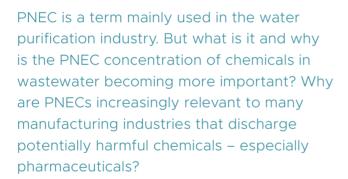


Ten things you should know about PNEC levels

Here's our 10-point guide to PNEC with some background to put it all into context.



Many pharmaceutical companies will already be working towards a risk-based EHS Policy for wastewater. This will probably specify which compounds need to be controlled and what their PNEC values should be.

So PNEC is often the internal target set by pharma companies exploring responsible management of water.

As an engineer, you may be given a PNEC target to achieve. But what does it mean and how should you deal with it?



PNEC stands for Predicted No Effect Concentration. (It's normally pronounced 'pea-neck'.)

It's the concentration of chemicals (often antibiotics and organics) which mark the limit below which no adverse effects in an ecosystem are measured.

By their very nature, PNEC levels are meant to be conservative and indicate the concentration at which the chemical or compound in question probably won't have a toxic effect. 'Probably' is the operative word here, as different testing regimes can result in varying PNEC values for any given compound.





2. Why do PNEC values vary?

At present there is no accredited world-wide standard for PNECs; just recommended levels of concentration from organisations such as:

- the AMR Industry Alliance (a group of CSR-oriented pharma companies working to set standards to reduce the problem of AMR worldwide.)
- the OSPAR Commission (the mechanism by which 15 Governments & the EU cooperate to protect the marine environment of the North-East Atlantic.)
- and the European Chemicals Agency under the REACH regulations. (The ECA works for the safe use of chemicals throughout the EU.)

3. Are PNEC values the same for each class?

It's possible to calculate a PNEC value for every potentially toxic compound. However, the safe concentrations vary greatly - between 70.5 and 0.00014 $\mu g/L.$

In OSPAR's Background Document they suggest that toxic substances for classification are subdivided into:

- 1. Metals
- 2. BTEX
- 3. Dispersed oil
- 4. PAHs
- 5. Phenol/alkylphenols
- 6. Organic acids

Some of these classes require a different method of treatment. And some are more challenging to remove from wastewater than others. This is where Arvia can help.

More on this later or contact us to find out how.

4. Why are PNEC levels so important when considering AMR?

Antimicrobial resistance (AMR) is increasing worldwide because of greater access to antibiotic drugs in developing countries. According to World Health Organization estimates, ten million deaths per year could be caused by AMR by 2050.

One industry group attempting to change this is the AMR Industry alliance, which brings together biotech, diagnostics, generics and research-based pharmaceutical companies, to drive and measure industry progress to curb antimicrobial resistance.

This is done through research into vaccines, innovative new antibiotics and dosage forms, educating patients and practitioners on appropriate use of antibiotics as well as ensuring manufacturing chains control the release of antibiotics into wastewater.



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5. Working to achieve suitable PNEC values in wastewater

As mentioned in (3) above, PNEC values are measured in parts per billion or trillion. To get down to those levels specialist water treatment is often required. Fortunately, the Arvia Nyex™ system can deliver just that and we have many case studies showing how compounds critical to the world-wide battle against AMR can be reduced to below measurable levels in wastewater.

Very few water treatment processes currently available to build-in or retrofit in production lines are capable of delivering these low levels; most of Arvia's competitor systems reply on hydroxyl OH* radicals indiscriminately attacking pollutants in the water. Once lower concentrations are achieved, the chances of the hydroxyl colliding with the pollutant are reduced, and thus they become inefficient when attempting to deliver equivalent 'below measurable levels' of concentration.

However, the Arvia Nyex-a system gets around this by adsorbing the pollutant onto the treatment media before electricity is passed through it, thus mineralising it, thereby achieving very low targets - in parts per billion - where required.

6. Why set PNEC levels now?

From an Environmental Health and Safety point of view, it's prudent to set PNEC levels now, putting in place a risk-based approach to wastewater management before regulations start to be brought into force.

Currently only India has draft legislation in progress to control PNECs in wastewater, but it's inevitable that other countries will follow suit.

In any case, setting PNEC levels sooner rather than later will ensure a benchmark for when considering new or revised manufacturing processes or wastewater recycling.

7. CSR and PNECs

Currently the CSR value of setting limits on chemicals in wastewater is debatable; the terms 'PNEC' or 'wastewater' don't feature anywhere in the Greenpeace website for example, so perhaps currently this is not a subject that creates a lot of public debate.

However the predicted death rates will ensure that eventually AMR will rise to prominence in the news agenda, meaning that organizations who already have a PNEC policy and limits established will be at an advantage.

Also, as we know, R&D cycles in pharma often take many years, so organizations will need to be several steps ahead of legislation to ensure new products do not contain chemicals that could lead to future issues with discharges.

So far, the member companies of the AMR Alliance have proved to be very responsible in leading the way on these important issues.

8. Should I be worried about PNEC levels?

Larger multi-nationals have already started setting PNEC limits on all chemicals and compounds identified in process wastewater to ensure they comply with future regulations and to ensure their Environmental Risk Assessments are up to date and relevant.

If your company hasn't yet started, it's likely that your EHS team will be considering it for the near future, possibly under the guidelines set by the European Chemicals Agency. For instance, the AMC Alliance has already published a list of chemical PNECs that would be suitable for a risk assessment.

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9. Is PNEC a standard?

A PNEC shouldn't be confused with a COD or even BOD rating; these older, out-of-favour methods of measurement only cover the total amount of potentially toxic compounds in wastewater, rather than the concentrations of the individual chemicals that make up the load.

PNEC will eventually become the standard so it's important to familiarize yourself with its implications now.

10. Achieving PNEC targets with Nyex™

As noted above, Arvia's tertiary water treatment systems are capable of removing many chemicals and compounds identified as contributing to AMR to below measurable levels. Our systems can also be retro-fitted in almost any plant and depending on the application and throughflow required, can be very space-efficient.

One of the many advantages of Arvia's Nyex™ reactors is that their treatment systems overcome the challenges experienced with traditional AOPs (advanced oxidation processes), providing a robust and effective solution for the removal of organic chemicals (chemical oxygen demand) as well as colour from wastewater. This is all done without creating any toxic waste, which in equivalent competing systems has to be regularly removed and then taken away to be incinerated.

Not only is our Nyex™ system more efficient than our competitors, it's also more environmentally friendly and from a CAPEX/OPEX point of view, very cost-effective in the long term. Our systems are really effective at removing harmful antibiotics and hormones - in fact, many different types of APIs - to very low levels, ensuring current and future PNEC targets are regularly achieved and sustained.

For more information or to speak to one of our chemical engineers who'll understand your organisation's unique wastewater issues.

Call us on +44 1928 378983 or email us at info@arviatechnology.com today.



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