What does it take to add a new tool to the tool box?

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The following process has been highly simplified with the purpose of illustrating a long and complex process from development to sales of a conventional plant protection product. The story begins when a farmer encounters a challenge that compromises the health of his crop. First, the problem must be accurately identify, a potential product must be selected (screen >100,000 potential candidates to select one for submission), an initial formulation developed and efficacy testing initiated to determine the interim Directions For Use (DFU's). Second, registrants must demonstrate that the product can be safely used and will not result in any unreasonable adverse effects to humans and the environment. In this stage, residue, toxicology, environmental, ecotoxicology and metabolism studies are conducted on the active ingredient and DFU's are finalized. Simultaneously, the synthesis process and formulation are optimized. All the scientific data are incorporated into a risk assessment to ensure safe use and regulatory compliance. Third, with a positive result, the registrant assembles the dossier according to regulatory agency requirements and company regulatory strategies (register in one country, one region, or globally). The review and approval process can take 2 or more years. Finally, in the USA, either at dossier submission or after registration, companies must apply for state regulatory approvals, where they plan to sell, distribute or use the product. The state registration process can take from 1-18 additional months. Only then will the farmers/end-users be able to add a new plant protection tool to their toolbox. In the USA, this process is estimated to cost approximately 250 million dollars or more.