

Time and Cost of **New Agrochemical Product Discovery, Development and Registration**

Study Results

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AgbioInvestor



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Executive Summary



Executive Summary:

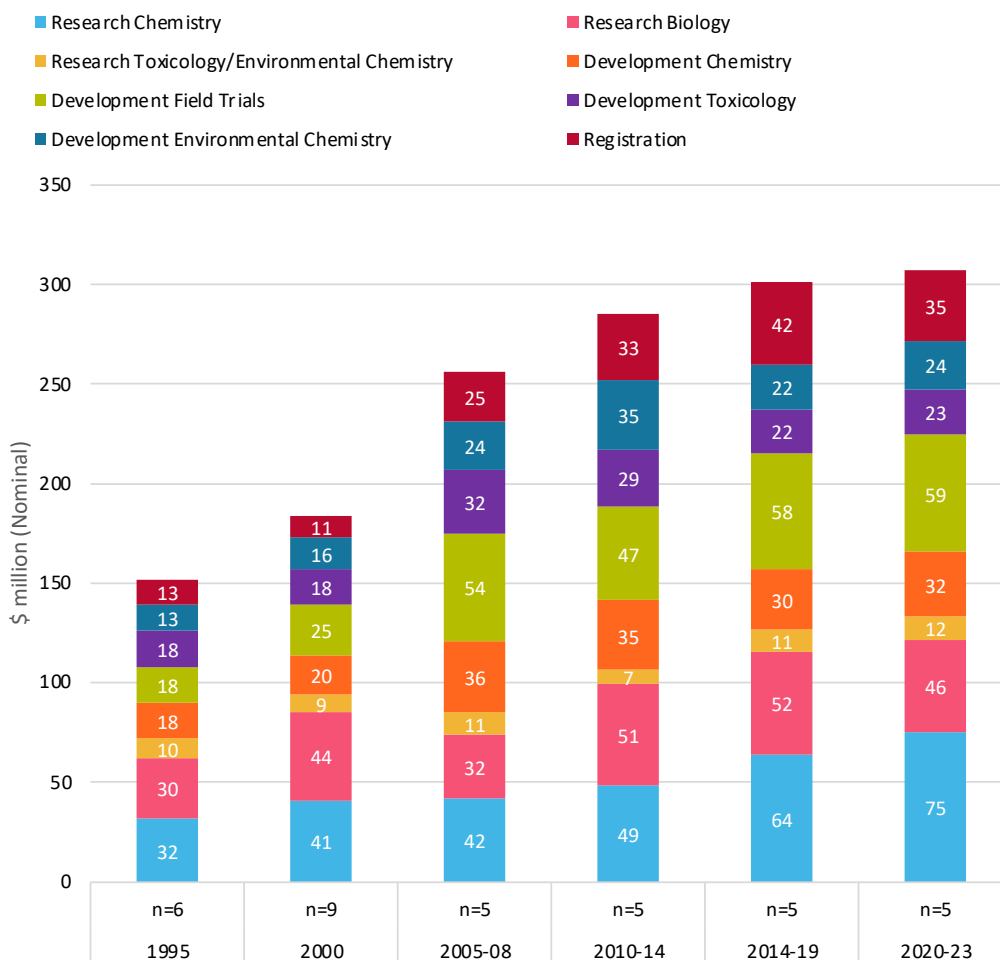
The Cost to Bring a New Active Ingredient to the Market

This study presents the results of a survey of the leading crop protection companies designed to determine:

- The expenditure necessary for discovering and developing a new crop protection AI in 1995, 2000 and in the 2005 to 2008, 2010 to 2014, 2014 to 2019 and 2020 to 2023 periods, in nominal terms.
- The average time between initial synthesis and launch.
- Nominal costs associated with obtaining and maintaining a CODEX MRL (new active, additional/new use and periodic review) in the 2020 – 2023 timeframe.
- Nominal costs associated with the re-registration (including fees, studies etc.) of an AI that was re-registered in the 2020 – 2023 timeframe.

Five companies were surveyed for the period 2020 -2023, and the results were as follows:

Discovery & Development Costs of a New Active Ingredient (Mean Average)



Note: Chart values are rounded to the nearest \$ million for presentation purposes. The overall total reported in the text is based on unrounded figures.

n = the number of survey responses. Component values may not sum to the total due to rounding.

Executive Summary: The Cost to Bring a New Active Ingredient to the Market

The overall costs of the discovery and development of a new crop protection AI increased by 21.1% from \$152 million (€115 million) in 1995, to reach \$184 million (€140 million) in 2000. From 2000 to the 2005-08 period, costs increased by 39.1% to \$256 million (€189 million). From 2005-08 to the 2010-14 period, costs further rose by 11.7% to \$286 million (€215 million). Between the 2010-14 and 2014-19 periods, costs rose by 5.7% to \$301 million (€261 million). The latest survey indicated that the costs associated with bringing a new active ingredient to the major US and European markets had increased by 1.9% to \$307 million (€276 million).

The survey results demonstrated that the average cost of new AI research rose by 30.6% from \$72 million per AI in 1995 to \$94 million in 2000, but declined slightly to \$85 million in 2005-08, attributed to cost savings potentially made due to greater efficiency from high throughput screening, combinatorial chemistry and genomics. However, between 2005-08 and 2010-14, the cost of researching a new agrochemical active ingredient increased by 25.9% to \$107 million, with the 2014-19 survey results indicating that research expenditure increased a further 18.9% to \$127 million. In the latest survey, spending increased by a further 5.3% to \$133 million.

The survey results demonstrated that the average cost of taking an AI through development stages increased from \$67 million in 1995 by 17.9% to \$79 million in 2000, by 84.8% to \$146 million by 2005-08 period and remained at that level in the 2010-14 period. For the 2014-19 period, spending decreased by 8.5% to \$133 million. The latest results show a 4.0% increase in expenditure on the development phase, driven by increased development spending on chemistry (+6.9%), biology (+0.6%), toxicology (+5.1%) and environmental chemistry (+8.0%) studies.

Between 2014-19 and 2020-23, the average cost of chemistry (synthesis and formulation) in the research phase rose by 17.4% to \$75 million, representing the largest single operational cost in the R&D of a new agrochemical. The next largest cost is field trials (large scale and registrations) in the development phase, which increased marginally by 0.7% to \$59 million. Biological screening expenditure has declined by 9.9% to \$46 million, accounting for only 15% of total R&D expenditure allocated to new crop protection product discovery and development. As recently as the 2010-14 study, biological screening represented the most significant cost involved in the process.

Executive Summary: The Cost to Bring a New Active Ingredient to the Market

The 2020-23 survey indicates that average registration costs have decreased by 15.4% to \$35 million, representing approximately 12% of the total expenditure. This represents a decline from the previous study, in both nominal and proportionate terms (registration accounted for 14% of expenditure in previous study), although both the nominal and proportionate values remain high by historical standards. Over the longer term, registration costs have increased both in nominal terms and as a proportion of overall costs since the first edition of this survey, rising from an average of \$13 million in 1995 at 8.6% of the overall costs.

While costs have steadily increased, the survey results also demonstrated that the average lead time between the first synthesis of a new crop protection molecule and its subsequent commercial introduction has decreased from the previous study to just over 11 years, although the longer term trend indicates growing lead times. This increase could reflect greater complexity in the data requirements of regulatory bodies. Another potential contributing factor could be that regulatory bodies refrain from granting conditional approvals.

Crop Protection AI Discovery and Development Lead Time						
	1995	2000	2005-08	2010-14	2014-19	2020-23
Number of years between the first synthesis and the first sale of product containing AI	8.3	9.1	9.8	11.3	12.3	11.4

Executive Summary: Breakdown of Expenditure Devoted to the R&D Process 2023

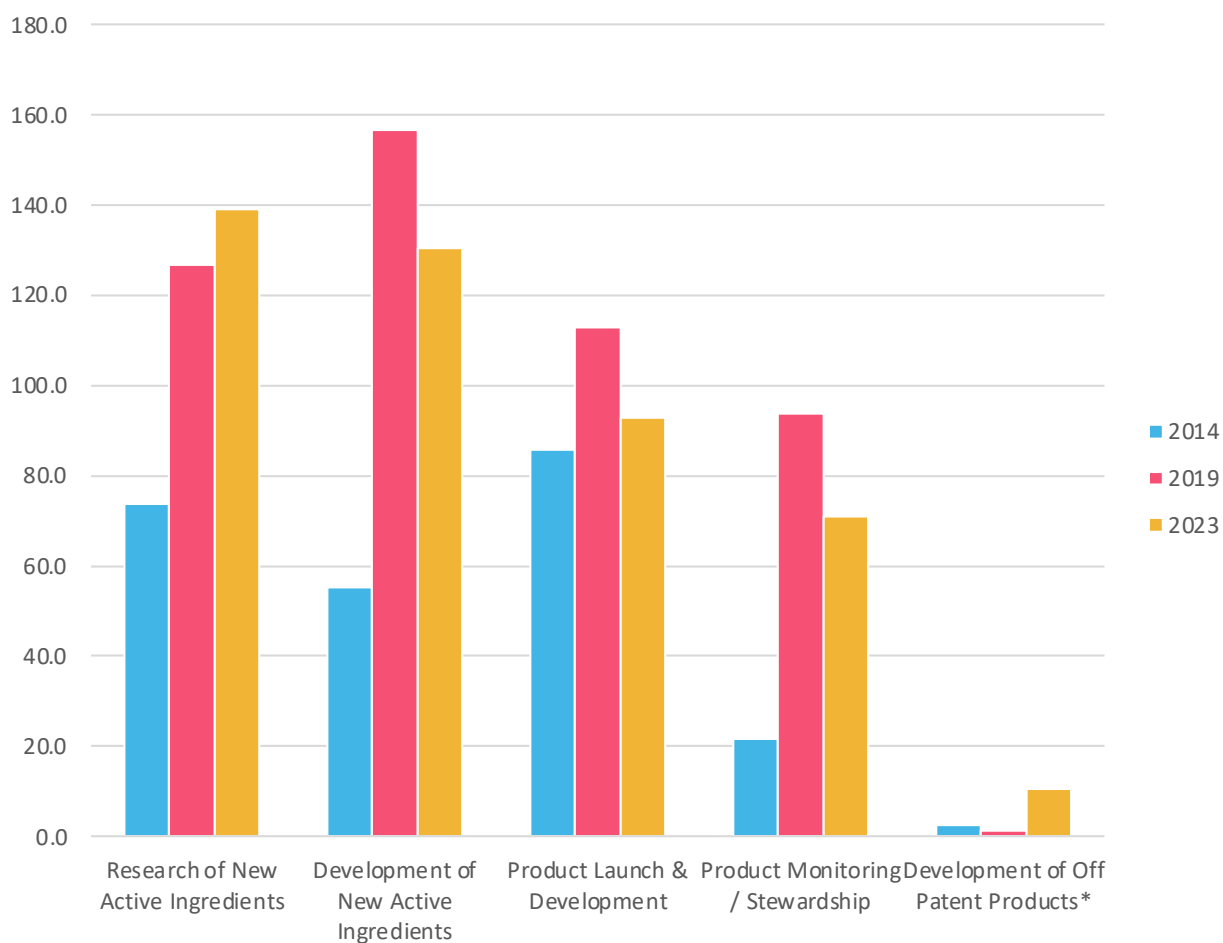
Breakdown of Expenditure Devoted to the R&D Process 2023

This study presents the results of a survey of the leading crop protection companies in order to determine:

- The overall level of expenditure devoted by the agrochemical industry to the research and development (R&D) process.
- The proportion of the R&D budget that is targeted at new AI discovery, development and managing the existing business, including product stewardship and monitoring.
- Changes in R&D expenditure between 2014, 2019 and 2023.

Responses to the survey were received from five companies.

Comparison of Average R&D Expenditure Breakdown of the Participating Companies

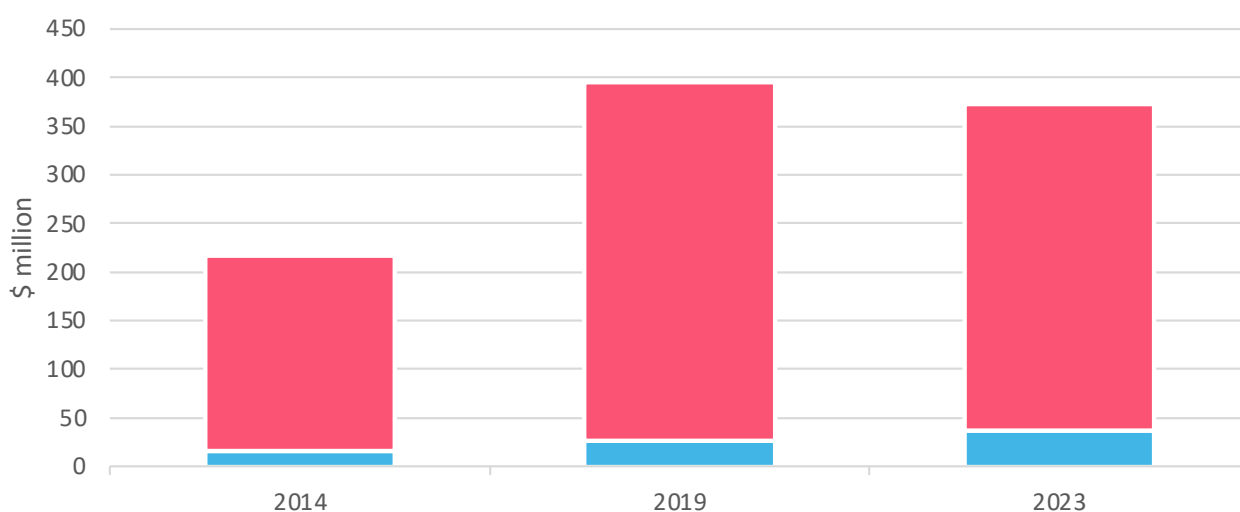


Executive Summary: Breakdown of Expenditure Devoted to the R&D Process 2023

From the previous edition of the survey, R&D expenditure of the participating companies declined by approximately 9.7% between 2019 and 2023, driven by declines in spending allocated to the development of a new active substance (-16.8%), product launch and development (-17.9%) and product monitoring and stewardship (-24.4%). Despite the decrease in overall expenditure, budget allocations for activities relating to the research of new active ingredients (+9.8%) and the development of off patent products (+7.2%) actually increased.

Respondents were also asked to provide a breakdown of R&D costs between chemical and biocontrol products (all the R&D criteria above except product monitoring and stewardship). In 2014, the average expenditure of the participating companies was \$217 million, rising to \$396 million in 2014. In this latest study, spending declined by 5.9% to \$373 million.

Agrochemical Industry R&D Expenditure by Sector



Sector	2014		2019		2023	
	\$ million	% Share	\$ million	% Share	\$ million	% Share
Biological CP	16	7%	26	7%	37	10%
Chemical CP	201	93%	370	93%	336	90%
Total (\$ million)	217		396		373	

Executive Summary: Breakdown of Expenditure Devoted to the R&D Process 2023

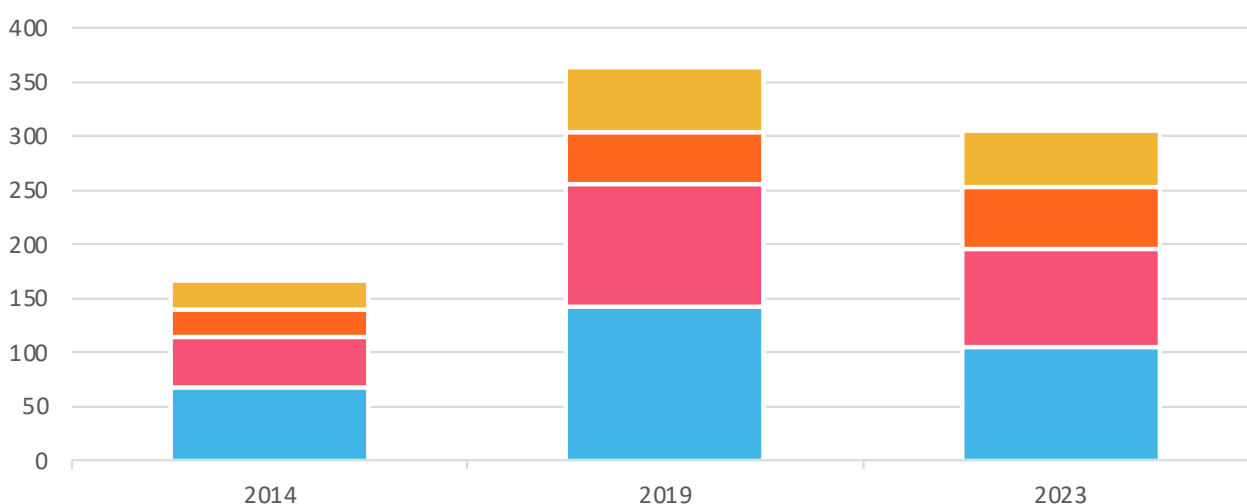
In 2014, chemical products accounted for 93% of the R&D budget at \$201 million, with spending rising to \$370 million in 2019, although still accounting for 93% of overall spend. The latest data indicate that spending on conventional chemical R&D has declined by 9.3%, while the proportion of overall spending has also decreased, falling to 90% of overall spend.

Conversely, spending on R&D for biological products has increased in nominal terms, from \$16 million in 2014, to \$26 million in 2019, and again, by 43.4% in 2023 to reach \$37 million. Proportionate expenditure has also increased to 10% in the latest version of the survey.

Respondents were also asked to provide a breakdown of development and stewardship costs by region (all the R&D criteria above except research of new AIs), focusing on where products in development were targeted. In 2014, average expenditure on regionally focused R&D operations was \$166 million, rising to \$364 million in 2019. The 2023 responses show that regionalised spending has declined by 16.4% to \$304 million.

Within this, the majority of spending is allocated towards activities in Europe (34%), followed by North America (30%), the Rest of the World (19%) and Central and South America (17%). Regionalised spending declined in nominal terms for each tracked region, except Central and Rest of the World, where R&D expenditure increased by 19.1% to reach \$56 million.

Agrochemical Industry R&D Expenditure by Region of the Participating Companies



Executive Summary:

Breakdown of Expenditure Devoted to the R&D Process 2023

Agrochemical Industry R&D Expenditure by Region of the Participating Companies						
Sector	2014		2019		2023	
	\$ million	% Share	\$ million	% Share	\$ million	% Share
Europe	68	41%	142	39%	105	34%
North America	47	28%	114	31%	92	30%
RoW	25	15%	47	13%	56	19%
C&S America	26	16%	61	17%	52	17%
Total (\$ million)	166		364		304	

Executive Summary:

CODEX MRL Costs

CODEX MRL Costs 2020-23

Responses to the survey were received from five companies. The average total cost of obtaining a CODEX maximum residue limit was \$183,000, with the average cost of submissions per additional use valued at \$36,000 and the average cost of periodic reviews at \$132,000. Inter-company variability was largest for costs associated with periodic review of CODEX MRLs, followed by costs of obtaining a CODEX MRL for a new AI and costs of submission for additional uses.

CODEX MRL Costs	
Currency	\$ million
New AI	0.183
Per Additional Use	0.036
Periodic Review	0.132



Executive Summary: Re-registration Costs

Re-registration costs were highest in the EU at \$15.3 million, approximately 10 times higher than re-registration costs in the US (\$1.5 million) and more than 17 times higher than re-registration costs in other jurisdictions. The higher costs associated with re-registration in the EU is likely a result of the more resource intensive regulatory landscape that exists in this jurisdiction. For example, some participants indicated that they only tracked re-registration costs in the EU as data generated through the European application process is sufficient to support applications in other jurisdictions.

Costs Associated with Re-registering an AI Between 2020 and 2023			
	Category	\$ million	No. Responses
Geography	EU	15.3	4
	US	1.5	4
	Other	0.9	2

Section 1:

The Cost to Bring a New Active Ingredient to the Market

A decorative graphic in the bottom right corner consisting of numerous small orange and yellow dots arranged in a pattern that forms a large, stylized '01' shape.

01

Section: 1

Introduction & Study Definitions

Introduction

During 2025, on behalf of CropLife International, AgbiolInvestor undertook a survey of the leading global agrochemical companies designed to provide information on the comparative costs involved in the discovery, development and registration of a new conventional chemical crop protection AI.

This study was carried out to update previously published information, which showed that the overall level of expenditure required to develop and register a new crop protection AI had grown from Deutsche Mark 50 million. (\$23.1 million.) in the 1975-1980 period to Deutsche Mark 250 million. (\$157 million.) for the 1990-1995 timeframe (see Appendix 1). This study was updated in 2003, 2009, 2015 and 2022 with the composite results seen in Appendix 2.

Study Definitions

The process leading to the discovery, development and commercialisation of a new agrochemical molecule is complex, costly and time consuming. The overall process can be split into three main stages, firstly the research programme leading to the discovery of a new molecule, secondly its development and lastly its registration with the appropriate regulatory authority.

Research

For a new chemical crop protection AI, the discovery or research process involves the synthesis of candidate molecules. These candidate molecules are subsequently subjected to a series of biological research tests or screens which are designed to demonstrate the biological activity of the new molecule. The screening process is likely to involve a number of increasingly complex stages to ensure that the new chemical has a suitable biological activity to merit further development. Although the synthetic and biological screening programme will lead to the discovery of molecules whose biological activity has been quantified, the decision as to whether the new chemical is suitable for full development will also involve other criteria, namely, it must be able to be patented, possess good toxicological and environmental properties and display good commercial prospects.

Section: 1

Introduction & Study Definitions

In order to satisfy these latter criteria, the research process generally includes preliminary toxicological and environmental testing as well as undertaking an evaluation of the new chemical's commercial prospects. Individual companies will set their own measure for success for these tests.

In previous years, the chemical synthesis stage has been enhanced through the development of combinatorial chemical methods, which have resulted in companies having the ability to synthesise large numbers of molecules, however, this procedure has now lost popularity. Similarly, the development of high throughput screening methods has enabled a greater number of molecules to be subjected to the biological research process. Biological research has also been enhanced through the use of genomics as a means for the discovery of new active molecules and potential sites of activity within target organisms.

Overall, the ultimate goal of the discovery process is to provide product leads or candidates with biological, chemical, toxicological, environmental and commercial characteristics suitable for further development.

Development

Agrochemical product development encompasses a broad range of processes which by definition are all aimed at developing the AI for subsequent commercialisation.

An important area of chemistry development is formulation evaluation. This generally involves testing and optimising various formulations of the new crop protection product to ensure that the AI can be delivered safely and effectively for subsequent field use.

Chemical development processes include the establishment of a pilot plant to produce suitable quantities of material for further biological and safety testing. Studies on optimising the manufacturing process for commercial production are subsequently undertaken with the aim of arriving at a suitably cost-effective manufacturing process.

Section: 1

Introduction & Study Definitions

In the research stage, biological screens, normally conducted in the laboratory, will have established that an AI has potentially important crop protection activity. Further biological development of the new crop protection AI is designed to investigate the activity of the AI against a variety of target pests, weeds or diseases in a number of crops under a variety of environmental situations. These studies are conducted in actual field situations and comprise both small and large-scale field trials. As well as testing the relative efficacy of the new AI, these field trials also encompass formulation evaluation and are used as a basis for the determination of the fate of the molecule and its metabolites or residues in the environment, soil and plants.

Although some preliminary safety testing will have been undertaken at the research stage, the development programme for a new crop protection AI includes significantly expanded toxicology and environmental chemistry testing to meet the statutory requirements of the regulatory bodies in the USA and the EU. The information generated from the regulatory process in these geographies is generally then used to fulfil regulatory requirements in alternative geographies.

Registration

The results of the developmental studies are subsequently submitted to the regulatory body for review. On acceptance, the AI is registered by the regulatory body, and commercialisation of the new crop protection product can then occur.

The following page contains a glossary of the main terms used in describing the research, development and registration process for a new crop protection AI.

Section: 1

Glossary of Terms

Glossary of Terms	
Term	Definition
Research	The discovery of new active ingredients, either from natural sources or by chemical synthesis, and subsequent screening to assess biological activity. Research stages generally also include preliminary toxicological and environmental testing before making the decision as to whether to progress the AI to full development.
Chemistry	The production of new chemical entities for assessment as potential active ingredients, either by conventional chemical synthesis that has now been enhanced by combinatorial chemistry techniques, or by extraction from natural sources.
Biology	Assessment of the biological efficacy of a potential new active ingredient. Conventional screening has now been enhanced by rapid throughput techniques. Biological Research has also expanded to cover Genomics.
Chemical Synthesis	Production of new potential active ingredients from basic chemical entities, this process is now enhanced by combinatorial chemistry.
Combinational Chemistry	A rapid mechanised system for the production of a large number of potentially active ingredients from basic chemical reagents.
High Throughput Screening	Rapid, mechanised system for assessing the biological activity of very low volumes of chemical.
Genomics	The application of biotechnology to further understand genetic structure and function.

Section: 1

Glossary of Terms

Glossary of Terms	
Term	Definition
Development	The progression of selected potential AIs from discovery to commercialisation. Includes regulatory studies required to support active ingredient and crop protection product registration as well as investigating the biological efficacy of the product in the field against a variety of pests in multiple crops, the manufacturing processes and formulation chemistry.
Chemistry	The scale up of chemical synthesis to produce volumes required for product development and then for commercial introduction. Also the development of formulations suited to the target crop applications.
Field Trials	The assessment of activity against target weeds / pests / diseases in the field, including comparison with standard treatments already on the market.
Toxicology	Safety assessment of the product candidate in biological systems.
Environmental Chemistry	Investigation of the physical and metabolic breakdown of a potential product in plant, animal, soil and water systems. Identification and assessment of the residues of the compound and its breakdown products in these systems.
Registration	Preparation and submission of data dossiers to, and subsequent negotiations with, registration authorities with the aim of obtaining approval to market a new product.

Section: 1

Study Scope & Methodology

Study Scope

As described above, the primary aim of this study was to determine the cost of several key parameters in the discovery and development process for a new crop protection product in the USA and the EU. The parameters to be investigated were:

- Cost of discovery, development and registration
- The lead time between the first synthesis of the AI and the commercial introduction of the new crop protection product containing the AI.

Methodology

The study was conducted during 2025 according to the protocol included in Appendix 3.

The primary data for this investigation was obtained from a questionnaire (see Appendix 4), which was sent to a group of agrochemical companies that were considered to have active discovery programmes for conventional chemical crop protection products.

The industry has undergone significant consolidation through various merger and acquisition (M&A) events, notably the Dow DuPont merger, which was announced in 2015 and from which Corteva Agriscience was spun out in 2018, and Bayer's acquisition of Monsanto in 2018. Consequently, the number of participating companies has fallen from previous editions of the survey.

Section: 1

Study Scope & Methodology

The companies included in this survey were:

- BASF Agricultural Solutions
- Bayer Crop Science
- Corteva
- FMC
- Syngenta

On receipt, the results of each company response were added to a matrix in which each company was listed by code number. Each company result was subsequently aggregated, and the mean value of each particular category was calculated. The results of the responses are shown in the report as mean values however, the variance within the actual responses is documented. In the case of Part 1 of the study, namely the evaluation of the cost of new product discovery and development, where a company response contained incomplete information on subcategories, the mean values were calculated on a pro rata basis to ensure that the mean category totals agreed with the subcategory values.

Average Exchange Rate to the US Dollar (2020-2023):

Dollar = 0.89974375 Euro

The results of each company, in US dollar terms, were subsequently aggregated so that a collective total was produced to represent the overall agrochemical industry.

Section: 1

Study Results 1995

Study Results

Cost of New Product Discovery and Development – 1995

Of the ten companies surveyed, data on six companies with respect to the 1995 situation for the cost of discovering and developing a new crop protection product were received. In some cases, the company responses did not contain information on all subcategories. As a result, subcategory mean values were calculated on a pro rata basis according to the number of responses received.

The actual number of responses and the mean values of the company responses are shown in the table below:

Discovery and Development Costs of a New Crop Protection Product (1995)			
Category	Subcategory	Cost (\$m.)	Number of Responses
Research	Chemistry	32	5
Research	Biology	30	5
Research	Toxicology/Environmental Chemistry	10	5
Research	Research total	72	6
Development	Chemistry	18	6
Development	Field Trials	18	6
Development	Toxicology	18	6
Development	Environmental Chemistry	13	6
Development	Development total	67	6
Registration		13	5
Total		152	6

Section: 1

Study Results

1995

In terms of total costs of new product discovery and development, the results of the survey were essentially identical to the previous investigation (see Appendix 1), where the costs were shown to be DM 250 million (\$152 million).

Overall, in 1995, the highest costs associated with new crop protection product R&D were in the research process leading to the discovery of a new product, with an overall cost of \$72 million. Within this chemical synthesis was the most costly stage in the discovery process with an average value of \$32 million followed by biological research screening with a mean cost of \$30 million.

Total development costs in 1995 were found to be \$67 million and these were relatively equally split amongst the various subcategories. The remaining expenditure deemed necessary for new product discovery and development comprised \$13 million for product registration.

Section: 1

Study Results 2000

Cost of New Product Discovery and Development - 2000

In total ten companies were surveyed. All companies responded to the questionnaire with nine companies returning responses containing quantitative data.

As with the 1995 data, some company responses were incomplete in that they did not contain information on all subcategories and as a result subcategory mean values were calculated on a pro rata basis.

The actual number of responses for each category and subcategory, and the mean values of the company responses are shown in the following table:

Discovery and Development Costs of a New Crop Protection Product (2000)			
Category	Subcategory	Cost (\$m.)	Number of Responses
Research	Chemistry	41	6
Research	Biology	44	6
Research	Toxicology/Environmental Chemistry	9	6
Research	Research total	94	9
Development	Chemistry	20	8
Development	Field Trials	25	8
Development	Toxicology	18	8
Development	Environmental Chemistry	16	8
Development	Development total	79	8
Registration		11	7
Total		184	9

Section: 1

Study Results

2000

The above results demonstrated that the overall costs for the discovery and development of a new agrochemical product in 2000 had risen to \$184 million (€140 million).

As with the 1995 results, product research or discovery remained the most significant category in new agrochemical R&D with an expenditure of \$94 million, equivalent to 51.1% of the total. Within this, biological screening was the most significant subcategory representing an expenditure of \$44 million followed by new product chemistry which accounted for a further \$41 million during 2000. Early-stage toxicology and environmental chemistry, similar to the 1995 situation, remained a relatively minor component of the research process.

Product development costs in 2000 represented a total expenditure of \$79 million, equivalent to 42.9% of the overall total. Within this category, field trials were the most significant costs with a value of \$25 million, followed by developmental chemistry which accounted for a further \$20 million and toxicology which was valued at \$18 million. The remaining expenditure in product development was environmental chemistry at \$16 million.

Registration costs in 2000 were assessed at \$11 million, equivalent to 6.0% of the total discovery and development expenditure.

Section: 1

Study Results 2005-08

Cost of New Product Discovery and Development – 2005-08

In total six companies were surveyed, responses from five have so far been received and are included in this report.

As with the 1995 data, some company responses were incomplete in that they did not contain information on all subcategories and as a result subcategory mean values were calculated on a pro rata basis.

The actual number of responses for each category and subcategory, and the mean values of the company responses are shown in the following table:

Discovery and Development Costs of a New Crop Protection Product (2005-2008)				
Category	Subcategory	Cost (\$m.)	Cost (€m.)	Number of Responses
Research	Chemistry	42	32	5
Research	Biology	32	24	5
Research	Toxicology/Environmental Chemistry	11	8	5
Research	Research total	85	64	5
Development	Chemistry	36	26	5
Development	Field Trials	54	40	5
Development	Toxicology	32	23	5
Development	Environmental Chemistry	24	17	5
Development	Development total	146	107	5
Registration		25	18	5
Total		256	189	5

Section: 1

Study Results

2005-08

The above results demonstrated that the overall costs for discovering and developing a new agrochemical product in 2005-08 period had risen to \$256 million (€189 million).

Unlike the 1995 and 2000 results, product development has now exceeded research or discovery as the most significant category in new agrochemical R&D with an expenditure of \$146 million, equivalent to 57% of the total. Within this category, field trials were the most significant cost with a value of \$54 million, followed by developmental chemistry, which accounted for a further \$36 million and toxicology, which was valued at \$32 million. The remaining expenditure in product development was environmental chemistry at \$24 million.

Product research costs in 2005-08 represented a total expenditure of \$85 million, equivalent to 33.2% of the overall total. Within this, new product chemistry was the most significant subcategory, representing an expenditure of \$42 million followed by biological screening, which accounted for a further \$32 million. Early-stage toxicology and environmental chemistry, similar to the 2000 situation, remained a relatively minor component of the research process.

Registration costs in bringing a new product to market in the 2005-08 period were assessed at \$25million, equivalent to 9.8% of the total discovery and development expenditure.

Section: 1

Study Results

2010-14

Cost of New Product Discovery and Development – 2010-14

In total, five companies were surveyed and have provided responses that have been consolidated and presented in this report.

As with the previous data, some company responses were incomplete in that they did not contain information on all subcategories and as a result subcategory mean values were calculated on a pro rata basis.

The actual number of responses for each category and subcategory, and the mean values of the company responses are shown in the following table:

Discovery and Development Costs of a New Crop Protection Product (2010-2014)				
Category	Subcategory	Cost (\$m.)	Cost (€m.)	Number of Responses
Research	Chemistry	49	37	5
Research	Biology	51	38	5
Research	Toxicology/Environmental Chemistry	7	5	5
Research	Research total	107	80	5
Development	Chemistry	35	26	5
Development	Field Trials	47	36	5
Development	Toxicology	29	22	5
Development	Environmental Chemistry	35	26	5
Development	Development total	146	110	5
Registration		33	25	5
Total		286	215	5

Section: 1

Study Results

2010-14

The above results demonstrated that the overall costs for the discovery and development of a new agrochemical product in 2010-14 period had risen to \$286 million (€215 million).

Similar to the results of the 2005-08 analysis, the development phase accounted for the largest share of the R&D cost. However, between the 2005-08 and 2010-14, the cost of the development phase remained stable at \$146 million. In comparison, the cost of the research phase increased by 25.9% to \$107 million. The largest increase was however recorded by registration, up by 32.0% to \$33 million, although these costs also include additional costs to achieve registration in the EU and USA.

In the development phase, the largest cost was field trials at \$47 million, although these costs declined by 13.0% from 2005-08, however the largest increase was seen for environmental chemistry testing, up by 45.8% to \$35 million.

In the research phase, the largest cost was biology (screening) at \$51 million, up by 59.4%, however, unlike in the development phase, the cost of toxicology/environmental chemistry testing fell by 36.4% to \$7 million.

Registration costs for bringing a new product to market in the 2010-14 period averaged \$33 million, equivalent to 11.5% of the total discovery and development expenditure.

Section: 1

Study Results

2014-19

Cost of New Product Discovery and Development – 2014-19

In total five companies were surveyed, and all have provided responses that have been consolidated and presented in this report.

As with the previous data, some company responses were incomplete in that they did not contain information on all subcategories and as a result subcategory mean values were calculated on a pro rata basis.

The actual number of responses for each category and subcategory, and the mean values of the company responses are shown in the following table:

Discovery and Development Costs of a New Crop Protection Product (2014-2019)				
Category	Subcategory	Cost (\$m.)	Cost (€m.)	Number of Responses
Research	Chemistry	64	55	4
Research	Biology	52	45	4
Research	Toxicology/Environmental Chemistry	11	9	4
Research	Research total	127	110	4
Development	Chemistry	30	26	5
Development	Field Trials	58	50	5
Development	Toxicology	22	19	5
Development	Environmental Chemistry	22	19	5
Development	Development total	133	115	5
Registration		42	36	5
Total		301	261	5

Section: 1

Study Results

2014-19

The above results demonstrated that the overall costs for the discovery and development of a new agrochemical product in 2014-19 period had risen to \$301 million (€261 million) from \$286 million in the previous iteration.

In nominal (\$) terms, costs associated with research have increased by 18.9% from \$107 million (2010-2014) to approximately \$127 million for the 2014-2019 period. Meanwhile, costs associated with product development have decreased by 8.5% from \$146 million in the previous iteration to \$133 million for the 2014-2019 period. Registration costs also increased, rising by 25.9% from \$33 million (2010-2014) to \$42 million (2014-2019).

In the research phase, the largest cost was chemistry at \$64 million, up by 31.6%. The cost of toxicology/environmental chemistry testing increased by 58.4% to \$11 million, whilst the cost of biological screening increased by 1.4% to \$52 million.

In the development phase, the greatest cost was field trials at \$58 million, representing a 23.9% increase over comparable figures from the previous iteration. Costs of all other developmental phases declined.

Registration costs for bringing a new product to market in the 2014-2019 period averaged \$42 million, equivalent to 13.9% of the total discovery and development expenditure.

Costs associated with product development still account for the largest share of total R&D costs at approximately 44.2%. However, unlike in the previous iteration, product development costs are comparable to costs associated with the research phase, which accounted for approximately 42.0% of total R&D costs. Registration costs account for approximately 13.9% of the total spend.

Section: 1

Study Results

2020-23

Cost of New Product Discovery and Development – 2020-23

In total five companies were surveyed, and all have provided responses that have been consolidated and presented in this report.

As with the previous data, some company responses were incomplete in that they did not contain information on all subcategories and as a result subcategory mean values were calculated on a pro rata basis.

The actual number of responses for each category and subcategory, and the mean values of the company responses are shown in the following table:

Discovery and Development Costs of a New Crop Protection Product (2020-2023)				
Category	Subcategory	Cost (\$m.)	Cost (€m.)	Number of Responses
Research	Chemistry	75	68	5
Research	Biology	46	42	4
Research	Toxicology/Environmental Chemistry	12	10	5
Research	Research total	133	120	-
Development	Chemistry	32	29	5
Development	Field Trials	59	53	4
Development	Toxicology	23	21	5
Development	Environmental Chemistry	24	22	5
Development	Development total	138	125	-
Registration		35	32	-
Total		307	276	-

Section: 1

Study Results

2020-23

The above results highlight that the overall costs for the discovery and development of a new agrochemical product during the 2020-23 period rose to \$307 million (€276 million) from \$301 million in the previous iteration.

In nominal (\$) terms, costs associated with research have increased by 5.3% to approximately \$133 million for the 2020-23 period. Meanwhile, costs associated with product development have increased by 4.0% to \$138 million. Conversely, registration costs have fallen, declining by 15.4% to \$35 million.

In the research phase, the largest cost was chemistry at \$75 million, up by 17.3% from the previous study. The cost of toxicology/environmental chemistry testing increased by 5.9% to just under \$12 million, while the cost of biological screening decreased by 9.9% to \$46 million.

Costs increased for all identified stages of product development, with the greatest developmental costs associated with field trials at \$59 million, up by 0.6% from the previous iteration. This is followed by chemistry at \$32 million (+6.9%), environmental chemistry at \$24 million (+8.0%) and toxicology at \$23 million (+5.1%).

Registration costs for bringing a new product to market in the 2020-2023 period averaged \$35 million, representing a decline of 15.4% from the previous study. As a proportion of the total discovery and development expenditure, registration represents 11.5% of total costs, down from 13.6% in the previous study.

Costs associated with product development continue to account for the largest share of total R&D costs at approximately 45.1%, with product development costs largely comparable, at 43.4% of total R&D costs.

Section: 1

Study Results Comparison

Comparison between 1995, 2000, 2005-08, 2010-14, 2014-19 and 2020-23 Costs

The following table summarises the 1995, 2000, 2005-08, 2010-14, 2014-19, and 2020-23 survey results.

New Crop Protection Product Discovery and Development Costs – Historical Development								
Category	Sub-Category	Cost (\$m.) 1995	Cost (\$m.) 2000	Cost (\$m.) 2005-08	Cost (\$m.) 2010-14	Cost (\$m.) 2014-19	Cost (\$m.) 2020-23	Change % 2020-23/ 2014-19
Res.	Chemistry	32	41	42	49	64	75	17.3
Res.	Biology	30	44	32	51	52	46	-9.9
Res.	Toxic./Env. Chem.	10	9	11	7	11	12	5.9
Research total		72	94	85	107	127	133	5.3
Dev.	Chemistry	18	20	36	35	30	32	6.9
Dev.	Field Trials	18	25	54	47	58	59	0.6
Dev.	Toxic.	18	18	32	29	22	23	5.1
Dev.	Env. Chem.	13	16	24	35	22	24	8.0
Development total		67	79	146	146	133	138	4.0
Registration		13	11	25	33	42	35	-15.4
Total		152	184	256	285	301	307	1.9

Res.= Research; Dev. = Development; Toxic. = Toxicology; Env. Chem. = Environmental Chemistry

Section: 1

Study Results Comparison

The above results demonstrate that the overall costs of discovery and development for a new crop protection product for the EU and the USA markets have risen by 1.9% from 2014-19 to reach \$307 million in 2020-23.

In 2005-08, biology costs were believed to have declined due to the adoption of advanced rapid throughput screening/genomics. However, biology costs in 2010-14 increased beyond the level of 2000. In the latest edition, the cost associated with biological product screening declined 9.9%, driven by declines in efficacy testing costs, which fell 15.4%. Costs associated with conducting small plot trials rose considerably, more than doubling to over \$2 million, although still accounting for less than 5% of the expenditure within research biology.

Similarly, in 2005-08 combinatorial chemistry was thought to have slowed the increase in the cost of chemical synthesis. However, these techniques have lost some popularity and the chemistry / synthesis cost in the research phase increased significantly in the period to 2010-14. In the 2020-23 period, chemical synthesis costs increased by a further 17.9% to \$72.3 million. Research costs of formulations technologies has also increased, rising by 8.8% to \$2.9 million.

It is a major commercial decision for a company to progress a product candidate from Research into Development and dedicate a further \$174 million in costs (development and registration) to bring that product to market. The company needs to be confident with the efficacy, safety and commercial potential of a candidate product to make this decision, particularly passing the more and more stringent regulatory requirements, reflected by the increased expenditure in the Research phase.

In the development phase, the cost of chemistry (phase up to production of commercial quantities and formulation development) increased by 6.9% to \$32.4 million between 2014-19 and 2020-23. However, the nominal value of expenditure in this latest study remains below that in the 2010-14 study. The costs of scaling up manufacturing have increased 8.1% to \$23.3 million, while the costs of developing formulation technologies have increased 4.0% to \$9.1 million.

Toxicology costs in the development cycle rose rapidly from 2000 to 2005-08 but fell again in the 2010 to 2019 period. In the latest study, toxicology costs increased by 5.1% to \$23.0 million, driven by a 16.4% increase in environmental toxicology costs, while chronic mammalian toxicology costs fell 5.6%. It is worth noting that some of these costs have transferred to the research phase, where mammalian subchronic toxicology costs (+32.6%) and environmental toxicology costs (+75.5%) have increased.

Section: 1

Study Results Comparison

Field trial costs in the development phase overall increased marginally by 0.6% between 2014-19 and 2020-23 to \$58.8 million. The latest survey also shows that large field trial costs have increased again, rising by 22.9% to \$28.4 million. In the previous study, large scale trial costs more than doubled. The increase in large scale trial expenditure has largely been offset by falling Registration field trial costs, which have declined by 14.0% to \$30.4 million.

The survey results indicate that environmental costs in the product development phase have increased from the 2014-19 edition, rising by 8.0% to \$24.3 million. Within this, Environmental residue costs increased by 12.4% to \$13.0 million, while the cost of metabolic studies rose by 3.3% to \$11.3 million.

Average registration costs associated with bringing a new AI to market fell by 15.4% in the 2020-23 survey to \$35.4 million. Registration costs in the EU declined by 12.1% to \$21.4 million, despite statutory fees (+0.2%) and the costs associated with internal registration activities (+6.9%) both increasing, as expenditure on additional studies that are only requested in the EU and have no use in any other country or registration jurisdiction has declined by 18.8%.

Similarly, registration costs in the US have declined, falling by 20.0% to \$14.0 million, driven by declines in statutory fees (-23.4%) and additional studies that are only requested in the US (-25.1%). However, Internal Registration Costs increased by 60.5% to \$1.6 million.

Discussion

There are several considerations to keep in mind when comparing inter-company costs. Firstly, it is likely that the participating companies will have different rules regarding cost allocations within a development project, which has the potential to introduce significant inter-company variability.

Other considerations include the impact of the surveys timing on company R&D expenditure. For example, participants noted that new product R&D does not happen at regular time intervals and instead noted that R&D projects for new active ingredients tend to occur in batches during periods of intensive R&D expenditure. Consequently, whether a company's strategy is oriented towards new product R&D during the surveys observation period will significantly impact expenditure and, consequently, will impact inter-company variability.

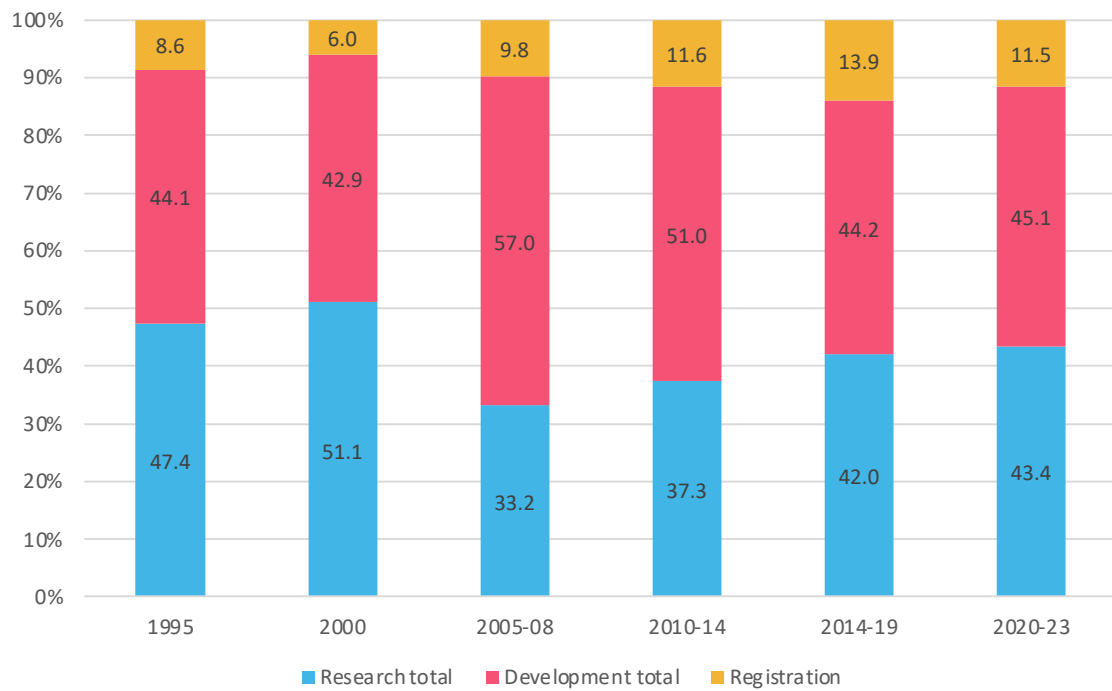
It is also worth highlighting that the scope in terms of geography and complexity will vary between product development projects within indications.

Detailed Comparison of Historical Results							
Cat.	Sub-category	Sector	Cost (\$m.)				Change% 2020-23 / 2014-19
			2005-08	2010-14	2014-19	2020-23	
Res.	Chem.	Synthesis	41.4	47.0	61.3	72.3	17.9
Res.	Chem.	Formulation	0.6	1.7	2.7	2.9	8.8
Res.	Chemistry Total		42.0	48.7	64.1	75.2	17.3
Res.	Biology	Efficacy Testing (Glasshouse)	23.5	41.3	35.4	30.0	-15.4
Res.	Biology	Small plot trials	3.9	3.0	0.9	2.3	153.3
Res.	Biology	Field trials	4.7	6.6	15.3	14.3	-6.8
Res.	Biology Total		32.1	50.9	51.6	46.5	-9.9
Res.	Toxic.	Mammalian acute	2.4	2.3	4.9	4.5	-7.2
Res.	Toxic.	Mammalian sub chronic	4.6	1.4	2.5	3.3	32.6
Res.	Toxic.	Environmental	1.9	1.3	0.9	1.6	75.5
Res.	Toxicology Total		8.9	5.0	8.4	9.4	12.4
Res.	Env. Chem.	Residue analysis	0.4	0.8	0.7	1.5	118.6
Res.	Env. Chem.	Metabolism	2.0	1.1	1.9	0.7	-64.0
Res.	Environmental Chemistry Total		2.4	1.9	2.6	2.2	-14.9
Research Total			85.4	106.5	126.6	133.3	5.3
Dev.	Chem.	Scale up of Manufacture	19.7	26.6	21.6	23.3	8.1
Dev.	Chem.	Formulation	16.5	8.4	8.7	9.1	4.0
Dev.	Chemistry Total		36.2	35.0	30.3	32.4	6.9
Dev.	Biology	Large Scale Field trials	43.4	9.9	23.1	28.4	22.9
Dev.	Biology	Registration Field trials	11.0	37.2	35.3	30.4	-14.0
Dev.	Biology Total		54.4	47.1	58.4	58.8	0.6
Dev.	Toxicology	Chronic Mammalian	21.9	15.4	11.2	10.6	-5.6
Dev.	Toxicology	Environmental	9.9	13.2	10.7	12.5	16.4
Dev.	Toxicology Total		31.8	28.6	21.9	23.0	5.1
Dev.	Env. Chem.	Metabolism	15.3	11.7	10.9	11.3	3.3
Dev.	Env. Chem.	Residues	8.4	23.1	11.6	13.0	12.4
Dev.	Environmental Chemistry Total		23.7	34.8	22.5	24.3	8.0
Development Total			146.1	145.5	133.1	138.5	4.0
Reg.	EU	Registration fees	5.7	5.2	2.2	2.2	0.2
Reg.	EU	Internal Reg. Costs	13.5	5.6	4.7	5.0	6.9
Reg.	EU	Additional studies*	2.3	9.1	17.4	14.1	-18.8
Reg.	EU Total		21.5	19.9	24.3	21.4	-12.1
Reg.	US	Registration fees	0.6	2.9	2.1	1.6	-23.4
Reg.	US	Internal Reg. Costs	1.3	3.0	1.0	1.6	60.5
Reg.	US	Additional studies*	1.5	7.4	14.4	10.8	-25.1
Reg.	US Total		3.4	13.3	17.5	14.0	-20.0
Registration Total			24.9	33.2	41.8	35.4	-15.4
Grand Total			256.4	285.2	301.5	307.2	1.9

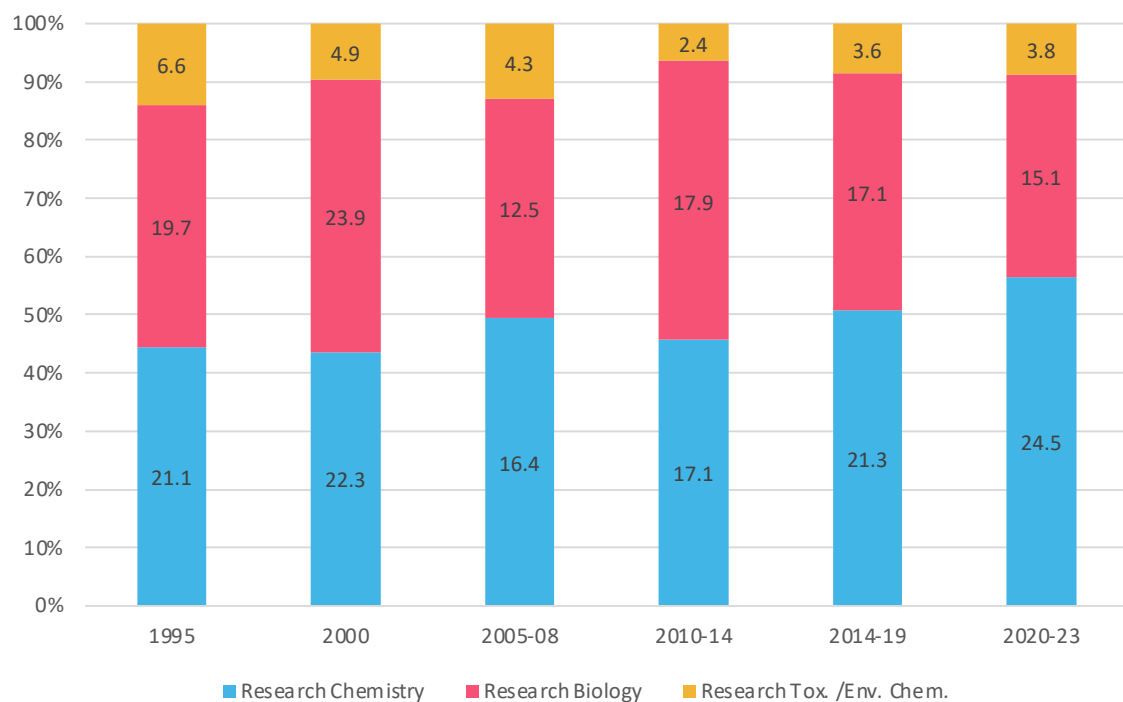
Section: 1

Study Results Comparison

New Crop Protection Product Discovery and Development Costs (% of Overall Costs)



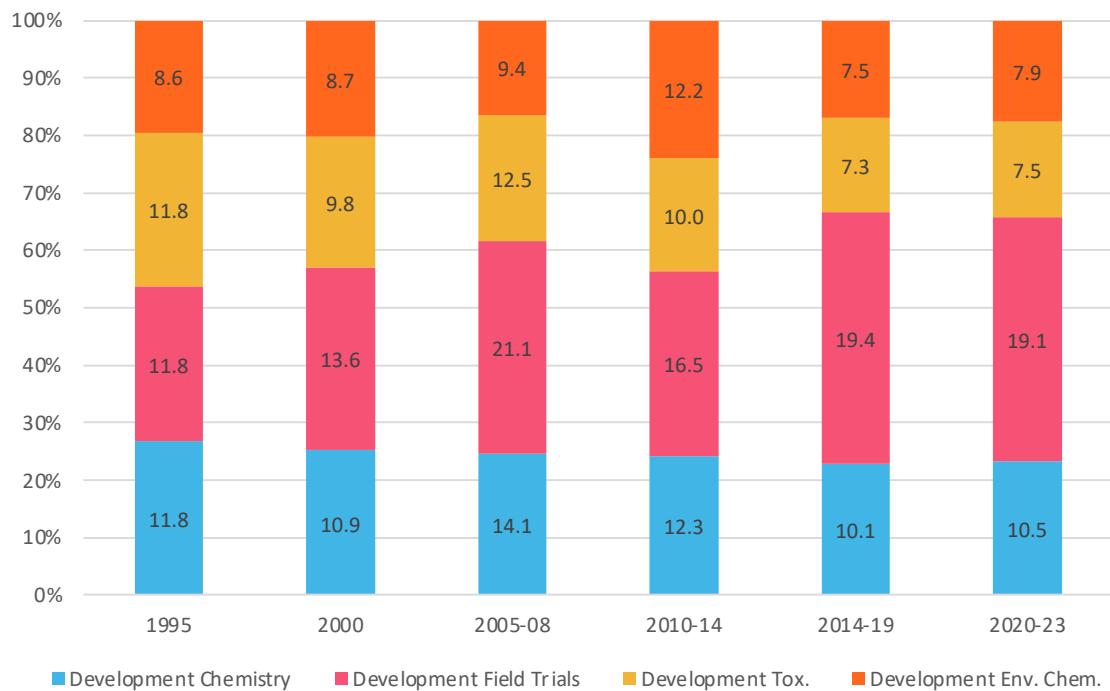
New Crop Protection Product Research Costs (% of Overall Costs)



Section: 1

Study Results Comparison

New Crop Protection Product Discovery and Development Costs (% of Overall Costs)



New Crop Protection Product Discovery and Development Costs (% of Overall Costs)						
	1995	2000	2005-08	2010-14	2014-19	2014-19
Research Chemistry	21.1	22.3	16.4	17.1	21.3	24.5
Research Biology	19.7	23.9	12.5	17.9	17.1	15.1
Research Toxic. / Env. Chem.	6.6	4.9	4.3	2.4	3.6	3.8
Research total	47.4	51.1	33.2	37.3	42.0	43.4
Development Chemistry	11.8	10.9	14.1	12.3	10.1	10.5
Development Field Trials	11.8	13.6	21.1	16.5	19.4	19.1
Development Toxicology	11.8	9.8	12.5	10.0	7.3	7.5
Development Env. Chem.	8.6	8.7	9.4	12.2	7.5	7.9
Development total	44.1	42.9	57.0	51.0	44.2	45.1
Registration	8.6	6.0	9.8	11.6	13.9	11.5
Total	100.0	100.0	100.0	100.0	100.0	100.0

Env. Chem. = Environmental Chemistry

New Crop Protection Product Discovery and Development Costs (% of Overall Costs)						
Cat.	Subcategory	Sector	2005-08	2010-14	2014-19	2020-23
Res.	Chemistry	Synthesis	16.2	16.5	20.3	23.5
Res.	Chemistry	Formulation	0.2	0.6	0.9	1.0
Res.	Chemistry Total		16.4	17.1	21.3	24.5
Res.	Biology	Efficacy Testing (Glasshouse)	9.2	14.5	11.8	9.8
Res.	Biology	Small plot trials	1.5	1.1	0.3	0.7
Res.	Biology	Field trials	1.8	2.3	5.1	4.6
Res.	Biology Total		12.5	17.9	17.1	15.1
Res.	Toxicology	Mammalian acute	0.9	0.8	1.6	1.5
Res.	Toxicology	Mammalian sub chronic	1.8	0.5	0.8	1.1
Res.	Toxicology	Environmental	0.7	0.5	0.3	0.5
Res.	Toxicology Total		3.5	1.8	2.8	3.1
Res.	Environmental Chemistry	Residue analysis	0.2	0.3	0.2	0.5
Res.	Environmental Chemistry	Metabolism	0.8	0.4	0.6	0.2
Res.	Environmental Chemistry Total		0.9	0.7	0.9	0.7
Research Total			33.3	37.3	42.0	43.4
Dev.	Chemistry	Scale up of Manufacture	7.7	9.3	7.2	7.6
Dev.	Chemistry	Formulation	6.4	3.0	2.9	2.9
Dev.	Chemistry Total		14.1	12.3	10.1	10.5
Dev.	Biology	Large Scale Field trials	16.9	3.5	7.7	9.2
Dev.	Biology	Registration Field trials	4.3	13.0	11.7	9.9
Dev.	Biology Total		21.2	16.5	19.4	19.1
Dev.	Toxicology	Chronic Mammalian	8.5	5.4	3.7	3.4
Dev.	Toxicology	Environmental	3.9	4.6	3.6	4.1
Dev.	Toxicology Total		12.4	10.0	7.3	7.5
Dev.	Environmental Chemistry	Metabolism	6.0	4.1	3.6	3.7
Dev.	Environmental Chemistry	Residues	3.3	8.1	3.8	4.2
Dev.	Environmental Chemistry Total		9.2	12.2	7.5	7.9
Development Total			57.0	51.0	44.2	45.1
Reg.	EU	Registration fees	2.2	1.8	0.7	0.7
Reg.	EU	Internal Registration Costs	5.3	2.0	1.6	1.6
Reg.	EU	Additional studies*	0.9	3.2	5.8	4.6
Reg.	EU Total		8.4	7.0	8.1	7.0
Reg.	US	Registration fees	0.2	1.0	0.7	0.5
Reg.	US	Internal Registration Costs	0.5	1.1	0.3	0.5
Reg.	US	Additional studies*	0.6	2.6	4.8	3.5
Reg.	US Total		1.3	4.7	5.8	4.6
Registration Total			9.7	11.6	13.9	11.5
Grand Total			100.0	100.0	100.0	100.0

Res.= Research; Dev. = Development; Reg. = Registration

Section: 1

Additional Costs & Product Development Lead Time

Additional Costs

This part of the questionnaire focused on the quantification of any additional R&D costs associated with the discovery and development of a new crop protection product that had not been identified in Part 1 of the study.

A number of companies identified additional expenses covering registration fees and costs outside the EU and the US, averaging \$14.7 million and additional toxicology studies focusing on human health and safety, averaging \$21.0 million.

Product Development Lead Time

The final section of the questionnaire asked each company to provide details of the time from the first synthesis of a new crop protection product until the first sales of the product. Four companies included these details, and the mean values of the responses are outlined in the following table:

Crop Protection Product Discovery and Development Lead Time						
Period	1995	2000	2005-08	2010-14	2014-19	2020-23
No. years between initial product synthesis and the first product sale	8.3	9.1	9.8	11.3	12.3	11.4

Section: 1

Additional Costs & Product Development Lead Time

Based on the results of the survey, over the period from 2014-19 to 2020-23, the lead time between the first synthesis of a new crop protection product and its commercialisation has decreased from an average of 12.3 years to 11.4 years. However, the longer term trend indicates that development lead times have increased, rising from an average of 8.3 years in the original study in 1995.

This has occurred despite the adoption of rapid throughput techniques and enhanced fast track registration procedures for selected products. It is possible that the rise is due to an increase in the complexity and volume of data required by regulatory bodies and the time taken to develop this data.

Other possible contributing factors include the impact of Brexit on the EU's capacity to conduct and complete the registration procedure, as well as the adoption of Commission Regulation (EU) 2018/605, which set the criteria for determining endocrine disrupting properties in the EU.

The UK had been a key contributor to the EU in terms of pesticide regulation and approval, prior to its withdrawal on 31st January 2020. The UK had been responsible for maintaining the registration process for 45 active substances and maintaining the maximum residue level procedure for 56 substances, with these processes being reallocated throughout the remaining EU member states following Brexit, with this increase in workload likely impacting administration and processing times.

Similarly, the adoption of Commission Regulation (EU) 2018/605 in April 2018, which set the criteria for determining endocrine disrupting properties in the EU, necessitated that several active substances be re-evaluated according to the new criteria. This has similarly increased workloads for EU member states and is likely to have contributed to increased timescales for the registration process of new substances in the EU, particularly during the 2014-19 and 2020-23 study timeframes.



Section: 1

Survey Variance

Survey Variance

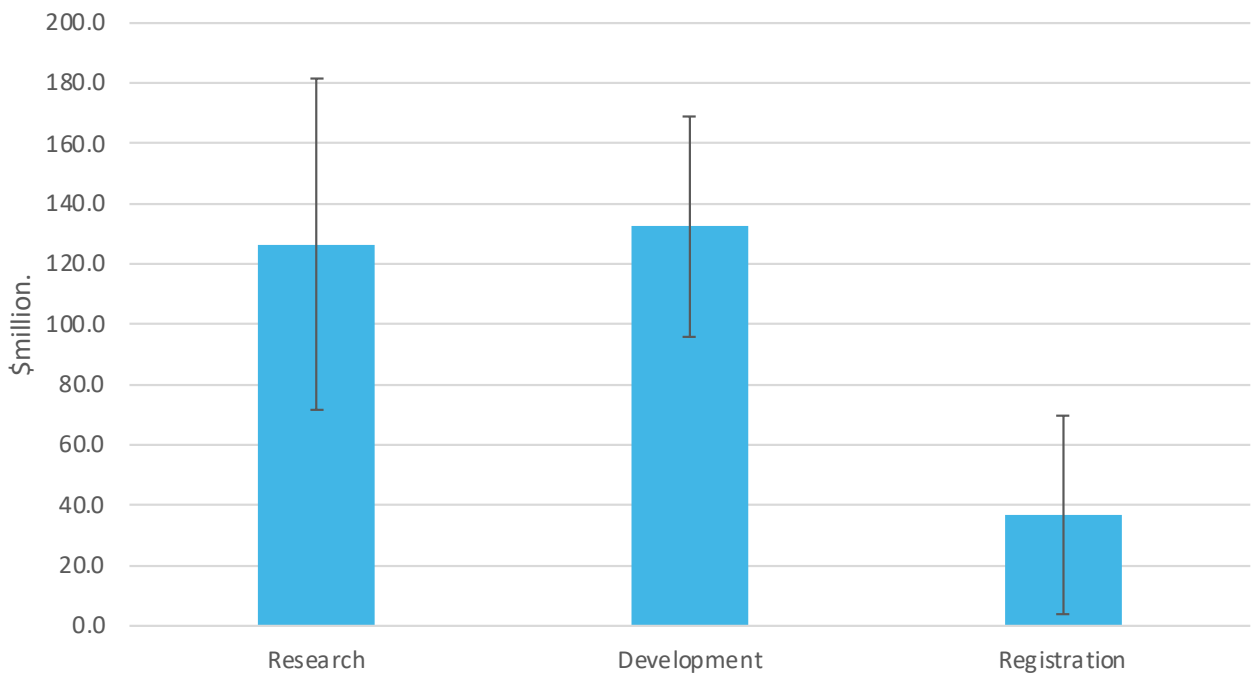
As described in the methodology section, one of the primary purposes of the study was to assess the level of expenditure made by crop protection companies that is required to discover, develop and register a new crop protection product for the EU and USA markets in 2020-23.

The companies chosen to participate in the survey were those that are considered to be active in novel active ingredient R&D. This is exemplified by the fact that these companies accounted for over 78% of R&D expenditure of the leading 30 global agrochemical companies in 2024. (Source: AgbiolInvestor AgbioCrop).

The survey results can therefore be considered to reflect those companies with a meaningful programme of new crop protection product discovery and development for the EU and the USA markets.

The following figure shows the mean value and variance (as measured by standard deviation) within the results of the survey on product discovery and development in 2020-23.

Survey Results - Mean and Standard Deviation			
	Research	Development	Registration
Standard Deviation	54.8	36.6	32.9
Average (\$m.)	126.4	132.4	36.9



Section 2:

Breakdown of Expenditure Devoted to the R&D Process 2023

Section: 2

Introduction & Study Definitions

Introduction

In 2002 Phillips McDougall undertook a study on behalf of the European Crop Protection Association (ECPA, now CropLife Europe) and CropLife America that was designed to determine the level of expenditure involved in the discovery, development and registration of a new conventional chemical crop protection AI. As reported in Section 1 of this report, this study was repeated to provide information on the costs involved in bringing a new agrochemical active ingredient from the initial discovery process to the marketplace, however, the study does not provide information on the overall level of R&D expenditure or expectations for the future. CropLife International commissioned further studies on company R&D expenditure, first in 2004, then again in 2009 (covering 2007 expenditure and expectations for 2012), and in 2016 (covering 2014 expenditure and expectations for 2019). The most recent prior study focused on 2019 expenditure but did not include future projections. Similarly, this latest survey focuses solely on historical R&D expenditure in 2023.

This survey undertaken and reported in this second section is designed to provide a greater understanding of the annual overall expenditure of the agrochemical industry on R&D.

Study Scope

As outlined above, this current study was designed to measure the overall level of expenditure devoted by the agrochemical industry to the R&D process.

- The proportion of the R&D budget that is targeted at new product discovery, development and managing the existing business, including product stewardship and monitoring.

Section: 2

Introduction & Study Definitions

Methodology

The results of this study are based on the responses to a questionnaire, which was sent to the following group of companies that were considered to be representative of the industry. The questionnaire that was sent to the companies is outlined in Appendix 3 of this report.

The companies that responded and that are included in the survey were:

- BASF Agricultural Solutions
- Bayer Crop Science
- Corteva Agriscience
- FMC
- Syngenta

The responses of each company were added to a database, with each company allocated a code number. For companies reporting in non-US dollar terms, the values were converted to US dollar using average year exchange rates:

Average Exchange Rate to the US Dollar (2023):

Dollar = 0.9248333333333333 Euro

The results of each company, in US dollar terms, were subsequently aggregated so that a collective total was produced to represent the overall agrochemical industry.

Section: 2

Introduction & Study Definitions

Study Definitions

The overall scope of the R&D process within the agrochemical industry encompasses the discovery of new agrochemical products and the research, developmental and regulatory processes associated with managing and maintaining the commercial and regulatory status of each company's products following their introduction.

Typically, the R&D process for new products can be split between activities relating to the screening and discovery of a new AI, and development. Both these stages involve a number of related scientific and regulatory disciplines that are designed to determine the relative efficacy of the product whilst ensuring that the new active ingredient satisfies the various tests established by regulatory bodies to demonstrate that the product is safe from both a human and environmental viewpoint.

In addition to the various studies associated with new product discovery, the agrochemical industry undertakes significant R&D to maintain and develop the existing product portfolio. Some of these studies will be undertaken to extend the application and use of the product following launch to other crop and pest scenarios or to other country markets. Increasingly a number of studies are also being undertaken to satisfy the re-registration requirements of regulatory bodies such as the EU and the US EPA.

The definition of R&D Expenditure and the main R&D phases that were included as categories in the questionnaire were:

R&D Expenditure (scope): The total expenditure on all agrochemical R&D activities for crop protection and non-agricultural uses. This covers R&D related to conventional crop protection in agriculture, pest control, industrial and consumer applications, public health and lawn and garden use. It also includes salaries and all other staff-related costs, as well as costs related to R&D administration, rent, supplies, equipment, materials, etc. Activities carried out (for the purpose of agrochemical development) within the corporation but outside the crop protection organization (for those companies having R&D centres/capacities outside of crop protection divisions) are also included. Corporate research programs, expenditure on joint ventures, alliances, and research agreements with third parties are included. Depreciation costs related to R&D assets are also included. Capital expenditure on R&D is excluded.

Section: 2

Introduction & Study Definitions

Research of New Active Ingredients: All of the R&D activities associated with the discovery of new agrochemical active ingredients up to the start of new product development.

Development of new active ingredients: Starts at the point when a company commits a new active ingredient to full development, generally marked by the decision to commence long-term toxicity tests. It ends with the registration and launch of a product in a major crop market (generally an OECD country).

Post launch development: All product development activities following the launch of a new active ingredient into a major market.

- **Re-registration/registration maintenance:** refers to any activities or studies that must be undertaken in response to the requirements of registration authorities in order to maintain a product's registration.
- **Other:** includes activities required to satisfy regulatory requirements for registration in non-OECD countries and line extensions of existing products.

Development of Off-Patent products new to your company:

The above sections predominately relate to the R&D of new active ingredients, however, a significant level of investment is made by generic companies in the development of off-patent products for introduction.

Product Monitoring and Stewardship: This relates to the costs associated with undertaking the requirements of the regulatory authority's post-introduction.

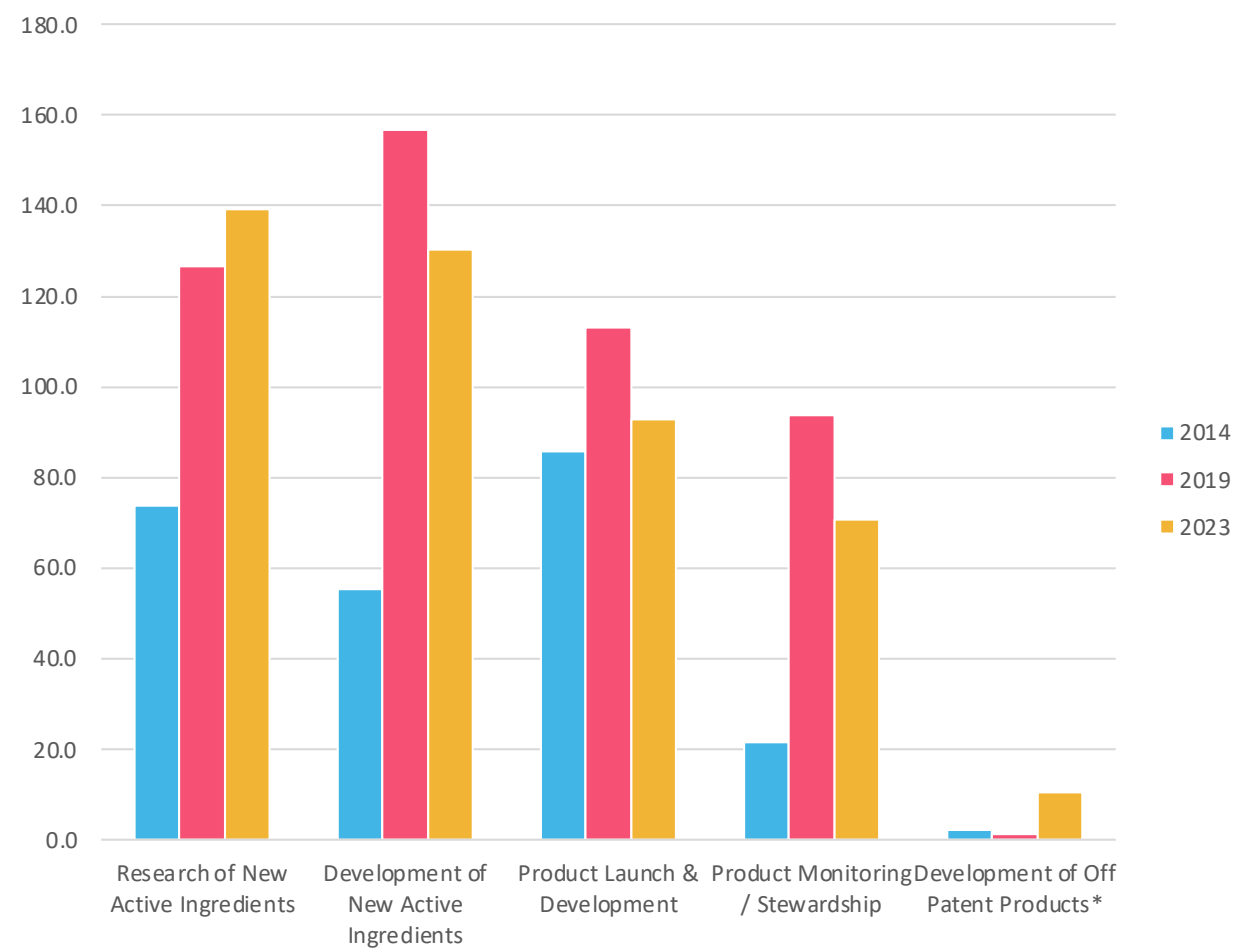


Section: 2
Study Results

Study Results: Breakdown of Expenditure Devoted to the R&D Process 2023

Responses to the survey were received from five companies. The total agrochemical R&D budgets for the participating companies in 2023 were \$2,729 million, equivalent to 5.5% of their agrochemical sales.

Comparison of Average R&D Expenditure Breakdown of the Participating Companies



*2023 value expressed as median of responses

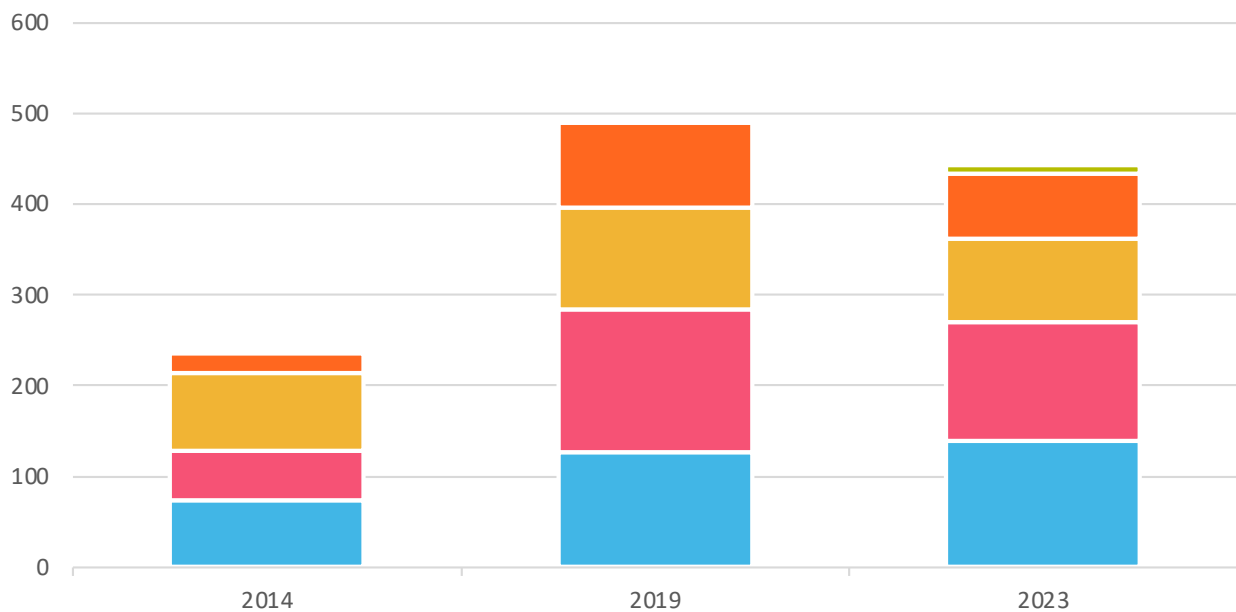
The survey indicates that the level of expenditure involved in the discovery, development and registration of a new crop protection AI has declined by 9.7% to \$444 million in 2023. Within this, spending in 2023 has declined from 2019 for activities associated with the development of new active ingredients, product launch and development, and product monitoring and stewardship. However, average expenditure on research of new active ingredients has increased by 9.8%, to approximately \$139.2 million, while spending on the development of Off Patent products has risen substantially to almost \$11 million.

Section: 2

Study Results

Expenditure on the development of new active ingredients has decreased by 16.8% to \$130.3 million, while average expenditure on product launch and development activities has declined by 17.9% to \$92.7 million, and similarly, expenditure on Product Monitoring and Stewardship operations has declined by 24.4% to \$70.9 million.

Comparison of Average R&D Expenditure Breakdown of the Participating Companies



Function	2014		2019		2023	
	\$ m.	% Share	\$ m.	% Share	\$ m.	% Share
Research of New Active Ingredients	74	31%	127	26%	139	31%
Development of New Active Ingredients	55	23%	157	32%	130	29%
Product Launch & Development	86	36%	113	23%	93	21%
Product Monitoring / Stewardship	22	9%	94	19%	71	16%
Development of Off Patent Products	2	1%	1	0%	11	2%
Total (\$ million)	239		491		444	

Section: 2

Study Results

As a proportion of the total R&D expenditure, spending on research into new active ingredients has risen from 26% of total R&D expenditure in 2019 to 31% in 2023, in line with the proportionate spending recorded in the 2014 study.

Proportionate spending on the development of new active ingredients fell from 32% in 2019 to 29% in 2023. Similarly, allocations for product launch and development dropped from 23% to 21%, and for product monitoring and stewardship from 19% to 16% over the same period. In each of these areas, nominal expenditures also declined compared with the previous study. By contrast, investment in the development of off-patent products increased sharply, rising from less than 1% of spending in 2019 to 2% in 2023, amounting to around \$11 million.

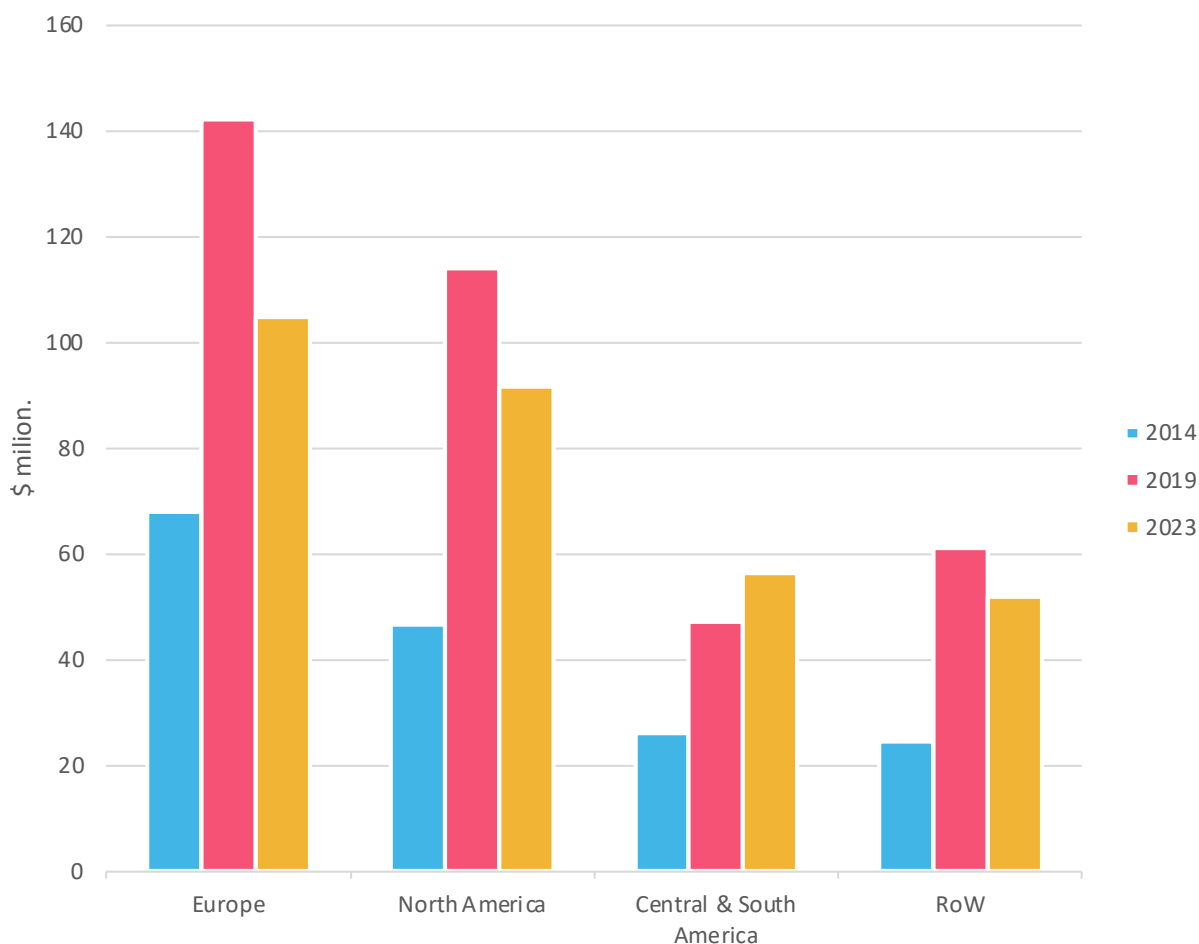
The increase in spending on off-patent product development may reflect a slowdown in the creation of novel chemistries and active ingredients. The growing number of required studies and the volume of supporting data needed for registration applications have raised both the time and cost of these processes. As a result, companies developing new actives must focus greater resources on fewer candidates, leading to fewer substances successfully progressing through regulatory approval. Since patents last for 20 years, the rate at which substances come off patent is tied to the pace of new product development, with a 20 year lag from the time a patent is granted. An imbalance between the rate of new approvals and the rate of substances losing patent protection would shift an increasing share of the crop protection market toward off-patent products, increasing the vulnerability of companies specialising in new product R&D to competitive pricing from manufacturers of generic substances. The apparent increased investment in off-patent technologies appears to represent a defensive strategy, aimed at preserving premium pricing for substances once their intellectual property protection expires.

Respondents were also asked to provide a breakdown of development and stewardship costs by region (all of the R&D criteria except research of new active ingredients, which is more centrally focused). The analysis was to focus on where products in development were targeted for introduction. The average total R&D expenditure that is targeted to specific geographies decreased by 16.4% from \$364 million in 2019 to \$304 million in 2023.

Section: 2

Study Results

Comparison of Average R&D Expenditure Breakdown of the Participating Companies by Region



The graph above illustrates that the regional distribution of R&D expenditure in 2023 has changed from the previous edition of the study. Europe remains the leading regional focus of R&D expenditure, accounting for \$105 million of regionalised spending, down 26.2% in nominal terms.

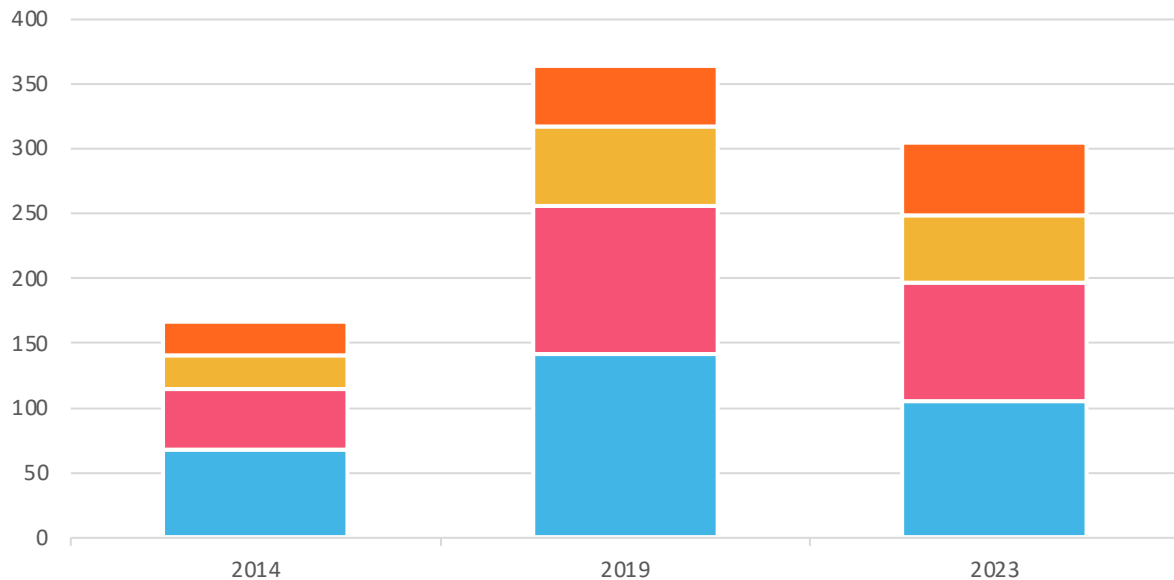
Spending in North America, the second most significant region in terms of average R&D expenditure, decreased by 19.7% to \$92 million, while spending in the “Rest of the World” region declined by 15.1% to \$52 million.

Contrastingly, spending in Central and South America increased, rising by 19.8% to \$56 million. The latest results indicate that the leading companies now allocate a greater proportion of their R&D budgets to the Central and South American region than to the remaining non-European and North American markets.

Section: 2

Study Results

Agrochemical Industry R&D Expenditure by Region of the Participating Companies



Region	2014		2019		2023	
	\$ m.	% Share	\$ m.	% Share	\$ m.	% Share
Europe	68	41%	142	39%	105	34%
North America	47	28%	114	31%	92	30%
RoW	25	15%	47	13%	56	19%
Central & South America	26	16%	61	17%	52	17%
Total (\$ million)	166		364		304	

Within geographically focused R&D expenditure, the share directed at the European market continued to decline, falling from 39% in 2019 to 34% in 2023. Spending on the North American market also decreased, dropping from 31% in the previous study to 30% in 2023. These reductions are balanced against increases in spending focused in Central and South America, with its share rising from 13% to 19%, while expenditure focused on the “Rest of the World” region remained flat at 17%.

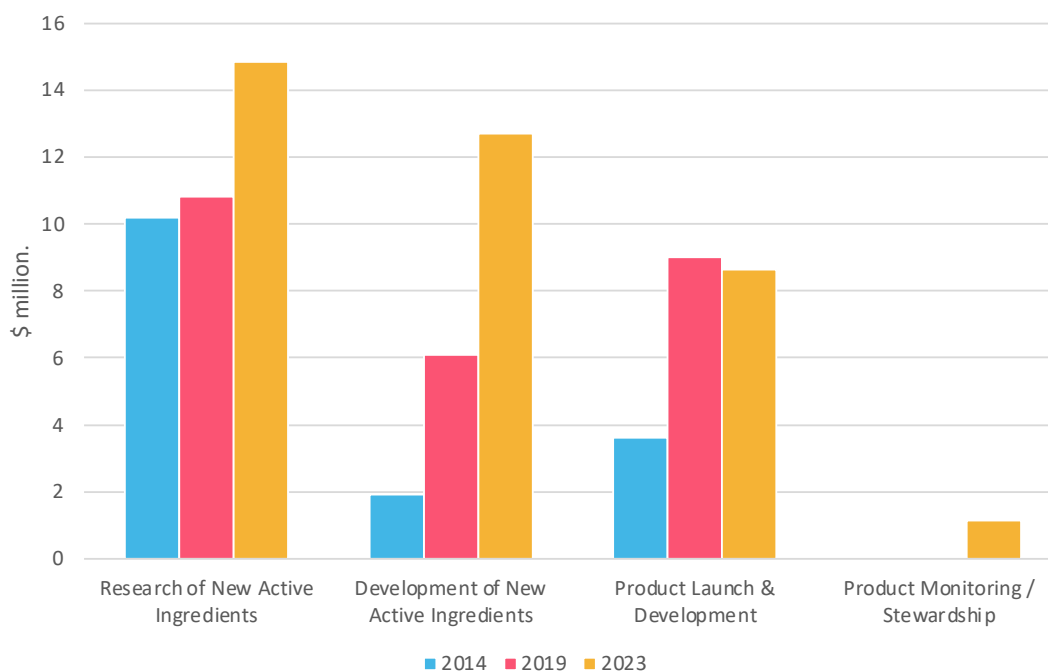
Respondents were also asked to provide a breakdown of R&D costs between chemical and biocontrol products (all the R&D criteria above except product monitoring and stewardship). In 2023, the average budget was \$373 million, representing a decrease of 5.9% from 2019.

Section: 2

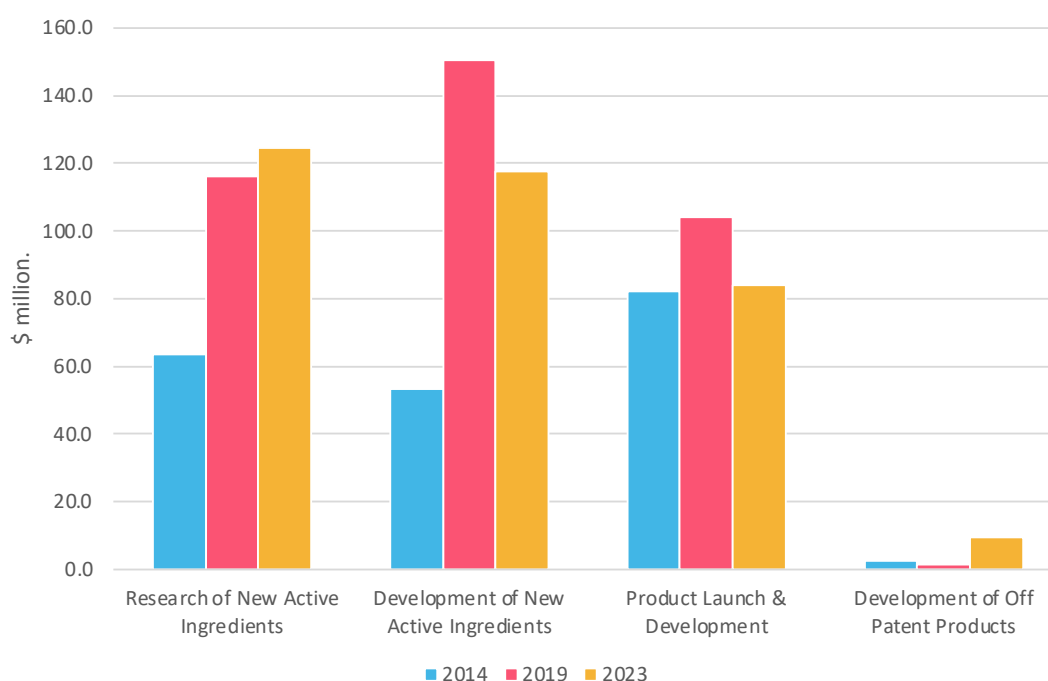
Study Results

The following tables represent the average of the responses received from the participating companies. The data has been presented graphically and discussed below.

Agrochemical Industry Biological CP R&D Expenditure by Function



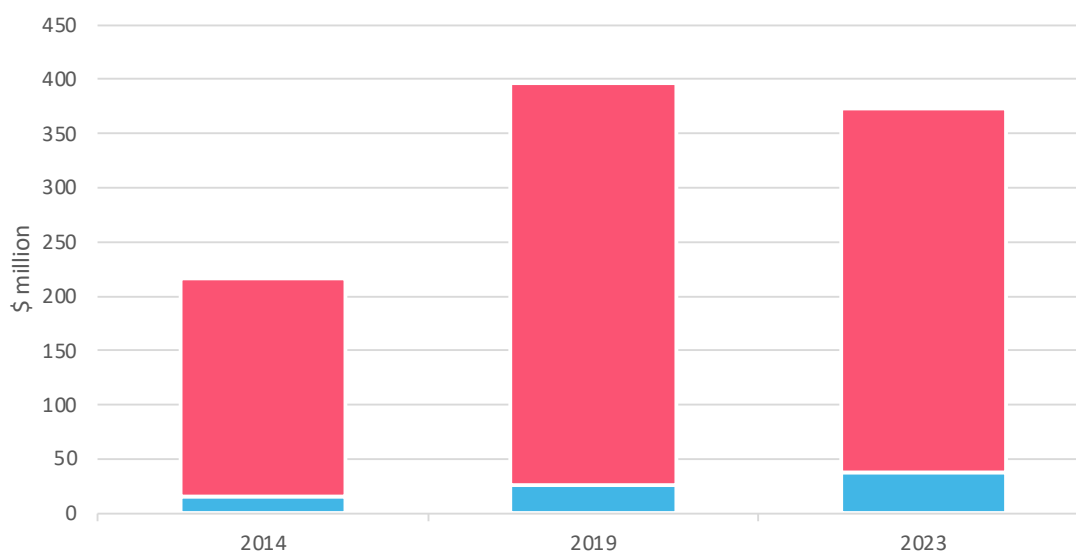
Agrochemical Industry Chemical R&D Expenditure by Function



Section: 2

Study Results

Agrochemical Industry R&D Expenditure by Sector



Sector	2014		2019		2023	
	\$ m.	% Share	\$ m.	% Share	\$ m.	% Share
Biologicals	16	7%	26	7%	37	10%
Chemical	201	93%	370	93%	336	90%
Total (\$ million)	217		396		373	

The latest survey results indicate that R&D expenditure on the chemical crop protection product sector decreased in value terms, falling by 9.3% to \$336 million from the previous study. Over the same time period, R&D expenditure for biological crop protection products increased by 43.4% in nominal terms to \$37 million.

In 2014, chemical products accounted for 93% of the R&D budget, with the proportion of R&D expenditure across biological and conventional chemical products remaining similar in 2019. The 2023 results indicate a relative increase in the proportion of R&D expenditure committed to biological products at 10% of the overall R&D budget.

It should, however, be remembered that the respondents in this study were predominantly the leading crop protection companies, some of which have acquired positions in the Biocontrol sector. There are also many other companies with interests in the Biocontrol industry that were not part of this survey.

Section 3:

CODEX MRL

Costs 2020-23

Section: 3

Introduction & Study Scope

Introduction

In 2025 AgbiolInvestor undertook a study on behalf of the CropLife International that was designed to determine the level of expenditure associated with obtaining and maintaining a CODEX Maximum Residue Limit (MRL) for a new active ingredient.

Study Scope

This study presents the results of a survey of the leading crop protection companies in order to determine:

- The overall level of expenditure associated with obtaining a CODEX MRL for a new active ingredient during the period between 2020 and 2023.
- The costs associated with obtaining additional uses of a CODEX MRL beyond the scope of the initial application during the period from 2020 to 2023.
- The costs associated with maintaining a CODEX MRL through periodic review between 2020 and 2023.

A MRL is the maximum concentration of a pesticide residue (expressed as mg/kg) that is legally permitted in or on food commodities and animal feeds when pesticides or crop protection products are applied correctly in accordance with Good Agricultural Practice (GAP). The amounts or residues in and on food/feed must be safe for consumers and as low as reasonably achievable.

CODEX MRLs are internationally agreed food standards covering pesticide residues in or on food and feed, with pesticide residue limits evaluated by the Joint Meeting on Pesticides Residues (JMPR) of the Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organisation (WHO). Each year, the JMPR recommends MRLs to the CODEX Committee on Pesticide Residues (CCPR) for consideration to be adopted by the Codex Alimentarius Commission (CAC) as CODEX MRLs.

Section: 3

Methodology

Methodology

The results of this study are based on the responses to a questionnaire, which was sent to the following group of companies that were considered to be representative of the industry. The questionnaire that was sent to the companies is outlined in Appendix 3 of this report.

The companies that responded and that are included in the survey were:

- BASF Agricultural Solutions
- Bayer Crop Science
- Corteva Agriscience
- FMC
- Syngenta Crop Protection AG

The responses of each company were added to a database, with each company allocated a code number. For companies reporting in non-US dollar terms, the values were converted to US dollars using average year exchange rates:

Average Exchange Rate to the US Dollar (2020-2023):

Dollar = 0.89974375 Euro

Section: 3

Study Results

Study Results: CODEX MRL Costs 2014-19

Responses to the survey were received from four companies. The average total cost of obtaining a CODEX MRL was \$183,000, with the average cost of submissions per additional use valued at \$36,000 and the average cost of periodic reviews at \$132,000.

Inter-company variability was largest for costs associated with periodic review of CODEX MRLs, followed by costs of obtaining a CODEX MRL for a new active ingredient and costs of submission for additional uses.

CODEX MRL Costs	
Currency	\$ million
New Active Ingredient	0.136
Per Additional Use	0.036
Periodic Review	0.132

Section 4:

Re-registration

Costs

Section: 4

Introduction & Study Scope

Introduction

In 2025 AgbiolInvestor undertook a study on behalf of CropLife International that was designed to determine the level of expenditure associated with the re-registration process of an active ingredient that was re-registered within the 2020 to 2023 timeframe.

Study Scope

This study presents the results of a survey of the leading crop protection companies to determine:

- The overall level of expenditure associated with re-registering an active ingredient within the 2020 to 2023 timeframe.
- The costs associated with re-registering an active ingredient in each of the major crop protection markets (EU, US and Other jurisdictions).

Methodology

The results of this study are based on the responses to a questionnaire, which was sent to the following group of companies that were considered to be representative of the industry. The questionnaire that was sent to the companies is outlined in Appendix 4 of this report.

The companies that responded and that are included in the survey were:

- BASF Agricultural Solutions
- Bayer Crop Science
- Corteva Agriscience
- FMC
- Syngenta Crop Protection AG

The responses of each company were added to a database, with each company allocated a code number. For companies reporting in non-US dollar terms, the values were converted to US dollars using average year exchange rates:

Average Exchange Rate to the US Dollar (2020-2023):

Dollar = 0.89974375 Euro

The results of each company, in US dollar terms, were subsequently aggregated so that a collective total was produced to represent the overall agrochemical industry.

Section: 4

Study Results

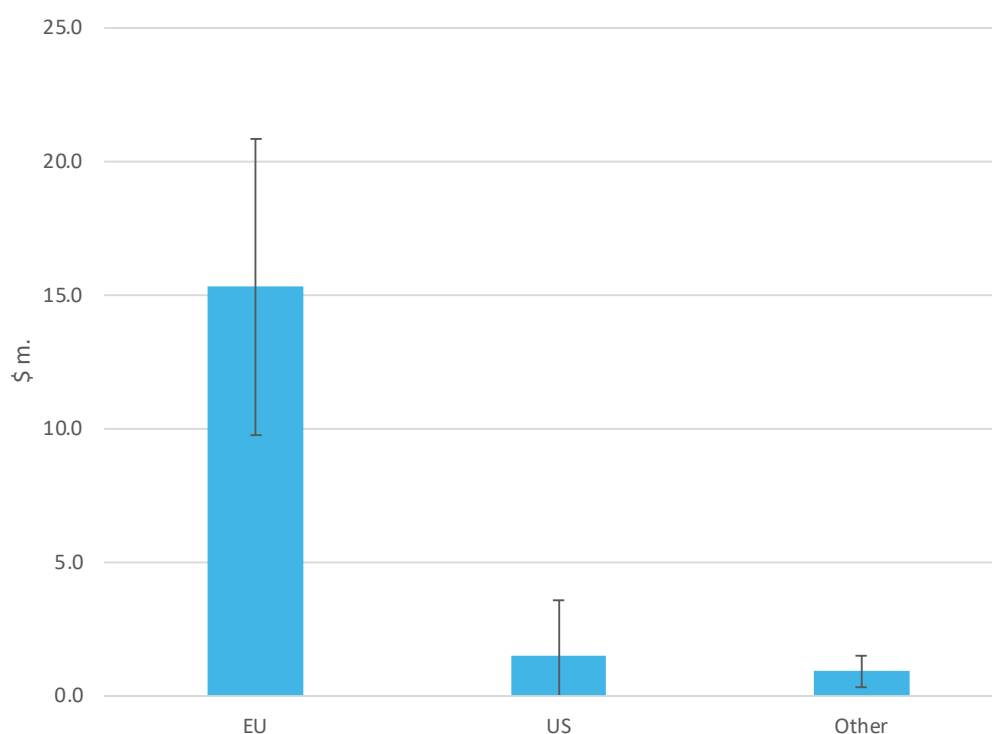
Study Results: Re-registration Costs

The survey responses indicate that costs associated with the re-registration of an active ingredient vary depending on geography and product type.

Regarding geography, re-registration costs were highest in the EU at \$15.3 million, more than ten times higher than re-registration costs in the US (\$1.5 million) and almost 17 times higher than re-registration costs in other jurisdictions. Study participants indicated that higher costs associated with re-registration in the EU were driven by jurisdiction-specific data requirements, including the use of the IUCLID system for data submission. Some participants also noted that they tracked re-registration costs only for the EU, as data generated through the European application process was sufficient to support applications in other jurisdictions.

Costs Associated with Re-registering an Active Ingredient Between 2020 and 2023			
	Category	\$ million	No. Responses
Geography	EU	15.3	4
	US	1.5	4
	Other	0.9	2

Costs Associated with Re-registering an Active Ingredient Between 2020 and 2023 by Geography



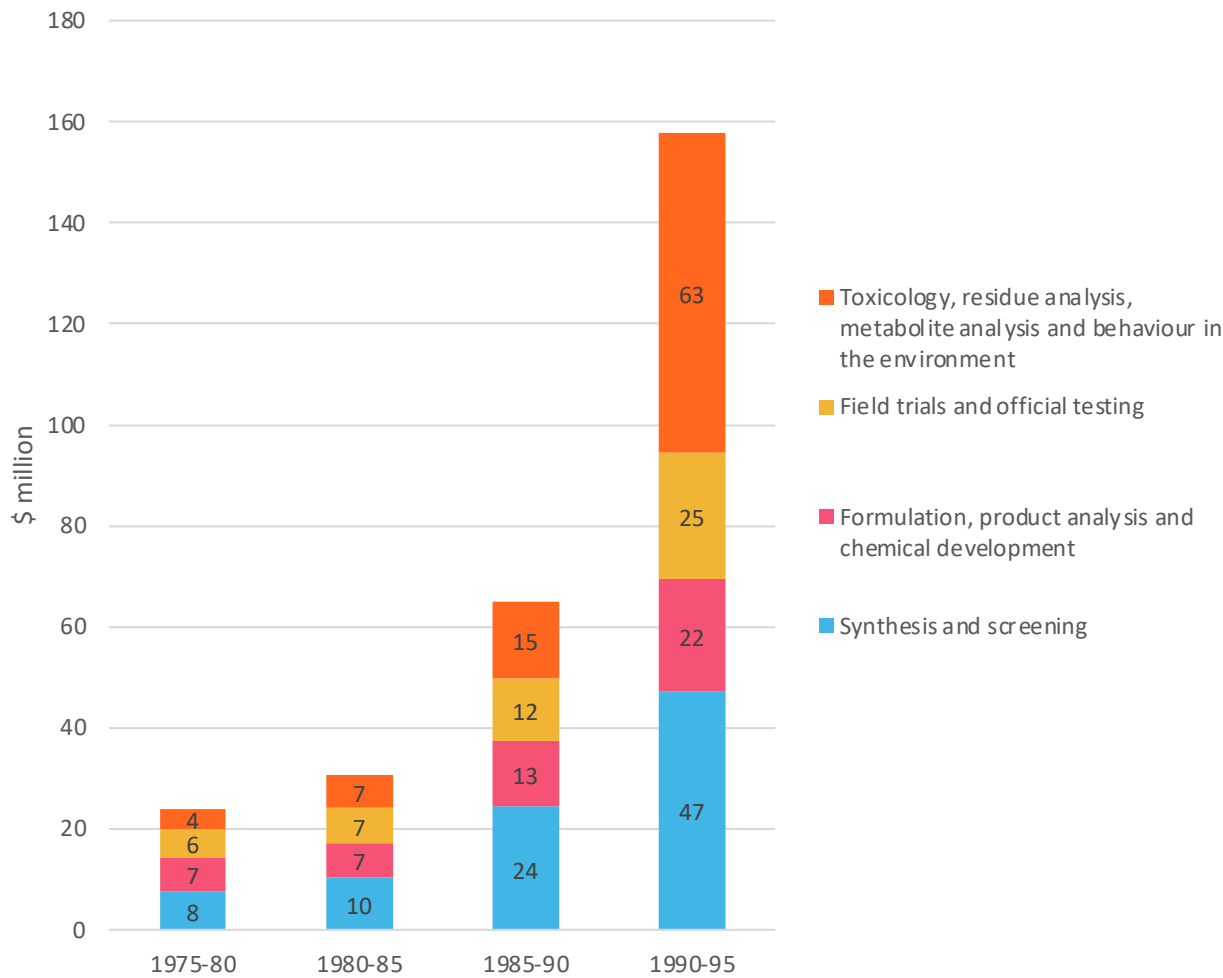


Appendices



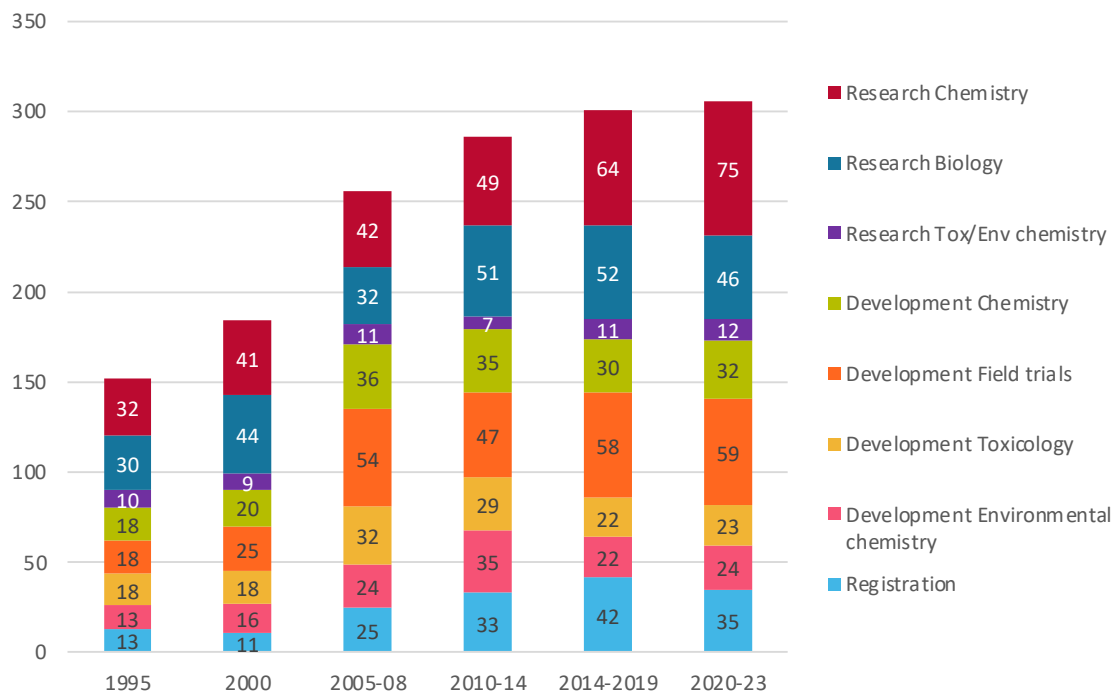


Appendix 1: Development Costs for a Crop Protection Product

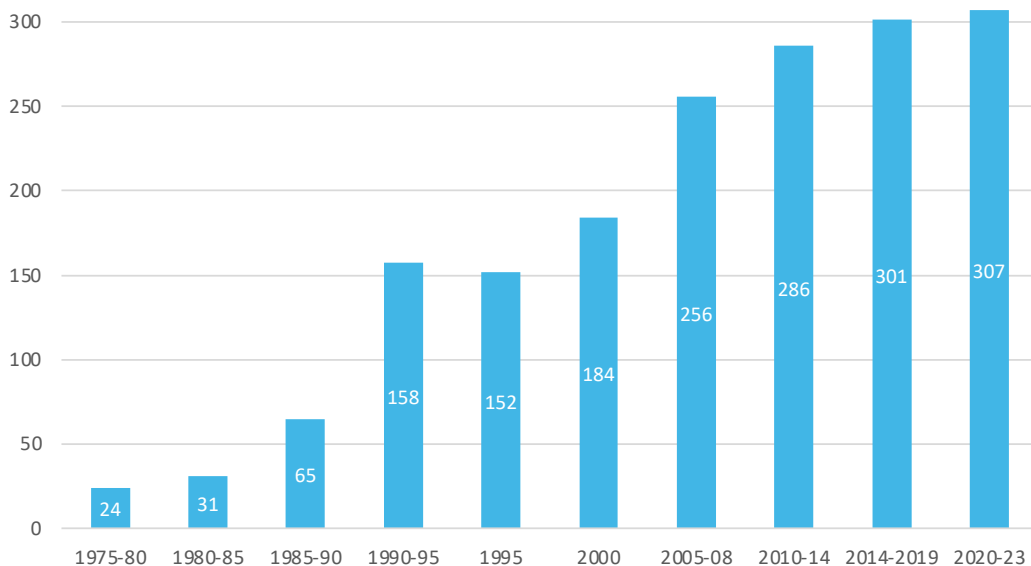


Appendix 2:

Discovery and Development Costs of a New Crop Protection Product



Historical Comparison of Total Discovery and Development Costs of a New Crop Protection AI



Due to changes in methodology and classifications of expenditure results for 1995 and 2000 are looked at in singularity rather than over a defined 3-to-5-year period. The above graph shows amalgamated survey results to demonstrate the change in overall expenditure over time.

Appendix 3:

Study Questionnaire

Summary

The primary aim of this study is to continue previous analyses and provide an up-to-date view on the cost necessary to develop a novel crop protection product. The study is being conducted on behalf of CropLife International.

The leading R&D focused crop protection companies are being asked to participate in a black box study by providing data via a questionnaire.

Guidelines for Completing the Questionnaire

Please complete all parts of the questionnaire with the relevant data. Also please indicate the reporting currency.

Part 1: Breakdown of R&D Expenditure for Bringing a Single New Active Ingredient to a Major Market in the 2020 - 2023 Timeframe.

It is recognised that the various cost allocation sectors outlined in the attached questionnaire are somewhat idealised and will depend on the individual approach of each company to product research and development. However please complete each section according to what you believe best fits your company development programme. If you are able to identify a particular R&D cost that is not shown on the table, we would be grateful if you could indicate this in the final section.

The object of the overall exercise is however to identify the average costs for the industry that are incurred in:

- Firstly, discovering a new crop protection active ingredient
- Secondly, in the whole process involved in product development through to product registration

In addition the study will look at identifying any costs that arise because of additional data or study requirements necessary for registration in the EU versus the USA and vice-versa. For this reason it would be helpful if the development costs reflect those associated with a crop protection product that has applications in major food crops in the EU and the USA.

Appendix 3:

Study

Questionnaire

In completing the questionnaire please bear in mind that the cost of the various studies associated with the research phase are those that are necessary to discover and register **one new active ingredient**. Hence, research costs should reflect the total cost incurred in synthesising, screening and testing of the appropriate number of products that you consider will lead to one successful product launch. For example if your experience is that it is necessary to synthesise 40,000 molecules to discover one new crop protection product, then the research costs should reflect the total incurred for the synthesis and testing of 40,000 molecules. Similarly if your company believes that for every new molecule registered there has to be X molecules going into the development process then the development costs should reflect the total expenditure on X. Please report expenditures before capitalisation. In addition, joint development needs to be clearly accounted for.

For the purposes of this study, biologicals include microbials, natural products including those derived from fermentation, semiochemicals (such as pheromones) and biostimulants. The definition does not include biofertilisers or macrobials (e.g. insects/natural predators).

Appendix 3:

Study Questionnaire

Part 2: Breakdown of R&D

Please provide the breakdown of total non-capitalised R&D expenditure in 2023. The regional split should be based on the market focus of the spending, and not where the money is spent. (e.g. where work is carried out in Europe to develop a product for the Central and South America market, this should be included in the Central and South America data).

Total R&D Expenditure: The total 2023 non-capitalised expenditure on all research and development activities relating to agrochemicals for both crop protection and non-agricultural uses. This covers R&D related to conventional crop protection in agriculture, pest control, industrial and consumer applications, public health and lawn and garden use. It also includes salaries and all other staff-related costs, as well as costs related to R&D administration, rent, supplies, equipment, materials, etc. Activities carried out (for the purpose of agrochemical development) within the corporation but outside the crop protection organization (for those companies having R&D centres/capacities outside of crop protection divisions) should also be included. Corporate research programs, expenditure on joint ventures, alliances, and research agreements with third parties should be included. Depreciation costs related to R&D assets should also be included. Capital expenditure on R&D is excluded.

Research of New Active Ingredients: Includes all of the R&D activities associated with the discovery of new agrochemical active ingredients up to the start of new product development.

Development of New Active Ingredients: Starts at the point when a company commits a new active ingredient to full development, generally marked by the decision to commence long-term toxicity tests. It ends with the registration and launch of a product in a major crop market (generally an OECD country).

Additional costs, Product Launch & Development: Incorporates all regulatory costs linked to product launch, label expansions and product defence (e.g. formulation development and field trials). It excludes all sales and marketing costs associated with the product launch.

Product Monitoring / Stewardship: All product development activities following the launch of a new active ingredient into a major market, including re-registration/registration maintenance: refers to any activities or studies that must be undertaken in response to the requirements of registration authorities in order to maintain a product's registration. Also includes activities required to satisfy regulatory requirements for registration in non-OECD countries, and line extensions of existing products.



Appendix 3:

Study Questionnaire

Part 3: CODEX MRL Costs During 2020 - 2023

Please indicate costs associated with obtaining and maintaining a CODEX MRL (new active, additional/new use and periodic review) in the 2020 – 2023 timeframe.

Part 4: Re-Registration Costs During 2020 - 2023

Please provide costs (including fees, studies etc) for the re-registration of an active ingredient that was re-registered in the 2020 – 2023 timeframe.

Company Information

All information provided by respondents will be anonymised, with all data in the final published report being mean values.

Please provide the name of the company and the currency used in responses to the questionnaire. Any non-US dollar currencies will be converted to US dollar using average yearly exchange rates.

Company Name	
Currency Used	

Appendix 3: Part 1

Part 1: Breakdown of R&D Expenditure for Bringing a Single New Active Ingredient to a Major Market in the 2020 - 20123 Time frame

Please provide indicative data for a product introduced around the 2020 - 2023 time frame

Activity Stage			Cost
Research	Chemistry	Synthesis	
		Formulation	
	Biology	Efficacy Testing (Glasshouse)	
		Small plot trials	
		Field trials	
	Toxicology	Mammalian acute	
		Mammalian sub chronic	
		Environmental	
	Environmental Chemistry	Metabolism	
		Residue analysis	
Development	Chemistry	Scale up of Manufacture	
		Formulation	
	Biology	Large Scale Field trials	
		Registration Field trials	
	Toxicology	Chronic Mammalian	
		Environmental	
	Environmental Chemistry	Metabolism	
		Residues	
Additional Costs – EU		Registration fees	
		Internal Registration Costs	
		Additional studies*	
Additional Costs - US		Registration fees	
		Internal Registration Costs	
		Additional studies*	

*Additional studies refer to specific studies that are only requested in the EU or US and have no use in any other country or registrations region

Appendix 3:

Additional Costs

Part 1 & 2

Any Additional R&D Costs Associated with New Product Development for a product introduced between 2020 – 2023 not Identified in Part 1

Item	Cost

Development Lead Time

Item	Time
In your opinion please indicate the number of years between the first synthesis and the first sale of the product.	

Part 2:

Breakdown of R&D Budget

		Research of New Active Ingredients	Development of Off Patent Products ²	Development of New Active Ingredients ³	Additional costs: Product Launch & Development ⁴	Product Monitoring / Stewardship ⁵
Total R&D Expenditure						
Spending by Sector	Chemical					
	Biologicals					
Market Focus of Spending¹	Europe					
	North America					
	C&S America					
	Rest of the world					

1. The regional split should be based on the market focus of the spending, and not where the money is spent. (e.g. where work is carried out in Europe to develop a product for the Central & South America market, this should be included in the Central & South America data)
2. Development of off patent products new to your company
3. Regulatory costs would be covered under this heading – except data that is specifically related to product launch
4. This should include all regulatory costs linked to product launch, label expansions and product defence (e.g. formulation development and field trials). It excludes all sales and marketing costs associated with the product launch
5. As required by terms of registration

Appendix 3:

CODEX MRL Costs 2020 - 2023

Part 3

Please indicate costs associated with obtaining a CODEX maximum residue limit in the period 2020 – 2023.

Item*		Cost
	New Active Ingredient	
	Per additional use	
	Periodic Review	

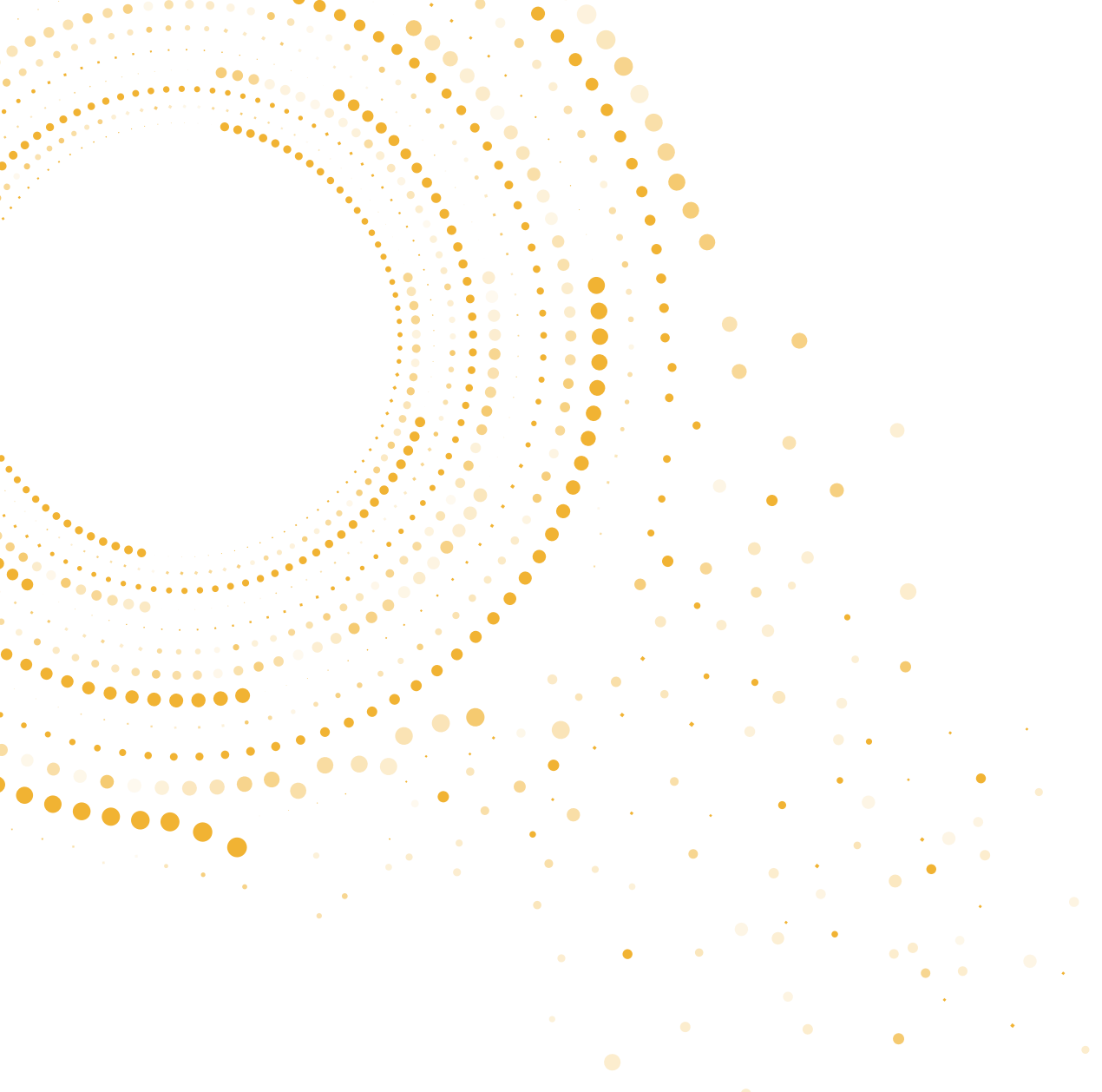
*Please indicate if the chosen active ingredient was a herbicide, insecticide or fungicide

Part 4:

Re-Registration Costs During 2020 - 2023

Item*	Geography	Cost
	European Union	
	United States	
	Other Jurisdictions (please specify)	

*Please indicate if the chosen active ingredient was a herbicide, insecticide or fungicide



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