Phillips McDougall

The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014.

R&D expenditure in 2014 and expectations for 2019

A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association

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Section 1:

The Cost of bringing a new Active Ingredient to the Market

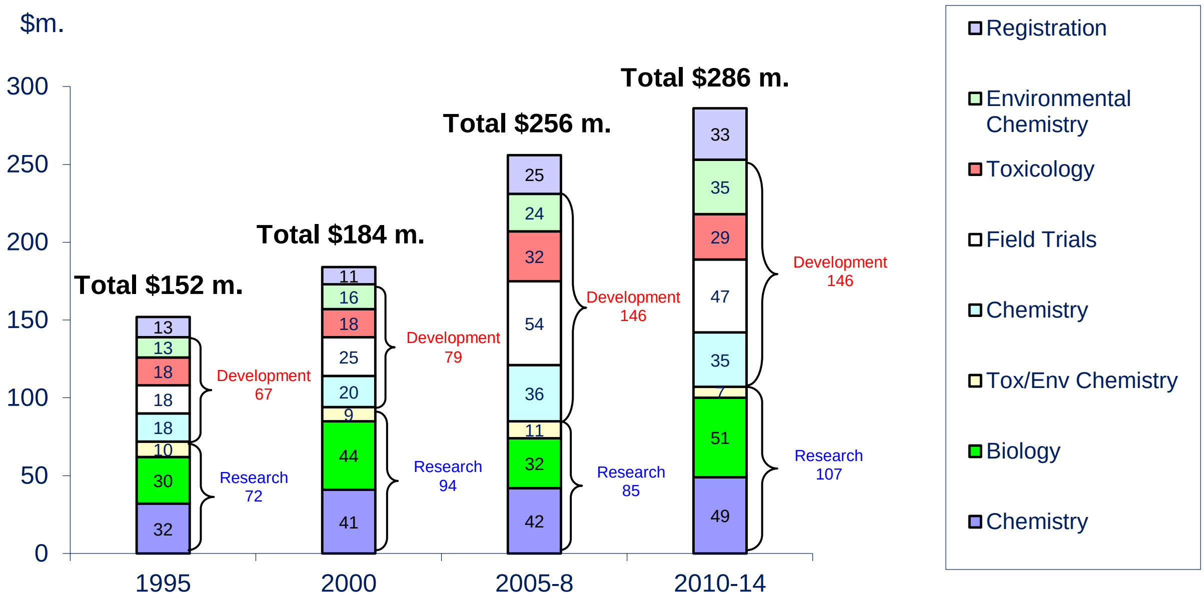
Executive Summary

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

- The expenditure necessary for the discovery and development of a new crop protection product in 1995, 2000 and in both the 2005 to 2008 and 2010 to 2014 periods.
- The number of new molecules that have to be synthesised and tested to lead to the discovery of a new product
- The average time between initial product synthesis and product launch

Five companies were surveyed and the results were as follows:

Discovery and Development Costs of a New Crop Protection Product



The overall costs of discovery and development of a new crop protection product increased by 21.1% from $152 m. (€115m.) in 1995, to reach $184 m. (€140m.) in 2000. From 2000 to the 2005-8 period, costs increased by 39.1% to $256 m. (€189 million). From 2005-8 to the 2010-14 period, costs increased by 11.7% to $286 m. (€215 million)

The survey results demonstrated that the average cost of taking a product through development stages increased from $67 m. in 1995 by 17.9% to $79 m. in 2000, by 84.8% to $146 million by 2005-8 period but remained at that level in the 2010-14 period. Within this the greatest rise was seen in the costs of Environmental Chemistry studies which were shown to have risen by 45.8% from 2005-8 to $35 m. in 2010-14. It is likely that this increase can be attributed to a rise in environmental safety data required by regulatory bodies. The largest single cost in the development cycle remains due to field trials which at $47 m. account for 32.2% of the total spend on product development.

Overall costs of new product research rose by 30.6% from $72 m. per product in 1995 to $94 m. in 2000, but declined slightly to $85 m. in 2005-8, attributed to cost savings potentially made due to greater efficiency from high throughput screening, combinatorial chemistry and genomics. Between 2005-8 and 2010-14 the cost of research of a new agrochemical has risen by 25.9% to $107 m. Unlike the development phase, it was Biology including preliminary field trials that saw the greatest increase in expenditure between 2005-8 and 2010-14, rising by 59.4% to $51 m. Toxicology / Environmental testing in the research phase saw a decline between the 2005-8 and 2010-14 periods, the reverse of what was seen in the development phase.

Between 2005-8 and 2010-14, the average cost of biology (screening) in the research phase rose by 59.4% to $51 m. making this the largest single cost in the R&D of a new agrochemical. The next largest cost is Chemistry (synthesis) in the research phase up by 16.7% to $49 m., both sectors now exceeding the cost of field trials in the development phase, where expenditure declined by 13.0% to $47 m. After biology (screening), the next largest increase was seen in environmental chemistry in the development phase (+45.8%). Registration costs, incorporating extra studies required to satisfy EU and US regulators, rose by 32.0% between 2005-8 and 2010-14 to $33 m. on average.

The results of the survey on product synthetic leads showed that the average number of new molecules that are synthesised and subjected to biological research in order to lead to the registration of one new crop protection product has increased again between the 2005-8 period and 2010-14.

Number of Products Processed leading to a Successful Product launch

		1995	2000	2005-8	2010-14
Research	Synthesis	52500	139429	140000	159574
Development		4	2	1.3	1.5
Registration		1	1	1	1

While both costs and the number of developmental leads 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 also increased.

Crop Protection Product Discovery and Development Lead Time

	1995	2000	2005-8	2010-14
Number of years between the first synthesis and the first sale of the product	8.3	9.1	9.8	11.3

This increase could reflect greater complexity in the data requirements of regulatory bodies however it could also indicate the time taken to satisfy the regulators.

Introduction

During 2015, on behalf of CropLife International, CropLife America and the European Crop Protection Association (ECPA), Phillips McDougall 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 product.

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 product had grown from DM 50m. ($23.1m.) in the 1975-1980 period to DM 250m.($157m.) for the 1990-1995 timeframe. (See Appendix 1). This was updated again in 2003 (See Appendix 2), and again in 2009 (See Appendix 3).

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 product 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.

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 recent 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. In addition the development of high throughput screening methods have 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 that have 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 product for subsequent commercialisation.

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.

Another important area of chemistry development is formulation evaluation. This generally involves the testing and optimisation of a variety of formulations of the new crop protection product to ensure that the product can be delivered in a safe and effective manner for subsequent field use.

In the research stage, biological screens, normally conducted in the laboratory, will have established that a product has potentially important crop protection activity. Further biological development of the new crop protection product is designed to investigate the activity of the product 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 product, 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 product includes significantly expanded toxicology and environmental chemistry testing to meet the statutory requirements of the regulatory bodies in the USA, the EU and elsewhere.

Registration

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

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

Glossary of Terms

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 prior to making the decision as to whether to progress the product 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.
Combinatorial 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.
Development	The progression of selected potential products from discovery to commercialisation. Includes regulatory studies required to support 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.

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 number of products processed by companies in order to commercialise one new crop protection active ingredient
- The lead time between the first synthesis and the commercial introduction of the new active ingredient

Methodology

The study was conducted according to the protocol which is included as Appendix 4.

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

The companies included in this survey were:

- BASF
- Bayer
- Dow
- DuPont
- 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 as Appendix 5.

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 sub categories, the mean values were calculated on a pro rata basis to ensure that the mean category totals agreed with the sub category values.

Study results – Part 1

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 sub categories and as a result sub category 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	**Sub category**	**Cost ($m.)**	**Number of Responses**
Research	Chemistry	32	5
	Biology	30	5
	Toxicology/Environmental Chemistry	10	5
Research total		**72**	**6**
Development	Chemistry	18	6
	Field Trials	18	6
	Toxicology	18	6
	Environmental Chemistry	13	6
Development total		**67**	**6**
Registration		**13**	**5**
Total		**152**	**6**

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 250m. ($157m.)

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 $72m. Within this chemical synthesis was the most costly stage in the discovery process with an average value of $32m. followed by biological research screening with a mean cost of $30m.

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

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 sub categories and as a result sub category mean values were calculated on a pro rata basis.

The actual number of responses for each category and sub category, 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	Sub Category	Cost ($m.)	Number of Responses
Research	Chemistry	41	6
	Biology	44	6
	Toxicology/Environmental Chemistry	9	6
Research total		**94**	**9**
Development	Chemistry	20	8
	Field Trials	25	8
	Toxicology	18	8
	Environmental Chemistry	16	8
Development total		**79**	**9**
Registration		**11**	**7**
Total		**184**	**9**

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

As with the 1995 results, product research or discovery remained the most significant category in new agrochemical R&D with an expenditure of $94m., equivalent to 51.1% of the total. Within this, biological screening was the most significant sub category representing an expenditure of $44m. followed by new product chemistry which accounted for a further $41m. 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 $79m., equivalent to 42.9% of the overall total. Within this category, field trails were the most significant costs with a value of $25m., followed by developmental chemistry which accounted for a further $20m. and toxicology which was valued at $18m. The remaining expenditure in product development was environmental chemistry at $16m.

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

Cost of New Product Discovery and Development – 2005-8

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 sub categories and as a result sub category mean values were calculated on a pro rata basis.

The actual number of responses for each category and sub category, 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	Sub Category	Cost ($m.)	Cost (Euro m.)	Number of Responses
Research	Chemistry	42	32	5
	Biology	32	24	5
	Toxicology/Environmental Chemistry	11	8	5
Research total		**85**	**64**	**5**
Development	Chemistry	36	26	5
	Field Trials	54	40	5
	Toxicology	32	23	5
	Environmental Chemistry	24	17	5
Development total		**146**	**107**	**5**
Registration		**25**	**18**	**5**
Total		**256**	**189**	**5**

The above results demonstrated that the overall costs for the discovery and development of a new agrochemical product in 2005-8 period had risen to $256m. (Euro 189 m.).

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 $146m., equivalent to 57% of the total. Within this category, field trials were the most significant costs with a value of $54m., followed by developmental chemistry which accounted for a further $36m. and toxicology which was valued at $32m. The remaining expenditure in product development was environmental chemistry at $24m.

Product research costs in 2005-8 represented a total expenditure of $85m., equivalent to 33.2% of the overall total. Within this, new product chemistry was the most significant sub category representing an expenditure of $42m. followed by biological screening which accounted for a further $32m. 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 2005-8 period were assessed at $25m., equivalent to 9.8% of the total discovery and development expenditure.

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 sub categories and as a result sub category mean values were calculated on a pro rata basis.

The actual number of responses for each category and sub category, 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	Sub Category	Cost ($m.)	Cost (Euro m.)	Number of Responses
Research	Chemistry	49	37	5
	Biology	51	38	5
	Toxicology/Environmental Chemistry	7	5	5
Research total		**107**	**80**	**5**
Development	Chemistry	35	26	5
	Field Trials	47	36	5
	Toxicology	29	22	5
	Environmental Chemistry	35	26	5
Development total		**146**	**110**	**5**
Registration		**33**	**25**	**5**
Total		**286**	**215**	**5**

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 m. (Euro 215 m.).

Similar to the results of the 2005-8 analysis, the development phase still accounted for the largest share of the R&D cost. However, between the 2005-8 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 m., 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 m., although these costs declined by 13.0% from 2005-8, 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 m., 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 $33m., equivalent to 11.5% of the total discovery and development expenditure.

Comparison between 1995, 2000, 2005-8 and 2010-14 Costs

The following table summarises the survey results for 1995, 2000, 2005-8 and 2010-14.

New Crop Protection Product Discovery and Development Costs

(2010-14 versus 2005-8, 2000 and 1995)

Category	Sub Category	Cost ($m.)				Change (%)
		1995	2000	2005-8	2010-14	2010-14/2005-8
	Chemistry	32	41	42	49	+16.7
	Biology	30	44	32	51	+59.4
	Toxicology/ Environmental Chemistry	10	9	11	7	-36.4
Research	**Total**	**72**	**94**	**85**	**107**	**+25.9**
	Chemistry	18	20	36	35	-2.8
	Field Trials	18	25	54	47	-13.0
	Toxicology	18	18	32	29	-9.4
	Environmental Chemistry	13	16	24	35	+45.8
Development	**Total**	**67**	**79**	**146**	**146**	**0.0**
Registration		**13**	**11**	**25**	**33**	**+32.0**
Total		**152**	**184**	**256**	**286**	**+11.7**

The above results demonstrate that the overall costs of discovery and development for a new crop protection product for the market in the EU and the USA have risen by 11.7% from 2005-8 to reach $286 m. in 2010-14.

The total cost of research has risen between 2005-8 and 2010-14 ahead of the increase in the cost of development processes, whilst the survey has shown that the expenditure required for the actual product registration process has significantly increased again to $33m. by 2010-14. Statutory registration fees represent only a small proportion of the overall registration process, with the largest element of this increase being the internal costs for preparing dossiers and additional studies required by the regulatory bodies in the EU and USA.

The table above indicates that between 2005-8 and 2010-14, Research costs have risen for biology (product screening), chemistry (synthesis and formulation) but declined for preliminary toxicology and environmental chemistry testing, prior to making any decision to take a product candidate into development. In 2005-8, biology costs were thought to have declined due to the adoption of advanced rapid throughput screening/genomics. However biology costs in 2010-14 have increased to over the level of 2000, the largest increase being seen in the cost of glasshouse efficacy testing. Similarly, combinatorial chemistry was thought in 2005-8 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.

It is a major commercial decision for a company to progress a product candidate from Research into Development and dedicate a further $179 million in costs (development and registration) to bring that product to market. The company needs to be comfortable with the efficacy, safety and commercial potential for a product candidate to make this decision, reflected in the rise in biology expenditure in the Research phase.

In the Development phase, the cost of chemistry (phase up to production of commercial quantities and formulation development) and toxicology declined slightly between 2005-8 and 2010-14. This follows big increases in these costs from 2000 to 2005-8. In that period the adoption of more advanced formulation chemistry was believed to have driven this increase, however it could now be the case that the costs of those technologies has now come down. The greatest increase in development chemistry costs from 2005-8 to 2010-14 as seen in the scale up of manufacturing processes.

Toxicology costs in the development cycle rose rapidly from 2000 to 2005-8, but fell back again in the 2010-14 period. In the research phase, all sectors of toxicology and environmental chemistry except residue analysis, saw a decline in costs between 2005-8 and 2010-14, despite the need to assess potential toxicity before a product enters the development phase. The more detailed analysis shown below shows that the costs of chronic mammalian toxicology have actually declined between 2005-8 and 2010-14, however the costs for environmental toxicology testing have increased significantly.

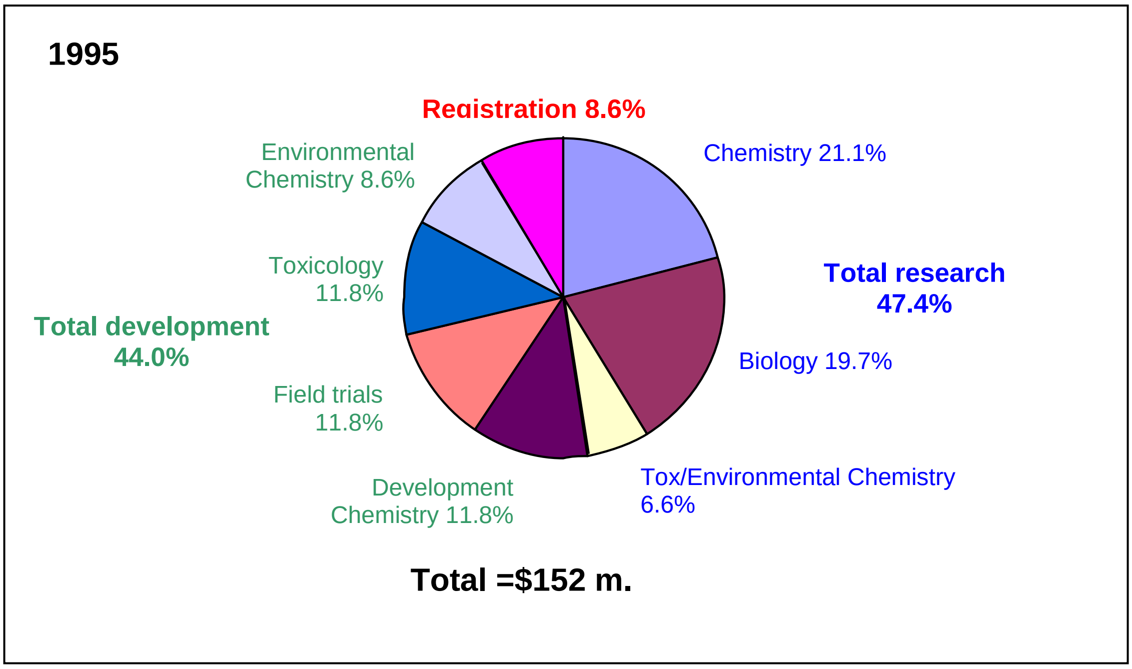
Field trial costs in the development phase overall registered a decline between 2005-8 and 2010-14, however there was a big swing in cost away from large scale field trials to registration field trials driven by the requirements of the regulatory bodies. However, the greatest rise in costs in the development phase was seen for environmental chemistry testing, driven by a significant increase in the cost of residue analysis, whilst the expenditure on metabolic studies actually declined.

Both field trails and environmental chemistry reflect the demands of the regulatory bodies to show improved efficacy in comparison with existing products, and also to ensure safety in the environment.

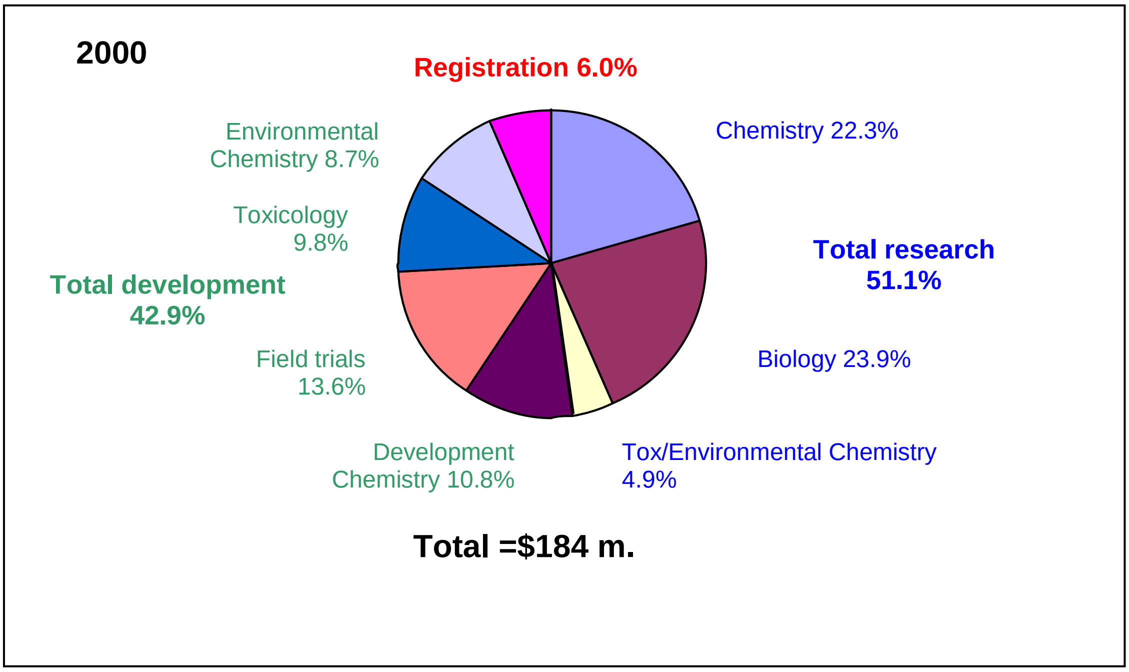
Detailed Comparison of 2005-8 and 2010-14 Results

Category	Sub Category	Sector	Cost $m		Change %
			2005-8	2010-14	2010-14 / 2005-8
Research	Chemistry	Synthesis	41.4	47.0	13.4
		Formulation	0.6	1.7	171.2
		Sub Total	42.1	48.7	15.7
	Biology	Efficacy Testing (Glasshouse)	23.5	41.3	75.3
		Small plot trials	3.9	3.0	-23.8
		Field trials	4.7	6.6	39.7
		Sub Total	32.1	50.9	58.4
	Toxicology	Mammalian acute	2.4	2.3	-5.3
		Mammalian sub chronic	4.6	1.4	-70.0
		Environmental	1.9	1.3	-32.3
		Sub Total	8.9	5.0	-43.8
	Environmental Chemistry	Metabolism	2.0	1.1	-45.2
		Residue analysis	0.4	0.8	129.6
		Sub Total	2.4	1.9	-19.0
Total - Research			**85.5**	**106.5**	**24.6**
Development	Chemistry	Scale up of Manufacture	19.7	26.6	35.2
		Formulation	16.5	8.4	-49.1
		Sub Total	36.2	35.0	-3.3
	Biology	Large Scale Field trials	43.4	9.9	-77.2
		Registration Field trials	11.0	37.2	237.5
		Sub Total	54.5	47.1	-13.5
	Toxicology	Chronic Mammalian	21.9	15.4	-30.0
		Environmental	9.9	13.2	33.7
		Sub Total	31.8	28.6	-10.2
	Environmental Chemistry	Metabolism	15.3	11.7	-23.7
		Residues	8.4	23.1	176.5
		Sub Total	23.7	34.8	47.0
Total - Development			**146.2**	**145.5**	**-0.5**
Registration	EU	Registration fees	5.7	5.2	-9.1
	EU	Internal Registration Costs	13.5	5.6	-58.4
	EU	Additional studies **	2.3	9.1	289.4
		Sub Total	21.5	19.9	-7.5
	USA	Registration fees	0.6	2.9	413.1
	USA	Internal Registration Costs	1.3	3.0	124.4
	USA	Additional studies **	1.5	7.4	381.5
		Sub Total	3.4	13.3	286.8
Registration - Total			**25.0**	**33.2**	**33.0**
Grand Total			**256.6**	**285.2**	**11.1**

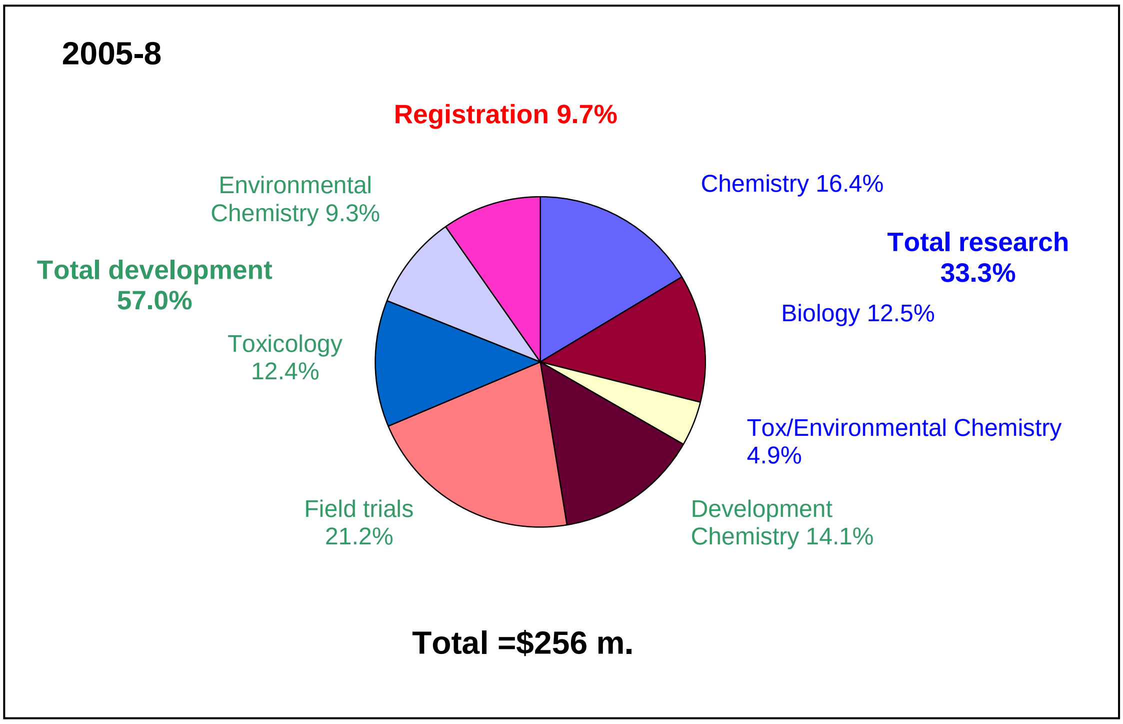
Comparison with 2000 data not possible due to incomplete survey returns.

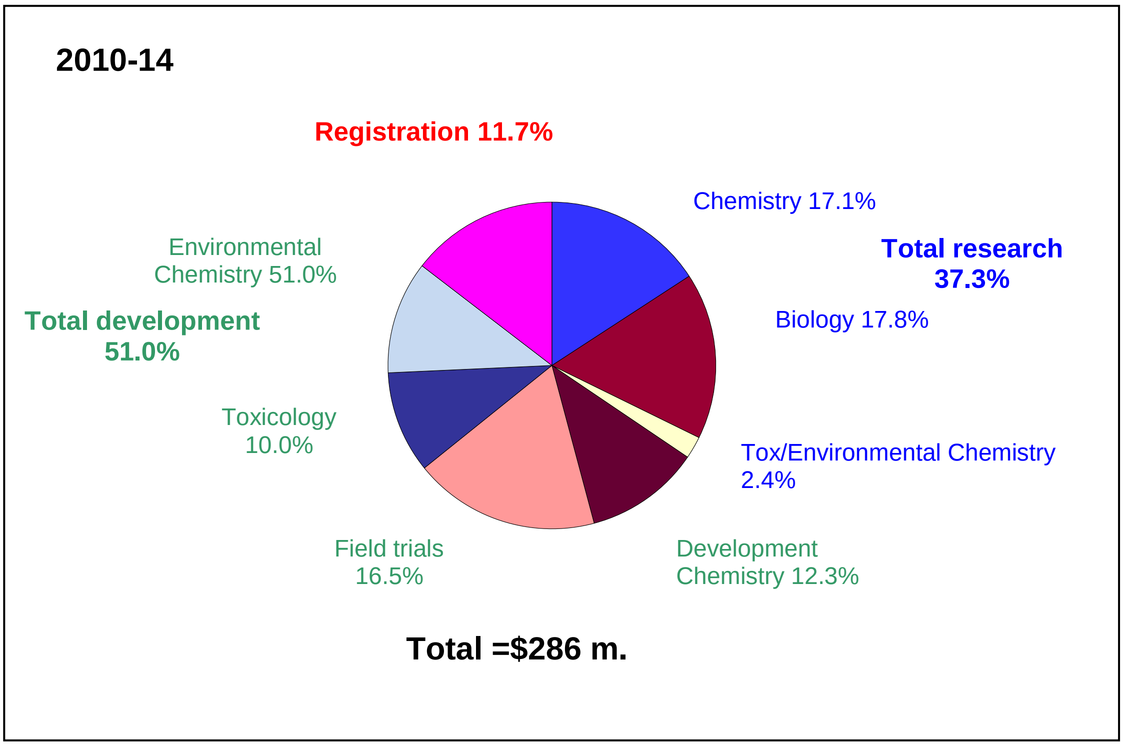


New Crop Protection Product Discovery and Development Costs



New Crop Protection Product Discovery and Development Costs





Study results – Parts 2 to 4

Part 2: Additional R&D Costs

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

A number of companies identified additional expenses, however all responses highlighted very different costs. For the majority of respondents these additional costs did not exceed $5 million

Part 3: Number of Products Processed Leading to a Successful Product Launch

This section of the questionnaire asked each company to identify the number of products synthesised that would result in the development and launch of a new crop protection product. The responses received showed huge variability. The following table outlines both means and medians of results of this survey section:

Number of Products Processed leading to a Successful Product launch

		1995	2000	2005-8	2010-214
Research	Synthesis	52,500	139,429	140,000	159,754
	Post Synthesis	**	**	**	**
Development		4	2	1.3	1.5
Registration		1	1	1	1

Note: ** - insufficient data

It is apparent from the above that the number of products that are synthesised and screened to lead to a successful product launch has been steadily increasing since 1995.

Despite the high number of products entering the agrochemical R&D chain, it is notable that the average number of products which make it through to the developmental stage has declined from an average of 4 in 1995 to only 1.5 on average in 2010-14. In essence this reflects a greater certainty in the decision making process in product development as the majority of products in development reach commercialisation.

Although this result may also reflect an increasing level of difficulty in finding new product leads it will also reflect the caution and financial screening of product candidates coming out of research before acceptance for development. This study has shown the increasing costs of bringing a product through development stages, companies need to satisfy themselves that potential commercial return can justify this expenditure. It is believed that a significant number of product leads do not pass into development stages as the potential returns may not justify these costs.

Part 4: 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. Five 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

	1995	2000	2005-8	2010-14
Number of years between the first synthesis and the first sale of the product	8.3	9.1	9.8	11.3

Based on the results of the survey, over the period from 2005-8 to 2010-14, the lead time between the first synthesis of a new crop protection product and its commercialisation has increased from an average of 9.8 years to 11.3 years. 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. Another potential contributory factor could be the pressure on regulatory bodies to ensure that registration dossiers are absolutely complete prior to authorisation, rather than issuing a provisional approval.

Discussion: Section 1

This study was designed to determine the relative cost of new crop protection product discovery, development and registration in 2010-2014. During this time frame several important factors have impacted the industry and led to significant changes in the sector:

- Between 2010 and 2014, the expansion of the GM seed industry continued, whilst a number of major companies acquired interests in the Biocontrol sector. Both of these factors have put additional strain on R&D budgets.
- The global value of the conventional chemical crop protection market has been in a trend of steady improvement.
- A number of mid-sized companies reduced basic research capabilities to focus on inward licencing of product leads for commercialisation.
- All the major companies in the agrochemical industry now also support an R&D effort in the seeds and traits area.
- Continuing regulatory activity, particularly in the EU, with a shift from risk based to hazard based assessment of agrochemicals.

All of these factors have significantly affected the outlook for the conventional crop protection sector and importantly how companies view their future in the industry. Crop protection research is clearly one of the most important factors in determining the relative competitive position of the companies within the industry especially from a growth prospect viewpoint.

The results of this study in comparison with previous work have clearly shown the increasing cost to Crop Protection Companies to bring new active ingredients to the market. In 1975-80 the cost of bringing a new product through research, development and registration averaged $23.1 million; this study has shown that this figure has increased to $152 million in 1995, $184 million in 2000, $256 million in the 2005-2008 timeframe and $286 million in 2010-14.

In the 2005-8 period a number of new technologies were adopted with the aim of increasing the breadth and rate of new product discovery and screening, notably genomics and rapid throughput screening that assist biological research for new products and their assessment, and combinatorial chemistry that increases the number of new product leads from chemical sources. Despite the questioning of the success of combinatorial chemistry, the number of analogues synthesised for each product eventually reaching the market rose again from 2005-8 to 2010-14.

In 1995, the average cost of the research phase amounted to 47% of the total cost of bringing a new product to market; in 2000 this share of expenditure had increased to 48%. However in the 2005-2008 timeframe this share fell to 33.3%, only to rise again to 37.3% in 2010-14.

Between 1995 and 2000, the most significant factor contributing to this was the substantial increase in the costs of biology research, in part a consequence of the adoption of high throughput screening and new discovery techniques. However between 2000 and 2005-8, the focus of expense appeared to have shifted toward the development stage of the cycle.

As a result the share accountable to development stages declined from 44% to 43% between 1995 and 2000, but increased to 57% by the 2005-8 period. However, in 2010-14, this share fell back to 51.0%.

A major contributor to increasing R&D costs between 2005-8 and 2010-14 has been an increase in Environmental chemistry and Environmental toxicology costs in the development phases, with Residue analysis seeing a significant increase in expenditure.

A notable factor in 2005-8 was increasing costs in the field trials area, although overall this expenditure declined by 2010-14, although the costs for field trials required by the regulatory bodies registered a significant increase. The increase in expenditure in field trials for efficacy testing in the research phase was more modest.

With the high share of expenditure on the development phase, the move to take a product from research into development remains a key financial decision for any company, the study clearly showing that the number of potential products that approach this stage has been maintained.

An interesting factor is a significant increase in the costs of registration between 2005-8 and 2010-14. The study identified the major reason for this being an increase in the cost of additional studies required for the regulatory bodies in the EU and USA. The results show a greater rise in registration costs in the USA due to an increase in fees, whilst the average fees for registration in the EU show a decline.

Section 2: R&D Expenditure 2014 and Expectations for 2019

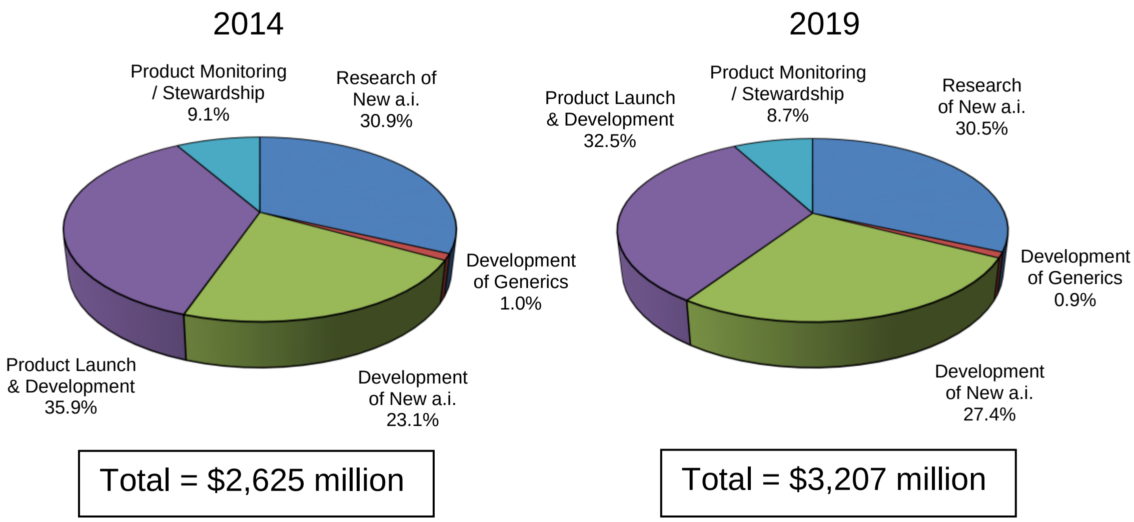
Executive Summary

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 process.
- The proportion of R&D budget that is targeted at new product discovery, development and managing the existing business including product stewardship and monitoring.
- Expectations for change in R&D expenditure between 2014 and 2019

Responses to the survey were received from eleven companies. The total cost of agrochemical R&D expenditure in 2014 for these eleven companies was $2625 m., a value equivalent to 5.4% of their agrochemical sales. These companies also provided expectations of R&D expenditure in 2019, overall the expectation was for a 22.6% increase in expenditure over this five year timeframe, at an average rate of increase of 4.1% p.a.

Agrochemical Industry R&D Expenditure by Function
(Eleven reporting companies only)

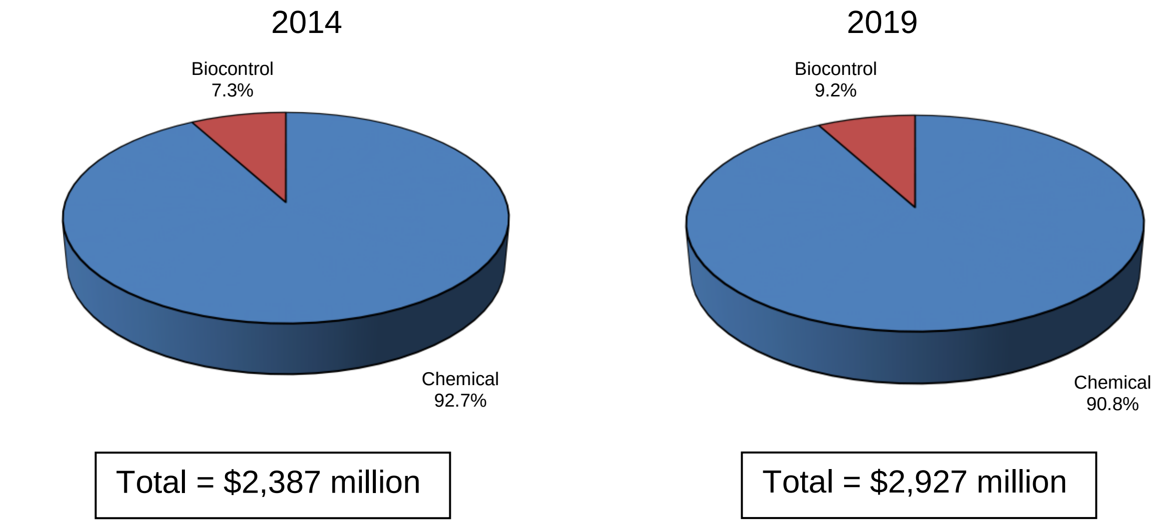


Whilst there was large inter-company variability in the expected growth in R&D expenditure between 2014 and 2019, overall all sectors within R&D expenditure are expected to increase, with the largest growth in expenditure expected in the area of development of new active ingredients (+44.7%), followed by research of new active ingredients (+20.6%) and then product monitoring and stewardship (+17.6%). The largest single sector of the budget in both 2014 and again in 2019, product launch and development, is however only expected to increase by 10.5%.

Comparisons of the expected R&D budget in 2012 (from the last iteration of this study) with the actual breakdown of the budget in 2014 shows that research of new active ingredients and product launch and development costs account for a larger share of the overall budget than was anticipated, but that the other three sector account for less.

Respondents were 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, this budget was $2,387 million and was expected to rise by 22.6% to $2,927 million by 2019.

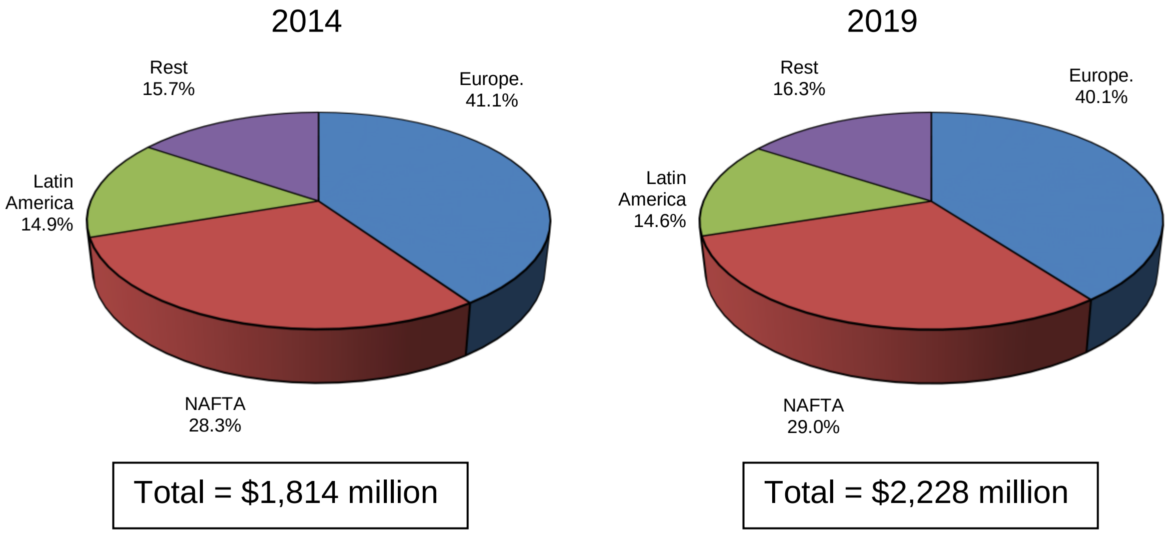
Agrochemical Industry R&D Expenditure by Sector
(Eleven reporting companies only)



In 2014, chemical products accounted for 92.7% of the R&D budget, with expenditure expected to rise by 20.1% by 2019. The R&D budget for biocontrol products, whilst only 7.3% of the total in 2014, is expected to rise by 54.6% by 2019 to account for 9.2% of the total.

Respondents were also asked to provide a regional breakdown of development and stewardship costs by region (all the R&D criteria above except research of new active ingredients), focussing on where products in development were targeted. In 2014, this development budget was $1,814 million and is expected to rise by 22.8% to $2,228 million by 2019.

Agrochemical Industry Development Expenditure by Region
(Eleven reporting companies only)



Europe accounted for the largest share of the development budget in 2014 at 41.1%, although this share is expected to fall to 40.1% by 2019, although in value terms this equates to an increase of 19.7%. The greatest growth in the focus of development costs is expected in the ‘Rest of the World’ region, expected to rise by 27.0% between 2014 and 2019, followed by the NAFTA region at 26.1%. Surprisingly, despite the growth of agrochemical usage for the region as a whole, Latin America accounts for the smallest share of the regional development budget at 14.9% in 2014, and also with a lower growth expectation through to 2019, at 20.7%. Within this data Latin America accounts for a low proportion of expenditure on the development of new active ingredients, but a higher share in product launch and development costs. This indicates that Latin America is not the primary regional target for new active ingredients, however once developed these products are subsequently launched in the region.

Background

In 2002 Phillips McDougall undertook a study on behalf of the European Crop Protection Association (ECPA) 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 product. This study has now been repeated as reported in Section 1 of this report. Whilst this study provides information on the costs involved in bringing a new agrochemical active ingredient from the initial discovery process to the market place, it does not provide information on the overall level of R&D expenditure or expectation for the future. A further study was undertaken on behalf of CropLife International regarding company R&D expenditure in 2004, this study was repeated in 2009, but for 2007 and expectations for 2012. This second study is a repeat of the 2009 study but for the 2014 to 2019 period.

This survey undertaken and reported in this second section is designed to provide a greater understanding of the level of annual overall expenditure made by the agrochemical industry on research and development, and also its expectations for the future.

Study Scope

As outlined above, this current study was designed to measure the overall level of expenditure devoted by the agrochemical industry to the research and development process.

- The proportion of R&D budget that is targeted at new product discovery, development and managing the existing business including product stewardship and monitoring.
- Expectations for change in R&D expenditure between 2014 and 2019.

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	Bayer CropScience	Dow AgroSciences
DuPont	Syngenta	Monsanto
Amvac	Nufarm	De Sangosse
ISK	Belchim	

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 Year Exchange Rates to the US Dollar (2007):
Euro: 0.753
Australian Dollar: 1.11
Japan Yen: 105.859

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.

Study Definitions

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

Typically the R&D process for new products can be split between the discovery process and product 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 a significant amount of research and development aimed at maintaining and developing 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 pest situations 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 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) 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.

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 research and development 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 authorities' post-introduction.

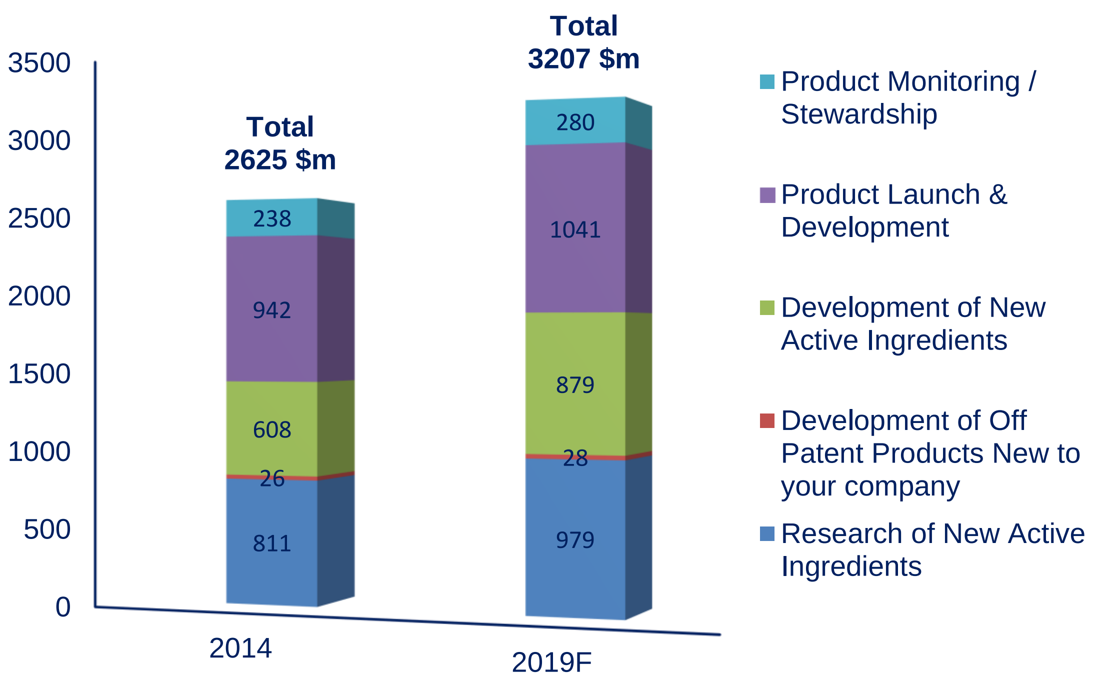
Study results – Part 2

R&D Expenditure 2014 and Expectations for 2019

Responses to the survey were received from eleven companies. The total agrochemical R&D budgets in 2014 for these eleven companies was $2,625 m., a value equivalent to 5.4% of the agrochemical sales of these companies. This level of expenditure, 5.4% of sales, is below the level ascertained in the previous study undertaken of R&D expenditures in 2004, which was 7.5% and in 2005-8 at 6.7%. Unfortunately there is no comparison between the level of total expenditure as the audience of reporting companies has changed.

The responding companies also provided expectations of R&D expenditure in 2019; overall the expectation was for a 22.6% increase in expenditure over this five year timeframe, at an average rate of increase of 4.1% p.a.

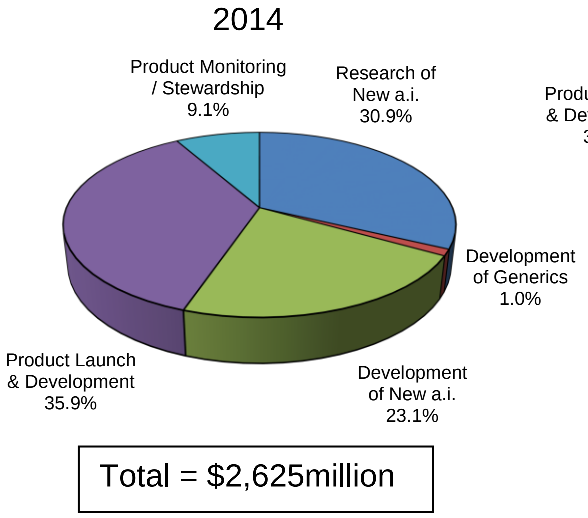
R&D Expenditure Breakdown of the Fourteen Responding Companies

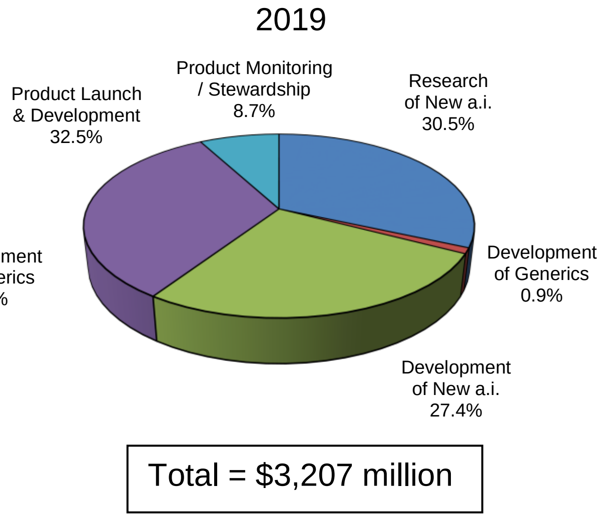


As can be seen in the graph above, the expectations of the eleven responding companies is that expenditure will increase between 2014 and 2019 in each of the sectors which comprise overall R&D expenditure. The greatest increase being expected in the development of new active ingredients, up by 44.7% to $879 million, followed by research of new active ingredients, up by 20.6% to $979 million. This is a change in emphasis from the 2007 to 2012 study where the expectations for the greatest growth were in product stewardship/monitoring and development of new generics. Perhaps this indicates a greater emphasis on new product R&D rather than on older chemistry. Between 2014 and 2019, product stewardship/monitoring is expected to rise at the lesser rate of 17.6%, and development of off-patent products new to your company by only 8.8%.

The largest single sector of the combined budgets of the reporting companies was however in product launch and development, at $942 million in 2014 and expected to rise to $1041 million in 2019, a rise of 10.5%.

Agrochemical Industry R&D Expenditure by Function (Eleven reporting companies only)

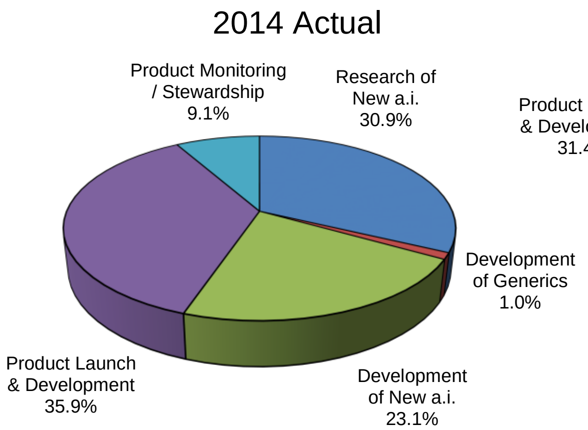


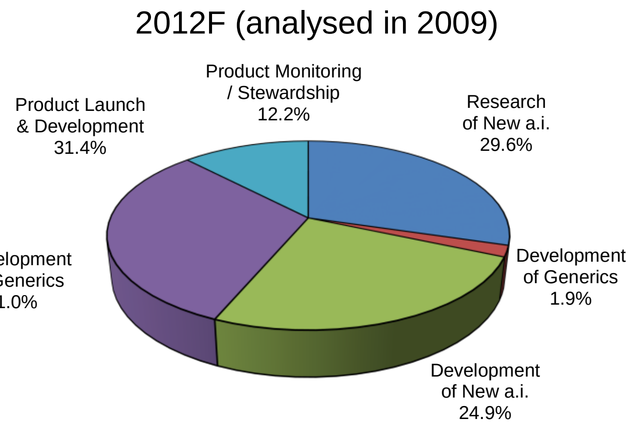


Whilst there was large inter-company variability in the expected growth in R&D expenditure between 2014 and 2019, overall all sectors within R&D expenditure are expected to increase, with the largest growth in expenditure expected in the area of development of new active ingredients (44.7%), followed by research of new active ingredients (+20.6%) and then product monitoring and stewardship (+17.6%). The largest single sector of the budget in both 2014 and expected in 2019, product launch and development, is however only expected to increase by 10.5%.

Comparisons of the expected R&D budget in 2012 (from the last iteration of this study) with the actual breakdown of the budget in 2014 shows that research of new active ingredients and product launch and development costs account for a larger share of the overall budget than was anticipated, but that the other three sector account for less.

Agrochemical Industry R&D Expenditure by Function





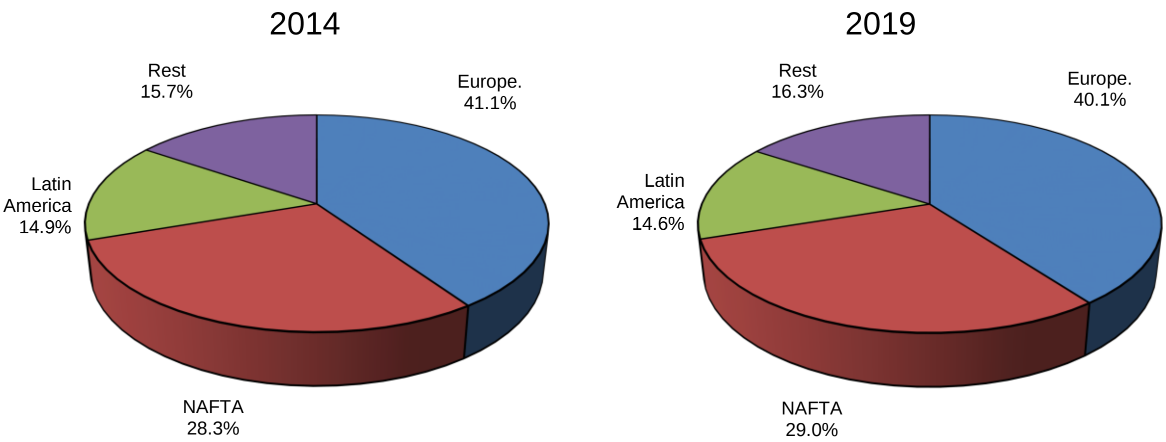
Comparison with the last iteration of this study is of academic interest as the list of responding companies is different between the two studies. However, it does give an indication of changes in intentions. In the 2009 study, the expectations for 2012 were for a significant increase in the share of R&D budgets related to off patent product development and product monitoring/stewardship costs. Comparison with the breakdown of actual R&D budgets in 2014 shows that neither of these actually occurred. Product launch and development costs were shown to have risen in the 2009 project, but were forecast to account for a similar proportion of the budget by 2012, in fact by 2014 the share had increased quite significantly. It was anticipated that the share of R&D budgets devoted to new active ingredient research would decline by 2012, however, the 2014 data shows that the share of the budget has declined, but not by as much as anticipated.

In the period to 2007, development costs for new active ingredients had been rising, and it was anticipated that they would account for a larger share of the R&D budget by 2012, however in 2014 that share had actually declined to below 2007 levels.

This analysis indicates a sustained investment in new active ingredient research, but a lower than expected share of the budget being required for product development, but a larger share for product launch and development.

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 focussed). The analysis was to focus on where products in development were targeted for introduction. In 2014, this development budget was $1,814 million and was expected to rise by 22.8% to $2,228 million by 2019.

Agrochemical Industry Development Expenditure by Region (Eleven reporting companies only)



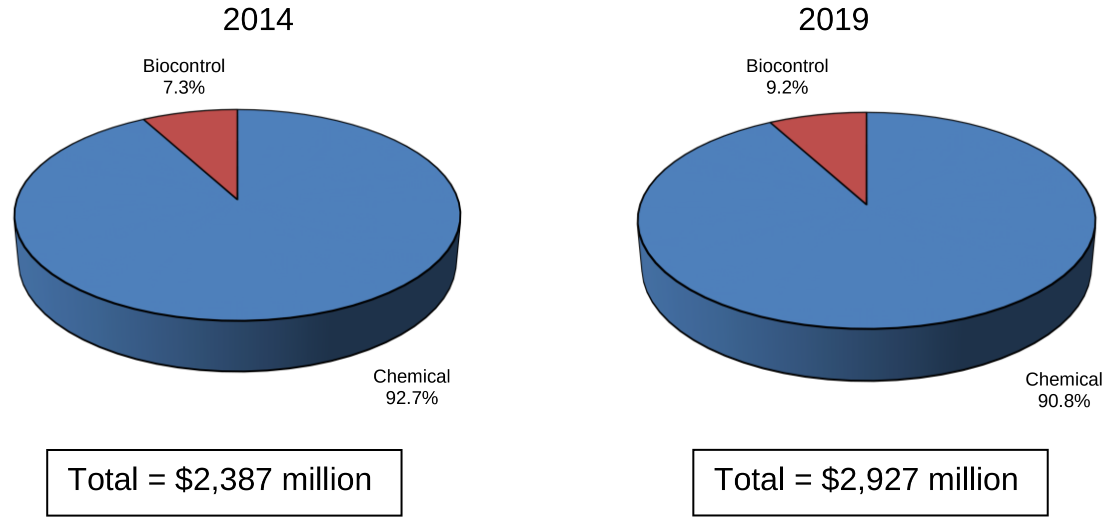
Total = $1,814 million

Total = $2,228 million

Europe accounted for the largest share of the development budget in 2014 at 41.1%, although this share is expected to fall to 40.1% by 2019, although in value terms this equates to an increase of 19.7%. The greatest growth in the focus of development costs is expected in the 'Rest of the World' region, expected to rise by 27.0% between 2014 and 2019, followed by the NAFTA region at 26.1%. Surprisingly, despite the growth of agrochemical usage for the region as a whole, Latin America accounts for the smallest share of the regional development budget at 14.9% in 2014, and also with a lower growth expectation through to 2019, at 20.7%. Within this data Latin America accounts for a low proportion of expenditure on the development of new active ingredients, but a higher share in product launch and development costs. This indicates that Latin America is not the primary regional target for new active ingredients, however once developed these products are subsequently launched in the region.

Respondents were 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, this budget was $2,387 million and was expected to rise by 22.6% to $2,927 million by 2019.

Agrochemical Industry R&D Expenditure by Sector
(Eleven reporting companies only)



In 2014, chemical products accounted for 92.7% of the R&D budget, with expenditure expected to rise by 20.1% by 2019. The R&D budget for biocontrol products, whilst only 7.3% of the total in 2014, is expected to rise by 54.6% by 2019 to account for 9.2% of the total. 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.

The following tables represent the summation of the responses received from the eleven participating companies. The data has been presented graphically and discussed above.

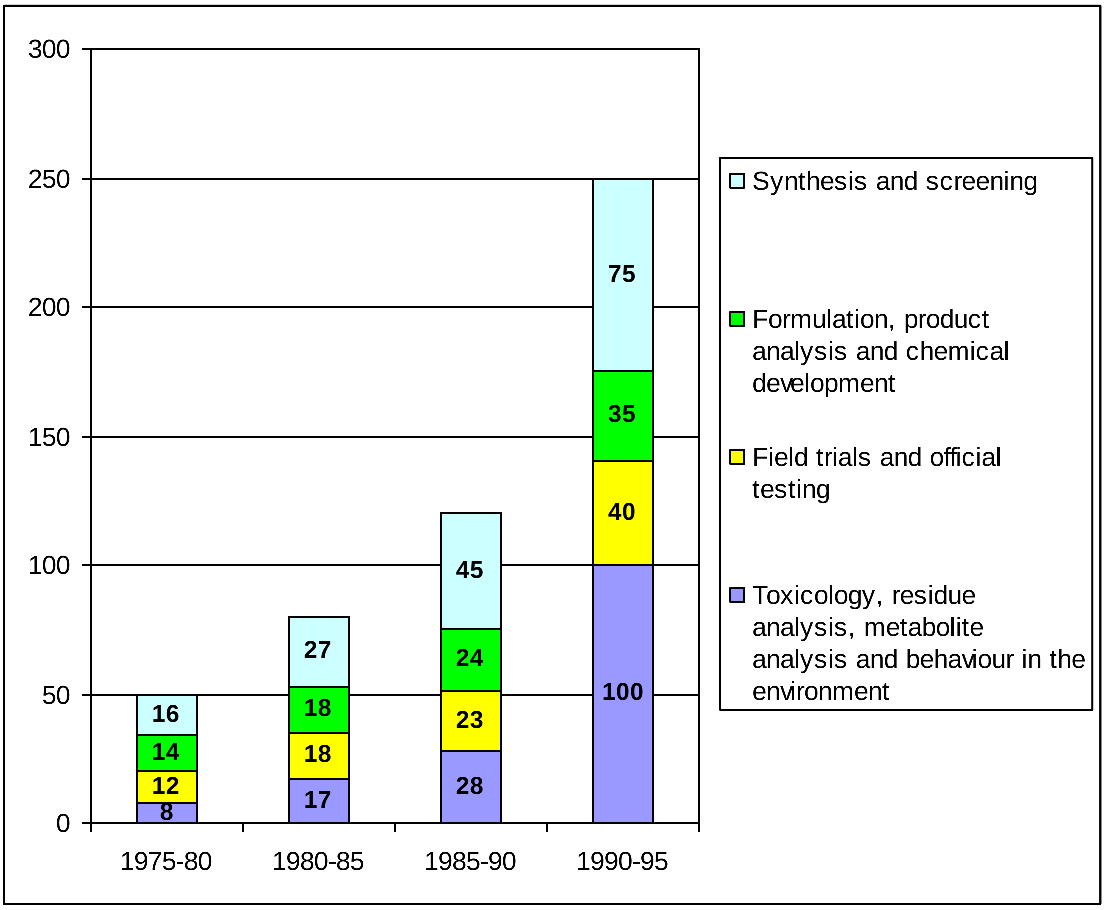
Agrochemical Industry R&D Expenditure by Sector (Summation of the eleven reporting companies only)

	Spending by sector					
	2014			2019 F		
	Total	**Chemical**	**Bio-control**	**Total**	**Chemical**	**Bio-control**
Research of New Active Ingredients	811.4	699.0	112.4	978.5	821.9	156.6
Development of Off Patent Products New to your company	26.1	25.7	0.4	28.4	28.2	0.2
Development of New Active Ingredients	607.6	586.6	21.0	879.0	826.9	52.1
Product Launch & Development	942.0	902.2	39.8	1040.6	981.1	59.5
Product Monitoring / Stewardship	238.0			280.0		
SUM	**2625.1**	**2213.5**	**173.6**	**3206.5**	**2658.1**	**268.4**
Share %		**92.7**	**7.3**		**90.8**	**9.2**

Agrochemical Development Expenditure by Region (Summation of the eleven reporting companies only)

	Spending by sector							
	2014				2019 F			
	Europe	**NAFTA**	**Latam**	**Rest**	**Europe**	**NAFTA**	**Latam**	**Rest**
Research of New Active Ingredients								
Development of Off Patent Products New to your company	10.1	9.9	4.1	2.0	15.0	8.8	3.7	0.9
Development of New Active Ingredients	220.1	205.5	78.5	103.5	308.3	330.4	105.2	135.1
Product Launch & Development	391.0	241.5	161.3	148.2	419.0	245.4	187.7	188.5
Product Monitoring / Stewardship	124.5	55.8	26.0	31.9	150.3	62.1	29.3	38.3
SUM	**745.7**	**512.7**	**269.9**	**285.6**	**892.6**	**646.7**	**325.9**	**362.8**
Share %	**41.1**	**28.3**	**14.9**	**15.7**	**40.1**	**29.0**	**14.6**	**16.3**

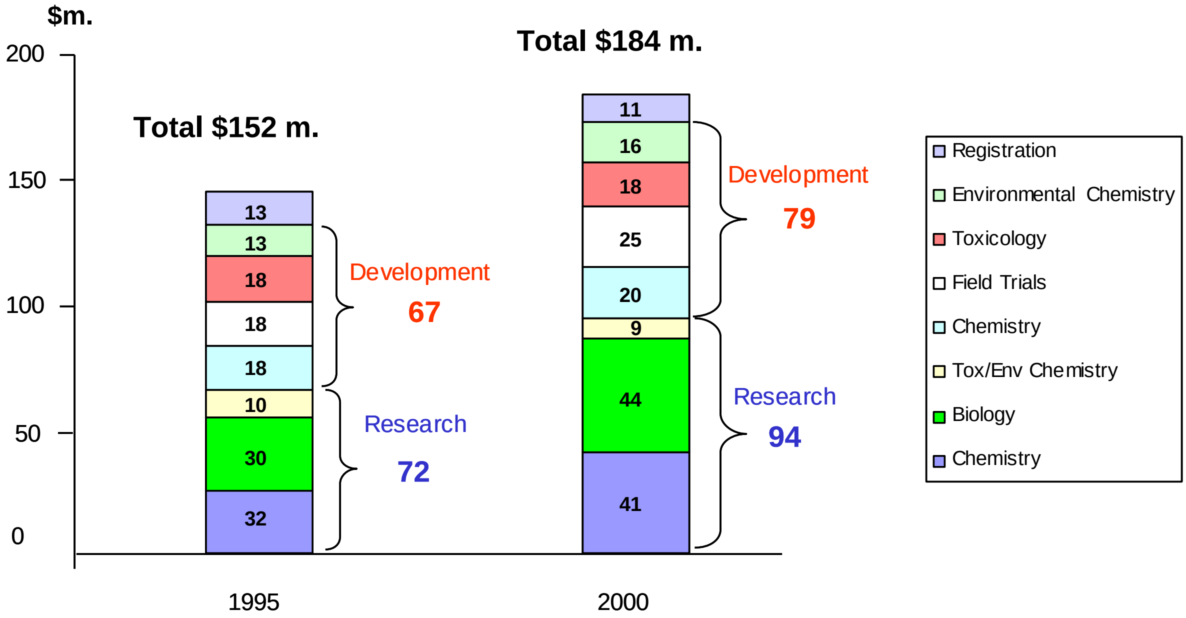
Appendix 1: Development Costs for a Crop Protection Product



Appendix 2

2003 Study

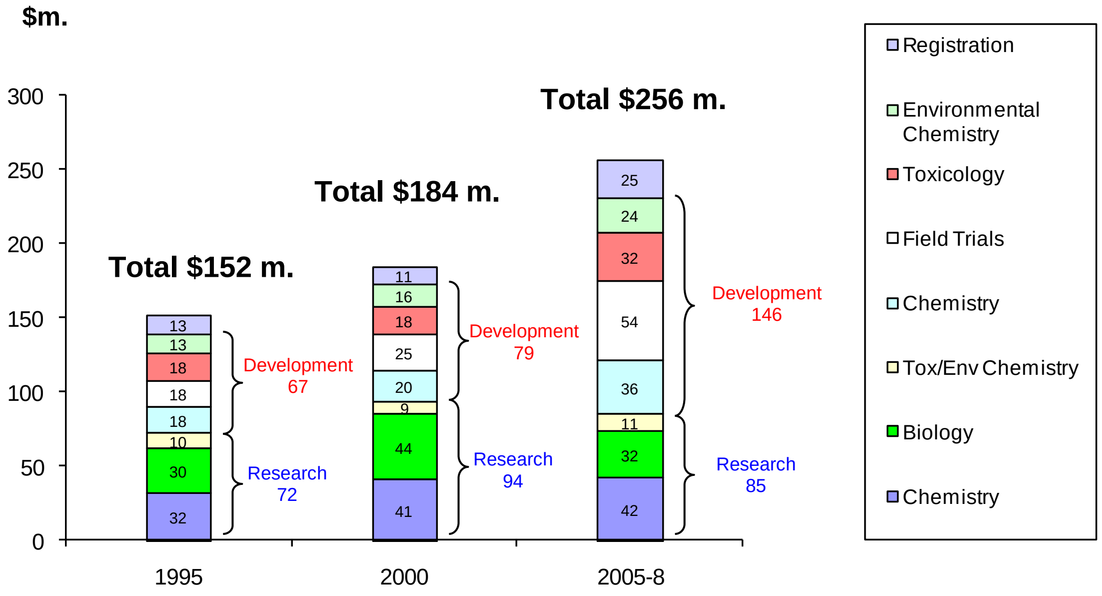
Discovery and Development Costs of a New Crop Protection Product



Appendix 3

2009 Study

Discovery and Development Costs of a New Crop Protection Product



Appendix 4: Study Plan

Guidelines for Completing the R&D Questionnaire 1

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

It is recognised that the various cost allocation sectors outlined in the attached questionnaire are somewhat idealised and will depend to 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.

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.

Guidelines for Completing the R&D Questionnaire 2

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

R&D Expenditure: The total 2014 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).

Post Launch Development: 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.

Company Questionnaire 1

<u>Questionnaire on behalf of ECPA / CropLife America</u>

Part 1: Breakdown of R&D Expenditure for bringing a single New Active Ingredient to a major market

Please provide indicative data for a product introduced around the 2010-2014 timeframe

Company:________________________ **Currency :**__________________

			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**

Questionnaire on behalf of ECPA / CropLife America (Continued)

Company:__________________________ **Currency :**___________________

Part 2

Any Additional R&D Costs Associated with New Product Development Not Identified in Part 1?

Item	2010-2014

Part 3

Number of Products Processed to Lead to Successful Product Launch

		2010-2014
Research	Synthesis	
	Post Synthesis	
Development		
Registration		1

Part 4

Development Lead Time

	2010-2014
In your opinion please indicate the number of years between the first synthesis and the first sale of the product	

Company Questionnaire 2

<u>Questionnaire on behalf of ECPA / CropLife America</u>

Breakdown of R&D Budget in 2014 and expectation for 2019

Company:________________________ Currency :__________________

2014	***Total***	***Spending by sector***		***Market focus of spending (by region)[1]***			
		Chemical	Bio-control (& other non-chemical	Europe	NAFTA	LATAM	Rest of the world
Research of New Active Ingredients							
Development of Off Patent Products New to your company							
Development of New Active Ingredients							
Product Launch & Development*							
Product Monitoring / Stewardship**							

2019	***Total***	***By sector***		***Market focus of spending (by region)***			
		Chemical	Bio-control (& other non-chemical	Europe	NAFTA	LATAM	Rest of the world
Research of New Active Ingredients							
Development of Off Patent Products New to your company							
Development of New Active Ingredients[2]							
Product Launch & Development[3]							
Product Monitoring / Stewardship[4]							

[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 LATAM market, this should be included in the LATAM data)

[2] Regulatory costs would be covered under this heading – except data that is specific related to product launch

[3] 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

[4] as required by terms of registration

Appendix 5: Cost of New Product Discovery: 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 2010-14.

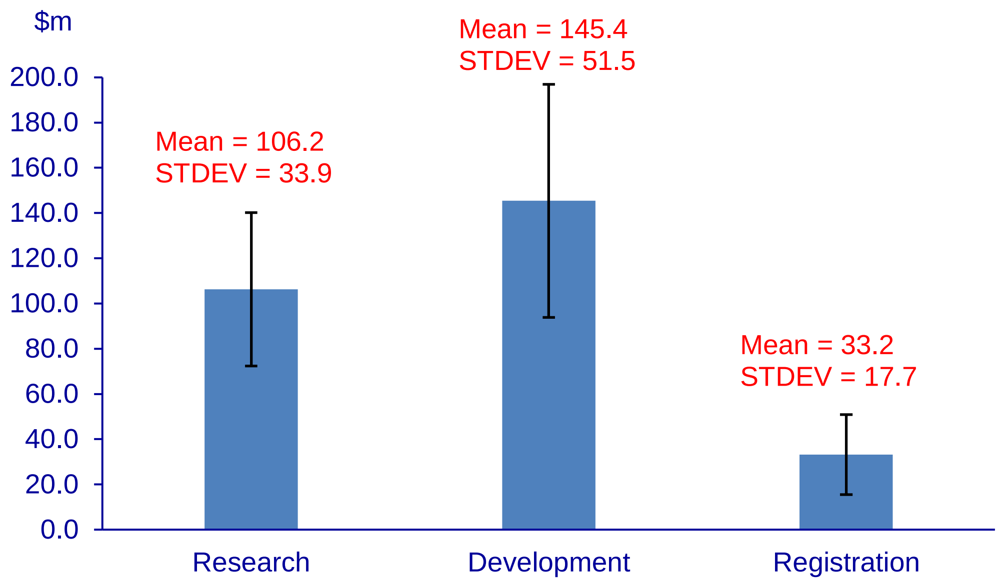
The companies chosen to participate in the survey were those that are considered to be active in new active ingredient research and development. This is exemplified by the fact that these companies accounted for 76% of research and development expenditure of the leading 35 global agrochemical companies in 2014. (Source Phillips McDougall AgriService).

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 2010-14.

New Crop Protection Product Discovery and Development Costs – 2010-14

Survey Results (Mean and Standard Deviation)



As outlined above there was considerable variation within the company responses, however this is not unexpected particularly as the extent and focus to which research is conducted within these companies varies significantly.