

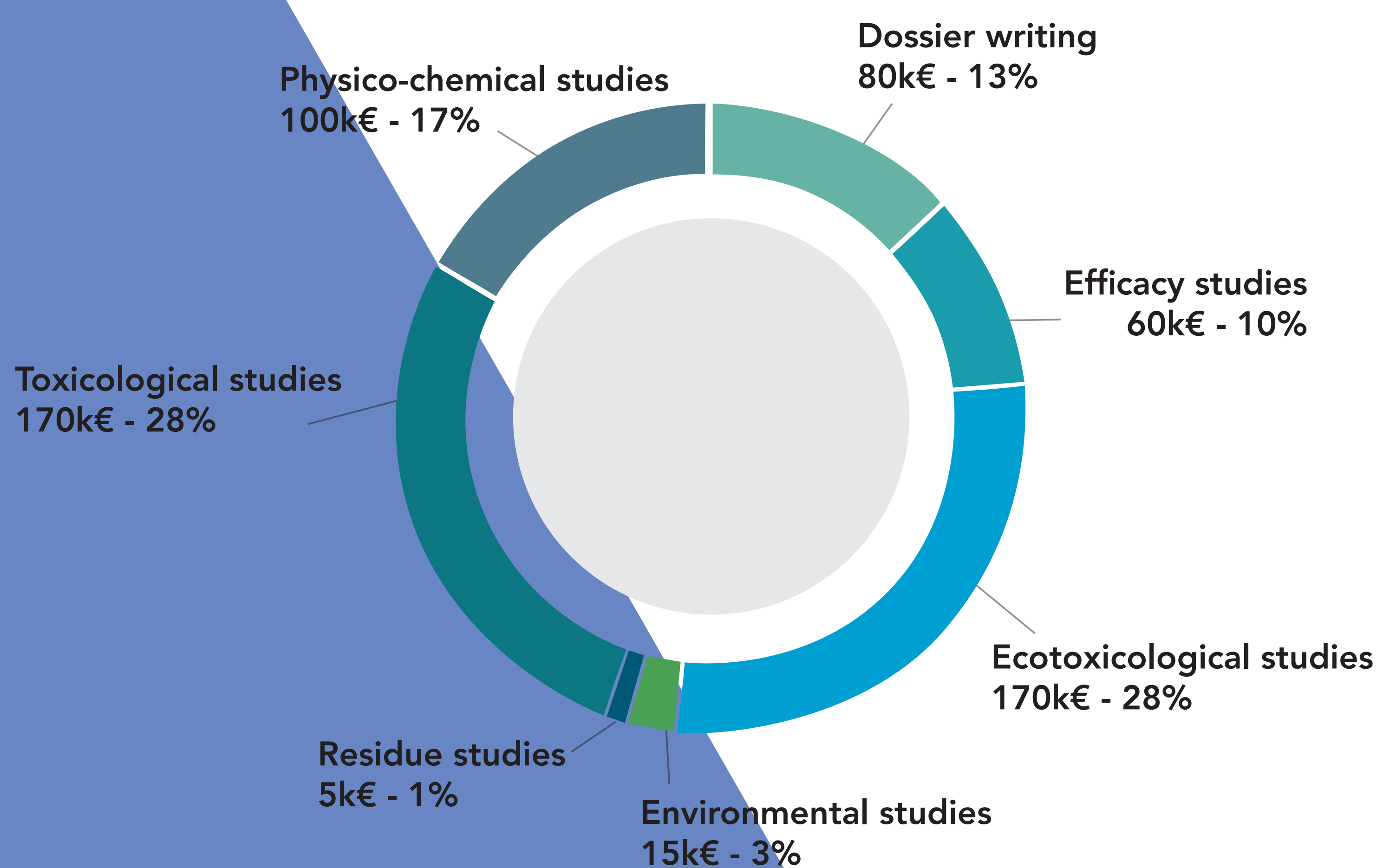
HOW TO REGISTER A BIOPESTICIDE PRODUCT IN EUROPE?

In Europe, biopesticides have been commonly defined as a form of plant protection product based on microorganisms or natural product. They therefore contain biological control agents (microbials, natural substances, pheromones, etc).

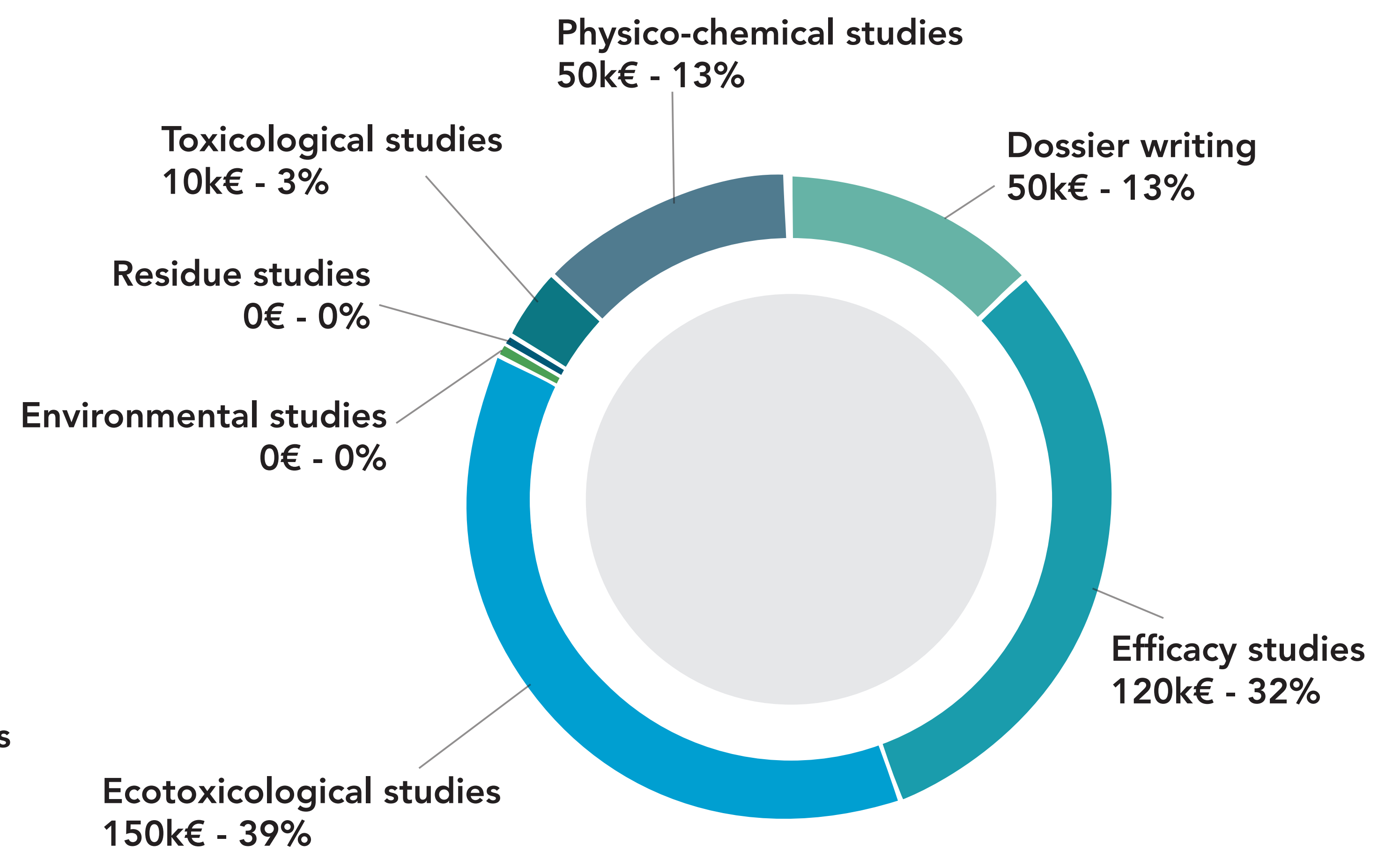
What budget?

The data required covers different areas which are listed in Regulation (EC) No 1107/2009 and other related regulations, guidelines and guidance documents; some can be specific to a biopesticide type (ex. Microorganismes, botanical extracts). The assessment of biopesticides follows the same process as other pesticides in Europe: the approbation of the active substance at European level followed by a registration of the product at country level. In the registration dossier, reliable and robust studies are essential for classification, as well as for assessing exposure risk using the provided data in conjunction with suitable models and tools.

Example of cost for development of Active Substance dossier, for low risk natural extract (september 2023)
600 k€ / 1-1,5 years vs synthetic 7-10 M€ / 3-5 years



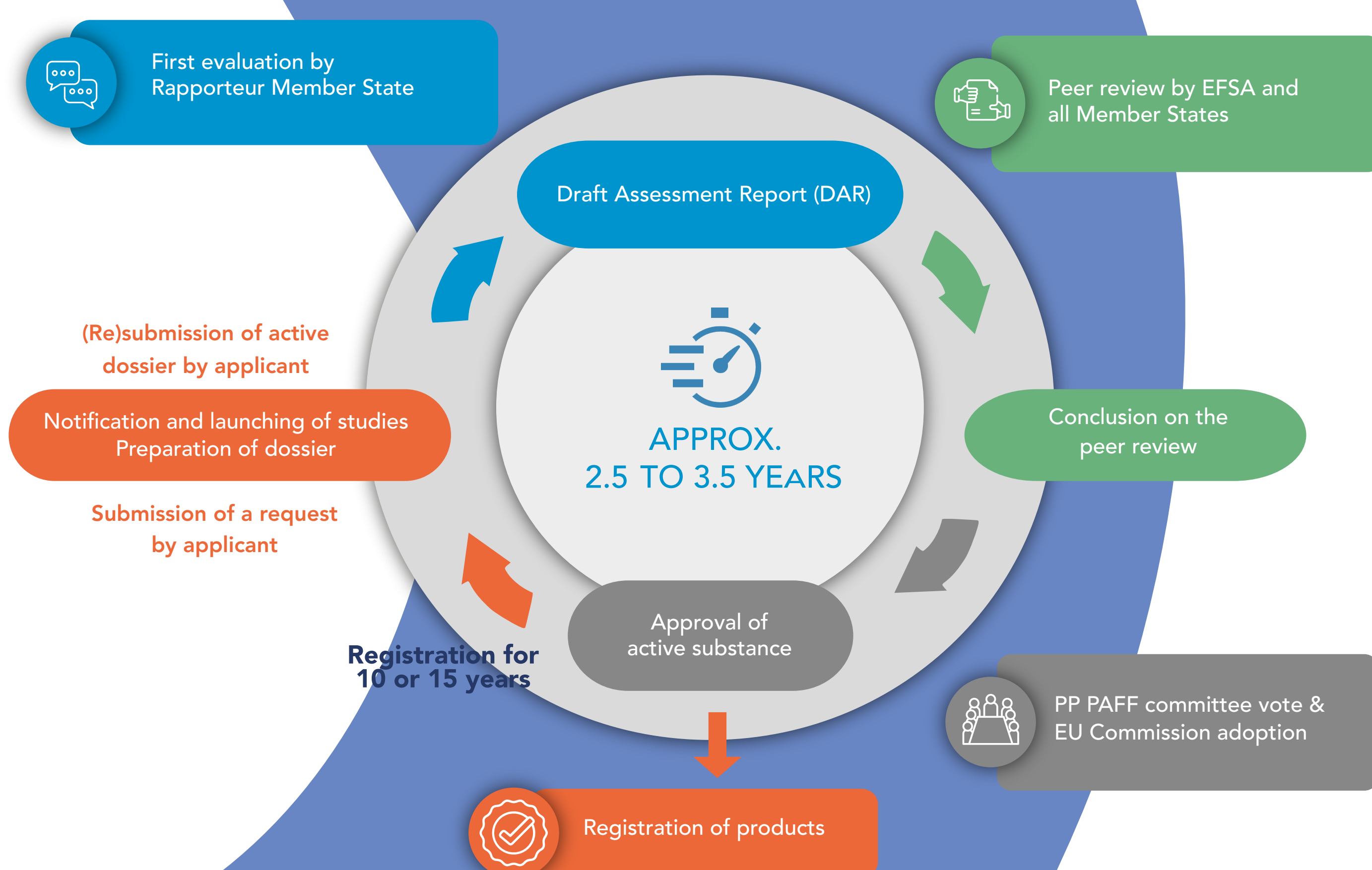
Example of regulatory development cost of a biopesticide Product dossier excluding registration fees (september 2023)
380 k€ / 1-1,5 years vs synthetic 0,5-1 M€ / 5 years



What timeline?

Approval of Active Substance in Europe

Evaluation of an active substance may lead to a low risk classification (criteria set out in Reg. com. (EU) 2017/1432). But as the criteria may not always be fully completed, expert judgment is often required.



National registration of the product

The European zonal authorisation system is divided into three zones: Northern, Central and Southern.

An EU country assesses an application on behalf of other countries in their zone and sometimes on behalf of all areas for indoor and greenhouse uses, post-harvest treatments and seed treatments.



Think it's that simple?

In this complex landscape, Staphyt team is uniquely equipped to tackle these key challenges with a tailor-made approach:

- What are the risks associated with your biopesticide?
- Finding the perfect regulatory match for your product?
- How to have reliable and robust studies based on accurate markers?
- What is the mode of action, the efficacy of your substance?

Come meet us on booth #97