

Mr Martin O'Reilly
Office of Environmental Enforcement
Environmental Protection Agency
Regional Inspectorate
Inniscarra
Co. Cork

24th January 2019

Dear Mr O'Reilly,

Under condition 1.4 of the current license, Eli Lilly wishes to inform the Agency of its intention to introduce one new step to an existing process for manufacture in a validation campaign. This step was previously produced at a contract manufacturing organization. The validation campaign will be run as a batch process during Q2 and Q3 of 2019.

This product is used for the treatment of breast cancer. The following should be noted with respect to the upcoming campaign:

- The validation campaign will be run in the IE08 facility which is equipped with environmental emission abatement systems.
- This process uses 2-chloro-5-chloromethyl-pyridine in THF Solution, 1-Ethylpiperazine, RuPhos, and Bis (benzonitrile) palladium (II) chloride that have not previously been used onsite. All necessary precautions have been put in place to manage these materials and waste streams will be incinerated onsite.
- All other solvents used for this process have previously been used onsite and liquid wastes from the process will be routed to the waste solvent storage tanks for onsite incineration.
- All solid waste generated by the process will be segregated at source and managed by the site waste contractor and treated appropriately.
- Gaseous emissions from all steps of the process will be routed to the site fume incinerator for treatment.
- We don't expect this process to have any adverse environmental impacts or to pose a challenge to any of our current license conditions.

If you need any further information or clarification on this process, please don't hesitate to contact me.

Yours sincerely,

Mary Hamilton

Environmental Compliance Representative