

Responsible Care Report 2021







Chairperson's Forward

BioPharmaChem Ireland (BPCI) is pleased to present its 2021 annual Responsible Care report outlining the performance of the sector over the previous year. This is the first time we have reported annual data rather than aggregated data of the three previous years (2018- 2020).

During the three-year period, the numbers employed in the sector increased by ca. 9.1%. This is the eight consecutive year of increasing employee numbers in the industry.

The focus on environmental sustainability has risen up the corporate agenda within our sector and as such Ireland's Green credentials are a key element of BPCI's strategy - working with member companies, BPCI have initiated several cross sectoral working groups and initiatives to drive an increased focus nationally. The energy performance of the sector has continued to improve with small increase in energy consumption relative to a higher increase in production volume. This is driven by a combination of grid decarbonisation coupled with a move to greener electricity and more energy efficient operations.

Our sector has a strong reliance on its talented people. The safety of our employees continues to be the top priority for our member companies. The Lost Time Injury rate is still at a relatively low value of 1.71 Lost Time Injuries per million manhours worked. The BioPharmaChem sector needs to continue to lead the way and set the highest standards in everything we do, and so our member companies will ensure we stay laser focused on creating cultures of safety performance. BPCI has several EHS related Working Groups, with very strong engagement from member companies and is regarded as a leading voice in Ireland, and these groups will continue to enable Safety to remain as a priority in the sector.

Employee wellbeing has become a key element of creating an environment where the safety of the whole person is considered. Ibec is helping all companies in Ireland embrace corporate wellness through the KeepWell Mark programme. This programme focused on the key areas of the workplace wellbeing ranging from leadership, mental health and absence management to physical activity and healthy eating. BPCI continues to support this initiative within the sector and up to the end of 2021, we now have 10 BioPharmaChem Ireland member companies who have achieved the KeepWell Mark, with another 4 enrolled on the programme.

Responsible Care is acknowledged as the fundamental non-corporate Environmental, Health and Safety initiative. As such, as activity in the sector continues to grow, the green performance, the focus on the wellbeing & the safety of our people in our member companies continues to improve. This is a tangible demonstration of our commitment to sustainability and our members will drive continual improvement in all aspects of the performance of our sector in the years ahead.

Mr. Paul McCabe Chief Operating Officer at VLE Therapeutics, Chair, BioPharmaChem Ireland

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 and biopharmaceutical companies to operate safely, profitably and with due care for future generations.







In Ireland, each member of BioPharmaChem Ireland (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 most cases, by the Chief Executive Officer or Site Leader
- 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.

BPCI 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.

Key Performance Indicators (2020) for 2021 Responsible Care Report

Each year member companies report on their performance on several key indicators which are like their EPA annual reporting requirements. In previous years the figures reported were aggregated over a three-year period for all member companies, however this year, the data reported refers to 2020 data only. This brings the reporting in line with that forwarded to Cefic for inclusion in the European Responsible Care report.

This year we have again achieved a high level of participation with an 85% response rate. The web enabled online data collection system is now well established and has continued to facilitate significantly more efficient data collection and analysis.

We are pleased that the upward trend in the numbers employed in the member companies has continued with an increase of 9.1% over the year in question.

The energy performance of the sector has continued to improve with small increase in energy consumption compared to a higher increase in production volume. Water consumed by our member companies increased broadly in line with the increase in production volume.

The lost time injury rate (LTIR) is still at a relatively low value of 1.71 lost time Injuries per million manhours worked. While we challenge ourselves by using a 1 day lost time measure instead of the 3-day measure, this aspect of the overall sector performance will continue to provide a clear focus for our member companies in the year ahead. Although the number of lost time injury incidents has increased, we have seen a reduction in their severity by ca. 16% as measured by the number of days lost. Every day lost is one day too many and increasing efforts will be made by our members to continue this reduction.

In this period hazardous waste and non- hazardous waste both increased while non-hazardous waste for recycling continues a positive upward trend. The overall recycling rate for the industry now stands at ca. 84% of all non-hazardous waste produced. COD to waters increased over the reporting period and will be monitored closely over the next year. SO2 & NO2 values essentially remained the same and still represents a very small proportion of the total national emissions quantity. VOCs showed a big increase over the previous reporting period, but it is more than 30% below the value reported in 2018.

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 continue to encourage all our members to continue their efforts to consolidate the achievements made over recent years and to drive further continual improvement in all aspects of the performance of our sector in the years ahead.

Safety

The safety of our employees continues to be the top priority for our member companies.

Lost Time Injury Rate -10.1%

The one day lost time injury rate has decreased by 10.1% since 2019. The number of days lost due to lost time injuries has also decreased from 1131 to 945 over the same period. However, this could be a direct consequence of reduced staffing levels on site due to the Covid-19 pandemic. There is also a s is welcome reduction in the severity of lost time accidents. Each of these days represents one day too many for one of our employees so this will increase our determination to do everything we can to provide a safe and healthy workplace for all our employees in the years ahead

Number of process safety incident +2.9%

There were 142 process safety incidents recorded, an increase 4 over that reported in 2019 (+2.9%). As this is the newest parameter being reported, it is too early to determine if this increase is due to an increased level of risk, or greater awareness amongst reporting companies. A separate process safety working group has been established within BPCI to share experiences in this area.

Key Performance Indicators



Resources

Employees: + 6.2%

Between 2019 and 2020, the numbers employed in the sector increased by ca. 6.2%. This is the eight consecutive year of increasing employee numbers in the industry. This positive trend in employment numbers is a good indicator for the industry and illustrates that the biopharmachem sector continues to provide high quality employment opportunities for talented people across the country. We look forward to this strong trend continuing in the years ahead.

Production

As this has traditionally been reported in million metric tonnes year, this has increasingly become an unreliable figure to measure the performance of the Irish sector where some sites produce 10's of kilograms of material valued in the 100's of millions. Indeed, in recent years, some sites do not report their production figures. Therefore, this is the first year that this figure is not reported

Key Performance Indicators



Resources

Energy Consumption + 4.2%

The energy consumed by the member companies increased by a modest 4.2% over the last year. The total CO2 emissions (direct plus Electricity) decreased by 6.7% in the same period and is strongly influenced by our member companies moving towards renewable energy to power their operations as well as focussing on ongoing energy conservation activities.

We will continue to emphasise the importance of taking a structured approach to energy management in the years ahead to increase overall energy efficiency and to further reduce the energy and environmental impact of our operations.

Water Consumption +5.7%

Water consumption has shown a modest increase of ca. 5.7 % over the past year. This is broadly in line with the increase in production output over the same period.

The conservation of water will continue to be a focus for all member companies to do whatever we can to reduce pressure on this important resource.

Environmental performance

Hazardous Waste + 25.3%

The volume of hazardous waste generated has increased substantially again this period. This is the second period showing an increase in this. There is a strong pareto effect here with ca. 25% of the member companies accounting for nearly 85% of the hazardous waste produced by the sector. These member companies will put increased focus on controlling the generation of hazardous waste to stabilise or reverse this trend in the coming years.

Non- Hazardous Waste +72.7%

The amount of non- hazardous waste increased significantly this year by nearly 73%. Some of the increase in non-hazardous waste is linked to an increased usage of additional ppe because of the pandemic.

On a positive note, our member companies recycled nearly 46,100 tonnes of non-hazardous waste in 2020 representing a recycling rate of 84% demonstrating the strong commitment to waste recycling across our membership. We expect this figure to increase in the coming years.

Sulphur Dioxide -0.5%

Sulphur Dioxide emissions showed a very small decrease in the past year. 90% of all SO2 emissions is accounted for by one member company using oil as a source of thermal energy. The total emissions quantity for all members amounts to under 76 tonnes for the most recent year. This represents just 0.7% of the estimated national SO2 emissions quantity based on latest available EPA data. We will continue to monitor this trend in the coming years, but we can expect to see some degree of variability continue due to the relatively small number of oil users in the sector where cleaner natural gas is the predominant source of thermal energy.

Key Performance Indicators



Environmental performance

Nitrogen Dioxide 0%

Like the SO2 emissions, there has been no change in NO2 levels this year and they remain at a low level.

Volatile Organic Compounds +73.5%

Emissions of VOCs have increased by 73.5 % in the past year. While this is a big increase over the previous reporting period, it is more than 30% below the value reported in 2018. This parameter has tended to vary more than most others as it is correlated to the activities of several members companies working in the contract manufacturing space, where activity varies significantly from year to year. In all instances, each site that reported VOC data for 2020 operated well within their license limits. We will continue to monitor it closely to ensure these emissions remain under tight control.

Total CO2 emissions -6.7%

The total CO2 emissions (direct plus Electricity) decreased by 6.7% between 2019 and 2020. This is a combination of direct and indirect CO2 emissions.

The direct CO2 emissions have increased by nearly 18% over the past three years and we believe that this increase has been driven by some member companies increasing their use of onsite Combined Heat and Power plants as imported electricity fell by 0.4% while natural gas usage increased by ca. 5%.

The trend towards greener electricity is borne out by the 52% reduction in carbon dioxide associated with electricity consumption. This is driven by a combination of grid decarbonisation coupled with a move to greener electricity and more energy efficient operations.

As the Climate Action Plan is implemented over the next decade the industry will continue its drive towards both energy and carbon efficiency as this plan unfolds.

Key Performance Indicators



Key Performance Indicators



Chemical Oxygen Demand +26%

We have seen a significant increase in this parameter in the current period compared with a significant decrease significant decrease of ca. 31 % in the previous reporting period. The protection of water quality is an important facet of our environmental programmes and will continue to receive a high level of focus in the years ahead. All sites that reported an increase in COD in 2020 did so with figures that were well within their licence limits.

Phosphorous Compounds -18.2%

The phosphorous emissions value has dropped by 36.9 % following a 6.5 % decrease reported last year. We are particularly pleased that this parameter is on a downward trajectory.

Nitrogen Compounds -17.5%

This parameter had continued it reducing trend with a 17.5 % decrease this year following a 29 % reduction reported last year.

Participating Companies

- 1. Alexion Pharma International Trading
- 2. Alkermes Pharma Ireland Limited
- 3. Allergan
- 4. Amgen
- 5. Arran Chemical Co. Ltd.
- 6. Astellas Ireland Co Ltd.
- 7. Astellas Ireland (Kerry)
- 8. BASF
- 9. BioMarin Manufacturing Ireland
- 10. BMS Cruiserath
- 11. Cara Partners & Wallingston Co. Ltd.
- 12. Clarochem Ireland Ltd
- 13. Eli Lilly SA Irish Branch
- 14. GE Healthcare
- 15. Guerbet
- 16. Helsinn Birex Pharmaceuticals Ltd.
- 17. Henkel Ireland Ltd.
- 18. Hovione
- 19. Ipsen Manufacturing Ireland Ltd.
- 20. Janssen Biologics Ireland Ltd
- 21. Janssen Pharmaceutical Little Island
- 22. Jazz Pharmaceuticals Ireland Ltd.
- 23. LEO Pharma
- 24. Merck Carrigtwohill
- 25. MSD Brinny
- 26. MSD Ireland (Ballydine)
- 27. Mylan Pharmaceuticals
- 28. Novartis Ringaskiddy Limited
- 29. Pfizer Grange Castle
- 30. Pfizer Ireland pharmaceuticals (Ringaskiddy)
- 31. Pfizer Ireland Pharmaceuticals Newbridge
- 32. Recordati
- 33. Sanofi
- 34. Sigma Aldrich Ireland Itd
- 35. SK Biotek
- 36. Takeda Ireland Ltd. (Bray)
- 37. Takeda Grange Castle
- 38. Thermo Fisher Scientific Cork
- 39. Upjohn Manufacturing Ireland
- 40. Zoetis





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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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.

