

Incorporating Uncertainty in Pharmaceutical Environmental Risk Assessments with Bayesian Networks



Background

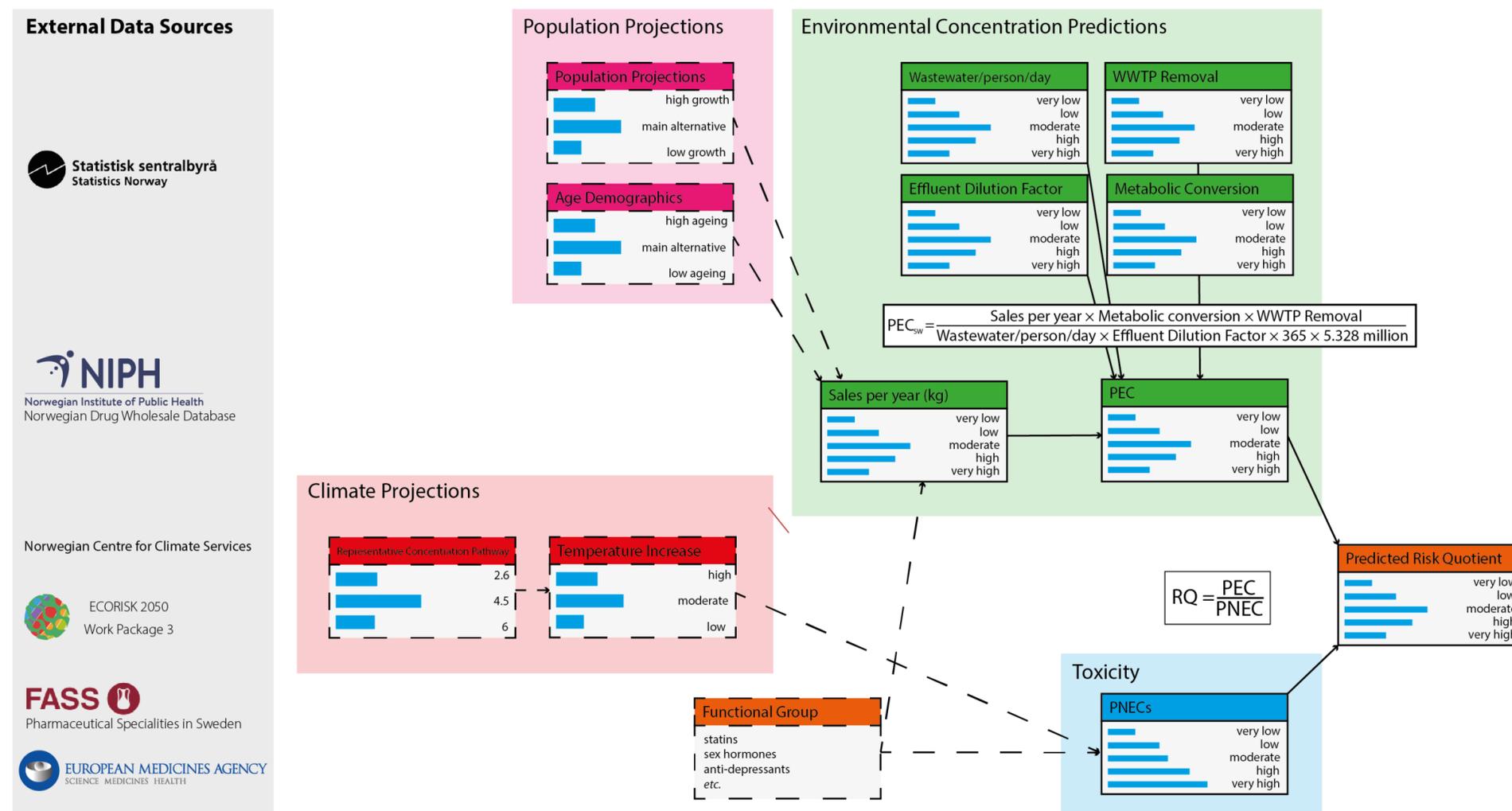
- Existing pharmaceutical environmental risk assessment in the EU compares Predicted Environmental Concentrations (PECs) based on with Predicted No-Effect Concentrations (PNECs) to predict risk, using a principle of maximising conservatism to account for uncertainty (EMA, 2006) (see [Presentation 5.19.03](#))
- Currently, PECs are calculated based on predicted market share and defined daily doses, rather than empirical data on use
- Norwegian drug wholesale data allows for more accurate prediction of PECs, including combination drugs
- Bayesian Networks are a promising approach for the calculation of risk quotients while retaining and quantify uncertainty, and are an intuitive tool for risk assessment
- BNs also a promising tool for risk communication

Approach

- We aim to develop a Bayesian Network for probabilistic risk assessment of pharmaceuticals to Norwegian surface waters
- Probability distributions are retained at each node of the network, allowing a final prediction to be made with uncertainty integrated across the nodes
- Once completed, this model will allow the prediction of environmental risks posed by pharmaceuticals with integrated uncertainty in predictions

Planned Work

- In order to predict the evolution of future risks, we plan to use national climate and population projections to model risks under a variety of different scenarios
- Pharmaceuticals will be grouped by function, allowing for better prediction of mixture risk where modes of action are similar
- Incorporating an assessment of persistence will further enable more complete assessment of substances



Acknowledgements

This research was funded by ECORISK2050, with funding from European Union's Horizon 2020 research and innovation program, grant agreement No. 813124. (H2020-MSCA-ITN-2018). The authors thank Solveig Sakshaug and the rest of the WHO Collaborating Centre for Drug Statistics Methodology for their advice and assistance, as well as Sophie Mentzel (NIVA).

References

European Medicines Agency. 'Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use', 2006. http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf.

- A simple conceptual Bayesian Network for the probabilistic risk assessment of a given pharmaceutical
- Risk is predicted based on Predicted Environmental Concentration (PEC) and Predicted No-Effect Concentration (PNEC)
- Incorporating future population and climate scenarios is planned for predicting the evolution of risk over the coming decades