

Human Pharmaceuticals in Surface Waters of the Elbe River Basin



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Emission, Fate and Exposure Assessment

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EU regulations for evaluating environmental fate and effects of human pharmaceuticals have not been finalised as yet. Regarding to aquatic exposure assessment, a draft of the **European Agency for the Evaluation of Medicinal Products (EMEA)** [1] suggests a comparably crude calculation of a predicted environmental concentration (PEC) based on a fix dilution factor of 10. It has been shown that this overall assumption cannot be justified in particular with consideration of extreme low water conditions [2]. Therefore the exposure model GREAT-ER [3] is recommended as a more accurate tool for calculation of local and regional PECs.

2 Calculated and measured concentrations of Diclofenac and Paracetamol

Diclofenac

analysis and GIS.

Mean concentrations of the two analgesics Paracetamol and Diclofenac have been simulated in the river network of the Elbe river basin as part of a project sponsored by the German Federal Environmental Agency (UBA) [4]. Surface water sampling and measurements were performed by R. Schmidt in august and september 1999 (Paracetamol) and august 2000 (Diclofenac and Paracetamol).



The high degradability of Paracetamol is reflected by the steeper slopes in the concentration profile. Highest concentrations are observed, where emissions from nonbiological treatment plants occur.

in the Elbe catchment

Substance property data and consumption resp. excretion rates have been taken from literature. A complex mode-III-simulation has been performed for Diclofenac, considering photolysis in the river-submodel.

Tab.1 GREAT-ER Model assumptions and EMEA-PECs

	Diclofenac	Paracetamol	Ref.
excretion per capita and year	0.124 g	1.75 g	[5],[6],[7]
WWTP-removal (biolog.)	69 %	99 %	[7]
lumped in-stream- removal rate [1/h]	-	0.0525	[8]
surface-near photolysis [1/h]	0.5	-	[9]
light extinction coefficient [1/m]	10.97	-	[10]
PEC, EMEA approach, no in-stream-removal	88 ng/l	40 ng/l	[1]



The comparably high deviations to measured values at two sampling sites downstream Dresden, which may be due to an underestimation of loads from Czechian territory. Deviations between measured and predicted concentrations of both substances are below a factor of 3 and thus within the range of accuracy targeted for GREAT-ER.



Fig.4 Paracetamol in the Elbe river and its main tributaries

References

3 Conclusions

The prognostic accuracy of GREAT-ER for two pharmaceuticals was demonstrated above. Due to the availability of monitoring data only concentration profiles of the Elbe river and its main tributaries, thus comparably opportune dilution situations have been regarded. Nonetheless, the PECs calculated by the EMEA approach are exceeded at some locations, although no instream removal was taken into account.

[1] EMEA (2001) Discussion Paper on Environmental Risk Assessment of Non-Genetically Modified Organisms (Non-GMO) Containing Medicinal Products for Human Use.

[2] Matthies M, Schröder A (2002) Verdünnung von kommunalen Abwässern im Einzugsgebiet der Elbe. Wasser & Boden 54(6) (in press)

[3] Matthies M, Berlekamp J, Koormann F, Wagner JO (2001) Georeferenced simulation and aquatic exposure assessment. Wat. Sci. Technol. **43**(7), 231-238

[4] USF (2002) Institute of Environmental Systems Research at University of Osnabrück: GREAT-ER-Homepage, the http://www.usf.uni-osnabrueck.de/projects/GREAT-ER/

[5] Schwabe U, Paffrath D (1994) Arzneimittelverordnungsreport '94, Gustav Fischer Verlag, Stuttgart/Jena 1994

[6] Rote Liste 1994, Arzneimittelverzeichnis des Bundesverbandes der pharmazeutischen Industrie (BPI), Hrsg. BPI, ECV Verlag.

[7] Ternes T (1998) Abbau und Verhalten von Pharmaka in aquatischen Systemen; Schriftenreihe Wasserforschung 6, ESWE Institut für Wasserforschung und Wassertechnologie, Wiesbaden

[8] Richardson ML, Bowron J (1985) The fate of pharmaceuticals in the aquatic environment. J Pharm Pharmacol 37:1-12

[9] Poiger T, Buser HR, Müller MD (2001) Photodegradation of the pharmaceutical drug diclofenac in a lake: Pathway, field measurements and mathematical modeling. Environ Toxicol Chem **20**(2), 256-263

[10] LfU, Landesamt für Umweltschutz Sachsen-Anhalt: Gewässergüteberichte Sachsen-Anhalt 1995-1999. Halle.