BioPharmaChem Ireland

Responsible Care Report 2023

Our commitment to sustainability

biopharmachem Ireland
Ibec

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

BioPharmaChem Ireland

The transition to carbon neutral is critical for our industry, and the patients we serve at home and around the world.

We have a proven track record of innovation in bringing new products to patients and to drive competitiveness and we are leveraging this to lead the way in becoming greener.

Brian Killen, Transformation Lead,
MSD Manufacturing Division, Chair,
BioPharmaChem Ireland

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Foreword

BioPharmaChem Ireland (BPCI) is pleased to present its 2023 annual Responsible Care report outlining the performance of the sector over the previous three years (2020-2022).

Being a Responsible Business starts with managing our business with ethics and integrity, guided by our purpose and values, extending responsibility throughout the value chain.

It entails creating customer value while actively considering people, ethics, fairness, and environmental impacts, ultimately aiming for profitability.

Responsible Care is our commitment to sustainability, and it aims to continuously improve the biopharmaceutical and chemical industry's safety and sustainability performance in the products we manufacture and the communities in which we operate.

The BioPharmaChem industry is at the heart of Ireland's manufacturing sectors. The sector employs 45,000 people directly and is responsible for €116bn in exports annually. The sector is making a global impact. Ireland is the world's third-largest exporter of pharmaceuticals, underscored by its strong reputation for operational and innovational excellence, with an exemplary compliance record.

We are pleased to share that the efforts of members, as outlined in this report, which strongly support the objectives of the 2023-2027 BioPharmaChem Ireland strategy document 'Make Ireland the Global Leader in Sustainable Biopharmaceutical and Chemical Manufacturing'. One of the key challenges facing our industry over the next 10 years is the transition to a carbon-neutral society. The European climate law commits Europe to achieve climate neutrality by 2050, with a 55% reduction in net greenhouse gas emissions by 2030. The CSRD, effective in 2023, mandates larger companies to report

ESG activities using EFRAG-defined metrics, promoting transparency and accountability.

The results outlined in this report build on the advancements initiated by our members in the late 1990s, leading to the achievement of our goal.

A focus on energy and water conservation continues to be a major cornerstone of our members' sustainability strategies. The trends show that performance has continued to improve with energy consumption and water conservation both down a half of a percent against nearly a 50% increase in production. Recycling waste continues to be top of mind, with an overall recycling rate for the industry at ca. 72% for non-hazardous waste. While waste has increased slightly, this is attributed to construction work required for plant expansions, of which there have been many over the past three years.

It is clear that companies are adopting cleaner technologies, energy-efficient practices, and seeking sustainable alternatives, with many fostering innovation and operational efficiency to reduce cost. Our case studies give a snapshot of some of the great work being undertaken by transitioning to greener options. While progress has been made, there is much more we need to do as a sector, to make progress towards sectoral targets.

As the activity in the sector continues to grow, green performance, and the focus on the wellbeing and safety of our people in our member companies, continues to improve. Our members will constantly work to enhance every aspect of our sector's performance.

We would like to thank our members for continuing to support this initiative by providing data year-on-year. Thank you to the companies that supplied case studies covering different aspects of environmental sustainability, from developing future leaders to water and energy conservation. Thank you to our independent and external consultants for supporting this work, Mr Liam Tolton, Second Sight Technical.

Sinead Keogh, Director,
BioPharmaChem Ireland
Head of Sectors, Ibec

Brian Killen, Chair,
BioPharmaChem Ireland
Transformation Lead,
MSD Manufacturing Division

As part of Ibec, we will continue to advocate with relevant national and EU stakeholders on behalf of our members to shape a fit-for- purpose landscape, which supports the green transition.

Sinead Keogh, Director
BioPharmaChem Ireland

BioPharmaChem Ireland

Responsible Care insights

Responsible Care insights

Each year, member companies report on their performance on several key indicators which are similar to their EPA annual reporting requirements.

We are pleased to report that employment in our member companies has continued to rise, with a notable increase of 12.6% over the last three years. When set against the increases in production volume of 48.2% over the same time frame, this is a testament to the productivity of those working in this sector.

On energy the sector has continued to improve with a slight decrease in energy consumption of -0.4%, again against a backdrop of a significantly higher increase in production volume.

On air emissions, levels of carbon dioxide associated with energy consumption have remained relatively flat. This is driven by a combination of grid decarbonisation coupled with a move to greener electricity and more energy-efficient operations in the context of significantly increased production volumes.

Sulphur dioxide (SO2) values again decreased significantly, and now represent an even smaller proportion of the total national SO2 emissions quantity.

Volatile Organic Compounds (VOCs) have seen a significant rise compared to the last reporting period. This highlights an area where a small number of our member companies will need to focus more effort in the coming years.

On discharges to water, Chemical Oxidation Demand (COD) to waters showed a significant decrease of 91% and COD to Local Authority treatment plants showed a 20% decrease. Phosphorus and nitrogen showed relatively modest increases when compared to the scale of the production increases reported.

In this period, hazardous waste and non-hazardous waste both increased, while non-hazardous waste for recycling continues at a high level with an overall recycling rate for the industry now standing at ca. 72% of all non-hazardous waste produced.

Consequently, we are pleased to report that the one-day lost time injury rate (LTIR) has now reached a relatively low value of 1.34 lost time injuries per million hours worked. While we challenge ourselves by using a one-day lost time measure instead of the national three-day standard measure, this aspect of the overall sector performance will continue to provide a clear focus for our member companies in the year ahead.

Responsible Care is acknowledged as the fundamental non-corporate Environmental, Health and Safety initiative. All manufacturing companies, that are BPCI members, fall under the remit of Responsible Care and the vast majority of the reporting companies here are licensed by the Environmental Protection Agency (EPA).

BPCI steering groups work through the principles of Responsible Care to support its members in meeting their environmental, social and governance (ESG) objectives.

"The figures reported look at aggregated trends over a three-year period for all member companies. The web-enabled online data collection system is now well established and has continued to facilitate efficient data collection and analysis."

Michael Gillen,
EHS Expert, BPCI

Michael Gillen
EHS Expert, BPCI

What is Responsible Care?

Responsible Care is our commitment to sustainability: the global chemical industry's unique initiative to improve its EHS performance.

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

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 in implementing the commitment.
- The progressive development of indicators against which improvements in performance can be measured.
- An ongoing process of communication on health, safety and environment matters with interested parties both inside and outside the industry.
- Provision of forums in which companies can share views and exchange experiences on the implementation of the commitment.
- Adoption of a title and a logo which clearly identifies 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 (ICCA) manages Responsible Care at a global level.

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

Impact of BioPharmaChem in Ireland

90+
pharmaceutical companies operate in Ireland

45,000
people directly employed with the same number indirectly employed, covering both manufacturing and services

€116bn+
annual exports

50
FDA-approved pharma and biopharma plants

€10bn+
in investment announced

No. 3
exporter of complex pharmaceutical goods and medicines in Europe

No. 3
exporter of antisera and immunological products in Europe

No. 2
exporter of vaccines in Europe

"Ireland is the world's third largest exporter of pharmaceuticals, according to the UN International Trade Statistics database. The sector continues to evolve, expanding its capabilities to include innovation, digitalisation and next-generation technologies."

Sinead Keogh,
Director, BPCI

BioPharmaChem Ireland

Key Performance Indicators* of the Responsible Care programme for 2023

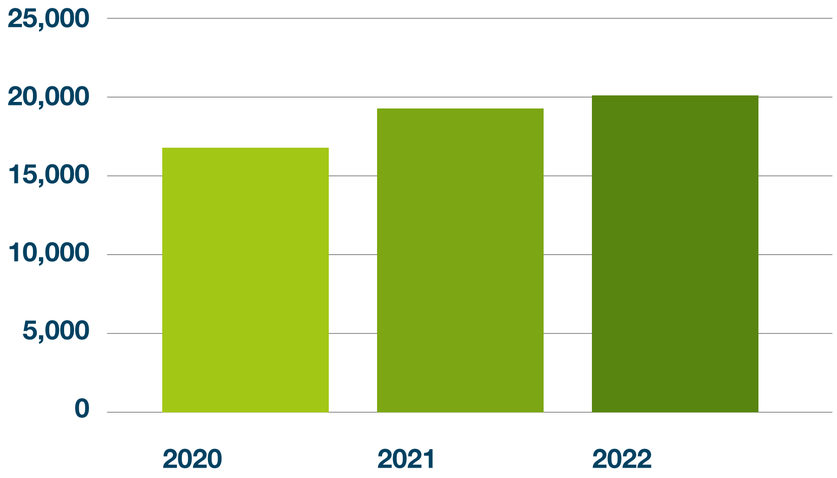
* Note: for figures from a company to be included in that year's data, the company must have submitted at least three years' worth of data up to and including the year in question. This 'smoothing' of data, while conservative, is done to remove noise from the data set. This allows important trends and patterns to more clearly stand out.

Economic Factors

Employees: +12.6 %

During the three-year period, the numbers employed in the sector increased by ca. 12.6%. This is the tenth consecutive year of increasing employee numbers in our member companies. It's not surprising given the scale of expansion in the sector over the last number of years. 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 to increase in the years ahead, with over 10,000 jobs forecast over the next five years.

Number of employees



Employment numbers in participating BPCI member companies (43 reporting sites in 2022). The headline KPI is based on data where manufacturing sites reported for three consecutive years from 2020-2022 inclusive.

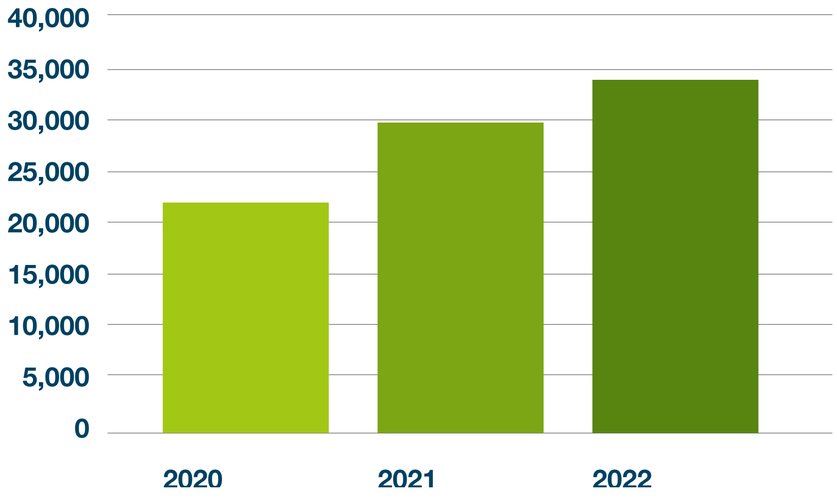
Production: +48.2%

The production output from the industry has shown another very strong increase of 48.2% in 2022 reported over the three-year period.

This trend continues to demonstrate the strong productivity performance of the industry year-on-year and illustrates the commitment of the industry and its employees and stakeholders to continual improvement in overall efficiency.

This parameter does vary somewhat, as not all member companies manufacture multi-tonnage products with some member sites counting their output in the high kilograms range, whereas others manufacture hundreds of tonnes of product. Nonetheless, it is representative of the strong growth across the sector.

Production (tonnes)



Production output in participating BPCI member companies (43 sites in 2022). The headline KPI is based on data where manufacturing sites reported for three consecutive years from 2020-2022 inclusive.

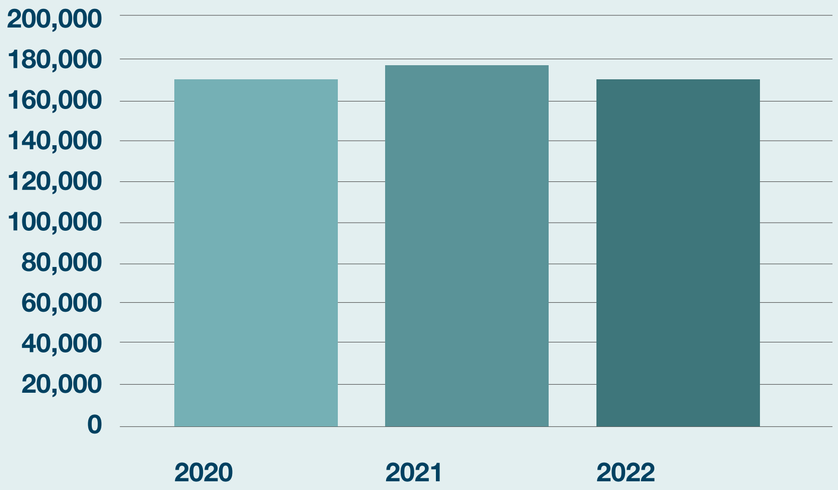
Energy and water

Energy consumption: -0.4%

The energy consumed by the member companies was reduced by ca. 0.4% over the last three-year period. The carbon dioxide associated with electricity remained relatively flat, as did the carbon dioxide produced from fuels consumed on member sites. Overall, the energy-efficiency performance is very positive for our member sites considering the significant increase in production output over the reporting period.

We will continue to emphasise the importance of taking a structured approach to energy management in the years ahead to increase overall energy-efficiency. As the goal of reducing absolute carbon emissions aligns more closely with national efforts, we will keep striving to minimise the carbon footprint from our energy use.

Energy Consumption (tonnes of Oil equivalent)

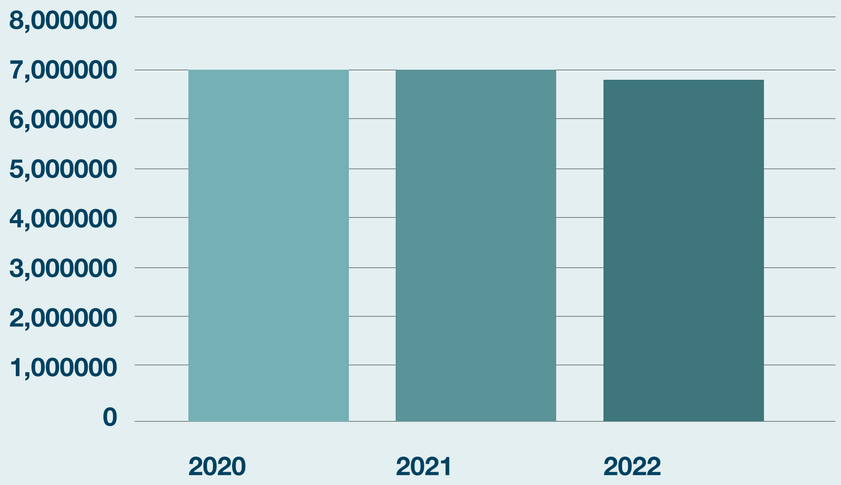


Energy consumption in participating BPCI member companies over the past 3 years

Water consumption: -1.2%

Water is the key solvent for the manufacture of biologics and is widely used in all other areas of the sector, to generate steam, as a coolant, and so forth. Water consumption has decreased by ca. 1.2%. This is an excellent performance taken in the context of significant increases in production output. The management and conservation of water will continue to be a focus for all member companies to make our contribution to conserving this important resource.

Total Water Consumption (m^3)



Water consumption in participating BPCI member companies over the past 3 years

Air emissions

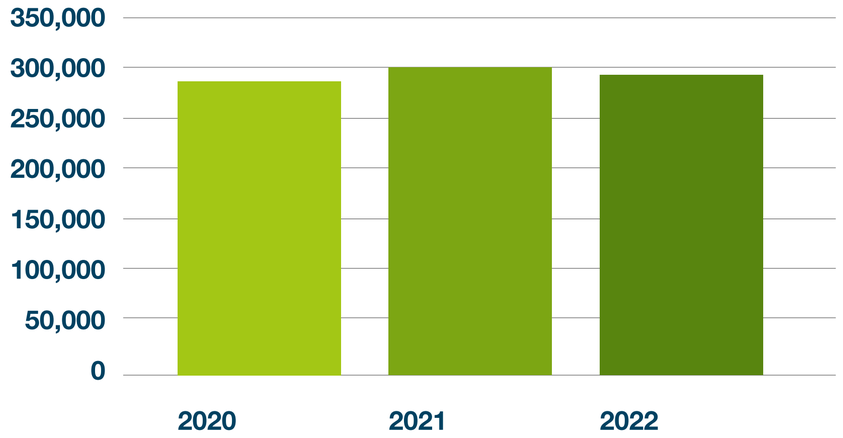
Carbon Dioxide: +1.1%

The three-year trend in CO2 emissions has only shown a very small increase of ca. 1.1%. This is a good performance when considered in the context of increased production volumes. The total Carbon Dioxide associated with all energy consumption including electricity would have amounted to ca. 514,000 tonnes in 2022. However, as a considerable portion of our membership chose to use carbon-neutral electricity as part of their energy procurement, the effect was to reduce the total energy-related carbon impact to ca. 380,000 tonnes. This approach resulted in a reduction of ca.135,000 tonnes of Carbon Dioxide from the energy-related impact of our operations.

Our member companies continue to review options to decarbonise their operations as much as reasonably practicable. A significant number of the larger member sites are members of the EPA Emissions Trading regime and very close attention is paid to Carbon Dioxide emissions from fuels consumed on-site.

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. The industry will continue to monitor technology developments which may provide more practical ways to decarbonise heat, especially in the higher temperature ranges.

CO2 Emissions (tonnes CO2)



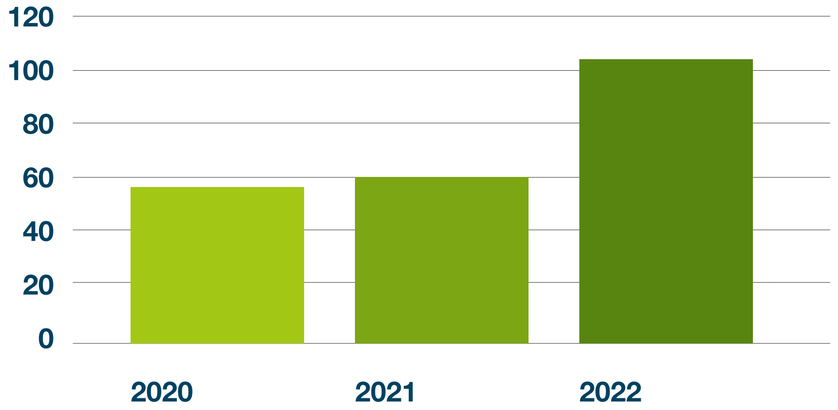
Carbon Dioxide emissions in participating BPCI member companies (43 sites). The headline KPI is based on data where manufacturing sites reported for three consecutive years from 2020-2022 inclusive.

Volatile Organic Compounds: +82 %

Volatile Organic Compounds [VOCs] arise from the use of organic solvents, which are used in the manufacture of all small molecule medicines.

Emissions of VOCs have increased by ca. 82%, again with some double-digit increases and decreases noted over recent reporting periods. This issue affects a smaller portion of our members, with just a few contributing the majority of these emissions. While there appear to be significant increases in emissions, in all instances they are well below the threshold set in the individual sites IED licence. While this parameter has tended to vary more than most others, we will continue to monitor it closely to ensure these emissions remain under tight control and are maintained within licensed limits.

Volatile Organic Compounds (tonnes)



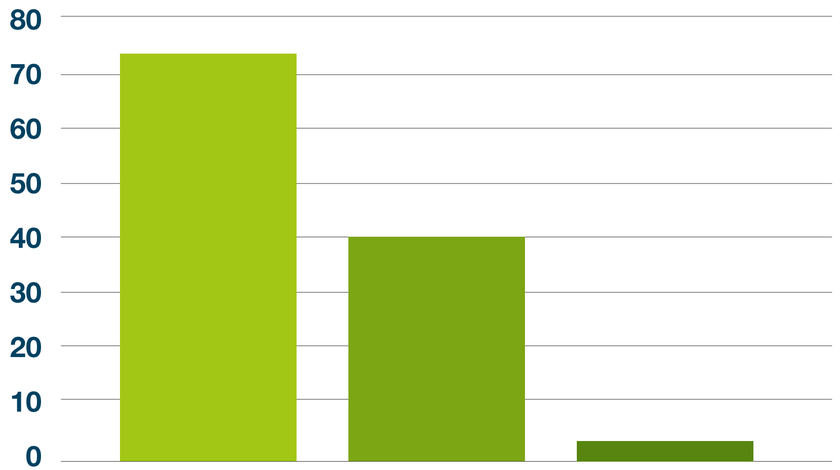
Volatile Organic Compound emissions in participating BPCI member companies. Due to the small number of companies responsible for VOC emissions, this number can vary substantially year-on-year.

Sulphur Dioxide: -94%

Sulphur Dioxide is a by-product of the combustion of heavy fuel oil. As sites move towards greener forms of energy, this will continue to fall. Sulphur Dioxide emissions showed a significant decrease of ca. 94% in the three-year period with most of this taking place in 2021.

One member site has converted from oil-based fuel to lower sulphur alternatives with the corresponding decrease in the overall sector emissions of sulphur dioxide being seen here for the full year. The total quantity emitted in 2022 was just 4.6 tonnes. This represents less than 0.05% of the estimated national SO2 emissions quantity based on the latest available EPA data. We are expecting this trend to stabilise at its new lower level in the coming years.

Sulphur Dioxide: -94%



Sulphur dioxide emissions in participating BPCI member companies (43 sites) over the past three years.

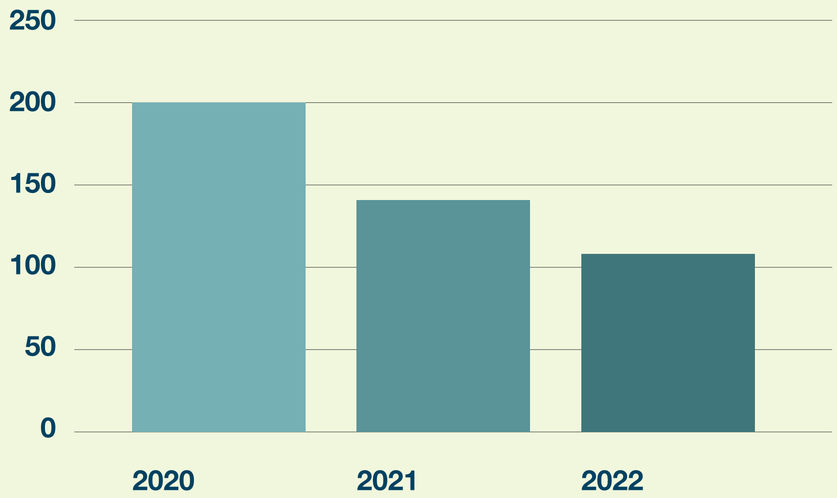
Water discharges

Chemical Oxygen Demand to waters: -91%

Chemical Oxygen Demand (COD) analysis is used as an indirect measure of pollutants (organics) in a water sample. It is an important parameter in water quality analysis, helping to reduce risk to humans and the environment. COD is an excellent way of monitoring the efficiency of water treatment plants.

This parameter has shown a significant decrease in 2022 following some increases in previous reporting periods. This is welcome news for our sector, where we consider the protection of water quality as an important facet of our environmental programmes. This aspect of our performance will continue to receive a high level of focus in the years ahead.

Chemical Oxygen Demand to waters (O2 tonnes)

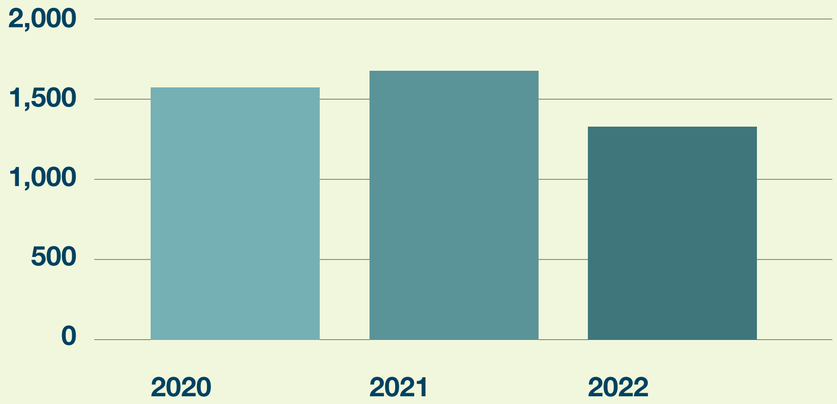


Chemical Oxygen Demand to waters in participating BPCI member companies (12 sites)

Chemical Oxygen Demand to Local Authority sewers: -20%

Similar for COD direct to waters, this parameter – COD to Local Authority sewers (after treatment on site) - has also shown a significant decrease in 2023.

Chemical Oxygen Demand to Local Authority treatment (O2 tonnes)

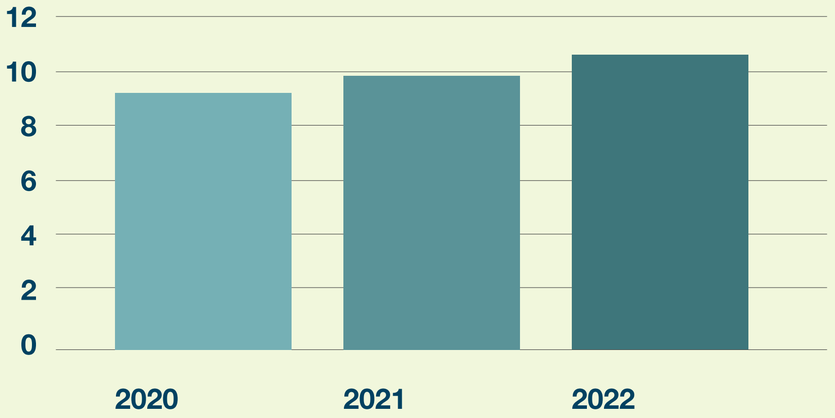


Chemical Oxygen Demand to sewers in participating BPCI member companies (19 sites)

Phosphorus: +15.6%

The phosphorus emissions (aquatic release of phosphorus compounds) value has increased somewhat in the most recent three-year period following decreases reported over the last two years. An increased level of production is likely the reason for this increase, but nonetheless, we will continue to monitor it as an important indicator of water quality. The main sources of phosphates in the biopharmaceutical sector included detergents and buffers.

Aquatic release of Phosphorus Compounds (tonnes of P)

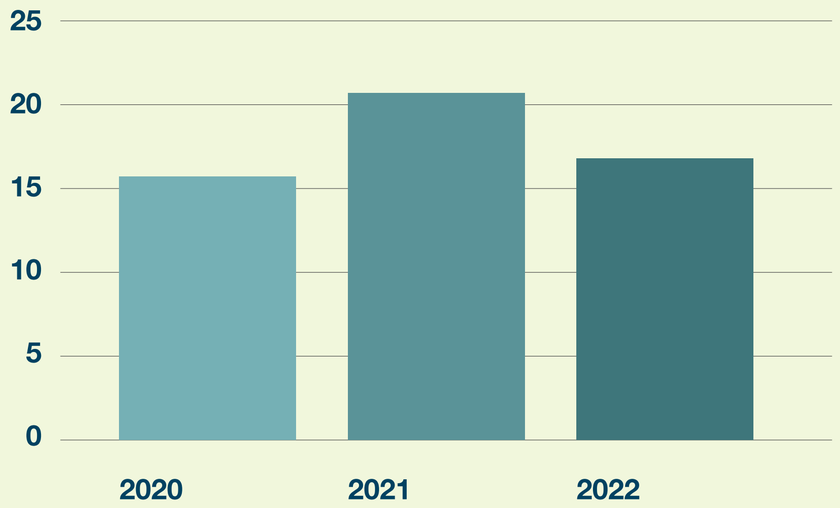


Phosphorus emissions in participating BPCI member companies.

Nitrogen: +14.6%

Similar to phosphorus, the nitrogen parameter [aquatic release of nitrogen compounds] has increased by a comparable percentage, while the three-year trend is slightly increased. We will continue to monitor this parameter as it is an important indicator of overall waste water quality.

Aquatic release of Nitrogen Compounds (tonnes of N)



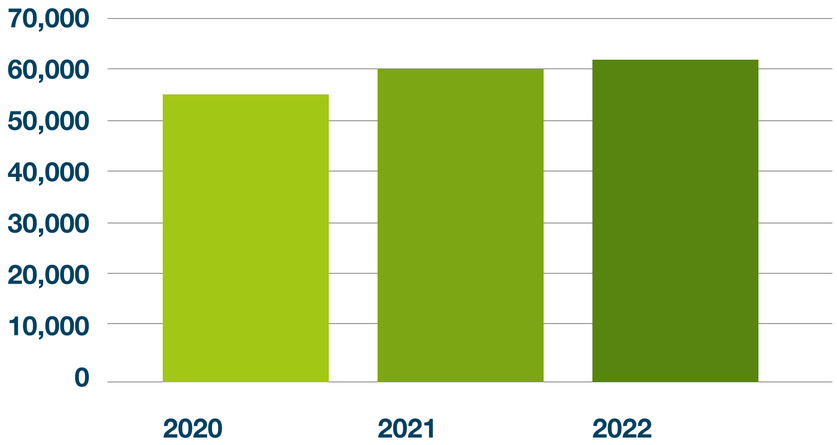
Nitrogen emissions in participating BPCI member companies (43 sites) over the past 3 years is +14.6%

Waste disposal

Hazardous Waste: +12.6%

The volume of hazardous waste generated has increased by ca. 12.6% over the three-year period. The increase in hazardous waste was driven to some extent by the increased levels of production. But the waste quantity generated per unit of production has shown a significant decrease. As a sector, we are acutely aware of our responsibilities to minimise the quantity of waste generated in our operations and to manage the residual waste to the highest environmental standards in full compliance with our licence conditions.

Hazardous Waste for Disposal (tonnes)

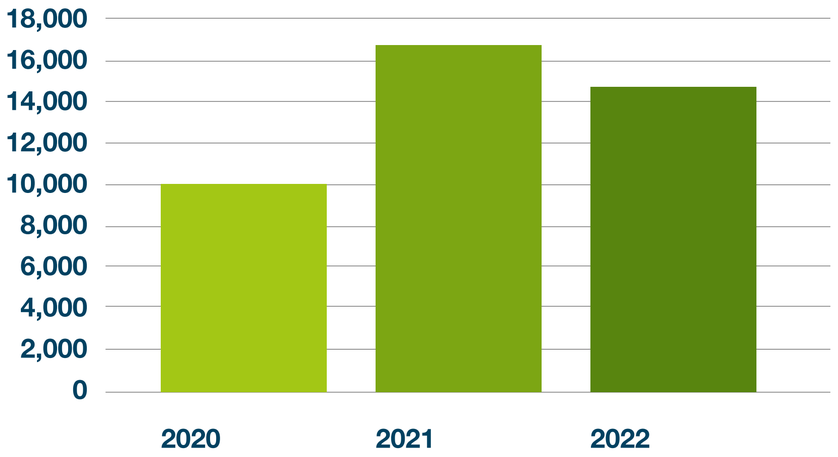


Hazardous waste generated in participating BPCI member companies.

Non-Hazardous Waste: +50%

The amount of non-hazardous waste increased this year by ca. 50% over the three-year reporting period. These member companies will continue to put increased focus on controlling the generation of non-hazardous waste in an effort to continue to reverse this trend in the coming years. In some member companies, non-hazardous waste arises due to the demolition of older facilities to make way for new investment projects on our member sites.

Non-Hazardous Waste for Disposal (tonnes)



Non-hazardous waste generated in participating BPCI member companies over the past three years

Safety

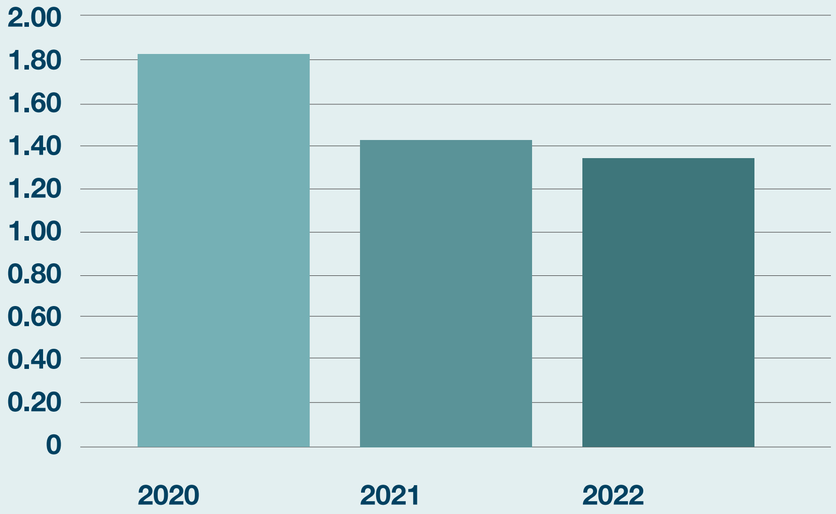
Lost Time Injury Rate: -26.7%

The safety of our employees continues to be the top priority for our member companies. The one-day lost time injury rate has reduced by ca. 26.7% to 1.34.

Of the companies reporting, the total number of lost time injuries again remains relatively flat at 51. This is a very welcome improvement in safety-related performance. The total number of days lost due to lost time injuries increased to 1,624 in 2022, indicating that while the number of lost time injuries has remained relatively flat, the severity of some of these injuries appears to be increasing. Each of these days represents one day too many for one of our employees, so this will again increase our determination to do everything we can to continue to provide a safe and healthy workplace for all our employees in the years ahead.

While these numbers are always a cause for concern, they are based on a one day lost time measurement, instead of the more usual national measure which is based on three days. While the absolute value is significantly less than other industries, this will not distract us from doing our very best to eliminate all such incidents on our sites.

Lost time injuries frequency rate > 1 day off per million hours worked



Lost Time Injury Rate in participating BPCI member companies over the past three years.

BioPharmaChem Ireland

What we need from policymakers

Accelerate the transition to carbon neutrality by scaling up and expanding industry supports

Corporate sustainability has taken on new meaning and importance in recent years. What was once primarily an environmental concern, now encompasses a wide range of environmental, social and governance (ESG) risks and opportunities. This imperative naturally favours businesses that champion the interests of all stakeholders, and that have a proactive approach to climate action, improved air and water quality, the circular economy transition, and biodiversity (including the marine environment). Government policy must be tailored to ensure firms meet their sustainability ambitions in a timely and cost-effective way.

We welcome the Government's investment ambition set out in Budget 2024, particularly the establishment of the National Infrastructure Fund which has the potential to enhance critical infrastructure delivery over the coming decade. Ireland's efforts to build essential infrastructure and meet increasing demand have been hindered by expensive and complex planning procedures, ineffective spatial planning, and high development costs. In the short to medium term, affordable energy remains a primary concern for businesses. Ireland must develop a robust long-term energy transition plan to avoid a repeat of the recent electricity supply challenges and ensure Ireland transitions to carbon neutrality in a secure and cost-effective way.

Recommendations to Government:

- Strengthen financial and advisory supports for Irish firms developing sustainability strategies in line with industry best practices and legislative requirements.
- Accelerate the transition to carbon neutrality by scaling up and expanding industry supports for renewables and energy-efficiency. Provide new financial supports and tax credit incentives to encourage firms to embed eco-design principles when innovating.
- Streamline and adequately resource the regulatory, planning and consent regime to enable the delivery of world-class regulatory, transport and utilities infrastructure.
- Ensure that the EU energy market reform proposals currently being developed by the European Commission take sufficient account of the cross-border nature of the all-island Single Energy Market. There will also be a continuing need to support Irish firms whose viability remains under threat due to energy costs.

The Urban Wastewater Treatment Directive, as currently written, will not address all the pollutants as it only targets two sectors

We acknowledge the objective of the Urban Wastewater Treatment Directive (UWWTD) which is to protect the environment and human health from the potential adverse effects from micropollutants in urban wastewater effluent. BPCI is committed to playing our part in achieving the objectives of the UWWTD in a fair and equitable way. We recognise the important role played by Uisce Éireann and other State Agencies in the operation of wastewater treatment plants, which are an essential part of demographic concentrations in urban areas.

The Commission's impact assessment report indicates that pharmaceuticals and cosmetic products contribute to 92% of the toxic load that enters wastewater treatment. The basis for this assumption is not provided and cannot be verified or reproduced, by company experts. By singling out only two sectors (pharmaceuticals and cosmetics) the UWWTD proposal obliges these two sectors to pay for pollution caused by other sectors. While the biopharma sector is willing to pay its fair share, this approach will not incentivise the unnamed sectors to reduce micropollutants or produce greener products.

An essential first step requires the Commission to conduct an accurate impact assessment of the implementation of an Extended Producer Responsibility (EPR) scheme for quaternary treatment.

Recommendations to Government:

- A substance-based approach rather than a sector-specific products-based approach will deliver a water protection framework that is fit for purpose. This would facilitate a more proportionate, risk-based approach by providing comprehensive coverage, and ensuring correct polluter accountability. This approach could identify the correct polluters and thus make them liable proportionally to the risks in the water environment. It will also help allocate resources effectively, ensuring that efforts are directed toward managing the most critical risks and protecting human health and the environment.
- The proposed UWWTD needs to include hazardous pharmaceutical and cosmetic products alongside specific substances from all stakeholders that are considered to cause risks to human health or the aquatic environment, in particular priority substances, priority hazardous substances, or specific pollutants identified under the Water Framework Directive.
- The biopharma sector is willing to pay its fair share. Increasing the scope of the UWWTD from the two sectors that were specifically targeted by the Commission's impact assessment will result in a water protection framework that is fit for purpose.

Impact of Proposed PFAS Restriction on the BioPharmaChem sectors

Medicinal product manufacturing facilities are heavily dependent upon fluoropolymer components present in utilities, piping, equipment (process/utilities), and single use systems. While some alternatives exist, these materials are widely used to maintain safe working environments and enable the production of safe and effective medicines.

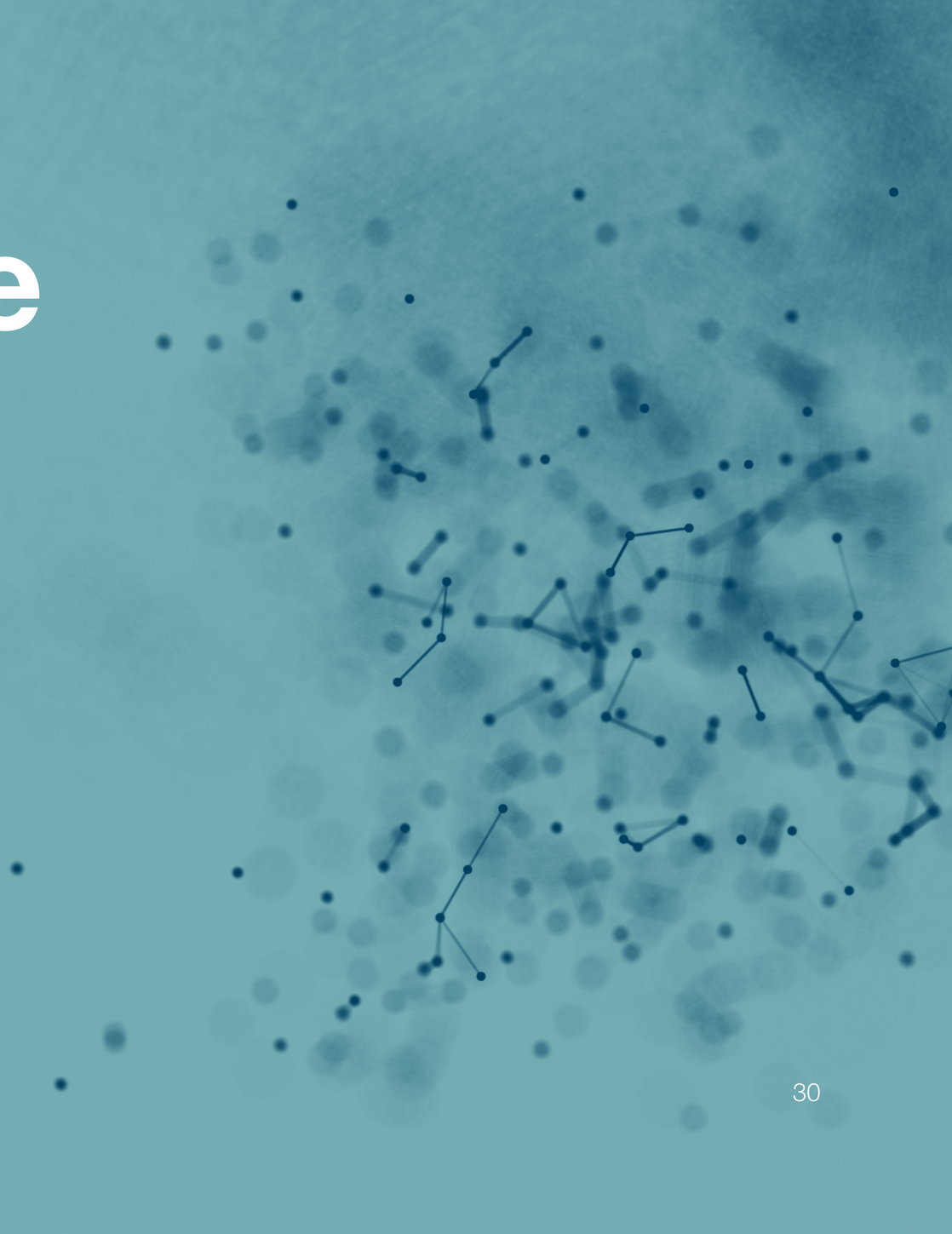
The manufacturing of medicines, whether biologic or synthetic in origin, requires materials that are chemical and corrosion resistant. An alternative that exhibits all the properties of the fluoropolymers used in medicinal product manufacturing facilities is not available at this time. If the proposed PFAS restriction prohibits the supply of these critical raw materials, medicinal manufacturing operations at Irish and EU facilities will cease and supplies will dry up once contingency stock levels are depleted. Therefore, a time unlimited derogation for the industrial use of fluoropolymers in medicinal product manufacturing facilities is a necessary mitigation measure to avoid medicine shortages.

Recommendations to Government:

- Pfas restriction as proposed will mean Ireland and Europe will lose the ability to produce and supply key medicines for patients globally. Ireland must use its voice at a European level to ensure that legislation achieves its objectives of promoting a cleaner environment, while not putting patients' lives at risk,. Notwithstanding, putting the EU at a competitive disadvantage vis-a-vie our competitors.

BioPharmaChem Ireland

Responsible Care case studies



Responsible Care case studies

Astellas – a journey towards sustainability

Eamonn Foley, Environmental and Health and Safety Manager at Astellas, talks about the company's pioneering approach to sustainability and their strides in energy self-sufficiency

Astellas Pharma, a global leader in pharmaceuticals, has a major presence in Ireland, with Plants in both Dublin and Kerry. Since it set up its facility in Killorglin, Co Kerry in 1992, the site's primary focus has been producing immunosuppressants and secondary packaging of biological products, employing over 400 staff.

Eamonn Foley, in his role as the Environmental and Health and Safety Manager, speaks about the site's sustainability initiatives.

Eamonn says, "The culture of sustainability at Astellas has been embedded since the early 2000s. The first initiative started when the Killorglin site implemented the environmental standard ISO 14001 in 2003 and continued through achieving ISO 50001 certification in 2011. It is not just about achieving the standards but also the continuous pursuit of excellence required to further promote change and ensure the sites long term sustainability goals"

Astellas' journey in Killorglin began with a vision to integrate sustainable practices into its core operations. This has led to significant achievements, such as a 98% reduction in CO2 emissions and a 70% reduction in the generation of non-hazardous waste since 2005.

The initiatives at Astellas not only benefit the environment, but also positively impact employees and the local community. Eamonn says, "One of industry's biggest challenges is to develop manufacturing processes that do not un-necessarily burden the environment and to develop sustainably within the local community. Astellas's proactive approach incorporates all of our key stakeholders our patient, our employees, our community and our company in the understanding of the need for the site to grow and expand but to do so

sustainably, reducing energy intensity and decoupling site activity from energy use, waste and carbon emissions.”

This consciousness extends to their latest projects and continuous improvement in waste management and energy efficiency.

Sustaining energy

Their journey toward this goal is marked by the adoption of innovative and sustainable energy solutions.

A key aspect of their sustainability strategy is their energy sources. “The biomass boiler is doing 98% of our thermal load, and all the biomass comes from within 50 kilometres of the plant and is harvested from FSC certified forestry”. This supports sustainable forestry and Astellas in partnership with Coillte saw the establishment of South Kerry Woodchip which provides 6 local jobs within the community.

An impact on the environment

As well as the Biomass boiler, Astellas also has a Wind Turbine and has embraced solar energy, installing photovoltaic panels on the LEED ARK building. These moves have provided a substantial portion of the site’s energy needs.

“120kWp of Solar PV is installed on the roof of the ARK building providing 10% of that buildings electrical requirement. The wind turbine does about 20% of the base load here in Kerry and we’re up to 65% of our on-site energy coming from renewable resources.

“We’ve had a 95% reduction in our CO2 emissions since 2016. We implemented waste handling changes that enabled up to 80% of solid hazard waste generated to be incinerated in Ireland, and we reduced the amount of water we use per million units packed, by 40%.”

They have implemented the Water Stewardship programme and have Green Labs Certification, which certifies the company’s dedication to minimising the negative environmental impact of laboratory work.

Eamonn says so many companies in Ireland are now looking at the green space and the journey towards sustainability. Astellas’ energy self-sufficiency showcases the feasibility and benefits of these sustainable practices in the industry.

“We’re trying to show Ireland as a green hub, and that it’s a good place to do business where you have the ability to reduce your carbon footprint.

“Astellas have signed up to science-based targets for CO2 reduction and are looking at different sources of energy, so we can handle new products efficiently. The only sustainable development is no development, and that’s never going to sustain us. It’s about how we can do more with less, keeping our outputs high but keeping our inputs as low as possible.”

Eamonn adds, “Our increased investment in renewable energy sources underscores our commitment to a sustainable future.”

“The culture of sustainability at Astellas has been embedded since the early 2000s. The first initiative started when the Killorglin site implemented the environmental standard ISO 14001 in 2003 and continued through achieving ISO 50001 certification in 2011.”

Eamonn Foley,
Environmental and Health and Safety Manager, Astellas

Creating future leaders in sustainability through school initiatives

Jennifer Murphy, Health, Safety and Environment Specialist at Sanofi, Waterford, speaks about how the organisation is supporting future generations through green initiatives at primary and secondary level

For over 20 years in Ireland, Sanofi has been developing and manufacturing healthcare solutions within areas including cardiovascular disease, diabetes, multiple sclerosis and vaccines. Along with improving patients' lives through medicine in breakthrough science, the organisation also realises a shared responsibility to create a healthier planet and make a positive impact on their people and local communities.

Jennifer Murphy says, "We're on a journey towards making our global operations carbon neutral by 2030 and to achieving net zero emissions by 2050. To help us achieve this, we have many various measures in place under our Planet Care programme, in areas including waste and energy. This requires commitment from everyone across our company.

"But we realise that while there's a culture across Sanofi to engage employees in environmental ambitions, it also needs to extend outside the company, in the community and at the school level – they are the future generation, after all."

Educational awareness

In 2021, under its global environmental sustainability programme 'Planet Mobilization', Sanofi called on employees across its global sites to submit ideas for new solutions to improve the environmental footprint. More than 500 employees from 63 sites in 29 countries pitched ideas.

“Sanofi Waterford was selected as one of the three top projects and we were awarded €3 million from Sanofi’s Planet Mobilization fund,” says Jennifer. “Our project was called ‘Waterford Loves Planet Not Plastic’, an education project to help reduce plastic waste.”

From this, Jennifer wanted to build on the idea and use their awarded funding to further develop educational awareness projects.

“Under our Planet Care strategy, we’ve developed two programmes. The first is called ‘It’s our Planet’, a primary school course aimed at third- and fourth-class students, which was developed in conjunction with Junior Achievement Ireland (JAI). “Our volunteers deliver the programme for an hour each week for over five weeks, providing fun and informative modules on topics including water conservation, biodiversity, animal habitats and waste.”

“We believe that as young students become more aware of these impacts, they will carry that message home and equally influence and encourage their families in a shared mission to protect our planet.”

Jennifer adds, “In 2023, we had 102 volunteers delivering 100 ‘It’s our Planet’ programmes across 14 counties in Ireland, reaching 2,091 students from 81 schools.

“The programme is available for delivery across Ireland from the JAI online portal and we have been awarded additional funding from Science Foundation Ireland to extend the reach to schools.”

The second programme, ‘Environmental Leadership’, is aimed at Transition Year students and it has been successfully piloted at Ardscoil na Mara School in Tramore in 2023.

“The aim of the programme is to not only teach the students about environmental topics, but they’re also developing leadership skills, as they share their knowledge by hosting workshops for other students in the school. It’s about upskilling our teenagers, who can potentially become environmental leaders in years to come.”

Jennifer adds, “14 TY students at the school then received an Environmental Leadership award at a celebration at our Sanofi site after completing the programme.”

Collective change

The programme is now in its second year of development. “There are plans to build on the success of this pilot programme and roll out training to more teachers and schools, with the support of the Waterford Education Support Centre and the Irish Schools Sustainability Network,” says Jennifer. “We’d also encourage other companies to support more schools to implement it.”

Jennifer feels that, as big drivers within the Irish industry, biopharmaceutical organisations have a huge part to play in empowering people to make a change. “The things you do on-site tend to work their way into people’s everyday lives.

"For example, we've recently introduced waste audits within our site. By making employees aware of simple things like how to segregate waste, then that's something they'll take home and implement in their own daily routine. It all comes back to the collective impact of doing things correctly. Together, we can make an environmental change."

"But we also realise that while there's a culture across Sanofi to engage employees in environmental ambitions, it also needs to extend outside the company, in the community and at the school level – they are the future generation, after all."

Jennifer Murphy,
Health, Safety and Environment Specialist,
Sanofi

Responsible Care case studies

Full steam ahead – a sustainable heating strategy for pharma manufacturing

How Takeda's innovations in energy management are driving the rapid transition towards a net zero future

"Reaching sustainability goals isn't just something Takeda aspires to do," says Michelle Farrell, EHS Head at Takeda Grange Castle. "Sustainability drives everything we do."

Biopharmaceutical company Takeda has a history of over 240 years of providing leading innovation in medicine. The organisation's presence in Ireland was established in 1997 Bray, Wicklow, and in 2004, they set up their first state-of-the-art active pharmaceutical ingredient (API) facility outside Japan, in Grange Castle, Dublin.

Since beginning commercial operations in Ireland, Takeda Ireland has grown in strength. At the Pharma Industry Awards 2023, Takeda Ireland won the award for Sustainability Initiative of the Year.

Road to net zero

With sustainability, Michelle says Takeda has three main priorities: "To minimise the environmental impact of the products we produce, to decarbonise our operations and supply chain, and to empower our employees and our contractors to go above and beyond to conserve the world's natural resources. This starts right from the top of the business, at the leadership level."

"All of our manufacturing locations have Climate Action Programmes (CAPS), focused on reducing the GHG emissions from our operations. Through CAPS, global EHS and Engineering leaders from across the world meet regularly to review where we are and what we can do better."

Initially, Takeda had a target to achieve net zero greenhouse gas emissions before 2040. Recently, that target has been accelerated to 2035. Along with adopting measures including using 100% renewable electricity to achieve this target, one such unique project on the Grange Castle site is the installation of a 2.2MW electric element boiler.

Gavin McGlone, Project Engineer at Takeda Grange Castle, says, “We have two 4.2 tonne-per-hour gas work boilers, which are used to produce steam for heating within production buildings and in the production process. However, this represented around 70% of our gas usage on-site.

“To maintain continuity of supply, we’ve installed a 2.2MW electric element boiler to eventually replace one of the gas boilers. The electric element boiler produces steam at 95% efficiency using electricity from Eirgrid’s green energy supply.

Gavin explains the electric boiler will be run in a demand side unit, in line with an external utility provider, allowing the site to contribute load generated by steam production to the grid, helping to balance it during periods of high wind.

“During periods of high winds, the electric boiler is remotely switched on, and load is added to the grid. This helps ensure electricity consumption matches electricity production at any moment within the grid, and that continuity of supply at 50Hz is maintained.” says Gavin.

Purpose

Gavin says that running an electric boiler can be costly, “During the commissioning phase, we ran the e-boiler for four days, which resulted in increased operating expenses. However, we believe this is the right thing to do and an important step in reducing our carbon emissions.”

“If we run it with the demand side unit, which is operating around 1,000-1,200 hours per year, this will reduce our carbon gas emissions by 15%.”

“We are also implementing other measures to help reduce the usage costs of the electric boiler. For example, the use of a heat pump on our heat transfer system.”

Gavin continues, “We use heat transfer to heat and cool the processes in our production plant, and there’s a lot of waste heat that we don’t capture. The heat pump is potentially going to capture that heat and reuse it for space heating.

“We expect that the emission savings we’re making will only increase over the next couple of years.”

As Takeda continues to prioritise sustainability, Gavin says “it’s crucial to explore innovative solutions that avoid fossil fuels, harness the forces of nature and maximise energy utilisation”.

Michelle adds, “Becoming greener is the right thing to do. We must do what we can, not just for ourselves, but for future generations.”

Michelle Farrell,
EHS Head, Takeda

Responsible Care case studies

Pioneering sustainable practices in biopharmaceuticals

Colt Schafer, Sustainability Officer and Karol Landziak, Energy Lead for, Janssen Sciences Ireland UC talk about the development of sustainable innovations, and charting a more sustainable future in the industry.

"Industry represents 17.8% of Ireland's final energy use and over 10% of Ireland's Greenhouse Gas Emissions[1]," says Karol Landziak, based at Johnson & Johnson's Janssen site in Ringaskiddy, Co Cork, "so, it's essential for industry to do their part."

Johnson & Johnson has not only been at the forefront of medical innovation, but it has also taken great strides in environmental sustainability. Our biologics site in Ireland, as Colt Schafer, the Sustainability Officer, says, "was established in 2005, manufacturing medicines in oncology and immunology. We have a workforce of about 1,300 people at the site."

Colt says Johnson & Johnson has a responsibility towards the environment and the communities they serve. The site's sustainability strategy is a key aspect of delivering on this responsibility.

Colt says, "Johnson & Johnson has been setting and achieving sustainability and carbon reduction goals for more than two decades, and our site tries to go above and beyond these goals. For example, part of Johnson & Johnson's climate goals is to have 100% renewable electricity in our operations by 2025, but our site achieved 100% renewable electricity in our operations by 2021 through our on-site wind turbine.

"The turbine produces on average about 30% of our site power with the remainder from a power purchase agreement with wind farms in Co Kerry and Clare."

[1] *National Energy Balance | Key Publications | SEAI*

Improving operations

The company's progress over the last decade has been significant. Karol Landziak highlights the adoption of the ISO 50001 standard. This is a standard that provides a practical way to improve energy use, through the development of an energy management system.

"We were one of the early adopters back in 2014. This led to a successful energy management system and numerous energy-saving projects like the wind turbine which was a major improvement to our energy strategy."

Over the years, the Company's sustainability strategy has evolved to address multiple aspects of sustainability. The Ringaskiddy site has focused on key areas for sustainable development including reducing their carbon footprints, optimising waste management, supporting site biodiversity, and improving water circularity.

One major practice has been the collection of grey water - rainwater harvested from the facility's roofs.

"We've always had a rain harvesting system and it was expanded in 2018. We had a major expansion to on-site so we installed rain harvesting systems on those new buildings too."

This has been a pioneering step in sustainable water use. The collected water is used on-site, reducing their dependence on municipal water supplies.

Success in sustainability

Addressing their challenges and successes, Karol notes the sites' decarbonisation strategy.

"We started with a heat mapping study which led to a projects roadmap to decarbonise our operations," says Karol. "This roadmap is categorised into three phases, focusing on energy efficiency, electrification of low-grade heat, and finally, decarbonising steam generation.

"The biggest challenge when it comes to electrification is the maximum import capacity from the grid, but we are in the process of increasing ours to enable implementation of projects. We are also looking to decarbonise our location-based Scope 2 emissions through further integration of renewable energy sources on site."

All these initiatives at Johnson & Johnson have not only had an impact on the environment, but also on employees at the site and the community surrounding it. Karol says, "What we're doing in this area sets us apart and helps us to attract talent, particularly young talent who are more conscious of these challenges.

"Ireland is ahead of the curve compared to other countries and it is considered to be a leader in the Johnson & Johnson network in energy efficiency, energy management, and now decarbonisation."

Looking ahead, Colt Schafer mentions how the site is continually exploring new ways to reduce its environmental impact, improve resource efficiency and contribute positively to communities.

Johnson & Johnson has even been recognised for this work, as a World Economic Forum designated Sustainability Lighthouse site and these efforts set a benchmark for the industry and position them as a leader in driving progress towards a more sustainable future.

“Ireland is ahead of the curve compared to other countries and it is considered to be a leader in the Johnson & Johnson network in energy efficiency, energy management, and now decarbonisation.”

Colt Schafer, Sustainability Officer
and Karol Landziak, Energy Lead
for Johnson & Johnson

Factory of the future – developing the largest state-of-the-art biomanufacturing facility in Ireland

How WuXi Biologics manufacturing facility in Dundalk is designed, built and operated under the greenest standards

WuXi Biologics' investment in Ireland has been a welcome addition to Ireland's growing number of next-generation biopharmaceutical companies. Not only has the site generated jobs locally, but their facility in Dundalk is one of the first and largest greenfield pharmaceutical projects by a top global CRDMO (contract research development manufacturing organisation) in Ireland.

WuXi Biologics leverages its technologies and expertise to provide customers with efficient and cost-effective biologics discovery, development and manufacturing solutions in a sustainable and responsible way.

Brendan McGrath, Ireland Site Head, VP of Manufacturing for WuXi Biologics, says, "Our Dundalk site was awarded the 'Facility of the Year' in the operations category for new facilities from the International Society for Pharmaceutical Engineering in 2023, which we were delighted to have won.

"It's one of the largest single-use bioreactor capacities of its kind globally. The plant uses 6x1K litre single-use bioreactors for perfusion and 12x4K litre single-use bioreactors for fed-batch processes instead of stainless-steel vessels and kilometres of pipework, which require extensive cleaning and sterilisation using water, steam, detergents and energy."

Single-use bioreactors are containers in which cells are grown to produce biological products. Brendan says, "Single-use bioreactors contain all the elements for cell growth within. Because it is a fully enclosed system, when we harvest the product from the single-use bag, we do not have to clean down the system. Instead, the bag is removed, processed through a dedicated waste stream and incinerated to produce energy in a process that uses less energy and avoids cross-contamination risk."

Brendan adds, “The single-use bioreactors are used to manufacture biologic drug substances on a round-the-clock basis and can be quickly adapted for different processes or scales. This reduces downtime between production runs and accelerates the overall production timeline. Along with reducing water and energy consumption, single-use bioreactors are more efficient in terms of productivity and pose lower safety risks.”

Environmental excellence

When setting up in Ireland, WuXi Biologics was conscious of its carbon and resource footprint. Its ambition was to create a state-of-the-art facility that excels in environmental leadership, with the goal to reduce 50% carbon intensity by 2030 and to achieve net-zero GHG emissions by 2050.

James Atherton, Utilities Lead for WuXi Biologics Ireland and Chair of its Sustainability Committee, says, “We continually assess risks and opportunities arising from the impacts of climate change. We optimise greenhouse gas (GHG) emissions and energy management systems, as well as implement environmentally friendly and low-carbon innovative technologies and processes.

“Energy usage is always our main focus. We use LED lights and motion control sensors, and maximise the use of glass to harness daylight, to reduce energy consumption.”

James continues, “The manufacturing process involves growing cells that require consistent food, heat and light with an uninterrupted electricity supply. Our electricity supply is 100% renewable sourced and the security building is carbon neutral with 100% energy supplied by on-site solar panels. We introduced hydrotreated vegetable oil (HVO) on-site for our emergency generator biofuel and rainwater harvesting system, with 1,943m3 of water usage reduced per year.”

In 2023, the Dundalk site achieved a total reduction of 6.5GWh of energy, compared to the previous year (4.8GWh of natural gas and 1.7GWh of electricity). “We also have zero waste to landfill, 100% hazardous waste is recovered, and 100% non-hazardous waste is recycled.”

Next-generation goals

In addition, the Dundalk site has developed several ESG initiatives, which Xiaoyu Xie, PR Lead for WuXi Biologics Ireland and member of their Sustainability Committee, says are crucial in establishing WuXi Biologics as a responsible company. “Such initiatives that integrate employee wellbeing and diversity are instrumental in building a resilient and agile workforce, prepared for future challenges.”

Xiaoyu adds, “Ireland is emerging as a leader in sustainable biopharmaceutical and chemical manufacturing. However, to maintain and enhance this leadership position, continued investment in innovative technologies, fostering a skilled workforce in sustainable practices, and strengthening regulatory frameworks for environmental protection are essential.”

“WuXi Biologics’ goals for the future focus on safe, responsible, and sustainable manufacturing, as we continue to integrate next-generation biomanufacturing technologies and clean-energy sources.”

“Ireland is emerging as a leader in sustainable biopharmaceutical and chemical manufacturing. However, to maintain and enhance this leadership position, continued investment in innovative technologies, fostering a skilled workforce in sustainable practices, and strengthening regulatory frameworks for environmental protection are essential.”

Xie Xiaoyu,
Corporate Communication
& Public Affairs, WuXi Biologics

BioPharmaChem Ireland

Ibec Academy ESG and corporate sustainability programme highlights

Ibec Academy ESG and corporate sustainability programme highlights

We offer a number of programmes including accredited development programmes with our strategic partner, Technological University Dublin.

We align with our policy team in Ibec and subject matter experts to ensure that our training courses are best in class.

We create an ongoing learning experience for our members and students with annual seminars and training sessions in the area of ESG/ Corporate Sustainability. We are introducing a new CPD Certificate in Environmental Sustainability in 2024 (4 days). We will also host a half-day seminar for our ESG alumni in October 2024. You can register your interest for related seminars and courses with elainem.bowers@ibec.ie

Ibec Academy ESG and corporate sustainability programme

CPD Certificate in Corporate Sustainability/ESG
4 days

This highly popular course meets the needs of those in the development and/or delivery of a corporate sustainability strategy and who need to develop their knowledge and understanding of corporate sustainability and ESG in theory and practice.

ESG Competent Boards for Senior Business Professionals
12 sessions online

Ibec Academy Global in partnership with Competent Boards is delighted to offer this unique programme for senior leaders. The ESG mindset leaders of today need to adapt, transform and pivot to a new global reality. Join online dialogues with renowned global leaders focusing on crucial ESG issues. Gain access to carefully curated reading lists, original case studies and thought-provoking questions to help you create value, enhance resilience, and establish good governance.

Foundations in Sustainability and ESG for Business
1 day

This workshop will equip participants with foundational knowledge on what sustainability means for business and how corporate sustainability/ESG strategies are developed and reported on, learning from best practice approaches and examples.

Accredited OSH Diploma, Level 7 NFQ
12 days

This programme focuses on applying current Occupational Safety and Health (OSH) legislation and guidance in the development of best practice in OSH management and identifying core skills in managing OSH within an organisation. It has been very useful for those who support the EHS/OSH Management system function on-site and continuous professional development.

Ibec

Climate Action: A toolkit for business

Ibec has launched ‘Climate Action: A toolkit for business’ in collaboration with Accenture. This comprehensive toolkit provides businesses with the information they need for their climate action journey and provides practical guidance on developing an enduring climate action strategy.

Through this Climate Action Toolkit, Ibec and Accenture share learnings, experience, and best practice, which can be used by executives to understand the business imperative, and more importantly, to develop a best practice approach to support businesses to deliver on carbon reduction.

It provides an overview of key concepts and developments in climate change science and regulation, while also setting out five steps businesses can take on carbon measurement and subsequent reduction roadmap. It also provides additional insights and guidance for four large sectors of the Irish economy.

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List of sites that submitted data to the 2023 Responsible Care Report

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

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Independent data collection and analysis process

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.

About

BioPharmaChem Ireland

BioPharmaChem Ireland represents the biopharma and chemical sectors. We influence, support and represent 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 Ireland as a leading location for the supply and development of pharmaceutical products.

Our Laboratory apprenticeship programmes allow companies an unrivalled opportunity to grow and develop their talent pipeline and drive business growth into the future. In addition, our BPCI Skillnet encourages companies with shared training needs to collaborate and achieve their training goals in a cost-effective manner.

BPCI steering groups work through the principles of Responsible Care to support its members in meeting their environmental, social and governance (ESG) objectives. Find out more here: www.biopharmachemireland.ie

Ibec

Ibec is Ireland's largest lobby and business representative group. Our purpose is to help build a better, sustainable future by influencing, supporting and delivering for business success. With over 300 employees, Ibec engages with key stakeholders in Ireland and internationally through our six regional offices and our Brussels office, along with an extensive international network in the UK and US.

Ibec positions are shaped by our diverse membership, which range from small to large, domestic to multinational and our 40 trade associations cover a wide range of industry sectors. Ibec members employ over 70% of the private sector workforce in Ireland. As well as lobbying, Ibec provides a wide range of professional services and management training to members on all aspects of human resource management, occupational health and safety, employee relations and employment law.

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