



biopharmachem
Ireland



Our Commitment to Sustainability

**BioPharmaChem Ireland
Responsible Care Report
2016**



RESPONSIBLE CARE®
OUR COMMITMENT TO SUSTAINABILITY

Foreword . BioPharmaChem Ireland Chairperson

BioPharmaChem Ireland (BPCI) is pleased to present its 2016 annual Responsible Care report outlining the performance of the sector over the previous three years (2013- 2015). The report is a commentary on the collective performance of BPCI members in the area of environment, health & safety (EHS).

2015 was a good year for Responsible Care and BPCI member companies. The green shoots that we started to see in 2014 have continued and this has led to an increase of 6.7 % in the numbers employed in our companies. As with last year, we anticipate these figures will increase even more rapidly over the next few years as the contribution of newer member companies, primarily in the biopharma area, continues to impact.

However there was one indicator that ensures we remain vigilant; for the first time in a number of years our lost time injury rate (LTIR) increased. While the actual number of lost time injuries is still very small in a European context, even one injury is one too many for our members. This indicator will provide a focus for member companies to redouble their efforts in the health and safety area in the coming year.

Most of the environmental indicators continued their downward trend. However, both Phosphorous and Nitrogen discharges increased, though still well within their limits. These will continue to be a focus for member company attention in the coming year. Likewise, while hazardous waste reduced by 9%, we saw an increase in non-hazardous waste by 6.7%.

BioPharmaChem Ireland member companies are proud of what we do. Our products allow people to lead fuller and more productive lives. Our products make a difference across the globe and that is why ours is an industry that recognises its role in working responsibly. BPCI remains dedicated to strengthening chemicals management systems, safeguarding people and the environment, and engaging stakeholders to work toward sustainable solutions. Our member companies 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 biopharmachem 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;

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.

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.

2016 Responsible Care Awards

Irish Responsible Care Award

This year, BioPharmaChem Ireland worked with the Irish Pharma Industry Awards in selecting the Irish Responsible Care Award of 2016.

14 entries were received from 11 different sites and the calibre of submission was the highest yet observed. The submissions covered two broad categories; occupational health & safety and sustainability initiatives.

The overall winner was Astellas (Kerry) for their 'Changing tomorrow' programme. This submission outlined their journey of sustainability that now sees the site generate 64% of their energy needs through the use of onsite renewable energy sources. This includes a combination of wind, biomass and solar. Since 2011, this has led to cumulative energy savings of more than €3.5 million.

Other initiatives under the same umbrella have seen significant reduction in water usage, increased recycling, re-use & waste minimisation together with a number of social and environmental programmes in conjunction with the local community.



Pat McCartan accepts the European Responsible Care Award on behalf of MSD Swords.

2016 European Responsible Care Award

We are also pleased to report that MSD Swords was the recipient of the 2016 Occupational Health & Safety Responsible Care Award for their submission, "Commitment in Challenging Times". This initiative provided details of the site safety performance during temporary high production demand.



Michael Gillen, Senior Executive, BioPharmaChem presents the Responsible Care Award 2016 to Rachel Keating, Gina Halliday and Eamon Foley, Astellas Kerry.



Responsible Care
OUR COMMITMENT TO SUSTAINABILITY

2016 Benchmarking Analysis

Every year, BioPharmaChem Ireland collects a lot for a number of different performance indicators. Indeed this data makes up the bulk of the national Responsible Care report and is also used for onwards transmission to Cefic so as to collate a European wide perspective.

In recent years we have conducted some ad hoc benchmarking at the request of member companies. This has usually been around areas like lost time injury rate (LTIR) and some environmental parameters such as volatile organics (VOCs).

This year we have decided to prepare a number of pareto curves that allows member companies to map where their site sits against the cumulative aggregation of the industry in Ireland, for that given performance indicator. Each site that submits data is given a unique code that allows them to benchmark their performance against the rest of the industry.

Initially we have chosen a cross section of commonly reported indicators. If there is sufficient demand, we will look at expanding the number of indicators analysed in forthcoming years. The indicators chosen initially were:

Energy & water

Total energy (tonnes of oil equivalent), CO2 (from fuel mix of the site), Electricity, Gas, Water

Environment

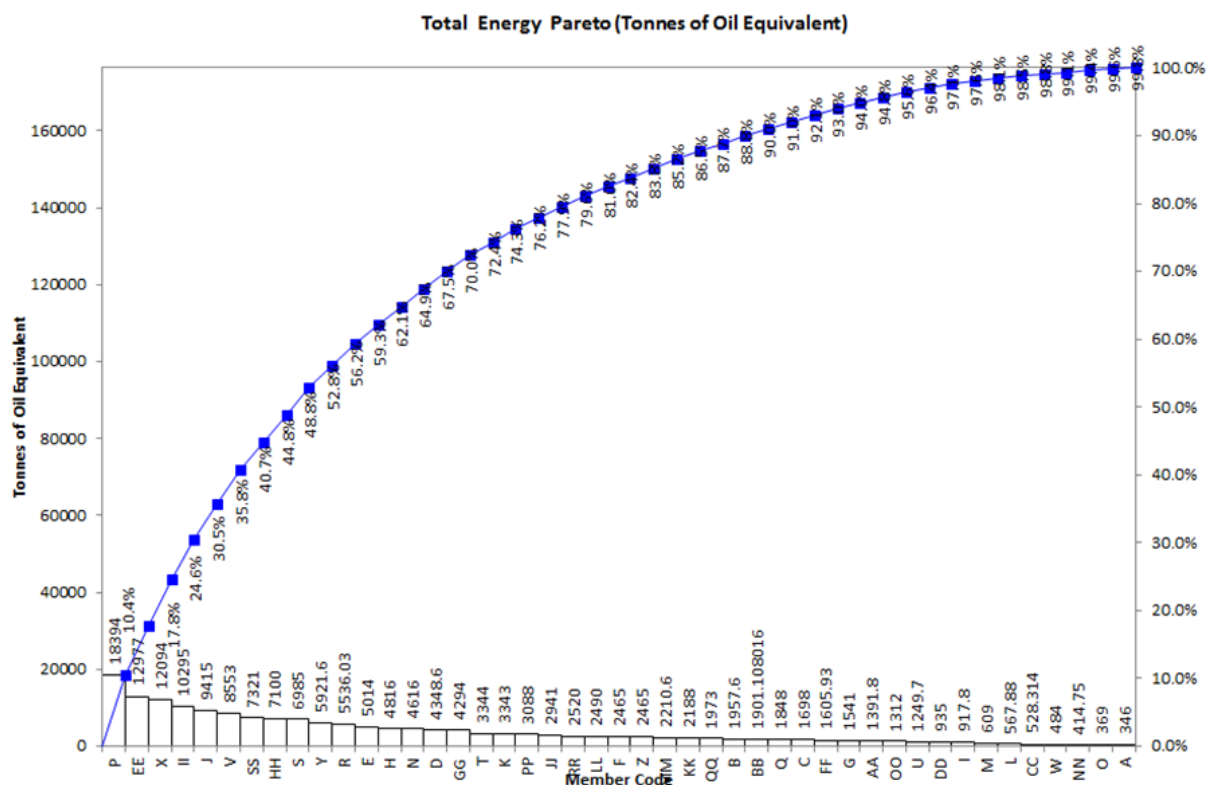
Incidents reported to EPA, COD to water, hazardous waste, non-hazardous waste, non-hazardous waste (recycled), phosphorous to water, nitrogen to water, VOC

Safety

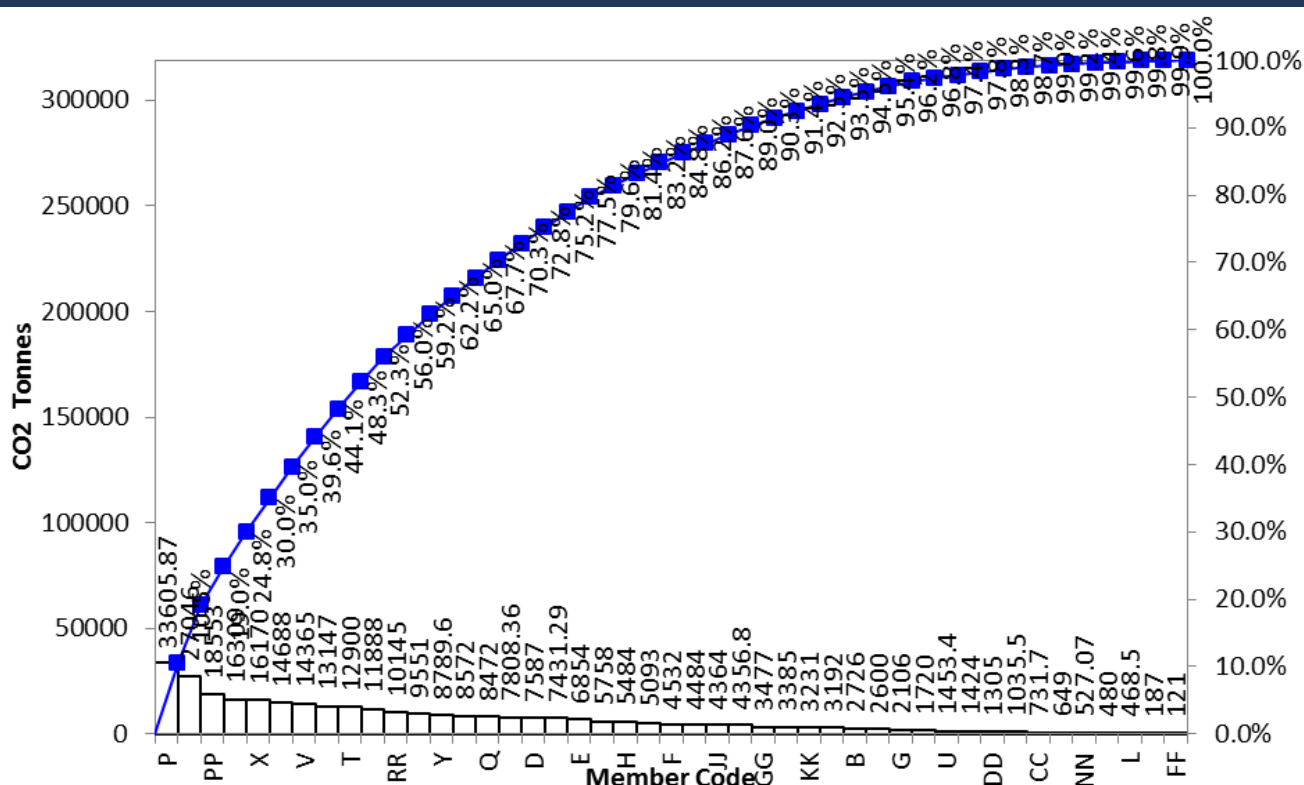
Lost time injuries, lost time injury rate

2016 Benchmarking Analysis

Total Energy Pareto

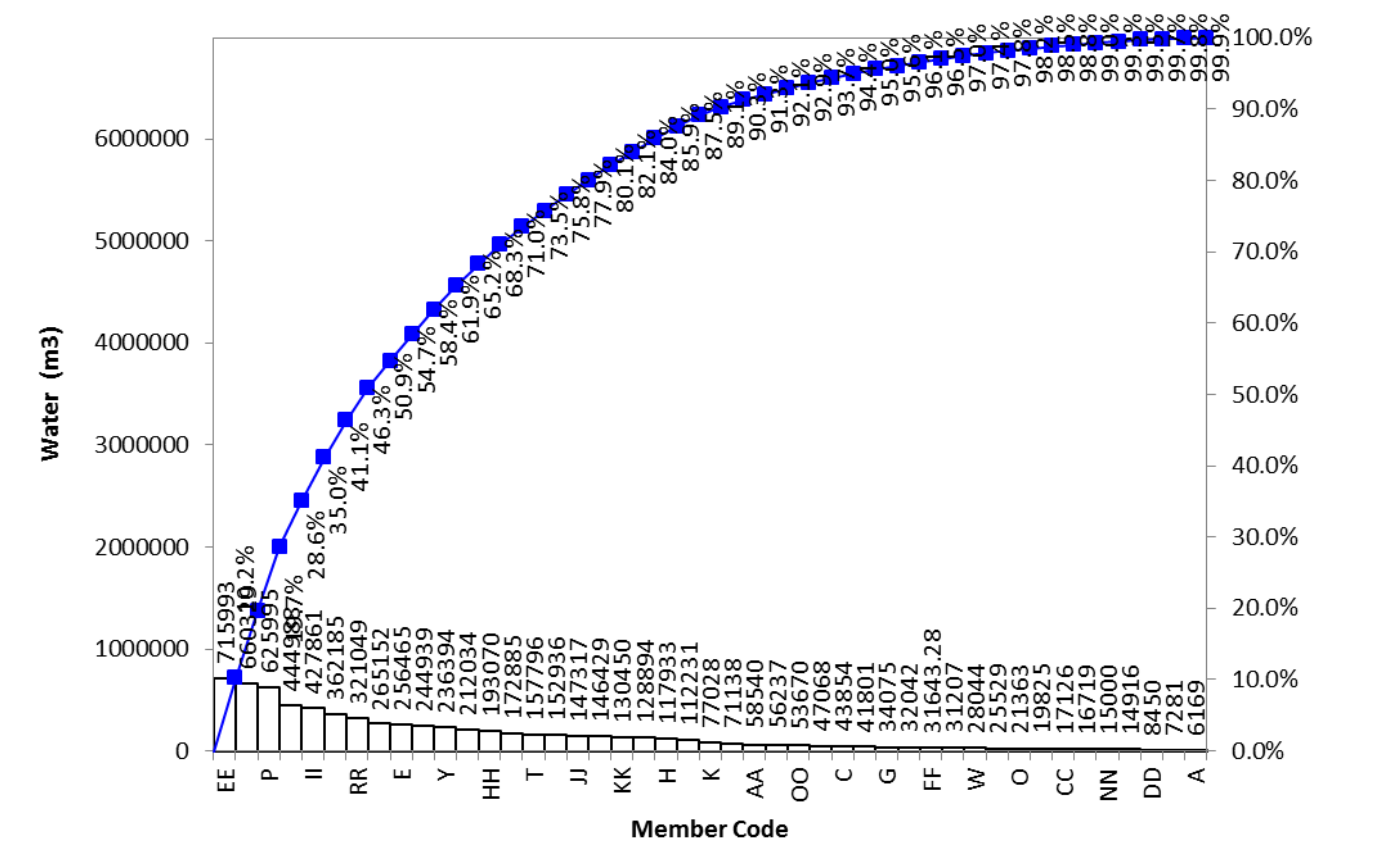


Co2 (from fuel mix of the site)

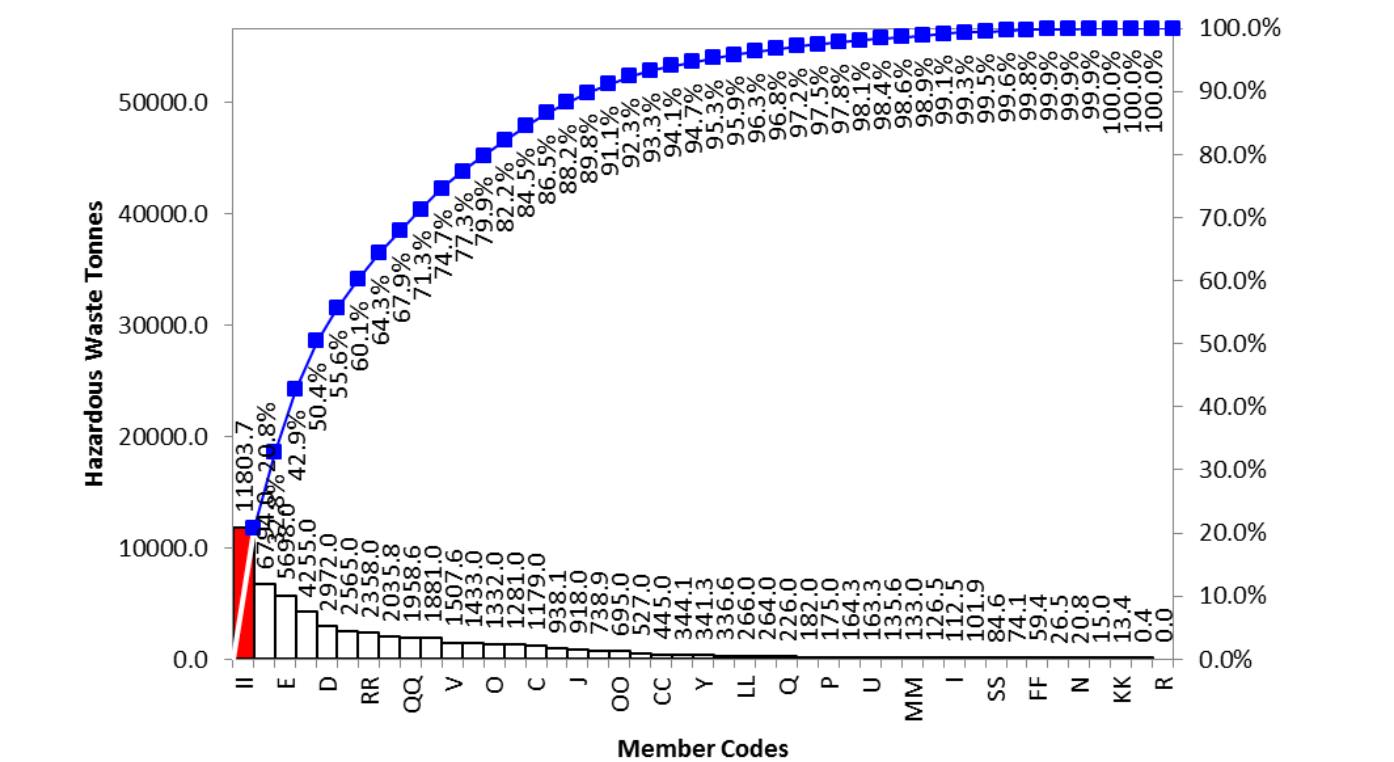


2016 Benchmarking Analysis

Water Usage

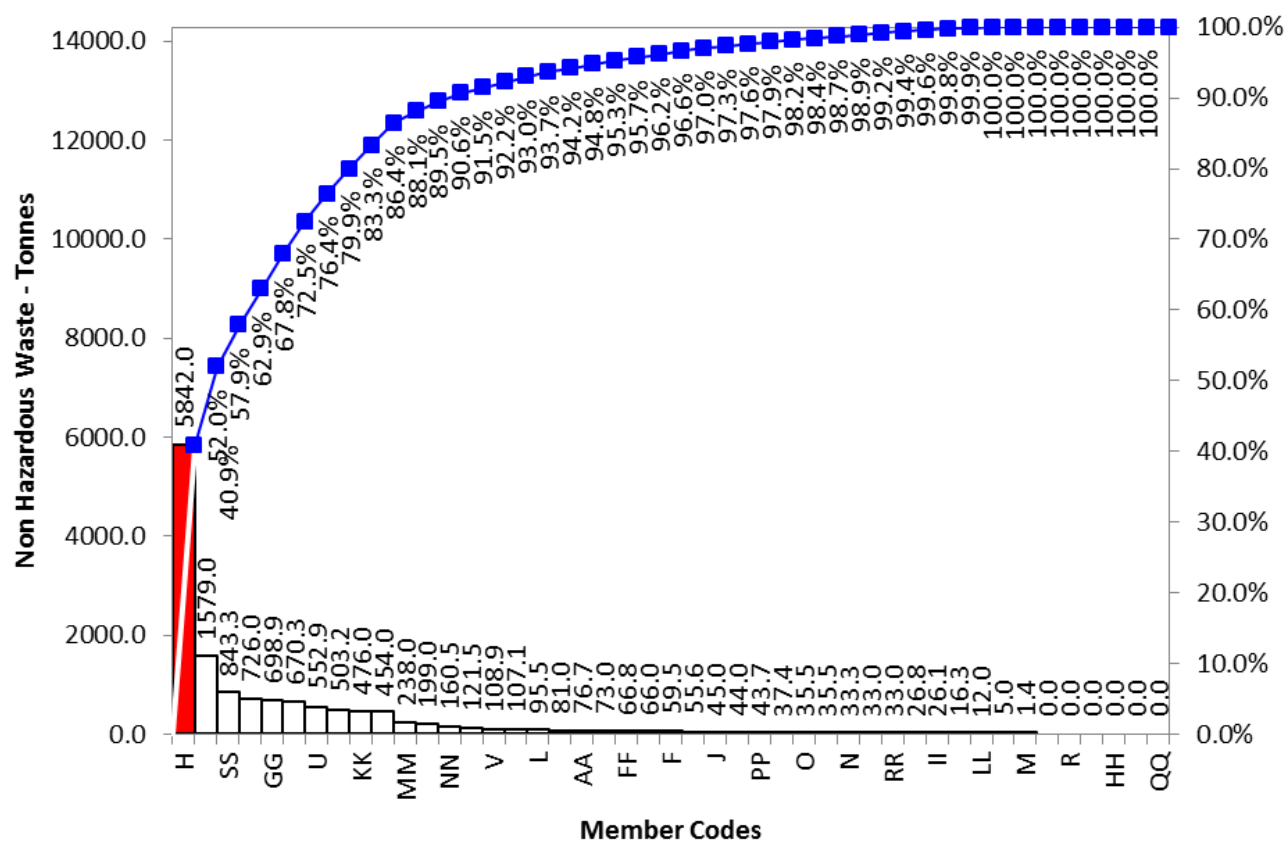


Hazardous Waste

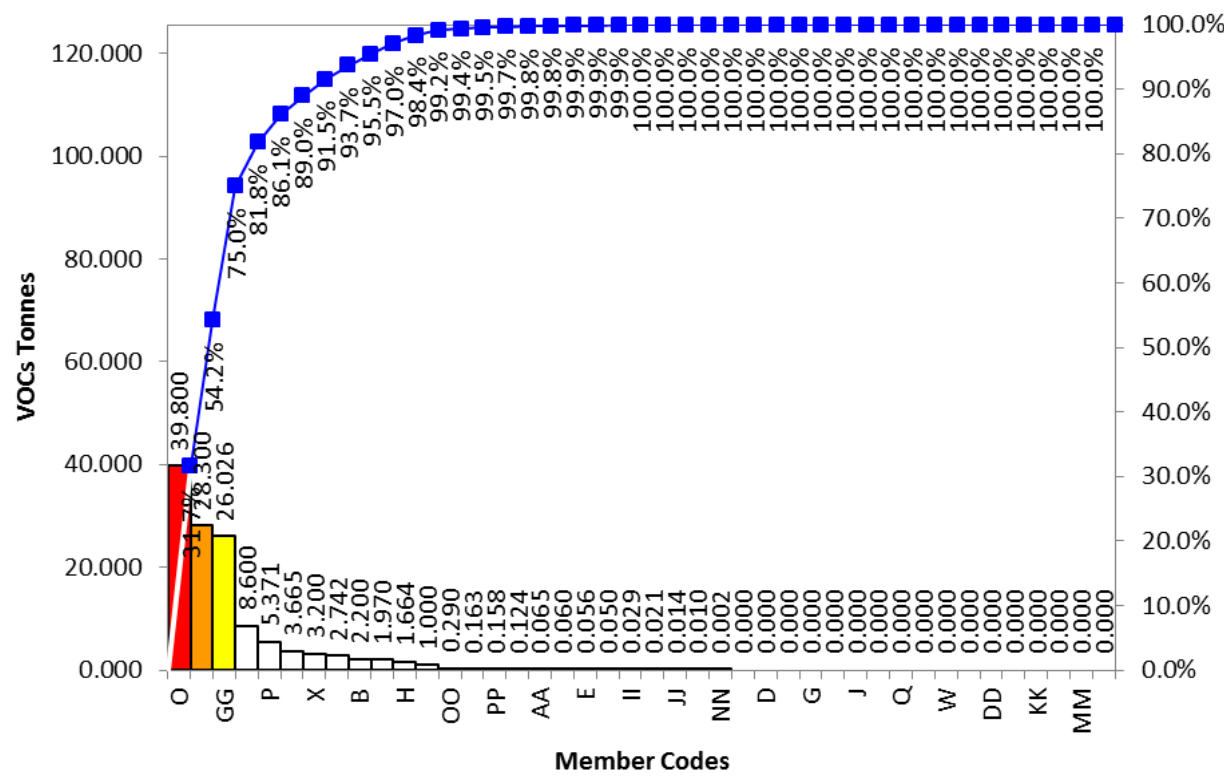


2016 Benchmarking Analysis

Non-Hazardous Waste

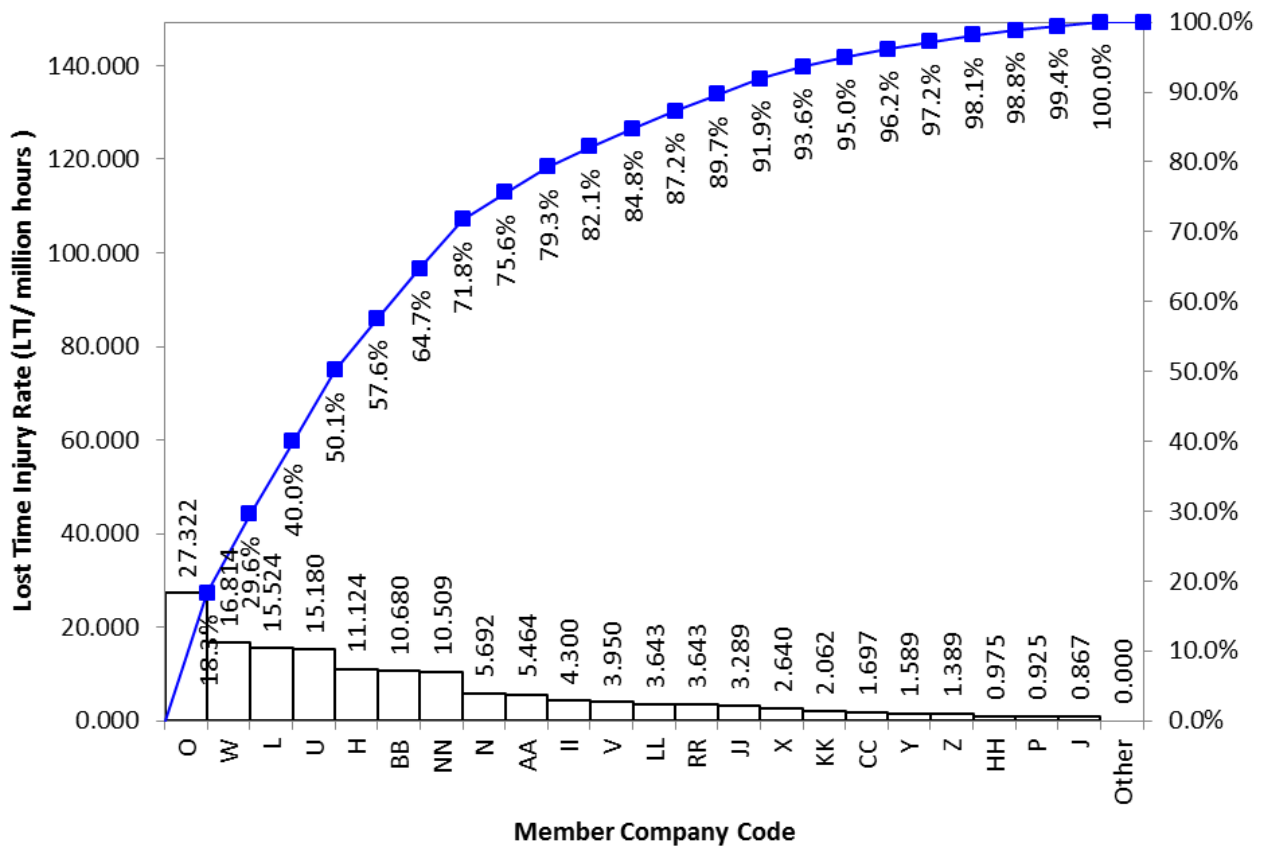


VOC



2016 Benchmarking Analysis

Lost Time Injury Rate (LTIR)



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

Performance Indicators of the Responsible Care Programme for 2016

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. 92 % of companies submitting data. This is the same participation rate as last year.

This is the fourth year since the introduction of a web enabled on line data collection system which has facilitated significantly more efficient data collection and analysis. The self-assessment codes have now all reached maturity and it has been decided to discontinue these and concentrate on using the indicator data for benchmarking purposes.

We are pleased that the downward trend in the numbers employed in the member companies seen in recent years has reversed with a strong increase of 6.7 % in the numbers employed in 2015. The production volume has effectively stabilised with only a very small reduction of 1.5 % reported. 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 coupled with some decreases in a small number of companies who manufacture relatively high volumes of product.

We are pleased to report continued decreases in Carbon Dioxide emissions and energy consumption over the reporting period. COD to waters again showed a significant reduction, decreasing by 29 % during the period. However, both Phosphorous and Nitrogen discharges increased. These will continue to be a focus for member company attention in the coming year. Volatile Organic Compounds emissions decreased slightly during the period. In this period hazardous waste reduced by 9% whereas non-hazardous waste increased slightly by ca. 6.7%

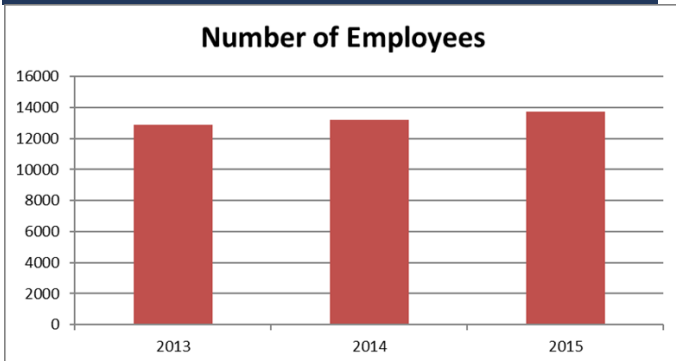
The lost time injury rate increased somewhat which provides a focus for member companies to redouble their efforts in the health and safety areas in the coming years

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.

We will continue to encourage all our members to continue their efforts to further consolidate the achievements made over the years and to further improve the performance of our sector in the years ahead.

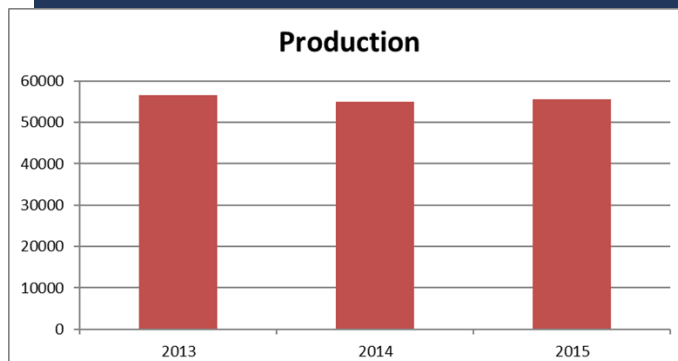
Performance Indicators of the Responsible Care Programme for 2016

Employees: + 6.7 %



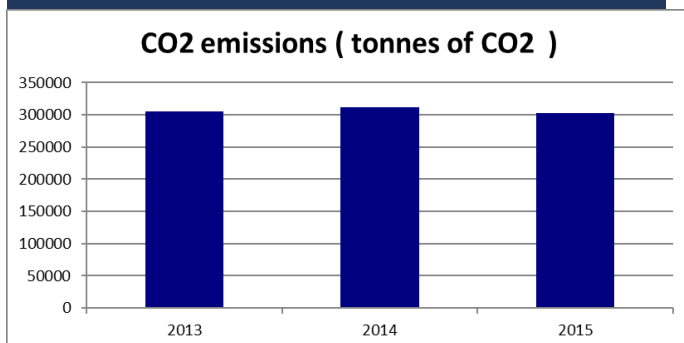
During the three-year period, the numbers employed in the sector increased by ca. 6.7 %. This is the fourth year of increasing employee numbers in the industry following a number of years of decreasing numbers in the sector. This is a positive indicator for the industry and shows that the biopharmaceutical 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.

Production – 1.5 %



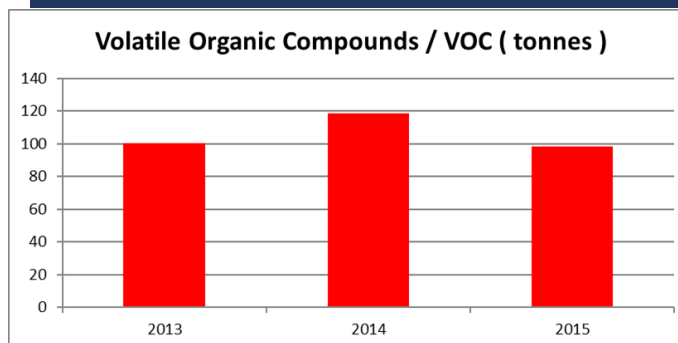
The output from the industry has shown a very slight decrease of 1.5% this year following an 8.3 % decrease last year over the three year period. The trend in the last year is a small increase of ca. 1 % indicating that production output appears to have stabilised. The move in some companies to lower volume higher value products may also be a contributory factor in this result. 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 – 0.8 %



The trend in CO2 emissions showed a slight decrease of ca. 0.8% over the three-year period following on a decrease of 5.7 % last year. The carbon dioxide emissions dropped by ca. 3 % over the last year. The stabilisation of this parameter may point to the fact that a lot of progress has been made in the area of energy reduction in the last few years and a lot of the 'low hanging fruit' has been harvested. This may also suggest that further reductions may require some significant capital investment in the years to come. We continue to collect more detailed energy utilisation data to ensure that these trends can be tracked more closely in the future.

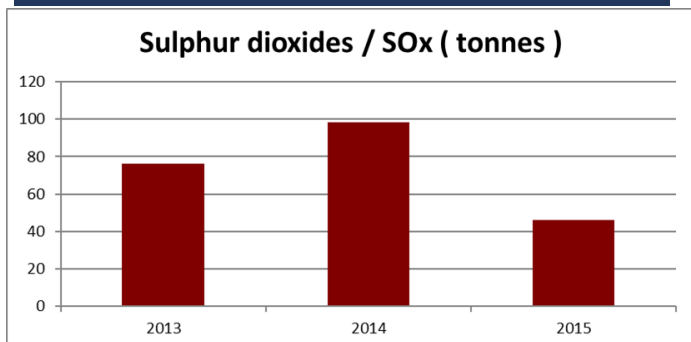
Volatile Organic Compounds -2 %



Emissions of VOCs have shown a decrease of 2 % over the 3-year period. This reversed the trend seen last year when this parameter increased by 10%. The year on year drop between 2014 and 2015 was 17%. While this parameter tends to vary more than others it now appears to be stabilising somewhat but we will continue to monitor it closely in the years ahead to ensure that these emissions continue to be tightly controlled.

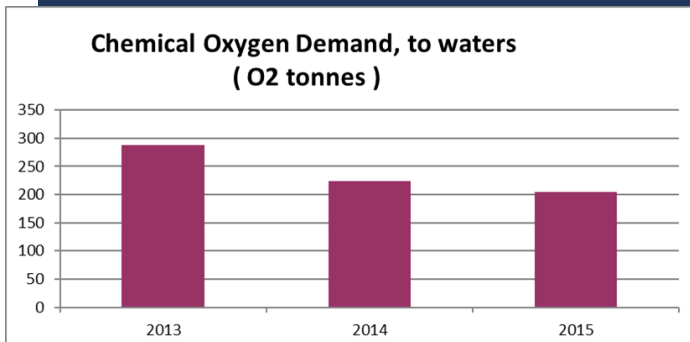
Performance Indicators of the Responsible Care Programme for 2016

Sulphur Dioxide -40%



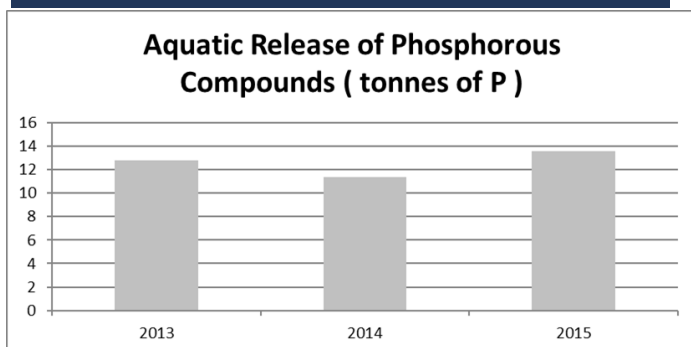
Sulphur Dioxide emissions showed a decrease of 40 % this year following an increase of 23 % last year. While it has now reached a record low the changes in this parameter are influenced by a relatively small number of the respondents due to the move from oil to natural gas over the years. We will continue to monitor this trend in the coming years.

Chemical Oxygen Demand -29%



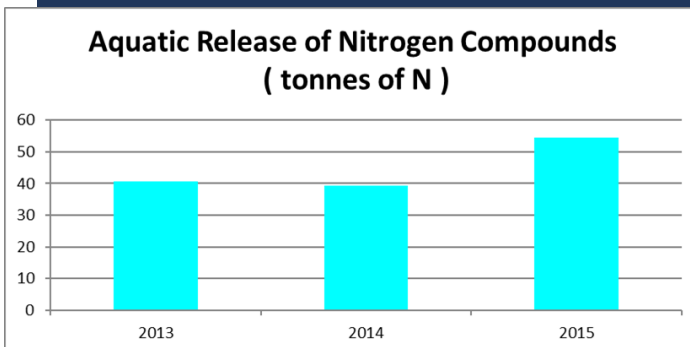
This parameter has shown another significant decrease of 29 % this year following a 36 % decrease reported last year. This demonstrates the importance of careful operation of waste water treatment plants on member sites and our ongoing commitment to protecting our valuable water resources.

Phosphate +6%



The phosphorous emissions from members' sites increased by 6 % over the three-year period following on from a 2 % increase reported last year. However, this must be considered in the context of a reduction of 46 % reported since 2009. We will continue to monitor this trend closely and our members will continue to actively manage the control of phosphorous in our waste water treatment plants.

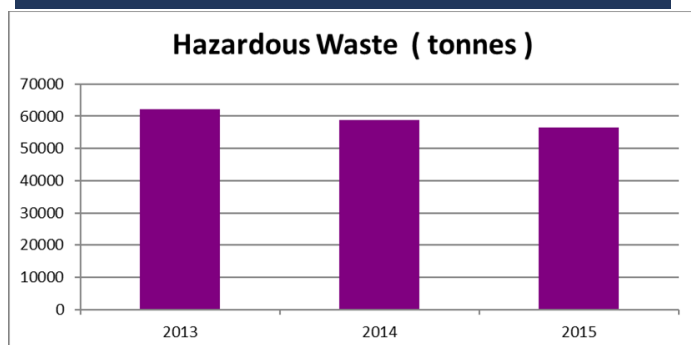
Nitrogen +34%



This parameter has displayed a significant increase this year following on from a much smaller increase last year. This followed eight consecutive years of reductions in aquatic release of nitrogen. The reversal of this trend is a concern for our member companies and we will continue our efforts to reduce the levels of aquatic nitrogen releases in the coming years to minimise the impact of nitrogen on receiving waters.

Performance Indicators of the Responsible Care Programme for 2016

Hazardous Waste -9%



The hazardous waste generated decreased by 9 % in this period following on from a 19.6 % increase last year. This parameter has shown decreases of 6.5 % and 14 % over the previous two reports and it is pleasing to see the downward trend re-established.

All our member companies continue to minimise the amount of hazard waste generated and ensure the correct handling and disposal of this type of waste.

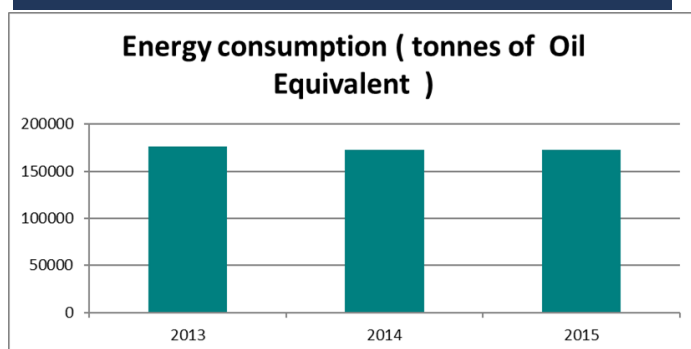
Non-Hazardous waste +6.7%



The amount of non- hazardous waste increased by 6.7 % following on from significant decreases of 18.5 % and 6.3 % reported over the last two periods. The year on year decrease in this parameter was 4.1 % thereby re-establishing the downward trend.

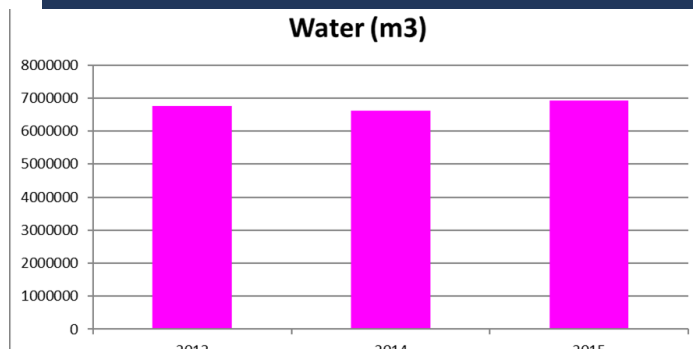
Our member companies recycled almost 32000 tonnes of non-hazardous was in 2015 almost 2.5 times the amount of waste disposed of. This indicates the high level of recycling in our member companies.

Energy Consumption -1.7%



The energy consumed by the member companies has decreased by 1.7 % over the last 3-year period following on from a decrease of 3.5% reported last year. The carbon dioxide associated with electricity decreased by a further 7.6% % over the same period. This demonstrates that our member is increasingly moving towards renewable energy to power their operations. Our member companies will continue to emphasise the importance of good energy management in the years ahead to increase overall energy efficiency and to further reduce the energy impact of our operations.

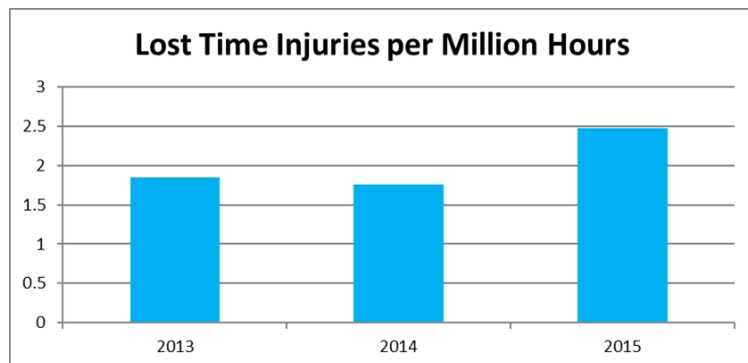
Water Consumption +2.4%



Water consumption has shown a small increase of ca. 2.4 % following on from a reduction of 7.6 % reported last year and a reduction of 7.2% the year before. The conservation of water remains a high priority for all member companies to ensure that we conserve this important resource.

Performance Indicators of the Responsible Care Programme for 2016

Lost Time Injury Rate +34%



The lost time injury rate has shown a marked increase this year following a 23 % reduction reported last year. This increase has brought us to similar levels as were achieved in 2012 and still substantially better than our European competitors. We will redouble our efforts to reverse this trend next year and return to the record low levels we achieved in 2014. We will continue to strive to provide a safe and healthy workplace for all of our employees to ensure that the 25 million hours we expect to work next year are as safe as possible.

“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)
Avara Shannon Pharmaceutical Services Ltd.

BASF Ireland Limited

BioMarin International Limited
Bristol Myers Squibb Cruiseraith

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
Guerbet (Mallinckrodt Medical Imaging)

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

Rottapharm Ireland

Servier Ireland Industries Limited

Sigma Aldrich Ireland Limited
Stiefel laboratories Ireland Limited
Swords Laboratories - BMS

Takeda Ireland Bray

Takeda Ireland Grangecastle
Temmler Ireland Limited
Teva Pharmaceuticals Ireland Limited



BioPharmaChem
Ireland gratefully
acknowledges 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.

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

Director

Second Sight Technical

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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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