



Responsible Care  
OUR COMMITMENT TO SUSTAINABILITY®

# Our commitment to sustainability

Pharmaceutical Ireland  
Responsible Care  
Report 2014

# Chairman's Foreword, PharmaChemical Ireland



## **Once again it is my pleasure to review and comment on the Responsible Care activities of PharmaChemical Ireland (PCI) member companies.**

These activities cover areas across environment, health & safety (EHS) and are acknowledged for making a positive contribution to the wellbeing of employees and the communities that we work in. It is primarily due to the work of individual member companies that Responsible Care continues to be the most recognised and beneficial non-corporate Environmental, Health and Safety initiative in Ireland.

Last year we noted that 2013 was the year that uncertainty in global markets started to abate. We are pleased to report that this has been reflected in a slight increase in the numbers employed in member companies with an increase of 1.3% between the years 2011 and 2013. While the coming years will bring other challenges, Responsible Care will continue to be a cornerstone in the environment health and safety programmes for all Pharmachemical Ireland member companies. Pharmachemical Ireland will continue to encourage all our members to reinforce their efforts to achieve the very best in their EHS commitments.

The pharmaceutical industry works towards the discovery, development and delivery of products that makes people's lives better. Doing this in a sustainable manner makes sense ethically, financially and legally. In Ireland we are proud of the commitment that all member companies have towards the principles of Responsible Care. We believe that this commitment will continue to be an advantage to the Irish industry and we remain committed to Responsible Care in everything we do.

John Nason, VP Global External Manufacturing. Bristol Meyers Squibb  
Chairman, PharmaChemical Ireland

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# Introduction

## PharmaChemical Ireland is pleased to present its 2014 annual Responsible Care report outlining the performance of the sector over the previous three years (2011- 2013).

This report follows the Responsible Care ethos and highlights the member companies' commitment and initiatives that were taken to demonstrate continuous improvement of operational performance.

A selection of the various Responsible Care activities is covered in this report including initiatives in communications, the environment and safety.

### Responsible Care Activities in 2014

Each year members of PharmaChemical Ireland seek ways to improve their environmental, health and safety performance. Data submitted in the Responsible Care report is analysed and areas where improvement is needed are identified and programmes put in place to address member needs. The following is a brief outline of some of the channels of communications used for the disseminating of the Responsible Care message.

### Communications

#### • Sharing Best Practice – Quarterly meetings

Members of the Responsible Care environment, health & safety group met four times in 2013. The meetings allow members to network and share experiences in all aspects of environment, health & safety matters. All four meetings in 2014 were held on sites and we are very grateful to GSK Cork, Pfizer Grangeacastle, Alkermes and Takeda Grangeacastle for hosting these meetings. We are also indebted to Genzyme for hosting our Resilience workshop in October and Takeda Grangeacastle for hosting our process safety sub-group meeting, which was also held in October.

#### • EHS updates

This year we continued with our practice of EHS updates that were circulated throughout the year. A total of 23 updates have been circulated to date. It should be noted that these are in addition to the numerous updates on specific issues such as REACH, financial provisions, Seveso III consultation and specific workshops, amongst others.

# What is Responsible Care?

## Responsible Care is our commitment to sustainability: the global chemical industry's unique initiative to improve its health, safety and environmental performance.

Responsible Care is the global Chemical industry's environmental, health and safety (EHS) initiative to drive continuous improvement in performance of the pharmaceutical and chemical sector in all aspects, which directly and indirectly impact on the environment, employees or the general public. Responsible Care companies actively strive to maintain leadership in safety and environment performance.

The Responsible Care ethic helps chemical companies to operate safely, profitably and with due care for future generations. In Ireland each member of PharmaChemical Ireland is expected to voluntarily adopt the following commitments and principles;

- A formal commitment on behalf of each company to a set of Guiding Principles signed, in the majority of cases, by the Chief Executive Officer
- A series of codes, guidance notes and checklists to assist companies to implement the commitment
- The progressive development of indicators against which improvements in performance can be measured
- Ongoing process of communication on health, safety and environment matters with interested parties inside and outside the industry
- Provision of forums in which companies can share views and exchange experiences on implementation of the commitment
- Adoption of a title and a logo which clearly identify national programmes as being consistent with and part of the concept of Responsible Care
- Consideration of how best to encourage all member companies to commit to and participate in Responsible Care
- Systematic procedures to verify the implementation of the measurable (or practical) elements of Responsible Care by the member companies.

Pharmaceutical Ireland manages Responsible Care at a national level; the European Chemical Industry Council (Cefic) manages Responsible Care at an EU level; and the International Council of Chemical Associations manages Responsible Care at a global level.

# 2014 Responsible Care Awards

Pharmaceutical Ireland would like to acknowledge the commitment and effort of all of those who make our workplaces safe and sustainable places to work. 2014 saw an entry of 4 high calibre submissions for both the national and European Awards (organised by Cefic) from member companies of Pharmaceutical Ireland (PCI). The national Responsible Care awards are presented at the Pharmaceutical Ireland agm which is held every October.

The following submissions were received.

**Pfizer Little Island - Building process safety knowledge**

Alkermes - Development and roll-out of the CaRE behavioural based system

BMS Cruiserath - Environmental and Energy Management initiatives at Cruiserath

Helsinn Birex - Well-being programme

**The winning submission came from Pfizer Little Island**

Shane Horgan, EHS leader for Pfizer accepting his award from John Mason, Pharmaceutical, Ireland



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# Building Process Safety Knowledge

**In 2012 the Pfizer site on Little Island site proactively initiated a review of the Process Safety Program. The review took place at a time when experienced colleagues were exiting the network, resulting in a potential gap in process safety knowledge onsite.**

As an outcome of this review, Pfizer Little Island approached Cork Institute of Technology (CIT) to embark on a pioneering partnership to build a bespoke Process Safety Course addressing the immediate and direct need for up skilling within the Pfizer Little Island site, extended Pfizer Network and indeed across the wider pharma industry.

Process safety, the need for it and the leadership of it must be properly understood at every level in the organization – this collaborative project, between a leading industry and academic institution directly addresses this need and is a prime example of the site's commitment to achieving excellence in process safety.

At a fundamental level, the Process Safety Course seeks to bridge the knowledge gap of colleagues at every level and function across the site. Too often Process Safety is seen as the "job" of the H & S departments within organizations. This new and innovative course challenges that perception and empowers colleagues from senior management to operators to learn, improve and share Process Safety knowledge.

Specifically the aims of the course were to;

- empower staff to challenge, to be critical and to seek better operation and safer practices continually
- enable staff to recognize and challenge uncertainties or doubts in process safety
- identify the importance of Process Safety, when assessing the hazards arising from the processing of chemicals at industrial level
- understand the key elements of Process Safety and of Process Safety Management,
- to recognize the causes and consequences of where things can go wrong.

Since the first cohort started the course in the spring of 2013, 28 colleagues have successfully completed the course and module assessments including 5 from their sister site in Ringaskiddy.

# Development and roll-out of the CaRE behavioural based system

In early 2013, a strategic review was completed by Alkermes' Athlone site's environmental health, safety and security (EHSS) steering group. This steering group comprises of the General Manager & Vice President of Operations plus leaders from a number of key functions such as manufacturing, engineering, Environmental Health Safety and Security (EHSS), Development, Human Resources (HR) and Quality Control (QC) laboratories.

Out of this strategic review, a site-wide objective was established to develop and implement an in-house behavioural based programme to further engage the whole workforce in identifying and reducing risk. In August 2013, a cross functional working group was established by the Director of Manufacturing and the Associate Director of EHSS. Over a number of working sessions the philosophy of "CaRE" was developed, CaRE is an acronym for Collaborative Risk-focused Engagement.

In partnership with key stakeholders across the site, the CaRE working group developed the required tools, systems, communications and training to support roll-out of the programme. Initially starting with a strong focus on EHSS, CaRE knits together existing expectations, systems and tools into one integrated, collaborative and risk-focused way of communicating and working.

“**CaRE follows a “plan-do-check-act” continuous improvement philosophy, an approach which is already familiar to employees through the site's Operational Excellence “lean” Six Sigma programme.**”

## Plan-Do-Check-Act

**Plan:** CaRE begins with identifying risks within work areas, equipment and tasks and implementing control measures which protect people, the environment and the business. Simple tools such as “one minute risk assessment” and “STAR” (an acronym for Stop Think Act and Review) empower employees to ensure that work areas, equipment and tasks are safe before commencing work. These partner with more traditional, structured risk assessment approaches and increase ownership and drive continuous improvement.

**Do:** Corrective and preventive actions (CAPAs) arising out of risk assessments become “good saves,” or opportunities to drive improvement. This integrates the existing good save system, which has been in place since 2010 and has helped reduce workplace accidents by 83% through employee engagement and ownership.

**Check:** Structured, collaborative monthly walk-throughs engage teams and colleagues across the site. Focusing on behaviours, practices and working conditions; continuous improvement is promoted through discussion, feedback, encouragement and empowerment. This process involves a randomised list of observers partnering together to visit areas they may never have been to before; thus raising awareness, knowledge, increasing collaboration and engaging a wide spectrum of colleagues across the site.

**Act:** An innovative, leading metric – Key Performance Indicator (KPI) measures engagement, focus and progress. This metric encourages success to be celebrated and for performance to be re-aligned when it doesn't meet expectations. The KPI is “owned” by the General Manager, with monthly site leadership meetings taking place to ensure participation and drive continuous improvement. Through a simple to understand/ measure formula, targets can be adjusted and the “bar raised” as time progresses. CaRE is therefore forever challenging and far reaching. The use of a leading, proactive metric is a paradigm shift away from out-dated, reactive and unpredictable accident/ incident data.

# Environmental and Energy Management initiatives at Cruiserath

**Bristol Myers Squibb Cruiserath (BMSC) has always been conscious of the need for sustainable operations, ensuring that state-of-the-art containment, abatement and waste treatment systems were installed at the facility during construction, to permit them to achieve exceptional environmental and safety standards. Environmental considerations are part of Business-As-Usual at their facility, with such activities as Environmental, Health and Safety Week and Energy Awareness Day as annual entries on the BMSC calendar.**

## Energy Management

The Cruiserath facility is certified to the International Energy Management Standard ISO 50001, which mandates a systematic approach to sustainable energy efficiency.

Since 2009, numerous energy projects have been implemented coupled with the monitoring and improvement of existing systems for optimum energy use. The management of new energy initiatives and focus on sustaining the reductions already achieved have resulted in savings of 26,900 mWh of energy in the period 2008 to 2013 (this has achieved an enormous 25% energy reduction in the 5 year period) which translates to 9,140 tonnes of CO2 Emissions prevented.

## Water Management

By placing focus on water consumption, real opportunities for savings were identified and, with the endorsement and full support of the organisation's management, acted upon. Again, the key to identifying opportunities truly understands the usage needs of the site and monitoring to ensure the site is not exceeding the required amounts in terms of consumption. In BMSC, this approach resulted in a 22% reduction in water consumption from 2012 to 2013. The biggest contribution was delivered by a project to automatically control the amount of rust inhibitors and other chemicals in the cooling tower water and the annual savings are in excess of 40,000m3 per year.

## Waste Management and Chemicals

At a site level, the waste hierarchy is the basis for waste management at BMSC. All waste is subject to assessment, categorisation and, ultimately insertion into some category of the waste pyramid.

An excellent example of this commitment is the use of Isopropyl Alcohol (IPA) on site. The site has undertaken initiatives at all other levels of the pyramid to ultimately arrive at a situation where disposal of IPA is not required. Using these best practices, the company now purchases only one litre of IPA for every 7.2 litres used in their processes. BMS do not dispose of any IPA, and what cannot be recycled or reused, is used for heat recovery. This heat is used, in part, to provide the energy required for the distillation process. Similar programs are in place for many other opportunities for waste minimisation, ensuring that BMS keep focus on the waste hierarchy.

## Sustainability

BMSC is very conscious that while environmentally beneficial actions can be implemented by a small group of individuals, sustainable and systemic environmental responsibility needs to be underpinned by an organisational culture that builds such concerns into everything it does. The site has a programme in place to ensure that environmental stewardship is cascaded into the organisation. Each department that impacts on the sites carbon footprint or can help minimise waste streams has assessed its operating procedures to consider these impacts. For example, procurement decisions necessitate a lifecycle review for items being purchased, ensuring that considerations such as energy efficiency and waste management are considered as part of the decision.



# Helsinn Birex Well-Being programme

In 2013 Helsinn Birex introduced a Well-Being Programme to facilitate the promotion of a healthy lifestyle amongst all its employees. This Programme was founded on Helsinn's on-going commitment to the welfare of staff.

## The Aims of the Programme were:



The Programme was self-funded through the waste refund programme and employed consultation through the EHS Committee.

The results of the Programme thus far have been positive. There was a high level of participation in all events. The level and variety of participation has increased as the programme has progressed. A wide range of topics have been covered in the areas of mental and physical wellbeing.

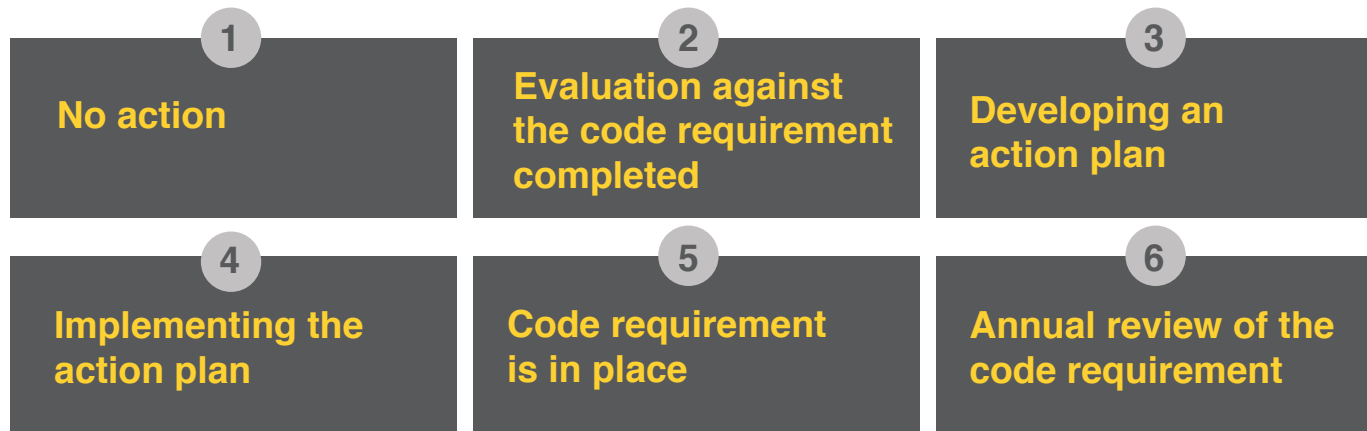
## Two of the key successes of the programme were as follows:

- Introducing mental health into everyday discussions. This was not about forcing the subject on anybody. This was about passively introducing common terms on mental health into the workplace. This was about giving definitions of common terms in a language that employees can understand. They used information stands, silent background presentations and emails to help debunk some of the myths and fears people have. This sets the foundation for any proactive measures of management.
- Diabetes day. A nurse was invited to site to talk to interested staff and perform a indicative test. While the information on diabetes was readily available from other sources, it was the fact that there was an on the spot test that drew staff in.

The Well-Being programme is still running. Since its beginning the site has seen some clear successes. Nonetheless the original aims are being met in that Helsinn is providing information to staff on a range of topics and is working towards a holistic approach to the physical and mental health of all staff.

# Codes of Practice

Companies are required to assess their performance against Responsible Care management codes of good practice in environment management, process safety, and energy management and newly introduced last year Product Stewardship management. While this procedure is self-assessment it does require the Company Director or Chief Executive Officer to verify any report at stage 5 or stage 6. The numeric scale used for the various stages has the following meanings:

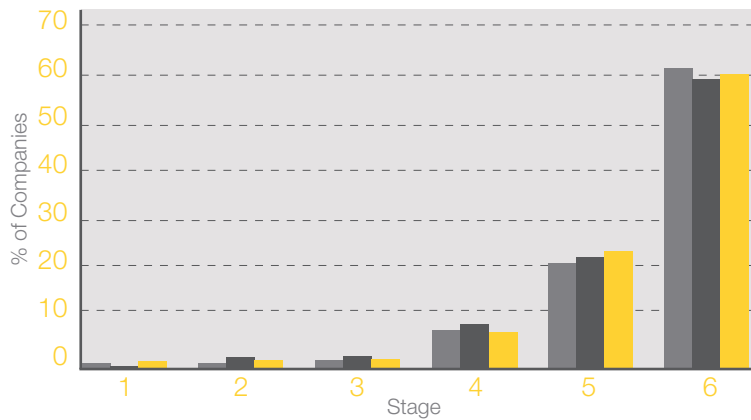


This year the report will compare the overall performance of the codes to the last two years of results in order to see more clearly the progress companies are making. A detailed breakdown of how companies are rated in each section of the code will be available as an appendix on the PharmaChemical Ireland website ([www.pharmachemicalireland.com](http://www.pharmachemicalireland.com)). The participation in this aspect of the Responsible Care initiative continues at a very high level with ca. 92% of the companies participating in the Safety, Environment and Energy Codes with ca. 88% contributing to the Product Stewardship Code and Security codes.

# Codes of Practice

## Environment Code

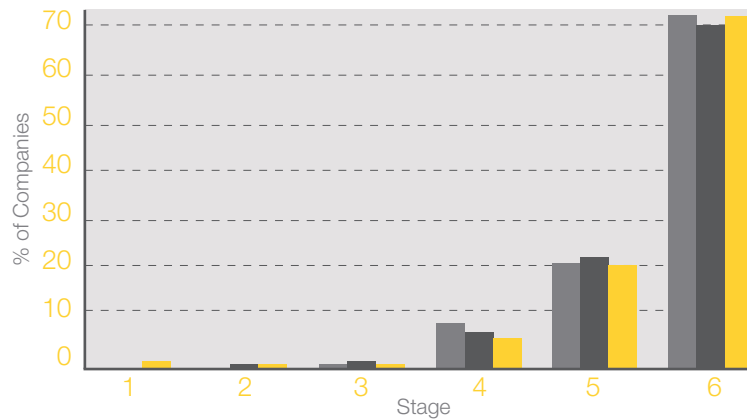
Environment Summary



The progress in implementation of the Environment Code across member companies continues steadily with over 87% of participants achieving Level 5 or greater and 95% of respondents being at Level 4 or above. These levels of achievement are testament to the strong culture of continuous improvement in environmental performance in accordance with the principles of Responsible Care.

## Health and Safety Code

Health & Safety Summary

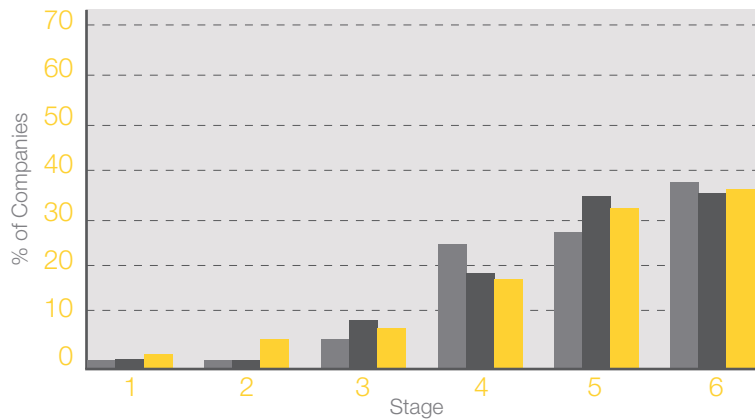


The Health and Safety Code continues to show a very high level of achievement with in excess of 93% of member companies achieving Level 5 or greater and 97% rated at Level 4 or above. The strong focus on safety continues to be reflected in the steady reduction in the overall accident rate in the sector with a further 17% reduction achieved in the last three year period following on from a 7% improvement over the previous period. We have commenced collecting data on the days lost as a result of lost time injuries and have noted a 50% reduction in this parameter in the last three years. The health and safety of our employees is of paramount importance to our member companies as evidenced by the efforts made to continuously improve the Safety performance of our facilities.

# Codes of Practice

## Energy Code

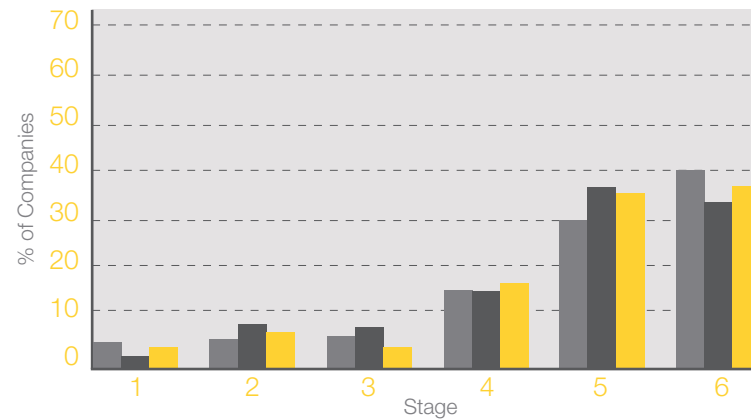
Energy Summary



The returns for the Energy Code this year show that 66% of companies are performing at Levels 5 or 6 with 84% of companies operating at level 4 or higher. The energy code has now reached maturity with results similar to the more mature Safety and Environment Codes albeit with some potential for further improvement at the lower scoring levels. We remain committed to reducing our energy consumption to the lowest practicable level thereby reducing our dependence as a society on imported energy.

## Product Stewardship Code

Product Stewardship Summary

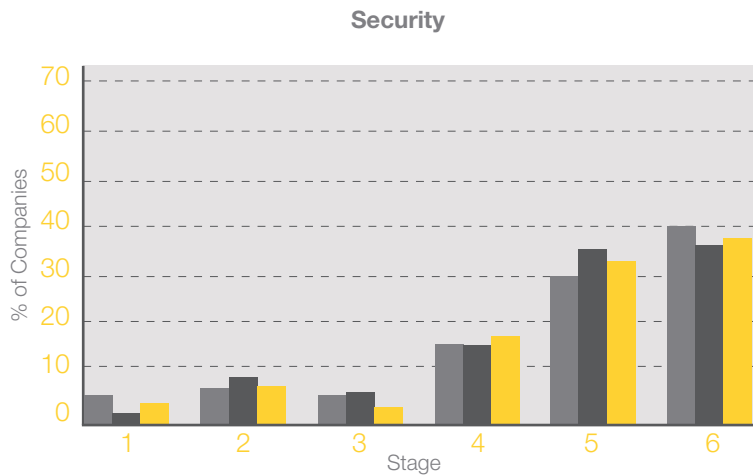


Under Responsible Care, the member companies of PharmaChemical Ireland are committed to improving the responsible management of our products throughout their lifecycles – from the input of raw materials to ultimate product end-use and disposal. The goal of product stewardship is to ensure that parties up and down the product supply chain have active management systems to ensure the safe, environmentally sound, and socially responsible handling of the product. The following code is seen as a holistic approach for companies to manage their Product Stewardship requirements and bring together all aspects of the supply chain.

We are pleased to report that over 77% of the member companies are rated at Level 5 or Level 6 with over 88% rated above Level 4. Based on our experience with the Energy Code, this code is showing signs of stabilising and is likely to reach maturity in the next few years.

# Codes of Practice

## Security Code



Under Responsible Care, the member companies of PharmaChemical Ireland are committed to ensuring that their facilities, raw materials and products are maintained in a secure environment at all times. The goal of the security code pilot is to ensure that member companies have structured security systems and procedures in place to manage this important aspect of their operations.

This is a relatively new code which was first formally adopted in 2011 and is gradually maturing. We are pleased to report that over 71 % of companies are operating at Level 5 or 6, and 87 % operating at Level 4 or above. This trend in this code is also showing signs of stabilising with the code reaching maturity in the next few years.



**The goal of the security code pilot is to ensure that member companies have structured security systems and procedures in place to manage this important aspect of their operations.**

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# Performance Indicators for the Responsible Care Programme for 2014

Each year member companies report on their performance on a number of key indicators which are similar to their EPA annual reporting requirements.

**The figures reported look at trends over a three-year period for the member companies as a whole.**

This year we have again achieved a very high level of participation with ca. 94% of companies submitting data. This is similar to the participation level last year.

This is the second year since the introduction of a web enabled on line data collection system which has facilitated significantly more efficient data collection and analysis.

The downward trend in the numbers employed in the member companies seen in recent years has stabilised with no change between 2011 and 2012 and a small increase in 2013. However, the production volumes dropped slightly following a 10% increase over the previous 3 year period. It is likely that this is a result of some products coming off patent combined with a shift from higher volume to lower volume higher value products in some parts of the sector.

We are pleased to report decreases of 44% in Sulphur Dioxide and a small decrease in Carbon Dioxide emissions to air. COD to waters showed a modest decrease, however both Phosphorous and Nitrogen discharges increased slightly. These will be the focus of member company attention in the coming year. Water consumption continues to decrease with a 7.2% drop this year whereas energy consumption has effectively stabilised. Volatile Organic Compounds emissions tend to vary somewhat year on year and do not show a consistent trend either upwards or downwards. This is most likely due to changes in product mix in some member companies from year to year. Both hazardous and non-hazardous waste showed decreases over the last 3 year period. We have commenced collecting data on recycling rates for non-hazardous waste which have increased by 6.1% over the period.

There was a decrease of 17% in the lost time injury rate over the three year reporting period. This indicator continues on a long term downward trend. We have now started to collect data on the number of days lost due to lost time injuries. The number of days lost has dropped by ca. 50% over the three year period.

Responsible Care is acknowledged as the fundamental non-corporate Environmental, Health and Safety initiative contributing positively to our employees and the communities in which we operate.

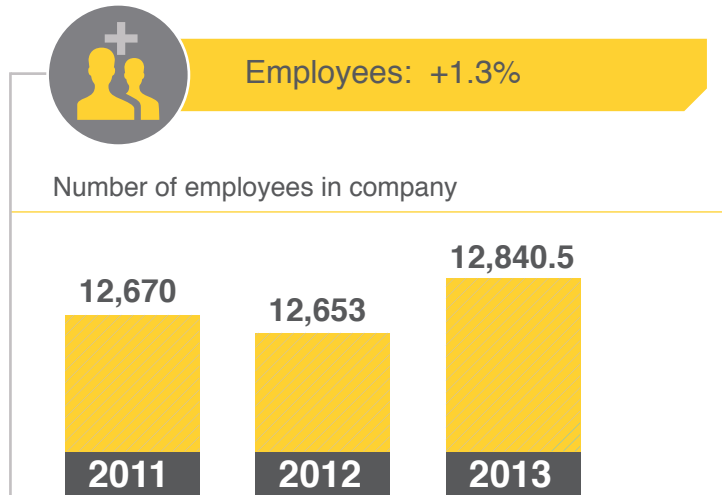
We will continue to encourage all our members to reinforce their efforts to sustain the gains made over the years and to achieve even more in the years ahead.



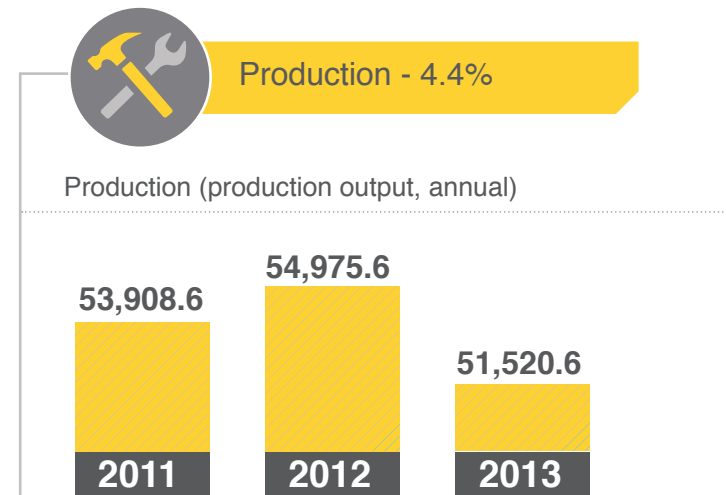
**This year we have again achieved a very high level of participation with ca. 94% of companies submitting data. This is similar to the participation level last year.**

# Performance Indicators for the Responsible Care Programme for 2014

## Economic Factors



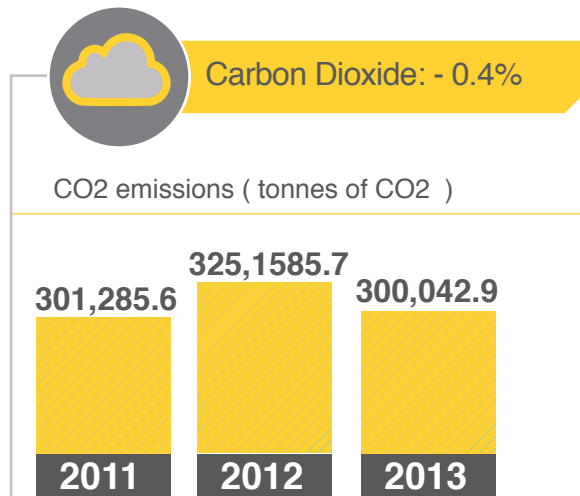
During the three-year period, the numbers employed in the sector increased by ca.1.3%. This is in line with the prediction made last year that the employee numbers had stabilised and was at that time expected to grow following a number of years of decreasing employment in the sector. This is positive news for the industry and shows that the sector continues to provide high quality employment opportunities for talented people across the country. It is hoped that this trend will continue in the years ahead.



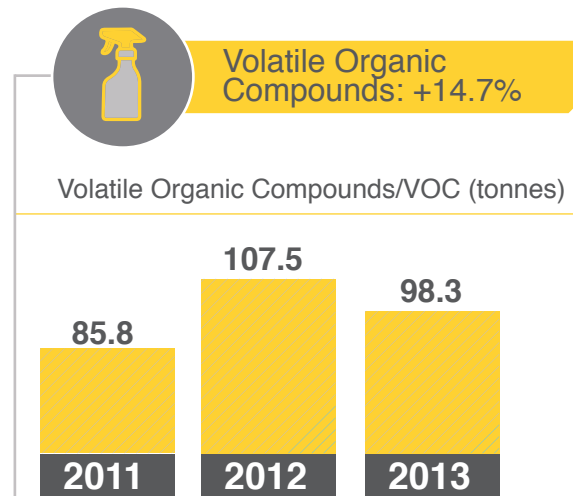
The output from the industry has shown a small decrease following a 10% increase reported last year. This may be as a result of a drop in some of the long established products coming off patent but may also reflect a move towards lower volume, higher value products in some of the member companies. This trend should be interpreted in conjunction with the increase in employee numbers during the period indicating that the move to higher value products is most likely taking place.

# Performance Indicators for the Responsible Care Programme for 2014

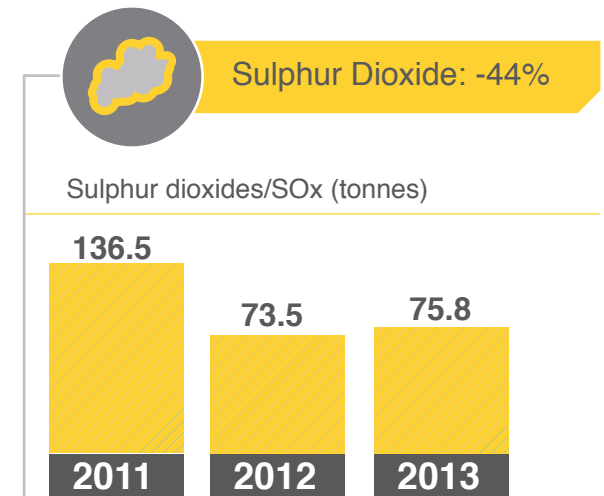
## Air Emissions



The trend in CO2 emissions showed only an increase of ca. 0.4% over the three year period reversing a slight increase of the same magnitude reported last year. The decrease in the emissions of Carbon Dioxide is a result of more of our member companies putting structured energy management systems in place and moving towards the adoption of the ISO 50001 Standard Energy Management Systems. We expect this trend to continue in the years ahead as more companies continue to focus on reducing their energy consumption as long term energy prices continue to rise. We have commenced the collection of more detailed energy utilisation data to ensure that these trends can be tracked more closely in the future.



Emissions of VOCs have shown an increase of 14.7% over the 3 year period. This parameter tends to vary more than others as can be seen by the 8.5% decrease year on year between 2012 and 2013. This trend has stabilised somewhat in recent years but will continue to be a focus of our member companies in the years ahead to ensure that emissions of VOCs are tightly controlled.

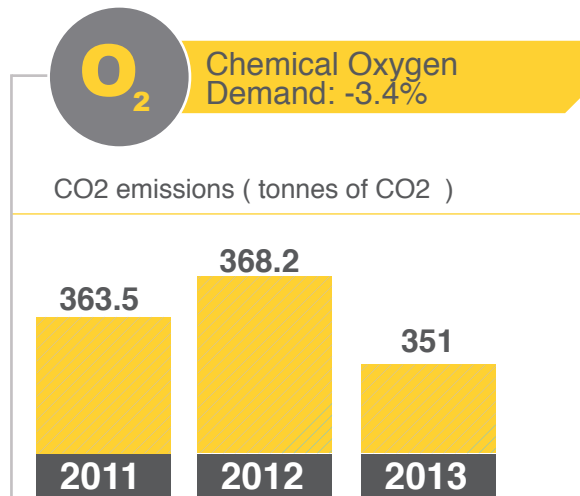


Sulphur Dioxide emissions showed a decrease of 44% over the three-year period, building on a reduction of 62% reported last year. This parameter has now essentially stabilised at the lowest level it has ever reached. This has resulted from the ongoing move away from oil to natural gas over recent years.

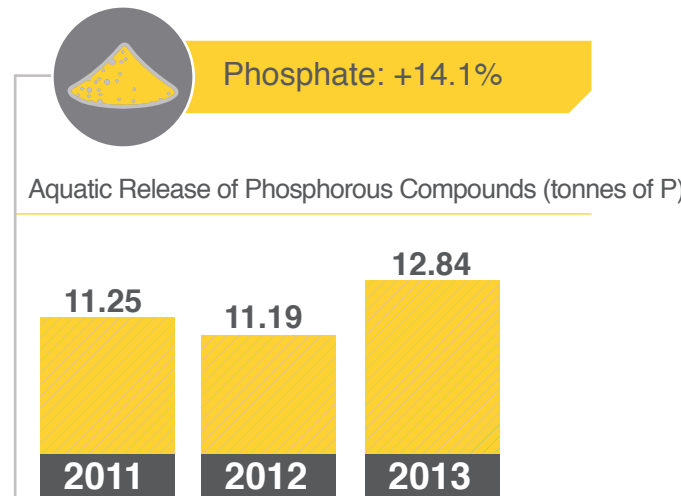


# Performance Indicators for the Responsible Care Programme for 2014

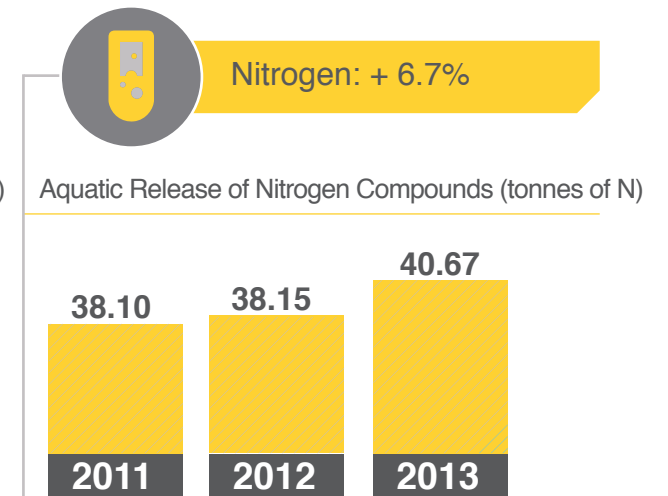
## Water Discharges



This parameter has shown a modest decrease of 3.4%, an improvement on the 0.8% decrease reported last year. This shows the continued emphasis on close monitoring of waste water treatment plants on member sites and the importance attached to protecting our valuable water resources.



The phosphorous emissions from members' sites increased by 14.1% over the three-year period. However, this must be considered in the context of reductions of 44% and 49% reported over the last 5 years. Our member companies will continue to monitor this trend closely and will continue to place a high priority on the control of phosphorous in our waste water treatment plants.



This year is the first time this parameter has shown a slight increase following eight consecutive years of reductions in aquatic release of nitrogen. This parameter now appears to have stabilised as predicted last year making further reductions more difficult to achieve. However, our member companies will monitor this parameter closely and continue to operate our waste water treatment plants effectively to minimise the impact of nitrogen on receiving waters.

# Performance Indicators for the Responsible Care Programme for 2014

## Waste Disposal



The correct treatment and disposal of hazardous waste is given the highest priority by all member companies and is critical to the success of the Responsible Care initiative. The reduction of 2.4% achieved follows on from a 6.5% decrease reported last year and a 14% reduction the year before last. All our member companies work hard to minimise the amount of hazard waste generated and ensure the correct handling and disposal of this type of waste.

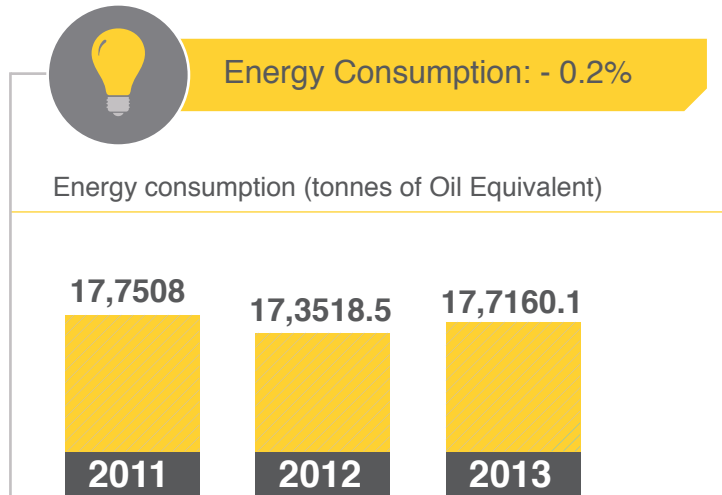


The quantity of non- hazardous waste decreased by 6.3% over the three year period. As this parameter can be impacted by the amount of construction waste generated as a result of capital investment activity, it can vary significantly year on year as can be seen in the graphical representation of the 3 year trend.

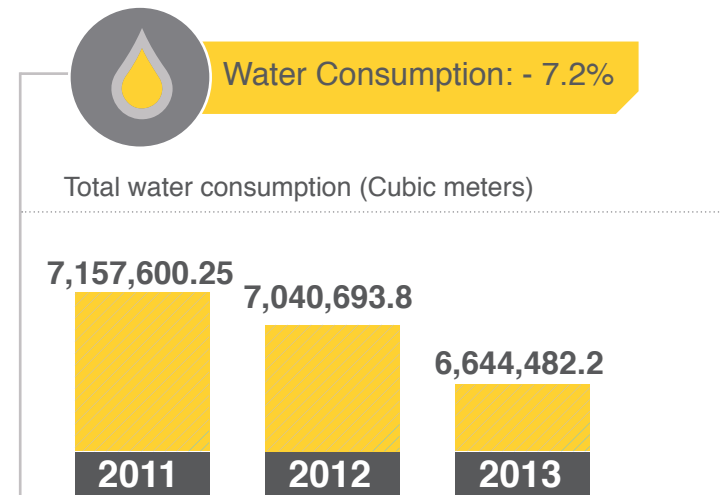
We have commenced collection of data on the amount of non-hazardous waste recycled and this has shown an increase of 6.1% over the 3 year period. When taken together with the decrease in non-hazardous waste for disposal, these trends show that the industry is now moving from disposal to recycling for non-hazardous waste arising on the member sites. Our member companies' commitment to Responsible Care means we will continue to improve the levels of reuse and recycling across all member sites in the years ahead.

# Performance Indicators for the Responsible Care Programme for 2014

## Waste Disposal



The energy consumed by the member companies has essentially stabilised over the last 3 year period showing only a slight reduction of 0.2% following a reduction of 6.6% over the previous 3 year period. This is similar to the trend in carbon dioxide emissions. While the energy consumption trend has effectively remained stable, the trend in the Carbon Dioxide emissions associated with purchased electricity has decreased by 12.6% over the three year period. This demonstrates that many member companies have opted to purchase a higher proportion of their electricity from renewable sources. Our member companies will continue to place a high priority on energy management in the years ahead to consolidate the gains made in recent years and to further reduce the energy impact of our operations.



The output from the industry has shown a small decrease following a 10% increase reported last year. This may be as a result of a drop in some of the long established products coming off patent but may also reflect a move towards lower volume, higher value products in some of the member companies. This trend should be interpreted in conjunction with the increase in employee numbers during the period indicating that the move to higher value products is most likely taking place.

# List of companies involved

PharmaChemical Ireland gratefully acknowledges the assistance of the following companies in compiling this report:

1. **AbbVie (Fournier Laboratories)**
2. **Alkermes Pharma Ireland Limited**
3. **Allergan Pharmaceuticals Ireland**
4. **Arran Chemical Co. Ltd**
5. **Astellas Ireland (Dublin)**
6. **Astellas Ireland (Kerry)**
7. **BASF Ireland Limited**
8. **BioMarin International Limited**
9. **Bristol Myers Squibb Cruiserath**
10. **Cara Partners & Wallingstown Co Ltd**
11. **Clarochem Ireland**
12. **Eli Lilly S A - Irish Branch**
13. **FMC International**
14. **GE Healthcare Bio Sciences**
15. **Genzyme Ireland**
16. **Glaxo Smith Kline Cork**
17. **Helsinn Birex Pharmaceuticals Limited**
18. **Henkel Ireland Limited**
19. **Hovione Limited**
20. **Ipsen Manufacturing Ireland Limited**
21. **Janssen Pharmaceuticals Limited**
22. **Janssen Biologics Ireland Limited**
23. **Leo Pharma**
24. **Mallinckrodt Pharmaceuticals**
25. **MSD Ballydine**
26. **MSD Brinny**
27. **MSD Swords**
28. **MSD Rathdrum**
29. **Novartis Ringaskiddy Limited**
30. **Pfizer Grangeecastle**
31. **Pfizer Little Island**
32. **Pfizer Newbridge**
33. **Pfizer Ringaskiddy**
34. **Recordati Ireland Limited**
35. **Roche Ireland Limited**
36. **Rottapharm Ireland**
37. **Servier Ireland Industries Limited**
38. **Sigma Aldrich Ireland Limited**
39. **Swords Laboratories - BMS**
40. **Takeda Ireland Bray**
41. **Takeda Ireland Grangeecastle**
42. **Temmler Ireland Limited**
43. **Teva Pharmaceuticals Ireland Limited**
44. **UCB Manufacturing Ireland**

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# Data Collection



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Mr. Liam Tolton of Second Sight Technical independently collected, analysed and reviewed the data used in the generation of this report and prepared the initial draft report.

**Liam Tolton B.E. B.A. M.Sc. (Eng). C.Eng. M.I.EI. DGSA CMVP**

**Director**

**Second Sight Technical**

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Email: [liam@secondsighttechnical.com](mailto:liam@secondsighttechnical.com)

## Second Sight Technical

Second Sight Technical is an engineering consultancy headed up by Mr. Liam Tolton. Mr. Tolton holds primary degrees in Engineering and Economics with a Master's Degree in Process Safety and Loss Prevention. He has worked in Oil Refining and Bulk Pharmaceutical Manufacturing as a Project Engineer, Engineering Section Head and Department Manager with responsibility for Engineering, Utilities, Environment and Safety. He is a certified Dangerous Goods Safety Advisor and a Six Sigma Black Belt.

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# Pharmaceutical Ireland Vision and Mission statements



## Vision

With the support of industry, Ireland will enhance its reputation as a recognised centre of excellence for innovation and development in pharmaceutical, biopharmaceutical and chemical supply, thereby becoming the location of choice for the launch of new products.



## Mission

As the representative body for the industry, PharmaChemical Ireland will continue to assist the sector in realising its ambition by bringing together all relevant stakeholders in the State, namely: industry, the Government, the research community and the public at large, to effectively communicate the unique attractiveness of this country as a leading location for the supply and development of pharmaceutical products.



**The pharmaceutical industry works towards the discovery, development and delivery of products that makes people's lives better.**

# Appendix One

The following appendix contains the detail of the following codes of practice, Environment, Health & Safety, Energy & Product Stewardship.

## Environment Code

Section	Guideline	% Companies at each stage														
<p><b>1. Senior Management Commitment</b></p> <p>Senior management commitment to reduction of emission releases and waste generation. Commitment to the use of cleaner technology</p>	<ul style="list-style-type: none"> <li>• Policy in place endorsed by top management including commitment to pollution prevention and continuous improvement</li> <li>• Policy is available to all employees and to the public</li> <li>• Resources have been dedicated to the implementation of the policy</li> </ul>	<table border="1"> <caption>% Companies at each stage for Senior Management Commitment</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>10</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>10</td></tr> <tr><td>5</td><td>25</td></tr> <tr><td>6</td><td>75</td></tr> </tbody> </table>	Stage	%	1	5	2	10	3	10	4	10	5	25	6	75
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<p><b>2. Identification of Significant Impacts</b></p> <p>Evaluation of the potential impacts of operation on employees, public and environment</p>	<ul style="list-style-type: none"> <li>• Procedure in place for identifying and evaluating the potential environmental impact of activities and releases</li> <li>• Based on the assessment a list of priority actions is in place with an implementation plan also available</li> </ul>	<table border="1"> <caption>% Companies at each stage for Identification of Significant Impacts</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>10</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>25</td></tr> <tr><td>6</td><td>65</td></tr> </tbody> </table>	Stage	%	1	5	2	10	3	10	4	15	5	25	6	65
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<p><b>3. Compliance with Legislation</b></p> <p>Awareness and compliance with Environmental Legislation</p>	<ul style="list-style-type: none"> <li>• Information mechanism in place to ensure current legal requirements identified</li> <li>• Legal requirements communicated to all concerned parties</li> <li>• Procedure to ensure compliance with all legal requirements in place</li> </ul>	<table border="1"> <caption>% Companies at each stage for Compliance with Legislation</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>10</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>25</td></tr> <tr><td>6</td><td>60</td></tr> </tbody> </table>	Stage	%	1	5	2	10	3	10	4	15	5	25	6	60
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# Appendix One

## Section

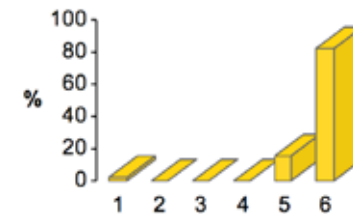
## Guideline

## % Companies at each stage

### 4. Environmental Reporting

Reporting of environmental indicators to ensure appropriate action

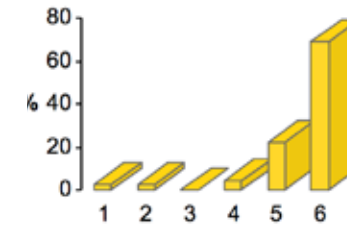
- Mechanism in place for tracking, recording and reporting environmental indicators



### 5. Environmental Emissions Management

Control and reduction of emissions with potential environmental impact

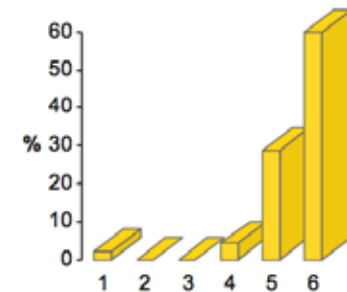
- Identification of emission sources
- Monitoring programme of emissions
- Procedure to identify impact of emissions
- Abatement programme



### 6. Waste Management

Waste management programme and practices

- Inventory of wastes established
- Waste reduction plans state preference for complying with the hierarchy of: Avoidance/Reduction/Recycle/Treatment & Disposal
- Control of waste documentation in place and available
- Periodic reviews conducted for on and off site waste management practices, operations & equipment
- Periodic environmental assessments conducted of all external waste handling facilities
- Reviews include a check to evaluate the potential for use of alternative methods to further eliminate/ reduce environmental releases and the waste generation



# Appendix One

## Environment Code

Section	Guideline	% Companies at each stage														
<p><b>7. Communication</b></p> <p>Education and dialogue with employees and public about company activities which may have environmental impacts</p>	<ul style="list-style-type: none"> <li>• Channels of communication established both internally and externally on environmental matters</li> <li>• Documented procedure in place to ensure communication procedure is effective.</li> <li>• Process in place for communicating to employees the environmental impact of activities</li> <li>• Forum in place for open communication with the public on the environmental impact associated with the releases to air, water, land and the waste produced</li> <li>• Periodic performance update made available to all employees and public in a manner that provides them with a forum for open discussion</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 7</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>8</td></tr> <tr><td>3</td><td>12</td></tr> <tr><td>4</td><td>18</td></tr> <tr><td>5</td><td>35</td></tr> <tr><td>6</td><td>50</td></tr> </tbody> </table>	Stage	%	1	5	2	8	3	12	4	18	5	35	6	50
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<p><b>8. Resources for Environmental Management</b></p> <p>Provision of adequate resources to ensure good environmental management</p>	<ul style="list-style-type: none"> <li>• Procedure to evaluate resource requirements associated with programme implementation</li> <li>• Adequate funds, facilities and human resources available to meet environmental policy requirements and fulfil environmental objects and targets</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 8</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>8</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>30</td></tr> <tr><td>6</td><td>60</td></tr> </tbody> </table>	Stage	%	1	5	2	8	3	10	4	15	5	30	6	60
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<p><b>9. Management of supply and distribution.</b></p> <p>Requirement for high environmental standards from suppliers, contractors and vendors. Control of distribution methodology to ensure minimum impact on environment</p>	<ul style="list-style-type: none"> <li>• Procedure in place covering a pre selection review of all new contractors/ toll manufacturers, including an assessment of their environmental management practices against a predetermined set of criteria</li> <li>• Compliance criteria used for selection</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 9</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>8</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>25</td></tr> <tr><td>5</td><td>30</td></tr> <tr><td>6</td><td>45</td></tr> </tbody> </table>	Stage	%	1	5	2	8	3	10	4	25	5	30	6	45
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# Appendix One

## Section

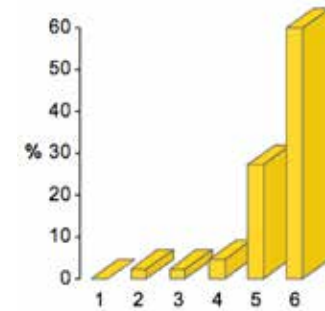
## Guideline

## % Companies at each stage

### 10. Environment Training

Training of personnel in good environmental practice and efficiency

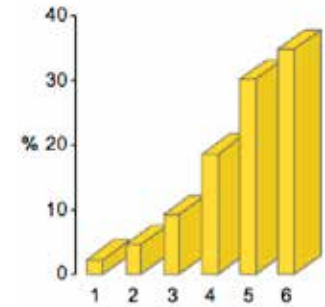
- Training requirements regarding environmental management identified
- Training programme in place on environmental management
- Awareness training provided on possible implications of employee action on company's environmental performance



### 11. External Promotion of Environmental Best Practice

Ongoing programme for promotion and support of waste and release reduction by others

- Support through industry federations and groups for of waste and release reduction measures and technologies
- Source suppliers using measures to implement cleaner production and reduce/ eliminate environmental releases and waste generation



# Appendix One

## Safety Code

### Section

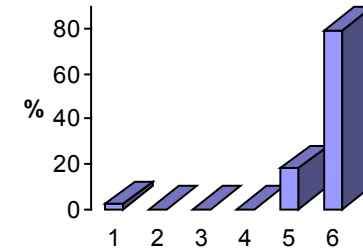
### Guideline

### % Companies at each stage

#### 1. Occupational Health and Safety Policy

Top management commitment to safety management and risk minimisation

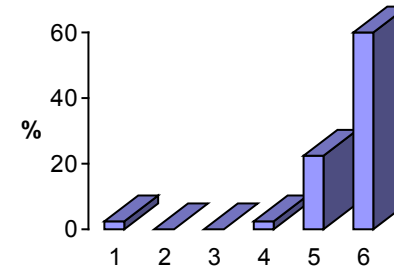
- Endorsement by top management
- Periodically reviewed
- Include current main OHS objectives
- Compliance with legislation
- Commitment to continuous improvement
- Communicated to all relevant personnel
- Commit adequate resources and personnel



#### 2. Hazard and Risk Assessment

Identification of risks, hazards and priorities

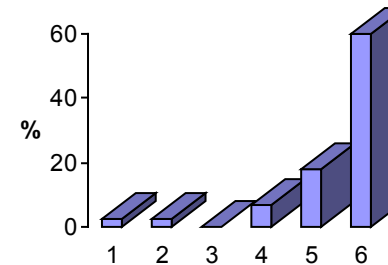
- Risk/Hazard Assessment procedure in-place
- Risk assessment(s) carried out for all significant facilities, activities including contractor and visitor activities
- Risk assessment procedure for all new processes and operations in place
- Risk and Hazards to be classified to allow prioritisation



#### 3. Legislation

Legislative and Regulatory compliance

- Established mechanism for keeping up to date with relevant OHS legislation
- Documented assessment on relevance of legislation to Company
- Procedure to ensure legislation compliance



# Appendix One

## Section

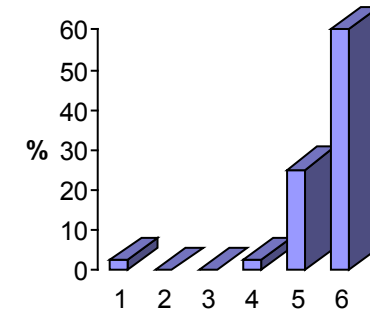
## Guideline

## % Companies at each stage

### 4. Change Control

Control of distribution methodology to ensure minimum impact on environment

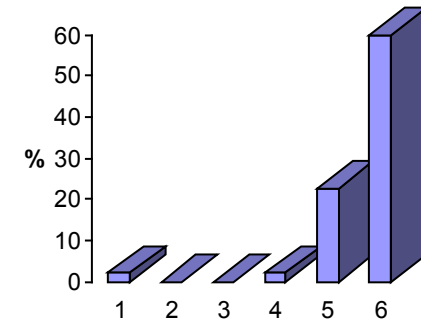
- Processes and operations with inherent risks identified
- Procedure for reassessment of alterations to safety sensitive operations in place
- Procedure for pre-approval of changes for safety sensitive issues in place



### 5. Objectives and targets

Safety objectives to be established and maintained to ensure continuous improvement

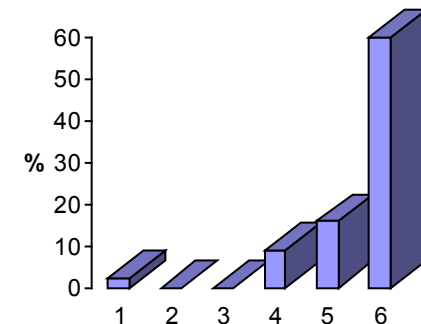
- Specific and measurable objectives established
- Objectives must take into account legislative, regulatory requirements, risk assessment findings, operational and business constraints and contributions from interested parties
- Objectives must be reviewed periodically



### 6. Management plan

Documentation and communication of OHS management plan

- Annual Management Plan setting out objectives, targets and previous performance
- Summary of the plan available to employees and interested parties



# Appendix One

## Safety Code

Section	Guideline	% Companies at each stage														
<b>7. Resources</b>  Provision of resources and personnel	<ul style="list-style-type: none"> <li>• Senior manager assigned responsibility for establishing, maintaining and implementing the OHS management plan</li> <li>• Adequate resources assigned, including personnel, to ensure the plan is properly implemented</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 7</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>2</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>8</td></tr> <tr><td>4</td><td>12</td></tr> <tr><td>5</td><td>25</td></tr> <tr><td>6</td><td>60</td></tr> </tbody> </table>	Stage	%	1	2	2	5	3	8	4	12	5	25	6	60
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<b>8. Training and safety awareness</b>  OHS Training plan in place which is based on an assessment of training requirements	<ul style="list-style-type: none"> <li>• Training needs assessment carried out for all OHS significant functions, the findings from the risk assessment should be taken into account</li> <li>• Personnel should receive training and information on policy, objectives and targets</li> <li>• Consultation with employees on OHS significant issues should be established</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 8</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>2</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>8</td></tr> <tr><td>4</td><td>12</td></tr> <tr><td>5</td><td>30</td></tr> <tr><td>6</td><td>60</td></tr> </tbody> </table>	Stage	%	1	2	2	5	3	8	4	12	5	30	6	60
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<b>9. Emergency preparedness</b>  Emergency response procedures appropriate to the facility, to be established, training given and routinely tested	<ul style="list-style-type: none"> <li>• Establish and maintain emergency response procedures, facilities and personnel appropriate to the operation.</li> <li>• Carry out periodic testing of the emergency procedures</li> <li>• Communication and co-operation established between the Company and external emergency services</li> </ul>	<table border="1"> <caption>% Companies at each stage for Section 9</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>2</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>8</td></tr> <tr><td>4</td><td>12</td></tr> <tr><td>5</td><td>25</td></tr> <tr><td>6</td><td>60</td></tr> </tbody> </table>	Stage	%	1	2	2	5	3	8	4	12	5	25	6	60
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# Appendix One

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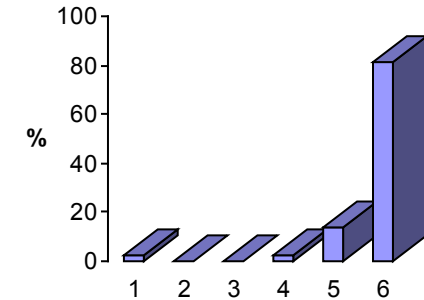
## Guideline

## % Companies at each stage

### 10. Accident and Dangerous incidents

Procedures for the notification, investigation and corrective actions for all accidents and incidents and adequate facilities and training for such potential events

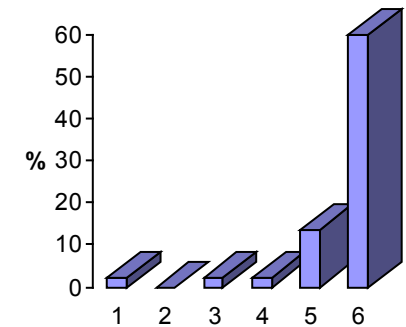
- First aid facilities and properly trained personnel appropriate to the operations
- Procedure for notification of all accidents and dangerous incidents
- Procedure for the investigation of all accidents and dangerous incidents and mechanism for identifying appropriate corrective actions and implementation of same



### 11. Health Protection

Provision of employee health screening, monitoring of operations and health promotion within the Company

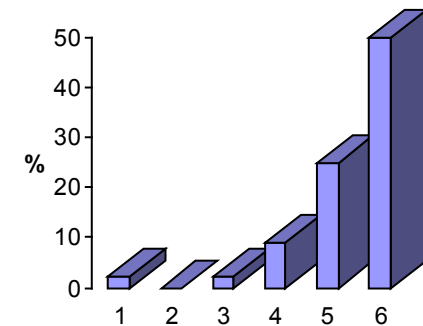
- Pre-employment health checks for all new employees
- Health screening program for all employees which takes into account the work functions of the individual
- Active support for health promotion initiatives within the Company



### 12. Auditing and verification

Active internal audit program for OHS and suitable corrective action documentation and tracking system.

- Procedure for ensuring that identified corrective actions are properly carried out
- Company shall have an audit program in place which checks effectiveness of OHS management system, response to accident and dangerous incidents and compliance with legislation
- Follow up procedure for audit findings to be in place



# Appendix One

## Energy Code

### Section

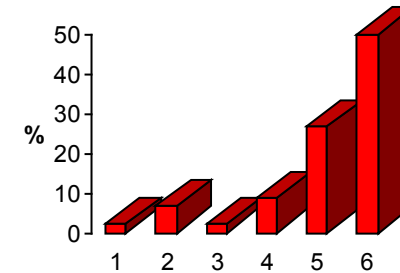
### Guideline

### % Companies at each stage

#### 1. Energy Policy

Top management committed to energy efficiency and reductions in greenhouse gas emissions

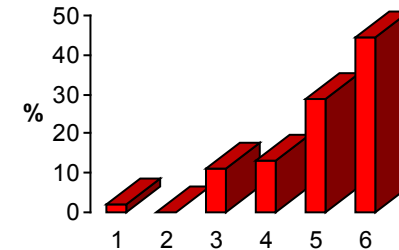
- Policy in place and signed by General Management
- Reviewed at least annually
- Included key objectives from the management plan
- Requires Company to comply with legislation
- Publicly available
- Commits adequate resources



#### 2. Identification of energies used

Establish detailed inventory and methods of measurement for all energies used on site and all energies available.

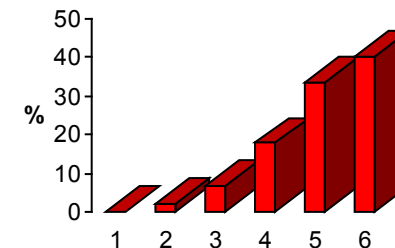
- List all energy types used on site
- Identify all potential energies available locally
- Establish an inventory of all significant energy users
- Establish logical sub-groups for monitoring
- Provision for monitoring of each sub group for all energy types



#### 3. Legislation and guidelines

Identification, awareness and compliance with all relevant legislation and licences. Review of all applicable 'best practice' guidelines and compliance with them where relevant to the site

- Audit programme in place which checks compliance with energy policy and effectiveness of energy management plan
- Follow up procedure for audit findings
- Adequately trained auditor to be available for the audits





# Appendix One

## Section

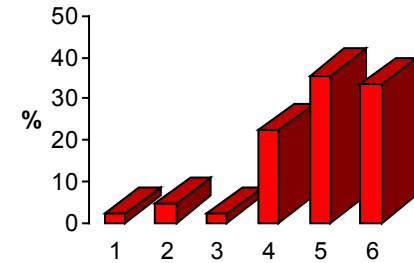
## Guideline

## % Companies at each stage

### 4. Energy Monitoring

To ensure there is adequate monitoring of all energy usage and Carbon Dioxide emissions to comply with legislative requirements and support the energy management plan.

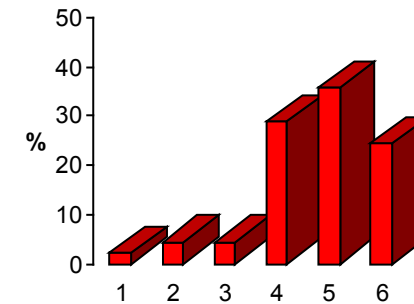
- Establish logical sub-groups for monitoring purposes
- Provision of monitoring for all sub groups and for relevant energy types
- Maintain calibration procedures for key metering
- Suitable data recording and reporting in place to support management objectives



### 5. Optimum operating methods

To identify practical and energy efficient procedures and equipment for all the production processes and ancillary activities.

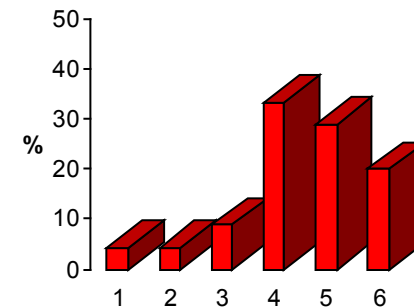
- Identify key production and ancillary activities with significant energy consumption
- Identify realistic energy efficient methodologies for each of the key activities
- Establish potential energy requirements for the new methodology.



### 6. Energy Gap analysis

To identify the gap between existing practice and legislation requirements and/or applicable best practice taking into account technical, financial and procedural requirements necessary to close the identified gap.

- Equipment and procedural alterations necessary to close the identified gaps are identified
- Technical requirements specified
- Budget estimated
- Cost benefit analysis carried out



# Appendix One

## Energy Code

Section	Guideline	% Companies at each stage														
<p><b>7. Objectives and Targets</b></p> <p>To establish clear and measurable energy reduction objectives and targets that are prioritised based on the gap analysis and cost efficiency.</p>	<ul style="list-style-type: none"> <li>• Specific and measurable objectives and targets established</li> <li>• Objectives prioritised based on legislative requirements, gap analysis and cost.</li> </ul>	<table border="1"> <caption>% Companies at each stage for Objectives and Targets</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>25</td></tr> <tr><td>5</td><td>40</td></tr> <tr><td>6</td><td>45</td></tr> </tbody> </table>	Stage	%	1	5	2	5	3	10	4	25	5	40	6	45
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<p><b>8. Management Plan</b></p> <p>To formally document the Management Plan, including objectives and Targets and to report on progress of previous plan. To provide an effective reporting mechanism for interested stakeholders.</p>	<ul style="list-style-type: none"> <li>• Annual management plan in place setting out objectives and /targets, past progress</li> <li>• Key actions assigned to individuals</li> <li>• Plan approved by relevant Senior Manager or General Manager</li> <li>• Summary of plan made available to all employees and other relevant personnel.</li> <li>• Inclusion of the energy reduction plan into an existing annual Environmental report is acceptable.</li> </ul>	<table border="1"> <caption>% Companies at each stage for Management Plan</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>10</td></tr> <tr><td>4</td><td>20</td></tr> <tr><td>5</td><td>40</td></tr> <tr><td>6</td><td>45</td></tr> </tbody> </table>	Stage	%	1	5	2	5	3	10	4	20	5	40	6	45
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<p><b>9. Resources</b></p> <p>Provision of adequate resources and personnel to allow the Energy Policy and the supporting energy management plan to be reasonably and practically implemented.</p>	<ul style="list-style-type: none"> <li>• Senior Manager assigned the responsibility for monitoring and implementing the energy management plan.</li> <li>• Adequate resources assigned to ensure identified improvements can be reasonably implemented</li> <li>• Suitably trained personnel available for enacting the energy management plan</li> </ul>	<table border="1"> <caption>% Companies at each stage for Resources</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>15</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>45</td></tr> <tr><td>6</td><td>35</td></tr> </tbody> </table>	Stage	%	1	5	2	5	3	15	4	15	5	45	6	35
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# Appendix One

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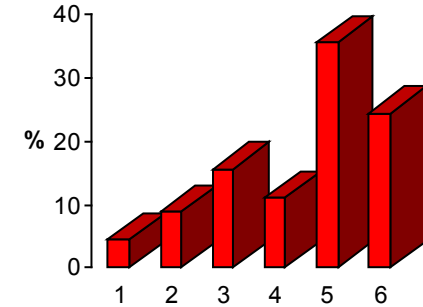
## Guideline

## % Companies at each stage

### 10. Training and Awareness

To ensure all personnel within the Company are aware of the requirements of the energy management policy, including the objectives of the energy management plan and have received suitable training to allow them proactively support the identified energy reductions.

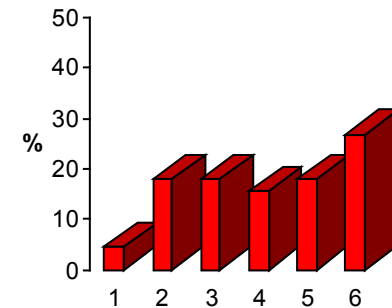
- Training plan based on the gap analysis and priority list, in place for all employees and contractors.
- Information on policy, energy management plan and objectives to be given to all interested parties
- Mechanism to encourage feed-back in place
- Programme supporting energy efficiency both inside and outside the Company in place



### 11. Auditing and Verification

To have an active internal energy audit system in place which monitors compliance with the energy policy and effectiveness of the energy management plan and its implementation

- Audit programme in place which checks compliance with energy policy and effectiveness of energy management plan
- Follow up procedure for audit findings
- Adequately trained auditor to be available for the audits



# Appendix One

## Product Stewardship Code

Section	Guideline	% Companies at each stage														
<p><b>1. Senior management Commitment</b></p> <p>Long-term commitment of senior management to product stewardship</p>	<ul style="list-style-type: none"> <li>• Policy in place and signed by senior management</li> <li>• Ensure that employees understand the product stewardship concept</li> <li>• Ensure that adequate resources are available to establish, review and maintain product stewardship practices on site</li> </ul>	<table border="1"> <caption>% Companies at each stage for Senior management Commitment</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>15</td></tr> <tr><td>3</td><td>20</td></tr> <tr><td>4</td><td>10</td></tr> <tr><td>5</td><td>40</td></tr> <tr><td>6</td><td>25</td></tr> </tbody> </table>	Stage	%	1	5	2	15	3	20	4	10	5	40	6	25
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<p><b>2. Raw Materials Acquisition</b></p> <p>Purchasing Policy in Place to ensure raw materials are obtained from reputable sources</p>	<ul style="list-style-type: none"> <li>• Inventory of all raw materials and relevant suppliers that are used in the products</li> <li>• Where required SDS requested, received and checked for compliance with legislative requirements and current CPL rules</li> <li>• Communicate up the supply chain information on product use</li> <li>• Actively seek input and advice from suppliers on their product and risk management experiences</li> </ul>	<table border="1"> <caption>% Companies at each stage for Raw Materials Acquisition</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>5</td></tr> <tr><td>3</td><td>5</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>45</td></tr> <tr><td>6</td><td>40</td></tr> </tbody> </table>	Stage	%	1	5	2	5	3	5	4	15	5	45	6	40
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<p><b>3. Supply &amp; Transport to site of raw materials</b></p> <p>Procedure in place for carrier election</p>	<ul style="list-style-type: none"> <li>• List of approved transporters who can transport goods on site – check history, emergency plans, membership of approved responsible care programmes etc</li> <li>• Transporters have appropriate licenses for the goods they are bringing on site.</li> <li>• DGSA appointed by both consignor and consignee where necessary</li> <li>• Goods checked and labelled to ensure they are correct and have the necessary paperwork.</li> </ul>	<table border="1"> <caption>% Companies at each stage for Supply &amp; Transport to site of raw materials</caption> <thead> <tr> <th>Stage</th> <th>%</th> </tr> </thead> <tbody> <tr><td>1</td><td>5</td></tr> <tr><td>2</td><td>10</td></tr> <tr><td>3</td><td>5</td></tr> <tr><td>4</td><td>15</td></tr> <tr><td>5</td><td>35</td></tr> <tr><td>6</td><td>45</td></tr> </tbody> </table>	Stage	%	1	5	2	10	3	5	4	15	5	35	6	45
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# Appendix One

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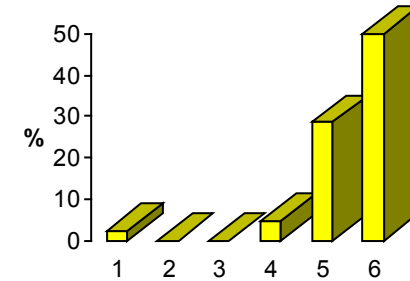
## Guideline

## % Companies at each stage

### 4. Handling & Storage

Appropriate storage facilities in place

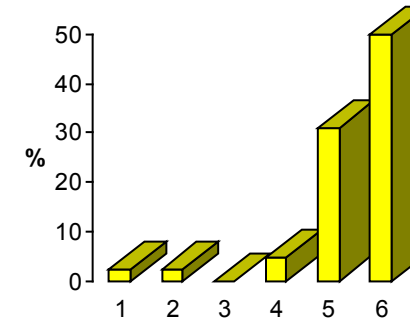
- Appropriate segregation policies for the materials being stored on site
- Ensure these facilities are secure
- Appropriate spillage containment provided



### 5. Management of Materials

Tracking of materials used in the production process

- Reconciliation procedure in place to account for hazardous materials brought on site
- Procedure in place to investigate discrepancies in raw material consumption
- Individual responsibilities for materials management clarified at each stage of the process.

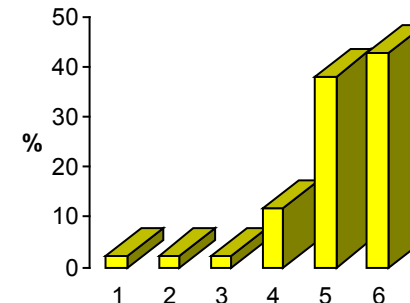


### 6. Distribution

Packing of product produced

Distribution to Downstream User

- Utilise environmentally friendly packaging and materials, including reusable, bulk and non-hazardous materials
- Ensure packaging is appropriate to the material being distributed
- Ensure that correct labelling is on packaging that is being transported off site
- Assess transporters history in relation to safety, environmental performance, fitness and regulatory compliance e.g. Contractor Evaluation Form



# Appendix One

## Product Stewardship Code

### Section

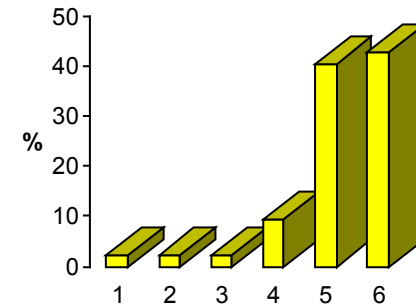
### Guideline

### % Companies at each stage

#### 7. Off site Incident Control

Plan in place to deal with chemical incidents off site

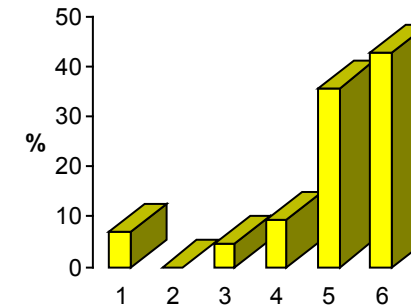
- Emergency Contact number present on product documentation
- Provide information to the emergency services on the hazards associated with the product and how it should be dealt with
- System in place to respond/assist in off site chemical incidents



#### 8. Downstream User

Downstream Users activities – consumption, storage and preparation

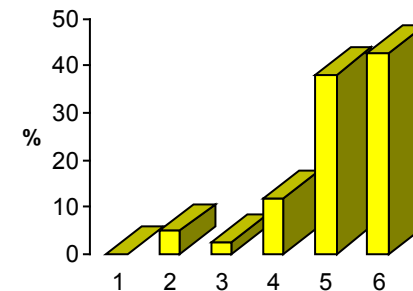
- Information on safe use and disposal of the product should be supplied either in SDS or by other method appropriate to the downstream users
- Request list of all uses on product from downstream users
- Verify that risk management measures employed by downstream users
- Verify that risk management measures employed by downstream user are compatible with yours



#### 9. Security

Considerations of the various security threats to products

- Analysis of threats to product, on site and off
- Implementation of security measures



# Appendix One

## Section

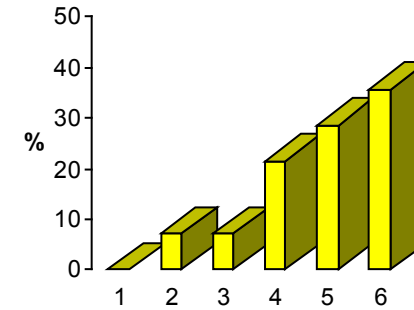
## Guideline

## % Companies at each stage

### 10. Public Concerns and Issues

Consideration of the relevant concerns of individuals or groups not in direct flow of product use

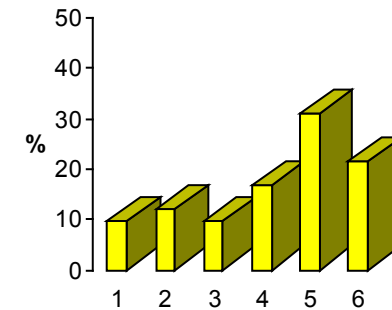
- Seek feedback from relevant stakeholder groups including government bodies, neighbours and environmental group
- Encourage different parts of the company to interact with outside interests to discuss EHS information, regulatory change etc
- 'Be actively involved in industry associations as a way to both give and receive the benefit of experience.



### 11. Employee Education

Employees should be trained and knowledgeable on product stewardship

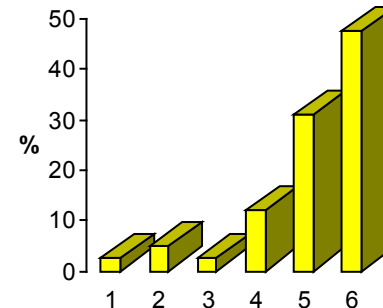
- Incorporate product stewardship education into existing employee training programmes
- Provide additional training to employees who have product stewardship responsibilities e.g. logistics



### 12. End of Life Cycle Control

Environmentally sound disposal is required

- Reusing, recycling or disposal procedure for excess or unused material and packaging in place based on risk assessment.



# Appendix One

## Security

### Section

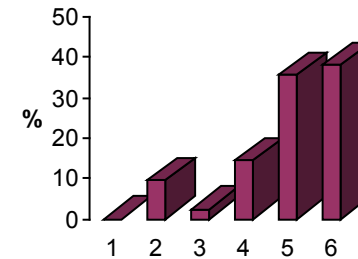
### Guideline

### % Companies at each stage

#### 1. Senior management Commitment

Senior leadership commitment to continuous improvement in Security Management through published policies, provision of sufficient and qualified resources and established accountability.

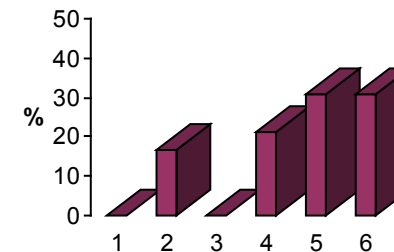
- Endorsement by top management
- Periodically reviewed (at least every 2 years)
- Include current main Security objectives
- Compliance with legislation
- Commitment to continuous improvement
- Communicated to all relevant personnel
- Commit adequate resources and personnel



#### 2. Analysis of Threats, Vulnerabilities and Consequences.

Prioritization and periodic analysis of potential security threats, vulnerabilities and consequences using accepted methodologies.

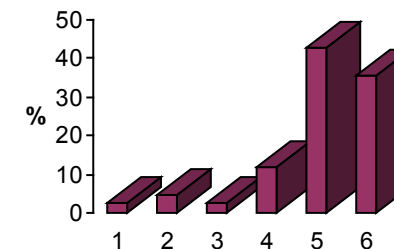
- Security Risk/Hazard Assessment procedure in-place
- Security Risk assessment(s) carried out for all significant facilities, activities including contractor and visitor activities, product sales , distribution and cyber security
- Security Risk assessment procedure for all new processes and operations in place
- Security Risk and Hazards to be classified to allow prioritisation
- Assess ability to upgrade security as required.



#### 3. Implementation of Security Measures

Development and implementation of security measures commensurate with risks, and taking into account inherently safer approaches to process design, engineering and administrative controls, and prevention and mitigation measures.

- Identify and Assess potential Security Risks
- Implement adequate physical security arrangements
- Implement appropriate data security arrangements
- Implement transport security arrangements





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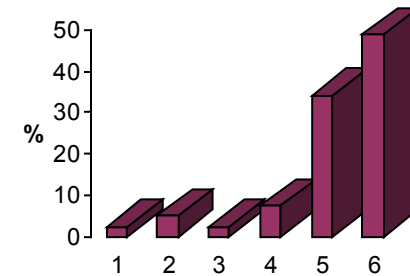
## Guideline

## % Companies at each stage

### 4. Information and Cyber

Recognition that protecting information and information systems is a critical component of a sound security management system.

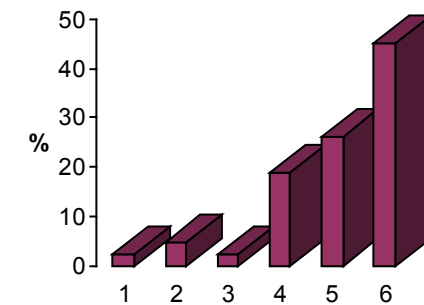
- Implement appropriate security of cyber assets including Information networks and IT systems.
- Security arrangements to include e-commerce, business management, telecommunications and process controls.
- Implement intrusion detection and access controls for voice and data networks, verification of information security practices applied by digitally-connected business partners, access to digital process control systems.



### 5. Documentation

Documentation of security management programs, processes and procedures.

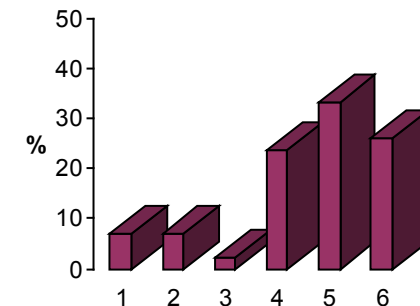
- The key aspects of the Security Programme will be documented.
- All critical security processes will be documented
- All key security procedures will be documented.



### 6. Training, Drills and Guidance

Training, drills and guidance for employees, contractors, service providers, value chain partners and others, as appropriate, to enhance awareness and capability.

- Keep pace with changes by enhancing security awareness and capabilities through training, drills and guidance.
- Contractors will be included when appropriate in security awareness programmes.
- Product distributors, emergency response agencies and other stakeholders to be included as appropriate.



# Appendix One

## Security

### Section

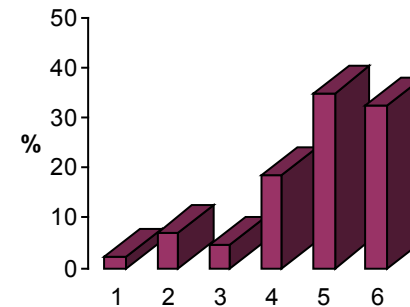
### Guideline

### % Companies at each stage

#### 7. Communications, Dialogue and Information Exchange.

Communications, dialogue and information exchange on appropriate security issues with stakeholders such as employees, contractors, communities, customers, suppliers, service providers and government officials and agencies balanced with safeguards for sensitive information.

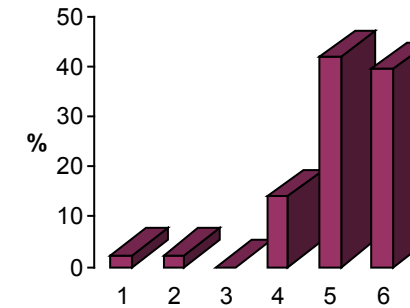
- Maintaining open and effective lines of communication includes steps such as sharing effective security practices with others throughout industry
- Maintain interaction with law enforcement officials.
- Understand the requirement to protect employees and communities where they operate, while safeguarding information that would pose a threat in the wrong hands.



#### 8. Response to Security Threats.

Evaluation, response, reporting and communication of security threats as appropriate.

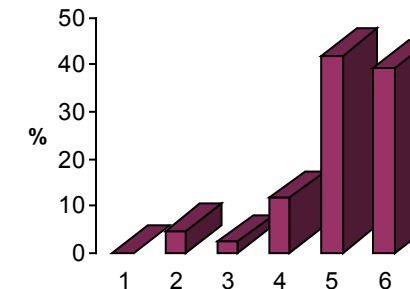
- Promptly will evaluate all threats and respond as appropriate.
- Report real and credible threats to company and law enforcement personnel as appropriate.
- Assess ability to upgrade security as required.



#### 9. Response to Security Incidents.

Evaluation, response, reporting and communication of security incidents as appropriate.

- Promptly respond and involve government agencies as appropriate.
- Incorporate key learnings from all security incident investigations and share those learnings with others in industry and government agencies as appropriate.
- Implement corrective actions.
- Establish and maintain emergency response procedures, facilities and personnel appropriate to the operation.
- Carry out periodic testing of the emergency procedures (at least annually)



# Appendix One

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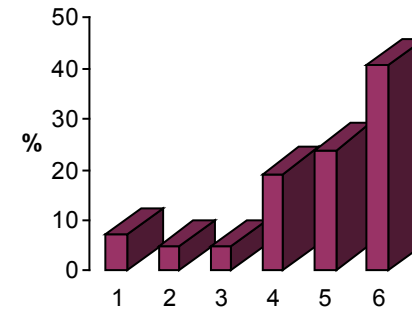
## Guideline

## % Companies at each stage

### 10. Audits

Audits to assess security programs and processes and implementation of corrective actions.

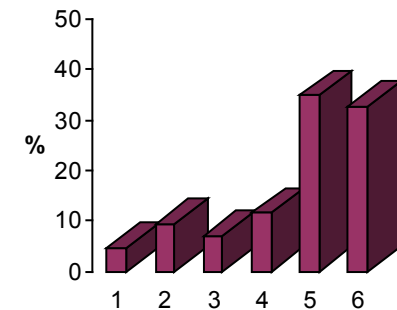
- Assess security programs and processes to affirm those programs and processes are in place and working and take corrective action as necessary.
- Assess the programs and processes of other companies with whom the company conducts business such as chemical suppliers, logistics service providers or customers as appropriate



### 11. Verification

Verification that, at facilities with potential off-site impacts, the physical site security measures are implemented.

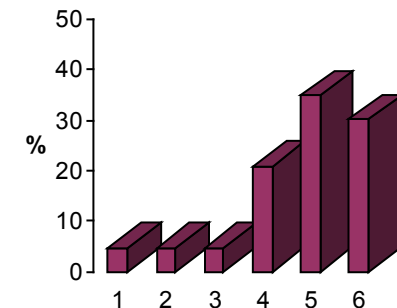
- Invite credible third parties – such as fire fighters, law enforcement officials, and insurance auditors – to confirm that the companies have implemented the enhanced physical security measures that they have committed to implement.
- Consult with these same parties as enhanced physical security measures are being considered and implemented.



### 12. Management of Change

Evaluation and management of security issues associated with changes involving people, property, products, processes, information or information systems.

- Evaluate and address related security issues in relation to all planned changes.
- Changes may include new personnel assignments, installation of new process equipment or computer software or hardware.



# Appendix One

## Security

### Section

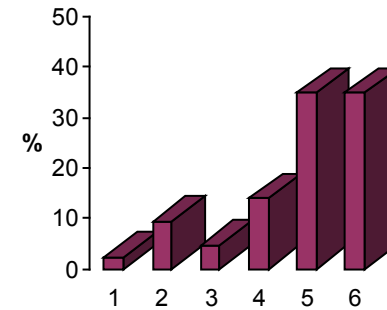
#### 13. Continuous Improvement

Continuous performance improvement processes entailing planning, establishment of goals and objectives, monitoring of progress and performance, analysis of trends and development and implementation of corrective actions.

### Guideline

- Seek continuous improvement in all security processes.
- Review security programs and measures reflecting new knowledge and technology.
- Track, measure and improve security arrangements to keep people, property, products, processes, information and information systems more secure.

### % Companies at each stage



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