



Our Commitment to Sustainability

**BioPharmaChem Ireland
Responsible Care
Report 2015**



RESPONSIBLE CARE[®]
OUR COMMITMENT TO SUSTAINABILITY

Foreword BioPharmaChem Ireland Chairperson

BioPharmaChem Ireland is pleased to present its 2015 annual Responsible Care report outlining the performance of the sector over the previous three years (2012- 2014). The report is a commentary on the collective performance of PCI members in the area of environment, health & safety (EHS).

This is an industry with people at the core; medicines produced in Ireland are used to treat and cure patients across the globe. This is also an industry that recognises its role in working responsibly. This is why it is my privilege to be associated with the excellent EHS performance of all of the companies who contributed to this report.

2014 was a good year for Responsible Care and BioPharmaChem Ireland (BPCI) member companies. The green shoots that we started to see last year have continued to grow and this has been reflected in the figures in this report. This upward trend in employee numbers continued in 2014 with a 2.5 % increase reported. Indeed we expect these figures to grow at a faster rate over the next few years as the contribution of newer member companies, primarily in the biopharma area, starts to impact.

Sustainability is at the core of our business and we continue to work hard at maintaining the advantage it affords the industry in Ireland. Consequently we are pleased to report decreases of 5.7 % in Carbon Dioxide emissions and 3.5 % decrease in energy consumption over the reporting period. These decreases, coupled with a 7.6% reduction in water consumption demonstrate the success of member companies in their resource management over the last three years. COD to waters showed a significant reduction, decreasing by 36 % during the period. Likewise we are pleased to note that the lost time injury rate continued its downward trend with a reduction of 23 % reported over the reporting period.

The members of BioPharmaChem Ireland remain committed to Responsible Care in everything we do.

Seamus Fives, Pfizer Ringaskiddy & Little Island API, Site Leader

Chairman, BioPharmaChem Ireland



What is Responsible Care?

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 BPCI is expected to voluntarily adopt the following commitments and principles;



Systematic procedures to verify the implementation of the measurable (or practical) elements of Responsible Care by the member companies.

BioPharmachem 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.

2015 Responsible Care Awards

BioPharmaChem Ireland would like to acknowledge the commitment and effort of all of those who make our workplaces safe and sustainable places to work.

2015 saw an entry of 4 high calibre submissions for both the national and European Awards (organised by Cefic) from member companies of BioPharmachem Ireland (BPCI). The national Responsible Care awards are presented at the BPCI AGM which is held every October.



Photo of Timmy Carney EHS Manager at BioMarin International Ltd accepting the National Responsible Care Awards at the BioPharmaChem Ireland dinner which took place in Adare Manor Hotel, Co. Limerick 22 October. Also in the photo is Seamus Fives PCI Chair, and Michael Kilkelly, Recordati, Chair EHS Working group

The following submissions were received;

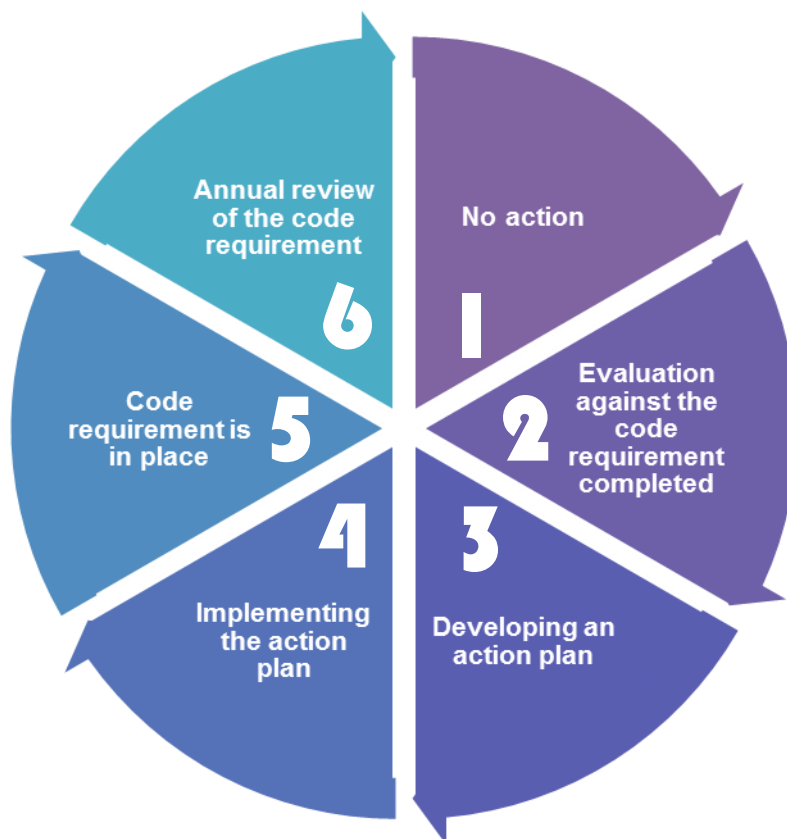
Allergan: Sustainable development through engagement with key Stakeholders
BioMarin: Sustainable health and wellness programme during the start-up phase
Genzyme: Healthy Workplace - Manage Stress
Leo Pharma: Essential Life Skills and Emergency Response
Ringaskiddy Industry & Residents group: Earth day, Clean up
Pfizer Newbridge: The TIC Safety Way - Using the Hermann Brain

Visit www.biopharmachemireland.ie



Codes of Practice

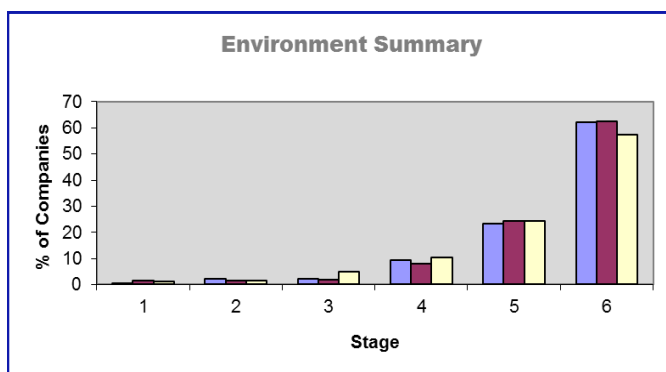
Companies are required to assess their performance against Responsible Care management codes of good practice in environment management, process safety, and energy management and newly introduced last year Product Stewardship management. While this procedure is self-assessment it does require the Company 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 BioPharmaChem Ireland website (www.biopharmachemireland.com). The participation in this aspect of the Responsible Care initiative continues at a very high level with over 90 % of the companies participating in the Safety, Environment and Energy Codes with in excess of 80 % contributing to the Product Stewardship Code and Security codes.

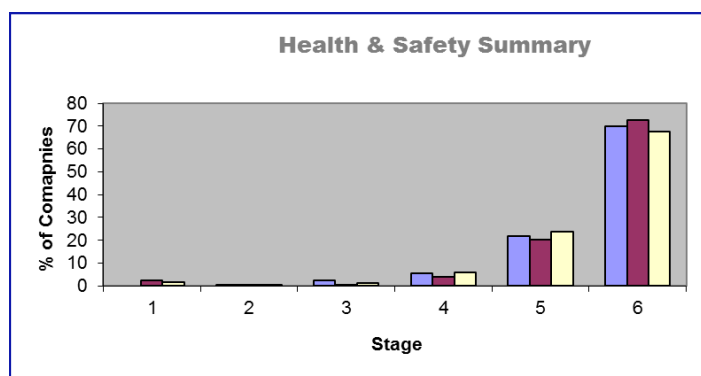
Codes of Practice

Environment Code



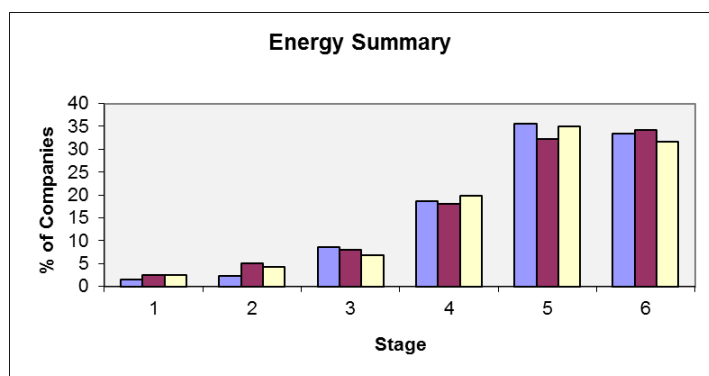
The progress in implementation of the Environment Code across member companies continues steadily with over 82 % of participants achieving Level 5 or greater and 92 % of respondents being at Level 4 or above. These levels of achievement are testament to the strong culture of continuous improvement in environmental performance in accordance with the principles of Responsible Care.

Health and Safety Code



The Health and Safety Code continues to show a very high level of achievement with in excess of 91 % 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 23 % reduction achieved in the last three year period following on from a 17 % improvement over the previous period. 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.

Health and Safety Code



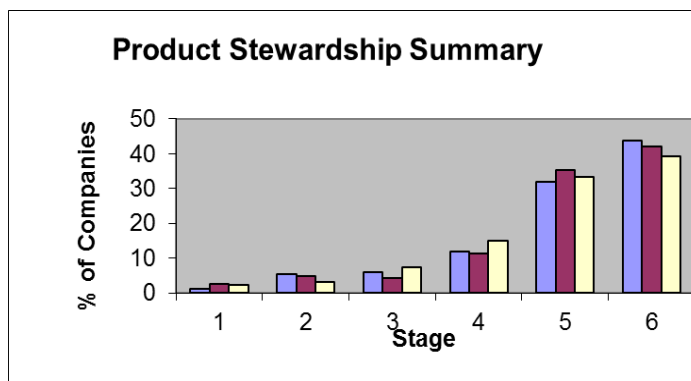
The returns for the Energy Code this year show that 67 % of companies are performing at Levels 5 or 6 with 87% of companies operating at level 4 or higher. The energy code his now showing signs of stabilisation in line with the more mature Safety and Environment Codes albeit with some potential for further improvement at the lower scoring levels. The industry is a significant energy user and we remain committed to reducing our energy consumption to the lowest practicable level thereby reducing our dependence as a society on imported energy.

Codes of Practice

Product Stewardship Code

Under Responsible Care, the member companies of BioPharmaChem 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.

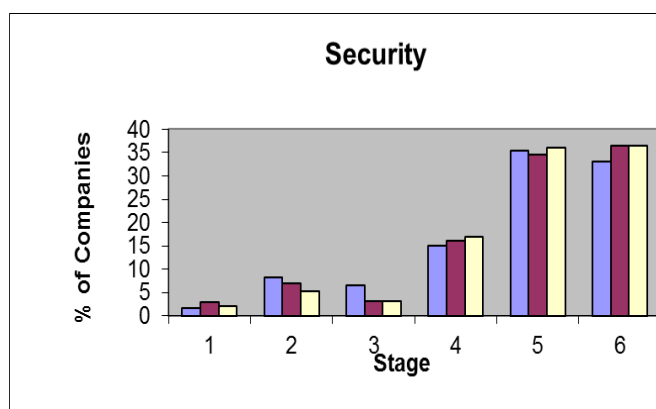
We are pleased to report that over 63 % of the member companies are rated at Level 5 or Level 6 with over 78 % rated above Level 4. Based on our experience with the Energy Code, this code is showing signs of stabilising and is likely to reach maturity in the next few years.



Security Code

Under Responsible Care, the member companies of BioPharmaChem Ireland are committed to ensuring that their facilities, raw materials and products are maintained in a secure environment at all times. The goal of 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 73 % of companies are operating at Level 5 or 6, and 90 % operating at Level 4 or above. This trend in this code is also showing signs of stabilising as the code reaches maturity in the next few years.



Performance Indicators of the Responsible Care Programme for 2015

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 92 % of companies submitting data. This is similar to the participation level last year. This is the third 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 had stabilised with no change between 2011 and 2012 and a small increase in 2013. This trend continued in 2014 with a 2.5 % increase in employee numbers reported.

However, once again the production volumes dropped somewhat this year with an 8.5 % volume decrease. 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 5.7 % in Carbon Dioxide emissions and 3.5 % decrease in energy consumption over the reporting period. These decreases, coupled with a 7.6% reduction in water consumption demonstrate the success of the member companies in their resource management over the last three years. COD to waters showed a significant reduction, decreasing by 36 % during the period. However both Phosphorous and Nitrogen discharges increased slightly. These will continue to be a focus for member company attention in the coming year. Once again this year Volatile Organic Compounds emissions tend to vary somewhat year on year with a small increase reported. This is most likely due to changes in product mix in some member companies from year to year. In this period hazardous waste showed an increase of 19.6 % whereas non-hazardous waste reduced by 18.5 %. The recycling rate for non-hazardous waste continues to rise with a 14 % increase reported this year.

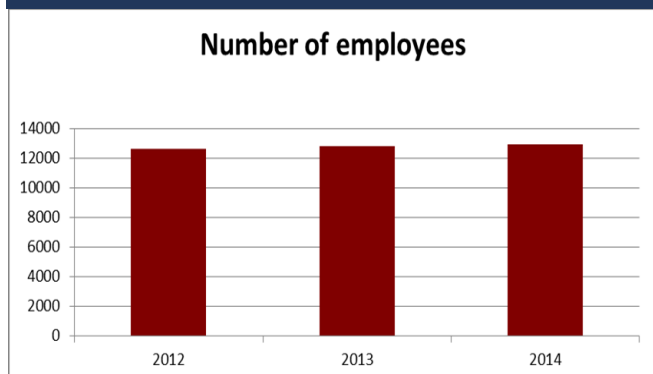
The lost time injury rate continued its downward trend with a reduction of 23 % reported over the three year reporting period.

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

BioPharmaChem Ireland encourages all member companies to continue their efforts to consolidate the achievements made over the years and to further improve the performance of our sector in the years ahead.

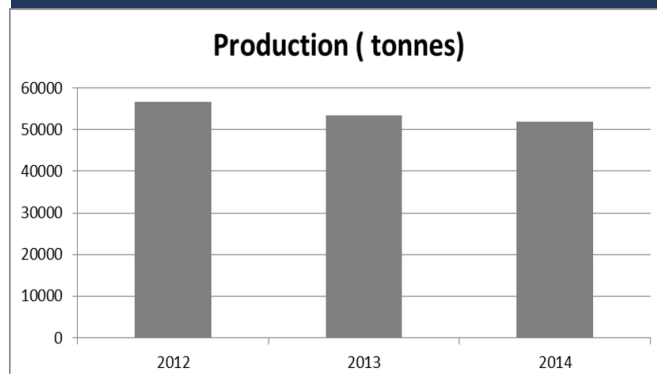
Performance Indicators of the Responsible Care Programme for 2015

Employees: + 2.5 %



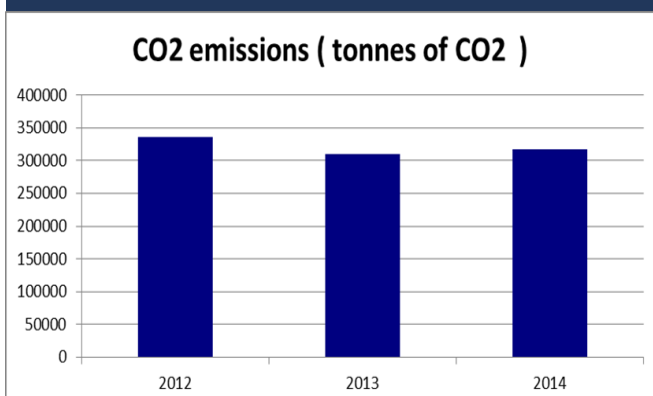
During the three-year period, the numbers employed in the sector increased by 2.5%. This is the third year of increasing employee numbers in the industry following a number of years of decreasing numbers in the sector. It is hoped that this trend will continue in the years ahead.

Production – 8.3 %



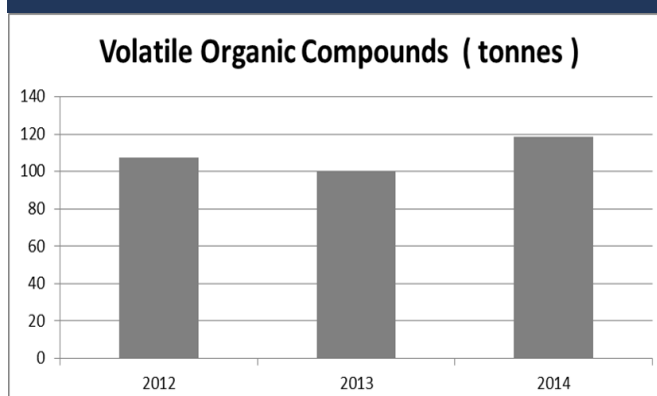
The output from the industry has shown a decrease of 8.3% this year. This trend should be interpreted in conjunction with the increase in employee numbers during the period indicating that the move to higher value products is most likely taking place.

Carbon Dioxide – 5.7 %



The trend in CO2 emissions showed a decrease of 5.7 %. This is evidence of more of our member companies putting structured energy management systems in place and moving towards the adoption of the ISO 50001 Energy Management Systems standard. We expect this trend to continue in the years ahead as more companies continue to focus on reducing their energy consumption.

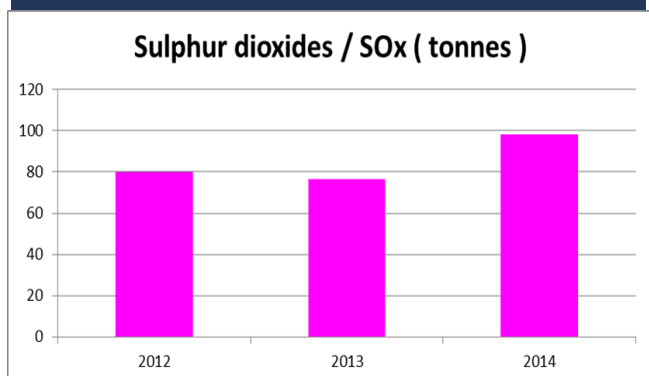
Volatile Organic Compounds +10 %



Emissions of VOCs have shown an increase of 10 % over the 3 year period. This parameter tends to vary more than others as can be seen by the 6.7 % decrease year on year between 2012 and 2013. While the trend has stabilised somewhat in recent years, it will continue to be closely monitored by our member companies in the years ahead to ensure that these emissions continue to be tightly controlled.

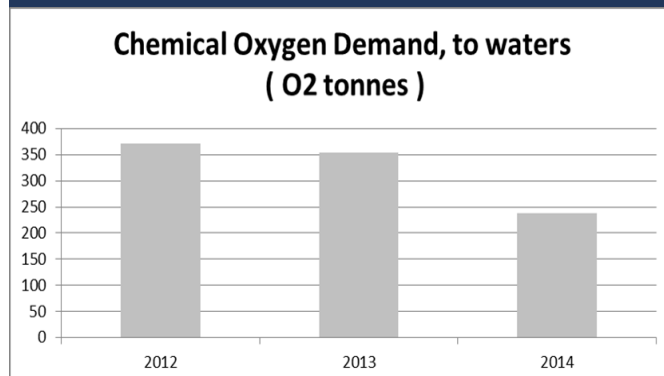
Performance Indicators of the Responsible Care Programme for 2015

Sulphur Dioxide 23 %



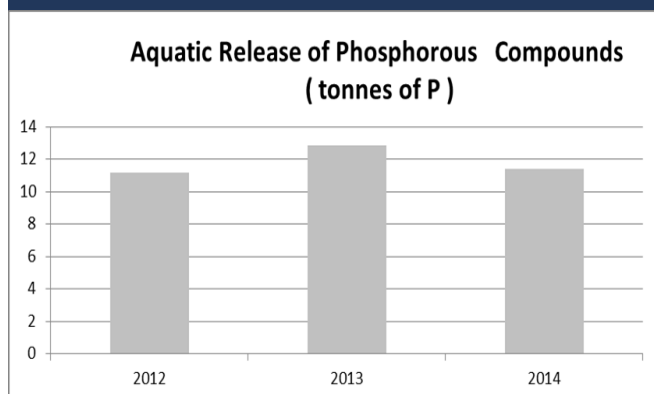
Sulphur Dioxide emissions showed an increase of 23 % following a decrease of 44 % over the previous three-year period and even larger decreases in previous years. The changes in this parameter are influenced by a relatively small number of the respondents due to the move from oil to natural gas over the years. We will continue to monitor this trend in the coming years.

Chemical Oxygen Demand -36 %



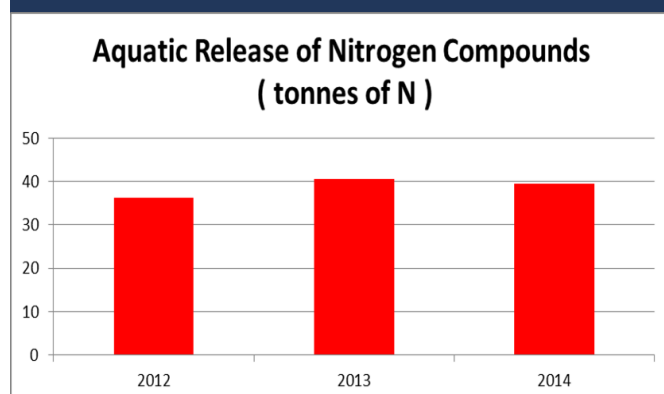
This parameter has shown a significant decrease of 36 %, following smaller improvements reported in the previous two years. This illustrates the importance of close monitoring of waste water treatment plants on member sites and our ongoing commitment to protecting our valuable water resources.

Phosphate + 2 %



The phosphorous emissions from members' sites increased by 2 % over the three-year period following on from a 14 % increase reported last year. However, this must be considered in the context of a reduction of 48 % reported since 2009.

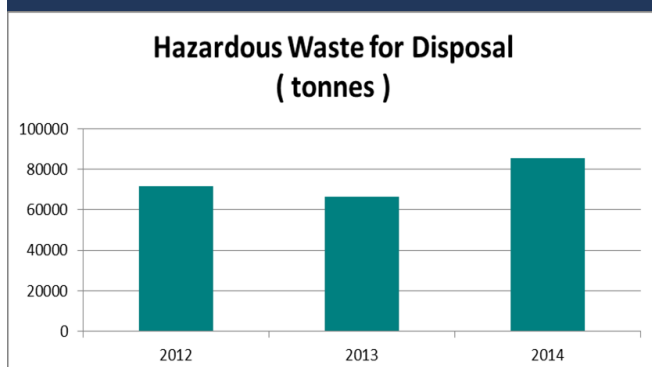
Nitrogen + 9.2 %



This year is the second year this parameter has shown a slight increase following eight consecutive years of reductions in aquatic release of nitrogen. The trend over the last two years has shown a reduction of 2.9% indicating that the parameter now appears to have stabilised making further reductions more difficult to achieve.

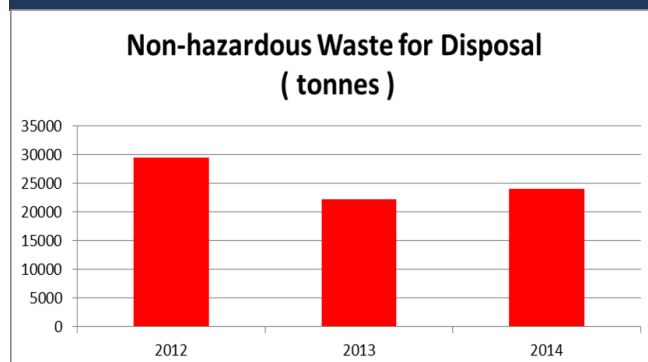
Performance Indicators of the Responsible Care Programme for 2015

Hazardous Waste + 19.6 %



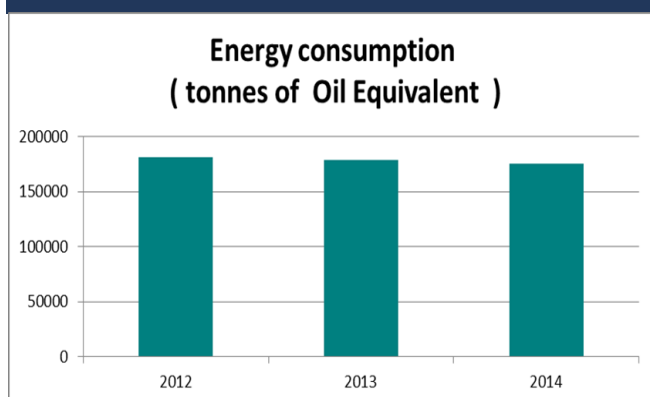
The hazardous waste generated increased by 19.6 % in this period. This parameter has shown decreases of 2.4 %, 6.5 % and 14 % over the last three reports. We will continue to focus on this important parameter to ensure that this trend is reversed in future years.

Non- Hazardous Waste – 18.5 %



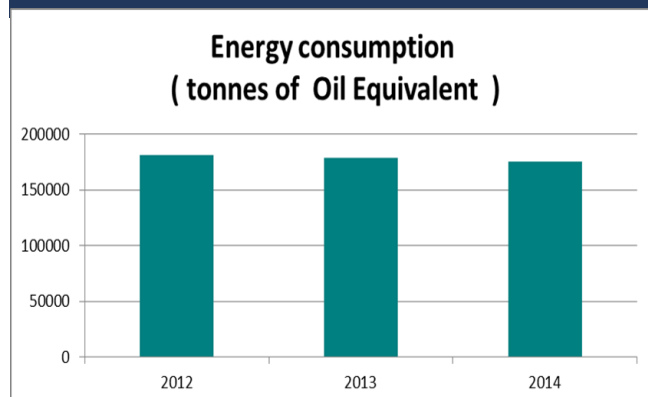
The amount of non- hazardous waste decreased by 18.5 % over the three year period following a 6.3 % reduction reported last year. The amount of non-hazardous waste recycled has shown an increase of 14 % over the 3 year period. This illustrates the move from disposal to recycling for non-hazardous waste arising on the member sites.

Energy Consumption – 3.5 %



The energy consumed by the member companies has decreased by 3.5 % over the last 3 year period. The carbon dioxide associated with electricity decreased by ca. 8 % over the same period. Our member companies will continue to place a high priority on energy management in the years ahead to increase energy efficiency and to further reduce the energy impact of our operations.

Water Consumption – 7.6%



We have achieved a reduction of 7.6 % in water consumed by our member companies over the three year period to 2014 following on from a 7.2 % decrease reported last year. The conservation of water is a high priority for all member companies as evidenced by the success in reducing consumption over the reporting period.

Performance Indicators of the Responsible Care Programme for 2015

Lost Time Injury Rate – 23 %



We are pleased to report a reduction of 23 % in the lost time injury rate following on from a 17 % reduction reported last year. This parameter has shown a consistent reduction over the last 10 years. With in excess of 26 million hours worked in the sector in 2014 this low level of lost time injuries demonstrates the continued overall effectiveness of the health and safety management systems in the sector. We will continue to strive to provide a safe and healthy workplace for all of our employees.



The Responsible Care ethic helps chemical companies to operate safely, profitably and with due care for future generations. “

The building blocks of Responsible Care

Communications

For projects that can demonstrate excellence in Responsible Care communications by reporting openly on performance, achievements and shortcomings, listen, engage and work with stakeholders to understand and address their concerns and expectations and cooperate with (local) authorities and organizations in the development and implementation of effective regulations and standards and to meet or go beyond them.

Energy Efficiency

First launched in 2013, the Energy Efficiency Award recognises and promotes outstanding projects in energy efficiency, renewable energy and clean transport. This area gathers projects that contribute to

the Europe 2020 strategy for smart, sustainable and inclusive growth and have a proven impact. This category addresses the efficient management of energy to improve practices and technologies in heat

and power generation, the review of the steam flow in processes and its optimization and the use of electricity.

Environment

For projects that demonstrate excellence in environmental processes and products over their life cycles so as to avoid harm to people and the environment by reducing their on-site emissions to air, water and soil and to limit environmental hazards related to their operations through the development of innovative technology. Also using resources efficiently and minimizing waste.

Occupational Health

This area recognises projects that have achieved excellence in occupational health demonstrated by improved or sustained health programme performance and a healthy workforce and workplace. The key characteristics of Occupational Health include management commitment, employee engagement and evidence of a culture of proactive health risk management and wellbeing support initiatives.

Distribution

For initiatives recognized that focus on risks through ensuring the safe distribution of chemicals.

Security

Promotes outstanding examples that describe fundamental management practices to protect people, property, products, processes, information and information systems by enhancing security, including security against potential terrorist attacks, throughout the chemical industry value chain covering the design, procurement, manufacturing

Process Safety

Outstanding initiatives which have an exemplary record in implementing effective process safety management systems from process design to continued operation and routine maintenance, best practices and improvements for chemical prevention, preparedness and response to reduce major process hazards and risks.

Product Stewardship

This area focuses on products that are developed, manufactured, distributed, used and disposed of in a safe and environmentally responsible manner. It recognises value chain projects that help companies set up and improve their chemicals management procedures. In line with chemicals regulations, Product Stewardship addresses management of risks and improvement of the performance of a product in the fields of safety, health and the environment during its entire life cycle.

List of companies involved

AbbVie (Fournier Laboratories)

Alkermes Pharma Ireland Limited
Allergan Pharmaceuticals Ireland
Amgen
Arran Chemical Co. Ltd
Astellas Ireland (Dublin)
Astellas Ireland (Kerry)

BASF Ireland Limited

BioMarin International Limited
Bristol Myers Squibb Cruiserath

Cara Partners & Wallingstown Co Ltd

Clarochem Ireland Ltd

Eli Lilly S A - Irish Branch

FMC International

GE Healthcare Bio Sciences

Genzyme Ireland
Glaxo Smith Kline Cork

Helsinn Birex Pharmaceuticals Limited

Henkel Ireland Limited
Hovione Limited

Ipsen Manufacturing Ireland Limited

Janssen Pharmaceuticals Limited

Janssen Biologics Ireland Limited

Leo Pharma

Mallinckrodt Pharmaceuticals

MSD Ballydine
MSD Brinny
MSD Swords
MSD Rathdrum

Novartis Ringaskiddy Limited

Pfizer Grangecastle

Pfizer Little Island
Pfizer Newbridge
Pfizer Ringaskiddy

Recordati Ireland Limited

Roche Ireland Limited
Rottapharm Ireland

Servier Ireland Industries Limited

Sigma Aldrich Ireland Limited
Swords Laboratories - BMS

Takeda Ireland Bray

Takeda Ireland Grangecastle
Temmler Ireland Limited
Teva Pharmaceuticals Ireland Limited

UCB Manufacturing Ireland Limited



BioPharmaChem
Ireland gratefully
acknowledges the
assistance of our
member companies
for their assistance in
compiling this report.





Responsible Care™

OUR COMMITMENT TO SUSTAINABILITY



Data Collection

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.

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DGSA CMVP

Director

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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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