Regulatory Process - EU-legislation

1-2

This is the phase, where the product is developed and where all the relevant studies are conducted. **It takes 8 to 10 years** and only **one out of 160,000 to 180,000 molecules** would come through.

8 - 10 years

80,000 pages

1. Risk research

2. Active substance dossier

2

The Active-Substance dossier contains the whole information on the active substance and can comprise easily **80,000 pages with hundreds of studies**. This package also contains the first residue studies and it also contains the information on the so called representative formulation with at least **one safe use**. This safe use is the **pre-requisite for the registration** of an active substance on EU-level.

3

The dossier is submitted to a so called **Rapporteur Member State (RMS**) who is then the caretaker for this active substance in the EU. After a "Check of Completeness", the RMS (sometimes supported by a Co-RMS) creates the **Draft Assessment Report (DAR)**, which is the first evaluation of the new compound on EU-level. (This process takes app. **1.5 to 2 years**)

3. Draft Assessment Report (DAR)

1.5 - 2 years

4-6

The DAR is distributed among the member states and is also sent to the **EFSA (European Food Safety Authority)** that conducts a **Peer Review** and comes up with an EFSA conclusion. Before the peer review, there is also a **public commenting phase**, where anybody can place comments.

4. Comments by EU member states, EFSA and the public

5. EFSA member state peer review plus final DAR

6. EFSA opinion

7-9

After this, the EFSA- and MS(member state)-peer reviewed opinion goes to the **EU Commission, DG SANTE,** who prepare a **legislative proposal** for discussion in a Standing Committee and finally **voted or rejected by all MS.** A positive vote requires a **qualified majority of MS voting for the active substance.**

7. Proposal of the EU Commision (EC)

8. Vote on EC proposal by EU member states

9. European approval of active substance by EC

10 - 14

Only after the successful approval of the active substance, the products, containing this active substance can be submitted to the member states. **The EU is divided into 3 zones** (northern, central and southern zone plus one so called inter-zone for glasshouse and seed treatment uses). In each zone a so called **zonal rapporteur member states** evaluates the product dossier (which is much shorter than the active substance-dossier, but it contains all planned uses for the zone). The zonal evaluation is shared among the other countries of a zone and after the first approval in the zonal RMS, the other countries of the zone can also approve the product by mutual recognition. This does not happen in all cases, sometimes, **countries refuse to accept the mutual recognition and impose their own restrictions and limitations.**

10. Product dossier

11. Zonal evaluation by zonal rapporteur member state (ZRMS)

12. Comments by concerned member states (CMS)

13. Product approval by ZRMS

14. National evaluation / mutual recognition by national authority

15. National product approval

16-17

After authorisation in a country, the product can be sold to the farmer and can be applied by the farmer according to the registered GAPs (Good Agricultural practice) and label restrictions.

16

Some big retailers (e.g. ALDI, LIDL…) have their own internal rules and limit the number of pesticides used on an agricultural commodity or they reduce the residue level (MRL) on fruits and vegetables below the official MRL. This can lead to an additional restriction in usage of plant protection products.

16. Private market restrictions

17. Product for farmer

ECHA classification

The European Chemical Agency (ECHA) is in charge of the classification of all industrial chemicals according to the Global Harmonized System (GHS). Agrochemicals and Biocides are also evaluated and classified by ECHA. The ECHA classification is independent of the EFSA evaluation. Nevertheless, a classification as Carcinogenic, Mutagenic, Reprotoxic (CMR) 1a or 1b or as PBT (persistent, bioaccumulative and toxic) can lead to a ban of a product according to EU Regulation 1107/2009.

Maximum Residue Limits

The setting of MRLs follows a different regulation (EU Reg. 396/2005) but it is also conducted by EFSA and undergoes a similar procedure as the evaluation of the active substance: RMS-EFSA-COM (Standing committee) and in addition scrutiny by EU Parliament. Only if MRL are set, a product can be placed on the market.