	Deadline	AT	BE	BG	HR	CY	CZ	DK	EE	FI	FR	DE	EL	HU	IE	IT	LV	LT	LU	MT	NL	NOR	PL	PT	RO	SK	SI	ES	SE	# MS response	On Time %	Average	Maximum
Active Substance Evaluation as RMS	TBC																													0			0
Authorisation of PPP as ZRMS	12 to 18 months	18,3	18,0	18,0			19,0	10,6			22,6	51,9	14,2	24,0		24,0	15,0	15,0		12,0	26,0		15,0			24,0	16,0	16,8	13,2	19	58%	20	52
Authorisation minor uses PPP as ZRMS	12 to 18 months			18,0					0,5			21,7				12,0							14,0				10,0		6,4	7	86%	12	22
Authorisation low-risk PPP as ZRMS	4 to 10 months		7,0	10,0							14,5					16,0					10,0									5	60%	12	16
Authorisation PPP CfS as ZRMS	12 to 18 months	17,1	32,0	18,0			20,0				14,1					24,0	14,0			12,0	32,0							19,1		10	50%	20	32
Renewal of PPP as ZRMS	12 months	28,2	55,0	18,0			25,0	27,0			33,6	30,5	4,3	24,0		18,0	25,0	8,0		12,0	24,0		16,0	25,0			12,0	20,5	12,3	19	21%	22	55
Authorisation of PPP as CMS	4 months	23,3	10,0	6,0	8,0		4,0	39,4	6,0	12,7	8,4	7,6	7,0	13,0	4,0	6,0	3,3	3,5		4,0	8,3		6,0	2,6	10,0	22,0	9,0	10,9	3,2	25	28%	10	39
Minor uses PPP as CMS	4 months		9,0	6,0					0,5			5,5				6,0		3,5			4,8		5,0	3,0			6,0			10	30%	5	9
Low-risk PPP as CMS	4 months	19,2		4,0												6,0							3,5		10,0			4,7		6	33%	8	19
CfS as CMS	4 months	29,8	10,0	6,0	8,0		7,5				10,1						3,0	3,0			12,0		7,0		10,0	22,0		6,9	3,8	14	21%	10	30
Renewal of PPP as CMS	4 months	18,4	28,0	6,0			7,0		6,0	25,2	13,2	10,8	7,4	12,0		16,0	8,3	3,0	2,5		7,6		9,0	12,0	10,0	22,0	9,0	21,2	3,7	22	14%	12	28
Mutual Recognition	4 months	10,7	9,0	7,0	11,0	3,0	4,5	12,2	6,0	11,3	12,0	9,1	8,7	13,0	4,0	6,0	4,0	3,0	2,5	4,0	12,0	13,6	5,5	3,9	6,0	19,0	9,0	6,0	3,7	28	29%	8	19
Grant of Parallel Trade Permit	45 days	47,5	35,2	90,0	165,0	55,0	59,0				206,0	19,0	80,0		40,0	45,0	18,0	14,0	38,0	45,0	50,0		30,0	60,0	90,0	62,0	45,0	47,0	21,0	23	48%	59	206

# of responses MS	9	10	12	4	2	8	4	5	3	9	8	6	5	3	11	8	8	3	6	10	1	10	6	6	6	8	9	8
# on-time	1	3	5	0	1	1	1	2	0	1	1	2	0	3	2	6	8	3	6	1	0	4	3	0	0	4	1	7
% timeliness by MS	11%	30%	42%	0%	50%	13%	25%	40%	0%	11%	13%	33%	0%	100%	18%	75%	100%	100%	100%	10%	0%	40%	50%	0%	0%	50%	11%	88%

Legend
On time
Past due
No Data

ANNEX II: CHALLENGES REPORTED BY THE MEMBER STATES AND NORWAY TO COMPLETE THE AUTHORISATION PROCEDURES WITHIN THE APPLICABLE DEADLINE AND ACTIONS SUGGESTED TO OVERCOME THEM

Application process

- Low **quality of the dossiers** and increasing workload due to Brexit.
- Registration of products based on the conclusions of the evaluation of active substances at EU level is very complex, in particular because of the **data gaps**.
- **National legal procedures** that allow the submission of additional data at any time of the application procedure, thereby prolonging approval/authorisation processes.
- Extension of the timelines because of **the request of additional information to the applicant.**
- No maximum limit of applications accepted per year is established and no legal basis to reject applications because of this.
- Different attitude of authority to the lack of cooperation or insufficient information from applicant.

- **Quality of the applications** needs to be improved by providing complete and reasoned applications since the first steps.
- Data submitted in the dossiers must better comply with the endpoints validated at EU level and apply the current Guidance Documents. To improve compliance the agency of this Member State has introduced a **pre-submission form** for applicants.
- Organise **pre submission meetings** with the applicants to explain the existing requirements.
- Good **communication** between applicants and Member State during assessment phase.
- The National Authority of one Member State started to carry out an **administrative check on all the documents received from applicants** before the transmission of documents to technical experts. This reduces issues related to inadequate documentation provided from applicants, avoiding the need to address such shortcomings after the commencement of evaluations. The Authority has also started to compile a **reporting table before the finalisation of the Draft Registration Report** (DRR). The table is sent to the applicants, giving them an adequate opportunity to meet the requests before the finalisation of the DRR. This reduces issues, which are raised during or after the commenting period and that typically take a long time to address.

Evaluation process:

- **Complexity** of the active substances.
- Contribution to EU **glyphosate renewal**: delivering the glyphosate contribution within the required timelines did (and does) affect the other authorisation procedures.
- **Harmonise** the evaluation methodology and application of guidance documents.
- **Improve the EFSA conclusions** of the active substances.

- Closed connection between coordinators (authority) and experts (evaluation) are needed for an optimal authorisation process. In addition, both actors should be in the same place so that no email correspondence is required.
- Bureaucratic requirements should be reduced (e.g. committees with people from different ministries, involving different institutes into evaluation, etc.).

Art. 36 – Examination for authorisation:

- **Additional national risk assessment** is needed (**national Risk Mitigation Measures** – Art. 36(3)).
- Member States must have a **common understanding** on the application of Art. 36(3) in authorisation procedures. There must be agreement that the Zonal Rapporteur Member State (ZRMS) must evaluate the applications for the Concerned Member State (CMS). The ZRMS must make the decision for the CMS, and the CMS must adopt this decision. The CMS does not have the possibility to make their own assessment.

Art. 40 - Mutual recognition

- **Quality** of applications for mutual recognition should increase and be updated to include national environmental requirements when the mutual recognition is applied from a different Zone. This would aim to assure the protection of specific environmental conditions as in the Northern Zone because frequently the national/zone environmental requirements are not met in the original review report in particular when the risk assessment of the product is old.
- **Improve the unpredictability** of mutual recognition applications.
- There must be an agreement that Art. 34 – Exemption from the submission of studies- cannot be applied across the board to complete authorisations ("me too authorisations"). At the very least, it must be clear that authorisations issued by one Member State under Art. 34 must not be accepted for mutual recognition according to Art. 40 in another Member State.

Art. 43 – Renewal of authorisation

- More stability concerning **planning**. It is very **hard to foresee** when the re-assessment of an active substance will be completed and voted on in the PAFF-meetings. This makes it hard to plan to have available resources to do the Art 43 evaluations. The delays and repeated extensions of active substance approval periods also make it challenging to make a credible budget.
- Workload on Art. 43 after renewal of the active substance.
- Deadlines imposed by the Art. 43 are difficult to comply with. Updates on the guidance documents, adding additional data requirements requires time for teams and the applicants to adapt and it leads to an extension of the assessment.
- An **improvement in the finalisation of the EFSA conclusions** on active substances would make it easier to meet the deadlines for dossiers under Art. 43.

Maximum Residue Levels (MRLs):

- Timelines for setting MRLs according to Art. 10 of the Regulation (EC) No 396/2005 are difficult to predict. Then, even if the plant protection product assessment is completed, the decision is pending before the publication of the regulation that set the MRL for the concerned crop. The predictability of this procedure should be improved.

Regulatory deadlines:

- Mutual recognition: calculation of 120 days should start when the application is completed because many times the application needs to be completed by national requirements, administrative or technical documents.
- Deadlines are **unrealistic**.
- **Amendment of the Regulation** regarding the required deadlines.

Others:

- The decisive **state of science and technology** for authorisation procedures must be defined. The European Commission should make a clear statement on this: Is it permissible to anticipate ongoing approval procedures? Or is it rather the case that the state of the art in science and technology is defined by EU regulations valid at the time of application?
- National actions, such as improved national guidance, improved routines and prioritising to comment on other Member States' evaluations more actively.
- Reduce the **administrative burden.**
- A national **electronic system for the submission of applications** might help to comply with the deadlines.
- Full implementation of the electronic procedure.
- Priority in **development and updates of Commission Guidance Documents.**
- Possibility to **visit more experienced Member States to learn** and observe.
- Increase the **number of public officials** dealing with the authorisations and improve their job conditions.
- Lack of mechanisms to retain **younger experts**.
- Most of the time of the experts is used for assessing active substances rather than for plant protection products.
- More **trainings** to increase the expertise of the evaluators in particular in small Member States.
- Continuous training programs (e.g. BTSF) and meetings (e.g. EFSA meetings to discuss general recurring issues) relevant for the risk assessment of plant protection products. e.g. courses/webinars on new guidance documents, training in applications systems such as PPPAMS and IUCLID, training in procedures for evaluating active substances and plant protection products.
- **Merging** of all expert **workplaces** involved in the coordination and evaluation of active substances and plant protection products into one location to optimise the process and avoid as much as possible email correspondence.