

Workshop „Pharmaceuticals in Soil, Sludge and Slurry” of the German Federal Environment Agency (18th June to 19th June 2013)

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Welcome Note Workshop 18-19 June 2013

Ladies and gentlemen, dear colleagues,

I am pleased to welcome you to the International Workshop “Pharmaceuticals in Soil, Sludge and Slurry”. I am very happy that you meet in the Federal Environment Agency (UBA) in Dessau which gives me the opportunity to introduce this important workshop.

UBA has to give scientific advice to the Federal Ministry of Environment as well as to inform the public about nearly all environmental issues. Furthermore we have to manage emission trading and, in my division, we are involved in the enforcement of chemical legislation – not only for pharmaceuticals but also for plant protection products, biocides and industrial chemicals. Having these different pieces of enforcement consolidated in one unit is a great chance. We prepare proposals for harmonized approaches for environmental risk assessment and risk management. A substance in the environment poses the same risk regardless of it was released as biocide, pharmaceutical or technical product. Therefore, some topics of this workshop like monitoring strategies, uptake in plants and mixture toxicity are of general interest.

Environmental risk assessment of veterinary and human drugs is a relatively young discipline in Europe and worldwide. In the 1990s most people and administrators still believed that pharmaceuticals are “good” chemicals helping people to get healthy – in contrast to pesticides. But analytical findings and the occurrence of harmful effects convinced us that medicinal products may have a negative impact on environment. This is no surprise if you imagine that pharmaceuticals are biologically highly active substances. The harmful potential of medicinal products was not only perceived in Europe but was also recognized in other parts of the world. Therefore, in many countries a legislative process was initiated in order to implement environmental risk assessment in authorization procedure for pharmaceuticals. In addition, we must be aware that the use of pharmaceuticals will further increase due to demographic changes of population resulting in higher exposure to the environment.

Most active ingredients have a characteristic profile: they are not readily degradable because they must reach their target organ after oral intake and are excreted via urine as polar metabolites. This makes water compartment particularly sensitive to pharmaceuticals since elimination rate in wastewater treatment plants may be low. However, some medicinal products may be significantly adsorbed to sewage sludge which is a relevant exposure route to soil. We should be aware that wastewater technology is designed that sewage sludge should be a sink for micropollutants and is not aimed to produce clean fertilizers. This is why we should prefer to incinerate

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sludge instead of using it in agriculture. Our agency proposes a stepwise phasing out of agricultural use of sewage sludge because risks are higher than advantages.

There is another pathway from sewage to soil which will be mentioned in this workshop: the irrigation of arable land with treated wastewater. This plays no significant role in central Europe but may be important in arid countries. Risks of pharmaceuticals in this part of the water cycle should be estimated carefully.

Whereas wastewater is the major elimination pathway for HMPs, VMPs are applied to soil predominantly via manure and slurry. In contrast to sewage sludge these excretions of animals should not be incinerated but used as fertilizers. The amount of veterinary use of pharmaceuticals is less than the amount of human use but for soils the discharges of veterinary medicines are more important. And in consequence the ingredients or their metabolites may percolate into groundwater which often is used as drinking water resource.

Moreover, the relevant groups of antiparasitics and antibiotics play a major role in veterinary medicine. Antiparasitics – sometimes the same ingredients as in plant protection products – can damage dung and soil fauna. The use of antibiotics for veterinary use in Germany is three times higher than the human use. There are more and more scientific findings that antibiotics in the environment may contribute to the occurrence of resistant bacteria. Emergence of resistance in the environment by emitted antibiotics is not yet a criterion for approval of antibiotics. But it will be very interesting to listen to the contributions on this topic at this workshop how to tackle this new form of environmental risk.

What do we need to improve this situation?

First we need more reliable data. The environmental risk assessment in the authorization procedure is focused on new products. Data on widely used old products are missing. We therefore propose that we need a program to develop monographs of the old ingredients.

Furthermore we need more research on effects to soil organisms, on non extractable residues in soil and manure, on degradability and transformation in manure and on uptake of pharmaceuticals in plants.

Third we need more data on exposure. Meanwhile we know a lot about pharmaceuticals in surface water, but our knowledge about their occurrence in soil is very low. A targeted monitoring program would contribute to close this gap and may help us to identify indicator substances in order to announce when the impact on soils exceeds their capacity.

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Authorization of medicinal products knows the instrument of pharmakovigilance. This system of reporting upstream eventual health problems caused by intake of drugs works well but an environmental counterpart is missing.

For water, in consequence to the analytical monitoring findings, environmental quality standards have been developed and may be implemented in the European framework of water legislation in near future. In the medium term, we may need the same for soils.

However, monitoring and better scientific knowledge is not very effective to reach the target to reduce the impact of pharmaceuticals on the environment. Therefore we need strategies, how to reduce medication without impairing human and animal health and how to dispose of unused residues of pharmaceuticals safely.

It is one aspect of sustainability that we should preserve our soils. Clean and healthy soils are essential for producing food of high quality for future generations and a well functioning environment with high biodiversity. Pharmaceuticals in soil is one point which should be reflected in this context.

Many of the above mentioned topics will be discussed in this workshop. We need this exchange of scientific views and results. Again, a very warm welcome to our agency and a lively and fruitful discussion. Thank you!