

Incorporating Uncertainty in Pharmaceutical Environmental Risk Assessments with Bayesian Networks

Background

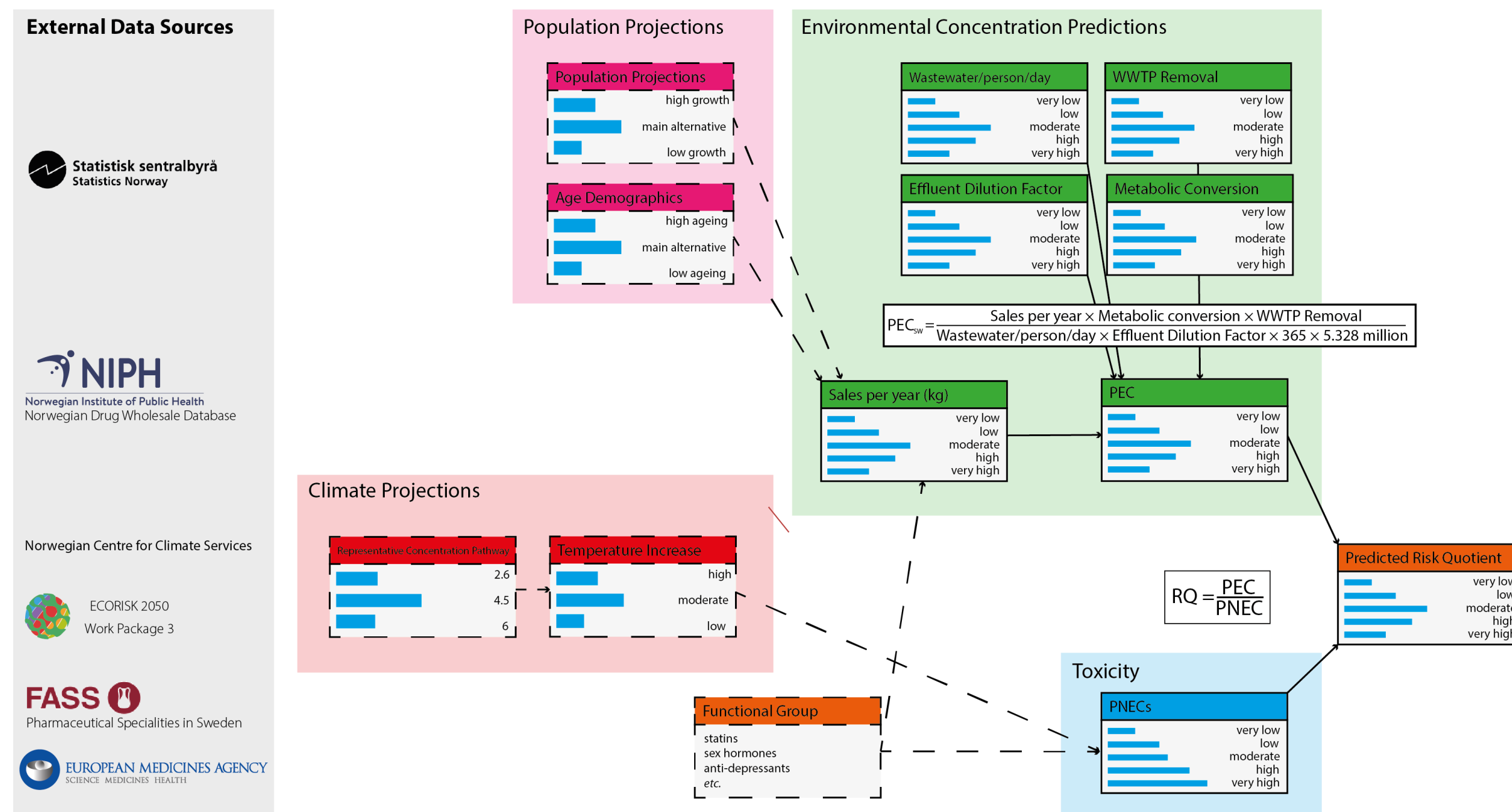
- Existing pharmaceutical environmental risk assessment in the EU compares Predicted Environmental Concentrations (PECs) based on with Predicted No-Effect Concentrations (PNECs) to predict risk, using a principle of maximising conservatism to account for uncertainty (EMA, 2006) (see [Presentation 5.19.03](#))
- 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



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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

