

Approval / Renewal of approval of Active Substances: Overview of timing for delivery of by the RMS (Rapporteur Member State) , EFSA (European Food Safety Agency) and the Commission

(State of play May 2020)

The figures below summarise delivery times for 4 steps in the regulatory process for the approval of active substances:

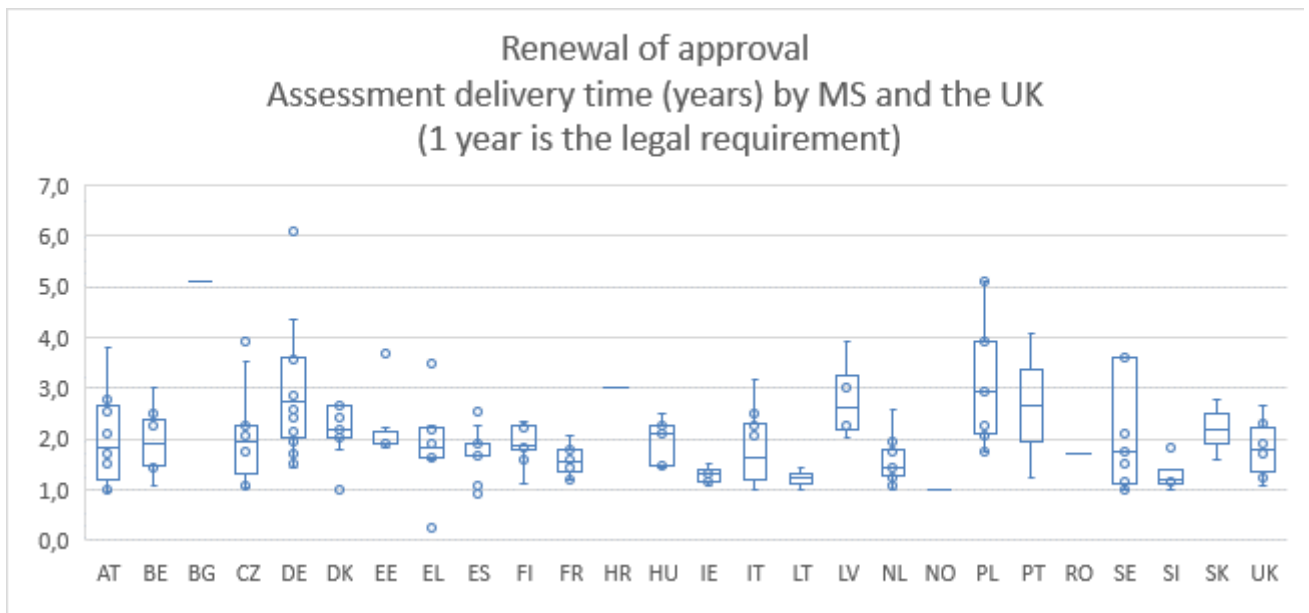
- 1) time for Rapporteur Member States (and co-rapporteur Member States) to deliver the draft Assessment Report (DAR) or draft Renewal Assessment Report (RAR) to EFSA on the basis of an application dossier
- 2) time for EFSA to conclude on the peer review (from the time it receives the draft DAR or RAR) and make available to the Commission the finalised EFSA Conclusion
- 3) time for the Commission to deliver a draft review report/renewal report to the Standing Committee for Plants, Animals, Food and Feed (PAFF Committee)
- 4) time between the 1st presentation of the draft review report/renewal report to Member States and the final vote in the PAFF Committee

The figures below are given in Box-plot graphs, which represent:

- The box represents 50 % of the cases, between the 25 % and the 75 % quartile. The line in the middle represents the average (mean).
- The lines coming out of the boxes represent the standard deviation.
- Open circles represent each single case.

1) Delivery time for Rapporteur Member States (and co-rapporteur Member States) to deliver the Assessment Report (DAR or RAR) to EFSA on the basis of an application dossier (legal deadline one year; extendable by 6 months for new active substances but not for renewals)

- a) The number of dossiers assessed by Member States vary : some are dealing with significantly more dossiers than others
- b) Evidence shows that almost all DARs and RARs are delivered late
- c) Delays vary from a few months to several years

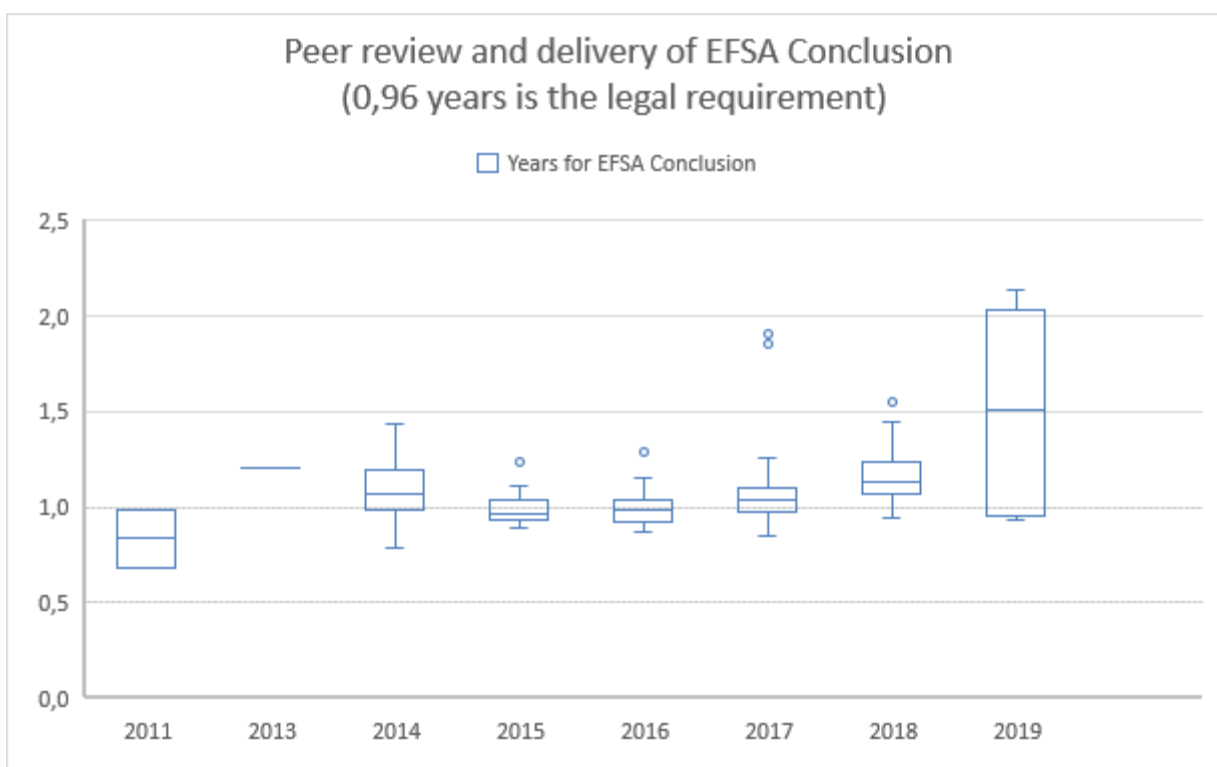


Explanation: This analysis is based on 204 dossiers for renewal of approval of active substances as follows:

- Only renewal dossiers for which an application and dossier was received and considered admissible are included (withdrawn dossiers were not considered)
- Dossier submission under Regulation (EC) No 1107/2009 until February 2019 (first dossiers submitted in 2012)
- DAR/RAR submission by Rapporteur Member States from 2014 onwards (if no Assessment Report was submitted so far, the default date of 31 May 2020 was taken for the purpose of statistics)
- For many of the dossiers, the peer review or decision-making processes are still going on or not yet initiated, therefore the sample size (204) is higher than for the graphs below

2) Delivery time for EFSA (European Food Safety Agency) to conclude on the peer review (from the time it receives the draft DAR or RAR) and to send to the Commission its conclusions (maximum legal deadlines are 11,5 months for renewals, 13,5 months for new active substances)

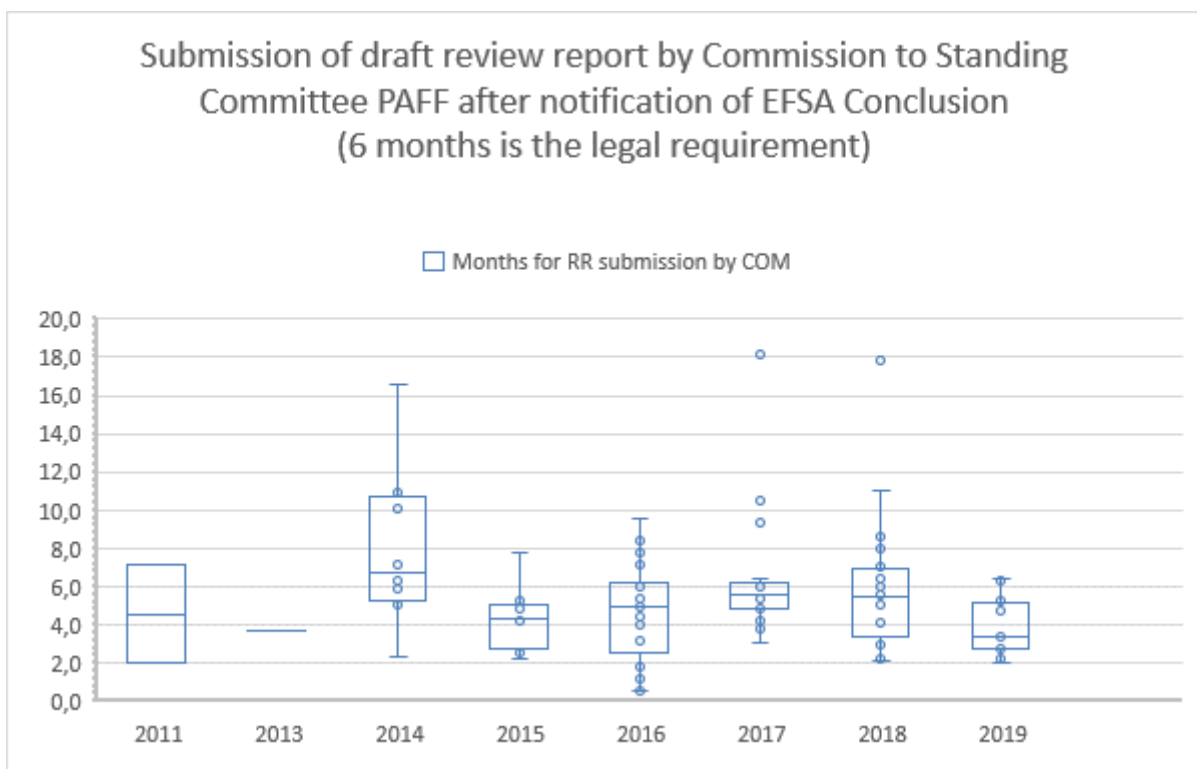
- a) **EFSA has historically been delivering rather well** within the foreseen timeframe, with few exceptions
- b) Starting in 2018, and even stronger in 2019, an increase of the time needed by the Authority can be seen, which is explained by the implementation of the new criteria to identify endocrine disruptors. These criteria trigger an additional “stop the clock” mechanism of up to 30 months followed by 7 months for the assessment of the newly submitted data. For those substances, the 11.5 months deadline is no longer applicable.



Explanation: This analysis is based on 103 dossiers for which the EFSA Conclusion was available from 2011 until the end of 2019. Withdrawn dossiers were not considered. The years in the x-axis indicate the year the EFSA Conclusion was finalised.

3) Delivery time for the Commission to submit a draft review report/renewal report to the Standing Committee for Plants, Animals, Food and Feed (legal deadline 6 months)

With the exception of 2014, the **average delivery time for a first presentation of a draft review report/renewal report (RR) to the PAFF has been mostly within the legally required time of 6 months**. However some considerable delays have been observed in individual cases, e.g. 2014, 2017, 2018.

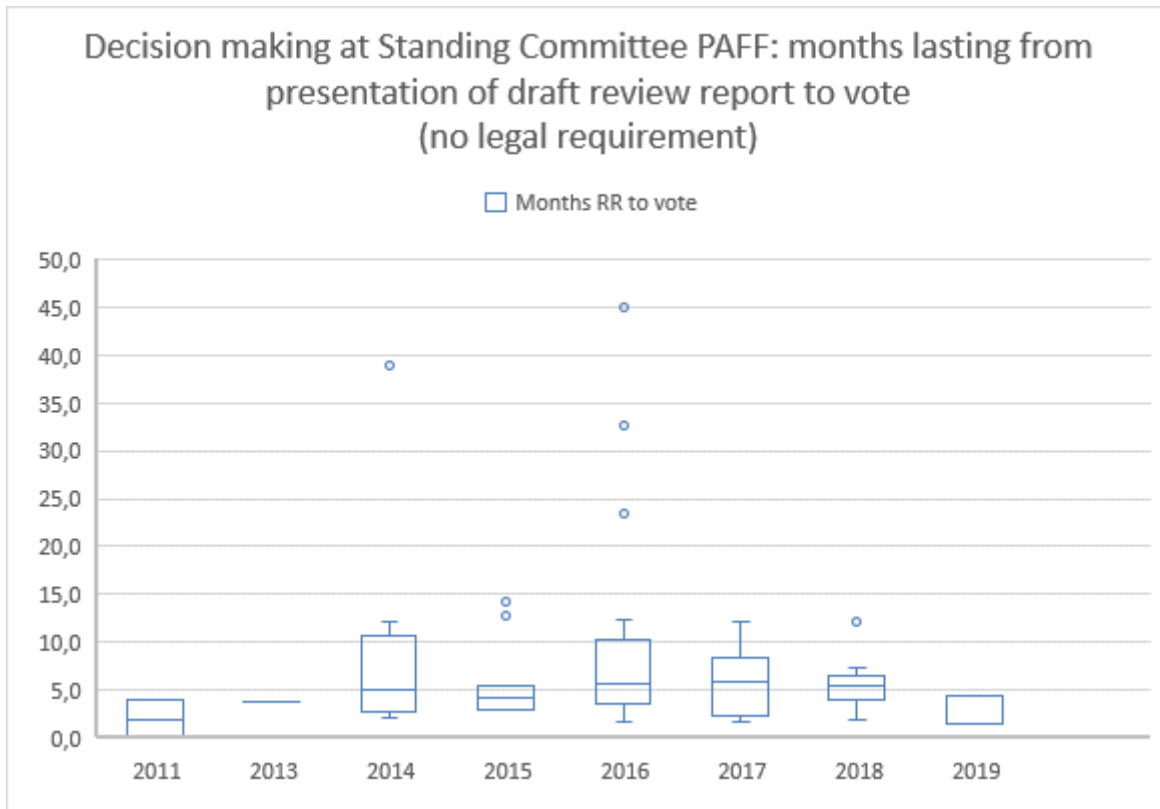


Explanation: This analysis is based on 103 dossiers for which the EFSA Conclusions were available from 2011 until end of 2019. Withdrawn dossiers were not considered. EFSA Conclusions published in 2020 were not considered because the 6-month period for submission has not yet expired.

The years in the x-axis indicate the year the EFSA Conclusion was finalised

4) Time between the 1st presentation of the draft review report/renewal report to Member States and the final vote in the PAFF Committee (discussion time at Committee level)

The discussion time in PAFF from the 1st presentation of a draft RR until the vote is in **average around 5 months**, although in some cases it can take several years (e.g. for some cases mandates had to be sent EFSA for re-evaluation of certain aspects, which were considered necessary to clarify in order to progress with decision-making and to achieve qualified majority at the Committee).



Explanation: This analysis is based on 103 dossiers for which the EFSA Conclusion was available from 2011 until end of 2019. Withdrawn dossiers were not considered. EFSA Conclusions published in 2020 were not considered.

The years in the x-axis indicate the year the EFSA Conclusion was finalised.