Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Risk assessment of contaminants in sewage sludge applied on Norwegian soils

Opinion of the Panel on Contaminants in the Norwegian Scientific Committee for Food Safety

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Summary

SUMMARY

The Norwegian Scientific Committee for Food Safety (VKM) was asked by the Norwegian Food Safety Authority to assess the risk of using sewage sludge as fertilizer and soil conditioner in agricultural lands and park areas as well as sludge mixed with soil sold to private households. VKM was specifically asked to evaluate the potential risk of dispersal of sewage sludge for soil living organisms, the aquatic environment, grazing animals, animals eating feed based on plants from sludge-treated soil, children eating soil, and humans consuming drinking water, crop plants and/or meat affected by the use of sludge as soil conditioner, in total a list of 12 defined exposure routes.

VKM was asked to perform a risk assessment of all these exposure routes for the following contaminants:

- Cadmium (Cd)
- Lead (Pb)
- Mercury (Hg)
- Nickel (Ni)
- Zink (Zn)
- Cobber (Cu)
- Chromium (Cr)
- Phthalates (DEHP, DBP)
- Octylphenols and octylphenol ethoxylates
- Nonylphenols and nonylphenol ethoxylates
- Alkylbenzenesulfonate, linear (LAS)
- Polychlorinated biphenyls (PCBs)
- Polycyclic aromatic hydrocarbons (PAHs)

VKM was also asked to evaluate the risk associated with pharmaceuticals belonging to the groups; hormones, fluoroquinolone and tetracyclines and other relevant pharmaceuticals depending on the findings from a screening study of pharmaceuticals in sewage sludge from the Norwegian Pollution Control Authority (SFT, 2007). Included in the request to VKM was as far as possible to assess a list of other substances for which insufficient data was available to complete the risk assessment. The VKM Scientific Panel on Contaminants has been responsible for this risk assessment.

The application of sewage sludge as fertilizer implies a potential dispersal of a wide range of contaminants to agricultural soils. These contaminants may be further transported to different environmental compartments such as air, surface water, ground water and nearby streams. Furthermore the contaminants in soil may be absorbed by crop plants or plants used for feed production or grazing purposes and result in animal and human exposure to the contaminants through feed or food. Concentration data for all these compounds in sludge-treated soil or other environmental compartments following the application of sludge are not available. The predicted environmental concentrations (PECs) in soil, as well as human and animal exposure to the contaminants following the use of sewage sludge as soil conditioner have therefore been estimated by use of mathematical modelling based on the guidelines given in the European Union's (EU) Technical Guidance Document on Risk Assessment (TGD). The guidelines were adapted to Norwegian conditions whenever relevant. The exposure of the aquatic environment has been estimated by use of models developed, validated and used for pesticides. The risk assessment should cover both an evaluation after one application and the potential accumulation of contaminants following repeated use of sewage sludge. The risks associated with estimated exposure levels were assessed.

There is very limited information on the occurrence of medicines in Norwegian sewage sludge. The selection of medicines included in the few studies available appears not to be based on risk of effect or probability of occurrence. The Panel on Contaminants therefore decided to develop a tiered approach to estimate the concentrations of pharmaceuticals in

sludge. A cut-off concentration of 100 µg/kg soil was used in the tiered approach. The environmental risk associated with concentrations of drug substances below this level are regarded as negligible by The European Medicines Agency (EMEA). For drug substances like hormones and anticancer drugs that usually exert an effect at very low concentrations, The Panel on Contaminants has applied an additional safety factor of 10, and the cut-off concentration for these substances was set to 10 µg/kg soil.The potential concentrations in sewage sludge were estimated based on statistical information on sold amounts of medicines and sewage sludge production volumes. The estimations were gradually refined by taking factors such as water solubility, biotransformation, and environmental degradation into account. The output of the tiered approach was a list of 14 drug substances with potential occurrence on soil after sewage sludge application exceeding the cut off values of 100 or 10 µg/kg soil. A more detailed risk assessment of these 14 drug substances was performed by using the same methods as used for other contaminants.

The potential risk of eutrophication of the aquatic environment following sewage sludge application and the effects of application of sewage sludge on areas with grazing animals without ploughing within 18 hours have not been assessed.

Hazard characterisations

The hazard characterisation has been based on available hazard assessments made by international organizations like The Joint FAO/WHO Expert Committee on Food Additives (JECFA), EU Chemical Bureau, European Food Safety Authority (EFSA), etc. For substances where no hazard characterisation has been made by any of these organisations, relevant national hazard characterisations have been used. For certain compounds in certain environmental compartments, no toxicological safe exposure limits have been found. The lack of available toxicological hazard characterisations has therefore been pointed out as knowledge gaps in this assessment. Establishment of new tolerable daily intake (TDI) or predicted no-effect concentration (PNEC) values has not been the scope of this assessment.

Exposure assessments

All levels of exposure have been estimated by use of mathematical models. The models are based on the guidelines in TGDs. Some modifications in the models have been made to adapt the exposure assessments to Norwegian conditions. To a large extent, this applies to soil parameters, weather parameters and agricultural practice. Soil concentrations have been calculated based on the levels of contaminants in sludge and the present use of sludge (class 1: 40 tons/hectare/10 year) and a possible 50% increase in the maximum permitted use of sludge (60 tons/hectare/10 year). To allow for the potential accumulation in soil with repeated use of sludge, the soil concentrations have been calculated in a 100 year perspective, background concentrations, evaporation, biodegradation, removal through plants and leaching to aquatic environments into account. The maximum concentration for each contaminant, either immediately after application of sewage sludge or after 100 years with repeated use (application every 10^{th} year), has been used as the exposure estimate in the risk assessment. Leaching to the aquatic environment has been estimated by the models developed and used for pesticides applied on soil. The model is validated for both organic and inorganic pesticides and is therefore considered suitable for the prediction of leaching to surface water as well as ground water.

Uptake of contaminants by plants was calculated, both to be able to estimate the potential accumulation of contaminants in soil and to provide concentrations for the calculations of animal and human exposure through ingestion of crop plants. The uptake of contaminants in plants was calculated according to the guidelines in TGD when possible. The guidelines in TGDs do, however, only allow for estimations of concentrations in root parts and was therefore used in estimations of concentrations in root plants such as potatoes and carrots. Other models from the scientific literature had to be used to estimate the concentrations in edible plant parts above the ground, such as lettuce and cereals. A comparison between several models was made and the most conservative model considered to be realistic was chosen. The resulting plant concentrations were then used in calculations of animal and human intakes of contaminants.

The models used for estimating plant uptake of organic contaminants from soil have not been validated for polar and ionisable compounds. Most drug substances have such chemical properties, and the concentrations of drug substances in plants could therefore not be estimated. Consequently, animal and human exposure to drug substances through plant derived feed or food could not be estimated.

There is no model available from the TGD to assess the transfer of metals from feed to animal-derived food products. A transfer of Cd, Pb and Hg in food producing animals has been estimated based on available values in the literature on intake and tissue concentrations. The concentrations of organic contaminants in animal-derived food items were estimated using a model from the TGD.

Human intakes of contaminants from food producing animals were calculated using the estimated plant concentrations combined with typical feeding rations to the different animals (species and age/type of production).

The human intakes were estimated based on the individual food consumption data from Norkost 1997 (Norwegian food consumption survey), estimated crop plant concentrations, estimated levels in animal-derived food items and estimated water concentrations. A consumption of drinking water of 2 L/day has been used, which is the water consumption used by WHO when the drinking water guidelines are prepared.

Risk characterizations

Soil environment

The estimated predicted environmental concentration (PEC) for each contaminant was compared with the available predicted no-effect concentration (PNEC) for soil.

The estimations showed that no metals would reach the PNEC values within the timeframe of 100 years. Consequently the Panel on Contaminants considers metals in sludge to constitute a low risk to soil living organisms. However, the model estimations indicate that the soil concentrations of Cd, Hg, Cu and Zn, and partly also Pb will increase following repeated use of sewage sludge. Cadmium and Hg, as well as Pb are of particular concern due to their inherent toxic properties and the increase is undesirable even if the soil concentrations are not estimated to exceed the PNEC values. Cadmium is also taken up in plants to a significant degree. Increased Cd concentrations in soil will therefore increase the human exposure to this metal. After 100 years with repeated use of sewage sludge on an average soil, the estimated soil concentration of Cd is still below the present maximum permitted soil concentration for further application of sewage sludge.

Octylphenols, nonylphenols and LAS were the only contaminants where the PEC exceeded the PNEC. However, these are rapidly degradable substances ($t_{1/2}$ in soil = 8-10 days) where the highest concentrations were found immediately after application of sewage sludge followed by a rapid decrease. Taking into account the uncertainties related to the occurrence levels, and the rapid degradation in soil, VKM considers octylphenols, nonylphenols and LAS to be of low concern. Only a few PAHs and PCBs are expected to accumulate with repeated use (every 10^{th} year) of sewage sludge in a 100 years period and the model indicates that the concentrations of these substances will be well below the PNEC value even at the end of the 100 year period. VKM considers all the assessed organic contaminants to constitute a low risk to the soil environment.

Of the more than 1400 drug substances sold in Norway, only 14 have been estimated to exceed the cut-off values of 100 or 10 μg/kg soil after sludge application. For the 14 identified drug substances no PNEC values in soil have been available to VKM. Soil PNEC values for pharmaceuticals have therefore been estimated from the aquatic PNEC values when available. The estimated soil concentrations of drug substances were low (concentration range 0.01 – 2 mg/kg dry weight (DW)) and well below the estimated PNEC values. The Panel on Contaminants considers drug substances in sewage sludge to constitute a low risk for soil-living organisms.

Aquatic environment

Neither metals, organic contaminants nor the drug substances assessed are expected to reach the environmental PNEC values on short or long-term. Most of the assessed contaminants reach maximum concentrations well below the PNEC values. Two PAHs (pyrene and indeno (1, 2, 3-cd)pyrene) are estimated to reach a water concentration approaching the PNEC value (Risk quotient of 0.99 and 0.88 respectively). The Panel on Contaminants considers the use of sewage sludge as soil conditioner therefore to be of low concern for the aquatic environment.

Food producing animals

From this risk assessment based on a contaminant based approach, the risk of adverse effects in farm animals grazing on or receiving feed from sewage sludge treated areas seem to be negligible for a range of contaminants. Meat-producing animals have in general a short life span and are consequently not expected to be subject to effects following long-term exposure to substances with a potential accumulation. Milk-producing and breeder animals have longer life span, but the exposure of food producing animals to contaminants through application of sewage sludge may anyway be regarded as low. However, lead seems to be an exception and may constitute a risk in young animals as the estimated extra contribution from sewage sludge to a high background level may imply an intake level close to that shown to reduce learning capability in lambs. In addition, there are limited data in the literature on the effects of several contaminants in food producing animals and the assessments of these contaminants are hampered with uncertainty. Furthermore, the knowledge of effects of combined exposure to the coctail of various known and unknown chemicals in sewage sludge is lacking. Even not directly comparable to the Norwegian use of sewage sludge, perturbated development of young ruminants pre- and postnatally exposed to sewage sludge treated areas has been revealed. However, such use of sewage sludge directly on grazing areas without ploughing has not been an issue in Norway and has therefore not been adressed in this report.

Human exposure

Human intake from food and drinking water
Presently about 60% of the sewage sludge produced is dispersed on agricultural soil. This would cover <5% of the cereal-producing areas at the maximum allowed amounts (40 tons/10 years). Due to this limited availability of sewage sludge, the fraction of agricultural soil receiving the maximum doses of sewage sludge will be so small that the added contribution from sewage sludge to the dietary intake for the general population will be low. For specific individuals, for example farmers, consuming only vegetables grown on such fields, the dietary intake may potentially exceed the tolerable daily intake (TDI) for Cd and the tolerable upper intake level (UL) for Cu in the long term. The Panel on Contaminants has not assessed the probability of this scenario to occur.

The human dietary intakes via the different exposure routes assessed are combined – i.e. drinking water and plants and animal derived food products. The estimated concentrations of contaminants in soil indicate that repeated application (every 10^{th} year) of sewage sludge on a field during a 100 year time period will lead to an increase in soil concentrations of certain heavy metals such as Cd and Hg. A consequence of this accumulation in soil may result in an undesirable increase in human dietary intake of particularly Cd, but also Hg.

The additional intake of metals from animal-derived food products or drinking water as a consequence of use of sewage sludge as fertilizer is estimated to be very low (<5% of estimated total intake) and of low concern.

The organic contaminants addressed in the present risk assessment are either degraded in the soil or poorly absorbed into crop plants. The estimates therefore indicate a low increase in human dietary exposure to organic contaminants from sewage treated soil and the Panel considers this additional exposure to constitute a low risk to the consumers.

Children eating soil
The highest concentrations of contaminants are found in soil mixtures sold for use in private homes. These mixtures may contain 30% sewage sludge. There is no requirement for further mixing of this product. The estimated intake of metals when children ingest 0.2 g of this soil products are low in comparison with the toxicological safety parameters (TDIs or ULs), with Pb being the highest, reaching approximately 13% of the TDI. Taking into consideration that this route of exposure only is likely to occur in a limited time period, and the relatively low intake in comparison with the TDI, the Panel on Contaminants considers this exposure route to be of low risk.

Development of antibacterial resistance
It is unlikely that antibacterial resistance may be promoted in the STP water, in the sludge or in the soil following application of sewage sludge as fertilizer. An exception may be a potential development of resistance to the fluoroquinolone ciprofloxacin in soil due to persistence and limited mobility of these substances into the subsoil.

Conclusions

Octylphenols, nonylphenols and LAS are the only contaminants in this assessment that is estimated to reach soil concentrations exceeding the PNEC in agricultural soils. These compounds are rapidly degradable in soil and the highest soil concentrations are reached immediately after each sewage sludge application. However, concentrations are uncertain and available occurrence data for octylphenols, nonylphenols and LAS in Norwegian sludge are limited. There is also limited information available on the effects of these compounds in soil, and the PNEC values for octylphenols and nonylphenols were derived from available aquatic PNEC and large safety factors were used in the assessment. Based on these findings, the Panel of Contaminants of VKM considers the use of sewage sludge to constitute a low risk to the soil ecosystem. The model does, however, indicate a potential increase in the soil concentration of the inherent toxic metals Cd and Hg as well as Cu and Zn. It is therefore recommended that the concentrations of these metals in sewage sludge used for agricultural purposes should be monitored. Furthermore, continued efforts to reduce the content of these metals in sludge are encouraged.

The use of sewage sludge is not expected to constitute a significant risk to the aquatic environment nor to food producing animals.

The Panel does not consider the risk associated with the use of sewage sludge as soil conditioner for the dietary intake (including drinking water) of the assessed contaminants to be of significance for the general population. The estimations do, however, indicate that a scenario of exclusive consumption of vegetables grown on sludge-treated soil could result in a dietary intake of Cd and Cu close to or above toxicological safe exposure limits (TDI or UL). The probability for such a scenario, for example a farmer only consuming vegetables grown on his own sludge-treated soil, to occur has not been assessed.

The risks have been assessed chemical by chemical, since no methodology for the risk assessment of the mixture occurring in sewage sludge is available. Most of the estimated exposures are well below any predicted effect concentration, making any interaction less likely, unless the contaminants have the same mode of action.