RISK ASSESSMENT OF CONTAMINANTS IN SEWAGE SLUDGE APPLIED ON NORWEGIAN SOILS

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

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0403 Oslo
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Gunnar Sundstøl Eriksen
Carl Einar Amundsen
Aksel Bernhoft
Trine Eggen
Kari Grave
Bent Halling-Sørensen
Torsten Källqvist
Trine Sogn
Line Sverdrup

CONTRIBUTORS

Persons working for VKM, either as appointed members of the Committee or as *ad hoc* experts, do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

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The members of the *ad hoc* group are:

VKM members:
Gunnar Sundstøl Eriksen (Chair), Panel on Contaminants (Panel 5)
Aksel Bernhoft, Panel on Animal Feed (Panel 6)
Trine Eggen, Panel on Contaminants, (Panel 5)
Kari Grave, Panel on Contaminants, (Panel 5)
Torsten Källqvist, Panel on Plant Protection Products (Panel 2)
Line Sverdrup, Panel on Plant Protection Products (Panel 2)

External experts:
Carl Einar Amundsen, the Norwegian Institute for Agricultural and Environmental Research (Bioforsk), Soil and Environment Division
Bent Halling-Sørensen, University of Copenhagen, Faculty of Pharmaceutical Sciences
Trine Sogn, the Norwegian University of Life Sciences (UMB), Department of Plant and Environmental Sciences

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Assessed by

The work from the *ad hoc* group has been evaluated and approved by Panel on Contaminants (Panel 5) in VKM.

Members of Panel 5: Janneche Utne Skåre (Chair), Jan Alexander, Augustine Arukwe, Trine Eggen, Gunnar Sundstøl Eriksen, Christiane Kruse Fæste, Kari Grave, Helle Katrine Knutsen, Amund Måge, Anders Ruus

Scientific Coordinator from the Secretariat: Anne Finstad, Marie Louise Wiborg, Siamak Yazdankhah

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 10th 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 10th 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 10th 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.

SAMMENDRAG

Faggruppen for forurensninger, naturlige toksiner og legemiddelrester (Faggruppe 5) i Vitenskapskomiteen for mattrygghet (VKM) har på oppdrag fra Mattilsynet risikovurdert bruk av avløpsslam som gjødsel og jordforbedringsmiddel på jordbruksarealer, grøntområder og i jordblandinger solgt til forbrukere. VKM ble spesielt bedt om å vurdere risiko knyttet til bruk av slam for jordlevende organismer, det akvatiske miljøet, beitende dyr og dyr som spiser fôr dyrket på slambehandlet jord. Vurdering av risiko for barn som spiser jord, og mennesker som drikker vann og spiser planter og/eller kjøtt influert av slambehandlet jord var også en del av oppdraget.

VKM ble bedt om å risikovurdere i alt tolv eksponeringsveier for følgende stoffer:

- Kadmium (Cd)
- Bly (Pb)
- Kvikksølv (Hg)
- Nikkel (Ni)
- Sink (Zn)
- Kobber (Cu)
- Krom (Cr)
- Ftalater (DEHP, DBP)
- Oktylfenoler og oktylfenoletoksylater
- Nonylpenoler og nonylfenoletoksylater
- Alkylbenzenesulfonater, linære (LAS)
- Polyklorinerte bifenyler (PCB)
- Polysykliske aromatiske hydrokarboner (PAH)

VKM ble også bedt om å vurdere risiko knyttet til legemidler av typen hormoner, fluorokinoloner og tetracycliner og andre relevante legemidler avhengig av hva som ble funnet i en undersøkelse av legemidler i avløpsslam gjennomført av Statens forurensningstilsyn (SFT, 2007).

Bruk av avløpsslam som gjødsel/jordforbedringsmiddel medfører en mulig spredning av en rekke forurensende stoffer til jord. Disse stoffene kan bli transportert til forskjellige miljøer slik som luft, overflatevann, grunnvann og nærliggende elver. Videre kan de forurensende stoffene i jord tas opp i planter skal brukes til mat eller fôr, noe som kan resultere i at dyr og mennesker eksponeres for stoffene gjennom maten og fôret de spiser. Konsentrasjonsdata for alle disse forurensende stoffene i slambehandlet jord eller i andre miljøer etter bruk av avløpsslam er ikke tilgjengelig. Estimert konsentrasjon i miljøet (predicted environmental concentration (PEC)) i jord, og eksponering av dyr og mennesker etter bruk av avløpsslam har derfor blitt estimert ved bruk av matematisk modellering basert på retningslinjer gitt i Europeisk unions (EUs) "Technical Guidance Document on Risk Assessment" (TGD). Retningslinjene er tilpasset norske forhold der dette er relevant. For beregning av konsentrasjoner i vann er det benyttet modeller som er utviklet, validert og brukt for plantevernmidler. Risikovurderingen skal både omhandle en vurdering av de forurensende stoffene etter en tilførsel og vurdering av mulig akkumulering etter gjentatt bruk av avløpsslam. Risiko knyttet til eksponeringsnivåer ble så vurdert.

Det finnes lite informasjon om forekomst av legemidler i norsk avløpsslam. Utvelgelsen av legemidler inkludert i de få undersøkelsene som er tilgjenglige ser ikke ut til å være basert på risiko for effekter eller sannsynlighet for at de gjenfinnes i miljøet. Faggruppen har derfor utviklet en trinnvis tilnærming for å estimere konsentrasjoner av legemidler i avløpsslam. En terskelverdi (cut-off-verdi) på 100 mikrogram per kilo (µg/kg) ble brukt i den trinnvise tilnærmingen. Miljørisiko forbundet med konsentrasjoner av legemidler under dette nivået anses som neglisjerbar av de europeiske medisinmyndighetene (The European Medicines Agency, EMEA). For legemidler som tilhører gruppene anticancermidler og hormoner som er effektive ved veldig lave doser har faggruppen benyttet en ekstra sikkerhetsfaktor på 10, og terskelverdien for disse stoffene er satt til 10 µg/kg. Mulig konsentrasjon av legemidler i avløpsslam ble estimert på grunnlag av salgsstatistikk om legemidler og produsert volum av avløpsslam i Norge. De estimerte konsentrasjonene ble gradvis raffinert ved å ta hensyn til faktorer slik som vannløslighet, biotransformasjon og nedbrytning i miljøet. Utfallet av den trinnvise tilnærmingen er en liste på 14 legemidler som potensielt kan gjenfinnes i jord etter bruk av avløpsslam i konsentrasjoner over terskelverdiene på 100 eller 10 µg/kg jord. En mer detaljert risikovurdering av disse 14 legemidlene ble gjennomført med samme metode som for de andre forurensende stoffene.

Mulig risiko forbundet med eutrofiering av det akvatiske miljøet som følge av bruk av avløpsslam og effekter forårsaket av avløpsslam brukt på beitearealer uten pløying innen 18 timer er ikke vurdert.

Farekarakterisering

Farekarakterisering er basert på tilgjengelige vurderinger utført av internasjonale organisasjoner som The Joint FAO/WHO Expert Committee on Food Additives (JECFA), EUs kjemiske byrå (EU Chemical Bureau), European Food Safety Authority (EFSA) og lignende. For stoffer der farekarakterisering ikke er utført av slike organer, er relevante nasjonale farekarakteriseringer brukt. For enkelte stoffer har faggruppen ikke funnet etablerte toksikologiske trygge eksponeringsverdier. Mangel på toksikologisk farekarakterisering er i disse tilfellene påpekt som kunnskapshull i risikovurderingen. Etablering av nye tolerable inntaksverdier (TDI) og estimerte ikke-effektsnivåer (predicted no-effect concentration, PNEC-verdier) har ikke vært en del av arbeidet i denne risikovurderingen.

Eksponeringsvurdering

Alle eksponeringsnivåene har blitt estimert ved bruk av matematiske modeller basert på retningslinjene i TGD. Noe modifisering av modellene er gjort for å tilpasse disse til norske forhold. I stor utstrekning gjelder dette bruk av jordparametre, forhold knyttet til vær og jordbrukspraksis. Jordkonsentrasjoner er beregnet basert på nivåer av forurensende stoffer i avløpsslam og dagens bruk av slam (klasse 1, 40 tonn/hektar/hvert 10. år) og en mulig 50 % økning av dagens maksimale bruk av avløpsslam (60 tonn/hektar/ hvert 10. år). For å ta hensyn til mulig akkumulering i jord etter gjentatt bruk av avløpsslam, er jordkonsentrasjonene beregnet i et 100-årsperspektiv hvor det er tatt hensyn til bakgrunnskonsentrasjoner, fordampning, nedbrytning, fjerning via opptak i planter og avrenning til vann. Maksimumskonsentrasjoner av alle de forurensende stoffene, enten rett etter bruk av avløpsslam eller etter gjentatt bruk av avløpsslam i 100 år (tilførsel hvert 10. år), er brukt i eksponeringsberegningene. Avrenning til det akvatiske miljøet er estimert med modeller utviklet for å vurdere bruk av plantevernmidler som tilføres jordbruksarealer. Modellen er validert både for organiske og uorganiske plantevernmidler og den er vurdert som egnet både for å estimere avrenning til overflatevann og grunnvann.

Opptak av forurensende stoffer i planter er beregnet, både for å kunne estimere mulig akkumulering av disse stoffene i jord og for å kunne estimere eksponering for dyr og mennesker som spiser planter. Retningslinjene i TGD tillater kun estimering av konsentrasjoner i rotdelene av plantene og TGD ble derfor benyttet til å beregne konsentrasjoner i rotgrønnsaker, slik som potet og gulrøtter. Andre modeller funnet i vitenskapelige artikler er benyttet for å estimere konsentrasjoner i spiselige deler av planter over bakken, slik som salat og korn. En sammenlikning av flere modeller er gjennomført og den mest konservative modellen som ble ansett å være realistisk, ble valgt. De estimerte konsentrasjonene i planter ble benyttet til å beregne inntak av forurensede stoffene hos dyr og mennesker. Modellene som er brukt for å beregne plantenes opptak av organiske stoffer fra jord er ikke validert for polare og ioniserbare forbindelser. De fleste legemidler har slike kjemiske egenskaper, og konsentrasjoner av legemidler i planter kunne derfor ikke beregnes. Dyrs og menneskers eksponering for legemidler fra fôr og mat kunne følgelig heller ikke beregnes.

Det finnes ingen modeller tilgjengelig i TGD for å vurdere overføring av metaller fra fôr til animalske matprodukter. En overføring av kadmium, bly og kvikksølv til matproduserende dyr er estimert på bakgrunn av tilgjengelige data om inntaks- og vevskonsentrasjoner funnet i litteraturen. Konsentrasjoner av organiske stoffer i animalske produkter er estimert ved bruk av modeller fra TGD.

Konsentrasjoner av forurensende stoffer i animalske matprodukter er beregnet ved å bruke estimerte plantekonsentrasjoner kombinert med typiske fôrmengder benyttet til de forskjellige dyrene (art og alder/produkjsjonsform).

Humant inntak av forurensende stoffer er beregnet med individuelle kostholdsdata fra Norkost 1997 (Norsk kostholdsundersøkelse) der estimert plantekonsentrasjon, estimerte konsentrasjoner i animalske produkter og estimerte vannkonsentrasjoner inngår i beregningene. For å beregne inntak fra drikkevann er en mengde på 2 liter vann per dag benyttet. Dette er i samsvar med de mengdene Verdens helseorganisasjon (WHO) bruker til å utarbeide retningslinjer for drikkevann.

Risikokarakterisering

Jordmiljø

Estimert konsentrasjon i jord (PEC) for hvert forurensende stoff ble sammenliknet med tilgjengelig estimert ikke-effektsnivå (PNEC-verdier) for stoffet i jord.

Beregningene viser at ingen av metallene når PNEC-verdiene etablert for jord innenfor tidsrammen på 100 år. Faggruppe 5 anser derfor at avløpsslam medfører en lav risiko for jordlevende organismer. Modellestimeringene viser imidlertid at jordkonsentrasjonene for kadmium og kvikksølv vil øke etter gjentatt bruk av avløpsslam. Disse tungmetallene er spesielt bekymringsfulle på grunn av sine toksikologiske egenskaper, og en økning av jordkonsentrasjoner av disse stoffene er uønsket selv om beregningene viser at konsentrasjonene ikke overstiger PNEC-verdiene. Kadmium tas opp i planter i signifikante mengder. Økte kadmiumkonsentrasjoner i jord vil derfor medføre økt human eksponering for dette metallet. Etter 100-års gjentatt bruk av avløpsslam i gjennomsnittlig jord er fortsatt de estimerte konsentrasjonene av kadmium lavere enn det som maksimalt er tillatt at jordbruksjord inneholder om slam skal kunne tilføres.

Oktyl-, nonylfenol og LAS var de eneste forurensende stoffene der PEC overskred PNEC. Disse stoffene brytes imidlertid raskt ned (halveringstid på 8-10 dager) og den høyeste konsentrasjonen ble funnet rett etter tilførsel av avløpsslam etterfulgt av rask reduksjon av konsentrasjonene. Ved å ta hensyn til usikkerheten knyttet til forekomstdataene, den raske nedbrytningen i jord og de store sikkerhetsfaktorene benyttet ved fastsettelse av PNEC-verdien for oktyl- og nonylfenol, anser Faggruppe 5 risikoen knyttet til disse stoffene å være av liten betydning. Noen få PAH- og PCB-forbindelser ble estimert til å akkumulere etter gjentatt bruk av avløpsslam. Modelleringen indikerer at konsentrasjonene er langt under PNEC-verdiene, selv etter 100-års bruk. Det finnes imidlertid ikke etablerte PNEC-verdier for PCB-forbindelsene. Faggruppen anser at de vurderte organiske forbindelsene utgjør en lav risiko for jordmiljøet.

Av de over 1400 legemidlene som selges i Norge, er kun 14 legemidler beregnet til å overskride terskelverdien etter slambruk. For de 14 identifiserte legemidlene har ingen terrestriske PNEC-verdier vært tilgjenglig for faggruppen. Terrestriske PNEC-verdier for legemidler har derfor blitt utledet fra akvatiske PNEC-verdier der slike har vært tilgjengelig. De estimerte jordkonsentrasjonene for legemidler er meget lave (konsentrasjoner fra 0,01-2 mg/kg tørrvekt) og langt under de estimerte PNEC-verdiene. Faggruppen anser at rester av legemidler i avløpsslam utgjør en lav risiko for jordlevende organismer.

Akvatisk miljø

Verken metaller, organiske stoffer eller legemidler vurdert i denne risikovurderingen forventes å komme opp i konsentrasjoner tilsvarende PNEC-verdier, verken på kort eller lang sikt. De fleste vurderte stoffene når maksimumskonsentrasjoner som er langt lavere enn de angitte PNEC-verdiene. To PAH-forbindelser (pyren og ideno(1, 2, 3-cd)pyren) er beregnet til å nå vannkonsentrasjoner som nærmer seg PNEC-verdiene (risikokvotient på henholdsvis 0,99 og 0,88). Faggruppen anser risiko ved bruk av avløpsslam som jordforbedringsmiddel i jordbruket til å være av liten betydning for det akvatiske miljøet.

Matproduserende dyr

Generelt har matproduserende dyr et kort livsløp, og de forventes derfor ikke å bli langtidseksponert for stoffer med akkumulerende egenskaper. Dette gjelder også for melkeproduserende dyr og avlsdyr, selv om de har et lengre livsløp en kjøttproduserende dyr. Matproduserende dyrs eksponering for forurensende stoffer via bruk av avløpsslam i jordbruket anses derfor som lav. Det finnes imidlertid begrenset informasjon i litteraturen på effekter av flere av de forurensende stoffene på matproduserende dyr og vurderingen av disse forurensende stoffene er derfor usikre.

Bruk av avløpsslam direkte på beiteområder uten nedpløying er ikke et tema i Norge og problemstillingen er derfor ikke vurdert.

Human eksponering

Humant inntak fra mat og drikkevann

I dag brukes omtrent 60 % av produsert avløpsslam på jordbruksområder. Dette vil dekke mindre enn 5 % av det kornproduserende arealet med maksimal tillatt bruk (40 tonn/hektar/hvert 10. år). På grunn av begrenset tilgang på avløpsslam vil andelen av jordbruksarealer som mottar maksimale mengder med avløpsslam være veldig liten, og antatt tilleggsbidrag fra avløpsslam til inntaket fra mat i den generelle befolkningen vil være lavt. For spesielle individer, for eksempel bønder som spiser egenproduserte grønnsaker fra jordarealer der slam er brukt, kan over tid få et inntak som overskrider tolerabelt daglig inntak (TDI) for kadmium og tolerabelt øvre inntaksnivå

(UL) for kobber. Faggruppen har ikke vurdert sannsynligheten for at dette scenarioet kan inntreffe.

Humant inntak av forurensende stoffer via drikkevann, planter og animalske produkter er beregnet. Modellberegningene indikerer at i et 100-årsperspektiv vil gjentatte tilførsler (hvert 10. år) av avløpsslam på et jorde, medføre økte jordkonsentrasjoner av visse tungmetaller, som kadmium og kvikksølv. En konsekvens av denne akkumuleringen i jord kan være en økning i inntaket av tungmetaller, spesielt kadmium, men også kvikksølv.

Tilleggsinntaket av metaller fra drikkevann og animalske produkter som følge av bruk av avløpsslam som jordforbedringsmiddel er estimert til å være veldig lavt (<5 % av estimert total inntak) og dette inntaket vil derfor være av liten betydning.

De organiske stoffene vurdert i denne risikovurderingen nedbrytes enten i jorda eller har lavt opptak i matproduserende planter. Beregningene indikerer en lav økning i human eksponering for disse organiske stoffene fra jord behandlet med avløpsslam, og faggruppen vurder at dette tilleggsbidraget er av neglisjerbar risiko for forbrukerne.

Barn som spiser jord
De høyeste konsentrasjonene av forurensende stoffer fra slam er funnet i jordblandinger som selges til private forbrukere. Jordblandingene kan inneholde opptil 30 % avløpsslam. Det er ingen krav til videre utblanding av disse produktene. Estimert inntak av metaller fra jordblandinger hos barn (konsum av 0,2 gram jord) er imidlertid lavt i forhold til fastsatte TDI og UL, og bly som utgjør det høyeste inntaket nærmer seg 13 % av TDI. Om en tar hensyn til at denne eksponeringsveien kun foregår i en begrenset periode, og det relativt lave inntaket sammenliknet med TDI, anser faggruppen at risiko forbundet med denne eksponeringsveien er lav.

Utvikling av resistens

Det er lite sannsynlig at antibakteriell resistens vil utvikles i avløpsvann fra slamrenseanlegget, i avløpsslammet eller i jord som følge av bruk av avløpsslam som jordforbedringsmiddel. Et unntak kan være mulig utvikling av resistens til fluorokinolonene ciprofloxacin i jord på grunn av persistens og begrenset mobilitet av disse forbindelsene i jord.

Konklusjoner

Oktyl-, nonylfenol og LAS er de eneste forurensende stoffene i denne risikovurderingen som er estimert til nå konsentrasjoner som overskrider PNEC-verdiene for jord. Disse stoffene brytes raskt ned i jord og de høyeste konsentrasjonene nås rett etter hver applikasjon av avløpsslam. Imidlertid er konsentrasjonene usikre, tilgjengelighet av forekomstdata for oktyl- nonylfenol og LAS i norsk avløpsslam er begrenset og det finnes begrenset informasjon om effektene av disse stoffene i jord. For Oktyl- og nonylfenol er PNEC-verdiene utledet fra akvatiske PNEC-verdier og store sikkerhetsfaktorer er benyttet. Basert på disse funnene finner VKMs Faggruppe 5 at bruk av avløpsslam medfører liten risiko for jordøkosystemet. Den benyttede modellen indikerer imidlertid en potensiell økning av jordkonsentrasjonene av metallene kadmium og kvikksølv i tillegg til kobber og sink. Det anbefales derfor at konsentrasjonene av disse metallene i avløpsslam som brukes i jordbruket bør overvåkes. Videre anbefales kontinuerlig arbeid med å redusere innholde av disse metallene i avløpsslam.

Bruk av avløpsslam antas ikke å utgjøre noen signifikant risiko for det akvatiske miljøet eller for matproduserende dyr.

VKMs Faggruppe 5 anser ikke at konsum av mat (inkludert drikkevann) som følge av bruk av avløpsslam som jordforbedringsmiddel vil utgjøre noe signifikant risiko i den generelle befolkningen for de vurderte forurensende stoffene. Inntaksberegningene indikerer imidlertid at et scenario der alle grønnsakene som konsumeres er dyrket på slamtilført jord, kan medføre et inntak av kadmium og kobber som overskrider tolerable inntaksverdier (TDI eller UL). Sannsynligheten for et slik scenario, for eksempel der bønder bare spiser egenproduserte grønnsaker, er ikke vurdert.

De beregnede risikoene i denne vurderingen har blitt vurdert stoff for stoff siden det ikke finnes noe metode for risikovurdering av kjemiske blandinger som finnes i avløpsslam. De fleste av de estimerte eksponeringene er lang under de fastsatte effektkonsentrasjonene. Dette gjør interaksjonen mellom stoffer mindre sannsynlig dersom ikke de forurensede stoffene har samme virkningsmekanisme.

CONTENT

ABBREVIATION

Abbreviations	Explanation
ADI	Acceptable daily intake
AF	Assessment factor
AMR	Antimicrobial resistant bacteria
BaP	Benzo[a]pyrene
BCF	Bioconcentration factor
BDF	Bio disposition factors
$BMDL_{10}$	Bench mark dose lower confidence limit, 10% incidence of measured endpoint
BOD	Biological oxygen demand
BPA	Bisphenol A
CEC	Cation exchange capacity
Cd	Cadmium
COD	Chemical oxygen demand
Cr	Chromium
Cu	Copper
DL-PCBs	dioxin-like PCBs
DM	Dry matter
DOC	Dissolved organic carbon
DT_{50}	Half-lives
DBP	Di-butylphthalate
DEHP	Di ethyl hexyl phthalate
DW	Dry weight
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
ERA	Environmental risk assessment
EqP	Equilibrium partitioning theory
Foc	Fraction of organic carbon
FW	Fresh weight
GL	Guideline level
Ha	Hectare
HBCD	Hexabromcyclododekan
Hg	Mercury
HMP	Human medical product
HRT	Hydraulic retention time
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
Kd value	Soil-pore-water partitioning coefficient
K_{oc}	Partition coefficient
K_{OW}	Octanol-water partition
LAS	Linear alkylbenzene sulfonate
LOAEL	Lowest adversed observed effect level
LOEL	Lowest observed effect level
MeHg	Metylmercury
MIC	Minimum inhibitory concentration
MOE	Margin of Exposure. This is exposure divided by the level expected to cause effect, e.g. $BMDL_{10}$
MT	Metallothionine
NDL-PCBs	Non-dioxin-like PCBs

Abbreviations	Explanation
Ni	Nickel
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOEL	No observed effect level
OP	Octylphenol
PAHs	Polycyclic aromatic hydrocarbons
PAH4=Σ PAH4	Sum of benzo (a)pyrene, chrysene, benz(a)anthracene and benzo(b)fluoranthene
Σ PAH	Sum of 15 indicator PAHs (Naphtalene, Acenaphtylene, Acenaphtene, Fenantrene, Antracene, Fluorene, Fluoranthene, Pyrene, Benzo(a)anthracene, Chrycene, Benzo(b)fluoranthene, Indeno (1,2,3-cd)pyrene, Dibenzo(a,h)antracene, Benzo(g,h,i)perylene, Benzo(a)pyrene)
Pb	Lead
PBDEs	Polybrominated diphenylethers
PCBs	Polychlorinated biphenyls
$PCB_6 = \Sigma PCB_6$	Sum of PCB-28, PCB-52, PCB-101, PCB-138, PCB-153, PCB-180
$PCB_7 = \Sigma PCB_7$	Sum of PCB-28, PCB-52, PCB-101, PCB-118, PCB-138, PCB-153, PCB-180
PC_{sludge}	Predicted concentrations in sewage sludge
Pe	Population equivalent. Pe is the unit of measure used to describe the size of a waste water discharge.
PEC	Predicted environmental concentration
PNEC	Predicted non effect concentration
PRZM3	Pesticide Root Zone Model
PTWI	Provisional tolerable weekly intake
QSAR	Quantitative structure activity relationship
RQ	Risk quotient
SFT	Norwegian Pollution Control Authority
SCF	Scientific Committee for Food
SOM	Soil organic matter
SRT	Sludge retention time
SSD	Species sensitivity distribution
STP	Sewage treatment plant
TBBPA	Tetrabrom bisphenol A
TDI	Tolerable daily intake

1. BACKGROUND

The Norwegian Food Safety Authority (Mattilsynet) received in 2005 a letter from Norsk Landbrukssamvirke Servicekontor AS (The Federation of Norwegian Agricultural Co-operatives) where they asked the authority to conduct a risk assessment for human health and the environment on the use of sewage sludge on Norwegian soils. They questioned if the risk associated with existing maximum values, restriction of the use of sewage sludge and levels of contaminants in sewage sludge were sufficiently evaluated in relation to food safety and environmental aspects. In addition, they questioned if the use of sludge in food production is safe for humans. They also wanted to receive an evaluation on how to monitor environmental contaminants in sewage sludge and in food produced from areas where sewage sludge has been used as fertilizer/soil conditioner.

The Norwegian Food Safety Authority asked the Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM) to conduct a risk assessment on the use of sewage sludge on Norwegian soils. The task was considered to be extensive and VKM decided to collect and evaluate the existing occurrence data on contaminants in sewage sludge (pre-project) before they started to work with the question from the Norwegian Food Safety Authority. Aquateam was asked to do the pre-project and VKM received a report in March 2006 (Aquateam, 2006).

This report was used as a basis for The Norwegian Food Safety Authority in cooperation with VKM to work out the terms of reference for the risk assessment. VKM appointed an *ad hoc* group consisting of VKM members and external experts to respond the request from the Norwegian Food Safety Authority. Panel on Contaminants (Panel 5) of VKM is responsible for the outcome of this work.

The *ad hoc* group has incorporated comments and suggestions from Panel 5 during their work with this opinion. The report from the *ad hoc* group has been evaluated and approved by Panel 5 of VKM.

2. TERMS OF REFERENCE

The Norwegian Food Safety Authority (Mattilsynet) has asked VKM to assess a risk assessment of contaminants in sewage sludge applied on Norwegian soils.

The risk assessment should cover the environmental and health-related risks sewage sludge may represent when used as soil conditioner on areas cultivated for food and feed and on green areas including parks, private gardens and road side vegetation according to Norwegian legislation. In addition the risk assessment should take into account a 50% increase in the maximum allowed amount of sewage sludge, and the use of sewage sludge on fields where vegetables, coarse fodder and potatoes are grown.

Different exposure routes were outlined in the pre-project (Aquateam, 2006) and the Norwegian Food Safety Authority would like the following exposure routes listed in Table 1 to be evaluated in the risk assessment:

Table 1. Exposure routes to be evaluated in the risk assessment of sewage sludge

Exposure route nr	Target organism	Description of scenario
	Plants	
1	Plants	Plants growing on soil where sewage sludge has been used
	Animals	
2	Soil organisms	Soil organisms living in soil where sewage sludge has been used
3	Aquatic organisms	Aquatic organisms living in rivers and lakes influenced by soil where sewage sludge has been used
4+5	Grazing animals	Animals eating grass and/or soil and soil organism from fields where sewage sludge has been used
6	Animals eating feed	Animals eating feed grown in fields where sewage sludge has been used
	Humans	
7	Children	Children eating soil
8	Humans eating plants	Humans eating plant products that have been grown on fields where sewage sludge has been used
9+10	Humans eating animal products	Humans eating products from grazing animals and/or products from animals eating feed grown in fields where sewage sludge has been used
11+12	Humans drinking water	Humans drinking surface- and/or groundwater influenced by soil where sewage sludge has been used

The risk assessment takes the following issues under consideration:

- Agricultural crops
- Terrestrial- and aquatic environment
- Animal health (grazing livestock and fish in the wild, but not grazing wild game)
- The general human population, especially groups at riskto the extent to which they can be identified.

In the pre-project, contaminants where divided into two categories according to the knowledge of hazard identification and the availability of occurrence data in Norwegian sewage sludge. For the heavy metals and organic contaminants listed in Table 2, it was assumed that there where sufficient data available to do a risk assessment for all 12 exposure routes.

For the compounds listed in Table 3 and Table 4 limited data exist for several inorganic and organic contaminants, pharmaceuticals, cosmetics, and biocides/pesticides. VKM should assess those substances according to the knowledge of each substance. The most relevant pharmaceuticals and chemicals in cosmetic products, which are most likely to be found in sewage sludge, should be covered. The contribution of certain pharmaceuticals (antibiotics) from the agriculture itself compared with the contribution from sewage sludge should also be evaluated.

Table 2. Compounds with sufficient data (according to the pre-project) to fulfil a risk assessment of the 12 exposure routes. The compounds are included in Part A of the risk assessment.

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

Table 3. Pharmaceuticals to be included, Part B of the risk assessment.

Pharmaceuticals
Hormones
Fluoroquinolone
Tetracylines
Others*

*Relevant pharmaceuticals should be covered. In addition, information from a screening survey of pharmaceuticals from Norwegian Pollution Control Authority (SFT) has to be taken into consideration in the risk assessment (SFT, 2006).

Table 4. Compounds with less data available (according to the pre-project)*.

Inorganic compounds	Organic compounds
Arsenic (As)	Organotin compounds
Silver (Ag)	Chlorinated aliphates
Tin (Sn)	Penta- and deca PBDE
Selenium (Se)	Other polybrominated diphenylethers (PBDE)
Bismuth (Bi)	Tetrabrom bisphenol A (TBBPA)
Vanadium (V)	Hexabromcyclododekan (HBCD)
Antimony (Sb)	Polychlorinated dibenzodioxins/ Dibenzofuranes)
Wolfram (W)	Polychlorinated naphthalens
Beryllium (Be)	Chlorinated phenols
Molybdenum (Mo)	Chlorinated benzenes
	Chlorinated paraffin's
	PFOS
	PFOA
	Bisphenol A
	Triclosane
	Galaxolide
	Tonalid
	Butylhydroxytoluen
	Irgarol
	Diuron
	Glyfosat
	DEET

*The list of compounds has not been evaluated further and the compounds are not included in this risk assessment. The Norwegain Food Safety Autority and VKM will discuss if this will be done at a later stage.

The Norwegian Food Safety Authority would like VKM to:

- perform recommendations regarding future surveys of contaminants in sewage sludge
- give priorities for compounds to be monitored in sewage sludge and in feed and food from areas where sewage sludge have been used
- indicate substantial knowledge gaps related to contaminants in sewage sludge
- comment, from a health- and environmental perspective, possible factors that might call for restriction on use of sewage sludge

3. INTRODUCTION

A complete risk assessment for the use of sewage sludge as fertilizer with regard to effects on the public health and environment has never previously been performed in Norway. In general, heavy metals and organic contaminants levels in Norwegian sewage sludge are low in comparison to other countries (e.g. Blytt, 2007).

About 70% of the sewage sludge produced by Norwegian sewage treatment plants (STPs) is recycled as fertilizer products. Sludge from STPs is widely used as a soil fertiliser (Table 5) and more than 82% are used for soil amendment purposes. The STPs have discharge permissions from the Norwegian Pollution Control Authority (SFT) and are obliged to monitor the treatment process and analyse sludge samples for selected undesirable substances such as certain heavy metals and organic contaminants. In addition, the authority has put in place special monitoring programs for a group of selected organic contaminants at the largest sewage plants in Norway. The purpose of this selection is to increase the knowledge about the discharge of such chemicals to the environment through the STPs (Amundsen *et al.*, 2001; Paulsrud & Nedland, 1997; Nedland & Paulsrud, 2001; Blytt, 2007). During the last decade, there has been a decline in the discharge of several contaminants (eg. PCB, PAH, DEHP and DBP) from Norwegian STPs (SSB, 2007, see Chapter 3.3.). However, the variations are large, even among the different STPs, due to different composition of the wastewater and the volume of water that is supplied to these STPs. The composition depends on the amount of wastewater from households, industry, and rain and from snow/ice melting (SSB, 2007).

Table 5. Utilisation of treated sludge as soil fertiliser in 2006 (www.ssb.no)

Use of sludge in Norway.	Utilisation of sludge, ton dry matter (DM)
Total	103 795
Farm land	50 818
Green areas	12 924
Soil producers	11 784
Cover for landfills	5 064
Deposited	5 606
Other	5 629
Unknown	11 971

3.1. Legislation

In 2003, the regulation of organic fertilizers, including sewage sludge, was organized under the same regulation (*Forskrift 4. juni 2003 nr.951 om gjødselvarer m.v. av organisk opphav*).

Under the new dispensation, the contaminants levels in sewage sludge put some restrictions on the use of sewage sludge for different purposes. This is especially important given the use of sewage sludge for agricultural purposes and on green areas. Maximum levels of seven heavy metals in sewage sludge were set in order to reduce the risk on different aspects such as environment, plant health and public health, as well as the need for having cut-off values.

Maximum levels for other contaminants were not given in the legislation, but there is a general demand that the agricultural products should be safe.

3.1.1. General demands

Sewage sludge cannot legally be applied to soil used for growing vegetables, berries, fruits, on pasture-land or in nurseries. Vegetables, berries and fruits can only be grown at minimum, three years after sludge amendment.

Sewage sludge has to be mixed into the soil immediately and at the latest 18 hours after application.

In private gardens, parks, playing grounds and related areas, sewage sludge may only be used as a part of the soil mixtures. The soil mixtures to be used may consist at maximum 30 volume percent of sewage sludge. Soil used in the mixture must not be taken from dumpsite, industrial areas or other related areas that could be polluted with environmental contaminants.

Sewage sludge can only be used if the heavy metal content in the soil is below the maximum levels given in Table 6.

Table 6. Quality demands for soil. Maximum levels for heavy metals (mg/kg DM) in soil where sewage sludge can be applied.

Heavy metals	Maximum levels in soil mg/kg DM
Cadmium (Cd)	1
Lead (Pb)	50
Mercury (Hg)	1
Nickel (Ni)	30
Zinc (Zn)	150
Copper (Cu)	50
Chromium (Cr)	100

3.1.2. Quality demands – heavy metals

According to the Norwegian regulation, sewage sludge is divided into four categories based on the content of heavy metals. It is not permitted to use sewage sludge as agricultural fertilisers if the content of heavy metals exceeds the given maximum levels. Alternatively, restrictions on the amount of sewage sludge to be used should be given. The different quality classes defined for sewage sludge are shown in Table 7.

Table 7. Quality demands for sewage sludge. Maximum levels for heavy metals (mg/kg DM) in different quality classes of sewage sludge.

Class:	**0** **mg/kg DM**	**I** **mg/kg DM**	**II** **mg/kg DM**	**III** **mg/kg DM**
Cadmium (Cd)	0.4	0.8	2	5
Lead (Pb)	40	60	80	200
Mercury (Hg)	0.2	0.6	3	5
Nickel (Ni)	20	30	50	80
Zinc (Zn)	150	400	800	1500
Copper (Cu)	50	150	650	1000
Chromium (Cr)	50	60	100	150
Application	No limitation on agriculture areas, and green areas (e.g. private gardens, parks)	40 tons dry matter per hectare per 10 year on agriculture areas, private gardens and parks.	20 tons dry matter per hectare per 10 year on agriculture areas, private gardens and parks.	Maximum 5 cm on green areas

Sewage sludge within class 0 can be amended on agriculture areas and green areas with no limitation. The amount used is adjusted to the plants need for nutrients.

Sewage sludge satisfying class I can be applied on agriculture areas, private gardens and parks at no more than 40 tons dry matter per hectare per 10 years. The products can also be used on green areas where foods or forage crops are not to be grown. The product shall be applied at maximum 5 cm layers and mixed into the soil at the site.

Sewage sludge complying with class II can be applied on agriculture areas, private gardens and parks at no more than 20 tons dry matter per hectare per 10 years. The products can also be used on green areas and similar areas where food or forage crops are not to be grown. The product shall be applied at maximum 5 cm layers and mixed into the soil at the site.

Sewage sludge within class III may be used on green areas where food or forage crops are not to be grown. The product shall be applied at maximum 5 cm layers every 10 year and mixed into the soil at the site. When used as cover on landfills the layer shall not exceed 15 cm.

Raw materials included in products of class I and II must comply with the requirements for heavy metal contents of class II. Similarly, raw materials included in class III products shall comply with the heavy metal requirements for class III.

3.1.3. Quality demands – organic contaminants

Producers, manufacturers and distributors of sewage sludge for fertilizing purposes should be attentive and take necessary precaution to restrict and prevent that their products contain amounts of organic contaminants, pesticides, antibiotics, chemotherapeutics or other xenobiotics that could pose risk to human health or the environment when used. No limits are given for such compounds by the authorities.

3.1.4. Other requirements

The products themselves and their use shall not pose risks for transmission of diseases to humans, animals or plants.

The products shall not contain *Salmonella* or infectious parasite eggs, and the content of thermo-tolerant coliforms shall be less than 2.500 per gram dry matter.

The products must be stabilised in order to avoid malodour or other environmental problems during storage or use.

In order to get approval for using sewage sludge as fertilizer, comprehensive documentation is required. These include - the origin of the raw material, treatment procedure, nutritional value, pH, liming value, conductivity, particle size distribution (texture), dry matter content, organic carbon, carbon/nitrogen ratio, heavy metal content, organic contaminant and pesticides, hygiene quality, stability, germinating weed seeds, plastics, glass and other extraneous matter.

3.2. Treatment of sewage and formation of sewage sludge

This chapter gives an overview and description of the key processes for treatment of municipal wastewater, treatment and use of sludge in Norway.

Most of the sewage treatment plants were built after 1970 and during the seventies and eighties there was a major increase in the number of plants with discharges to inland waters and narrow fjords. Due to different requirements for final discharges to the recipient and varying plant sizes, the STPs use different water and sludge treatment processes.

Sewage water is a mixture of wastewater from households, industries, hospitals and runoff waters from urban areas and leachates from landfills. The main purpose for wastewater treatment is to remove coarse debris, grit and organic material and phosphorus. A few STPs are built to remove nitrogen.

Discharge permissions are based on recipient considerations. With a few exceptions, STPs along the west coast from Lindesnes to the Russian border have discharge permissions based on removal of organic matters. From Lindesnes to the Swedish border, the STPs are required to remove phosphorus in addition to organic matters. The largest plants in the Oslo area also remove nitrogen from the wastewater.

3.2.1. Wastewater treatment methods

The discharge permissions dictate the treatment of wastewater methods. Table 8 summarises number of plants with different methods and the number of population equivalent (pe) connected to the plants. Population equivalent is the unit used to describe the size of a waste water discharge. Population equivalent is defined as the biodegradable load (organic matter) in waste water having a 5 day biochemical oxygen demand (BOD_5) of 60g of oxygen per day and does not necessarily reflect the actual population of a community.

Table 8. Treatment plants and connections in 2006 (www.ssb.no).

Types of treatment plants	No plants	Connected population equivalents (pe)*
Mechanical	1 100	861 000
Chemical	257	1 503 000
Chemical / Biological	286	1 131 000
Other	1 139	370 000
Total	2 782	3 865 000

*Population equivalent is the unit used to describe the size of a waste water discharge. Population equivalent is defined as the biodegradable load (organic matter) in waste water having a 5 day biochemical oxygen demand (BOD_5) of 60g of oxygen per day and does not necessarily reflect the actual population of a community.

Other STPs include plants with direct discharge (after screening) to the recipient, small plants (<50 PE) and soil-based plants with direct infiltration to the ground and special solutions.

Mechanical

Particulate matters are removed by sedimentation, screens or fine mesh sieves. It is used for moderate removal of organic matter, but will also remove some particulate-bound nutrients, micro-pollutants, heavy metals etc. Water-soluble micro-pollutants will mainly follow the discharges from the STP into the recipient medium.

Chemical

Dissolved phosphorus is precipitated with metal salts (iron or aluminium) and coagulated to larger flocks that can be removed by sedimentation, flotation or filtration. Chemical treatment will also coagulate small particulate matters, colloids, and thereby achieve a high degree of removal of organic matters (80%) and various degrees of heavy metals and organic micro-pollutants.

In addition to the removed substances, chemical precipitation will produce sludge from the formation of metal hydroxides (MeOH). The total sludge production will thereby be greater than the amount of removed substances.

Chemical/Biological

In the biological treatment unit, micro-organisms are used for removal of dissolved organic matters from the wastewater.

Biological removal of organic matters is normally an aerobic process, where micro-organisms utilize organic matter for growth by oxidative degradation of dissolved organic matters. The micro-organisms are either suspended (activated sludge) or fixed to surfaces (bio-film). The biomass is removed from the wastewater by means of sedimentation or floatation.

Nitrogen removal is based on the same biological processes. Dissolved ammonium (NH_4) is converted to nitrate (NO_3) in an aerobic nitrifying process. This unit is normally combined with removal of dissolved organic matters. Nitrate is converted to nitrogen gas (N_2) in an anoxic/anaerobic denitrifying process.

The generated biomass is removed from the wastewater by means of sedimentation or floatation.

Sludge production from these processes varies greatly, depending on treatment methods, retention time and required degree of removal. In general terms, STPs with a combination of chemical and biological treatment have greater potential to remove water-soluble micro-pollutants from the water.

Removal of organic matter

Biological removal of organic matters is normally an aerobic process, where micro-organisms utilize organic matter for growth by oxidative degradation of dissolved organic matters. The micro-organisms are either suspended (activated sludge) or fixed to surfaces (bio-film). The biomass is removed from the wastewater by means of sedimentation or floatation.

Nitrogen removal

Nitrogen removal is based on the same biological processes as discussed above. Dissolved ammonium (NH_4) is converted to nitrate (NO_3) in an aerobic nitrifying process. This unit is normally combined with removal of dissolved organic matters. Nitrate is converted to nitrogen gas (N_2) in an anoxic/anaerobic denitrifying process.

The generated biomass is removed from the wastewater by means of sedimentation or floatation.

3.2.2. Sludge treatment

Sludge treatment includes stabilization and hygienisation according to Norwegian regulations. Stabilizing sludge reduces odour. In addition sludge treatment comprises hygienisation for pathogen control.

Sludge from the separation unit is thickened from 0.5-3% DM to 3-6% DM before it is led to further sludge treatment. During or after treatment, sludge is dewatered to 25-40% DM.

Sludge produced in STPs has a high content of easily degradable organic matters and various mixtures of plant nutrients and micro-pollutants that are adsorbed to or incorporated in the sludge biomass. The sludge may also contain pathogens, but this is not evaluated in this risk assessment.

There are nine different combinations for sludge treatment in use in Norway (Figure 1). None of the treatment methods will reduce inorganic pollutants such as heavy metals. However, some of the biological processes have a potential to reduce and degrade persistent organic micro-pollutants. Treatment methods combining both aerobic and anaerobic treatments have the highest potential for removing inorganic pollutants. Volatile substances escape more easily from sludge when the temperature is increased in the treatment process.

Thermophilic aerobic digestion (wet composting, in-vessel)

Composting is a biological process that digests organic material in the presence of oxygen. Depending on the retention time, certain organic micro-pollutants may be degraded. A thermopilic process reaches temperatures above 55 °C.

Thermophilic aerobic pre-treatment + mesophilic anaerobic digestion
Anaerobic digestion is also a biological process in the absence of oxygen. Depending on the retention time in the digester, certain organic micro-pollutants may be degraded.

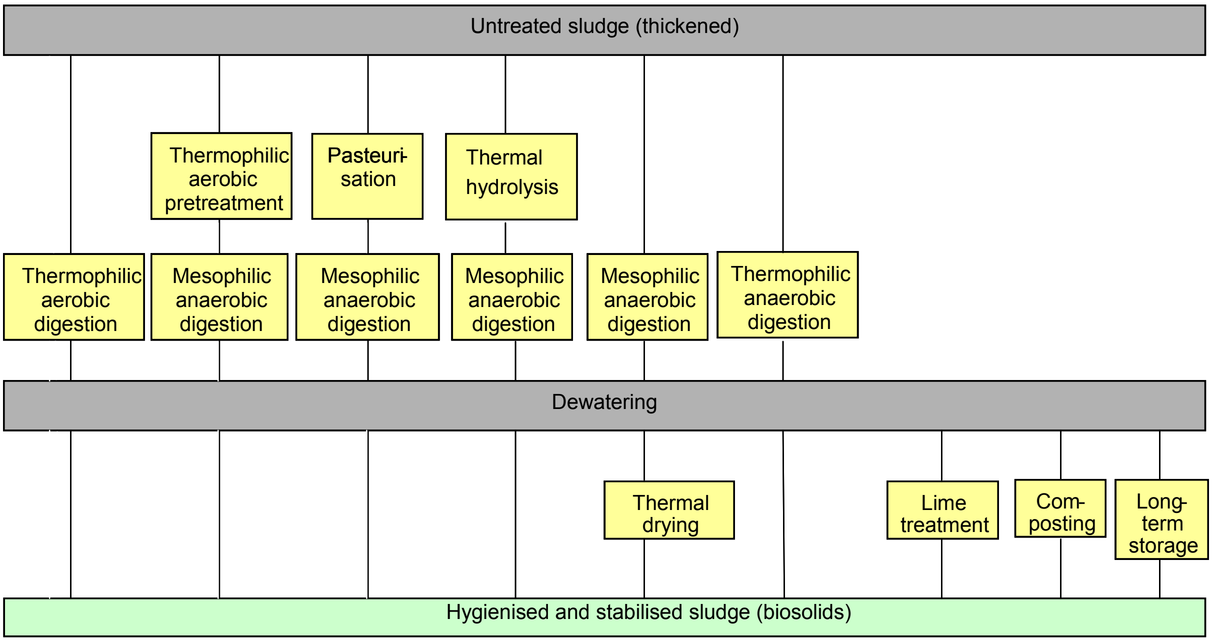

Figure 1. Processes for treatment of sewage sludge

Pasteurisation + mesophilic anaerobic digestion
Pasteurisation normally means a treatment process at 70 °C for at least 30 minutes. Anaerobic digestion is a biological process in the absence of oxygen. A mesophilic process has temperature between 35 - 40 °C. Depending of the retention time in the digester, certain organic micro-pollutants may be degraded.

Thermal hydrolysis + mesophilic anaerobic digestion
In a thermal hydrolysis process, the temperature is increased to above 130 °C. The biological fraction becomes more easily biodegradable in the digester. Depending on the retention time in the thermal hydrolysis and in the digester, certain organic micro-pollutants may be degraded.

Mesophilic anaerobic digestion + thermal drying
Depending of the retention time in the digester, certain organic micro-pollutants may be degraded.

Thermophilic anaerobic digestion
This process is operated at temperature above 55 °C. Depending of the retention time in the digester, certain organic micro-pollutants may be degraded.

Lime treatment
Dewatered sludge is treated by the addition of quick lime. The pH is increased up to 11-12, and the temperature increases to above 55 °C. Biological activity stops and biodegradation of organic micro-pollution is also stopped as a consequence.

Composting (windrow)
Composting is a biological process that digests organic material in the presence of oxygen. Sludge is mixed half and half with garden waste or bark or wood chips and the heap is turned several times during the composting period. Several organic micro-pollutants may be degraded. A well run composting process reaches temperatures above 55 °C.

Long-term storage
Presently, long term storage is not a defined treatment method. Basically, sludge is stored for as long as three years. Since the heap is hardly ever turned, there will be anaerobic zones with very low biological activity. The temperature hardly exceeds 30 °C during this treatment. It is a slow degradation of organic material and probably very little degradation of organic micro-pollutions during the long-term storage.

3.3. Norwegian studies on the effects of sewage sludge applications to soil

3.3.1. Levels and trends for some contaminants

3.3.1.1. Heavy metals (1993-2006)

The levels of heavy metals in sewage sludge have been reported by SSB since the early 1990ies. For cadmium, lead, mercury and copper the decrease in the period 1993-2006 has been 20-40%, while for zinc, nickel and chromium there has been only minor changes in the concentration level (Figure 2).

Compared to the concentration levels of heavy metals in Norwegian sewage sludge reported in 1980 (Hallberg & Vigerust, 1981), the levels of heavy metals in the period 1980-2006 have been reduced by 40 (zinc) to 90 (mercury and chromium) percent.

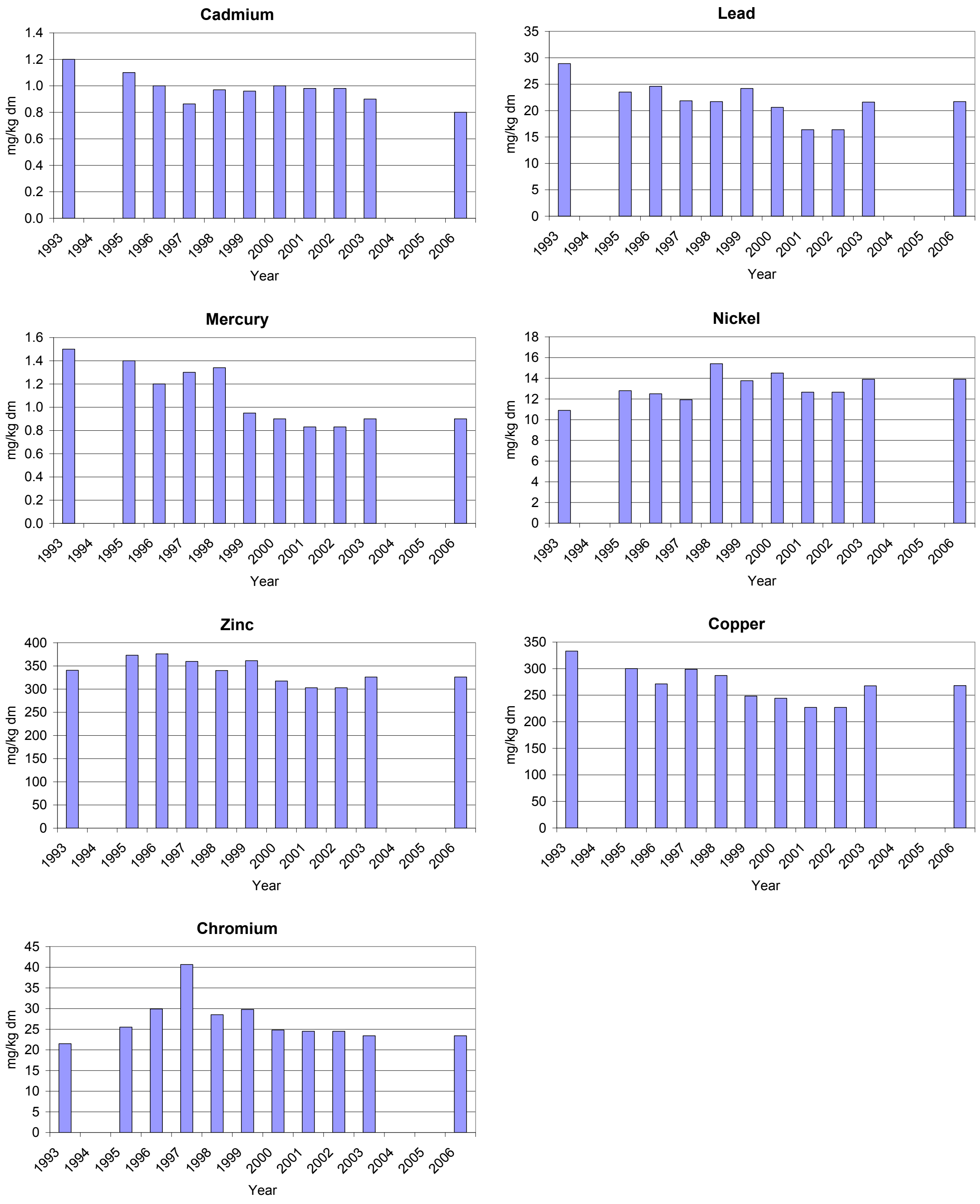

Figure 2. Concentration of heavy metals in sewage sludge from 1993-2006 (SSB, 2007).

3.3.1.2. Organic contaminants (1996-2007)

The levels of DBP, nonylphenol and nonylphenolethoxilates in Norwegian sewage sludge have decreased significantly during the last ten years, while the level of ΣPAH_{16}, LAS and DEHP have decreased less or do not show any significant reduction during the last ten years.

As input data in the calculation of soil concentrations, we have used the mean concentrations in sewage sludge from the last three investigations (2001-02, 2006 and 2006-07). This has been done when sampling and analysis methodology have been comparable. For LAS, however, the data from 2001-02 has been used, due to differences in analytical methods (Paulsrud, 1997; Brevik, 2001; Nedland, 2006; Blytt, 2007).

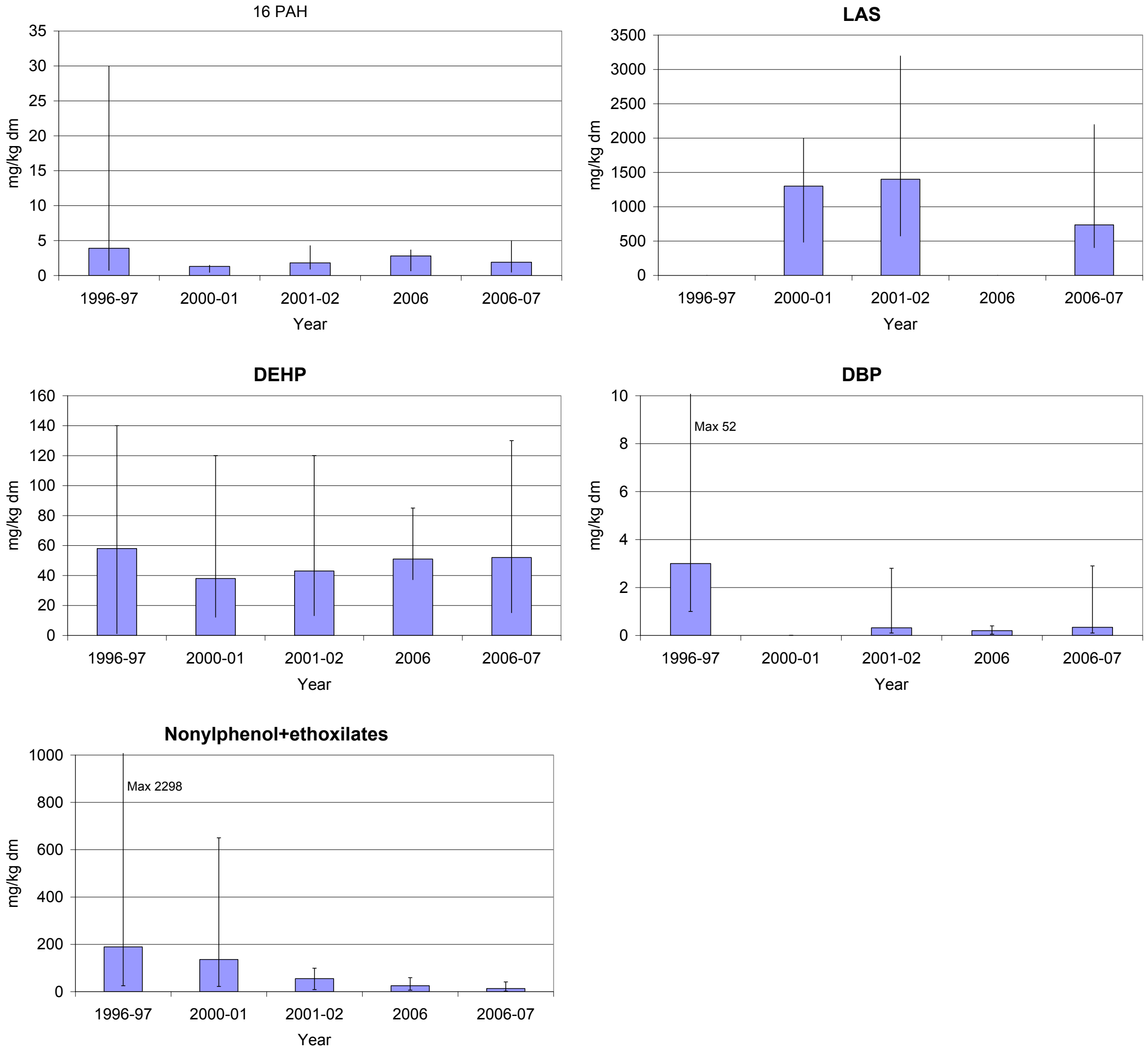

Figure 3. Concentrations of organic contaminants in sewage sludge from 1996-2007.

3.3.1.3. Pharmaceuticals

Data on the occurrence of drug substances in sludge in Norway are sparse. Only two survey studies have been performed so far (SFT, 2006; Thomas, 2007). Approximately 20 drug substances have been investigated, but the criteria for the inclusion of these drug substances were not outlined.

The latest study (Thomas, 2007) revealed considerable concentrations of antibacterial drug substances belonging to the tetracyclines (e.g. oxytetracycline (<0.01-2 µg/g wet weight), tetracycline (0.2-6.7 µg/g ww) and doxycycline (<0.01-1.3 µg/g ww) and fluoroquinolones (ciprofloxacin (4-97.5 µg/g ww)) in the sludges. In both surveys, estrogens were found only in very low concentrations in the sludge samples.

3.3.2. Effects of contaminants on soil and plants

Only few studies have been performed to reveal the potential negative effects of sewage sludge application to soils in Norway. The studies have focused on short term changes (i.e.1-4 years) and cannot be used to confirm whether sludge applications prior to 2007 had any effect on the exposure routes that will be evaluated in this risk assessment. Norwegian soils that have received sewage sludge since the 1970ies have not been subject to monitoring for soil and plant quality. Further more, the potential effects on soil living organisms have not been studied. *One consequence of this lack of experimental data is that the results from the modelling in this risk assessment cannot be calibrated, and the exposure and effect assessments cannot be validated.*

Some of the studies that have been performed regarding environmental contaminants in sewage sludge may give an indication on the response of soil biota (mainly plants) and effects on soil physical and chemical characteristics that may be expected when applying sewage sludge according to present Norwegian legislations.

3.3.2.1. Uptake of heavy metals from sludge amended soils by plants

The influence of sewage sludge amended soil on plants content of heavy metals in Norway has been investigated (Vigerust & Selmer-Olsen, 1985). Uptake of Cd, Cr, Cu, Hg, Ni, Pb, and Zn in different food and feed crops was measured. Highest increases in plant concentrations were measured for Zn and Ni, while the lowest increases were obtained for Cd, Pb and Cu.

An extensive number of experiments were performed in the period 1981-1983 (Vigerust & Selmer-Olsen, 1985). These experiments can be divided into two categories: 1) Growing of food and feed plants in soils from different parts of Norway that have received 0-120 tons of sewage sludge per ha; 2) Growing of food and feed plants in soils (20 cm deep) mixed with 10 cm sewage sludge or only sewage sludge (40 cm). The purpose of the experiments were to investigate how sewage sludge influences the content of Cd, Cr, Cu, Hg, Ni, Pb, and Zn in food and feed crops and to investigate how metal contents in different plant parts respond to sludge application.

The experiments show that Zn and Ni obtained the highest concentration increase in plants as a result of sludge application, while Cd, Pb and Cu increased less with an increasing amount of sewage sludge. The experiments also show that plant species responded differently to sludge application. Other conclusions from the experiments were that application of sewage sludge to soil influences soil pH, soil structure, total metal concentration in soil and thus also the metal uptake in plants.

Analysis of different plant parts (root, stem, leaf and grain), performed in the same study (Vigerust & Selmer-Olsen, 1985), showed that the concentration of Cd was higher in stem and leaves, compared with grain or root.

Taking all the different plant part into account, the experiments performed by Vigerust & Selmer-Olsen (1985) showed that the concentrations of Zn and Ni increased the most in plants after sludge application, while Cd, Pb and Cu increased less or did not change at all (Figure 4).

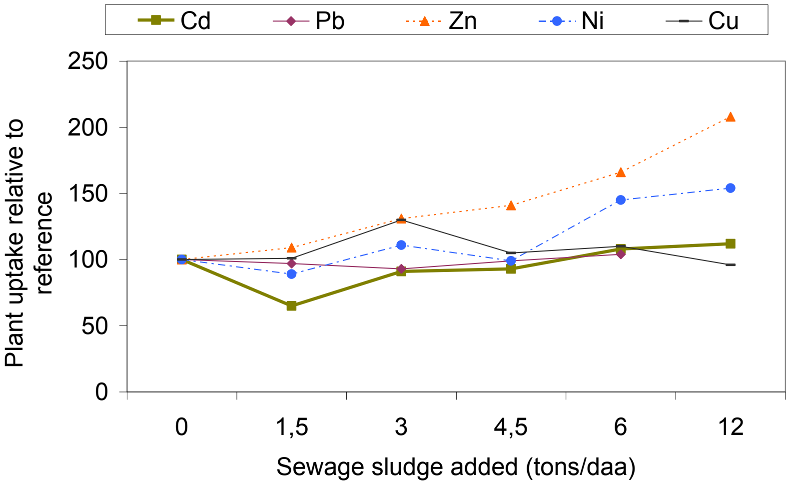

Figure 4. Uptake of heavy metals in food- and feed crops from soils that have received increasing amounts of sewage sludge (multiply with 10 in order to get added sewage sludge in tons/ha). The plant concentrations are given relative to reference plants (grown in soil with no sewage sludge application).

It should be noted that the concentrations of heavy metals in sewage sludge used in the experiments performed by Vigerust and co-workers in the early 1980ies, generally were higher than at present time: the concentrations of Cd, Pb, Hg, Ni and Cr were 4-10 times the present concentrations, while the concentrations of Zn and Cu were about twice the present levels in sewage sludge (Amundsen *et al.*, 2001).

3.3.2.2. Chemical and biological changes in soil due to sludge application

Experiments were performed in the period from 1996 to 2001 to look at changes in soil chemistry and biology caused by sewage sludge applications. Three types of sewage sludge (lime-treated, pasteurised and anaerobic stabilized sludge and anaerobic stabilized and thermal dried sludge) were used (Amundsen *et al.*, 1997b). The sewage sludge was mixed with three different soil types (loam, sandy loam and loamy sand) at rates proportional to 20 and 200 tons per ha which corresponded to the legal 10 and 100 years dosages. The concentrations of heavy metals in the sewage sludge used in these experiments were only slightly higher than the concentrations found in sewage sludge today.

Application of 20 tons of sewage sludge per ha (10 year dosage) did not result in significant changes in the soil total content of metals. Detection limits, uncertainty and variations in the methods used for analyses of trace metal species limits the possibilities for detection of those minor changes in total contents caused by sewage sludge application. However, two hundred tons of sludge per ha resulted in significant increases in both total and soluble Cd, Zn and Cu in soil. Concentrations of soluble Cd and Zn were found to vary with soil pH, while soluble Cu was more dependent on the amount of dissolved organic carbon (DOC) in soil solution.

In general, no negative effects on enzymatic (dehydrogenase, phosphatase and urease) and microbial (soil respiration, ammonium oxidation potential) activities were observed after sludge application. Soil enzymatic and microbiological activities increased proportionally with sludge application. This trend was quite consistent throughout the period between 1997 and 2000, i.e. implies positive effects on soil microbial activity were seen during the short-term period (i.e. 1-4 years after sludge application).

The conclusions from these experiments are that negative effects on soil microorganisms are rare when exposed to Norwegian sewage sludge. Relatively low concentrations of contaminants and high content of nutrients in sewage sludge, is the most likely explanation for the lack of negative responses or effects.

4. OVERVIEW OF THE EXPOSURE ROUTES

The Norwegian Food Safety Authority has asked for a risk assessment on the use of sewage sludge as soil conditioner and specified 12 exposure routes to be included in the assessment (Table 1). The exposure routes were selected after evaluations of the most important transfer pathways of contaminants from sludge amended soil or sludge-soil mixtures (Aquateam, 2006).

A model to predict concentrations of the contaminants after application of the sewage sludge has been developed in order to make a risk assessment of all the required exposure routes (Figure 5 and Table 1). The model involves a set of different scenarios for different applications of the sludge.

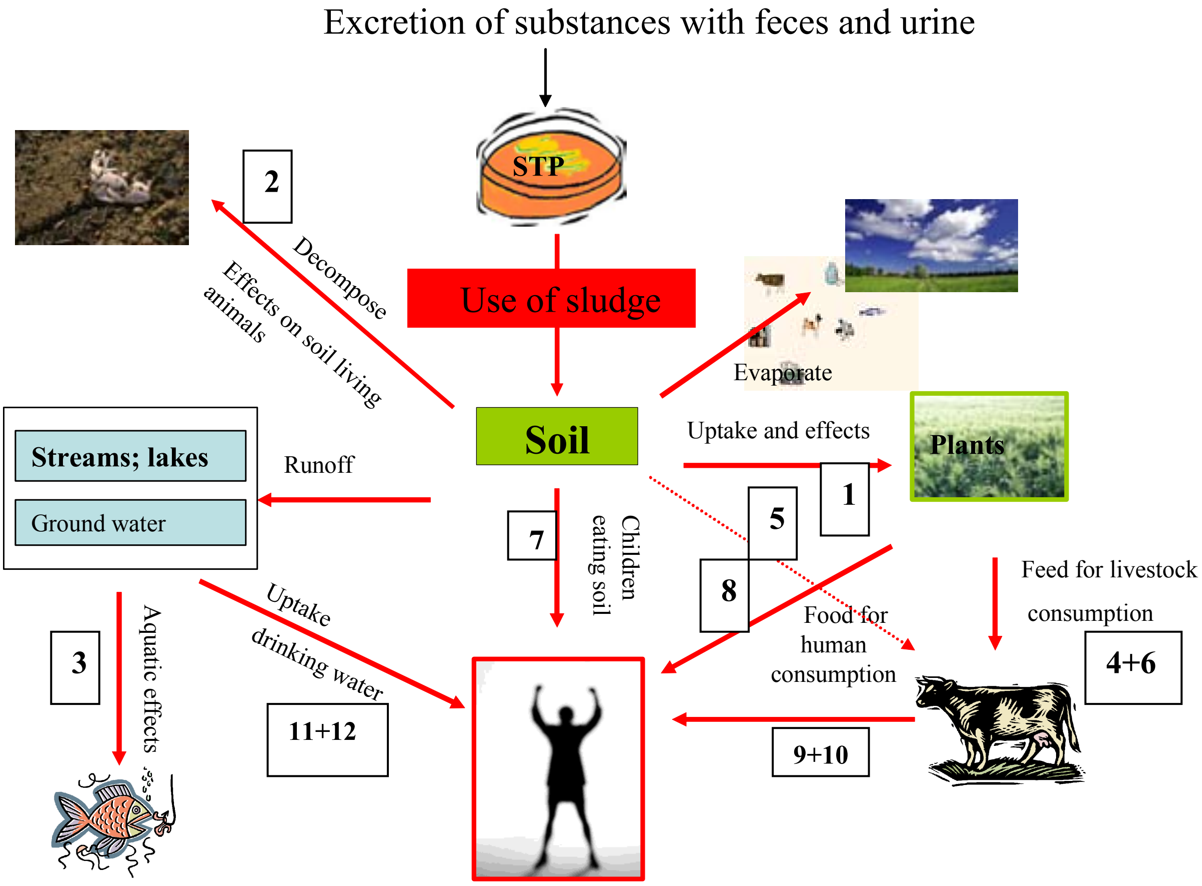

Figure 5. Overview of the exposure routes after use of sewage sludge as soil conditioner. The 12 exposure routes to be assessed are indicated with numbers.

The calculated concentrations of contaminants in soil or soil products after sludge application are the basis for assessing the risks for some target organisms (e.g. soil organisms and effects on plants). Furthermore, the calculated soil concentrations are used to estimate concentrations in plants, which in turn are used to estimate exposure levels for livestock and humans. The calculated soil concentrations are also essential starting points for calculations of predicted environmental concentrations (PECs) in aquatic environments in the vicinity of the sludge amended areas.

VKM was also asked to take the potential accumulation of the contaminants in soil into account. To achieve this, the mass balance of the contaminants through input by repeated use of sewage sludge and other sources and output through vaporisation, biodegradation, leaching, and removal through plant uptake has been estimated.

Four different sewage sludge application scenarios have been used to give maximum predicted concentration levels of contaminants in soil using the following scenarios:

1. Application of 40 tons of sewage sludge per hectare every 10 years on agricultural soils following the Norwegian regulation described in Section 3.1.
2. In accordance with the assignment from the Norwegian Food Safety Authority, an assessment of applying a 50% higher dose than the upper legal application is performed i.e. 60 tons per hectare every 10 years.
3. Application of 5 cm sewage sludge on green areas (mixed with 10 cm soil)
4. Application of 30% volume percent of sewage sludge in soil mixtures used in private gardens.

These four application scenarios lead to the highest predicted ions of contaminants in soil. The predicted concentrations of contaminants are estimated based on the actual levels found in sewage sludge, and the quality classes for heavy metals defined in the legislation (Table 7) are not used for this purpose. For medicines the concentration in soil is calculated be a tiered approach.

A more detailed description of the model and all parameters involved in the risk assessment are given in Chapter 5.

4.1. Exposure route 1: Plants

Uptake of contaminants by plants from soil is important for the exposure of animal and human (exposure routes 4, 5, 6, 7 and 8) to the contaminants (Table 1). Dependent on soil physico-chemical properties, only a fraction of the total contaminant concentration in soil is available for plant uptake (bioavailable fraction).

The main route of uptake of contaminants into plants is through the root system (active and passive uptake), but contaminants may also be absorbed through gaseous and particulate deposition to above-ground shoots and through direct contact between soil and plant tissues. For highly volatile pollutants, uptake of chemicals via leaf might be an important pathway. Possible elimination processes of contaminants in plants are volatilization via leaf due to plant transpiration and plant metabolism. Due to lack of rate constants of these processes they are not included in this risk assessment.

Transfer of contaminants from roots to above-ground plant parts (translocation) and further to leaves and grain are particularly important for the transfer of contaminants from plant to animals and human beings.

The predicted soil concentrations are used for the risk assessment of plants ($PNEC_{soil}$ based on European Commission Technical Guidance Document on Risk Assessment (TDG), see chapter 5.1.1).

4.2. Exposure routes 2-6: Animals

4.2.1. Soil living organisms

The soil ecosystem consists of producers, herbivores, predators and decomposers. When sludge is added to soil, chemicals in the sludge are easily accessible to soil organisms. Plants and soil organisms may accumulate inorganic and organic contaminants depending on their physio-chemical and toxicokinetic properties.

Exposure of soil living organisms is either through digestion of sludge amended soil (solid phase) or through soil solution that is more or less in equilibrium with the solid phase. Although most soil organisms are physically exposed to pore-water and air, and soil particles, several studies have shown that pore-water is the main exposure route for organic chemicals with low to intermediate lipophilicity (Ronday *et al.*, 1997; Jager *et al.*, 2000; Ma *et al.*, 1998). For highly lipophilic substances, uptake through the gut might also be important (Belfroid *et al.*, 1994; Ma *et al.*, 1998).

When pore-water that contains the fraction of the chemical that is available to the soil organisms (i.e., the bioavailable fraction) is the main exposure route, - the bioavailable fraction of the total soil concentration depends on the partitioning of a substance between the soil particles and the pore-water at equilibrium. This relationship is used as a rational for extrapolation of toxicity data from the aquatic to terrestrial environment, which may be useful in cases where no terrestrial ecotoxicity data are available. For any combination of a specific soil and chemical, the equilibrium partitioning parameter is termed the Kd-value (soil - pore-water partitioning coefficient).

The sorption of chemicals and hence their bioavailability and toxicity to soil organisms, may depend on soil characteristics. Strictly spoken this means that the results of tests conducted in different soils, with different characteristics, cannot be compared as such, but should be normalised to standard conditions. For non-ionic organic compounds the data should be normalised on the basis of the organic matter content, because it is assumed that the bioavailability for non-ionic substances is determined by the organic matter content only (EC, 2003). For metals, sorption in soil depends on soil characteristics such as organic matter content, clay content and pH, and the complex issue of soil sorption is adressed with separately for each individual metal.

In this risk assessement maximum exposure concentration for accumulating contaminants (heavy metals and some PAHs and PCBs) will be the concentrations after 100 years of sludge application. For more rapidly degradable organic contaminants in this risk assessment, named non-accumulating substances and defined as compounds with half-lives lower than 300 days, no accumulations over time occur in the soil and the maximum exposure for soil organisms will occur in the period just after sludge application.

4.2.2. Aquatic organisms

Exposure of aquatic organisms living in rivers or lakes close to areas where sludge are disposed may be exposed to contaminants due to leakage, to drainage or erosion of soil. The leakage potential of contaminants in the sludge is dependent on the same factors that govern the distribution in soil pore water. Models have been developed to predict the concentration of contaminants in drainage water based on the physio-chemical properties of the chemical, the soil characteristics and metrological data.

Contaminants that are adsorbed to soil particles may be transported to the aquatic environment by soil erosion, typically associated with snow melting and rain. Once the contaminants reach the aquatic environment they are redistributed between the water, suspended sediments and the bottom sediments.

Aquatic organisms inhabiting the water phase are mainly exposed to the dissolved fraction of contaminants, although exposure to contaminants adsorbed to suspended sediments may also be an important route for organisms that are filter-feeders.

Exposure of sediment-dwelling organisms may involve exposure through the pore-water and through the gut when feeding on sediment with adsorbed contaminants. As described for the soil, exposure through the pore-water appears to be the most important route for chemicals with low to intermediate lipophilicity, while exposure through the gut may also contribute significantly to exposure for highly lipophilic substances.

4.2.3. Production animals eating pasture and feed

Animals at pasture

For herbivore domestic animals as cattle, sheep, goats and horses at pasture, their whole ration may be the pasture plants. However, dairy cows and goats usually also receive grain-based feed (concentrate) when at pasture ranging from 0 to about 1/3 of total dry matter intake. As sewage sludge has to be mixed into the soil it is not used in rough grazing areas. Cultivated species of pasture plants (grass species) may grow in soil where sewage sludge has been used. According to Norwegian legislation, cows have to be kept outdoors at least 8 weeks per year, and sheep and goats at least 16 weeks per year. Sheep, goats and horses are usually not grazing sewage sludge treated pasture but cattle may do so.

Animals at pasture, cattle in particular, may also ingest some soil. The soil intake may depend on the pasture quality and the mineral need of the animals. The intake of soil is supposed to constitute only up to some percentages (<5%) of the dry matter ration.

Omnivore animals such as poultry and pigs moving outside may ingest grass and other vegetables. They may also ingest considerable amounts of soil and soil organisms as earthworms. However, these animals may not usually move around in sewage sludge spread areas.

Animals receiving feedstuff
For herbivore domestic animals like cattle, sheep, goats and horses receiving feedstuff (exposure route 6), the roughage use to constitute the main ration. In addition, concentrate (grain based feed) or in some cases potatoes etc. are given at a certain ratio (up to about 1/3 of the dry matter ration to these species).

Small grains, maize, oil seeds and array of seed leguems are common main ingredients in pig feed. The main feed ingredients in poultry feeds are maize and small grains. These feedingstuffs may be grown in soil containing sewage sludge.

4.3. Exposure routes 7-12: Humans

4.3.1. Children eating sludge amended soil

It is well known that children may ingest particles at playgrounds (exposure route 7). The highest concentrations of contaminants are found on soil surface due to the use of sludge-containing soil mixtures for private gardens. In an epidemiologic study 90% of the children ingested less than 0.2 g soil per day (Calabrese *et al*., 1989). This amount of soil has been used by SFT to establish quality classes for soil in kindergardens and playinggrounds for children in Norway (Alexander, 2006). VKM Panel 5 has therefore chosen to use 0.2 g soil/day as an amount a child could ingest of soil per day in this risk assessment.

4.3.2. Humans eating plants

Humans may be exposed to contaminants from sludge through eating cultivated crop plants produced on soil where sludge has been applied (exposure route 8). This exposure route can only occur for contaminants absorbed from soil into plants. For plants where plant parts above the ground are consumed, a further translocation of the contaminants from the roots to other parts above the ground is required.

The exposure of humans from plant-derived food materials has been estimated using consumption data from a national dietary survey (Norkost 1997, Johansson *et al.,* 1999) combined with estimated plant concentrations of heavy metals and organic contaminants for one of the model plants.

4.3.3. Humans eating animal products

Humans may be exposed to contaminants from sewage sludge through the consumption of animal-derived food products originating from animals grazing on sludge-amended soil (exposure route 9) or fed with animal feed produced on materials from such fields (exposure route 10). The contaminants could then be present either in the meat or entrails or the contaminant could be excreted in animal-derived food products such as milk or eggs. On the other hand the contaminants may also be rapidly metabolized and excreted through faeces or urine. (Metabolism and excretion does not imply “no exposure scenario” but rather diminished level of residues).

The exposure to contaminants through consumption of meat and dietary products has been estimated using food consumption data from the national dietary survey. For organic contaminants, the model given in TGD is used for the biotransfer into food products such as meat, milk and fat, while transfer of heavy metals metals have been estimated based on bioaccumulation factor from published studies.

4.3.4. Humans drinking water

Contaminants from sewage sludge amended fields may leak into waterways, either to surface water (exposure route 11) and/or ground water (exposure route 12) used for drinking water. Humans may be exposed to contaminants dissolved in the water or adsorbed to particles. A large proportion of the latter may be removed during filtration processes of the drinking water treatment plants. This potential removal process is not corrected for in the exposure estimations made in this report. A daily water consumption of 2 litres has been used in the exposure estimates. This is the same amount used by the WHO when proposing maximum limits for chemicals in drinking water (WHO, 2008).

4.3.5. Humans – total exposure (plants, animal products and water)

To estimate the total daily intake of contaminants from the use of sewage sludge, the exposures from all possible exposure routes (7-12) should be combined. To estimate a total mean intake of a contaminant from all sources, the mean intakes from the different food groups are summarised. Since it is unrealistic that one person can be a high consumer of all food items, a high intake of each contaminant has been estimated by combining the 95th percentile consumption of the food item with the highest contribution to the mean intake and the mean intake from all other food groups.

4.4. Structure of the risk assessment

The risk assessment has been divided into two parts according to the different contaminants listed in terms of reference (Chapter 2):

- Part A: Risk assessment on heavy metals and organic contaminants (listed in Table 2)
- Part B: Risk assessment on pharmaceuticals (listed in Table 3)

Risk assessment on cosmetics and other contaminants listed in Table 4 is not included in this report.

5. PART A: RISK ASSESSMENT OF INORGANIC AND ORGANIC CONTAMINANTS

In this part of the risk assessment heavy metals and organic contaminants listed in Table 2 in terms of reference is to be assessed for the 12 exposure routes requested by the Norwegian Food Safety Authority and described in Chapter 4.

The first step in the exposure estimation of all exposure routes is the estimation of the soil concentration after sewage sludge application. Chapter 5.1 summarises the hazard identification and characterization for the contaminants. The methodology and premises for risk assessment are described in Chapter 5.2. Predicted concentrations in plants and water are essential for several exposure routes in the risk assessment, and the methodology and premises for these estimations as well as the estimated plant and water concentrations are presented in chapter 5.3 and 5.4.

The methodology used to predict exposure concentrations for various exposure routes is based upon European Commission Technical Guidance Document on Risk Assessment (TGD), part II, (EC, 2003). This document assists authorities in carrying out the environmental risk assessment of existing and new substances. The methodology described in the TGD is not followed completely, but is adapted to Norwegian conditions and in particular to the use of sewage sludge according to Norwegian legislation. Modification of the methodology in TGD will be described when relevant. VKM has chosen to do the modelling of all exposure routes in a conservative way. This implies that the mass balance is not kept, meaning that the sum of each contaminant in all compartments may be higher than the input value. The model is therefore used to identify potential risks related to the application of sewage sludge. For substances where the estimated concentrations exceeding the levels considered being safe, a further evaluation of the risk is carried out in the discussion parts, taking experimental data into consideration.

5.1. Hazard identification and characterization

Environmental risk characterization

For environmental effects, the risk assessment is based on available Predicted No Effect Concentration (PNEC) values for the aquatic and terrestrial environment. The PNEC values from both the aquatic and terrestrial compartments are mainly adapted from EUs risk assessment reports connected to the “Existing Chemicals” program. These PNEC values are usually estimated by using available data from toxicity tests of relevant species from the terrestrial or aquatic environment, including plants, algae, invertebrates and microorganisms. When data are scarce, No Observed Effect Concentration (NOEC) or Effect Concentration (EC_{50} - Effect Concentration affecting 50% of tested individuals) for the most sensitive organism/species are used and PNEC is estimated with a high assessment factor (AF). The AFs were developed as a way of accounting for the several levels of uncertainty.

For the aquatic environment, a PNEC can be derived that, if not exceeded, ensures an overall protection of the environment. For many substances however, the pool of data from which to predict ecosystems effects is limited (f.i. only short term toxicity data available). Therefore AF must be used. The size of these depends on the confidence with which a PNEC can be derived from the available data. The assessment factors are as follows:

Table 9. Assessment factors (AF) used to derive PNEC values for the aquatic environment, according to the TGD**.**

Available data	**Assessment factor (AF)**
At least one short term $L(E)C_{50}$ from each of three trophic levels of the base-set (fish, *Daphnia* and algae)	1000
One long-term NOEC (either fish or *Daphnia*)	100
Two long-term NOECs from species representing two trophic levels (fish and/or *Daphnia* and/or algae)	50
Long-term NOECs from at least three species (normally fish, Daphnia and algae) representing three trophic levels	10
Species sensitivity distribution (SSD) method	5-1 (to be fully justified case by case)
Field data or model ecosystems	Reviewed on case by case basis

If a large data set from long-term tests for different taxonomic groups is available, statistical extrapolation methods may also be used to derive PNECs. The effect assessment (with assessment factors) can be supported by a statistical extrapolation method if the database on Species Sensitivity Distributions (SSDs) is sufficient for its application. Environmental NOELs (No Observed Effect Levels) are predicted based on the distribution of the measured dose-effect relations. The uncertainty related to PNEC derived by this method is generally considered to be lower than for PNECs derived by dividing the NOEC from one species with an assessment factor and therefore have a lower assessment factor (Table 10).

When only aquatic PNEC values are available, a terrestrial PNEC can be calculated from the aquatic PNEC. These calculated PNEC values might be regarded as more uncertain than the others since there are no toxicology data from environmentally relevant species available. The PNEC values used in the present risk assessment are given in Table 10 and Table 11. If the predicted environmental concentrations (PEC) are below the PNEC, the risk related to the chemical in question is considered to be low.

Grazing animals and animals eating feed

For the farm animals, values for their tolerable intake of substances based on risk assessment do not excist in a similar manner as for humans. Thus, the hazard characterizations in relevant species are based on original toxicological studies or reviews. Often, there is lack of relevant studies available for the substances and animal species of concern.

Human risk characterization

For humans, available values for tolerable daily intake (TDI) or equivalent are used for substances where this is available. For other substances, for which such values are unavailable, other approaches such as a margin of exposure (MOE) are used. These safety values are given in Table 12 and Table 13.

5.1.1. Effects on plants and soil living organisms (exposure routes 1-2)

The soil community is a functional unit that handles the production and decomposition of plant organic matter. The community includes microorganisms (bacteria, fungi and protozoan's), soil invertebrates (annelids, arthropods, nematodes, mites etc) and terrestrial plants. Recycling nutrients is a key function in nature and avoiding detrimental effects on the soil community is therefore crucial. In addition to the ecological aspect, direct negative effects on plants may cause reduced crop yield and quality.

Enhanced soil concentrations of contaminants may have negative impact on the survival, growth or reproduction of soil organisms that are the most commonly used endpoints for toxicity testing. Microorganisms are central to nutrient cycling, where the C- and N-cycles are represented in standard toxicity tests. To calculate a PNEC for soil living organisms, toxicity data on at least one invertebrate, one plant and one microbial process are recommended (EC, 2003).

All the PNEC values used here are taken from international risk assessment reports, preferably within the European Risk Assessment programme, but other sources are used where EU risk assessment reports were not currently available. These risk assessments are the result of comprehensive data compilations where individual test results are subject to an assessment of quality and relevance, and a subsequent derivation of a PNEC value. In cases where several PNEC values representing different soil types are suggested, a conservative value, which is relevant to Norwegian conditions, is selected.

5.1.1.1. Inorganic contaminants

For most of the relevant metals in sewage sludge, toxicity data for soil organisms are available and a PNEC value can be calculated either by use of an appropriate assessment factor or by statistical derivation from species sensitivity distributions (SSD method).

For zinc, lead, copper, cadmium and nickel toxicity data on several trophic levels were available and their PNECs were calculated by the SSD method. Individual references are given in Table 10, and readers are referred to individual references for further information on toxicity data evaluation. For mercury and chromium, less data were available and PNECs were calculated by the use of assessment factors. Chromium may be present in soil as either chromium (VI) or chromium (III), but the EU risk assessment states that once released into soil; it is likely that much of the chromium (VI) present will be reduced to chromium (III). Toxicity data are available for chromium (VI) and are likely to be influenced by the rapid conversion to chromium (III) in soil.

Direct toxicity to plants may be seen as inhibition of germination and growth, root damages, chlorosis (loss of chlorophyll), necroses or wilting of leaf tips and edges. Excess accumulation of one trace metal may sometimes appear as a deficiency symptom for another trace element due to antagonistic effects, i.e. competition between ions during uptake. The degrees to which metals are taken up and transported within the plant differ between metals and plant species. This has implications both for phytotoxic effects and for metal concentrations in plant tissue used for feed and food (see Chapter 5.3.).

Table 10. PNEC values (mg kg^{-1} soil DM) for inorganic and organic contaminants in soil and the AF used. PNEC values are all taken from international risk assessment reports (see individual references for detailed information). When several PNEC values were available, values considered to be the most relevant for Norway, based on soil characteristics, were selected.

Compound	**PNEC soil (mg/kg DW)**	**AF**	**Species**	**Source**
Cd	1.15	2	*SSD**	European Chemicals Bureau, 2007.
Pb	166	2	*SSD*	EURAS, 2008.
Hg	0.3	1000	*Soil background*	Euro-Chlor, Voluntary risk assessment, Mercury, 2004.
Ni	50	2	*SSD*	Danish Environmental Protection Agency, 2006.
Zn	26	2	*SSD*	VROM, 2008.
Cu	89.6	2	*SSD*	European Copper Institute, 2008.
Cr III	62	1	$PNEC_{water}$	European Chemicals Bureau, 2005.
Cr VI	0.035	10	*Plants*	
DEHP	>13	10	Plants	European Chemicals Bureau, 2008.
DBP	2	100	Zea mays	European Chemicals Bureau, 2004.
Octylphenol	0.0067**	EqP	*Apporctodea calignosa*	Environment Agency (UK), 2005.
Octylphenoletoxilate	-	-	-	No PNEC available
Nonylphenol	0.3	10	*Apporctodea calignosa*	European Chemicals Bureau, 2002.
Nonylphenoletoxilate	-	-	-	-
LAS	35	1	SSD	HERA, 2007.
Naphthalene	1.0	10	*Folsomia* candida	European Risk Assessment Report, 2006.
Anthracene	0.13	50	*F. fimetaria*	
Phenanthrene	1.8	10	*F. fimetaria*	
Fluoranthene	1.5	10	Nitrification	
Pyrene	1.0	10	*F. candida*	
9H-Fluorene	1.0	10	*F. fimetaria*	
Acenaphthylene	0.29	100	*F. fimetaria*	
Acenaphthene	0.038	50	***Lactuca sativa***	
Chrysene	0.55*	EqP		
Benzo[*a*]anthracene	0.079	10	*Oniscus asellus*	
Benzo[*b*]fluoranthene	0.28*	EqP		
Benzo[*ghi*]perylene	0.17*	EqP		
Benzo[*k*]fluoranthene	0.27*	EqP		
Benzo[*a*]pyrene	0.053	10	*Porcellio scaber*	
PCB_7	-	-	-	-

*No terrestrial data available. PNEC calculated by equilibrium partitioning theory (EqP) from $PNEC_{aquatic}$.
** The PNEC value for octylphenol is very uncertain. The value is based on EqP from $PNEC_{aquatic}$. In the reference report it is stated that the value for octylfenol is similar to nonylphenol and an expected PNEC would rather be in the same range as $PNEC_{terrestic}$ for nonylphenol (0.3 mg/kg).
- No PNEC available

5.1.1.2. Organic contaminants

Uptake and toxicity of organic chemicals in terrestrial organisms is less studied than for metals, and for some of the contaminants in sludge such information is scarce or non-existent. Where little information is available, estimated PNEC values are either very uncertain or calculation may not be possible. As all PNEC values referred here are thoroughly discussed in the referenced risk assessments, readers are referred to sources for detailed information.

Based on equilibrium partitioning theory (EqP), PNEC values for soil organisms may be calculated based on aquatic toxicity data and the soil – pore water partitioning coefficient. This approach is only used if no terrestrial ecotoxicity data are available, and has been done in the referenced risk assessments e.g. octylphenol and some of the high-molecular PAHs.

5.1.2. Effects on animals and aquatic communities (Exposure route 3-6)

Many metals are toxic to the environment and yet, they are naturally occurring in bedrock, soil and water. Some metals, i.e. copper, chromium, zinc and nickel, are essential elements for animals or plants but they are still toxic when the optimal concentration range is exceeded.

The toxic mechanisms of metals in cells are not fully understood, but generally the metals tend to bind to NH- or SH-groups in proteins. Non-specific binding of metals to an organism results in toxicity due to 1) blocking of the essential biological functional groups of biomolecules, 2) displacing essential metal ions in biomolecules, and 3) modifying the active conformation of biomolecules (Ochiai, 1977).

5.1.2.2. Aquatic organisms

Inorganic contaminants

Heavy metals are more or less toxic to all groups of aquatic organisms, but some general differences in sensitivity are often seen. It is commonly accepted that mechanisms of metal toxicity in algae are very different from those observed in fish and invertebrates. This seems logical, as the border between the intra- and extra-cellular environments in algae is not a gill but is generally composed of a polymeric cell wall and a plasma-membrane (European Copper Institute, 2007).

Metals are present as various species in water. The free ionic form is generally the most biologically available and hence, the most toxic form. Inorganic complexes i.e. with hydroxide and carbonate which are formed in natural surface water are in general less toxic. Complexation of metals with organic matter in the form of humic and fulvic acids also tends to reduce the biological availability. The pH-value plays an important role in modifying the aquatic toxicity of metals since it affects the chemical specification. In addition, H^+-ions may compete with the metal ions in binding to the biological ligands or uptake sites on the organisms. Similarly other cations like Ca^{2+} and Mg^{2+} (i.e. the water hardness) generally reduces the uptake of metal ions by competition. Models known as Biological Ligand Models (BLM) have been developed to predict the complex interactions between abiotic factors such as water hardness, pH and dissolved organic matter with the toxicity of various metals (Di Toro *et al.*, 2001).

For metals occuring in different oxidation states, differences in properties of these have to be accounted for. Chromium occurs as chromium III or chromium VI in the environment. While chromium III is an essential element in animal nutrition, chromium (VI) compounds are not thought to be nutritionally useful forms of chromium. Due to the high mobility (bioavailability) in biological systems and powerful oxidising properties of chromium (VI) compounds, these are considered to be much more toxic to biological systems than the chromium (III) forms (European Chemicals Bureau, 2005).

Mercury may be transformed to methyl mercury by microbial metabolism in anaerobic environments like sediments. Both forms of mercury are toxic to aquatic organisms. Mercury is readily absorbed in tissues and in particular methyl mercury is accumulated in food chains.

Organic contaminants

The organic contaminants in sewage sludge included in this risk assessment have generally a low solubility in water. In spite of this, water and aquatic organisms are important for transport and distribution of these contaminants in the environment. The organic contaminants may bioconcentrate in aquatic organisms and reach levels cause acute or chronic toxic effects even if the concentrations in the water phase are low. Persistent contaminants not readily excreted may bioaccumulate in food chains.

Many lipophilic organic contaminants, e.g. PAHs and PCBs do not affect specific organs, organ systems or biochemical pathways. Rather, they cause reversible dysfunctions (Van Wezel & Opperhuizen, 1995). Some of the most hazardous pollutants have additional specific modes of toxic action. PCB congeners with a planar configuration bind to a specific receptor (Ah-receptor), which causes changes in gene expression, affecting cell growth, form and function (Bernes, 1998).

PAHs are known for their photoinduced toxicity (Arfsten *et al.*, 1995). This may occur by photosensitization or photomodification. Photosensitization generally leads to the production of singlet oxygen, a reactive oxygen species (ROS), which is highly damaging to biological molecules. Photomodification of PAHs, usually via oxygenation, results in the formation of new compounds (oxyPAHs), and can occur under environmentally relevant levels of actinic radiation (Lampi *et al.*, 2006).

Some pollutants e.g. alkylphenols and phthalates have endocrine disrupting properties, which may cause various physiological and behavioural effects in animals (White *et al.*, 1994).

PNECs are available for most of the selected components from risk assessments carried out under the European programme for existing chemicals or from the Water Quality Standards (WQS) that have been developed for priority substances under the Water Framework Directive. The PNEC and the WQS are assumed to protect from chronic effects from long-term exposure. For those substances not included in the EU risk assessment or water quality standards, PNEC has been obtained from other sources. The proposed PNECs for aquatic life in surface water are compiled in Table 11. For PCBs no PNECs are available and toxicity data are not sufficient for calculation of PNECs for various congeners according to the principles of the TGD.

Table 11. PNECs for the assessed contaminants in the aquatic environment. The PNEC values are extracted from the EU programme for risk assessment when available (published and drafts).

	PNEC ug/L	**Source**
Cadmium	0.08[2]	EU RAR, (European Chemicals Bureau 2007)
Lead	7.2	
Mercury	0.047+BC	WQS (Lepper 2002)
Nickel	5[4]	EU RAR, (Danish Environmental Protection Agency 2006)
Zinc	7.8+BC	EU RAR, (TNO/RIVM 2008)
Copper	7.8[3]	EU RAR, (European Copper Institute 2007)
Chromium	3.4	EU RAR, (European Chemicals Bureau 2005)
DEHP	n.c. [1]	EU RAR, (European Chemicals Bureau 2008)
DBP	n.c. [1]	EU RAR, (European Chemicals Bureau 2004)
Octylphenol	0.12	WQS (Lepper 2002)
Octylphenoletoxilate	3.5	Calculated from LC50 (fish): 3.5 mg/l (ECOTOX)
Nonylphenol	0.33	WQS (Lepper 2002)
Nonylphenoletoxilate	125	Calculated from NOEC (frog): 1.25 mg/l (ECOTOX)
LAS	0.27	HERA (2007)
Naphtalene	2.4	WQS (Lepper 2003)
Acenaphtylene	1.3	EU RAR, (The Netherlands 2008)
Acenaphtene	3.8	EU RAR, (The Netherlands 2008)
Fenantrene	1.3	EU RAR, (The Netherlands 2008)
Antracene	0.1	EU RAR, (The Netherlands 2008)
Fluorene	2.5	EU RAR, (The Netherlands 2008)
Fluoranthene	0.1	WQS (Lepper 2002)
Pyrene	0.023	EU RAR, (The Netherlands 2008)
Benzo(a)anthracene	0.012	EU RAR, (The Netherlands 2008)
Chrycene	0.07	EU RAR, (The Netherlands 2008)
Benzo(b)fluoranthene	0.03	WQS (Lepper 2002)
Indeno (1,2,3-cd)pyrene	0.006	WQS (Lepper 2002)
dibenzo(a,h)antracene	0.0014	EU RAR, (The Netherlands 2008)
Benzo(g,h,i)perylene	0.006	WQS (Lepper 2002)
Benzo(a)pyrene	0.05	WQS (Lepper 2002)
PCB_7	-	-

[1] No PNEC derived because of lack of toxic effects at the limit of solubility
[2] Proposed PNEC for soft water
[3] Proposed PNEC for most sensitive EU scenario (HC5/1)
[4] Proposed PNEC for most sensitive EU scenario (HC5/2)
- No PNEC available

5.1.2.3. Animals eating pasture and feed

Inorganic contaminants

The trace elements boron (B), cobalt (Co), chromium (Cr), copper (Cu), fluor (F), iodine (I), iron (Fe), manganese (Mn), molybdenum (Mo), selenium (Se), silicium (Si), and zinc (Zn) are known to be required by animal species for normal life processes. In addition, some other trace elements may also be required, based on limited evidence obtained with one or more animal species.

However, the animal intake of required trace elements should anyway be below certain limits as all inorganic elements as most other nutrients may be unhealthy or even toxic to animals when ingested in excess amounts.

The margin between the minimum amount required in the diet and amount that produces adverse effects varies among the elements and according to conditions. Thus a wide array of trace elements may imply a possibility of toxicity to animals. However, we will focus on those elements that may represent more pressing practical problems for animal as well as human health and about which considerable knowledge is available. These toxic elements include Cd, Pb and Hg. Furthermore excess of Mo in the plants may create disease in grazing animals as it interferes with Cu uptake and produces a secondary deficiency of Cu in grazing animals. On the other hand, low Mo related to Cu in plants may create Cu intoxication in sheep in inland areas of Norway. Fluor pollution and intoxication in grassing animals have been a local problem around aluminium melting industry. A toxicological problem of flour via sewage sludge is not likely.

Cadmium is of particular concern due to the in general relatively high uptake in food/feed plants combined with its accumulation and toxicity in animals as well as in humans. The rate of absorption of cadmium in the animal diet depends on occurrence with other trace elements, and the cadmium level may also influence the absorption of other elements, for instance it may reduce the copper absorption in ruminants. The cadmium absorption in animals is usually below 10% (Osweiler, 1996). Upon absorption, cadmium is bound with high affinity to metallothionine (MT), which represents the major transport form as well as maintainins cadmium in the organism. Cadmium accumulates in the kidney and to a lesser extent in the liver. The cadmium concentrations in muscle and milk are low and usually negligible. Cadmium does not readily cross the placenta (Klaassen, 2008). Cadmium is released by lysosomal enzymes and particularly in proximal tubular cells. Thus, kidney damage is the primary effect of Cd exposure. Furthermore, Cd exerts a variety of other toxic effects including osteoporosis, neurotoxicity, carcinogenicity and genotoxicity, teratogenicity, and endocrine and reproductive effects. In most domestic animal species, distinct clinical symptoms are unlikely to occur if dietary Cd concentration is below 5 mg/kg feed (EFSA, 2004a). However, as Cd disposition is significantly influenced by dietary interactions with other elements as Zn, Cu, Fe and Ca, in some cases even lower Cd concentration in the feed may induce adverse effects. The present maximum level for Cd set by EU in complete feeding stuffs is 0.5 mg/kg (at moisture content of 12%) for most animal species and 1.0 mg/kg for adult ruminants.

Lead toxicity affects several organs and tissues. A main effect is microcytic, hypochromic anemia as a result of decreased survival time of red blood cells with excessive hemolysis and a decrease in red blood cell formation from a block in the heme synthesis. In the kidneys, pathological changes occur resulting in an amino aciduria, glucosuria and hyperphosphaturia. In the stomach and small intestine, necrosis, hemorrhage and ulceration occur. In the brain, petechial hemorrhages and loss of myelin from nerve sheaths, and after long term exposure cerebrocortical softening, are reported. Lead intoxication also affects the skeleton, causing osteoporosis - reduced bone matrix formation and excess resorption of mineral bone. Enlarged joints commonly occur in lead intoxicated pigs and horses. The absorption from the gastrointestinal tract is variable but generally low (usually <10%) (Osweiler, 1996; Mertz, 1986). It may vary with a range of factors, among which other minerals as calcium are the most important. Young animals may show higher absorption (up to 50%). Lead is transported in the red blood cells, and stored in liver and kidney and finally in the bones. Limited evidence suggests that lead is excreted in milk in a ratio that equals approximately 5% of the blood concentration. Lead crosses the placenta and the foetal blood level correlates with the maternal level, but may be some what lower (Klaassen, 2008). A reliable estimate of dose-dependent effects is regarded as impossible due to lack of data (EFSA, 2004b). Lambs born from ewes exposed to a sub-clinical dose of 4.5 mg/kg dry matters feed during gestation, showed decreased learning at one year of age (Carson *et al.*, 1974). For adult cattle, 100 mg/kg diets have been estimated as a maximum tolerable level (Bellof *et al.*, 2000). The present limit for lead in feed materials and complementary feed is 10 mg/kg (at moisture content of 12 %) with the exception for green fodder (40 mg/kg), and 5 mg/kg for complete feeding stuff.

Mercury combines preferentially with –SH groups and thus inhibits enzyme systems containing such groups. Mercury accumulates in the cells´ lysosomes and may be associated with their rupture and thus destruction of cells. Mercury intoxication produces tissue necrosis, particularly of the tubuli of the kidneys. Selenium protects against this effect probably via formation of relatively insoluble selenium- mercury compounds of low toxicity. Organic alkylmercury interferes with metabolic activity and prevents synthesis of essential proteins, leading to cellular degeneration and necrosis. The brain is the most important target organ for alkylmercury. Inorganic mercury are absorbed from the gastrointestinal mucosa at 7-15%, transported in red blood cells and in particular accumulated in the renal cortex (Klaassen, 2008; EFSA, 2008a). Inorganic mercury does not readily pass into the brain or cross the placenta barrier. The distribution into milk and eggs seems to be limited. Alkylmercury are highly absorbed (>90%) and distributed to all tissues including the muscles. Relatively high concentration is found in the brain. Methyl mercury has been shown to cross the placenta barrier and may also more easily than inorganic mercury distribute into milk and eggs. High levels of methyl mercury are found in hair. For calves, yearling cattle, young pigs and chickens, NOAELs for methyl mercury have been derived at 5.0, 11, 3.4, and 2.2 mg/kg feed, respectively (corresponding to 0.1, 0.23, 0.19 and 0.22 mg/kg b.w. per day, respectively). These animals were exposed for 90, about 60, 60 and 33 days, respectively. A LOAEL have been derived for yearling sheep at 7.7 mg/kg feed (0.23 mg/kg b.w. per day) when exposed for 42-59 days. The main clinical symptoms were manifestations on dysfunction of the central nervous system with ataxia and incoordination, as well as digestive, genito-urinary and skin problems (reviewed by EFSA, 2008). For inorganic mercury, chronic toxicity was observed following ingestion 0.4 mg/kg b.w. per day over a period of several weeks in a horse (Guglick *et al.*, 1995). The main clinical signs were renal failure and ulceration of the digestive tracts. The present limit for mercury in vegetable feed materials and complete feeding stuff is 0.1 mg/kg (at moisture content of 12 %), and complementary feeding stuff 0.2 mg/kg.

Nickel has low toxicity and generally above 250 mg/kg diet is required to produce signs of toxicity in various animal species (Mertz, 1987). Essentiality of nickel in higher animals is questionable. It has low absorption via food (about 1%).

Zinc participates in a wide variety of metabolic processes, supports a healthy immune system and is essential for normal growth and development. Acute toxicity from excessive ingestion is uncommon but gastrointestinal distress and diarrhea has been reported following ingestion of beverages standing in galvanized cans. Following long-term exposure to elevated doses of zinc, symptoms generally result from decreased dietary copper absorption and early symptoms of copper deficiency. The absorption from the gastrointestinal tract is homeostatically regulated. About 20-30% of ingested zinc is absorbed (Mertz, 1986; Pond *et al.*, 1995).

Copper is primarily absorbed in the small intestine, and the absorption shows high variability due to dietary factors, in ruminants first of all dependent on the molybdenum and also of sulphur concentrations. It is transported in the blood with selected proteins. Copper is utilized by essentially every cell in the body bound to various copper dependent enzymes. Copper may accumulate in the liver in sheep. Even normal levels of copper in feed (10-20 mg/kg) may cause hepatic accumulation when the molybdenum level in the feed is low (less than 1 mg/kg). As the copper: molybdenum increases above 6:1, the risk of copper accumulation increases, and diets whose ratio is above 20:1 is very dangerous for sheep (Mertz, 1987; Pond *et al.*, 1995; Radostits *et al.*, 2007). Toxic liver accumulation of copper can develop over a matter of weeks before a haemolytic crisis may be released in affected animals. Affected animals show weakness, anorexia, icterus, pale mucous membranes and dyspnoea. Cattle are normally far less sensitive to copper. Pigs and poultry also appear to be relatively tolerant of high dietary copper. In pigs, 250 mg/kg feed and above produced liver toxicity wity jaundice (Suttle & Mills, 1966). The effects were eliminated by providing additional levels of zinc and iron. In poultry, 500 mg/kg feed slowed growth and egg production (Jensen & Maurice, 1979). Acute intoxication after short time exposure with copper is not relevant in concern of use of sewage sludge. The general range for acute effects in various species is 25-50 mg/kg b.w.

Chromium (trivalent) is an essential trace nutrient important for glucose metabolism. It has low absorption (0.5-2%) and low toxicity. It is unlikely to be a toxicological problem in farm animals via use of sewage sludge. Hexavalent chromium is more toxic and has a higher absorption (2-10%). Accidental ingestion of high doses may cause renal failure but kidney damage from lower-level chronic exposure is equivocal (Mertz, 1987).

Organic contaminants

As present elsewhere in the report, organic contaminants of concern in general show a low or even negligible plant uptake. Thus, the animal exposure to these contaminants via plant uptake may be low in relation to the potential concentrations available in the sewage sludge treated soil. However, the organic compounds may also contaminate the surface of the growing plants. Furthermore, when high concentrations are present in the sewage sludge and then in the soil, the plant uptake of various organic compounds may potentially anyway be considerable and constitutes a potential risk for animal health and carry-over to food products of animal origin. In addition grazing animals ingest soil particles. These hazards are therefore characterized as far as found relevant and possible from available data for animals eating pasture and feed.

The phthalates DBP and DEHP are lipophilic and have antiandrogenic action. Adverse effects are documented after *in utero* exposure in experimental animals. Underdevelopment of reproductive tissue of male offspring was found when rats were exposed to DBP at daily oral dosage levels of 50-100 mg/kg b.w. from day 10 to 22 of gestation (reviewed in Klaassen, 2008). A significant but low incidence of similar effect was found after exposure of DEHP at 11 mg/kg b.w. and above.

Male piglets were exposed orally three times weekly to 300 mg/kg b.w. of DEHP between 3 and 7 weeks of age and compared with controls in a split-litter design to study endocrine, morphological and behavioural effects related to reproductive development (Ljungvall *et al.*, 2006; Ljungvall *et al.* 2008). Lasting effects on the hypothalamus-pituitary-gonadal axis were suggested, as well as precocious maturity of bulbourethral glands with persistent effects lasting into adulthood. To study kinetics of DEHP, male piglets were treated with a single oral dose at 1000 mg/kg b.w. (Ljungvall *et al.*, 2004). The parent compound did not consistently rise in the blood above control level but its metabolite mono(2-ethylhexyl)phthalate (MEHP) reached the systemic blood circulation. The halvlife of MEHP in the blod was about 6 hours.

Alkylphenols and their ethoxylates are lipophilic substances exerting apparent estrogenic action in *in vitro* and *in vivo* testing systems. A 3-day uterotropic assay in prepubertal rats (three days oral exposure) revealed significant increased uterine weight for 4-tert-octylphenol (OP) at 100 mg/kg b.w. and above per day, and for 4-nonylphenyl at 50 mg/kg b.w. and above per day (Laws *et al.*, 2000).

The effects of intrauterine exposure to OP on reproductive parameters were studied over 3 generations in pigs (Bøgh *et al.*, 2001). Sows were treated daily from day 23 to 85 of pregnancy with 0, 10 or 1000 µg/kg b.w. Treatment with OP extended pregnancy length and induced basal cell proliferation in the cervical epithelium of the parental generation in a dose dependent way. In F1 offspring of sows treated with the low dosage of OP, onset of puberty was accelerated, and when F1 offspring (gilts and boars) from the high dosed sows were bred, they got reduced litter size.

Sweeney *et al.* (2000) examined the pituitary gland and testes from lambs exposed *in utero* when the ewes were injected subcutaneously twice weekly with OP equivalent to 1 mg/kg b.w. per day from day 70 of gestation to birth. The treatment suppressed FSHβ-messenger RNA levels and the number of FSHβ-immunopositive cells in the pituitary gland and reduced testis weight and its number of Sertoli cells. In another experiment by the same group, ewes received a continuous infusion of OPl at 1 mg/kg b.w. per day from days 110-115 of gestation. The foetuses were chronically catheterized *in utero* and blood was sampled to monitor gonadotropin secretion. The FSH concentration was suppressed but no effect was revealed on the LH concentration.

Ewes were twice weekly injected subcutaneously with OP equivalent to 1 mg/kg b.w. per day from day 70 of gestation to birth or to weaning, or from birth to weaning to study the reproductive development in ewe lambs (Wright *et al.*, 2002). All treatment intervals advanced the onset of puberty but did not disrupt FSH concentrations or the dynamics of ovarian follicular growth. The same treatment protocol was used by Sweeney *et al.* (2007) to study FSH concentrations and semen quantity and quality in postpubertal rams. The maternal pre- and/or postnatal exposure to OP did not affect FSH concentrations, semen volume, percentage live, motility or *in vitro* maturation/fertilisation characteristics, but exposure from birth to weaning increased the number of morphologically abnormal sperm cells in the rams′ ejaculates.

To conclude, exposure to the phthalates DBP and DEHP, and to the alkylphenols and their ethoxylates during fetal or postnatal development may be the most senstive time periods for longstanding effects still present when adult.

LAS has minimal uptake in plant roots and tubers of various plants. The transport to the stem and leaves is negligible. The risk of subsequent LAS transfer to animals and humans has also been evaluated to be minimal (Schowanek *et al.,* 2007).

PCBs accumulate in lipid tissue and tend to biomagnify primarily in the marine food web. PCBs in plants grown on sewage sludge treated soil and used as pasture and feed are unlikely to reach concentrations implying adverse effects in farm animals or significant residues in products. However, residues in eggs and fat could constitute a problem if contaminated soil is available for poultry and pigs. But sewage sludge is probably not used in such areas. A no observable adverse clinical effect level for PCB (Aroclor 1254) of 5 mg/kg diet in broiler chicken has been found. In pigs, 20 mg/kg diet (42 and 54% chlorine) was found to elicit effects on weight gain and foetotoxicity. In lambs, 20 mg/kg diet (42 and 54% chlorine) was found to reduce feed efficiency and the rate of weight gain (reviewed by EFSA, 2005a). The transfer rate to milk for PCBs in ruminants varies from 5-90% (Rychen *et al.*, 2008). Van Eijkeren et al. (2006) reported a transfer rate into hens′ eggs at 53 and 59%, respectively, for two of the main PCB congeners (PCB-138 and -153) and 49% for the most toxic congener (PCB-126). In growing animals continuously exposed to PCB, the PCB concentration in the fat compartment will continuously increase and steady state conditions will not be obtained (EFSA, 2005a).

Polycyclic aromatic hydrocarbons (PAHs) suppress the immune system, and metabolism via cytochrome P450 releases potentially carcinogenic and mutagenic metabolites (Klaassen, 2008). The acute toxicity is low, oral LD_{50}s of the representative compound pyrene in rats and mice are 2700 and 800 mg/kg, respectively (Wexler, 1998). The knowledge of potential effects of PAHs in livestock is scarce. The PAHs are lipophilc and temporarily distributed into lipid rich tissues before metabolism and potentially covalently binding to tissue constituents such as proteins and nucleic acids, or expression in urine or faeces. Protein-bound metabolites are likely to persist, for periods that do not exceed the normal lifetime of the protein itself. The whole body distribution of PAHs has been studied extensively only in rodents. Sufficient information about PAH concentrations in farm animal organs and tissues related to exposure levels are not available. Concentrations of PAHs have been measured in various organs of pigs and cattle (Von Lucky *et al*., 1992; Ciganek & Neca, 2006) but it is not possible to relate these levels to quantified intake. The transfer of PAH compounds into milk has been studies in lactating goats after oral ingestion (Grova *et al.*, 2002; Grova *et al.,* 2006; Grova *et al.,* 2008). The milk transfer varied from negligible to considerable for the various PAHs. When present, the hydroxylated metabolites dominated. During oral administration of a mixture of PAHs at 20 µg/kg b.w. per day for 28 days, monohydroxylated fluorene and –phenanthrene reached maximum during the first exposure week at 0.41 and 0.22 µg/L, respectively, whereas hydroxylated pyrene reached maximum of 0.97 µg/L after 14 days. Studies of milk transfer in goats after single oral exposure of C-14 labelled compounds have revealed rather low milk transfer for phenanthrene and pyrene (1.6-1.9%) and below detection limit for benzo-a-pyrene (<0.2%), when compared to that of 2,3,7,8-TCDD, which was mainly excreted in milk (7.8%) (Grova *et al.*, 2002). Rychen *et al.* (2008) indicate a transfer rate of PAHs to milk of 0.5-8%. A study of exposure pathways of PAHs for farm animals has identified the feed as the major source (Ciganek *et al*., 2002). As PAHs have carcinogenic potencies the levels in animal feed and their remaining environment should be as low as possible.

5.1.3. Effects on humans (exposure route 7-12)

Human exposure to contaminants from the different exposure routes (food and drinking water) is summarized and the estimated intakes are compared to the tolerable daily intake (TDI), tolerable upper intake level (UL)[1] or equivalent toxicologically derived limits. Tolerable weekly intake (TWI) is used for persistent compounds. TDIs (TWIs) set by international scientific committees such as WHO/FAO Joint Expert Committee for Food Additives and Contaminants (JEFCFA), European Food Safety Authority (EFSA), EUs former Scientific Committee for Food (SCF) will be used for substances where such internationally derived values are available.

For substances where no TDI or TWI has been derived, the significance of the sludge-related human intake will be compared to a margin of exposure (MOE) for some substances. This approach will be used for substances where previous international or national evaluations based on MOE are available (e.g. NDL-PCBs, octylphenol, PAHs). Margin of exposure (MOE) is based on the margin between the estimated exposure and the available no observed effect level (NOEL) or lowest observed effect level (LOEL) from experimental studies or epidemiological observations.

For substances where an internationally derived TDI/TWI/UL or MOE is not available, a national derived value will be used when available.

5.1.3.1. Inorganic contaminants

Cadmium is absorbed in the intestines and accumulates in the kidneys and liver in particular. The metal is excreted slowly (the biological half-life is 10-30 years) and is accumulated with age. The largest concentration can be found in the cortex of the kidney. The effects of cadmium have been well-documented in a number of experimental and epidemiological studies (WHO-IPCS, 1992). Kidney damage with proteinuria is the primary effect of exposure to cadmium, sometimes accompanied by perturbation of calcium and vitamin D metabolism, which may lead to loss of bone mass and possibly osteoporosis. Long-term effects have also been observed in the liver, in the organs associated with blood formation, the immune system and the cardiovascular system.

A tolerable weekly intake (TWI) set by EFSA at 2.5 µg/kg body weight on the basis of studies on humans has been used in the evaluation (EFSA, 2009).

Lead accumulates in several tissues and organs of the body, and the intake of lead may result in many different toxic effects, i.e. on the nervous system, blood formation and the kidneys. The most important target following long-term, low level exposure to lead is the nervous system.

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[1] "The maximum level of total chronic daily intake of a nutrient (from all sources) judged to be unlikely to pose a risk of adverse health effects to humans. 'Tolerable intake' in this context connotes what is physiologically tolerable and is a scientific judgement as determined by assessment of risk, i.e. the probability of an adverse effect occurring at some specified level of exposure. ULs may be derived for various life stage groups in the population. The UL is not a recommended level of intake. It is an estimate of the highest level of intake which carries no appreciable risk of adverse health effects. To establish whether an exposed population is at risk requires a risk assessment to determine what is the fraction (if any) of the population whose intake exceeds the UL and the magnitude and duration of the excessive intake" (SCF, 2000).

Small children, and foetuses in particular, are most vulnerable, and exposure to lead may result in impaired development of cognitive functions (learning ability) and motor skills. The mechanism underlying the neurotoxicity of lead is that lead passes easily through the blood-brain barrier, causing cell death and interference with the transfer of signals between nerve cells and in support cells. Lead is not genotoxic, but it can cause tumours in laboratory animals. Due to the effects of lead on children and foetuses, the provisional tolerable weekly intake (PTWI) was set at 25 µg/kg body weight by JECFA in 1986. The PTWI was based on studies on lead in children and was set with the aim of avoiding the accumulation of lead in the body. In 1993 and 2000 JECFA confirmed this PTWI value and expanded it to include all age groups (WHO, 1993; WHO, 2000).

<u>Mercury:</u> There are different forms of mercury, both inorganically and organically bound. Methyl mercury is absorbed in the intestine (95%), crosses the placenta and blood-brain barrier and is also excreted in breast milk. The average half-life is 70 days in adults (JECFA, 2003). Methyl mercury is neurotoxic and the foetal brain is especially vulnerable. Increased concentrations of methyl mercury may result in impaired cognitive skills as well as motor skills. In 2003, JECFA revised its earlier assessment of mercury. The previous PTWI value for methyl mercury was reduced from 3.3 to 1.6 µg/kg body weight (JECFA, 2003). PTWI for total mercury was maintain at 5 µg/kg body weight.

<u>Nickel</u>: Nickel has not been shown to be essential for humans. Absorbed nickel is mainly excreted in the urine, but to a minor extent also in bile and sweat. It is secreted into human milk (Heseker, 2000). Orally ingested nickel salts can cause adverse effects on kidneys, spleen, lungs and the myeloid system in experimental animals. Furthermore, perinatal mortality was reported to be increased in the offspring of female rats ingesting nickel salts, even at the lowest administered dose (1.3 mg nickel/kg body weight/day). While there is evidence that inhaled nickel salts are carcinogenic in rodents and humans, orally ingested nickel salts have not been shown to be carcinogenic; however the data presently available are very limited (EFSA, 2005b). Individuals sensitized to nickel through dermal contact and who have allergic contact dermatitis develop hand eczema from oral, as well as dermal, exposure to nickel salts. Oral intakes of nickel as low as about 500 microgram/day (about 8 microgram/kg body weight/day) have been reported to aggravate hand eczema in nickel sensitized subjects. In the absence of adequate dose-response data for these effects, it is not possible to establish a tolerable upper intake level (EFSA, 2005b)

The Panel on Nutrition, Dietetic Products, Novel Food and Allergy of VKM has also evaluated nickel and they concluded as follows: “As nickel has not been shown to be essential for humans and has no nutritional value, and since nickel may inhibit the absorption of divalent essential metals, excessive intake from fortified foods and food supplements should be avoided until a tolerable upper intake level can be established. Nickel should not be permitted in supplements or fortified foods“ (VKM, 2008a).

<u>Zinc</u>: Zinc is an essential element in the nutrition of mammals. It has been identified as an integral part of numerous enzyme systems. The absorption of ingested zinc is highly variable and a number of dietary factors have been found to interfere with the absorption of zinc both in experimental animals and humans. High zinc concentrations are found in prostate, bone, muscle and liver. The excretion takes place mainly via the gastrointestinal tract, and to a smaller extent via urine and sweat. The biological half-life of zinc in humans is in the order of 1 year.

Zinc is not stored in the body, and excess intakes result in reduced absorption and increased excretion. Most reports on toxic effects of zinc in humans relate to acute effects such as nausea, vomiting, epigastric pain, abdominal cramps and diarrhoea, and are usually associated with the ingestion of acid drinks or food that have been stored in galvanized vessels. In humans, the most prominent effects of acute zinc toxicity are gastrointestinal disturbances. The emetic dose of zinc has been estimated to correspond to 225-450 mg (Fosmire, 1990). These effects are due to acute irritation in the gastrointestinal tract.

Chronic zinc toxicity is associated with symptoms of copper deficiency. Adverse effects, such as anaemia, neutropaenia and impaired immune response, are evident only after intake of zinc in the form of dietary supplements in excess of 150 mg/day for long periods (SCF, 2003a)

Scientific Committee on Food (2003) expressed an opinion on the UL of zinc in 2003. A NOAEL of 50 mg/day based on the absence of any adverse effects on a wide range of relevant indicators of copper status (as the critical point) was used in their derivation of an UL. They established an UL for adults, including pregnant and lactating women, of 25 mg Zn/day by applying an uncertainty factor of 2 to the NOAEL of 50 mg/day (SCF, 2003a).

Copper: Copper is both an essential nutrient and a drinking water contaminant. Copper in living organisms, including humans, forms an essential component of many enzymes (cuproenzymes) and proteins, and the biochemical role for copper is primarily catalytic. The primary sources of copper exposure in developed countries are via food and water. After oral exposure in mammals, absorption of copper occurs primarily in the upper gastrointestinal tract and the majority of copper is transported to the liver. Excretion in the bile is the main route of elimination in humans with only minor amounts being excreted in the urine (SCF, 2003b).

Available data clearly show that copper can cause adverse effects in humans. The occurrence of either acute or chronic systemic copper toxicity in humans, however, is rare, and tends to be confined to certain subpopulations, such as populations with high copper concentrations in drinking water, populations that utilise copper vessels e.g. for boiling and storing milk, and those individuals who have a hereditary predisposition to copper toxicity (SCF, 2003b).

Scientific Committee on Food (2003) expressed an opinion on the UL of copper in 2003 (SCF, 2003b). Liver damage in humans was selected as the critical endpoint because it perhaps is a more reliable indicator of long-term chronic ingestion of cobber than local gastrointestinal effect. A NOAEL of 10 mg/day was based on the absence of any adverse effects on liver function as the critical endpoint in humans. SCF derived an UL for adults of 5 mg/day based on the NOAEL of 10 mg/day and an uncertainty factor of 2 to allow for potential variability within the normal population. The UL of 5 mg/day was not considered applicable during pregnancy or lactation due to inadequate data related to this critical life stage (SCF, 2003b).

Chromium: Chromium is ubiquitous, occurring in water, soil and biological systems. It occurs in two main forms; trivalent chromium (CrIII) and hexavalent chromium (CrVI). Analytical results of earth samples are often given as total amount of chromium. Chromium may be present in soil as either Chromium VI or Chromium III, but it is likely that much of the Chromium VI present will be reduced to Chromium III.

SCF evaluated Chromium III in 2000 and they concluded that there were insufficient data to establish a UL for Chromium III (SCF, 2003c). In 2002 an Expert Group on Vitamins and Minerals in UK (EGVM, 2002a) suggested a guideline level (GL) at 9 mg/day. Based on new scientific literature, the Panel on Nutrition, Dietetic Products, Novel Food and Allergy in VKM encouraged a restrictive GL at 1 mg/day for adults (VKM, 2007). They emphasise that further studies are needed to conclude.

A TDI or UL value set by internationally recognized expert organs are available for several of the metals (Table 12). No such value has been found for nickel and chromium. For chromium a GL value of 1 mg/day has been used.

Table 12. Tolerable weekly intake (TWI), upper intake level (UL) or other safety limits for heavy metals used in this risk assessment.

Metals	TWI/PTWI µg/kg bw/week	UL mg/day	Other safety parameters mg/day	Reference
Cadmium	2.5			EFSA, 2009
Lead	25			JECFA, 2000
Mercury*	5/1.6			JECFA, 2003
Nickel	-	-		
Zinc		25		SCF, 2003a
Copper		5**		SCF, 2003b
Chromium***	-	-	1	VKM, 2007

*Mercury (total)/methylmercury
**The UL of 5 mg/day was not considered applicable during pregnancy or lactation due to inadequate data related to this critical life stage.
***Guideline level (GL)

5.1.3.2. Organic contaminants

DEHP (Bis(2-ethylhexyl)phthalate): In 2005 the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) in EFSA re-evaluated bis(2-ethylhexyl)phthalate (DEHP) for use in the manufacture of food contact materials(EFSA, 2005c). Based on all the available toxicological evidence, the Panel concludes that effects on reproduction and development are the most sensitive end-points on which to base the risk assessment. The Panel considers also that the Wolfe and Layton study (2003) was more robust than those underpinning the previous NOAELs based on reproductive toxicity, and that a NOAEL of 5 mg/kg bw/day related to testicular toxicity can be derived from it.

Based on the above statement, the Panel allocated a TDI of 0.05 mg/kg bw, based on a NOAEL of 5 mg/kg bw/day and making use of an uncertainty factor of 100 (EFSA, 2005c).

Di-butylphthalate (DBP): In 2005 the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) in EFSA re-evaluated di-butylphthalate (DBP) for use in the manufacture of food contact materials (EFSA, 2005d). Based on all the available toxicological evidence, the Panel concludes that effects on reproduction and development are the most sensitive end-points on which to base the risk assessment for DBP.

Previous reviews have identified as pivotal several rat reproduction studies conducted in the last decade, which gave NOAELs or LOAELs in the region of 50 mg/kg bw/day, with the critical effect being on male reproductive development.

A developmental toxicity study in the rat (Lee *et al*., 2004), with dietary exposure to DBP during the period from late gestation (gestational day 15) to the end of lactation (postnatal day 21), has shown effects on the development of male and female offspring at lower doses than those found previously, having examined the development of reproductive tissues in considerable detail at various ages postnatally. Based on loss of germ cell development and mammary gland changes at 20 mg/kg in the diet (the lowest tested dose), EFSA noted that a NOAEL could not be established. However, given the reversibility of the effects at all dose levels and especially at the lowest dose level (20 mg/kg feed, which corresponds to 1.5 to 3 mg/kg bw/day) and also given that in several reproductive toxicity studies with longer exposure periods only approximately 30-fold higher NOAELs or LOAELs have been determined, a safety factor of 200, to derive a TDI for DBP based on the LOAEL of 20 mg/kg feed from the Lee *et al.* (2004) study is considered sufficient. According to the above statement, EFSA allocated a TDI for DBP of 0.01 mg/kg bw, based on a LOAEL of 2 mg/kg bw/day and making use of an uncertainty factor of 200 (EFSA, 2005d).

<u>Octylphenol, Octylphenol ethoxylates, Nonylphenols, Nonylphenol ethoxylates and LAS</u>: No safety paramters have been found for these organic contaminants. Establishment of new TDIs has not been within the scope of this assessment, and therefore, a further description of octylphenol ethoxylates, nonylphenols, nonylphenol ethoxylates and LAS has not been performed.

<u>PAH</u>: Among the PAHs, there are several mutagenic compounds, and some of them are possible or probable human carcinogens (IARC Group 2A or 2B) (IARC, 1987, SCF, 2002d). Some PAHs bind to the Ah-receptor and may trigger a number of toxicological effects on the immune, reproductive and cardiovascular systems. However, the carcinogenic and genotoxic effect is considered to be the most critical. Benzo[a]pyrene (BaP) has been classified by IARC in Group 2A as one of the most potent carcinogenic PAH compounds. Like several others PAH compounds, when BaP is absorbed, it is metabolised in the liver and other tissues into reactive compounds that can bind to DNA and cause mutations. It is believed that the carcinogenic mechanism occurs primarily by mutations. BaP causes tumours in the stomach and liver, and in combination with other PAHs it causes lung tumours as well as tumours in other organs.

JECFA assessed PAHs in February 2005 (JEFCA, 2005) and calculated the margin of exposure (MOE) between the 'benchmark dose lower confidence limit' for 10% incidence (BMDL10) = 100 µg/kg body weight/day for tumours in laboratory animals and the estimated intakes. At an estimated intake of 4 (average consumption) and 10 (high consumption) ng BaP/kg body weight/day, margins of exposure of 25 000 and 10 000, respectively, were estimated. JECFA concluded that at the estimated intake levels of BaP, there is little cause for concern for human health. Nonetheless, JECFA recommended that measures should be implemented to reduce PAH contamination in food. EFSA evaluated PAH in food and concluded that the sum of benzo (a)pyrene, chrysene, benz(a)anthracene and benzo(b)fluoranthene (PAH4) were better indicators of the occurrence of carcinogenic PAHs than benzo(a) pyrene alone or the sum of benzo(a) pyrene and chrysene, while PAH8 provided little added value compared to PAH4.

Furthermore, EFSA concluded that the high consumers have an estimated MOE of 9500 – 10 800 which is close to the MOE of 10 000 recommended by EFSA and indicated a potential need for risk management action (EFSA, 2008b). A Bench Mark Lower Dose (BMDL10) of 0.34 mg/kg bw/day for PAH4 was used in the calculations of MOE.

A TDI or TWI is only available for few of the organic contaminants in sewage sludge (Table 13). The Norwegian Scientific Committee for Food Safety has previously evaluated PAHs and NDL-PCBs and based their evaluation on a MOE (VKM, 2007b; VKM, 2008b). The same principle for the evaluation of these substances will be used here as in the previous evaluations.

PCB: Dietary PCB-exposure involves both dioxin-like PCBs (DL-PCBs) and non-dioxin-like PCBs (NDL-PCBs). For the NDL-PCBs, there is no tolerable intake established by international bodies working with risk assessment of contaminants. For the dioxins and DL-PCBs the TWI at 14 pg TEQ/kg body weight/week was established by the SCF in 2001.

They concluded that the overall margin of the body burden (MoBB2) is about 10, based on median levels of NDL-PCBs in human milk samples in European countries (240 ng/g fat, corresponding to a body burden of 48 µg/kg body weight, assuming a body fat composition of 20%) and the NOAEL BB of the most sensitive effects in rats (500 µg/kg body weight, based on liver and thyroid toxicity). They noted that the observed effects in studies on NDL-PCBs might be explained by minor contamination (in the range of 0.1%) with potent dioxins and/or DL-PCBs. They also noted that subtle developmental effects, being caused by NDL-PCBs, DL-PCBs and/or dioxins, may occur at maternal body burdens that are only slightly higher than those expected from the average daily intake of these contaminants in European countries, which was estimated to range between 10-45 ng/kg body weight per day on average (EFSA, 2005a).

Based on human studies involving perinatal exposure, benchmark dose calculations (5% incidence in neurological and immune effects in children) indicate a 95% lower confidence limit (BMDL) of approximately 1 µg PCB/g lipid in the body of the mother. Since effects of DL-PCBs could not be differentiated from those of NDL-PCBs, these studies were excluded as a basis for the evaluation of NDL-PCBs in EFSA’s opinion on NDL-PCBs (EFSA, 2005). However, a recent study indicates that adverse effects on cognitive function are related to the total concentration of dioxins and PCBs rather than dioxins and DL-PCBs (Lee *et al*., 2007). If the toxicokinetic model of the EFSA opinion is used (EFSA, 2005a), a daily intake of 40 ng PCBs/kg body weight/day would result in a serum level of 1 µg PCB/g lipid. Assuming that the 6 indicator NDL-PCBs (sum of PCB-28, PCB-52, PCB-101, PCB-138, PCB-153 and PCB-180) constitute about 50% of the BMDL value of 1 µg PCB/g lipid, this would correspond to 0.5 µg PCB6/g lipid, and an intake of about 20 ng PCB6/kg body weight per day.

Recently, the French Food Safety Agency (Afssa) published their opinion on the establishment of relevant maximum levels for NDL-PCBs in some foodstuffs (Afssa, 2007). In 2003, Afssa adopted a reference dose of 20 ng/kg body weight/day for all 209 PCB congeners.

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[2] BB: Total amount of substance in the body.

The tolerable daily intake of 10 ng PCB6/kg body weight/day as established by Afssa, is half the intake value of 20 ng PCB6/kg body weight/day that can be derived from the BMDL from human studies described in the EFSA opinion (see above). Based on these considerations, VKM's panel 5 decided to use 10 ng PCB6/kg body weight per day as a reference value in its evaluation of the protective effect of the TWI for dioxins and DL-PCBs on NDL-PCBs in the diet of Norwegians (VKM, 2007b).

Table 13. Tolerable daily intake (TDI) and other safety limits for human intake of organic contaminants used in the risk assessment.

Contaminants	TDI µg/kg bw/day	Other safety parameters	Reference
DEHP*	50		EFSA, 2005c
DBP	10		EFSA, 2005d
Octylphenols	-	-	
Octylphenol ethoxylates	-	-	
Nonylphenols	-	-	
Nonylphenol ethoxylates	-	-	
LAS	-	-	
PAH4***		BMDL$_{10}$ of 0.34 mg/kg bw/day****	EFSA, 2008b
Sum PCB 6**		BMDL$_{10}$ of 20 ng/kg bw/day****	VKM, 2007b

* calculated from a TDI set by EFSA.
** PCB-28, -52, -101, -138, -153, -180
*** Benzo (a) pyrene, chrysene, benz(a)anthracene and benzo(b)fluoranthene
****BMDL=Benchmark dose lower limit for 10% confidence interval
-No safety parameters available

5.2. Predicted soil concentrations after sewage sludge application

The aim of this chapter is to estimate the soil concentrations of contaminants after long-term application of sewage sludge. A range of processes affecting the fate of contaminants in soil have been estimated, such as input from sewage sludge and other sources, biodegradation, leaking to water, removal from soil through plant uptake and harvest have been discussed and the most important factors have been incorporated into the mathematical modelling.

In all calculations, the mean concentrations of contaminants in Norwegian sewage sludge are used. It was assumed that it was very unlikely that one particular site would receive the most contaminated sludge every time sludge was dispersed. Furthermore, for substances where time trends are available, it seems like there is a decreasing concentration in the sewage sludge for the metals at most concern as well as certain organic contaminans (see Figure 2 and Figure 3). VKM therefore found it reasonable to use the mean values and not the maximum values or similar.

The soil concentrations are estimated for three different time points: immediately after application of the sewage sludge, 90 days after application and after 100 years with the maximum allowed application, including a possible 50% increase in the maximum allowed use of sludge. The concentrations immediately after sewage sludge application are used in the risk assessment of non-accumulating substances while the 100 years are used in the modelling for accumulating substances. This assumption has been chosen in similar work (Amundsen *et al.*, 2000), and a time scale of 100 years should be sufficient to uncover undesirable effects of accumulating contaminants after use of sewage sludge. The concentrations after 90 days are assumed to represent the average concentration during a growth season of 180 days and are used in the calculation of plant concentrations for other exposure routes for non-accumulating substances.

The highest estimated soil concentration of contaminants has been used in the risk assessment of the various exposure routes. Further, the highest possible concentration of contaminants (worst-case scenarios) in the other compartments (water, plants) has been chosen for different exposure routes. This means that maximum leaching has been estimated for the aquatic exposure routes, while maximum uptake in plants has been used in other exposure routes. This approach implies a variable mass balance for each compound.

At present, sewage sludge cannot legally be applied to soil used for vegetables, berries or fruit production. The soil can only be used for production of these plants at minimum three years after sludge application. Because of this, acute effects on vegetables following sewage sludge application are not relevant. However, the long term effects of sewage sludge application to agricultural soil (accumulation in soils) will be relevant since vegetables can be grown on soil that have received sewage sludge for 100 years (berries and fruits are not considered relevant for human exposure in relation to sewage sludge).

Sewage sludge cannot legally be used on pastureland. The regulations do not, however, give any restrictions on growing grass on areas that earlier have been used for e.g. grain production and which then may have received sewage sludge. These former grain production areas may in principle also be used as pastures a year after sewage sludge application. In this risk assessment therefore, it is assumed that grass from pastureland as well as soil on pastureland are influenced by sewage sludge i.e. 40 and 60 tons per hectare for 100 years.

Sewage sludge has to be mixed into the soil immediately and at the latest 18 hours after application. Direct run off of sewage sludge has therefore not been taken into consideration in this risk assessment. Erosion from soils that have received sewage sludge for 100 years is however considered in the risk assessment of waterliving organisms.

5.2.1. Factors affecting the fate of contaminants in soil

There are regional and local differences in the composition and properties of Norwegian soils that can be explained by different geological and varying climatic variations (e.g. temperature and precipitation).

In this chapter, the variations in soil properties are discussed and the influence of sewage sludge on these properties are emphasised.

The overview of regional differences in soil properties and Norwegian climatic conditions below is based on data from Amundsen et al. (2000) collected as basis for risk assessment of Cd in mineral fertilisers. Three regions defined by Amundsen *et al.*, (2000) are relevant for this risk assessment: Østfold, Akershus and Vestfold (Region 1), Hedmark (Region 2), and Sør-Trøndelag (Region 3). These regions are important for the production of grains and vegetables and most of Norwegian sewage sludge (about 70%) is produced and applied within these regions. In the selection of data necessary for the model calculations, data from region 1 or values considered to be representative for region 1 is used.

5.2.1.1. Dry soil bulk density

Soil bulk density (g/cm^3) is highest in Region 1 where the clay content is highest and somewhat lower in Region 2 where the content of organic matter is higher (Table 14). The mean dry soil density for Norwegian agricultural areas is 1.1 g/cm^3 while the dry bulk density in Region 1 and Region 3 is somewhat higher, 1.2 g/cm^3 (or 1200 kg/m^3) (Table 14).

Table 14. Mean, median, minimum and maximum dry soil density (g/cm^3) of Norwegian agricultural soils. (Data from Amundsen *et al.*, 2000).

Region	No of samples	Mean	Median	Minimum	Maximum
Region 1	102498	1.20	1.18	0.04	1.99
Region 2	16896	1.09	1.10	0.04	1.88
Region 3	36208	1.17	1.19	0.10	1.99
Country	186104	1.1	1.15	0.04	1.99

According to TGD (2003) the wet bulk density of the soil compartment may be calculated according to the equation:

$$RHO_{soil} = Fsolid_{soil} \cdot RHO_{solid} + Fwater_{soil} \cdot RHO_{water} + Fair_{soil} \cdot RHO_{air}$$

Where

RHO_{soil} = bulk density of wet soil [kg m^{-3}]

RHO_{solid}, RHO_{water}, RHO_{air} = density of solid phase, water and air: 2500, 1000 and 1.3 kg m^{-3}

$Fsolid_{soil}$, $Fwater_{soil}$, $Fair_{soil}$ = volume fraction of solid phase, water and air in soil: 0.6, 0.2 and 0.2

Using equation 1 the dry soil density is 1500 kg/m^3 (TGD 2003) which is somewhat higher than the measured densities in Norwegian soils (Table 14).

Since the organic carbon content in Norwegian soils is above European average, it was decided to use a mean dry soil density of 1200 kg m^{-3} in this assessment (equal to the Region 1 and 2). Using 1200 instead of 1500 kg m^{-3} in the calculations, results in higher soil concentrations.

5.2.1.2. Sludge dry density

The density of sewage sludge is relevant when used in park areas and soil mixtures because it will influence the calculated soil concentration.

In this risk assessment a bulk dry density of 500 kg m^{-3} has been used *(*Aquateam, 2006*).*

5.2.1.3. Soil depth

The amount of soil that the sewage sludge is mixed into is dependent upon the depth of the soil - mixing zone. When used in park areas, it is supposed that the sludge is mixed into the upper 0.1 meters of soil, while when used on agricultural soil a mixing depth of 0.2 meters is used. When sewage sludge is mixed with soil to make artificial/commercial soil products, a mixing ratio of 30 percent sludge and 70% soil is used (which is in accordance with the Norwegian legislation).

5.2.1.4. Rainfall and leaching

There are large variations in annual precipitation across the country. In the southeastern parts of Norway, the precipitation varies from 300-800 mm, but the region also has areas with extremely low precipitation below 300 mm annually. The southeastern parts of Norway are characterised by relatively high mean temperature, little wind and low air humidity (Table 15). The precipitation is higher in the western parts of the country, ranging from 1500 to 3000 mm. Most of the agricultural areas in this region have lower annual precipitation and the rainfall in these areas is in the range of 1200-1500 mm annually. In general, this region is the windiest in Norway and has the highest relative air humidity. In the northern parts of the country, the annual precipitation is relatively high and the area is characterized by high wind velocity and low temperature (Table 15).

Table 15. Typical annual wind speed, air temperature, relative air humidity and precipitation for different meteorological stations in Norway. The numbers are mean values for the period 1994-98. The estimated drainage rates are also shown. (Data from Amundsen *et al*., 2000).

Meteorological station	**Region**	**Wind speed m/sec**	**Air temperature °C**	**Relative air humidity %**	**Precipitation mm**	**Drainage ml/cm^2/year**
Oslo	South East	2.8	6.2	75.2	680	30
Kjevik	South East	3.6	7.2	77.5	1182	70
Sola	South West	4.6	7.8	84.9	1225	90
Værnes	Middle	3.5	5.5	75.9	824	60
Bodø	North	6.7	5.1	76.6	1207	100
Tromsø	North	3.4	2.6	75.3	1092	90

Due to humid and cold climate in Norway, the precipitation exceeds the evaporation in all major agricultural areas. In the western and northern parts of the country, the drainage rates are quite high and in general 2-3 times the typical rate for the agricultural areas in South East Norway (Table 15).

These climatic variations are the reason why the amount of precipitation that infiltrates the soil also varies throughout the country. In former risk assessments, a precipitation excess of 0.2-0.4 has been used (Amundsen *et al*. 2000) even if the precipitation excess seems to be higher at least in western and northern parts of Norway. Using data from Table 15, the precipitation excess varies from 0.4 (Oslo) to 0.8 (Bodø, Trømsø, northern Norway). In the calculation of future soil concentration in this risk assessment, a mean precipitation excess of 0.25 is used which is identical to the default value suggested in TGD (EC, 2003). Using low values for the precipitation excess will increase soil accumulation. In the calculation of drainage to surface waters and surface runoff (Chapter 5.4.), other values based upon measurements at specific sites have been used.

The significance of varying this parameter is highlighted in the sensitivity analysis (see Chapter 5.7.).

5.2.1.5. Overview of the parameters used in the risk assessment

Table 16 gives an overview of the parameter/defaults values used in the risk assessment of sewage sludge.

Table 16. Common parameters used for calculating soil concentrations after application of sewage sludge. (Data from Amundsen *et al*., 2000).

Parameter	Value	Unit
Mixing zone green area/ploughing layer agriculture	0.1/0.2	meters
Rate of sludge application: agriculture	40 and 60	tons ha^{-1} $10year^{-1}$
Green area (one application)	5	cm sludge in 10 cm soil
Mixing ratio for artificial/commercial soil products	30	% sludge and 70 % soil
Bulk density dry/wet soil	1200/1400	kg/m^3
Density sewage sludge (dry)	500	kg/m^3
Period of sludge application:		
For contaminants with T ½ a year or less	0 and 90	days
For contaminants with T ½ more than a year	100	years
Fraction of precipitation infiltrating the soil	0.25	-

When calculating the exposure concentrations for water living organisms using the MACRO-model (Chapter 5.4.) a soil clay content of 4-6% and a soil organic matter content of 3.5% was used to maximize the exposure concentration.

5.2.1.6 Other factors affecting the fate of contaminants in soil not included in the model

The most important soil properties known to be decisive for the fate of contaminants in soils are pH, content of clay and organic matter. Neither of these parameters are however included in the model calculations that predicts future soil concentrations after sewage sludge application. But they are included in the general discussion on how soil properties may influence future soil concentrations and availability of contaminants in soils. One example of where these parameters are applied is in the comparison of different models for Cd uptake in crops (Appendix A1). In the discussion of modelling results it is useful to have an overview of both the level of these parameters in Norwegian soils and the regional variations. Clay content and soil organic matter influence the bulk density of soils that influence soil concentrations greatly.

Soil pH

The pH in Norwegian soils is mostly in the acidic range (Table 17). A considerable seasonal variation in pH is typical for all the regions, but there are small differences in mean yearly pH (Table 17). Mean pH in the Region 1 area is 6.1, a bit lower in Region 2 (5.9) and Region 3 (6.0).

Table 17. Mean, median, minimum and maximum pH in different regions and in the whole country. (Data from Amundsen *et al*., 2000).

Region	No of samples	Mean	Median	Minimum	Maximum
Region 1	102498	6.1	6.1	2.9	9.5
Region 2	16896	5.9	5.9	4.1	8.1
Region 3	36208	6.0	5.9	3.1	8.8
Country	186399	6.0	6,0	2.9	9.5

Natural soil processes, as well as sludge application (except the lime stabilised), result in a lowering of soil pH (e.g. Brady 1984). To maintain pH at an agronomical favourable level, liming is necessary in most Norwegian soils. Soil liming is especially important in areas with limited buffering capacity such as areas in Region 3.

In the risk assessment it is assumed that pH is kept constant (pH 6.1) throughout the period of sludge application (100 years).

Clay content

The exact content of clay in Norwegian agricultural soils has not been determined on a regional or national scale. Soils have been classified with regard to the clay content using a semi-quantitative method which has been regularly calibrated against standard qualitative methods for texture analysis. The data for the classification of about 186000 samples are presented in Table 18.

Table 18. Percent distribution of soil samples of different clay content classes in different regions and in the whole country. (Data from Amundsen *et al*., 2000).

Region	No of samples	<5% clay	5-10% clay	10-25% clay	25-40% clay	>40% clay	>20.5% (organic matter)
Region 1	102503	1.4	23.1	26.3	46.8	1.6	0.9
Region 2	16896	5.6	72.0	8.2	7.0	0.8	6.4
Region 3	36208	1.2	82.9	12.2	0.4	0.0	3.4
Country	186404	3.7	46.8	17.9	26.5	0.9	4.1

The clay content in Region 1 is markedly higher than in Region 2 and Region 3 due to influence of marine clay in a large fraction of the agricultural soils in Region 1.

In the risk assessment, clay content of 25% is used in those cases where this parameter is needed for calculation purposes. Soil with clay content of 25-40% is the most common in Region 1 where most of the Norwegian sewage sludge is applied.

Organic matter

The cold and humid climate in Norway is the main reasons for relatively high content of soil organic matter (SOM), with a mean value of 5.8% (Table 19).

Table 19. Mean, median, minimum and maximum of soil organic matter (%) in agricultural soils for different regions and for the whole country. (Data from Amundsen *et al*., 2000).

Region	No of samples	Mean	Median	Minimum	Maximum
Østfold, Vestfold, Akershus	8589	4.7	4.0	0.1	20.3
Sør-Trøndelag	1572	7.5	7.0	0.3	20.4
Hedmark	2461	5.2	4.4	0.1	20.2
Country	15870	5.8	4.8	0.1	20.4

The mean content of SOM is highest in Region 2 and lowest in Region 1. Assuming SOM is equal to 1.7 x soil organic carbons a SOM of 4.7% is equal to about 2.8% organic carbon.

The most apparent change that will occur after continuous sludge application is an increase in SOM. Using the model ICBM (The Introductory Soil Carbon Balance Model) (Andrèn & Kätterer, 1997; Kätterer & Andrén, 1999), the increase in soil organic carbon (assuming that SOM generally contains 58% organic carbon) can be calculated when 40 and 60 tons of sewage sludge is applied per ha every 10th year. The simulations show that application of 40 tons sewage sludge per ha will increase the organic carbon content from 6.72 kg C/m^2 (mixing layer of 0.2 m, soil density of 1200 kg/m^3) to 9.6 kg $orgC/m^2$ within 100 years, while application of 6 tons will increase the content to 10.52 kg $orgC/m^2$.

For public gardens and park areas, as well as for mixtures of soil and sewage sludge, the change in soil properties after the first application will be more pronounced. Mixing 5 cm sewage sludge into 10 cm soil or 30% sewage sludge with 70% soil (soil with density 1200 kg/m^3 and a SOM content of 4.7%), will result in a soil with approximately 12% SOM (density 902 kg/m^3) or an organic carbon content of 6.9%.

Increased SOM content influences the distribution coefficients in soils (K_d, K_{oc}) and will most probably reduce leaching and plant uptake which will in turn increase the fraction of contaminant that accumulate in soil. The possible influence of SOM (in some equations written OM%) on plant uptake is discussed in Chapter 5.3.

In the calculations in this risk assessment, a value of 4.7 % is used for SOM, which is the mean value for Region 1.

5.2.2. Input of contaminants to soils

For most contaminants considered in this risk assessment, sewage sludge is not the only source of input to soils, even if it is quantitatively the most important at the areas where it is applied. Other sources contributing to the soil concentrations are atmospheric deposition (both local and long range transport), mineral fertilisers, and lime. When relevant Norwegian data is available, these sources of input are included in the exposure assessment of heavy metals. For the organic contaminants, sewage sludge is the only contaminant source evaluated in the risk assessment, even analysis of Norwegian soil samples also indicate that higher amounts of organic contaminants such as PAHs and PCBs are deposited in southern compared to central and northern Norway (Aamodt *et al.* 1996; Lead *et al.* 1997).

5.2.2.1. Sewage sludge

Agriculture: As shown (Chapter 3.1.) the Norwegian regulations allow 40 tons dry weight per hectare every 10 years (class I). In addition to the sludge dose permitted in the regulations, the calculations have taken into consideration a 50% increase (60 tons dry weight per ha every 10 year) in the allowed amount according to the present regulations.

The mean concentrations of the contaminants found in Norwegian sewage sludge are used in the risk assessment and are shown in Appendix A1.

The concentration in agricultural soils after one sludge application can be calculated according to equation 1A:

$$C_{\mathrm{SludgeSoil\ 1}}(0) = \frac{C_{\mathrm{Sludge}} \cdot \mathrm{APPL}_{\mathrm{Sludge}}\,\mathrm{x}10}{\mathrm{DEPTH}_{\mathrm{Soil}} \cdot \mathrm{RHO}_{\mathrm{Soil}}} \qquad \textbf{Eq. 1A}$$

Where

$C_{\mathrm{Sludge\ Soil\ 1}}$ – concentration of contaminant in soil after one application of sewage sludge [t=0, mg kg^{-1}]

C_{Sludge} – concentration in dry sewage sludge [mg kg^{-1}] (Appendix A1)

$\mathrm{APPL}_{\mathrm{Sludge}}$ – dry sludge application rate [tons $hectare^{-1}$] (Table 16)

$\mathrm{DEPTH}_{\mathrm{Soil}}$ – mixing depth of soil [m] (Table 16)

$\mathrm{RHO}_{\mathrm{Soil}}$ – bulk density of soil [kg m^{-3}] (Table 16)

The soil mixing depth for agricultural soils is 0.2 (Table 16). The change in soil density due to the sludge application is not accounted for.

Equation 1A calculates the concentration of contaminant after a single sludge application. To calculate the soil concentration after repeated applications of sewage sludge, equations 10A and 11A are used instead.

Park areas and soil mixtures

When using sewage sludge in park areas and soil mixtures, the change in soil density has to be considered when calculating the soil concentration. In green areas, 5 cm sewage sludge is mixed with 10 cm soil (33% sewage sludge on a volume basis), while 30% sewage sludge (by volume) is mixed with 70% soil in soil mixtures. The calculation of soil concentrations for park areas and soil mixtures are done according to equation 2A and 3A, respectively:

$$C_{park\,area} = \frac{0.67 \cdot C_{soil}(0) \cdot RHO_{soil} + 0.33 \cdot C_{sludge}(0) \cdot RHO_{sludge}}{0.67 \cdot RHO_{soil} + 0.33 \cdot RHO_{sludge}} \qquad \textbf{Eq. 2A}$$

$$C_{soil\,mixture} = \frac{0.7 \cdot C_{soil}(0) \cdot RHO_{soil} + 0.3 \cdot C_{sludge}(0) \cdot RHO_{sludge}}{0.7 \cdot RHO_{soil} + 0.3 \cdot RHO_{sludge}} \qquad \textbf{Eq. 3A}$$

Where

$C_{\mathrm{park\ area,\ soil\ mixture}}$ = concentration in park area or soil mixture [mg kg^{-1}]

$C_{\mathrm{soil}}(0)$ = concentration of contaminant in soil used in soil mixture [mg kg^{-1}]

$C_{\mathrm{sludge}}(0)$ = concentration of contaminant in sewage sludge used in soil mixture [mg kg^{-1}]

$\mathrm{RHO}_{\mathrm{soil}}$ = bulk density of dry soil [kg m^{-3}]

$\mathrm{RHO}_{\mathrm{sludge}}$ = bulk density of dry sewage sludge [kg m^{-3}]

When calculating exposure concentrations after using sewage sludge in park areas and soil mixtures, the sludge is applied only once. In the calculations of exposure concentrations for these applications, soil background values is used for heavy metals (Appendix A1), while for the organic contaminants, soil concentration is set to be zero

5.2.2.2 Other sources

Atmospheric deposition (both local and long range transport)

The atmospheric deposition of contaminants due to long-range transport varies considerably between regions in Norway. It has long been shown that there is a south-north gradient in the deposition of acidifying compounds (SO_2, SO_4, NH_4, NO_3) and heavy metals (Aas *et al.*, 2008).

On soils that receive sewage sludge according to Norwegian legislation, the amount of heavy metals added to soils through atmospheric deposition is small compared to the amount applied by sewage sludge, even in the most loaded areas of Norway. A regional average contribution is therefore calculated by using deposition data from monitoring stations throughout the country. Table 20 shows the deposition rates used for various heavy metals.

Mineral fertilisers

The amount of heavy metals in mineral fertilisers depends mainly on the quality of the phosphate rock used as raw material for P fertilizer. Complete fertiliser (Fullgjødsel® NPK) produced by Yara is based on phosphate rocks from the Kola Peninsula that is known to have a low level of heavy metals. As a consequence, the present contribution of heavy metals from mineral fertilizers to agricultural soils in Norway is low. Table 20 shows the addition of heavy metals through mineral fertilisers.

Lime

Liming of soils is performed regularly in Norwegian agriculture to maintain a favourable pH in soils. The amount of heavy metals added through liming products is low compared to mineral fertilisers and atmospheric deposition. Table 20 shows the addition rate for liming products.

Table 20. Annual input of heavy metals from atmospheric deposition, mineral fertilisers, liming products and sewage sludge used in the risk assessment. The unit is mg/ha year. (Data from Amundsen *et al.*, 2000).

Parameter	Cd	Pb	Hg	Cu	Cr	Ni	Zn
Atm deposition	347	7324	122	10740	2975	6560	40010
Mineral fertiliser	43	752		6670	6265	2416	5135
Liming products	51	940		1375	920	775	2000
Sewage sludge 40 tons/ha	3200	86800	3600	1070400	93600	55600	1304000
Sewage sludge 60 tons/ha	4800	130200	5400	1605600	140400	83400	1956000

The input from other sources than sewage sludge is calculated according to equation 4A:

$$Input_{OS} = \frac{Input_{Atm} + Input_{MinFert} + Input_{Lime}}{DEPTHsoil \cdot RHOsoil} \qquad \textbf{Eq. 4A}$$

Where

$Input_{OS}$ – sum of input from other sources than sewage sludge [$mg \cdot kg^{-1} \cdot day^{-1}$]

$Input_{Atm}$ – annual average atmospheric deposition flux [$mg \cdot m^{-2} \cdot day^{-1}$]

$Input_{MinFert}$ – annual average application of mineral fertiliser [$mg \cdot m^{-2} \cdot day^{-1}$]

$Input_{Lime}$ – annual average application of contaminant using lime [$mg \cdot m^{-2} \cdot day^{-1}$]

$DEPTH_{Soil}$ – mixing depth of soil [m]

RHO_{Soil} – bulk density of soil [$kg\ m^{-3}$]

5.2.3. Soil background concentrations

The concentration of contaminants measured in agricultural soils is due to the background concentration i.e. the concentration that is due to occurrence in the bedrock and natural sources like forest fires, volcanoes etc. and the sources that is due to anthropogenic activity (mineral fertilisers, atmospheric deposition, liming, and pesticides). In this risk assessment the anthropogenic sources will be divided into sewage sludge and other sources. $PEC_{local\ soil}$ i.e. the soil concentration that is used is then calculated according to equation 5A.

$$PEC_{Local\ soil} = PEC_{regional\ natural\ soil} + C_{Other\ sources\ soil} + C_{Sludge\ soil} \qquad \textbf{Eq. 5A}$$

As mentioned, sewage sludge has been applied to agricultural soils in Norway since the mid 1970s. Given that the regulations were followed with a permission of 40 tons sewage sludge per ha every 10th year, local agricultural soils may have received 3-4 doses of sewage sludge since the 1970s in areas where sewage sludge has been applied. During this period or at least prior to 1990, the concentration of contaminants in the sewage sludge was much higher than at present time (Amundsen *et al.* 2001). Areas that received sewage sludge during this period may have elevated concentrations of inorganic and organic contaminants, compared to the natural background levels in those areas.

Studies that were used as the basis for the regional contaminant values did not distinguish between soils that have received sewage sludge and those that did not. Taking into consideration that only a limited number of agricultural soils receives sewage sludge during a hundred years period (only 4.8 percent of the total grain area will receive the maximum amount of sewage sludge within a 100 year period), it may be reasonable to assume that the concentration of contaminants originally considered as natural background may be minimally influenced by the application of sewage sludge.

In this risk assessment, we consider the application that has been going on for the last 30 years as part of the soil background concentration ($PEC_{regional}$).

For heavy metals the available data on soil background concentrations are presented in Appendix A1 and the input to agricultural soil from mineral fertilisers, atmospheric deposition and liming products are summarized in Table 20. The database is extensive and makes a good basis for separation of the contribution from sewage sludge from other sources in the exposure assessment.

However, for organic contaminants data on both natural background levels in soils and the contribution from other sources is limited. Application of sewage sludge is therefore the only source included in the exposure estimations for the organic contaminants.

5.2.4. Removal of contaminants from the soil

The removal processes of contaminants included in the calculations of soil concentrations are volatilisation, leaching, biodegradation and plant uptake (assuming that the contaminant is translocated to plant parts that are removed from soil). The overall first order removal constant (k) is given by equation 6:

$$k = + k_{Leach} + k_{Plant} + k_{Biosoil} + k_{Volat} \qquad \textbf{Eq. 6A}$$

Where:

k – first order rate constant for removal from top soil

k_{Leach} – first order rate constant for leaching from top soil [day^{-1}] (**Eq. 7A**)

k_{Plant} – first-order rate constant for plant uptake from soil [day^{-1}] (**Eq. 9A**)

$k_{Biosoil}$ – first-order rate constant for biodegradation in soil [day^{-1}] (**Eq. 10A**)

k_{Volat} – first order rate constant for volatilisation from soil [day^{-1}] (**Eq. 12A**)

When considering the environmental dissipation of contaminants in soils after sludge application, all four removal processes may be relevant for organic contaminants, while for inorganic compounds, only leaching and plant uptake are relevant.

The higher the individual rate constant the more important is the process for the removal of the contaminant. The relative importance of the different processes may be compared by ranking their rate constants.

5.2.4.1. Leaching of contaminants from soil

As discussed in chapter 5.1.1.7. the precipitation and infiltration rate varies considerably in Norway. A precipitation rate of 700 mm per year and infiltration of 25% (0.25) is assumed to be representative for the southeastern parts of Norway were sludge production is largest (Region 1). The significance of varying precipitation and infiltration is shown in the sensitivity analysis (see Chapter 5.7.).

The leaching rate from the soil is calculated according to equation 7A:

$$k_{leach} = \frac{F\inf_{soil} \cdot RAINrate}{K_{soil-water} \cdot DEPTH_{soil}}$$ **Eq. 7A**

Where

$Finf_{soil}$ – fraction of rain-water that infiltrates into soil (0.25)

RAINrate – rate of wet precipitation (700 mm/year) [m day^{-1}]

$K_{soil\text{-}water}$ – soil-water partitioning coefficient [$m^3 \cdot m^{-3}$]

$DEPTH_{soil}$ – mixing depth of soil (0.2m)

k_{leach} –first order rate constant for leaching from soil layer [day^{-1}]

The soil-water partitioning coefficient, $K_{soil\text{-}water}$, can be calculated using equation 8A:

$$K_{soil-water} = Fair_{soil} \cdot K_{air-water} + Fwater_{soil} + Fsolid_{soil} \cdot \frac{Kd_{soil}}{1000} \cdot RHOsoil$$ **Eq. 8A**

Where

$Fwater_{soil}$ = volume fraction of water in soil compartment [$m^3 \cdot m^{-3}$] (0.2, TGD 2003)

$Fsolid_{soil}$ = volume fraction of solid in soil compartment [$m^3 \cdot m^{-3}$] (0.6, TGD 2003)

$Fair_{soil}$ = volume fraction of air in soil compartment [$m^3 \cdot m^{-3}$] (0.2, TGD 2003)

RHOsolid – density of the solid phase [kg m^{-3}] (2500)

Kd_{soil} – solids-water partition coefficient in soil [l kg^{-1}]

$K_{air\text{-}water}$ – air-water partitioning coefficient [$m^3 \cdot m^{-3}$]

$K_{soil\text{-}water}$ – soil-water partitioning coefficient [$m^3 \cdot m^{-3}$]

5.2.4.2. Uptake and elimination processes in plants

In the calculation of accumulation of contaminants over a long time-span (100 years) the removal of the contaminants from the soil through plant uptake and harvesting has been taken into account. Different scenarios for crop rotations, influencing the removal and thus the accumulation, have been assessed:

1. Autumn wheat
2. Autumn wheat-autumn wheat-oat-barly-oil seed
3. Potato-autumn wheat-oat
4. Carrot-potato-wheat
5. Grass-grass-wheat
6. Grass

For results and differences between crop rotations with respect to contaminant accumulation, see Annex A1.

The plant removal rate, k_p (day^{-1}), was calculated according to equation 9A:

$$k_{plant} = \left(\frac{CP \cdot C_{crop}}{DEPTH_{soil} \cdot RHO_{soil} \cdot C_{Sludge-soil} \cdot 0{,}001} \right) \cdot \frac{1}{365}$$ **Eq. 9A**

Where

k_{plant} = plant removal rate, k_{plant} [day^{-1}]

CP = crop production [kg DW $\cdot m^{-2} \cdot year^{-1}$]

C_{crop} = concentration in crop [$g \cdot kg^{-1}$ DW]

$DEPTH_{Soil}$ – mixing depth of soil [m]

RHO_{Soil} – bulk density of soil [kg m^{-3}]

$C\text{-}_{SludgeSoil}$ – concentration in soil due to sludge in first year at t=0 [mg kg^{-1}]

The concentrations in agricultural crops are calculated using bioconcentration factors (BCFs) (see Chapter 5.3.2.) an approach assumuing that plant concentrations are proportional to soil concentrations. In the calculations of future soil concentrations (100 years), the annual removal rate through crops in the 100 year period is calculated using the soil concentration after 50 years. This is assumed to be the best estimate of average removal rate in the period.

5.2.4.3. Degradation of contaminants in soil

Biodegradation rates of organic compounds are influenced by several factors including temperature, redox-potential, and microorganisms with capability to transform or degrade the given contaminant. In most agricultural soils the upper 0.2m will be aerobic and most organic contaminants degrade faster at these conditions compared to anaerobic conditions. Contaminants such as brominated flame-retardants and PCBs, however, have a higher degradation rate under anaerobic than aerobic conditions.

The DT_{50} used for the organic contaminants are taken from risk assessments reports performed in the EU or from "Handbook of physical-chemical properties and environmental fate for organic chemicals" (Mackay et al. 2006) (most contaminants).

Based upon the half-lives (DT_{50}) for degradable contaminants, a first order degradation rate constant is calculated and is converted to a rate constant, $k_{biosoil}$, by equation 10A:

$$k_{biosoil} = \frac{\ln 2}{DT50_{biosoil}}$$ **Eq. 10A**

$k_{biosoil}$ – first-order rate constant for degradation in soil [day^{-1}]

$DT_{50}bio_{soil}$ – half-life for biodegradation in bulk soil [days]

The half-lifes used for the organic contaminants in this risk assessment are shown in Annex A2.

Abiotic degradation processes like hydrolysis and photo-oxidation may be relevant to the risk assessment of removal processes in water phase, but this is less significant for soil and is not included in the model.

5.2.4.4. Volatilisation of contaminants from soil

The transfer of a substance from the aqueous- to the gas phase is estimated using Henry's Law constant.

The partition coefficient between air and water is calculated according to Eq. 11A

$$K_{air-water} = \frac{HENRY}{R \cdot Temp}$$

Eq. 11A

HENRY – Henrys law constant (Pa m^3 mol^{-3})

R – gas constant [Pa m^3 mol^{-3} k^{-1}]

Temp –[K] (285,TGD 2003)

As shown in Chapter 3.2.2. the sludge treatment process often involves temperatures above 50ºC that is far higher than Norwegian soil temperatures. Even so, for a few organic contaminants volatilisation from soil may be an important removal process and volatilisation is therefore included in the calculation of soil concentrations (Eq. 11A).

Henrys constant for the organic contaminants are shown in Annex 2A.

In TGD (EC, 2003), the transfer by diffisusion from soil to air is estimated using the classical two-film resistance model. The rate constant for volatilisation from soil is given by equation 12A.

$$\frac{1}{k_{volat}} = \left(\frac{1}{kasl_{air} \cdot K_{air-water}} + \frac{1}{kasl_{soilair} \cdot K_{air-water} + kasl_{soilwater}} \right) \cdot K_{soil-water} \cdot DEPTH_{soil}$$

Eq. 12A

Where

$kasl_{air}$ = partial mass transfer rate constant at air-side of the air-soil interface [m·day^{-1}] (120, TGD 2003)

$kasl_{soil-air}$ = partial mass transfer rate constant at soil-air-side of the air-soil interface [m·day^{-1}] (0.48, TGD 2003)

$kasl_{soil-water}$ = partial mass transfer rate constant at soil-water-side of the air-soil interface [m·day^{-1}] ($0.48 \cdot 10^{-5}$, TGD 2003)

$K_{air-water}$ = air-water equilibrium distribution coefficient [$m^3 \cdot m^{-3}$] (Eq.11A)

$K_{soil-water}$ = soil-water partitioning coefficient [$m^3 \cdot m^{-3}$] (Eq. 8A)

$DEPTH_{soil}$ = mixing soil depth [m]

k_{volat} = first-order rate constant for volatilisation from soil

Volatilisation is probably of a minor importance in heat-treated sewage sludge.

5.2.4.5. Sorption and bioavailability

Sorption processes include adsorption (attachment to 2-D matrix), absorption (strong association within a 3-D matrix like humus) and desorption. Sorption processes are highly dependent on the properties of both the compound itself and the soil (pH, SOM and clay content). For metals, charge and hydrophobicity influence the sorption. Polar organic compounds might be strongly influenced by pH, while non-polar compounds are highly influenced by their hydrophobic properties and the soil content of organic matters. The hydrophobicity of a compound is commonly expressed as its distribution between octanol and water (K_{ow}) and is often used to estimate bioaccumulation and association to organic matters. Sorption processes are represented by sorption coefficient $K_{d,soil}$ (distribution between solid phase and water phase), K_{oc} (soil organic carbon – water distribution coefficient) or $K_{d,DOM}$ (partition coefficient to dissolved organic matter). A compound's sorption properties have practical impact for the spreading potential in the environment and fate during treatment systems. For instance, hydrophobic compounds have higher potential to be trapped in sludge than water-soluble compounds. The lipophilic/hydrophobic properties of a compound will also influence the uptake potential in plants.

The Kd-value depends on both soil and chemical specific properties. For neutral (non-ionic) organic chemicals, the Kd-value is linearly related to the organic carbon content of the soil, and the soil sorption can be expressed relative to the fraction of organic carbon (f_{oc}) in the soil (the K_{oc}). For these non-ionic substances, the soil specific soil-pore water distribution coefficient can be estimated from the K_{oc} using the simple formula $Kd=K_{oc}*f_{oc.}$ For metals and cationic organics, a similar relationship can be found between the Kd-value and the cation exchange capacity (CEC) of the soil. The CEC for a specific soil depend on the soil pH. Anionic compounds tend not to be subject to retention in soil.

For metals, the free ion has been suggested as the species available for uptake in organisms. As a result, the bioavailability of metals in soil varies and this can be predicted by determining free-ion characteristics, such as soil pH: In turn, pH will also– influence sorption properties as well as metal speciation (Spurgeon & Hopkin, 1996; Van Beelen & Fleuren-Kemilä, 1997; Smit and van Gestel, 1998; Lock *et al.*, 2000), organic matter content (Spurgeon & Hopkin, 1996; Van Beelen & Fleuren-Kemilä, 1997; Smit & van Gestel, 1998), and/or cationic exchange capacity (Smit & van Gestel, 1998; Lock *et al.*, 2000). These characteristics are reflected in models currently suggested for assessing the toxicity of e.g. zinc to terrestrial invertebrates (see e.g. Lock & Janssen, 2001a). However, recent studies show that some complexes (e.g., chloride complexes of Cd; OH- and CO_3-complexes of Cu) are also available for uptake in plants, and that other cations may influence uptake of metals in a concept known as the biotic ligand model (Thakali, 2006).

Estimating the bioavailability of metals and organic contaminants from soil-pore-water partitioning studies performed on freshly contaminated soils in the laboratory generally overestimates the available fraction compared to historically contaminated soils. For instance, aged zinc-contaminated soils are less toxic than predicted from these models (Lock & Janssen, 2001b), and this is also the case for other metals and for organic chemicals (Alexander, 2000).

5.2.4.6. Summary of removal processes of contaminants in soil

For heavy metals, only leaching and plant uptake are relevant removal processes. For Cu and Zn, plant uptake is the most important removal processes, while leaching is the most important removal process for Cd, Pb, Hg, Cr and Ni. In general, the removal constants are small, clearly indicating that only a minor fraction of added heavy metals through sludge amendments are removed from the soil (i.e. high accumulation rate). The calculated removal constants for heavy metals are summarized in Appendix A3.

For all organic contaminants biodegradation is the most important removal process. In the sensitivity analysis the main focus is on the biological degradation.

The leaching rate calculated by equation 7A is used only for the calculation of removal from soil and not for calculation of surface and groundwater concentrations. The uncertainty in the leaching rate is therefore discussed in chapter 5.4. Volatilisation contributes considerably to the removal only for naphthalene. The uncertainty and eventual variation in constants important for volatilisation (K_H) is therefore not considered in the sensitivity analysis.

5.2.5. Choice of exposure time for the estimation of maximum soil concentration

Repeated application of sewage sludge is accepted within existing regulations. Persistant contaminants may therefore accumulate if not removal processes such as run-off with water, uptake in and removalof plants and evaporation exceed the input from sewage sludge and other sources. For such compounds, concentrations in soils will increase until a steady state concentration is reached. The time needed to reach steady state will depend on the soil concentration prior to the sludge application, the total amount of contaminant added through different sources, and the removal processes occuring. Previous calculations have shown that it may take several hundred years for heavy metals to reach the maximum levels in soil where sewage sludge can be applied (Amundsen & Grønlund 1997). For most heavy metals, it may take even longer to reach steady state conditions in soils. Several hundred or thousands of years, represent time spans that are incomprehensive in any risk management perspective.

Since 100 years seem reasonable both in a management and practical perspective (10 doses of sewage sludge every 10th years), it was decided to use the soil concentration after 100 years as the maximum exposure concentration for substances accumulating in soil.

The soil concentrations are estimated for three different time points: immediately after application of the sewage sludge, 90 days after application and after 100 years with the maximum allowed application, including a possible 50% increase in the maximum allowed use of sludge (Table 21). The concentrations immediately after sewage sludge application are used in the risk assessment of non-accumulating substances (DT_{50}<300 days) while the 100 years are used in the modelling for accumulating substances (DT_{50}>300 days). The concentrations after 90 days are assumed to represent the average concentration during a growth season of 180 days and are used in the calculation of plant concentrations for other exposure routes for non-accumulating substances.

Table 21. Description of exposure pathways (defined exposure routes) in the risk assessment, soil depth for the exposure routes, rate of sludge application which results in maximum exposure concentration, and averaging time used in the exposure calculation for the various exposure routes. For non accumulating substances the soil concentration 90 days after application is used to estimate the plant concentration in animal and human exposure.

Exposure route nr.	**Target organism**	**Soil depth (m)**	**Rate of sludge application**	**Average time exposure**	
				Degradable contaminants (days)	**Non-degradable contaminants (years)**
	Plant				
1	Plants	0.2 0.1	-40 or 60 tons of sewage sludge per ha every 10th year -5 cm of sewage sludge applied at gardens or park areas	0	100
	Animals				
2	Soil organisms	0.2 0.1	-40 or 60 tons of sewage sludge per ha every 10th year -5 cm of sewage sludge applied at gardens or park areas	0	100
3	Aquatic organisms	0.1	-5 cm of sewage sludge applied at gardens or park areas	0	100
4+5	Grazing animals	0.2	-40 or 60 tons of sewage sludge per ha every 10th year	90	100
6	Animals eating feed	0.2	-40 or 60 tons of sewage sludge per ha every 10th year	90	100
	Humans				
7	Children eating soil	0.1	-5 cm of sewage sludge applied at gardens or park areas -30 percent sewage sludge in commercial soil products used in private gardens	0	Not relevant
8	Humans eating plants		-40 or 60 tons of sewage sludge per daa every 10th year	90	100
9+10	Humans eating animal products	0.2	-40 or 60 tons of sewage sludge per daa every 10th year	90	100
11+12	Humans drinking water	0.1	-5 cm of sewage sludge applied at gardens or park areas	0	100

5.2.6. Calculations of soil exposure concentrations

To calculate the mean concentrations equation 13A is used (EC, 2003):

$$Clocal_{soil} = \frac{Input_{OS}}{k_{topsoil}} + \frac{1}{kt}\left[C_{soil1}(0) - \frac{Input_{OS}}{k_{topsoil}}\right] \cdot \left[1 - e^{-kt}\right]$$ **Eq. 13A**

Where

$Input_{OS}$ - sum of input from other sources than sewage sludge [mg·kg^{-1}·day^{-1}]

t– average time [days]

k–kleach+kplant+kbiosoil+kvolat (**Eq. 6A**)

$k_{topsoil}$ – first order rate constant for removal from top soil [day^{-1}]

$C_{soil\ 1}(0)$ – initial concentration in soil after first application of sewage sludge [mg kg^{-1}]

$Clocal_{soil}$ – average concentration in soil over T days [mg kg^{-1}]

Equation 13A calculates the average concentration within a certain time (t) after sludge application. To calculate the initial concentration in soil after a certain number of applications of sewage sludge (i.e. after 10-100 years), equation 14A is used (EC, 2003):

$$Csludge_{soil\,X}(0) = Csludge_{soil1}(0) \cdot \left[1 + \sum_{n=1}^{X-1} Facc^{n}\right]$$ **Eq. 14A**

Where

$Csludge_{soil\ X}$ – concentration in soil after X applications of sewage sludge [mg kg^{-1}]

$Csludge_{soil\ 1}$ – concentration in soil after first application of sewage sludge at t=0 [mg kg^{-1}]

Facc –fraction of a substance that remains in the top soil at the end of a year (**Eq. 15A**) (acc: accumulation)

The fraction of the substance that remains in the top soil at the end of a year is given by equation 15A:

$$Facc = e^{-365\ k}$$ **Eq. 15A**

Where:

k– first order rate constant for removal from top soil [day^{-1}] (**Eq. 6A**)

Facc – fraction accumulation in one year (**Eq. 14A**)

5.2.6.1 Estimated concentrations of heavy metals in soil after sludge application

The soil concentrations after 100 year of sewage sludge application to agricultural soils and after using sewage sludge on park areas and in soil mixtures are given in Table 22.

The increase in agricultural soil concentration after sludge application is highest for Hg, Cu, Zn and Cd (536, 381, 142 and 108%) and lowest for Ni, Cr and Pb (20, 25 and 27%). With the exception of Hg, all calculated soil concentrations are within the “natural” concentration range in

Norwegian soils that is expected due to geological and other natural variations. For Hg, however, the calculated concentrations (0.20-0.27 mg/kg, Table 22) are well above the highest concentrations measured in Norwegian agricultural soils (0.12-1.15 mg/kg, Esser 1996).

Logically, there should be no increase in soil concentrations for Pb, Cr and Ni since the concentrations in sewage sludge are lower than the natural soil concentrations. However, for agricultural soils, the model does not account for the volume of sewage sludge, but considers the sludge as a chemical. On the other hand, the organic fraction of sewage sludge will continue to degrade after sludge treatment and by this increasing the concentration of heavy metals in the sludge. It is still not fully understood how the organic fraction of the sewage sludge will influence the bioavailability of metals in soils. A fraction of the organic matter in sewage sludge resists decomposition, and could provide protection against plant metal uptake for decades. However, soluble organic fractions raise the carrying capacity of soil solutions for metal cations at any particular pH by forming soluble metal-organic complexes.

Applying sewage sludge on agricultural soils (40 and 60 tons per hectare every 10th year), in park areas (5 cm mixed into 10cm of soil) and in soil mixtures (30% by volume), will result in Cu soil concentrations above 50 mg/kg soil which is the maximum permissible concentration in soils that may receive sewage sludge (or other organic fertilizers) (Table 6). The calculated concentrations of the other heavy metals will be below these maximum permissible levels for all types of sludge applications investigated.

Table 22. Predicted soil concentrations of inorganic contaminants (mean soil values in mg/kg DW) after application of sewage slugde in soil mixture, park areas and respectively 40 and 60 tons sewage sludge on agricultural soil after 100 years.

	Cd	Pb	Hg	Ni	Zn	Cu	Cr
Conc. sewage sludge (mean)	0.80	22	0.90	14	326	268	23
Conc. in agricultural soil, other sources, 100 years	0.02	0.4	0.01	0.41	2.0	0.78	0.42
Conc. in soil (background)	0.22	24	0.05	21	64	19	27
Conc. in soil, sewage sludge, 40 tons, 100 years	0.13	3,6	0.15	2,3	54	44	3.9
Conc. in soil after 100 years, 40 tons	**0.35**	**28**	**0.20**	**23**	**118**	**63**	**31**
Conc. in soil (background)	0.22	24	0.05	21	64	19	27
Conc. in soil, sewage sludge, 60 tons, 100 years	0.20	5.4	0.22	3,5	81	66	5.8
Conc. in soil after 100 years, 60 tons	**0.42**	**29**	**0.27**	**25**	**145**	**86**	**33**
Park areas, 5 cm sewage sludge, 10cm soil	0.32	24	0.19	20	109	62	27
Soil mixture, 30% sewage sludge (w/w)	0.31	24	0.17	20	104	57	27

5.2.6.2. Estimated concentrations of organic contaminants in soil after sludge application

The calculated predicted soil concentrations of organic contaminants listed in Table 2 are shown in Table 23. Sources like atmospheric deposition (long-range transport, local industry, road traffic), pesticides, and irrigation water may contribute regionally and locally to the general background level of most organic contaminants in soils. Due to lack of representative background data for Norwegian soils, however, the background level for organic contaminants is not included in the calculated PECs.

Some data exists, however, that give an indication on what concentration levels that may be expected in Norwegian soils (Appendix A4).

The calculated agricultural soil concentrations of DEHP after 40 and 60 tons of sludge application per ha (0.89 and 1.3 mg/kg, Table 23), are comparable to the levels shown in Appendix A4. This indicates that the contribution sewage sludge to agricultural soil concentrations contribute at the same level as other sources. The calculated concentrations of DEHP in park areas and soil mixtures (Table 23) are much higher than values shown in Appendix A4 and sewage sludge therefore must be considered the main source for DEHP in these areas whenever sludge is used.

The calculated concentration of DBP in agricultural soils (0.011 and 0.016 mg/kg) is approximately 10 times lower than what is assumed to be the background concentration (Appendix A4). Calculated concentrations for park areas and soils mixtures are comparable to, but still somewhat lower than background concentrations.

No data exist on the background concentration of octylphenol and octylphenolethoxilates in soils.

The calculated short term (0 days) concentration levels of nonylephenol and nonylephenolethoxilates in agricultural soils (0.41-0.74 mg/kg) are at the same level or somewhat higher than the assumed background concentrations (Appendix A4). The calculated soil concentrations of octyl- and nonylephenols including ethoxilates in park areas and soil mixtures (Table 23) are significantly higher than the assumed background level (Appendix A4).

The calculated short term (0 days) concentrations of LAS for agricultural soils, park areas and soil mixtures (Table 23) are far higher than expected actual background concentrations (Appendix A4).

The calculated levels of PCBs in agricultural soils after applying 40 and 60 tons of sewage sludge per ha every 10th year for 100 years (0.0013 and 0.0019 mg/kg, Table 23), are below the background 0,003 mg/kg which is the mean concentration determined in Norwegian agricultural soil in the early 1990ies (Appendix A4). The calculated soil concentrations of PCB in park areas or soils mixtures are 0,002 mg/kg (Table 23), which is also below the background level for PCBs in Norwegian soils (Appendix A4).

The calculated concentrations for sum PAH in agricultural soils which have received 40 and 60 tons per ha are 0.04 and 0.06 mg/kg, which are well below the levels measured in topsoil in podzol profiles (Aamodt *et al*., 1996). Also the calculated soil concentrations for park areas (0.38 mg/kg) and soil mixtures (0.34 mg/kg) are below the level found in forest soils.

Table 23. Predicted soil concentrations of organic contaminants (mg/kg DW) after application of sewage slugde in soil mixture, park areas and respectively 40 and 60 tons sewage sludge on agricultural soil after 0 days, 90 days and 100 years. The concentrations after 100 years are immediately after the last application.

Compound	**Time**	**Sewage sludge (mg/kg DW)**	**Agricultural soil mg/kg DW**		**Park areas**	**Soil mixture**
		Mean	**40 tons**	**60 tons**	**5 cm sewage sludge, 10 cm soil**	**30% sewage sludge (w/w)**
DEHP	0 day	49.2	0.89	1.3	9.1	8.1
	90 days		0.68	1.0	6.9	6.2
	100 years		0.90	1.3	-	-
DBP	0 day	0.34	0.011	0.016	0.11	0.10
	90 days		0.003	0.005	0.01	0.01
	100 years		0.011	0.016	-	-
Octylphenols	0 day	0.47	0.10	0.15	1.0	0.90
	90 days		0.02	0.02	0.16	0.14
	100 years		0.10	0.15	-	-
Octylphenol ethoxylates	0 day	0.57	0.009	0.01	0.09	0.08
	90 days		0.001	0.001	0.01	0.01
	100 years		0.009	0.01	-	-
Nonylphenols	0 day	29.6	0.49	0.74	5.0	4.5
	90 days		0.08	0.12	0.8	0.72
	100 years		0.49	0.74	-	-
Nonylphenol ethoxylates	0 day	24.3	0.41	0.61	4.1	3.7
	90 days		0.03	0.05	0.33	0.30
	100 years		0.41	0.61	-	-
LAS	0 day	1441	24	36	245	218
	90 days		3.1	4.6	31	28
	100 years		24	36	-	-
ΣPAH4	0 day		0.006	0.009	0.062	0.055
	90 days		0.005	0.007	0.047	0.042
	100 years		0.006	0.009		
ΣPAHs	0 days	1.8	0.04	0.06	0.38	0.34
	90 days		0.02	0.03	0.23	0.20
	100 years		0.04	0.06	-	-
ΣPCB_7	0 days	0.012	0.0002	0.0003	0.002	0.002
	90 days		0.0002	0.0002	0.002	0.001
	100 years		0.0013	0.0019	-	-

ΣPAH4: Sum of benzo (a)pyrene, chrysene, benz(a)anthracene and benzo(b)fluoranthene, ΣPAHs: sum of 16 PAHs, ΣPCB_7: Sum of PCB-28, PCB-52, PCB-101, PCB-118, PCB-138, PCB-153, PCB-180.

5.3. Predicted concentrations in plants after sewage sludge application

This chapter discusses some important factors involved in plant uptake. Furthermore, the model used to calculate plant concentrations are described and plant concentrations are estimated. Uptake and concentration of contaminants in plants are not endpoints in the risk assessment, but important factors both for the accumulation of persistent contaminants in soil through the contaminant removal process and for estimating the exposure of animals and humans to the contaminants from sewage sludge.

The most important pathway for plant uptake of heavy metals and organic contaminants from soils, including pore water, is through the roots. Only this uptake will be considered in the plant uptake calculations in the present risk assessment. Uptake of contaminants through other exposure routes, such as uptake of evaporated contaminants from the air through the leaves are assumed to be of little significance and are not included in the exposure estimations.

The transfer of contaminants from bulk soil into the root zone (rhizosphere) is primarily mediated by the regular water uptake in the plants. The concentrations of contaminants in soil water are dependent on their mobility in soil. Despite considerable progress in recent years, the significance of factors such as speciation of e.g. trace metals, their mobility and transport remain an important area of research. Plant uptake processes involve predominately passive transport, caused by the plants water uptake and natural transpiration, however active uptake has been found for some compounds and some plant species (Bromilow & Chamberlain, 1995).

Another challenge in order to predict plant uptake based on measured soil concentrations is that soil conditions in the rhizosphere might be quite different from those in bulk soil. Through root respiration and excretion of root exudates plants influence pH, organic acid content, redox conditions etc. that in turn may influence the mobility and bioavailability of contaminants. Plant species differ widely in their ability to absorb and accumulate contaminants. Thus, to base plant uptake estimations on parameters measured in bulk soil may give uncertain results. However, as rhizosphere measurements are very labour-intensive and methodologically difficult to carry out, bulk soil analyses are usually the only measurements available, and will thus be used in the present risk assessment.

Transfer of contaminants from roots to above-ground parts (translocation) and further to leaves and grain is particularly important for the subsequent transfer of contaminants from plants to animals and human beings. Transport of contaminants from the root system to the stem, leaves and storage organisms, e.g. seeds, tubers, follows the same pathways as other compounds in the plants via the vascular transport system (include xylem (up-flow) and phloem (both up and down flow). During the translocation, the contaminants have to penetrate several plant tissues and at least one cell membrane. Water and solutes diffuse laterally into adjacent tissues and may become concentrated in plant shoot, tubers and fruits (McFarlane, 1995). This process is dependent on the equilibrium between water in the vascular system and the aqueous solution in cell tissues, and the sorption to cell walls. The translocation and accumulation in above-ground plant parts depends therefore on the combination of their aqueous solubility and their solubility in the lipid-rich cell membrane.

As already mentioned; in this risk assessment, the predicted plant concentrations are based only on soil/root exposure. Concentrations in both root- and above ground plant materials are estimated for a range of crops. For accumulating contaminants, e.g. for heavy metals and organic compounds with half-lives > 300 days, uptake in plants are estimated both one year and after hundred years with repeated sludge application. For degradable organic contaminants, the estimated soil concentration 90 days after sewage sludge dispersal is used in the estimations of plant concentrations. This is considered to represent the mean of an average soil concentration during the growth period in Norway of approximately 180 days.

5.3.1. Factors influencing the uptake

Plants only absorb the bioavailable fraction of a contaminant in soil. The bioavailable fraction of a contaminant will differ between plant species, several soil bio-physico-chemical parameters and characteristics of the contaminant itself. Measurements and prediction of bioavailable forms of contaminants in soil, and thereby the plant uptake, remain an important area of research. The plant uptake of contaminants predicted in this risk assessment is based on results from studies of relationships between plant uptake and well-defined parameters describing the contaminant and the soil conditions.

Soil pH and content of clay, organic matter and (hydro) oxides influence the mobility of contaminants in soil. Increasing content of organic matter in soil usually decreases the concentration of bioavailable metal species and organic chemicals in soil solution. A fraction of the organic matter in sludge will resist decomposition and could provide protection against e.g. plant metal uptake for decades. On the other hand, availability of sludge-born metals to plants is generally highest immediately after the application of sludge to soil. The reason for this initial high bioavailability is that rapid organic matter decomposition produces soluble organic carriers for metals. Organic matter appears to have different roles in controlling trace metal availability. Insoluble organic matter effectively inhibits uptake of contaminants that bind strongly to organic matter and thereby are prevented from diffusing to roots. However, soluble organics raise the carrying capacity of soil solutions for several sludge-borne metals forming soluble metal-organic complexes from where plants can extract the metal.

In addition to soil and the contaminants' chemical properties, the composition and physiology of the plant root itself is of importance, e.g. the plant lipid content. The plant uptake is based on equilibrium between the element concentration in soil water and the aqueous phase within the plant root and the chemical sorption to lipophilic root constituents' components, including membranes and cell wall lipids (Briggs *et al.*, 1983). Lipophilic organic compounds have a higher tendency to absorb to plant root lipids than hydrophilic chemicals. The lipophilic property of an organic chemical expressed as the octanol-water partition coefficient (K_{ow}), is therefore included in most equations and models for uptake of non-ionic organic chemicals in plant roots.

5.3.2. Uptake models for inorganic compounds

The root uptake and translocation of contaminants in plants involves complex processes both in the soil and in the plant (chapt. 5.3.1) and algorithms describing e.g. the relationship between plant concentrations and various soil parameters (e.g. total element concentration in soil, organic matter and clay content, pH, concentration of competing metal) are known for only a limited number of contaminants. In this risk assessment, therefore, plant concentrations are calculated using bio concentration factors (BCFs). This approach is based on the fact that the concentration of trace metals in plants or different parts of the plant (stem, leaf, grain etc.) is proportional to the total concentration in soil (Eq. 16A).

The BCFs are based upon empirical data (see Annex A5) where different plant species are grown on soil with varying properties. BCFs may differ not only between soils and plant varieties, but also between plants within the same plant variety (i.e. between geno types within the same variety).

In this risk assessment BCFs for leafy vegetables, carrots, potatoes, cereals and gras have been used. The BCFs have been calculated using different models (Chapter 5.3.3) or they are modifications of BCFs taken from literature (inorganic contaminants).

$$Cplant_{grain,stem,leaf} = Csoil \cdot BCF_{grain,stem,leaf} \qquad \textbf{Eq. 16A}$$

Where

$Cplant_{grain,\ stem,\ leaf}$ = concentration in grain, stem, leaf [mg kg^{-1} dw]

Csoil = total concentration in soil [mg kg^{-1} dw]

$BCF_{grain,\ stem,\ leaf}$ = bioconcentration factor for the actual plant part [dw plant/dw soil]

5.3.2.1. Predicted concentration of inorganic contaminants in plants

Table 24 shows shows the concentrations of heavy metals in different plant groups (i.e. leafy vegetables, root vegetables, etc.) growing in soil where 40 tons or 60 tons sewage sludge per ha and per 10th year, after 100 yrs (i.e. after 10 doses of sewage sludge) has been applied. The plant concentrations are estimated based on BCFs. Thus, the plant concentrations are correlated with the accumulated soil concentrations after 100 years of 40 or 60 tons/ha/10th years application (Table 22). For comparison, the background values for heavy metal concentrations in the plants growing in soil without any sewage sludge application are given (background).

The estimated figures show that for the heavy metals Cd, Hg, Zn and Cu sewage sludge application becomes the major source for plant uptake when the doses is as high as 60 tonns/ha/10yr. In addition to having only harmful effects on plant growth, Cd and Hg are certainly also unwanted in plant products for consumption by animals or human beings. Our estimations suggest about 50% increases in plant Cd concentration relative to the background values when the 60 tons/ha/10th year level is considered. Compared to the 40 tons/ha/10th year level it represents an unwanted increase, as well. The plant Hg concentration at the 60 tons/ha/10th years is not very high. However, at this application level sewage sludge represents 81% of the antropogenic source and any increase is alarming due to the toxisity of the element. Zn and Cu are essential plant nutrients, but higher plant concentrations than desired might be toxic to the plant or animals and human being consuming the plant product. As Zn concentration from 20 to 150 mg/kg DM is usually considered as the desired plant concentration. An increase to 44 mg/kg DM (Table 24) is certainly thus not alarming. For Cu plant concentrations between 2 and 20 mg/kg DW is the desired level. Taking other sources into account, 100 years with application of 60 tons sewage sludge per ha per 10th year will lead to an excess in cereals (22 mg/kg DW).

Table 24. Predicted concentrations of inorganic contaminants in different plants after 100 years of application of respectively 40 tons and 60 tons sewage sludge on agricultural soil every 10th year. The predicted concentrations are calculated using bioconcentrations factors (BCF) for each contaminant. Levels are given in µg/kg on dry weight (DW).

Inorganic				**Other**	**40 t, 100 years**			**60 t, 100 years**		
Contaminant	**Plant type**	**BCF**	**Background**	**sources 100 years**	**Sludge**	**Sum**	**% sludge of total**	**Sludge**	**Sum**	**% sludge of total**
Cadmium	Leafy vegetables	0.21	46	3.8	28	78	36	42	92	46
	Root vegetables	0.09	20	1.6	12	33		18	39	
	Cereals	0.13	28	2.3	17	47		25	56	
	Gras	0.21	46	3.8	28	78		42	92	
Lead	Leafy vegetables	0.002	36	0.56	5.4	42	13	8.1	45	18
	Root vegetables	0.0003	7.2	0.11	1.1	8.4		1.6	8,9	
	Cereals	0.0009	20	0.32	3.1	24		4.6	25	
	Gras	0.007	167	2.6	25	195		38	208	
Mercury	Leafy vegetables	0.005	0.21	0.02	0.67	0.91	74	1.0	1.2	81
	Root vegetables	0.005	0.21	0.02	0.67	0.91		1.0	1.2	
	Cereals	0.013	0.60	0.07	1.9	2.6		2.9	3.5	
	Gras	0.011	0.49	0.05	1.6	2.1		2.4	2.9	
Nickel	Leafy vegetables	0.021	443	8.5	49	500	10	73	524	14
	Root vegetables	0.030	633	12	69	715		104	749	
	Cereals	0.060	1255	24	138	1417		206	1486	
	Gras	0.070	1477	28	162	1667		243	1748	
Zinc	Leafy vegetables	0.30	19170	586	16214	35970	45	24321	44078	55
	Root vegetables	0.12	7668	234	6486	14388		9729	17631	
	Cereals	0.17	10863	332	9188	20383		13782	24977	
	Gras	0.28	17892	547	15133	33572		22700	41139	
Copper	Leafy vegetables	0.09	1728	70	3980	5778	69	5970	7767	77
	Root vegetables	0.09	1728	70	3980	5778		5970	7767	
	Cereals	0.26	4896	198	11276	16370		16914	22008	
	Gras	0.21	4032	163	9286	13481		13929	18124	
Chromium	Leafy vegetables	0.003	81	1.3	12	94	12	18	100	18
	Root vegetables	0.006	163	2.5	23	189		35	200	
	Cereals	0.017	461	7.2	66	534		99	567	
	Gras	0.021	569	8.9	82	660		123	701	

5.3.3. Uptake models for organic compounds

Several different generic plant uptake models for organic chemicals have been published. The models vary widely in their structure, complexity and in input requirements, ranging from regression-based simple steady-state equations describing a plant BCF for a single chemical parameter to complex and parameter-intensive dynamic models with several compartments (e.g. root, stem, foliage, fruit compartments) and uptake both from soil and air. Different crop-specific models have been developed by Stefan Trapp and co-workers (2003) and include models for uptake in foliar vegetation (Trapp and Matthies, 1995), in roots (Trapp *et al.*, 2007), and in potato (as a tuber and not a root fruit) (Trapp *et al.*, 2007). Trapp has also developed a plant uptake and transport model for ionic chemicals (Trapp, 2004). A comprehensive comparison and evaluation of different plant uptake models has been performed by UK Environment Agency (Collins *et al.*, 2006). Models compared in that study were Trapp & Matthies (1995), Travis & Arms (1988), Topp *et al.* (1986), Chiou *et al.* (2001), Ryan *et al.* (1988), Hung & Mackay (1997), and Briggs *et al.* (1982, 1983).

Since it was beyond the scope of this risk assessment to make our own comparison or verification of existing models, it was decided to select plant uptake models based on the evaluation of Collins and co-workers (2006). For predicting shoot concentration, the model of Ryan *et al.* (1988) and Briggs *et al.* (1982, 1983) proved to the best ones. However, the model by Ryan and coworkers (1988) was slightly better than Briggs and coworkers (1982, 1983) and was therefore chosen in this risk assessment. The model of Ryan *et al.* (1988) is a semi-mechanistic understanding of plant uptake and is based on the empirical studies of Briggs *et al.* (1982, 1983) including compounds in the range of log K_{ow} from 0-4. Even with the log K_{ow} restriction in other experiments (Briggs *et al.*, 1982, 1983), the shoot uptake model of Ryan and coworkers (1988) showed also a good verification at log Kow range of 4.5 – 6.5 in the evaluation done by Collins and coworkers (2006).

Prediction of root concentrations was found to be generally poor for all six models reviewed (Collins *et al.,* 2006). The best models were those by Travis and Arms (1988) and Trapp and Matthies (1995), however, these models had a tendency to under-predict and over-predict uptake, respectively. The model by Travis and Arms (1988) was established only for above ground plant parts but was evaluated both for uptake in leafy and root vegetables. In addition, the model by Travis & Arms (1988) showed in general, a better result for the estimation of root concentrations than leaves concentration. Both of these models are applied in our risk assessment (Collins *et al.,* 2006). Travis & Arms (1988), regression is obtained from a wide range of empirical data with different types of plants and chemicals with log K_{ow} ranging from 1.15 to 9.35. The model proposed by Trapp & Matthies (1995) (a mechanistic, generic and one-compartment model), incorporates the volume fraction of lipids in the calculations, as well as K_{ow}.

Since the plant uptake models by Ryan *et al.* (1988) is applied in the risk assessment procedure for contaminated land in Norway (SFT, 1999), this root uptake model is also included even though it showed highly over-prediction of root concentrations in the comparison performed by Collins *et al.* (2006).

All applied models in the risk assessment include the lipophilic property of the compound, expressed as log K_{ow}. Log K_{ow} is per definition only for neutral (non-dissociated) compounds, while log D is the octanol-water distribution coefficient that combines log K_{ow} and pK_a (acid dissociation constant) and produces an apparent partition coefficient for any pH value. The phenolic acids included in this risk assessment are all weak acids (pKa for 4-nonylphenol has been reported to be 10.7, Romano, 1991) and it is assumed that these compounds are present as neutral (non-dissociated) at pH 6.1 which is chosen pH for this work.

Trapp's (2004) model for uptake into roots and translocation of ionic compounds is highly complex and includes processes such as lipophilic sorption, electrochemical interactions, ion trap, and advection in xylem. A calculation for predicting uptake of ionic drugs in plants is not performed in this work.

The highest concentration calculated by the selected models was used for risk assessment for further endpoints depending on plant uptake.

5.3.3.1. Ryan *et al.* (1988).

The soil-to-plant root (root concentration factor, RCF) (Eq.17A) and the soil-to plant stem (stem concentration factor, SCF) (Eq. 18A) concentration factors modelled by Ryan *et al.* (1988) are calculated as:

$$RCF = \left(10^{0,77\log K_{ow}-1,52}+0,82\right)\cdot\left(\frac{\delta}{\theta+\delta K_{oc}f_{oc}}\right)$$ **Eq. 17A**

Where
RCF – calculated soil-to-plant root concentration factor [µg g^{-1} FW plant/ µg g^{-1} DW soil]
K_{ow} – octanol-water partition coefficient for the chemical
δ – soil bulk density [g DW cm^{-3}]
θ – soil-water content by volume [cm^3 cm^{-3}]
K_{oc} – organic carbon-water partition coefficient for the chemical [cm^3 g^{-1} DW]
F_{oc} – fraction of organic carbon in the soil

$$SCF = \left(10^{0,95\log K_{ow}-2,05}+0,82\right)\cdot\left(0,784\cdot 10^{-0,434\left(\frac{(\log K_{ow}-1,78)^2}{2,44}\right)}\right)\cdot\left(\frac{\delta}{\theta+\delta K_{oc}f_{oc}}\right)$$ **Eq. 18A**

Where
SCF – calculated soil-to-plant stem concentration factor [µg g^{-1} FW plant/ µg g^{-1} DW soil]
K_{ow} – octanol-water partition coefficient for the chemical
δ – soil bulk density [g DW cm^{-9})
θ – soil-water content by volume [cm^3 cm^{-3}]
K_{oc} – organic carbon-water partition coefficient for the chemical [cm^3 g^{-1} DW]
F_{oc} – fraction of organic carbon in the soil

5.3.3.2. Modified Trapp and Matthies, 1995 (from TGD).

In this model calculation of contaminant concentration in root tissue is based on equations where K_{ow} is corrected slightly for the differences between plant lipids and octanol (Trapp & Matthies, 1995). The $K_{plant\text{-}water}$ can be calculated as:

$$K_{plant-water} = Fwater_{plant} + Flipid_{plant} \bullet Kow^{b}$$ **Eq. 19A**

$Fwater_{plan}$	volume fraction water in plant tissue	$[m^3 \cdot m^3]$	0.65
$Flipid_{plant}$	volume fraction lipids in plant tissue	$[m^3 \cdot m^3]$	0.01
K_{ow}	octanol-water partitioning coefficient	$[m^3 \cdot m^3]$	
b	correction for differences between plant lipids and octanol	[-]	0.95
$K_{plant-water}$	partition coeff.between plant tissue and water	$[(mg \cdot m\ plant^3)/(mg \cdot mwater^3)]$	

Concentration in root tissue (Equation 20A) in mainly governed by physical sorption, and is given by:

$$Croot_{plant} = \frac{K_{plant-water} \bullet C_{porewater}}{ROH_{plant}}$$ **Eq. 20A**

$K_{plant-water}$	partition coeff.between plant tissue and water	$[m^3 \cdot m^3]$	
$C_{pore-water}$	concentration in porewater of soil	$[m^3 \cdot m^3]$	
RHO_{plant}	bulk density of plant tissue	$[kg \cdot m^3]$	700
$Croot_{plant}$	concentration in root tissue of plant	$[mg \cdot kg^{-1} FW]$	

5.3.3.3. Travis and Arms (1988).

The model by Travis and Arms is established for above-ground plant parts (Equation 21A) but have also been evaluated both for uptake in leafy and root vegetables by Collins *et al.* (2006). The bioconcentration factor by Travis and Arms is as follow:

$$\log BCF = 1.588 - 0.578 \cdot \log K_{ow}$$ **Eq. 21A**

Where
BCF – bioconcentration factor for above-ground plant parts ($\mu g\ kg^{-1}$ FW plant/$\mu g\ kg^{-1}$ DW soil)
Kow – octanol-water partition coefficient for the chemical

5.3.3.5. Predicted concentration of organic contaminants in plants

Predicted concentration of organic contaminants in plants is calculated based on the above mentioned different uptake models. Estimated concentrations of organic contaminants in plants growing in soil applied 40 tons or 60 tons sewage sludge are shown in Table 25. Soil concentration 90 days after the 1st sludge application is used for non-accumulating compounds. For accumulating compounds the soil concentration after 100 years application (every 10th year) is chosen for estimating plant uptake.

Only the predicted concentration that comes out highest is presented in Table 25. The result shows that the model by Ryan *et al.,* 1988 is the one that gives the highest predicted concentration for all the contaminants in Table 25 except for DEHP where Travis & Arms, 1988 gave the highest value and for root vegetables were the model by Trapps and Matthies applied in TGD (EC, 2003) gave the highest predicted concentrations.

The model by Trapps and Matthies gives increased uptake in root with increased lipophility of the compound. Highest estimated concentrations were seen for DEHP, followed by nonylphenols, nonylphenol etoxilates and ocylphenol (Table 25). The order reflects the compounds half lives, log K_{ow}, and soil concentration after sewage sludge application, where DEHP showed the highest estimated soil concentration (1.0 mg/kg DW), relatively high K_{ow} (7.5) and half life (300 d). The phenols had log K_{ow} around 4-4.5, $t_{1/2}$ 5-10 days and initial soil concentration from 0.001-0.12 mg/kg DW. For the above-ground plant parts (leafy vegetables, grass and cereals) nonylphenol etoxylates, nonylphenol and ocylphenol gave highest estimated concentration. This change of order (e.g. much lower DEHP concentration), reflect that estimated translocation of organic compounds to above-ground parts follows a bell-shaped curve in relation to lipophility.

As mentioned, the applied plant uptake models are valid only for neutral organic compounds. Prediction of plant uptake and further risk assessment of human or animal eating feed is therefore not performed for dissociable compounds except for the phenolic acids. These compounds have pK_a higher than 10 (Romano, 1991) and are assumed to mainly be present as neutral compounds at pH 6.1. A calculation for predicting uptake of ionic compounds by the model by Trapp (2004) is not performed in this risk assessment. For surface active compounds like e.g. LAS, Kow is not suitable prediction of environmental fate, and no models are available so far. Growth experiments with LAS uptake in plants have been performed in Denmark (Grøn, 1998; Petersen, 2003; Laturnus, 2007). Modeling of uptake of LAS different models, including Trapp and Matthies model in TGD, gave an high overestimation related to measured concentration (Grøn, 1998), however, as know, none of these models are suitable for predicting uptake neither ionic nor surface active compounds. In an article about risk assessment for LAS in sewage sludge used on agricultural soil (Schowanek, 2007), the authors claim no build-up or adverse impact on animal/human health have been reported for agricultural fields which has received sludge with high LAS levels for up to 30 years. Even there is relatively high concentrations of LAS in sewage sludge, their fast degradation ($t_{1/2}$ 8 days, Appendix A2), minimal uptake in plants and low bioaccumulation in the environment (Tolls 2000), reduce the risk of biotransfer via plants to animals and humans. Ingestion of agricultural food products is not expected to contribute to any significant extent to the total LAS exposure of consumers (HERA, 2007).

Table 25. Predicted concentration of organic contaminants in plants calculated with different plant uptake models. Figures are given in µg/kg dry weight (DW) and fresh weight (FW) after application of 40 and 60 tons sewage sludge 90 days after sewage sludge application (non accumulating compounds) or after 100 years with repeated sludge application every 10th year (accumulating compounds). Only the highest predicted concentration is presented here. Ryan *et al.*, 1988 gave highest predicted concentrations in leafy vegetables, cereals and gras, except for DEHP (Travis & Arms, 1998). Trapp and Matthies model in TGD gave the highest predicted concentration in root vegetables for all the organic contaminants.

	Leafy vegetables		**Root vegetables**		**Cereals**		**Gras**	
Concentrations in plants (µg/kg dw)	**40 tons**	**60 tons**	**40 tons**	**60 tons**	**40 tons**	**60 tons**	**40 tons**	**60 tons**
DEHP	1.6	2.4	4509	6763	1.2	1.8	1.2	1.8
DBP	1.1	1.6	56	84	0.37	0.56	0.37	0.56
Octylphenols	13	19.1	237	356	4.5	6.8	4.5	6.8
Octylphenol ethoxylates	0.66	1.0	10	15	0.23	0.3	0.23	0.3
Nonylphenols	25	38.0	1027	1541	8.9	13.4	8.9	13.4
Nonylphenol ethoxylates	30	45.6	470	705	11	16.1	11	16.1
ΣPAH4	0.095	0.1	24	36	0.083	0.12	0.083	0.12
ΣPAH	4.8	7.2	131	198	2.3	3.4	2.3	3.4
ΣPCB7	0.0080	0.0	11	18.7	0.0014	0.002	0.0014	0.002
Concentrations in plants (µg/kg fw)	**Leafy vegetables**		**Root vegetables**		**Cereals**		**Gras**	
	40 tons	**60 tons**	**40 tons**	**60 tons**	**40 tons**	**60 tons**	**40 tons**	**60 tons**
DEHP	0.48	0.72	1353	2029	1.0	1.6	0.30	0.46
DBP	0.32	0.48	17	25	0.32	0.48	0.093	0.14
Octylphenols	3.8	5.7	71	107	3.8	5.7	1.1	1.7
Octylphenol ethoxylates	0.20	0.30	3.1	5	0.20	0.30	0.058	0.09
Nonylphenols	7.6	11	308	462	7.6	11	2.2	3.4
Nonylphenol ethoxylates	9.1	14	141	211	9.1	14	2.7	4.0
ΣPAH4	0.029	0.043	7.1	11	0.070	0.11	0.021	0.031
ΣPAH	1.4	2.2	39	59	1.9	2.9	0.56	0.85
ΣPCB	0.002	0.0041	3.3	6	0.0012	0.0018	0.00036	0.0005

ΣPAH4: Sum of benzo (a)pyrene, chrysene, benz(a)anthracene and benzo(b)fluoranthene, ΣPAHs: sum of 16 PAHs, ΣPCB_7: Sum of PCB-28, PCB-52, PCB-101, PCB-118, PCB-138, PCB-153, PCB-180.

5.4. Predicted water concentrations after sewage sludge application

Spreading sewage sludge on agricultural land or on green areas may results in increased levels of contaminants in both surface- and ground water. This may pose a risk of effect on biota in surface waters as well as humans drinking surface water or ground water. Transport of contaminants from the soil to surface water occurs through the drainage system or by runoff on the soil surface. The amount of contaminants leaching into surface water depends on soil type, meteorological conditions and the physical/chemical properties of the contaminants. Models developed for estimation of leakage of pesticides to surface waters have been used for the prediction of concentrations of sludge contaminants in surface water.

Most drinking water in Norway originates from surface water sources. Surface waters used as drinking water sources are more remote from the agricultural land where sludge is applied than the primary receiving waters. Therefore, a higher dilution factor (100) has been used to calculate the PEC for drinking water. The concentrations of contaminants in the ground water have been set equal to the estimated pore water concentrations in shallow ground water at 1 m depth in the soil profile.

5.4.1 Drainage to surface water

The leakage of contaminants from sludge mixed to agricultural soil into drainage water has been calculated using the model MACRO GV (Stenmo *et al.*, 2005). The program is linked to the simulation model MACRO 5.0 (Larsbo & Jarvis 2003) using input data on weather, crop, soil texture and properties of the contaminant. The model simulates the leakage to ground water at 1 m depth in the soil and it is assumed that this water may be diverted to surface water through the drainage system. The simulation period in this model is 26 years. A safety factor is included in the simulations in accordance to the practice used in the Focus-scenarios (FOCUS 2000), which were used in the EU for the risk assessment of pesticides.

5.4.1.1. Parameterization of the model

A file containing climatic data for 26 years is used in the simulations. Parameters included are temperature, precipitation, radiation and humidity. The data selected are from Kongsvinger annual mean temperature 7.8 °C and 785 mm precipitation. The crop is spring cereal and the soil type is river deposited soil with 30-60% sand and 4-6% clay. Experience from modelling leakage of pesticides has shown that this soil type represents a worst case in terms of leakage potential. The chemical contaminants are characterized with regard to half-life and K_{OC}. The sludge dose used in simulation is 60 tons/ha added every ten years. The initial concentration in the soil is calculated assuming that the sludge is mixed into the upper 10 cm of the soil. The content of organic carbon in the soil after addition of sludge is assumed to be 2%.

The model output includes the mean and the 80th percentile of the contaminant concentration in drainage water for each year and the mean concentration in ground water at 1 m depth.

5.4.2 Surface run-off

The transport of contaminants from the sludge to surface by run-off on the surface of soils has been calculated using the Pesticide Root Zone Model (PRZM3).

The **P**esticide **R**oot **Z**one **M**odel (PRZM3) is a one-dimensional, dynamic, compartment model that can be used to simulate chemical movement in unsaturated soil systems within and below the root zone.

PRZM3 can be used to estimate runoff, leaching and associated pesticide loading. The model uses a Soil Conservation Service curve number technique to estimate runoff and the Universal Soil Loss Equation (USLE) to estimate erosion. Evapotranspiration is estimated directly from pan evaporation or based on an empirical formula. Evapotranspiration is divided among evaporation from crop interception, evaporation from soil and crop transpiration. Water movement is simulated by the use of generalized soil parameters, including field capacity, wilting point and saturation of water content. A more detailed description of the model can be found in Carousel *et al*. (2006).

5.4.2.1. Parameter estimation

The parameter estimation is normally performed at two stages: an uncalibrated simulation followed by a simulation with calibration of the most sensitive parameters to fit the measured values from field trials. The hydrology module is always calibrated first and the pesticide module last. This is important, as water is the carrier of pesticides through the soil and knowledge of the water flow is a prerequisite of a valid description of the movement of pesticides in soil. This procedure has been suggested in the Cost Action 66 project (Vanclooster *et al.*, 2000). Normally three main sources of information are used for parameter estimation: measurements or calculations based on measurements, the PRZM3 manual or other literature sources and expert judgments. After calibration validation is the next step. In the validated simulations, it is not allowed, according to Good Modelling Practice, to alter parameters with the exception of data changes that are dependent in the climate and pesticide properties due to the introduction of additional pesticides in the experimental field.

5.4.2.2. Prerequisite for the simulations of sludge

The simulation of the runoff is based on real data from a field trial at a farm (Foss gård, Lier) in the period from 1998 to 2001. The physical and chemical properties of the soil are described in Appendix A6 (in Norwegian). The size of the field plot was 40x25m with 5.9% slope and a slope length of 40m. The water run-off from plot number 2 was calibrated by using observed data in 1998 (Figure 6 and Figure 7) and validated with data from the year 2000 (Figure 8). There is a good correlation between the observed and the estimated values, indicating a good prediction by the model.

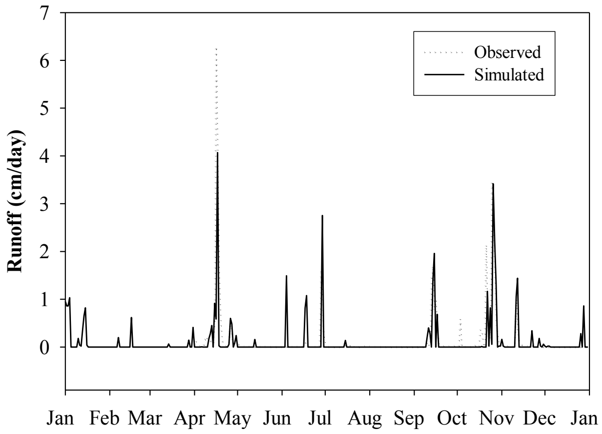


Figure 6. Calibrated run-off water 1998 (plot 2)

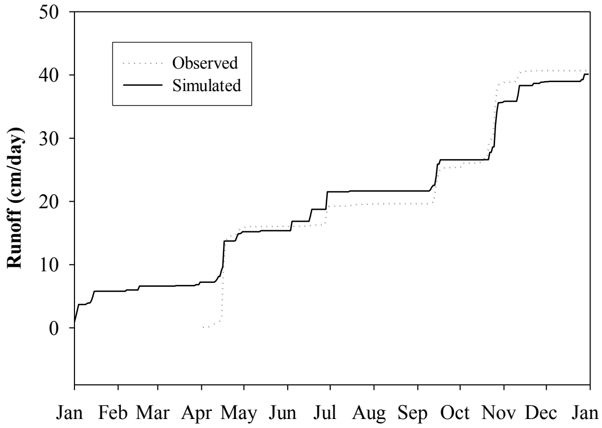


Figure 7. Calibrated cumulative run-off water 1998 (plot 2)

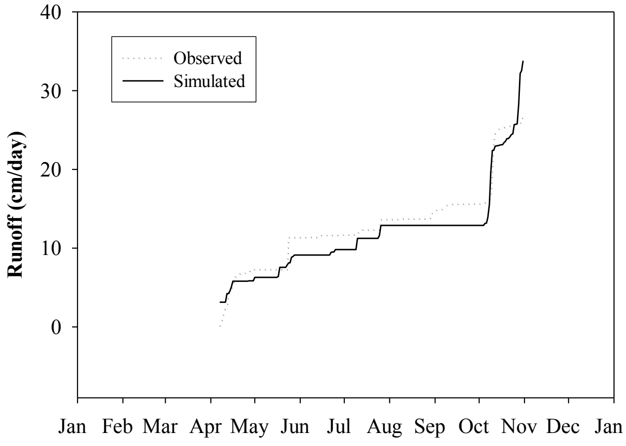


Figure 8. Validated cumulative run-off water 2000 (plot 2)

Instead of using pesticides, the simulation was performed with sludge (60 tons) applied on bare soil and incorporated in the soil down to 20 cm. The concentrations of the compound added correspond to the calculated amount of active ingredient according to the content of the different contaminant in the sludge. Ten years of climate data were used for the simulation. The output of the simulation is shown as concentrations of the simulated ingredients in the run-off solution at the edge of the field based on daily runoff events (Figure 9). No safety factor is included in the calculations. For the organic compounds, decay rates data from Chapter 5.2 are used. For the heavy metals, rates are set to the maximum of the model.

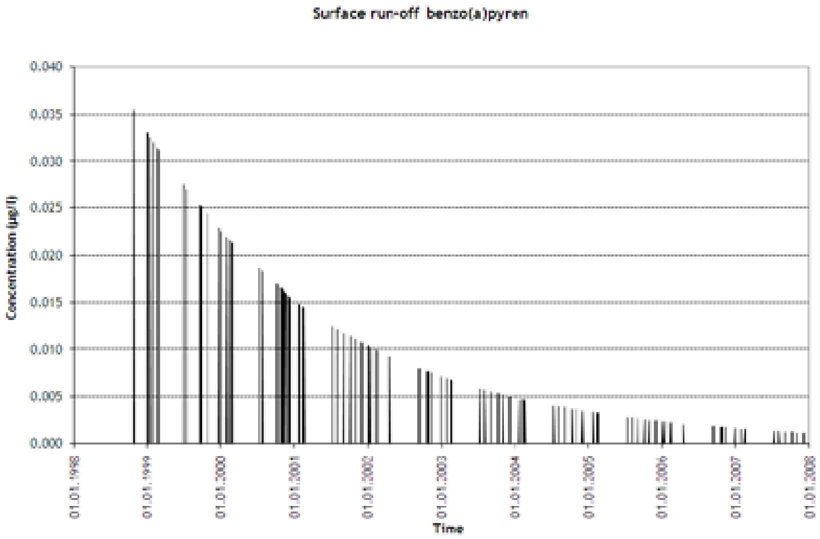


Figure 9. Concentrations of benzo[a]pyrene in surface run-off after 10 years as simulated by the PRZM3 model.

5.4.2.3. General comments to the results

According to Carousel *et al*. (2006), the PRZM3 model enable modeling of the fate of organic chemicals such as pesticides as well as organic and inorganic nitrogen species. In Norway, the model has previously been used and tested with field data from pesticide leaching and run-off. In this exercise, calibration with real field data from sludge amendments have not been done, only the water-flow has been calibrated. Therefore the results from the simulation should be handled with care.

5.4.3. Predicted concentrations in surface waters

Maximum concentrations in surface waters draining agricultural areas where sludge has been applied can be estimated from the sum of concentrations in drainage water and surface run-off. Furthermore, it is assumed that the drainage and run-off water is diluted a factor 10 in the primary recipient.

Table 26. Estimated concentrations of metals and organic contaminants in surface water draining agricultural areas after application of sewage sludge. Other sources for the contaminants are not included in the estimations. The concentrations in water draining through the soil, the run-off water on the soil surface and the total concentrations are given. $PEC_{Surface\ water}$ = predicted surface water concentrations. The drainage and run-off water is diluted a factor 10 in the primary recipient.

Substance	**Drainage µg/l**	**Run-off µg/l**	**Sum µg/l**	**$PEC_{Surface\ water}$ µg/l**
Cadmium	4.56E-15	0.027	0.027	0.0027
Lead	4.98E-22	0.368	0.368	0.0368
Mercury	5.60E-23	0.015	0.015	0.0015
Nickel	3.67E-22	0.236	0.236	0.0236
Zinc	3.20E-21	5.53	5.53	0.553
Copper	2.80E-21	4.55	4.55	0.455
Chromium		0.2	0.2	0.02
DEHP		0.038	0.038	0.0038
DBP	1.07E-11	0.022	0.022	0.0022
Octylphenol	2.46E-09	0.022	0.022	0.0022
Octylphenol etoxilate	2.12E-12	1.60E-09	1.60E-09	1.60E-10
Nonylphenol	5.80E-15	0.00007	7E-05	7E-06
Nonylphenol etoxilate	2.95E-11		2.95E-11	2.95E-12
LAS	8.15E-19	0.00014	0.00014	1.4E-05
Naphtalene	9.91E-04		0.00099	0.000099
Acenaphtylene	5.58E-06	0.33	0.330	0.033
Acenaphtene	6.22E-06	2.95	2.95	0.295
Fenantrene	1.21E-12	0.34	0.34	0.034
Antracene	2.23E-14	0.01	0.01	0.001
Fluorene	1.30E-07	0.52	0.52	0.052
Fluoranthene		0.099	0.099	0.0099
Pyrene	3.06E-20	0.228	0.228	0.0228
Benzo(a)anthracene		0.02	0.02	0.002
Chrycene		0.075	0.075	0.0075
Benzo(b)fluoranthene		0.095	0.095	0.0095
Indeno (1,2,3-cd)pyrene		0.053	0.053	0.0053
dibenzo(a,h)antracene		0.0037	0.0037	0.00037
Benzo(g,h,i)perylene		0.022	0.022	0.0022
Benzo(a)pyrene		0.035	0.035	0.0035

The calculations show that surface run-off is the dominating route of transport of pollutants from the soil to surface waters.

Table 27. Estimated concentrations of organic contaminants and metals in drinking water obtained from ground water and surface water reservoirs after application of sewage sludge as soil conditioner on nearby soil. Other sources for the contaminants are not included in the estimations. The concentrations of contaminants in the ground water have been set equal to the estimated drainage water concentrations. An additional dilution factor (10) has been used to calculate the PEC for surface drinking water.

Substance	**Ground water µg/l**	**Surface water µg/l**
Cadmium	4.56E-15	0.00027
Lead	4.98E-22	0.00368
Mercury	5.60E-23	0.00015
Nickel	3.67E-22	0.00236
Zinc	3.20E-21	0.0553
Copper	2.80E-21	0.0455
Chromium		0.002
DEHP		0.00038
DBP	1.07E-11	0.00022
Octylphenol	2.46E-09	0.00022
Octylphenol etoxilate	2.12E-12	1.6E-11
Nonylphenol	5.80E-15	7E-07
NFEO1	2.95E-11	2.95E-13
LAS	8.15E-19	1.4E-06
Naphtalene	9.91E-04	9.9E-06
Acenaphtylene	5.58E-06	0.0033
Acenaphtene	6.22E-06	0.0295
Fenantrene	1.21E-12	0.0034
Antracene	2.23E-14	0.0001
Fluorene	1.30E-07	0.0052
Fluoranthene		0.00099
Pyrene	3.06E-20	0.00228
Benzo(a)anthracene		0.0002
Chrycene		0.00075
Benzo(b)fluoranthene		0.00095
Indeno (1,2,3-cd)pyrene		0.00053
dibenzo(a,h)antracene		3.7E-05
Benzo(g,h,i)perylene		0.00022
Benzo(a)pyrene		0.00035

5.5. Grazing animals and animals eating feed: exposure assessment and carry-over in animal products

Production animals may be exposed to contaminants in sewage sludge through grazing and by getting feed from plants grown on sludge-amended areas. In addition the animals may be exposed to the contaminants by consumption of water affected by the sewage sludge. The latter route of exposure is not assessed in this risk assessment. The estimated water concentrations (Chapter 5.4) are, however, very low and are probably of minor importance for the exposure.

The intake of concentrates (grain-based feed), roughage and soil for the different production animals is given in Table 28 depending on if they are grazing pastureland or receiving feedstuff. As mention in Chapter 4.2.3 cattle, sheep, goats and horses at pasture may get their whole feed ration from pasture plants. However, dairy cows and goats usually also receive grain-based feed (concentrate) when at pasture. Cattle in particular, may also ingest some soil depending on pasture quality and the mineral need of the animals. The intake of soil is supposed to constitute only up to some percentages (<5%) of the dry matter ration.

Poultry and pigs moving outside may ingest grass and other vegetables and may also ingest considerable amounts of soil. However, these animals may not usually move around in sewage sludge spread areas.

Roughage use to constitute the main ration for herbivore domestic animals like cattle, sheep, goats and horses receiving feedstuff (exposure route 6). In addition, concentrate (grain based feed) or in some cases potatoes etc. are given at a certain ratio (up to about 1/3 of the dry matter ration to these species).

The dry matter intake relative for body weight for the different production animals is listed in Table 28. All values are based on Pond *et al.* (1995).

Table 28. Dry matter intake of farm animals related to body weight and their relative intake of concentrates, roughage and soil.

Animal species	**Weeks at pasture**	**Percent DW intake related to bw**	**Animals at pasture** Ratio of total intake (DW)			**Animals receiving feed** Ratio of total intake (DW)		
			Concentrates	Roughage	Soil	Concentrates	Roughage	Soil
Cattle								
Calves	8	3	0.1	0.85	0.05	0.25	0.75	0
Young heifers	8	2.7	0.1	0.85	0.05	0.25	0.75	0
Dry cows	8	1.7	0.1	0.85	0.05	0.15	0.85	0
High lactation cows	8	4	0.35	0.6	0.05	0.35	0.65	0
Sheep								
Newly weaned lambs	16	5.0	0	0.98	0.02	0.25	0.75	0
Finishing lambs	16	4.0	0	0.98	0.02	0.25	0.75	0
Adult sheep maintenance	16	2.0	0	0.98	0.02	0.1	0.9	0
Sheep with suckling twins	16	4.0	0	0.98	0.02	0.25	0.75	0
Goats								
Kids	16	3.5	0.1	0.88	0.02	0.1	0.9	0
Adult goats maintenance	16	2	0.1	0.88	0.02	0.1	0.9	0
High lactating goats	16	6	0.25	0.73	0.02	0.25	0.75	0
Horses								
Adult maintenance	16	1.5	0.25	0.7	0.05	0.3	0.7	0
Mares in lactation	16	3	0.25	0.7	0.05	0.3	0.7	0
Pigs								
Newly weaned piglets		10				0.9	0.1	0
Growing pigs		4				0.9	0.1	0
Adult pigs maintenance		1.2				0.9	0.1	0
Lactating sows		3.2				0.9	0.1	0
Poultry								
Growing chickens		10				0.9	0.1	0
Laying hens		6				0.9	0.1	0

5.5.1. Exposure to inorganic contaminants for grazing animals and animals receiving feed

Table 29 shows the background and predicted total intake of inorganic contaminants from sewage sludge, and Table 30 the predicted intake via grazing and received feed grown on cropland where sewage sludge have been used. The level of sewage sludge used for this calculation is 60 tons per 10th year for a period of 100 years, which implies a 50% increase compared to the present allowed level at 40 tons per 10th year as a worst case scenario.The predicted intake is based on the figures in Table 28 that shows the ratio of total dry matter intake for the different animals both at pasture and those receiving feed inside.

Table 29. Predicted intake of inorganic contaminants in livestock after eating plants grown on cropland where 60 tons of sewage sludge per hectare have been used every ten years of a period of 100 years. Figures are given in µg/kg body weight per day. The figures include both intake from pasture and received feed.

Animal species	Cd			Pb			Hg			Cu			Cr			Ni			Zn		
	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total	Back-ground	Sewage sludge	Total
Cattle																					
Calves	2.8	2.6	5.7	44	10	55	0.10	0.48	0.59	274	946	1230	73	16	90	116	19	137	1069	1356	2457
Young heifers	2.6	2.3	5.1	40	9	49	0.09	0.43	0.53	246	851	1107	66	14	81	104	17	123	962	1220	2212
Dry cows	1.6	1.5	3.3	25	6	31	0.06	0.27	0.33	154	531	691	41	9	51	66	11	78	618	784	1420
High lactation cows	3.5	3.2	7.0	57	13	70	0.14	0.65	0.80	377	1303	1695	96	21	118	151	25	179	1327	1683	3050
Sheep																					
Newly weaned lambs	4.6	4.1	9.1	39	8.76	48	0.10	0.46	0.57	429	1483	1929	82	18	101	165	27	195	1747	2217	4018
Finishing lambs	3.7	3.3	7.3	31	7.01	38	0.08	0.37	0.46	343	1186	1543	66	14	81	132	22	156	1398	1774	3214
Adult sheep maintenance	1.9	1.7	3.7	16	3.60	20	0.04	0.18	0.23	169	584	760	33	7	41	66	11	79	720	914	1656
Sheep with suckling twins	3.7	3.3	7.3	31	7.01	38	0.08	0.37	0.46	343	1186	1543	66	14	81	132	22	156	1398	1774	3214
Goats																					
Kids	3.2	2.9	6.4	27	6.19	34	0.07	0.32	0.40	299	1033	1344	58	12	71	116	19	137	1235	1567	2841
Adult goats maintenance	1.8	1.7	3.7	16	3.54	19	0.04	0.19	0.23	171	590	768	33	7	41	66	11	78	706	896	1623
High lactating goats	5.2	4.7	10.4	44	10.01	55	0.12	0.57	0.70	528	1824	2373	97	21	119	194	32	230	1991	2527	4579
Horses																					
Adult	1.4	1.2	2.7	22	4.90	27	0.05	0.24	0.30	139	482	627	36	8	44	57	9	68	513	651	1180
Mares in lactation	2.7	2.5	5.4	43	9.80	54	0.10	0.48	0.60	279	964	1254	72	16	89	114	19	135	1027	1302	2360
Pigs																					
Newly weaned piglets	3.0	2.7	5.9	3.50	0.79	4.4	0.06	0.28	0.35	481	1662	2162	47	10	58	128	21	151	1157	1467	2659
Growing pigs	1.2	1.1	2.4	1.40	0.32	1.7	0.02	0.11	0.14	192	665	865	19	4	23	51	8	60	463	587	1064
Adult pigs maintenance	0.36	0.32	0.71	0.42	0.10	0.52	0.01	0.03	0.04	58	199	259	6	1	7	15	3	18	139	176	319
Lactating sows	0.96	0.87	1.9	1.12	0.25	1.4	0.02	0.09	0.11	154	532	692	15	3	19	41	7	48	370	470	851
Poultry																					
Growing chickens	3.0	2.7	5.9	3.5	0.79	4.4	0.06	0.28	0.35	481	1662	2162	47	10	58	128	21	151	1157	1467	2659
Laying hens	1.8	1.6	3.6	2.1	0.48	2.6	0.04	0.17	0.21	289	997	1297	28	6	35	77	13	91	694	880	1596

Table 30. Predicted intake of inorganic contaminants in livestock after eating plants grown on cropland where 60 tons of sewage sludge per hectare has been used every ten years of a period of 100 years. Figures are given in µg/kg body weight per day. The figures include both intake from pasture and received feed.

	Cd		**Pb**		**Hg**		**Cu**		**Cr**		**Ni**		**Zn**	
	Total at pasture	Total received feed	Total at pasture	Total received feed	Total at pasture	Total received feed	Total at pasture	Total received feed	Total at pasture	Total received feed	Total at pasture	Total received feed	Total at pasture	Total received feed
Cattle														
Calves	3.2	2.5	50	4.9	0.50	0.092	658	573	70	20	86	50	1344	1113
Young heifers	2.8	2.2	45	4.4	0.45	0.083	592	516	63	18	78	45	1210	1002
Dry cows	1.8	1.5	28	3.1	0.28	0.051	373	318	39	12	49	29	762	658
High lactation cows	3.9	3.2	65	5.8	0.67	0.13	916	779	91	26	113	66	1631	1419
Sheep														
Newly weaned lambs	4.9	4.1	40	8.1	0.42	0.15	974	955	68	33	111	84	2163	1855
Finishing lambs	4.0	3.3	32	6.5	0.34	0.12	780	764	54	27	89	67	1730	1484
Adult sheep maintenance	2.0	1.8	16	3.8	0.17	0.059	390	370	27	14	44	34	865	790
Sheep with suckling twins	4.0	3.3	32	6.5	0.34	0.12	780	764	54	27	89	67	1730	1484
Goats														
Kids	3.3	3.1	27	6.6	0.30	0.10	696	648	47	24	77	60	1457	1383
Adult goats maintenance	1.9	1.8	16	3.8	0.17	0.059	398	370	27	14	44	34	833	790
High lactating goats	5.4	5.0	45	9.7	0.51	0.18	1228	1146	79	40	129	101	2353	2226
Horses														
Adult	1.5	1.2	25	2.3	0.25	0.046	338	289	35	9,9	43	25	636	544
Mares in lactation	3.0	2.4	49	4.6	0.50	0.093	675	579	69	20	85	50	1272	1089
Pigs														
Newly weaned piglets	0	5.9	0	4.4	0	0.35	0	2162	0	58	0	151	0	2659
Growing pigs	0	2.4	0	1.7	0	0.14	0	865	0	23	0	60	0	1064
Adult pigs maintenance	0	0.71	0	0.52	0	0.042	0	259	0	7,0	0	18	0	319
Lactating sows	0	1.9	0	1.4	0	0.11	0	692	0	19	0	48	0	851
Poultry														
Growing chickens	0	5.9	0	4.4	0	0.35	0	2162	0	58	0	151	0	2659
Laying hens	0	3.6	0	2.6	0	0.21	0	1297	0	35	0	91	0	1596

5.5.2. Concentration of inorganic contaminants in meat and liver for human consumption

Cadmium

Cadmium accumulates in the kidney and to a lesser extent in the liver. The cadmium levels in liver and kidney are highly correlated. In cattle and pigs fed elevated concentration of cadmium in the diet for 2-3 months, the correlation coefficients between cadmium in liver and kidney for cattle (N=57) and for pigs (N=37) were 0.98 and 0.87, respectively (Lyche & Bernhoft, 2005, unpublished report). The cadmium concentrations in the kidneys were 4-5 times higher than in the livers. In cattle, a daily dose of cadmium at about 0.07-0.08 mg/kg b.w. (Correspondingto about 2.5 mg/kg total dry matter diet) for 2 months resulted in a liver cadmium level of 0.5 mg/kg (which is the maximum permissible cadmium level in livers for human consumption). This corresponds to a total cadmium intake of 4.5 mg/kg b.w. during the exposure period. Thus, a biodisposition factor of 0.1 for liver concentration of cadmium related to total cadmium intake per kg body weight may be derived. The cadmium residues in meat and milk are low and usually negligible (Klaassen, 2008). In pigs fed elevated levels of cadmium for 2-3 months the liver cadmium level was about 150 times higher than the corresponding level in muscles, and the correlation coefficient was 0.82 (N=25) (Lyche & Bernhoft, 2005, unpublished report). The cadmium liver: muscle ratio was even higher for cattle.

In the present risk assessment, a liver: muscle ratio of 200 for cadmium in various animal species is used. The biodisposistion factor used is 0.1 for liver concentration and 0.0005 for meat concentration related to total cadmium intake per kg body weight.

Lead

Lead is far less absorbed in the plants than cadmium and in addition a biotransfer factor from feed intake to liver or kidney seems to be lower than for cadmium. Experimental studies in cattle, sheep and pigs fed diets containing lead levels at 15-25 mg/kg dry matters indicate that although residues in the liver and kidney were elevated compared with control animals, they remained below the maximum permissible levels for animal products (0.5 mg/kg fresh weight in offal's) (referred in EFSA, 2004b). As for cadmium, the lead concentration in muscles is usually negligible. In sheep a feed concentration of lead at even 100 mg/kg dry matter did not exceed the maximum permissible levels in liver and kidneys. However, in calves fed 100 mg lead/kg dry matter feed for 100 days (corresponding to 3 mg/kg b.w. per day), liver and kidney contained 2.3 and 4.7 mg/kg, but muscle tissue remained below the limit of detection. Thus, the biodisposition factor of lead in the calf liver related to the total lead intake per kg b.w. during the 100 days was 0.008.

Thus, the biodisposition factors used in the present risk assessment are 0.008 for liver and 0.00004 for meat concentration related to total lead intake per kg body weight using a liver: muscle ratio of 200 for lead in various animal species.

Mercury

For mercury even less quantitative data concerning transfer into animal products are available. For inorganic mercury the absorption and disposition is not very different from that of lead, and as an approximation due to lack of more exact data, the same biodisposition factor for liver and muscle may be used. Organic (methyl) mercury is the relevant compound to assess since the absorption is higher than for inorganic mercury and the distribution into eatable products as meat, and probably also into milk and eggs is considerable. In chickens fed methyl mercury in the diet for 8 weeks (0.05-1.35 mg/kg feed), the biodisposition factor into muscle of 0.7-1.0 may be derived (concentration in muscle from this exposure related to the total dose per kg b.w.). The corresponding disposition factor for liver was somewhat higher. In eggs from laying hens fed the same concentrations in the diet for 28 weeks, a steady state after 4 weeks was found for most doses. At steady state the biotransfer factor from feed to eggs was 0.13. The data on methylmercury levels in sewage sludge is limited but available data indicate that methylmercury constitute ca 3% or lower of the total mercury concentration (Carpi *et al*., 1997; Shoham-Frider *et al*., 2007). Therefore, we chose to neglect the risk of methyl mercury in the present risk assessment.

For the other inorganic compounds, risks related to possibly elevated residues in animal products seem unlikely.

Only the mean intake figures (μg/kg b.w. for their whole lifespan) for calves, young heifers, finishing lambs, growing pigs and growing chickens are used to calculate the predicted concentration in meat and liver since most of the food products humans eat are from these animal species.

Table 31. Bio disposition factors (BDF) for inorganic contaminants and the following concentrations in meat and liver (μg/kg w/w) when mean intake figures for calves, young heifers, finishing lambs, growing pigs and growing chickens are used (μg/kg b.w. for their whole lifespan).

	Cd	**Pb**	**Hg**
BDF Meat	0.0005	0.00004	0.00004
BDF Liver	0.1	0.008	0.008
Concentration Meat	0.44	0.26	0.003
Concentration Liver	89	52	7.6

5.5.3. Exposure to organic contaminants for grazing animals and animals eating feed

Table 32 shows the predicted intake of organic contaminants in animals after grazing and/or receiving feed grown on cropland where sewage sludge have been used. The level of sewage sludge used for this calculation is 60 tons per 10th year for a period of 100 years, which implies a 50% increase compared to the present allowed level at 40 tons per 10th year as a worst case scenario. The predicted intake is based on the figures in Table 28 which shows the ratio of total dry matter intake for the different animals, and the predicted concentration in plants (Table 25).

Table 32. Predicted intake of organic contaminants in ruminants after eating plants grown on cropland where 60 tons, of sewage sludge per hectare have been used every 10th year for a period of 100 years. Figures are given in µg/kg body weight per day and show the contribution from intake from pasture and received feed for one year.

	DEHP	DEHP	DBP	DBP	Octylphenols	Octylphenols	Octylphenol ethoxylates	Octylphenol ethoxylates	Nonylphenols	Nonylphenols	Nonylphenol ethoxylates	Nonylphenol ethoxylates	ΣPAH4	ΣPAH4	ΣPAH	ΣPAH	ΣPCB	ΣPCB
	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed	Pasture	Received feed
Cattle																		
Calves	0.018	0.022	0.0050	0.0067	0.060	0.081	3.1E-03	4.2E-03	0.12	0.16	0.14	0.19	1.1E-03	1.5E-03	0.030	0.041	2.2E-05	2.6E-05
Young heifers	0.016	0.020	0.0045	0.0060	0.054	0.073	2.8E-03	3.8E-03	0.11	0.14	0.13	0.17	1.0E-03	1.3E-03	0.027	0.037	2.0E-05	2.3E-05
Dry cows	0.010	0.011	0.0028	0.0032	0.034	0.039	1.8E-03	2.0E-03	0.068	0.078	0.0814	0.093	6.3E-04	7.2E-04	0.017	0.020	1.2E-05	1.2E-05
High lactation cows	0.035	0.034	0.0100	0.0103	0.12	0.12	6.2E-03	6.4E-03	0.24	0.25	0.29	0.30	2.2E-03	2.3E-03	0.06	0.062	4.2E-05	4.0E-05
Sheep																		
Newly weaned lambs	0.024	0.037	0.0069	0.011	0.083	0.14	4.3E-03	7.0E-03	0.16	0.27	0.20	0.32	1.5E-03	2.5E-03	0.041	0.068	2.8E-05	4.3E-05
Finishing lambs	0.019	0.029	0.0055	0.0090	0.066	0.11	3.4E-03	5.6E-03	0.13	0.21	0.16	0.26	1.2E-03	2.0E-03	0.033	0.054	2.3E-05	3.4E-05
Adult sheep maintenance	0.009	0.011	0.0027	0.0035	0.033	0.042	1.7E-03	2.2E-03	0.066	0.083	0.079	0.10	6.1E-04	7.7E-04	0.017	0.021	1.1E-05	1.3E-05
Sheep with suckling twins	0.019	0.029	0.0055	0.0090	0.066	0.11	3.4E-03	5.6E-03	0.13	0.21	0.16	0.26	1.2E-03	2.0E-03	0.033	0.054	2.3E-05	3.4E-05
Goats																		
Kids	0.020	0.020	0.0060	0.0061	0.072	0.073	3.7E-03	3.8E-03	0.14	0.15	0.17	0.17	1.3E-03	1.3E-03	0.036	0.037	2.4E-05	2.3E-05
Adult goats maintenance	0.012	0.011	0.0034	0.0035	0.041	0.042	2.1E-03	2.2E-03	0.082	0.083	0.10	0.10	7.6E-04	7.7E-04	0.021	0.021	1.4E-05	1.3E-05
High lactating goats	0.045	0.044	0.0133	0.013	0.16	0.16	8.3E-03	8.4E-03	0.32	0.32	0.38	0.39	2.9E-03	3.0E-03	0.080	0.081	5.3E-05	5.2E-05
Horses																		
Adult maintenance	0.012	0.012	0.0033	0.0036	0.039	0.044	2.0E-03	2.2E-03	0.078	0.087	0.094	0.10	7.3E-04	8.0E-04	0.020	0.022	1.4E-05	1.4E-05
Mares in lactation	0.023	0.024	0.0065	0.0072	0.079	0.087	4.1E-03	4.5E-03	0.16	0.17	0.19	0.21	1.5E-03	1.6E-03	0.039	0.044	2.8E-05	2.8E-05
Pigs													0					
Newly weaned piglets	0	0.14	0	0.044	0	0.53	0	0.0275	0	1.1	0	1.3	0	9.8E-03	0	0.27	0	1.7E-04
Growing pigs	0	0.058	0	0.018	0	0.21	0	0.011	0	0.42	0	0.51	0	3.9E-03	0	0.11	0	6.8E-05
Adult pigs maintenance	0	0.017	0	0.0053	0	0.064	0	0.0033	0	0.13	0	0.15	0	1.2E-03	0	0.032	0	2.0E-05
Lactating sows	0	0.046	0	0.014	0	0.17	0	0.0088	0	0.34	0	0.41	0	3.1E-03	0	0.086	0	5.4E-05
Poultry													0					
Growing chickens	0	0.14	0	0.044	0	0.53	0	0.0275	0	1.1	0	1.3	0	9.8E-03	0	0.27	0	1.7E-04
Laying hens	0	0.087	0	0.027	0	0.32	0	0.0165	0	0.64	0	0.76	0	5.9E-03	0	0.16	0	1.0E-04

5.5.4. Concentration of organic contaminants in meat and liver for human consumption

The concentrations of organic contaminants in meat and milk have been calculated using biotransfer factors from TGD (EC 2003). As stated by TGD, the biotransfer factor is defined as the steady state concentration in a receiving medium (meat, milk) divided by the animals' daily intake of the substance in source media (air/grass/soil/drinking water).

$$BTF_{meat} = 10^{-7.6 + \log Kow}$$

$$BTF_{milk} = 10^{-8.1 + \log Kow}$$

In this risk assessment, the respective biotransfer factors are used to calculate concentrations of in meat and milk after grazing and eating feed grown on soil that have been amended with sewage sludge.

Using bio transfer factors given in TDG predicted concentration in meat and milk could be calculated (Table 1). The predicted intake is calculated by using mean intake figures for calves, young heifers, finishing lambs, growing pigs and growing chickens since most of the food products humans eat are from these animal species.

Table 33. Bio transfer factors given in TDG (EC, 2003) for organic contaminants and the following concentration in milk and meat (µg/kg) when mean intake figures for calves, young heifers, finishing lambs, growing pigs and growing chickens are used (µg/kg /day).

	DEHP	**DBP**	**Octylphenols**	**Octylphenol ethoxylates**	**Nonylphenols**	**Nonylphenol ethoxylates**	**ΣPCB**	**ΣPAH4**	**ΣPAH**
BCF Meat	0.79	$9.3x10^{-4}$	$3.3x10^{-4}$	$2.5x10^{-4}$	$7.6x10^{-4}$	$2.5x10^{-4}$	0.01-0.40	0.009-0.31	$5.0x10^{-5}$-0.32
BCF Milk	0.25	$3.0x10^{-4}$	$1.0x10^{-4}$	$8.0x10^{-5}$	$2.4x10^{-4}$	$8.0x10^{-5}$	0.003-1.3	0.003-0.01	$6.3x10^{-5}$-0.10
Conc. Meat	0.027	$2.3x10^{-5}$	$4.1x10^{-5}$	$1.6x10^{-6}$	$1.9x10^{-4}$	$7.4x10^{-5}$	$2.9x10^{-6}$	$3.6x10^{-5}$	$9.9x10^{-5}$
Conc. Milk	0.0085	$7.3x10^{-6}$	$1.3x10^{-5}$	$5.0x10^{-7}$	$5.9x10^{-5}$	$2.3x10^{-5}$	$9.2x10^{-7}$	$1.1x10^{-5}$	$3.1x10^{-5}$

5.6. Exposure assessment humans (exposure route 7-12)

5.6.1. Total exposure - humans

The estimated concentrations of contaminants in food products as a result of dispersal of sewage sludge are combined with food consumption data. The food consumption data used in the exposure estimations are given in Table 34, and the estimated plant concentrations are found in Chapter 5.3. Table 34 also describes which model plant is used for the estimation of concentrations in individual food plants.

Table 34. Consumption of vegetables, meat and dietary products in Norway (NORKOST, 1997) and the model plants used for estimation of the concentrations.

Food item	Mean consumption g/day	High consumption (95th percentile) g/day	Model used for concentration
Cereals (wheat. oats rye. barley)	202	412	Cereal
Potato	122.6	261.2	Root plant
Carrot	31.6	98	Root plant
Swede	10.3	50	Root plant
Sum root plants	**165**	**409**	
Cabbage	3.6	16	Leafy vegetables
Cauliflower	0.5	2.8	Leafy vegetables
Chinese cabbage	3.9	14.8	Leafy vegetables
Cucumber	5.8	22.2	Leafy vegetables
Tomato	5.8	22.2	Leafy vegetables
Peppers	3.9	14.8	Leafy vegetables
Sum leafy vegetables	**23.5**	**93**	
Mixtures	21.3	67.8	Root plant
Unspecified vegetables	37.8	104.5	Root plant
Meat*	59.10	129.60	-
Liver*	0.70	4.50	-
Milk*	462.90	1091.50	
Cheese*	31.10	80.00	
Butter*	3.20	24.00	

* Animal-derived foot items are not included in the calculations for heavy metals since no transfer factor was available. Furthermore is is generally known that intake of the toxic heavy metals such as lead and cadmium is very low from meat products due to low concentrations in meat and low consumption of liver and kidneys in Norway.

The estimated intakes of the metals from food are summarized in Table 35 and Table 36. The estimated intakes from high consumers of the food item with the highest contribution to the estimated total dietary intake are also given. For metals, the background intake from plant-derived food items and carry-over through consumption of animal-derived food items have been estimated by estimating plant concentrations based on background soil concentrations and are included in the overall estimated intake for all metals. Intake of 3 heavy metals (cadmium, lead and mercury) included in the EU SCOOP projects from fish and crustaceans have been added to the estimated dietary intake from plants and animal-derived food products (respectively 3.55, 2.17 and 4.06 µg/day) (SCOOP, 2004). These intake estimates seem to be high. The median intake of Cd from fish and crustaceans has been estimated to 0.67 in another estimation of Cd intake (Fange, 2005). Similarly, the intakes estimated in SCOOP of Hg and Pb are probably overestimated. They are still used as additional intake from these food items, as other data were not available for all 3 metals. The use of these intakes from fish and crustaceans contribute to overestimations of the intakes of these metals. No intake from fish and crustaceans has been included in the intake estimates for the other metals as no data has been available to the working group.

For organic contaminants the background soil concentrations have not been included in the soil concentrations, and the mean intake from previous estimations of the Norwegian dietary intake have been added to the estimated intake from sewage sludge to give an estimation of the total intake following application of sewage soil. The Norwegian median dietary intake of PAH4 estimated by EFSA was used for PAHs (EFSA, 2008b) and the intake previously estimated for PCBs was used for PCB_6 (Helen E. Kvalem, personal communication, Kvalem *et al.*, in press).

The estimated intake from drinking water following contamination of water sources as a consequence of leakage following sewage sludge application is minimal (< 1% of the estimated intakes) and will not affect the estimated intakes.

Table 35. Mean og high intake of cadmium, lead and mercury from plants grown on cropland where sewage sludge have been used (present and after 100 years with repeated sludge application), and from meat and dietary products from animals given feed grown on cropland where sewage sludge have been used. High intake is calculated for the 95th percentile consumer of cereals, the main source of estimated dietary intake to metals and mean intake of metals from all other sources. Background intake is estimated with mean and 95th percentile consumption of cereals.

	Cadmium			**Lead**			**Mercury**		
	Background	**Total after 100 years**		**Background**	**Total after 100 years**		**Background**	**Total after 100 years**	
	Present	**40 tons/year**	**60 tons/year**	**Present**	**40 tons/year**	**60 tons/year**	**Present**	**40 tons/year**	**60 tons/year**
Food item	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**
Cereals	5.7	9.6	11	4.1	4.8	5.1	0.12	0.52	0.71
Root veg	3.3	4.7	6.5	1.2	1.4	1.5	0.03	0.15	0.20
Leafy veg	1.1	2	2	0.8	1.0	1.0	0.005	0.02	0.03
Mixtures	0.42	0.71	0.84	0.15	0.14	0.16	0.17	0.02	0.03
Unspecified vegetables	0.75	1.3	1.5	0.27	0.32	0.34	0.008	0.03	0.05
Meat	0.01	0.02	0.03	0.01	0.01	0.02	0.00003	0.0001	0.0002
Liver	0.03	0.05	0.06	0.03	0.03	0.04	0.0001	0.0003	0.0004
Fish	3.6	3.6	3.6	2.2	2.2	2.2	4.1	4.1	4.1
Total daily intake (mean)	**15**	**22**	**26**	**8.8**	**9.9**	**10**	**4.2**	**4.8**	**5.1**
High intake of main source	**21**	**32**	**38**	**13**	**15**	**16**	**4.1**	**5.3**	**5.8**

Table 36. Mean and high intake of nickel, zinc, copper and chromium from plants grown on cropland where sewage sludge have been used (present and after 100 years with repeated sludge application), and from meat and dietary products from animals fed on feed grown on cropland where sewage sludge have been used. High intake is calculated for the 95th percentile consumer of cereals, the main source of estimated dietary intake to metals and mean intake of metals from all other sources. Background intake is estimated with mean and 95th percentile consumption of cereals.

	Nickel			**Zink**			**Copper**			**Chromium**		
	Background	**Total after 100 years**		**Background**	**Total after 100 years**		**Background**	**Total after 100 years**		**Background**	**Total after 100 years**	
	Present	**40 tons/year**	**60 tons/year**	**Present**	**40 tons/year**	**60 tons/year**	**Present**	**40 tons/year**	**60 tons/year**	**Present**	**40 tons/year**	**60 tons/year**
Food item	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**
Cereals	254	286	300	2194	4117	5045	989	3307	4446	93	108	115
Root veg	104	118	123	1261	2367	2900	284	950	1278	27	31	33
Leafy veg	10	12	12	450	845	1036	41	136	183	1,9	2,2	2,4
Mixtures	13	15	16	163	306	376	37	123	165	3,5	4,0	4,3
Unspecified vegetables	24	27	28	290	544	666	65	218	294	6,1	7,1	7,6
Meat	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Liver	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Fish	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total daily intake (mean)	**406**	**458**	**480**	**4359**	**8180**	**10024**	**1416**	**4734**	**6365**	**131**	**152**	**162**
High intake of main source	**669**	**755**	**792**	**6641**	**12460**	**15269**	**2444**	**8172**	**10986**	**228**	**264**	**281**

n.c: not calculated
n.a. no data available

The estimated intakes of Cd, Pb and Hg may be compared with the results from the estimations made within the report on task from the Scientific Cooperation (SCOOP, 2004). The estimated total dietary intakes of Cd and Pd in Norway in this project were comparable to previous estimations of the intake of these metals (SCOOP, 2004; Fange, 2005). There are some differences relating to contribution from different food categories. These differences are likely to at least partly be derived from the different approaches used, especially related to modelling versus use of analytical results and a different categorazation of food items. The accordance with previous estimations increases the reliability of the modelling.

No other estimates of the intake of the other metals from food have been available to VKM. It s therefore not possible to estimate the total intake for those metals, and only the contribution originating in soil conenctrations has been included, which excludes other dietary sources such as fish and crustaceans.

Table 37. Mean intake (ug/day) of organic contaminants from plants grown on cropland where sewage sludge have been used (after 100 years with repeated sludge application of 40 and 60 tons), and from meat and dietary products from animals given feed grown on cropland where sewage sludge have been used. High intake is calculated as 95th percentile consumer of potato, the main source of estimated dietary intake to organic contaminants and mean intake of organic contaminants from all other sources. Mean body weight for adults is 70 kg.

40 tons application – 100 years	**DEHP**	**DBP**	**Oktylphenol**	**Octylphenol etoxilates**	**Nonylphenol**	**Nonylphenol etoxilates**	**Σ PAH 4**	**Σ PCB6**
Food item	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**
Cereals	0.21	0.06	0.77	0.04	1.54	1.84	0.01	0.0002
Root plants	222	2.8	11.7	0.50	48	23	1.2	0.50
Leafy vegetables	0.01	0.01	0.09	0.005	0.18	0.21	0.001	5.0E-05
Mixtures	29	0.4	1.5	0.06	6.6	3.0	0.15	0.06
Unspecified vegetables	51	0.6	2.7	0.12	12	5.3	0.27	0.11
Meat	0.001	3.9E-07	1.5E-06	6.1E-08	7.1E-06	2.8E-06	1.3E-06	1.0E-07
Milk	0.003	9.9E-07	3.8E-06	1.5E-07	1.8E-05	7.2E-06	3.4E-06	2.9E-07
Mean background intake (µg/day)	-	-	-	-	-	-	1.45	0.0047
Total intake (µg/day)	303	3.8	17	0.7	68	33.6	3.1	0.7
High Consumer of main source (µg/day)	490	6.1	25.9	1.1	109	51	4.1	1.1
60 tons application – 100 years	**DEHP**	**DBP**	**Oktylphenol**	**Octylphenol etoxilates**	**Nonylphenol**	**Nonylphenoletoxilates**	**Σ PAH 4**	**Σ PCB_6**
Food item	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**	**ug/day**
Cereals	0.31	0.10	1.16	0.06	2.30	2.76	0.02	0.0003
Root plants	334	4.2	18	0.75	71	35	1.8	0.85
Leafy vegetables	0.02	0.01	0.13	0.007	0.27	0.32	0.001	0.0001
Mixtures	43	0.5	2.3	0.10	9.8	4.5	0.23	0.11
Unspecified vegetables	77	1.0	4.0	0.17	17.5	8.0	0.41	0.20
Meat	0.002	5.8E-07	2.2E-06	9.1E-08	1.1E-05	4.2E-06	2.0E-06	1.5E-07
Milk	0.004	1.5E-06	5.7E-06	2.3E-07	2.7E-05	1.1E-05	5.1E-06	4.0E-07
Mean background intake (µg/day)	-	-	-	-	-	-	1.45	0.0047
Total intake (µg/day)	454	5.8	25	1.1	101	50	3.9	1.2
High Consumer of main source (µg/day)	735	9.2	38.8	1.7	163	77	5.4	1.9

-No data available

The estimated levels of exposure to organic contaminants from food are generally low. For most of the contaminants there are no other estimates of the human exposure from food in Norway available for comparision. The estimates indicate that consumption of root plants such as potatoes may be a major source of exposure to certain organic contaminants such as PCB_6 and PAH4 following the use of sewage sludge on agricultural soil. VKM considers this to be an artifact of the model used for plant uptake. Experimental studies show that less PCB is absorbed into potatoes than predicted by the models. Furthermore, most of tha PCB in potatoes will be present in the peel (further discussed in Chapter 5.8.3.). The model is therefore considered to overestimate the human exposure to PCB from root vegetables. This will probably also apply to other organic contaminants.

5.6.2. Children ingesting soil

As described in Chapter 4 children may ingest soil particles at playgrounds. VKM Panel 5 has chosen to use 0.2 g soil/day as an amount a child could ingest of soil per day. In Table 38 and Table 39 intake of inorganic and organic contaminants from 0.2 g sludge-treated soil is estimated.

There were only minor increases in the concentrations of contaminants when sewage sludge was added to different types of soil. The estimated intakes were only slightly higher than the intakes from soil with present background levels of inorganic contaminants (Table 38). The estimated intakes from soil are much lower than the estimated intakes from food (Table 35 and Table 36).

Table 38. Intake (ug/day) of some inorganic contaminants in children eating 0.2 g soil/day.

Inorganic Contaminant	Present background	Agricultural soil, 60 tons After 100 years	Park area	Soil mixture
Cadmium	0.04	0.09	0.06	0.06
Lead	4.8	6	4.7	4.7
Mercury	0.01	0.06	0.04	0.04
Nickel	4.2	5	4	4
Zinc	13	31	22	21
Copper	3.8	18	12	11
Chromium	5.4	6.7	5.3	5.3

For organic contaminants data on background levels in soil were not available, and the estimated intakes could not be compared with intakes from soil not influenced by sewage sludge (Table 39). The estimated intakes of organic contaminants among children eating soils are much lower than the estimated intakes from food (Table 37).

Table 39. Intake (ug/day) of some organic contaminants in children eating 0.2 g soil/day.

Organic contaminant	Agricultural soil, 60 tons After 100 years	Park area	Soil mixture
DEHP	0.3	1.8	1.6
DBP	0.0009	0.02	0.02
Octylphenols	0.005	0.2	0.2
Octylphenolethoxylates	0.0002	0.02	0.02
Nonylphenols	0.02	1	1
Nonylphenol ethoxylates	0.01	0.8	0.8
LAS	0.9	49	49
Sum PAH4	0.01	0.8	0.8
SUM PCB_6	0.00005	0.0004	0.0004

5.7. Sensitivity analysis - Discussion of methodology for exposure modelling

Sensitivity analysis involves calculations on how various constants and algorithms influence the results of the risk assessment. In every step of the model calculations, several values may be used (i.e. the concentration in sewage sludge, partitioning coefficients, etc).

5.7.1.1. Local versus regional exposure scenario

For all the exposure routes, the calculated local concentration (local exposure scenario), PEC_{Local}, may be used as a worst-case scenario. The worst-case scenario implies that humans and animals in the area of sludge application consume food or feed only from that area i.e. an area that receives the highest permissible amount of sewage sludge over 100 years. For humans, this is an unrealistic scenario since most of the consumed food is not from local soils but from the local supermarket.

For grazing animals, the use of sludge amended local soils is a more realistic exposure scenario since these animals may receive all their food from the local sludge-treated farmland.

To make a more realistic scenario for the human exposure of accumulating contaminants, we have to consider what fraction of the agricultural area receives sewage sludge.

The total area for grain production in Norway was 0.31 million ha in 2006 (84 780 ha (27 %) wheat, 149 750 ha (48%) barley, 72 820 ha (23%) oat) (SSB 2006). Assuming that the maximum amount of sewage sludge applied annually is 40 tons/ha and the annual production of sewage sludge for agriculture is 60 000 tons (about 60 % of the total production), 15 000 ha will receive the maximum amount of sewage sludge every year. Taking into consideration that the total Norwegian area for grain production is 0.31 million ha, only 4.8% of the area will receive the maximum permissible amount of sewage sludge in 100 years time. If all sewage sludge amended to agricultural soils is amended on areas used for wheat production, (84 780 ha), nearly 18% of the wheat area will receive the maximum amount of sludge during a 100 year period.

Regionally this may be somewhat different. In Oslo and Akershus counties the total area used for grain production was 60 970 ha and the wheat area 16 880 ha. In 2002 the amount of sewage sludge used for agricultural purposes was 23 119 tons (SSB 2008) and the grain production area which receive maximum amount of sewage sludge therefore is 5780 ha. During a 100 year period 9.5% of the total grain area or 34% of the area used for wheat production may have received sewage sludge.

Today 70-80 percent of Norwegian grain production is for feed production (mainly barley and oat). In a normal year 75% of the wheat for human consumption in Norway is produced domestically, 25% is imported. The Norwegian wheat for human consumption is produced (tons) in four counties:

- Vestfold: 57000
- Østfold: 135000
- Akershus: 81000
- Hedmark: 49000

This amount (322 000 tons) is processed at four mills in Norway. The wheat produced in Vestfold is milled in Skien and Oslo (Bjølsen), the wheat produced in Østfold is treated at Vaksdal (Bergen), Skien and Trøndelag (Buvika), the wheat produced in Akershus is milled at Bjølsen (Oslo) and the wheat produced in Hedmark is milled at Bjølsen and Trøndelag (Kilde: Olav Bruvik, Norgesmøllene AS).

The distribution of grain products from the mills is mostly regional which means that Oslo and Akershus counties will have the highest fraction of locally produced wheat. Based upon the information given above, this means that in a worst case scenario as much as 34% of the Norwegian produced wheat consumed by the population in Oslo and Akershus may have received maximum amount of sewage sludge. However, taking into account that some of the wheat produced in Vestfold and Hedmark (106 000 tons) also is milled at Bjølsen, the fraction of sewage sludge produced wheat is smaller, assumably about 20-25% (some of the wheat from Vestfold and Hedmark also will be produced on sludge amended soils).

The above information shows that the human exposure for sewage sludge produced wheat vary depending on the scale of exposure (national, regional) and whether sludge is amended to wheat areas only or to all grain areas (wheat, barley, oat) (Table 40).

Table 40. Overview of amount of sludge for agricultural production, area used for total grain and wheat production and percentage of area that will have received the maximum permissible amount of sewage sludge after 100 years. Data for Norway and Oslo and Akershus.

	Sludge (tons/year)	**Area (ha)**		**Area (%) recieving max sludge within 100 years**	
		Grain	**Wheat**	**Grain**	**Wheat**
Norway	67000	313390	84780	5.3	19.8
Oslo/Akershus	23000	60970	16880	9.4	34.1

A realistic worst-case scenario may be that 10% of the wheat consumed by the population in Oslo and Akershus in 100 years comes from sludge amended-areas.

5.7.1.2. Changes in soil properties with time

As mentioned (Chapter 5.2.1.6) an increase in SOM is expected after 100 years of sludge application to an agricultural soil. Increased SOM content will increase the sorption of both heavy metals and several organic contaminants in soils, reducing leaching and increase the fraction of contaminants accumulating in soils.

The degradation rates for compounds with low K_{ow} in soil seem to be relatively high while compounds with high K_{ow} have long degradation rates in soils (DT_{50} month-years) and may accumulate in the soil. Since the biological uptake of contaminants from soils is concentration-dependent, a compound's persistence in soil has an obvious impact on potential uptake both in the short and long term. In sustainable agricultural practice, the total input rate of organic contaminants to soil should not exceed the rate of degradation. The modelling of future soil concentrations show that DEHP, the sum PCB_7 and benzo(b)fluoranthen, indeno(123cd)pyrene, dibenzo(ah)antracene, benzo(ghi)perylene and benzo(a)pyrene accumulate in the soil. One important question in this context is whether the application of sewage sludge also increases degradation of organic contaminants, compared to the standard conditions used when determining the DT_{50}. Application of sewage sludge increases the amount of soluble organic carbon and nutrients in the soil and also increases the general microbial activity in the soil.

5.7.1.3. Discussion of plant uptake models (metals)

Using an algorithm for calculation of plant metal concentrations, explained in Appendix A1 or using BCFs, also explained in Appendix A1, represent two different ways of calculating plant trace metal concentration as a consequence of plant uptake from soil. The plant concentrations (plant uptake values estimated in µg (or mg) kg^{-1} DM (by algorithms or by BCFs, or by direct use of measured plant concentration values) is then transformed to amount of trace metal removed in µg (or mg)/m^2 by relating the plant metal concentration to the actual crop production in kg/m^2 (amount of crop yield and which type of growth) in Norway during a 100 year sequence.

The use of BCF's are based on the fact that for most trace metals, a positive correlation between plant trace metal concentration and total concentration of the same element in soil is found. The BCF reflects the relationship between the total amount in soil and the concentration in plant, i.e. the bioavailable fraction of the total soil content. As described in Chapter 5.3., the bioavailable parts of the total soil concentration is dependent on soil physico-chemical conditions that may vary with soil types (pH, content of clay minerals, (hydro) oxides, organic matter, etc.), climate and management practise. These variations are not considered using BCF. Strictly speaking, a BCF is relevant only for a particular soil, in a particular climatic situation (e.g. the ambient climatic conditions during one particular growth season), for a particular plant species (also genotypic variety of a species). Since such universal correlation studies are lacking, estimated BCFs are used to approach relationships under other conditions than those they were originally based on.

For a few trace elements (particularly Cd), several studies on relationships between soil physico-chemical relationships and plant uptake have been carried out. Based on these studies, multiple regression equations including correlations between those soil characteristics that are most important for the bioavailability of the trace metal and the plant concentration are developed. Usually these equations include soil pH and organic matter content, but sometimes also percentage of clay, (hydro) oxides and concentrations of competing trace elements. As mentioned in Chapter 5.3., rhizosphere conditions may be quite different from bulk soil conditions. The coefficients used in the algorithms (Appendix A1) may reflect these differences, as they appear to relate measured plant concentrations to bulk soil characteristics. However, the coefficients in the algorithms may be as site specific as the BCFs (method 2).

5.7.1.4. Discussion of plant uptake models (organic contaminants)

Selection of plant uptake models for this risk assessment was based on the evaluation and comparison of several models performed by Collins and co-workers (2006). In addition, the root uptake model by Ryan and co-workers (1988) was included since it is applied in Norwegian risk assessment procedure for contaminated land.

The models used in the calculation of plant concentrations are validated only for neutral organic compounds. In a paper discussing the limitation in EU Chemical Risk Assessment Scheme (Trapp & Schwarz, 2000), it is emphasised that the root concentration model in the

TGD document (Trapps & Matthies, 1995) is applicable for fine roots and not for root vegetables. In the comparison of different models by Collins *et al*. (2006), this model came out as the best one for root uptake prediction, however, with an overestimation for compounds with log K_{ow} above approximately 4.5 which include several of the contaminant groups assessed in this assessment.

An increase in SOM will decrease plant uptake using models that include porewater concentrations (Trapp & Matthies 1995 used in TGD 2003) because of reduced K_d/K_{oc}-values. An increase in organic carbon content from 2% (f_{oc} used in the present calculations) to 4 % which is the calculated organic carbon content in sludge amended soils after 100 years, will reduce plant uptake with 50 %.

An experimental method to quantify the effect of medium composition on the diffusive diffusive conductivity for hydrophobic organic chemicals has been described (Mayer *et al*., 2005). Experimental data using this method were compared to a developed model for diffusive uptake of organic chemicals from soil into potatoes, and also to field measurement in order to validate the method (Trapp *et al*., 2007). This work showed that diffusion through potato was slower than diffusion through carrot, and that estimated accumulation of PAHs in potato was in agreement with the field results. Furthermore, this plant specific model requires several assumptions and has limited applicability; for instance when validated for neutral chemicals, the soil pore-water concentration is calculated from K_{oc} and does not account for the factors and processes influencing the pore-water concentration. In addition, metabolism of the chemical in the potato is not included, and the model is based on a steady-state solution that does not consider differences in time and space.

Evaluation and selection of plant uptake models in this risk assessment has clearly showed the variation in out-put with the different models and it is important to be aware of the several factors and situations that may render a model outside its applicability. Explanations for the differences in predicted and experimental results are: i) bias inherent in the experimental procedures adopted, ii) use of inappropriate input parameters, and iii) deficiencies in the model theory such as failure of the models to adequately quantify the processes or failure of the models to consider all the relevant processes.

For chemicals that pose a risk in a risk assessment, one must carefully evaluate the limitation of the models or other not valid assumptions that might have been overlooked. For certain chemicals, laboratory and/or field studies are the only way of gaining plant uptake information. Example of such chemicals is perfluorated compounds, which are neither lipophilic nor hydrophilic and will not be able to be modelled neither by any existing uptake models, nor the model for ionic compounds.

5.7.1.4. Sensitivity analysis

In the calculation of soil concentrations (exposure concentrations), three steps are crucial for the final result:

1. Setting of overall parameters (precipitation excess (soil infiltration), soil depth, soil density)
2. Input of contaminants to soils (content of contaminants in sewage sludge)
3. Removal of contaminants from the soil (leaching, plant uptake, biodegradation, vaporisation)

The significance of various parameters for the final result of the risk assessment should be evaluated. In the sensitivity analysis below the significance of

1. Soil density
2. Precipitation excess (soil infiltration)
3. Soil distribution coefficient (K_d/K_{oc}-values)
4. Degradation rates
5. Significance of K_{ow} for plant uptake

are discussed. The significance of these parameters on soil concentrations, plant concentrations and human exposure are shown for all heavy metals, DEHP, LAS, nonylphenol, benzo(a)pyrene, phenanthrene, PCB-28 and PCB-180.

1. Soil density

Soil concentrations of heavy metals decrease as soil density increases (Table 41). The decrease for e.g Cd is 8-9%, while the decrease for Hg is 15-16%. The decrease is much less for Pb and Cr (2-3%).

Table 41. Soil concentrations (mg/kg) after 100 years of sludge application using soil density of 1200 used (in model) and 1500 kg/m^3.

Soil density(kg/m^3)	Sludge application	Cd	Pb	Cu	Cr	Hg	Ni	Zn
1200	40 tons/ha, 100 years	0.38	28.3	68.5	31.8	0.22	24.1	125
	60 tons/ha, 100 years	0.44	29.8	91.9	33.5	0.29	24.9	153
1500	40 tons/ha, 100 years	0.35	27.4	58.7	30.9	0.18	23.5	113
	60 tons/ha, 100 years	0.39	28.7	77.4	32.2	0.24	24.1	135

Since the exposure for the various endpoints is proportional to soil concentration, the human dietary exposure to heavy metals after 100 years of sludge application also decreases (Table 42).

Table 42. Human mean dietary intake (µg/day) of heavy metals after 100 years of sewage sludge application. Calculations made for soil density of 1200 (used in the model) and 1500 kg/m^3. The dietary intake is sum of background, sewage sludge and other sources (atmospheric deposition, mineral fertilisers and lime).

Soil density (kg/m^3)	Cd	Pb	Hg	Cu	Cr	Ni	Zn
1200	23,2	8,3	1,1	6840	165	487	10569
1500	20,8	8,0	0,9	5766	158	471	9333

2. Precipitation excess

The precipitation excess has been set to 0.25 i.e. 25% of the precipitation infiltrates the soil. As mentioned this is the default value used in TGD (2003), but is in the lower range of what could be expected in Norway. Using density 1200 kg/m^3 the significance of increasing the infiltration (which increases leaching from the soil) to 0.4 and 0.8 is calculated (Table 43).

As can be seen, the infiltration rate has almost no effect on soil heavy metal concentrations.

Table 43. Soil concentrations (mg/kg) of heavy metals using different parameters for precipitation excess (0.25 is used as default in the model).

Precipitation excess	**Sludge application**	**Cd**	**Pb**	**Cu**	**Cr**	**Hg**	**Ni**	**Zn**
0.25	40 tons/ha, 100 years	0.38	28.3	68.6	31.8	0.22	24.1	125
	60 tons/ha, 100 years	0.44	29.8	92.0	33.5	0.29	24.9	153
0.4	40 tons/ha, 100 years	0.38	28.3	68.4	31.8	0.22	24.1	125
	60 tons/ha, 100 years	0.44	29.8	91.7	33.5	0.29	24.9	153
0.8	40 tons/ha, 100 years	0.38	28.2	68.0	31.8	0.22	24.1	125
	60 tons/ha, 100 years	0.43	29.8	91.2	33.5	0.29	24.9	152

3. Soil distribution coefficient

The distribution coefficient is important for leaching of contaminants from the soil. For the heavy metals, however, reducing or increasing the K_d values relative to the default used in the model calculations has relatively little effect on future soil concentrations (Table 44) and the effects are generally lower than the effect of increasing soil density from 1200 to 1500 kg/m3 (Table 41).

Table 44. Soil concentrations (mg/kg DW) of heavy metals calculated using different K_d-values.

	Cd	**Pb**	**Cu**	**Cr**	**Hg**	**Ni**	**Zn**
Kd (default)	***500***	***1000***	***1000***	***2000***	***1000***	***1000***	***1000***
40 tons/ha, 100 years	0.38	28.3	68.5	31.8	0.22	24.1	125
60 tons/ha, 100 years	0.44	29.8	91.9	33.5	0.29	24.9	153
Kd	***30***	***100***	***100***	***200***	***100***	***100***	***100***
40 tons/ha, 100 years	0.36	28.1	66.6	31.8	0.21	24.0	123
60 tons/ha, 100 years	0.41	29.6	89.1	33.4	0.28	24.8	149
Kd	***5000***	***5000***	***5000***	***10000***	***5000***	***5000***	***5000***
40 tons/ha, 100 years	0.39	28.3	68.7	31.9	0.22	24.1	125
60 tons/ha, 100 years	0.44	29.9	92.2	33.5	0.29	24.9	153

The sensitivity analysis shows that soil density has a more pronounced effect on the calculated soil concentrations than precipitation excess and distribution coefficients. Increasing soil density from 1200 to 1500 kg/m^3 reduce soil concentrations from 2 (Pb, Cr) to 15% (Hg) when using sewage sludge for 100 years. Other factors have less influence on soil concentrations and thereby on the long-term human and animal exposure.

4. Degradation rates

For organic contaminants biological degradation in soils is the most important removal process (Chapter 5.2.6). The significance of varying this parameter for the exposure concentrations after 7, 30 and 90 days after sludge application is shown for DEHP, NPEO and benzo(a)pyrene (Table 45). In the calculations the half-life (days) is reduced to 50% and increased 10 times. This is done because an increase in half-life will be the worst case with regard to future soil concentration. Decreasing soil temperatures will often lead to reduced degradation in soil (increased half-life) for organic contaminants.

Table 45. Exposure concentrations by varying half-lives ($t_{1/2}$) for DEHP, LAS and benzo(a)pyrene 0, 7, 30 and 90 days after sludge application.

Days after sludge application	**DEHP** $t_{1/2}$: **150**	**300**	**3000**	**LAS** $t_{1/2}$: **4**	**8**	**80**	**Benzo(a)pyrene** $t_{1/2}$: **183**	**365**	**3650**
0	1.14	1.14	1.14	30.9	**30.9**	30.9	0.0012	0.0012	0.0012
7	0.94	0.95	0.95	16.2	**20.2**	25.1	0.00098	0.00099	0.001
30	0.9	0.92	0.95	5.86	**10.5**	23.1	0.00095	0.00097	0.00099
90	0.8	0.87	0.94	1.97	**3.95**	18.9	0.00087	0.00093	0.00099

Changes in degradation rate have practically no influence on mean soil concentrations of DEHP and benzo(a)pyrene, but have a profound effect on LAS that has a much shorter half-life (Appendix A2).

For contaminants with a relatively short half-life in soil (DBP, nonylphenol, octylfenol incl the ethoxilates, LAS) the degradation rate therefore may have a considerable effect on the human and animal exposure for these contaminants. Calculation of human dietary intake by using different degradation-rates shows that the half-lives have a huge effect on the calculated dietary intake (Table 46). In these calculations the log Kow-values given in Table 47 are used.

Table 46. Model calculations of mean human dietary intake of organic contaminants using different degradation rates in soils (DT_{50}, half-life).

	DEHP	**Nonyl-phenol**	**LAS**	**Phenantrene**	**Benzo(a) pyrene**	**PCB180**
DT_{50} (days) (default)	300	10	8	50	365	13000
Consumption (µg/day)	117	30.3	804	0.68	0.082	0.016
DT_{50} (days) (50% decrease)	150	5	4	25	180	6500
Consumption (µg/day)	116	15.2	402	0.46	0.080	0.014
DT_{50} (days) (10 times increase)	3000	100	80	500	3650	130000
Consumption (µg/day)	4277	123	3836	1.04	2.58	0.018

5. Significance of K_{ow} for plant uptake

The octanol-water partition coefficient (K_{ow}) is a crucial factor in the calculation of BCF for plants. As shown in Chapter 5.3.3. all three models that have been used in the calculation of plant BCFs include K_{ow}. Since plant uptake is only of minor importance for the removal of organic compounds from soils (Appendix A5) and thereby for future soil concentrations for accumulating compounds, plant uptake first of all is important for human and animal exposure of these compounds.

In the risk assessment calculations a value close to the mean value of the values given by Mackay *et al*. (2006) is used, while in the sensitivity calculations the minimum and maximum values are used (Table 47). Compounds that range of log K_{ow} cannot be taken from existing databases, minimum and maximum values are selected as 0.5 and 0.5 (log-units) lower and higher, respectively, than the value actually used in the assessment.

According to Mackay *et al.* (2006) any calculated log K_{ow} value above 7 should be regarded as suspect, and any experimental or calculated value above 8 should be treated with extreme caution. In this assessment two substances have log K_{ow} values above 7 i.e. DEHP and PCB180. For DEHP we have used the value used in the risk assessment of DEHP (EU, 2008), while the value used for PCB180 is the mean of the calculated values given in Mackay et al.

(2006). A value of 7.2 for PCB180 seems however reasonable: it is somewhat higher than for PCB138 and PCB153 (as could be expected), and it is the average of 12 values (mostly calculated, but also some measured).

As shown in Table 47 decreases in logK_{ow} results in an increase or no change in plant uptake for most compounds, but a slight decrease for nonylphenol and LAS. Increasing logK_{ow} compared to the default (mean) values used in the risk assessment results in lower plant concentrations for all compounds except for LAS that increase when increasing logK_{ow} from 3.7 to 4.2 (Table 47).

Table 47. Calculated plant concentrations (µg/kg DW) with varying logKow-values. The plant concentrations are calculated varying the K_{ow}-value (min, default, max). The default value is used in the model calculations in this risk assessment.

				K_{ow}=minimum (K_{ow} variation)			
Concentrations in plants	**DEHP**	**Nonylfenol**	**LAS**	**Fenantren**	**Benzo(a) pyren**	**PCB28**	**PCB180**
Log K_{ow} (min)	4.7	4.1	3.2	4.3	5.9	4.4	6.6
Leafy vegetables	100	36	2769	0.77	0.02	0.0095	0.00130
Root vegetables	4.45	263	7318	7.57	0.89	0.029	0.073
Potatoes	4.45	263	7318	7.57	0.89	0.029	0.073
Cereals	76	13	977	0.78	0.02	0.0038	0.00012
Gras	76	13	977	0.78	0.02	0.0038	0.00012
				K_{ow}=risk assessment (Table 48)			
Log K_{ow} (Table 48)	7.5	4.5	3.7	4.5	6.1	5.6	7.2
Leafy vegetables	2.40	38	3956	0.77	0.02	0.0019	0.00059
Root vegetables	2029	510	16866	10.19	1.39	0.40	0.27
Potatoes	2029	510	16866	10.19	1.39	0.40	0.27
Cereals	1.83	13	1396	0.62	0.01	0.0008	0.00005
Gras	1.83	13	1396	0.62	0.01	0.0008	0.00005
				K_{ow}=maximum (K_{ow} variation)			
Log K_{ow} (max)	9.6	6.4	4.2	4.8	8	5.8	7.4
Leafy vegetables	0.15	7.98	4768	0.73	0.0013	0.0015	0.00045
Root vegetables	200562	15218	40036	18	88.39	0.62	0.42
Potatoes	200562	15218	40036	18	88.39	0.62	0.42
Cereals	0.11	2.82	1683	0.40	0.0010	0.0006	0.00004
Gras	0.11	2.82	1683	0.40	0.0010	0.0006	0.00004

The logK_{ow} values have larger influence on plant concentrations of carrot and potatoes than on cereals and grass. The reason for this is that the models used to calculate BCF for root crops (EC, 2003 and Ryan *et al.*, 1988) are more influenced by logK_{ow} than the model used to calculate BCF for cereals and grass.

The human intake of organic contaminants also increases when K_{ow} increases (Table 48). As shown in Table 37, potatoes, carrot and unspecified vegetables are the most important source for the organic contaminants in question. The reason for this is that underground vegetables accumulate organic compounds due to high lipid content in the peel.

Table 48. Human intake (µg/day) of selected organic contaminants eating cereals, vegetables, meat and milk grown on soils that have received sewage sludge (60 tons/ha every 10th year) for 100 years. The intake values given are calculated varying the K_{ow}-value (min, default, max). The default value is used in the model calculations in this risk assessment.

	DEHP	Nonylphenol	LAS	Phenantrene	Benzo(a)pyrene	PCB28	PCB180
Kow min	4.7	4.1	3.2	4.3	5.9	4.4	6.6
Consumption Mean	14	19	678	0.65	0.06	0.003	0.005
Consumption High	19	48	1696	1.61	0.16	0.007	0.013
Kow (default)	**7.5**	**4.5**	**3.7**	**4.5**	**6.1**	**5.6**	**7.2**
Consumption Mean	136	37	1399	0.83	0.10	0.027	0.018
Consumption High	355	91	3541	2.11	0.25	0.071	0.048
Kow max	9.6	6.4	4.2	4.8	8	5.8	7.4
Consumption Mean	13454	974	3008	1.3	5.9	0.04	0.03
Consumption High	34988	2428	7706	3.3	15	0.11	0.07

The percent changes in intake of these contaminants for cattle on pasture is summarised in Table 49. For most compounds a decrease in Kow increases the intake in grazing cattle because the uptake in cereals (concentrated feed) and gras increase.

Table 49. Percent change in daily intake (µg/kg day) of selected organic contaminants in cattle on pasture when varying K_{ow}.

	DEHP	Nonylphenol	LAS	Phenantrene	Benzo(a)pyren	PCB28	PCB180
K_{ow}-Min	4.7	4.1	3.2	4.3	5.9	4.4	6.6
K_{ow}-Default	**7.5**	**4.5**	**3.7**	**4.5**	**6.1**	**5.6**	**7.2**
K_{ow}-Max	9.6	6.4	4.2	4.8	8	5.8	7.4
Percent change (Min)	3608	-4	-30	30	30	386	71
Percent change (Max)	-84	-79	21	-33	-90	-23	-14

Heavy metals
Soil density has the most pronounced effect on calculated soil concentrations compared to precipitation excess and Kd-values. The significance of increasing soil density from 1200 to 1500 kg/m^3 does not influence the conclusions regarding human exposure of heavy metals. The changes in soil concentrations when varying soil density, precipitation excess, and K_d-values within reasonable limits, will neither influence the conclusions regarding effects on plants and soil organisms.

Organic contaminants
Variations in logKow-values are much more important for human and animal exposure of organic contaminants than degradation rate.

5.7.1.5. Sensitivity analysis, groundwater calculations

To investigate how the groundwater concentrations vary as the input parameters K_d (K_{oc}) and degradation rate (DT_{50}) changes, calculations were performed for LAS. The concentrations of LAS given in Table 27 was calculated using K_d=100 and DT_{50}=8 days. Increasing the half-life ten times (8 to 80 days), increase groundwater concentration to 1.85x10^{-5} which is a substantial increase from 8.2x10^{-19} (Table 50). The same profound increase in soil concentration is achieved by using Kd 10 instead of 100. In this case the mean groundwater concentration increase to $5x10^{-5}$ i.e. the increase is in the same range as the increase caused by increasing the half-life. Decreasing the K_d value to 1 increase groundwater concentration to 1.6 µg/l that probably is close to the detection limit for this compound.

The results of the sensitivity analysis (Table 50) show that both degradation rate and K_d values are very important for the results of the groundwater calculations. The sensitivity analysis also indicates that even in the worst-case scenarios (long halvlifes, less binding to soil) the contaminant concentrations in the groundwater will be in the µg/l-range.

Table 50. Concentrations (µg/l) of LAS in groundwater using different half-lives and distribution coefficients (K_d-values). The “default-value” is calculated using K_d=100 and DT_{50}=8 days.

K_d-value /	**DT_{50} = 4**	**DT_{50} = 8**	**DT_{50} = 80**
1		1.599006	
10		1.44E-04	
100	1.65E-24	8.15E-19	1.85E-05

5.8. Risk characterisation of the exposure routes

Comparing the predicted concentrations with the relevant toxicological-based values for acceptable exposure levels set by relevant national or international bodies where available performs the risk characterisation for each exposure routes. For the environmental effects, the predicted concentrations of each contaminant have been compared to the predicted no effect concentrations (PNEC) for soil and aquatic environments and the TDI or equivalent have been used to assess the risk associated with the human exposure. No such general recognized threshold value is available for grazing animals.

The accumulated concentration after 100 years is used for accumulating contaminants, while the maximum concentration just after application of sludge is used for substances with a high removal rate. This was considered to be a conservative approach. It should be pointed out that for accumulating compounds this is an overestimate since the available sewage sludge produced in Norway will not be sufficient to cover more than 5% of the area for cereal production at the maximum allowed application rate. Furthermore, the mass balance is not kept constants and it is likely that the total amount of modelled contaminant in all departments will exceed the input of the contaminant.

5.8.1. Risk characterisation: Plants and other soil organisms (exposure route 1+ 2)

As explained in Chapter 5.1., the PNEC values for soil are set to protect both plants and other soil-living organisms.

5.8.1.1. Risk characterization for soil-living organisms exposed to inorganic contaminants from sewage sludge

Table 51. PEC (from Table 22), PNEC (from from Table 10) and RQ for inorganic contaminants in soil after application of 40 and 60 tons/ha/10th year for 100 years.

	PEC mg/kg DW				**PNEC mg/kg DW**	**RQ**			
Metal	**Agricultural soil, 40 years**	**Agricultural soil, 60 years**	**Park areas**	**Soil mixture**		**Agricultural soil, 40 years**	**Agricultural soil, 60 years**	**Park areas**	**Soil mixture**
Cd	0.35	0.42	0.32	0.31	1.15	0.30	0.37	0.28	0.27
Pb	28	29	24	24	166	0.17	0.17	0.14	0.14
Hg	0.20	0.27	0.19	0.17	0.3	0.67	0.90	0.63	0.57
Ni	23	25	20	20	50	0.46	0.50	0.40	0.40
Zn	118	145	109	104	26	4.5	5.6	4.2	4.0
Cu	63	86	62	57	89.6	0.70	0.96	0.69	0.64
Cr III	31	33	27	27	62	0.50	0.53	0.44	0.44

The model shows that the risk quotients (RQ) are above 1 for Zn (see a more detailed discription beneath) and close to 1 for Cu and Hg. Thus, an application rate of sewage sludge of 60 tons/ha/10 year for 100 years may result in soil concentrations exceeding the PNEC values for these metals and hence, a toxic effects on soil living organisms (plants and/or other soil-living organisms) in agricultural and park areas, as well as in soil mixtures with the current levels of metals in the sewage sludge can not be excluded. The PNEC values for Zn and Cu are estimated according to the SSD model with low assessment factors (AF) Concentrations exceeding these values may therefore have a negative impact on the most sensitive species. The PNEC value for Hg is based on toxicity data in invertebrates, and a large assessment factor of 1000 is used. There is little toxicological data available for soil living species and hence a large AF has been used when the PNEC value has been derived. This means that exceeding this PNEC value will reduce the safety margin between the exposure and levels known to have effect on soil living organisms.

Risk characterisation for Zn

The ratio PECadd/PNECadd for agricultural soils (40 and 60 tons sewage sludge per ha) and for park areas and soil mixtures are >1.

In a generic risk assessment, where site-specific information on soil properties is lacking, the lab-to-field correction is applied to the added concentration. According to EU-risk assessment, this leads to a lab-to-field corrected risk ratio of 0.8 [=(61/3)/26] for the agricultural soils receiving 40 tons of sewage sludge per hectare. The corresponding risk ratios for agricultural soils (60 tons per ha), park areas and soils mixtures are 1.2, 0.6 and 0.8, respectively (Table 52).

Table 52. Calculated PECadd, corrected PECadd-values, and PECadd/PNECadd calculations for Zn (see text for explanation).

	Factor	Parameter	Agricultural soil, 40 years	Agricultural soil, 60 years	Park areas	Soil mixture
		Calculated soil conc (Table 22)	125	155	109	104
		PECadd	61	91	45	40
		PECadd/PNECadd	2.3	3.5	1.7	1.5
		PECadd lab-field corr	20	30	15	20
Lab-to field correction	3/2*	PECadd/PNECadd	0.8	1.2	0.6	0.8
PECadd soil type corr						
Sandy soils	0.4	PECadd soil type corr	152	228	112	100
Marine clay soils	1.7	PECadd soil type corr	35	54	26	23
River clay soils	3.5	PECadd soil type corr	17	26	12	11
Soil type corrected		Soil type corrected				
Sandy soils	0.4	PECadd/PNECadd	2.0	2.9	1.4	1.9
Marine clay soils	1.7	PECadd/PNECadd	0.5	0.7	0.3	0.5
River clay soils	3.5	PECadd/PNECadd	0.2	0.3	0.2	0.2

*2 is used for soil mixtures

In the case of 60 tons per hectare, the risk ratio is > 1. Following the procedure from the EU risk assessment, the soil-type correction should be used, provided sufficient information is available on the soil type. Site-specific correction factors ($BioF_{soil}$) vary from 0.4 to 3.5 (se above). Using $BioF_{soil}$ for sandy soil, marine clay soils and river clay soils the factors are 0.4, 1.7 and 3.5, respectively (Table 52). The soil type corrected PEC_{adds} is 228, 54 and 26 mg/kg. The further lab-to-field correction results in risk ratios of 2.9, 0.7 and 0.3 (Table 52).

This means that sewage sludge application on sandy soils will result in a potential risk for soil living organisms and there is a need for limiting the risks. However, most Norwegian sewage sludge is applied on more clay-like soils (risk ratios are well below 1 (Table 52)). To make more site-specific risk assessment of sewage sludge applied on agricultural soils, information about soil background values, clay- and organic matter content, and pH is needed.

5.8.1.2. Risk characterization for soil living organisms exposed to organic contaminants from sewage sludge

Table 53. PEC (from Table 23), PNEC (from Table 10) and RQ for organic contaminants in soil.

Compound	Time	PEC mg/kg DW				PNEC	RQ	RQ	RQ	RQ
		Agricultural soil		Park areas	Soil mixture	mg/kgDW	Agricultural soil		Park areas	Soil mixture
		40 tons	60 tons				40 tons	60 tons		
DEHP	0 day	0.89	1.3	9.1	8.1	>13	<0.07	<0.10	<0.70	<0.62
	90 days	0.68	1	6.9	6.2		<0.05	<0.08	<0.53	<0.48
	100 years	0.9	1.3	-	-		<0.07	<0.10	-	-
DBP	0 day	0.011	0.016	0.11	0.1	2	0.006	0.008	0.06	0.05
	90 days	0.003	0.005	0.01	0.01		0.002	0.003	0.005	0.005
	100 years	0.011	0.016	-	-	-	0.006	0.008		
Octylphenols	0 day	0.1	0.15	1	0.9	0.0067	15	22	149	134
	90 days	0.02	0.02	0.16	0.14		3.0	3.0	24	21
	100 years	0.1	0.15	-	-		15	22	-	-
Octylphenol ethoxylates	0 day	0.009	0.01	0.09	0.08	-				
	90 days	0.001	0.001	0.01	0.01					
	100 years	0.009	0.01	-	-					
Nonylphenols						0.3				
	0 day	0.49	0.74	5	4.5		1.6	2.5	17	15
	90 days	0.08	0.12	0.8	0.72		0.3	0.4	2.7	2.4
	100 years	0.49	0.74	-	-		1.6	2.5		
Nonylphenol ethoxylates	0 day	0.41	0.61	4.1	3.7	-				
	90 days	0.03	0.05	0.33	0.3					
	100 years	0.41	0.61	-	-					
LAS	0 day	24	36	245	218	35	0.7	1.0	7.0	6.2
	90 days	3.1	4.6	31	28		0.1	0.1	0.9	0.8
	100 years	24	36	-	-		0.7	1.0		
Naphtalene	0 day	0.008	0.006	0.06	0.06	1	0.008	0.006	0.06	0.06
	90 days	0.003	0.002	0.02	0.02		0.003	0.002	0.02	0.02
	100 years	0.008	0.006				0.008	0.006		
Acenaphtylene	0 day	0.0006	0.0004	0.004	0.004	0.29	0.002	0.001	0.01	0.01
	90 days	0.0003	0.0001	0.002	0.002		0.001	0.000	0.01	0.01
	100 years	0.0006	0.0004				0.002	0.001		
Acenaphtene	0 day	0.002	0.002	0.02	0.02	0.038	0.06	0.04	0.4	0.4
	90 days	0.001	0.001	0.009	0.009		0.03	0.02	0.2	0.2
	100 years	0.002	0.002				0.064	0.043		
Fenantrene	0 day	0.012	0.008	0.08	0.08	1.8	0.007	0.004	0.05	0.05
	90 days	0.006	0.004	0.04	0.04		0.003	0.002	0.02	0.02
	100 years	0.012	0.008				0.007	0.004		
Antracene	0 day	0.001	0.001	0.009	0.009	0.13	0.010	0.006	0.07	0.07
	90 days	0.001	0.000	0.004	0.004		0.005	0.003	0.03	0.03
	100 years	0.001	0.001				0.010	0.006	-	-
Fluorene	0 day	0.005	0.004	0.04	0.04	1	0.005	0.004	0.04	0.04
	90 days	0.003	0.002	0.02	0.02		0.003	0.002	0.02	0.02
	100 years	0.005	0.004				0.005	0.004		

Compound	Time	PEC mg/kg DW				PNEC	RQ	RQ	RQ	RQ
		Agricultural soil		Park areas	Soil mixture	mg/kgDW	Agricultural soil		Park areas	Soil mixture
		40 tons	60 tons				40 tons	60 tons		
Fluoranthene	0 day	0.006	0.004	0.04	0.04	1.5	0.004	0.003	0.03	0.03
	90 days	0.004	0.003	0.03	0.03		0.003	0.002	0.02	0.02
	100 years	0.006	0.004				0.004	0.003	-	-
Pyrene	0 day	0.007	0.005	0.05	0.05	1	0.007	0.005	0.05	0.05
	90 days	0.005	0.003	0.03	0.03		0.005	0.003	0.03	0.03
	100 years	0.007	0.005				0.007	0.005	-	-
Benzo(a)anthracene	0 day	0.002	0.001	0.01	0.01	0.079	0.02	0.01	0.15	0.15
	90 days	0.001	0.001	0.008	0.008		0.02	0.01	0.11	0.11
	100 years	0.002	0.001				0.02	0.01	-	-
Chrycene	0 day	0.003	0.002	0.02	0.02	0.55	0.005	0.004	0.04	0.04
	90 days	0.002	0.002	0.02	0.02		0.004	0.003	0.03	0.03
	100 years	0.003	0.002				0.006	0.004	-	-
Benzo(b)fluoranthene	0 day	0.003	0.002	0.02	0.02	0.28	0.01	0.007	0.07	0.07
	90 days	0.002	0.002	0.02	0.02		0.008	0.006	0.06	0.06
	100 years	0.003	0.002				0.012	0.008	-	-
Indeno (1,2,3-cd)pyrene	0 day	0.001	0.001	0.01	0.01					
	90 days	0.001	0.001	0.01	0.01					
	100 years	0.002	0.001							
Dibenzo(a,h) antracene	0 day	0.0005	0.0003	0.003	0.003					
	90 days	0.0004	0.0003	0.003	0.003					
	100 years	0.0007	0.0004							
Benzo(g,h,i)perylene	0 day	0.002	0.001	0.02	0.02	0.17	0.01	0.01	0.09	0.09
	90 days	0.002	0.001	0.01	0.01		0.01	0.01	0.07	0.07
	100 years	0.003	0.002				0.02	0.01	-	-
Benzo(g,h,i)perylene	0 day	0.001	0.001	0.009	0.009	0.053	0.03	0.02	0.18	0.18
	90 days	0.001	0.001	0.007	0.007		0.02	0.01	0.14	0.14
	100 years	0.001	0.001				0.03	0.02	-	-

The model indicates that octylphenol and nonylphenol are the only organic contaminants that may reach concentrations above the PNEC value. These are both non-accumulating contaminants with short soil half-lives (10 days) and the highest concentrations are reached shortly after each application of sewage sludge. The uncertainty related to these PECs is also large since the estimations are based on occurrence in few samples of Norwegian sewage sludge.

Octylphenol has a very low PNEC in soil. There is very little information on environmental toxicity of octylphenol, and especially in the terrestrial environment. The PNEC value is therefore estimated from an aquatic PNEC value, based on a limited dataset. This conversion of an aquatic PNEC value to a soil PNEC is hampered by uncertainty and these PNEC values should be used with care. More information on both occurrence and effect of octylphenol is therefore needed to improve the risk assessment of this compound.

The PNEC has been adopted from a risk assessment of octylphenol by UK Environmental Agency (2005). No experimental data on the effect of octylphenol on terrestrial organisms were available and a provisional PNEC was calculated using the environmental partitioning approach from the aquatic PNEC (0.122 µg/l). The provisional PNEC is 0.0059 mg/kg wet weight that has been converted to mg/kg dry weight in this report. Comparisons with nonylphenol, for which experimental data on toxicity to soil organisms are available, indicate that the provisional PNEC for octylphenol may be overly conservative. In the EU Risk Assessment Report for nonylphenol PNECsoil has been calculated to 0.3 mg/kg wet weight, i.e. a factor 50 times higher than the provisional PNEC for octylphenol. The aquatic PNEC is, however, only 2.7 times higher for nonylphenol than for octylphenol. Based on the similarity of the PNECs for surface water for the two substances, the UK Risk Assessment Report concludes that the low terrestrial PNEC for octylphenol needs careful consideration. Assuming that the difference in $PNEC_{soil}$ should be same as $PNEC_{aquatic}$ for the two substances the $PNEC_{soil}$ for octylphenol would be 0.11 mg/l. However, the calculated PECs for octylphenol is sludge amended soil as shown in Table 53 are still higher than this, indicating that octylphenol will pose a risk of effects in the soil environment. Octylphenol is not accumulating following repeated application of sewage sludge.

5.8.2. Risk characterisation: Animals (exposure routes 3-6)

5.8.2.1. Aquatic organisms

Since information on the background levels of contaminants in the primary recipients of drainage from agricultural soils in Norway are not known, the risk assessment for the aquatic environment can only be made for the contribution of chemicals from sludge, i.e. the added risk.

The assessment shows that the risk quotients are below 1 for all the selected substances (Table 54). Only for some of the PAHs, RQs are above 0.1. This indicates that the use of sludge for soil fertilization and the leakage of the assessed organic pollutants from the sludge will not pose a risk of toxic effects in the aquatic environment.

For two of the PAHs (pyrene and indeno(1,2,3-cd)pyrene the risk quotients are close to 1, which means that the contribution of these compounds from sludge application to the surface waters may cause concentrations which are close to the limit when effects are expected to occur in surface waters. The unknown contributions from other sources to the soil and to the surface waters will probably result in exposure concentrations that exceed the PNEC. It should be noted, however, that the main route of transport of these substances from the soil to the surface water is through surface runoff and the estimated concentrations represent maximum concentrations occurring at the first runoff event after sludge application. The model used for calculation of runoff predicts a rapid decline of the concentrations, which will decrease the risk for effects.

Table 54. PEC, PNEC and RQ for aquatic organisms in surface water as a result of application of sewage sludge in soil.

Contaminants	PEC µg/l	PNEC µg/l	RQ µg/l
Cadmium	0.0027	0.08	0.0338
Lead	0.0368	7.2	0.058
Mercury	0.0015	0.047+BC	0.032*
Nickel	0.0236	5	0.00472
Zinc	0.553	7.8+BC	0.071*
Copper	0.455	7.8	0.0583
Chromium	0.02	3.4	0.0059
DEHP	0.0038	n.c.	-
DBP	0.0022	n.c.	-
Octylphenol	0.0022	0.12	0.0183
Octylphenol etoxilate	1.60E-10	1.7	4.58E-11
Nonylphenol	7E-06	0.33	2.12E-05
NFEO1	2.95E-12	0.13	2.36E-14
LAS	1.4E-05	0.27	5.185E-05
Naphtalene	0.000099	2.4	4.13E-05
Acenaphtylene	0.033	1.3	0.0253
Acenaphtene	0.295	3.8	0.0776
Fenantrene	0.034	1.3	0.0262
Antracene	0.001	0.1	0.01
Fluorene	0.052	2.5	0.0208
Fluoranthene	0.0099	0.1	0.099
Pyrene	0.0228	0.023	0.991
Benzo(a)anthracene	0.002	0.012	0.1667
Chrycene	0.0075	0.07	0.1071
Benzo(b)fluoranthene	0.0095	0.03	0.3167
Indeno (1,2,3-cd)pyrene	0.0053	0.006	0.8833
dibenzo(a,h)antracene	0.00037	0.0014	0.2642
Benzo(g,h,i)perylene	0.0022	0.006	0.3666
Benzo(a)pyrene	0.0035	0.05	0.07

*The risk quotient is based on the PNEC$_{add}$

No PNEC value for the evaluated substances in the aquatic environment is expected to be exceeded as a result of sewage sludge application. 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 model is considered to be a conservative model, and hence the content of contaminants in sewage sludge is considered to constitute a negligible risk to the aquatic environment following application of sewage sludge for agricultural use.

5.8.2.3. Exposure to grazing animals and animals eating feed

Inorganic contaminants

For cadmium, 100 years use of sewage sludge will almost double the daily intake compared with the background intake of today. For calves, young heifers and lambs, the total feed concentration would contain about 0.1 mg/kg of Cd, which is 50 times below a commonly regarded lower risk level for toxicological effects at 5 mg/kg diet.

For lead, the corresponding use of sewage sludge will imply about 25% increased daily intake compared with the per se background level. However, the calculated background lead intake in grazing animals is relatively high and any increase would imply an increased risk for subtle effects in animals, particularly developemental effects in young animals when exposed during gestation or early postnatally. Lambs from sheep exposed to 4.5 mg/kg feed during gestation showed reduced learning capability when tested at one year of age (Carson et al., 1974). This feed concentration of lead is about 2 times the derived dietary concentration for the grazing animals on sewage sludge treated fields.

For inorganic mercury, such use of sewage sludge will imply about 5 times increased animal intake. The highest intake of inorganic mercury would be in grazing animals (up to 0.5 µg/kg b.w. per day). Toxicological data of inorganic mercury in farm animals is almost lacking but the few data available, as well as the data from laboratory animal, indicate that the intake after using sewage sludge would be far below a level of toxicological significance.

For copper, the concentration in pasture grass and feed grown on fields treated with sewage sludge for 100 years, and thus, the animal intake would increase 4-5 times compared with the background levels of today. The increased levels would still be within an acceptable normal range. For sheep an increased level could result in copper accumulation and toxicity if combined with too low levels of influencing minerals, particularly molybden.

For zinc, a double intake has no toxicological significance. About 20% increased intake of nickel and chromium will neither constitute an animal toxicological problem.

Organic contaminants
The oral doses of the phtalates DBP and DEHP which are found to elicit reproductive effects in rats and pigs after in utero exposure are about 5-6 orders higher than the calculated exposure via pasture and feed from field treated with sewage sludge.

For alkylphenols (octylphenol and nonylphenol) and their ethoxylates, data on farm animal for risk characterization is lacking. However, oral doses for short time exposure producing uterotropic effect in rats were 5-6 orders higher than the calculated exposure via sewage sludge. Subcutaneous treatment with octylphenol in ewes during gestation or postnatally disrupting the reproductive development of the offspring was 3 orders higher than that calculated from the ingestion of grass/feedingstuff after sewage sludge treatment.

LAS is not regareded as a farm animal problem as far as the uptake in plants is minimal.

For sum PCBs the feed level shown to produce adverse clinical effects and reduce weight gain in pigs and lambs was almost 7 orders above the feed level calculated from the ingestion of grass/feedingstuff after sewage sludge treatment.

For PAHs effect data after chronic/repeated exposure in farm animals are lacking. The calculated levels in grass/feedingstuff after sewage sludge are in general low but as the compounds have carcionogenic properties their levels should be as low as possible. However, the farm animals have restricted lifespan and the carcinogenic risk and consequences are far less than correspondingly for humans.

Rhind and coworkers in the United Kingdom have extensively studied effects of pasture treatment with sewage sludge at a level of 2 x 2.25 tonnes of dry matter per year for up to 5 years. They have measured the soil concentrations, and uptake, distribution and effects in the grazing sheep and their lambs. In treated plots, moderately increased soil levels of endocrine disrupters like phtalates and alkyl phenols to about 50% increase relative to controls were found (Rhind *et al.*, 2002). The concentrations of potentially toxic metals were of similar order but differed with individual element (Rhind *et al.*, 2005a). Small, if any, increases in tissue concentrations of the organic and inorganic compounds in the animals due to grazing on sewage sludge treated pasture were revealed (Rhind et al., 2005a; 2005b; Wilkinson *et al.*, 2003). Furthermore, there was no significant effect of sludge treatment on milk concentrations of alkylphenols and phtalates (Rhind *et al.,* 2007). Nevertheless, exposure through this route was shown to be associated with perturbation of fetal testis development, fetal overian function and altered emotional and exploratory behaviour in the weaned offspring (Erhard and Rhind, 2004; Paul *et al.,* 2005; Fowler *et al.,* 2008). The sewage sludge was not ploughed into the soil during these experiments, but the animals were removed from the pasture for 3 weeks after the treatment. Thus, the contaminants may have been more available to the animals via soil and soil-contaminated herbage than when ploughed as demanded in Norway. Anyway, pre and postnatal exposure to the sewage sludge, with its cocktail of environmental chemicals or other factors, was found to perturbate the development of the young sheep.

The results from Rhind and coworkers show that the mixture of compounds in sewage sludge may elicit adverse effects in young animals. Their results may not be directly relevant for the Norwegian way of using the sewage sludge, but indicate that effects not easily explained from measured or predicted concentrations of known contaminants, may occur.

5.8.3. Risk characterisation: Humans (Exposures routes 7-12)

5.8.3.1. Human exposure to inorganic contaminants from food and drinking water

The estimations of the mean intake, based on the assumption that all agricultural soil, is treated with 40 or 60 tons sewage sludge/hectare/10 year is shown and compared with the safety parameters (TDI, UL and others) in Table 55.

Table 55. Estimated dietary exposure to metals through consumption of food produced assuming all food items were produced on sludge treated soil and toxicological safety values for each contaminant. Intakes are estimated for mean consumption of all food items and for high comsumers of cereals (the food items with the highest contribution to the mean dietary intake of all metals). Background intakes (estimated intakes without sewage sludge application) have been estimated for both mean consumption of food items and high comsumers of cereals. Mean body weight for adults is 70 kg. The toxicological safety parameters are expressed in µg/kg bw/day.

	Cd	**Pb**	**Hg**	**Ni**	**Zn**	**Cu**	**Cr**
Background intake (µg/day)	15	8.8	4.2	406	4359	1416	131
Background intake. High consumers (µg /day)	21	16	4.4	669	6641	2444	228
40 ton sludge/10 year							
Mean intake from food produced on sludge soil (µg/day)	22	9.9	4.8	458	8180	4734	152
Mean intake from food produced on sludge soil (µg/kg bw/day)	**0.31**	**0.14**	**0.07**	**6.5**	**117**	**68**	**2.2**
High consumers of cereals (µg/day)	32	15	5.3	755	12460	8172	264
High consumers of cereals (µg/kg bw/day)	**0.46**	**0.21**	**0.08**	**11**	**178**	**117**	**3.8**
60 ton sludge/10 year							
Mean intake from food produced on sludge soil (µg/day)	26	10	5.1	480	10024	6365	162
Mean intake from food produced on sludge soil (µg/kg bw/day)	**0.37**	**0.14**	**0.07**	**6.9**	**143**	**91**	**2.3**
High consumers of cereals (µg /day)	38	16	5.8	792	15269	10986	281
High consumers of cereals (µg/kg bw/day)	**0.54**	**0.23**	**0.08**	**11**	**218**	**157**	**4.0**
Safety parameters* (ug/kg bw/day)	**0.36**	**3.6**	**0.71**	**-**	**357**	**71**	**14**

*Tolerabel daily intake (TDI) for Cd, Pb and Hg. Upper intake level (UL) for Zn and Cu. Guideline level for Cr.
-No safety parameter available.

Estimations taking into account the limited availability of sewage sludge are shown in Table 56.

Table 56. Estimated dietary exposure to metals (ug/kg bw/day) - different percentage of the total production area in Norway is treated with sewage sludge. Intakes are estimated for mean consumption of all food items and for high comsumers of the cereals (the food items with the highest contribution to the mean dietary intake of all metals). Mean body weight for adults is 70 kg.

60 ton sludge/10 year	**Cd**	**Pb**	**Hg**	**Ni**	**Zn**	**Cu**	**Cr**
	ug/kg bw/day						
Mean consumer							
Background intake + Other sources	0.21	0.13	0.06	5.8	62	20	1.9
Mean consumer 5% treated soil	0.23	0.13	0.06	6.0	68	25	1.9
Mean consumer 10% treated soil	0.24	0.13	0.06	6.0	72	28	1.9
Mean consumer 20% treated soil	0.25	0.13	0.06	6.1	80	35	2.0
Mean consumer 30% treated soil	0.27	0.13	0.06	6.2	88	42	2.0
Mean consumer 50% treated soil	0.30	0.14	0.07	6.4	104	56	2.1
Mean consumer 100% treated soil	0.37	0.15	0.07	6.9	143	91	2.3
High consumer							
Background intake, High consumers + Other sources	0.30	0.22	0.06	9.6	95	35	3.3
High consumer 5 % treated soil	0.33	0.19	0.06	9.8	104	42	3.3
High consumer 10% treated soil	0.34	0.19	0.06	9.9	110	48	3.4
High consumer 20% treated soil	0.36	0.20	0.06	10	122	60	3.4
High consumer 30% treated soil	0.38	0.20	0.07	10	134	73	3.5
High consumer 50% treated soil	0.43	0.21	0.07	11	158	97	3.7
High consumer 100% treated soil	0.54	0.22	0.08	11	218	157	4.0
Safety parameters*	0.36	3.6	0.71	-	357	71	14

*Tolerabel daily intake (TDI) for Cd, Pb and Hg. Upper intake level (UL) for Zn and Cu. Guideline level (GL) for Cr.
-No safety parameter available.

The estimations shows that using the realistic amounts of sewage sludge available (enough to cover <10% of the agricultural soil with 40 tonns/10 year) the use of sewage sludge on Norwegian crop land is unlikely to lead to a metal concentration in food that will constitute any significant risk of to the general population (Table 56).

Locally, vegetable farmers or others covering their daily consumption of vegetables grown on soils that has received the maximum amount of sewage sludge during 100 years will exceed the toxicological safe parameter for Cd and Cu. The probability of this scenario has not been looked at by VKM. It may be desirable to consider the probability of this scenario.

The estimations do however, indicate that dispersal of sewage sludge has a potential to increase the human exposure to Cd and other metals through food consumption. This potential increase in metal intake, and particularly of Cd, Cu and Hg, is undesirable. On the other hand, the application of other fertilizers may have a similar contribution to the increase of dietary cadmium as sewage sludge. The model also shows that the dietary exposure to mercury may increase significantly with time, but will still be well below the PTWI. The estimated mean human intake of the other metals from food and drinking water affected by the application of sewage sludge are all below the TWI/UL (Table 56). Cereals are expected to be the main source of dietary intake of metals after application of sewage sludge, followed by potatoes.
The potential increase in dietary intake of toxic metals demonstrates the need to continue the ongoing efforts to reduce the levels of toxic metals in sewage sludge.

5.8.3.1. Human exposure to organic contaminants from food and drinking water

The estimated dietary intake of the organic contaminants where a TDI is set is well below the tolerable intake, even when use of sewage sludge on all cropland has been assumed (Table 57).

Table 57. Estimated dietary exposure to organic contaminants through consumption of food produced assuming all food items were produced on sludge treated soil and toxicological safety parameters for each contaminant. Intakes are estimated for mean consumption of all food items and for high comsumers of potatoes (the food items with the highest contribution to the mean dietary intake of all organic contaminants). Background intakes (estimated intakes without sewage sludge application) have been estimated for both mean consumption of food items and high comsumers of cereals. The toxicological safety parameters (TDI/MBDL$_{10}$) are expressed in µg/kg bw/day to allow direct comparision with the estimated intake. Mean body weight for adults is 70 kg.

40 tons application – 100 years	**DEHP**	**DBP**	**Oktylphenol**	**Octylphenol etoxilates**	**Nonylphenol**	**Nonylphenol etoxilates**	**Σ PAH 4**	**Σ PCB$_6$**
Mean total intake (µg/kg bw/day)	4.3	0.05	0.24	0.01	0.96	0.48	0.04	0.01
High Consumer of main source (µg /kg bw/day)	7.0	0.09	0.37	0.02	1.55	0.73	0.06	0.02
60 tons application – 100 years	**DEHP**	**DBP**	**Oktylphenol**	**Octylphenol etoxilates**	**Nonylphenol**	**Nonylphenoletoxilates**	**Σ PAH 4**	**Σ PCB$_6$**
Mean total intake (µg /kg bw/day)	6.5	0.08	0.36	0.02	1.5	0.72	0.06	0.02
High Consumer of main source (µg /kg bw/day)	10.5	0.13	0.55	0.02	2.3	1.10	0.08	0.03
Safety parmaters µg (µg/kg bw/day)	50	10	-	-	-	-	340*	0.02**

-no safety parameters available
*MOE: 340/0.08=4250
**MOE: 0.02/0.03= 0.66

A realistic proportion of the crop producing area treated with sewage sludge (<10%) the exposure of the general population to PCBs and other organic contaminants in food will increase marginally, indicating that the additional exposure following use of sewage sludge is of minor importance.

Locally, the models indicate that vegetable farmers or others covering their daily consumption of vegetables grown on soils that has received the maximum amount of sewage sludge during 100 years, will have an intake of PCBs exceeding the toxicological safe intake of these compounds, with no safety margin (Table 57). The main sources of intake of PCB in the estimates are potatoes and other root vegetables. There are, however, available experimental data with different varieties of potatoes and carrots grown in soil with PCB levels comparable with the soil concentrations expected after 100 years with repeated use of sewage sludge (Zohair *et al.,* 2006), clearly demonstrating that the modelled values are grossly overestimating the PCB concentrations in these food items. Residues of PCBs in four cultivars of potatoes and three cultivars of carrots organic farmed were measured by Zohair *et al.* (2006). The measured soil concentration of PCB_7 in this organically-farmed soil was slightly higher than the estimated soil concentration after 100 year with 50% higher sludge dose than legal limit, 3 – 5 µg/kg DW versus 2 µg/kg DW, were suitable for comparison. Congener PCB-138 was among the abundant both in soil (Zohair *et al.*, 2006) and in the sludge amended soil in this risk assessment. The peels and cores were measured separately in the study (Zohair *et al.,* 2006), and as observed by other studies (O'Connor et al, 1990, WHO 1998) where the concentrations in the peels were higher compared with the core. In three of the cultivars, the PCB_7 in the peels and the cores were in the range of 0.639-0.715 µg/kg fresh weight and 0.065-0.287 µg/kg fresh weight, respectively. In the fourth cultivar, the concentration was higher, 1.38 and 0.6 µg/kg fw in the peel and core, respectively. The higher accumulation of PCBs in peels than in cores is related to the higher lipid content in peels. The estimated PCB_7 concentration in potato in this risk assessment is 5.6 µg/kg fw that is considerably higher than the concentrations measured in the potato cores by Zohair *et al.*, (2006). The potatoes in Zohair's study were grown in soil with slightly higher PCB concentration than in our estimated soil concentration.

There are several possible reasons for this discrepancy. For example, in our assessment - the model by Trapp & Matthies (1995, applied in TGD) was used for calculation of PCBs concentrations in root vegetables. It is shown in the evaluation by Collins *et al.* (2006) that this model gave an over-estimation for compounds with increasing log K_{ow} above 4.5-5. Since PCBs have log K_{ow} in the range of 5.2 – 7.2, the overestimation might be rather high.

Trapp *et al.* (2007) have recently published a more specific potato model (see also Chapter 5.7.1.4.). A test calculation for uptake of PCB-138 in potato with use of the same soil concentration, K_{ow}, K_{oc} etc as in this risk assessment, was performed. The estimated root concentration of PCB-138 with the use of the TGD-model was at least 50 times higher than the newer potato model. Potato is a tuber and is a part of the stem and not connected to the root system and the transpiration stream. The study by Trapp *et al.* (2007) showed that diffusion through potato was slower than diffusion through carrot and obtained a reduced BCF than previous model.

It is important to note that the highest concentration of lipophilic compounds accumulate in the peeling. In the study by Zohair and coworkers (2006), it is estimated that as much as 52-100% of the PCBs are removed after peeling. In areas with specially suspected high content of lipophilic organic compounds, peeling root fruits may reduce concentration in edible parts. At present sewage sludge is not allowed to be used in soil where root vegetables are grown.

Taking the overestimate of PCBs concentrations in vegetables and the limited availability of sewage sludge into consideration, it is concluded that the dietary PCB intake following application of sewage sludge constitute a low risk for the general population. Peeling of root fruits grown in contaminated soil is recommended.

The Margin of Exposure (MOE) between the estimated exposure to PAH4 following use of sewqage sludge on all crop-producing soil and the $BMDL_{10}$ for PAH4 is 4250. This is also considered to be a gross overestimate of the intake due to overestimations of the uptake in potatoes as for PCBs. The estimated intake of PAH4 as a consequence of use of sewage sludge is well below the intake estimated from other sources (VKM, 2007b) and would have a low contribution to the overall intake.

Conclusion

The use of sewage sludge in agriculture will not lead to any significant risk for the general population related to the dietary intake of most contaminant. There may be an undesired increase in the intake of mercury and copper. The cadmium and copper intake may exceed the tolerable daily intake for local vegetable farmers only consuming vegetables from sludge-amended soil. VKM recommend a survey of the concentration of cadmium, copper and mercury in agricultural products derived from fields where sludge repeatedly has been applied. The estimations even indicate a potential undesirable increase in intake of PCBs for people consuming only vegetables from sludge-treated area. This increase would be considerably lower if the vegetables are peeled. A continuation of the present practice of not using sewage-sludge on soil for vegetable production will further limit the potential increase in PCB intake.

5.8.3.2. Children eating sludge amended soil

Inorganic contaminants

It may be concluded that children eating sludge-amended soils will not be at risk due to the content of heavy metals (Table 58).

Table 58. Estimated intake (ug/kg bw/day) of inorganic contaminants in children eating 0.2 g soil/day. Mean body weight for children is assumed to be 10 kg. Safety parameters are given as ug/kg bw/day to allow direct comparision with the estimated intake. Mean body weight for children is assumed to be 10 kg.

Contaminant	**Present background**	**Agricultural soil, 60 tons After 100 years**	**Park area**	**Soil mixture**	**Safety parameter***
	ug/kg bw/day	ug/kg bw/day	ug/kg bw/day	ug/kg bw/day	ug/kg bw/day
Cadmium	0.004	0.009	0.006	0.006	**0.36**
Lead	0.48	0.60	0.47	0.47	**3.6**
Mercury	0.001	0.006	0.004	0.004	**0.71**
Nickel	0.42	0.50	0.40	0.40	-
Zinc	1.3	3.1	2.2	2.1	**357**
Copper	0.38	1.8	1.2	1.1	**71**
Chromium	0.54	0.67	0.53	0.53	**14**

*Tolerabel daily intake (TDI) for Cd, Pb and Hg. Upper intake level (UL) for Zn and Cu. Guideline level (GL) for Cr.
-no safety parameters available

Organic contaminants

Soil concentrations of $\Sigma PAH4$ and ΣPCB_6 due to application of sewage sludge are far below the soil concentrations allowed for housing estates where vegetables are grown and consumed (Table 59). In addition, the calculated exposure by eating 0.2 g of sludge-amended soils daily is far below the safety parameters.

Table 59. Estimated intake (ug/kg bw/day) of organic contaminants in children eating 0.2 g soil/day. The toxicological safety parameters ($TDI/MBDL_{10}$) are expressed in μg/kg bw/day. Mean body weight for children is assumed to be 10 kg.

Organic contaminant	**Agricultural soil, 60 tons After 100 years**	**Park area**	**Soil mixture**	**Safety parameter**
	ug/kg bw/day	ug/kg bw/day	ug/kg bw/day	ug/kg bw/day
DEHP	0.03	0.18	0.16	50
DBP	0.00009	0.00218	0.00218	10
Octylphenols	0.0005	0.020	0.020	-
Octylphenolethoxylates	0.00002	0.002	0.002	-
Nonylphenols	0.002	0.10	0.10	-
Nonylphenol ethoxylates	0.001	0.08	0.08	-
$\Sigma PAH4$	0.001	0.08	0.08	340*
ΣPCB_6	0.000005	0.00004	0.00004	0.02*

-no safety parameters available
*$BMDL_{10}$

Conclusions

The estimated intake of contaminants from intake of 0.2 g soil/day is low. The estimated intakes of contaminants are well below the toxicological safe intake values for all substances were such a value has been available. Even for substances where such a value not is available the intake is low and considered to constitute a low risk.

6. PART B: RISK ASSESSMENT OF MEDICINES

The European Medicines Agency (EMEA) and the EU legislation, apply the term human or veterinary medicinal products (HMPs and VMPs) i.e. for products that consist of one or more active drug substances and various excipients. Furthermore, in EU regulations on environmental impact of HMPs and VMPs the term drug substance is used while regarding food safety following use of VMPs in food animals drug residues is applied. In the present risk assessment we apply the terms medicinal products, medicines, pharmaceuticals, drug substances or drug residues depending on the context.

Human-used medicines may by multiple routes or exposure pathways (see figure 5, Chapter 4) reach the environment (Halling-Sørensen *et al*, 1998). Following the use of medicines in humans, drug substances and their metabolites will be discharged to wastewater and end up in sewage sludge. Drug substances may also end up in sewages sludge after disposal of expired and unused medicines into the toilet.

Other sources which can potentially introduce drug substances into the environment are leaching from landfills following disposal of expired and unused medicines, release of unabsorbed externally applied medicines (e.g. lotions) to surface waters from activities such as swimming, excreta from animals including pets and other domestic animals, and industrial manufacturing waste waters. These exposure routes were however not the subject of this assessment.

Directive 2001/83/EC requires that an environmental risk assessment shall accompany an application for a marketing authorisation for a human medicinal product (HMP). It should be noted that whatever impact such a medicinal product is expected to have on the environment this does not constitute a criterion for refusal of a marketing authorisation by the EMEA (EMEA, 2006).

An environmental risk assessment is, however, only required for new medicinal products (from June 2006). This implies that for most medicines approved for marketing authorisation in Norway an environmental risk assessment has not been completed.

Norwegian screening studies of contaminants in sewage sludge have only involved a limited number of drug substances (SFT, 2006, Thomas, 2007), and the inclusion criteria for the drug substances in these studies are not based on any systematic evaluation of environmental or human risk or probability of occurrence in the sludge.

VKM Panel 5 therefore decided to develop a tiered approach to estimate the concentrations of the various drug substances, originated from the use of HMPs, in Norwegian sewage sludge and thereby identify those that may be potential hazards to the environment or human health following application of sewage sludge to soils. The outcome of this tiered approach was a list of drug substances, for which a risk assessment was performed. The exposure scenarios for these drug substances are estimated in the same way as in the risk assessment of other contaminants performed in Part A.

6.1. Hazard identification of medicines

6.1.1. Introduction

Medicines are developed with the intention of performing biological effects. It is therefore recognised that medicines may pose potential environmental hazards if they enter the aquatic or terrestrial ecosystems (Fent *et al.*, 2006). By entering into the drinking water or the food chain they might also become a hazard for human health.

The human-used medicines (HMPs) recognized as potential environmental and food hazards are primarily medicines used in high volumes and drug groups with special properties such as hormones, anticancer drugs and antibacterial drugs (Jørgensen & Halling-Sørensen, 2000: Halling-Sørensen *et al.*, 1998). These four groups can be described as follows:

1. High volumes HMPs include drug groups such as non-steroid anti-inflammatory drugs, beta-blockers and lipid lowering agents. For these drug substances, an environmental risk assessment (ERA) can be performed according to the methods establish for other chemical contaminants (Länge & Dietrich 2002)

   A typical example is diclofenac, a non-steroidal anti-inflammatory drugs used as analgesic, anti-arthritic and anti-rheumatic medicines. The inhibition of the prostaglandin synthesis by inhibition of cyclooxygenase (COX) is thought to be the principle mechanism of action. Diclofenac is decomposed mainly by photolysis and oxidation using ozone whereas biodegradation under environmental conditions is slow. In consequence, it has been detected in rivers, lakes and waste treatment facilities in different countries (Buser *et al.*, 1998, Ternes 1998). It is reported that the use of diclofenac in animals has led to a sharp decline (> 95 %) in the population of the oriental white-backed vulture (*Gyps bengalensis*) in the Indian subcontinent (Oaks *et al.*, 2004, Shultz *et al.*, 2004). By feeding on carcasses of diclofenac-treated livestock the vultures accumulated the drug that resulted in death by renal failure.

2. Hormones are substances involved in cell signalling. They are effective at low concentrations (ng/l level) and as pharmaceuticals they are used as natural, nature-identical and synthetic substances. As contaminants in the ecosystem, hormones have been shown to disrupt biological signal pathways (Daston *et al.*, 1997).

   The synthetic estrogen 17-α-ethinylestradiol (EE2) is one of the few drug substances for which significant extents of absorption to sludge and ecotoxicological affectivity has been documented (Temes *et al.*, 2002, Caldwell *et al.*, 2008, Sumpter *et al.*, 2005, 2008). EE2 has been detected in sewage treatment plant effluents in low nanogram-per-liter (ng/l) levels and occasionally also in surface waters in e.g. the U.S., U.K., Canada, Brazil, Germany. Reproduction dysfunctions in fish were identified as most sensitive endpoints in aquatic species (Länge *et al.*, 2001). Combining data from 39 published articles; non-observed effect concentrations (NOECs) for reproductive effects could be established for 26 fish species.

3. Anticancer drugs are optimally designed to kill/inhibit malignant tumour cells at doses that allow enough unaffected cells in critical tissues with high cell proliferation rates to survive so that recovery can occur. Different substance groups with specific mechanisms of actions are used in anticancer chemotherapy; however, all are generally genotoxic and mutagenic already at relatively low concentrations.

Several studies on the acute environmental toxicity of anticancer drugs have been performed in *in-vitro* or *in-vivo* ecotoxicological tests using i.e. bacteria, algae, daphnids or fish species. The hydrofolate reductase inhibitor methotrexate has been shown to elicit acute effects in ciliates only at 45 mg/l and teratogenicity in fish embryos was observed at even higher concentrations (Henschel *at al.,* 1997). It was therefore concluded that acute toxicity to aquatic organisms is unlikely to occur at the concentrations currently measured in the environment. However, few data on chronic effects due to long-time low exposure are available.

4. Antibacterial drugs are compound that kill or inhibit the growth of bacteria. Antibacterial drugs comprise a forth group of importance due to their potential for resistance development caused by selection for resistant bacteria.The development of antibacterial resistance is usually favoured by sub-inhibitory concentrations of these drugs. Antibacterial drugs can be found with increasing frequency in waste waters and sewage sludge, and in parallel, an increased level and frequency of resistant bacteria in the environment has been observed (Reinthaler *et al.,* 2003). Combined effects of different antibacterial drugs that were higher than predicted based on the assumption of concentration addition were shown.

   In a study on the occurance of *E. coli* in sewage and sludge it was shown that microorganisms with resistances to antibacterial drugs accmulated in the sludge (Reinthaler *et al.,* 2003). *E. coli* strains were found which were resistent to 16 out of 24 tested antibacterial drugs (penicillines, cephalosporines, carpanemes, aminoglycosides, quinolones, and others); the highest resistance rate (up to 57%) was found for tetracycline. It was concluded that agricultural use of sludge without adequate desinfection will lead to the dessimination of resistant bacteria in the environment.

6.1.2. Number of drug substances on the Norwegian market

Since 2000, the number of new drug substances marketed in Norway has increased by approximately 270 and reached a total of 1414 in 2006 (LMI, 2007) (Figure 10). The majority were used in humans although veterinary medicines are also included. Many drug substances are marketed in various pharmaceutical forms (salts, capsules, etc.) so that the actual number of available medicinal products was about 2500 in 2006 (LMI, 2007).

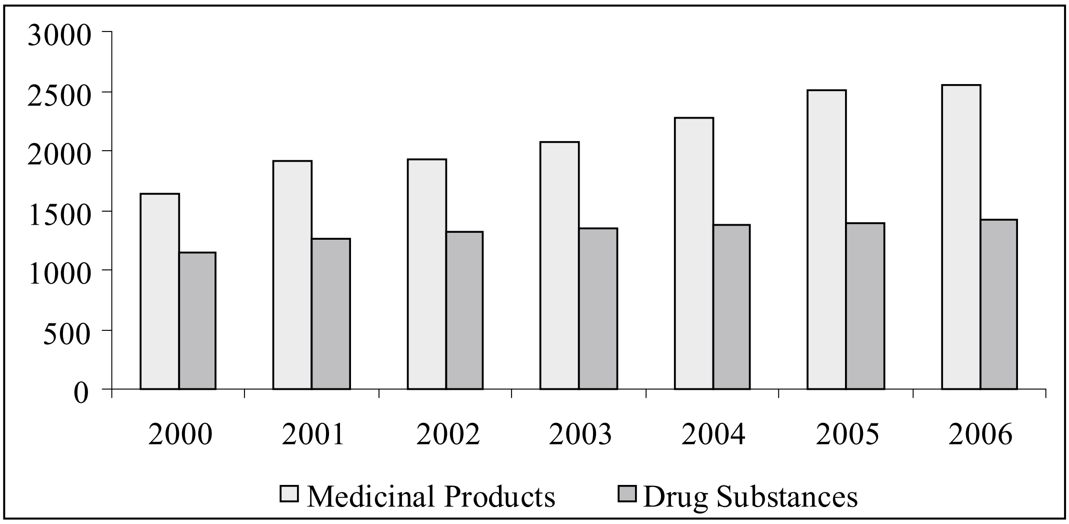


Figure 10. Number of human and veterinary medicinal products and drug substances in medicines marketed in Norway 2000 - 2006 (LMI, 2007).

6.1.3. Occurrence data of drug substances in sludge in Norway

Data on the occurrence of drug substances in sludge in Norway are sparse. Only two survey studies have been performed so far (SFT, 2006, Thomas, 2007). In the first study (SFT, 2006), sewage sludges from six STPs were investigated for 18 drug substances. In the second study (Thomas, 2007), 20 drug substances were determined in sewage sludge samples from VEAS (Vestfjorden avløpsselskap), a STP that serves a population of approximately 440 000 in the counties Oslo and Akershus, in addition to several large hospitals. In total, 610 000 population equivalents are connected to this STP that uses both chemical and biological treatments of the effluent. The study revealed antibacterial drug substances belonging to the tetracyclines (e.g. oxytetracycline (<0.01-2 µg/g wet weight), tetracycline (0.2-6.7 µg/g ww) and doxycycline (<0.01-1.3 µg/g ww) and fluoroquinolones (ciprofloxacin (4-97.5 µg/g ww)) in the sludges. In both surveys, estrogens were found only in very low concentrations in the sludge samples.

The criteria for the inclusion of the 18 and 20 drug substances, respectively, were not outlined in these two surveys and the selection made might overlook some important ones. Therefore, VKM Panel 5 has chosen to develop a tiered approach for the risk assessment of drug substances in Norwegian sewage sludges. At the starting point, all 1414 drug substances marketed in Norway were included. In the tiered process described below, the number was narrowed down by the application of specific criteria in several consecutive steps. Finally, the drug substances that had been determined to be the most relevant were evaluated.

Generally, the concentration of a drug substance in sewage sludge in a specific geographical area will depend on several factors, including:

- The consumption volume of a HMP in a specific geographical area
- The proportion of sewage sludge in the specific geographical area connected to a STP
- The fraction of the drug substance metabolised in the human body
- The biodegradation of the drug substance in the STP
- The ability of the drug substance to absorb to the sludge

6.1.4. Selection of drug substances for the risk assessment by a tiered approach

This chapter describes the tiered approach that was applied to identify the drug substances that require individual risk assessments. The calculation of predicted environmental concentrations in sludge (PEC_{sludge}) for the drug substances taking into concideration sales volumes, their physicochemical properties, drug metabolism in the human body and *in vitro* biodegradation data is critical in this evaluation process and basis for the use of specific cut-off values.

- Starting point: All HMPs marketed in Norway

- Tier 0: Initial exclusion of veterinary medicinal products. Exclusion of drug substances due to their properties, i.e. substances not considered toxic (e.g. proteins, vitamins), because of minor use or because of their formulation.

- Tier 1: Calculation of maximum $PEC_{sludge\ (max).}$ Exclusion of drug substances that have a $PEC_{sludge\ (max)}$ lower than the cut-off concentration of 587µg/kg, corresponding to <100µg/kg in soil.

- Tier 2: Exclusion of drug substances following a 1st refinement of the PEC_{sludge} considering physicochemical properties. Recalculation of $PEC_{sludge\ (Tier\ 2)}$. Application of the cut-off value as in Tier 1.

- Tier 3: Exclusion of drug substances following a 2nd refinement of the PEC_{sludge} considering the *in vivo* drug metabolism in the human body. Recalculation of $PEC_{sludge\ (Tier\ 3)}$. Application of the cut-off values as in Tier 1 and a cut-off concentration of 59µg/kg for anicaner drugs and hormones.

- Tier 4: Exclusion of drug substances considering experimental data on biodegradation and removal efficiencies in the STPs.

6.1.5. Calculation of predicted concentrations in sewage sludge (PEC_{sludge})

a) Maximum PEC_{sludge} (Tier 1)

A worst-case $PEC_{sludge(max)}$ estimations for the drug substances included in Tier 1 of the assessment were calculated by application of "rules" given in point 4.2, in the EMEA guideline on the environmental risk assessment of medicinal products for human use (EMEA, 2006):

- As a worst case scenario it was anticipated that the entire load of drug substances entered into the STP was all retained in the total amount sewage sludge produced.
- The use of the medicines was distributed evenly throughout the year and in the selected geographic area (counties).
- We anticipated that the excreted drug substances were evenly distributed in the total amount of sewage sludge produced in the selected geographic area
- In Tier 1, metabolism in the human body was not taken into account.
- In Tier 1, degradation of the drug substance or removal through effluent water in the STP was not taken into account.

The $PEC_{sludge\ (max)}$ for drug substances is calculated as ratio of the annual sales of the drug substance in a defined geographical area (M_{act}) and the yearly sludge production in the STPs in the same area (M_{sludge}).

$$PEC_{sludge\ (max)} = M_{act}/M_{sludge} * 10^{-6} \qquad [\mu g/kg] \qquad \textbf{Eq. 1B}$$

Where:

$PEC_{sludge\ (max)}$ = predicted maximum concentration of an drug substance in sewage sludge

M_{act} = the annual sales of the drug substance in a defined geographical area [kg]

M_{sludge} = the yearly sludge production in the STPs in the same area [tons]

The production and usage of sewage sludge varies considerably between the various regions in Norway. In sparsely populated rural area, e.g., Troms and Finmark, only a minor proportion of the households are connected to public sewage systems and consequently, the HMP consumed here will be discharged directly into recipient waters. The calculation of $PEC_{sludge\ (max)}$ based on the usage of HMPs for all Norwegian counties would therefore lead to overestimated values. However, since 97% of the households in the counties Østfold, Akershus, Oslo, Hedmark, Oppland, Buskerud and Vestfold are connected to STPs, only data from these counties were used for the calculation of the $PEC_{sludge\ (max)}$ in this risk assessment.

The total amount of sludge produced in these seven counties (M_{sludge}) accounted for 63 932 tons that represents 64% of the total amount of dry sewage sludge that was produced in Norway in 2006 (SSB, 2006). The 2006 sales statistics for HMP in the seven counties were obtained from the Norwegian Institute of Public Health. The sales data were expressed in kg for each drug substances (M_{act}).

The total consumption volume of HMPs was considered equal to the annual sales, assuming that the patients actually used the medicines they had purchased. Data from Sweden indicate that more than 90% of the sold HMPs are used (Swedish Medical Products Agency, 2004). Even if comparable data are not available for Norway, it can be assumed that the patients' behaviour is similar in both countries. It was also assumed that surplus/unused HMPs are disposed via the sewage wastewater.

b) $PEC_{sludge\ (Tier\ 2)}$ considering physiochemical properties (K_{ow} or K_{oc}) (Tier 2)

The lipophilicity of a drug substance is an important determinant for the fraction that is absorbed to sludge. In a discussion paper for calculating concentrations of human drug substances in surface water, EMEA recommended to assess the interaction potential of drug substances with sludge (EMEA-CPMP, 2005).

The equilibrium distribution of the amount absorbed to sludge and the amount remaining in the water is given by a substance's distribution coefficient (K_d). For organic molecules such as drug substances, K_d is often estimated by using the octanol-water distribution coefficient and by consideration of the fraction of organic carbon in the sludge (Shea, 1989):

$$K_d = f_{oc} * 0.41 * K_{ow}$$

Where:

K_d = distribution coefficient of a drug substance between sludge and water

f_{oc} = fraction of organic carbon in sludge

K_{ow} = distribution coefficient of a drug substance between octanol and water

Generally, the K_d value of a substance is dependent on its physiochemical properties as well as the organic matter content, mineral content, and/or pH of the sludge. If $\log K_d < 1.5$ this implies minor binding to sludge.

However, for substances containing polar functional groups, weak bases or acids, the correlation weakens as polarity increases and the sludge-water distribution gets pH-dependent (Oppel *et al.*, 2004). Therefore K_d for the various drug substances can not be estimated using the respective K_{ow} values as the vast majority of such substances are weak bases or acids.

The variability of the K_d of a drug substance among soils often is due to differences in organic matter content and can be reduced by adjusting K_d for soil organic carbon content. Considering the organic carbon partition coefficient (K_{oc}) and normalizing the partition coefficient to the organic carbon fraction of the soil (f_{oc}), K_d may also be estimated by the following equation (Hansen *et al.,* 1999):

$$K_d = f_{oc} * K_{oc} \qquad \textbf{Eq. 2B}$$

Where:

K_d = distribution coefficient of an drug substance between sludge and water

f_{oc} = fraction of organic carbon (0.35 in Norway)

K_{oc} = distribution coefficient of a drug substance between organic carbon (100%) and water

The mean organic matter content in Norwegian sewage sludges was 62.5% in 1996 (SSB 2008). Numbers given vary from 30% to 70% organic matter (Amundsen *et al.*, 2001) and 25% to 60% (Øgaard *et al.*, 2008), depending on the sludge treatment. Assuming that 50% of the organic material is organic carbon, the f_{oc}-values vary from 0.13 to 0.35. Therefore, f_{oc} = 0.35 is in the upper range of what can be expected for Norwegian sewage sludges, especially for anaerobically treated sludge and lime-amended sludge.

Based on the K_d or K_{oc} value, the predicted concentration of a drug substance in sludge (PEC_{sludge}) can be calculated using the following equation (Stuer-Lauridsen *et al.*, 2000):

$$PEC_{sludge(Tier2)} = \frac{M_{act} * 10^{-6}}{V_w / K_d + M_{sludge}} \quad [\mu g/kg] \qquad \textbf{Eq. 3B}$$

Where:

$PEC_{sludge\ (Tier\ 2)}$ = predicted concentration of a drug substance in dry sewage sludge [µg/kg]

M_{act} = the annual sales of the drug substance in a defined geographical area [kg]

K_d = distribution coefficient of a drug substance between sludge and water

V_w = the annual wastewater volume that enters the STPs in the included geographical area [m^3]; assuming water density $\delta = 1$, volume is equal to weight [tons]

M_{sludge} = the yearly sludge production in the STPs in the same area [tons]

The volume of waste water (V_w) used in the included area was calculated considering the number of inhabitants in 2006 and estimated use of wastewater per capita. By January 1st 2006, the number of inhabitants was 2 151 755 in the Norwegian counties included in this risk assessment. A wastewater volume (V_w) of 200 liters inhabitant^{-1} day^{-1} was estimated for Norway (SSB, 2006), resulting in a total annual usage of $1.52*10^{11}$ liters year^{-1}. This corresponds very well to value used by EMEA for the calculation of $PEC_{surfacewater}$ (EMEA, 2006). The yearly sludge production in the STPs in the area of interest (M_{sludge}) was 63932 tons (SSB, 2006).

Table 60 shows the increase of the predicted ciprofloxacin concentrations in sewage sludge and soil with increasing f_{oc}-values.

Table 60. Predicted ciprofloxacin concentrations in sewage sludge and soil with different f_{oc}-values. Levels are given in µg/kg DW.

f_{oc}-value	Sewage sludge	Agricultural soil		Soil mixture
	µg/kg DW	40 tons µg/kg DW	60 tons µg/kg DW	30% sewage sludge (v/v) µg/kg DW
0.2	1106	18.44	27.66	168
0.25	1323	22.05	33.07	200
0.3	1521	25.36	38.03	231
0.35	1704	28.40	42.60	258
0.4	1872	31.21	46.81	284

However, the distribution coefficients K_d or K_{oc} are available only for a few drug substances. Therefore, we have introduced a novel approach to estimate $K_{oc,}$ and consecutively K_d, by using the *in vivo* volume of distribution (V_D) of a drug substance. This method is based on the following hypothesis:

The volume of distribution (V_D) is the apparent volume into which a drug distributes in the body at equilibrium. It is a pharmacokinetic parameter that relates the amount of a drug substance in the body, i.e. the dose administered (D), to its concentration (c) in a reference fluid (e.g. plasma): $V_D = D/c$.

The V_D of a drug substance depends on its physicochemical properties like the octanol-water distribution coefficient (K_{ow}), the pKa value and the molecular size, but also on individual characteristics of the human body (e.g. the proportion of fat). A lipophilic drug substance with a high octanol-water partition coefficient (K_{oc}) will have a higher V_D than a less lipophilic substance because it will accumulate in the fat more easily.

In this approach, lipophilicity is assumed to be the determining factor for distribution of a drug subtance, either *in vivo* (V_D) or in sludge (K_d). Other determinants like the acidity seem to be of lesser importance because pHs are relatively constant in human body (about pH 7.3) as well as in sludges (ranging from pH 7 to 8). Therefore, the drug substances which in general are weak acids or bases will mainly occur in one charge state. However, distribution in sludges and human plasma might not completely be comparable considering the high carbon content (f_{oc} = 35% in Norway) in the sludges.

Nonetheless, assuming paralleled sensitivities of $V_{D,}$ and K_d or K_{oc}, respectively, with regard to drug substance properties and ambient factors in e.g. plasma or sludge, allows to draw the empirical equation $K_{oc} \sim V_D$.

The V_D of drug substances are usually known from pharmacokinetic studies which are performed during the developmental phase of new HMPs. In the present risk assessment, V_D data were therefore used to estimate K_{oc} values for the drug substances included in Tier 2 because only a few experimentally determined K_{oc} were available.

The equation relating K_{oc} to V_D was developed using the experimental data of 18 drug substances with known log K_{oc} and log V_D (Table 61).

Table 61. Data on log K_{oc} and log V_D for 18 drug substances.

Drug substance	**Log K_{oc}**	**Log V_D**	**Reference**
Atenolol	2.17	-0.022	William *et al*. 2004
Cyclophosphamid	2.50	-0.469	Genka *et al*. 1990
Diclofenac	2.92	-0.769	Gharfurian *et al*. 2006
Ethinylestradiol	3.66	0.578	Gharfurian *et al*. 2006
Ibuprofen	2.59	-0.903	Gharfurian *et al*. 2006 William *et al*. 2004
Iphosphamid	2.50	-0.559	Krisna *et al*. 2001
Ketoprofen	2.45	-0.796	Kokki H *et al*. 2002
Metformin	2.03	-1.221	JN 2002 vol 15(4) 398-402. www.sin-italy.org
Naproxene	2.54	-0.796	William *et al*. 2004
Noretisteron	3.43	0.342	William *et al*. 2004
Oxazepam	2.65	-0.004	Gharfurian *et al*. 2006
Salbutamol	1.51	-1.301	William *et al*. 2004
Terbutalin	2.73	-0.427	William *et al*. 2004
Estradiol	3.47	0.477	William *et al*. 2004
Desipramine	4.19	1.572	Devena *et al*. 1980
Flouoxetin	4.29	1.602	DKMA product summary
Citalopram	4.40	1.207	Rompono *et al*. 2006
Imipramine	3.99	1.324	William *et al*. 2004

Plotting log K_{oc} versus log V_D revealed a linear correlation between both values (Figure 11).

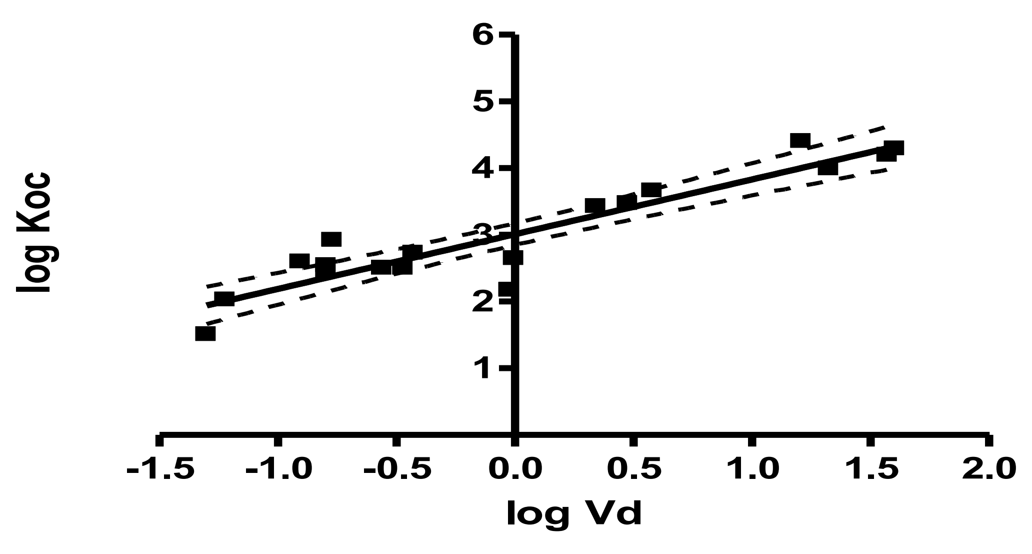


Figure 11. Relationship between log K_{oc} and log V_D for the 18 drug substances included in Table 61 ($r^2 = 0.8597$).

Linear regression resulted in the equation:

$$\log K_{oc} = 3.01+0.821*\log V_D$$ **Eq. 4B**

Where:

K_{oc} = distribution coefficient of a drug substance between sludge and water
V_D = volume of distribution at equilibrium in the human body

c) $PEC_{sludge\ (Tier\ 3)}$ considering drug metabolism in the human body (Tier 3)

Most drug substances are metabolised *in vivo* to facilitate elimination from the body. The metabolites are mainly excreted via urine or bile and may thus reach the environment. Metabolisation reactions include phase I reactions like oxidation, reduction or hydrolysis and phase II reactions like conjugations to glucuronides, peptides and sulphate (Figure 12). Phase I metabolites might be more reactive and toxic than the parent drug whereas phase II metabolites are normally inactive substances. Both phase I and phase II reactions change the physiochemical behaviour of a drug substance leading generally to greater hydrophilicity. [For a comprehensive overview of drug metabolism, see e.g. Gibson & Skett 2001]

If the main metabolites of a drug substance may have a potential for activity they should ideally be included in an environmental risk assessment. It should also be noted that phase II metabolites such as chloramphenicol glucuronide and N-4-acetylated sulphadimidine may be reconverted to the parent substances chloramphenicol and sulphadimidine, respectively, e.g., in samples of liquid manure (Berger *et al.*, 1986).

Sewage sludge may contain a mixture of drug substances, metabolites, and degradation products formed by both chemical degradation processes and bacteria. However, evaluating the available data, only parent drug substances (designated as drug substanses) have been assessed in the present risk assessment.

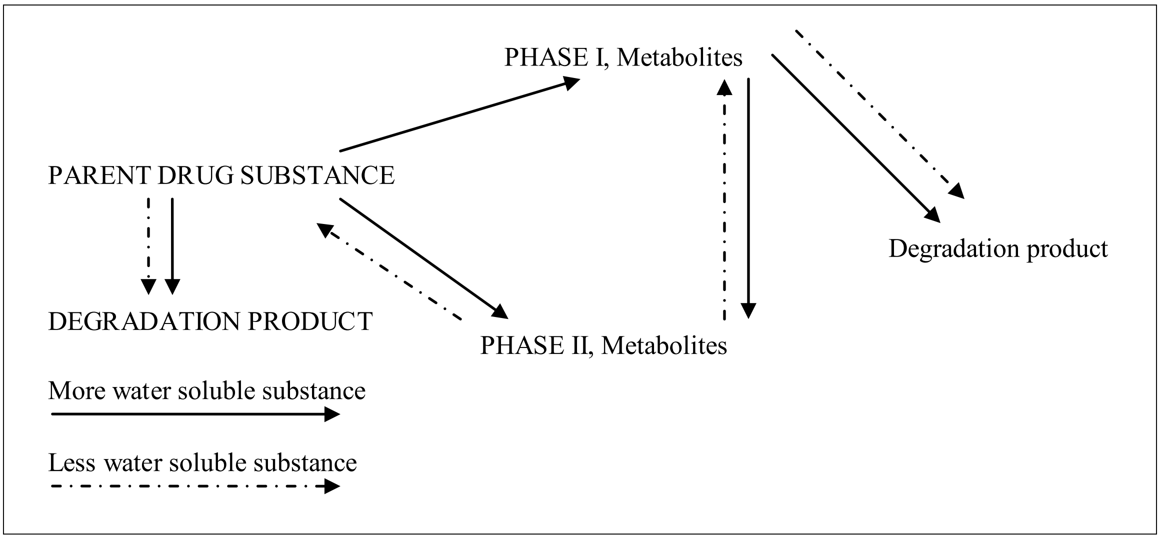


Figure 12. Metabolic pathways of drug substances forming phase I and phase II metabolites. Phase I metabolites may also degrade. Solid lines indicate transformation into more water-soluble molecules. Dotted lines indicate reconversion of phase II metabolites into less water-soluble molecules, caused by bacterial or chemical processes. (Reproduced partly after Halling-Sørensen *et al.*, 1998).

Drug substances may be metabolized *in vivo* so that less unaltered substances are excreted via urine and faeces than the dose administered. Metabolites are generally more hydrophilic than the parent substances although exceptions exist for the so-called pro-drugs that are activated by *in vivo* metabolism.

Metabolites will mostly have a decreased affinity to sludge when compared to the parent substance. Distribution data for metabolites are scarce, but because of the metabolites' more hydrophilic molecular properties, their volumes of distribution (V_D) are usually lower than those of the parent substances. Metabolites will therefore follow the effluent wastewater in the treatment plant to a larger extent than the parent substances and were consequently excluded in the 2nd refinement of the PEC_{sludge} calculations (Tier 3).

The PEC_{sludge} values obtained in Tier 2 were re-calculated using Equation 5B by multiplying the fraction of the given dose of the drug substance not metabolized in the human body (excreted unchanged) with $PEC_{sludge(Tier\ 2)}$.

$$PEC_{sludge(Tier\ 3)} = PEC_{sludge(Tier\ 2)} * f_{excretion\ unchanged} \qquad \textbf{Eq. 5B}$$

Where:

$PEC_{sludge(Tier\ 3)}$ = predicted concentration of a drug substance in sewage sludge [µg/kg]

$PEC_{sludge(Tier\ 2)}$ = predicted concentration of a drug substance in sewage sludge [µg/kg]

$f_{excretion\ unchanged}$ = fraction of administered drug substance that is excreted unchanged

6.1.6. Application of cut-off concentrations in the tiered approach

Drug substance in human medicinal products (HMPs) and veterinary medicinal products (VMP) may have harmful effects if they end up in the environment. In Europe, mandatory risk assessment for VMPs has been implemented by Directive 1981/852/EEC as amended by Directive 1992/18/EEC states. The European Medicines Agency (EMEA) has stated that precautionary measures that may be necessary to reduce such risks have to be identified (EMEA 2000, EMEA 2007).

For HMPs, the environmental impact should be assessed according to Directive 2001/83/EC as amended by Directives 2002/98/EC, 2004/24/EC, and 2004/27/EC, but it has also been stated that in any event this impact should not constitute a criterion for refusal of a marketing authorisation.

In the guidelines it is assumed that for the majority of drug substances exists a threshold value below which the risks for environmental harm is negligible. For VMPs, EU applies a cut-off concentration of 100 µg/kg soil, which was derived from calculating the predicted maximum environmental concentration (PEC_{max}) in soil after spreading manure/slurry as fertiliser. If the PEC_{max} of a VMP is below 100 µg/kg, EMEA does not consider it necessary to do an environmental risk assessment. A soil concentration < 100µg/kg of drug substance is below the level shown to have toxic effects in studies conducted on earthworms, microbes, and plants with VMPs currently registered in USA (EMEA, 2000).

In agreement with the EMEA guidelines, VKM Panel 5 has chosen to apply the cut-off concentration of 100 µg/kg soil (Cut-Off_{soil}) also in the evaluation of HMPs in the present risk assessment. Drug substances with a predicted environmental concentration (PEC_{sludge}) below this threshold are considered to represent negligible risks and are excluded from the risk assessment.

For drug substances like hormones and anticancer drugs that usually excert effect at very low concentrations (s. 6.1.1. Introduction), VKM Panel 5 has applied an additional safety factor of 10. Therefore, the cut-off concentration for these substances was set to 10 µg/kg soil.

The corresponding cut-off concentrations for sludge (Cut-Off_{sludge}) were calculated for application in agricultural areas under consideration of the guidelines regarding dry sludge application and mixing depth of soil as well as the bulk density of dry soil (Part A, Chapter 5).

$$\text{Cut-Off}_{sludge} = \text{Cut-Off}_{soil} * DEPTH_{soil} * RHO_{soil} / APPL_{sludge} * 10 \quad [\mu g/kg] \qquad \textbf{Eq. 6B}$$

Where:

Cut-Off_{sludge} = cut-off concentration for drug substances in dry sewage sludge [µg/kg]

Cut-Off_{soil} = cut-off concentration of drug substances in soil (10 or 100 µg/kg) [µg/kg]

$APPL_{Sludge}$ = dry sludge application (40 or 60 tons/hectare) [t/ha]

$DEPTH_{soil}$ = mixing depth of soil (0.2 m) [m]

RHO_{soil} = bulk density of dry soil (1200 kg/m^3) [kg/m^3]

For park areas and horticultural soil mixtures, Cut-Off_{sludge} concentrations were calculated under consideration of two different mixing ratios of soil and sludge (Part A, Chapter 5).

Park areas:

$\text{Cut-Off}_{sludge} = \text{Cut-Off}_{soil} * (0.67\ RHO_{soil} + 0.33\ RHO_{sludge})/0.33\ RHO_{sludge}$ [µg/kg] **Eq. 7B**

Soil mixtures:

$\text{Cut-Off}_{sludge} = \text{Cut-Off}_{soil} * (0.7\ RHO_{soil} + 0.3\ RHO_{sludge})/0.3\ RHO_{sludge}$ [µg/kg] **Eq. 8B**

Where:

Cut-Off_{sludge} = cut-off concentrations for drug substances in dry sewage sludge [µg/ kg]

Cut-Off_{soil} = cut-off concentration for drug substances in soil (10 or 100 µg/kg) [µg/kg]

RHO_{soil} = bulk density of dry soil (1200 kg/m^3) [kg/m^3]

RHO_{sludge} = bulk density of dry sewage sludge (500 kg/m^3) [kg/m^3]

Cut-off concentrations for drug substances in sludge (Cut-Off_{sludge}) were calculated for the three sludge application scenraios (agricultural areas, park areas, horticultural soil mixtures) and the two cut-off concentration in soil (Cut-Off_{soil}), 100 µg/kg or 10 µg/kg, using the equations 5B, 6B, and 7B (Table 62).

Table 62. Calculated cut-off concentrations for active substances in sludge (Cut-Off_{sludge}) corresponding a cut-off concentration in soil of 100µg/kg for most active substances and of 10 µg/kg for hormones and anticancer drugs. Three application forms, in agricultural areas, in park areas and in horticultural soil mixtures, are considered.

Application parameters	Agricultural areas		Park areas	Soil mixtures
	40 t/ha	**60 t/ha**	**5 cm sewage sludge, 10cm soil**	**30% sewage sludge (w/w)**
Cut-Off_{sludge} (corresponding to 100 µg/kg Cut-Off_{soil}) **Used in TIER 1-3**	6000 [µg/kg]	4000 [µg/kg]	587 [µg/kg]	660 [µg/kg]
Cut-Off_{sludge} (hormones, anticancer drugs) (corresponding to 10 µg/kg Cut-Off_{soil}) **Used in TIER 3**	600 [µg/kg]	400 [µg/kg]	59 [µg/kg]	66 [µg/kg]

It should be noted that cut-off concentrations (Cut-Off_{sludge}) decrease with increasing amounts sludge used per ha agricultural area. The lowest Cut-Off_{sludge} concentrations were calculated for the application of sludge in park areas.

In the approach to identify active substances in Norwegian sludges which might be hazardous to the environment, substances whose calculated PEC_{sludge} concentrations were similar to or higher than the lowest Cut-Off_{sludge} concentrations (587 µg/kg and 59 µg/kg, respectively) were evaluated in the different steps of the tiered process.

6.1.7. Identification of relevant substances in Norwegian sewage sludges by a tiered approach

Starting point: All HMPs marketed in Norway = 1414

Tier 0: Initial exclusion of veterinary medicinal products. Exclusion of various drug groups by application of the Anatomical Therapeutic Chemical Classification System (ATC) (Appendix B1):

Initial exclusion of veterinary medicinal products.

ATC Group B: Vitamins, electrolytes, amino acids, peptides, proteins, carbohydrates, vaccines and herbal medicinal products are exempted due to the nature of their constituents. Such substances/products are also exempted from the requirement of a pre-marketing environmental risk assessment for HMP by EMEA because they are unlikely to result in significant risk to the environment (EMEA, 2006).

ATC Group D: Dermatological preparations are applied locally, and therefore, the amount of drug substance ending into wastewaters and sewage sludge cannot be assessed reliably. In general, large-scale dermatological HMPs do not contain high-potent drug substances.

ATC Group S: Drug substances in preparations for sensory organs (eyes, ears, nose) are applied locally and only in limited amounts. The ratio that is entering the environment cannot be assessed reliably.

ATC Group V: Preparations which are used against intoxications, for diagnostic puposes as well as nutrients represent minor use, biologically inactive substances and nature identical substances. Therefore, they are considered to be of negligible environmental risk.

The number of drug substances was reduced by Tier 0 to = 595

Tier 1: Exclusion of drug substances that maximum predicted concentrations in sludge [PECsludge (max), (calculated by Eq. 1B, s. 6.1.5)] lower than the cut-off concentration [Cut-Offsludge = 587 µg/kg, (calculated by Eq. 7B, s. 6.1.6)].

For hormones, anti-cancer drugs, and antibacterial drugs, cut-off concentrations were not applied in Tier 1.

For HMPs containing combinations of drug substances, PEC_{sludge} were calculated exclusively for the main substance if the other ingredients were either electrolytes (e.g. KCl is added to diuretic HMPs) or instable under aerobic conditions (e.g. adrenalin). This was decided case by case.

For substance that are pro-drugs (e.g. tetracycline may be given as the pro-drug lymecykline), the amount sold is derived from the sales volume of the pro-drug.

The 137 drug substances with PEC_{sludge} (max) above the Cut-Off sludge concentration were from different therapeutical groups. Additionally, 7 hormone drugs, 28 anti-cancer drugs and 37 antibacterial drugs were transferred to the next step in the tiered approach.

The number of drug substances was reduced by Tier 1 to = 209

Tier 2: Exclusion of drug substances by a 1st refinement of the PEC_{sludge} considering physicochemical properties like lipophilicity. Recalculation of PEC_{sludge} (Tier 2) (by Eq. 3B, s. 6.1.5) by taking into concideration the distribution coefficient of drug substance between sludge and water [(Kd), calculated by Eq. 2B, s. 6.1.5] that is derived from the organic carbon partition coefficient (Koc). If Koc were not available from literature, they were calculated from the *in vivo* volumes of distribution [(V_D), as in Eq. 4B, s. 6.1.5)].

The V_D were derived from the special product characterizations (SPCs) published by the Norwegian Medicine Agency (www.legemiddelverket.no), the Swedish drug catalogue FASS (www.fass.se), Goodman and Gilman (11 ed), and PubMed (Medline). For the majority of the drug substances, V_D was given as ranges, and the upper value was chosen for each substance to calculate the PECsludge.

Applying the 1st refinement of the PEC_{sludge} to the outcome of Tier 1 led to the identification of 70 drug substances from different therapeutic groups with PEC_{sludge}(Tier2) exceeding Cut-Off_{sludge} = 587 µg/kg. Additionally, 7 hormones, 28 anti-cancer drugs and 37 antibacterial drugs were transferred to the next step in the tiered process.

The number of drug substances was reduced by Tier 2 to = 142

Tier 3: Exclusion of drug substances by a 2^nd^ refinement of the PEC_{sludge} considering the *in vivo* drug metabolism. Recalculation of $PEC_{sludge(Tier\ 3)}$ (by Eq. 5B, 6.1.5) by excluding the estimated fraction of metabolised drug substance ($f_{excretion\ unchanged}$).

Data on the metabolism of the different drug substances were obtained from special product characterizations (SPCs) published by the Norwegian Medicinal Agency), the Swedish drug formulary FASS (www.fass.se) and PubMed (Medline). For drug substances for which the fraction metabolized was given as a range, the lowest value was selected resulting in the highest estimate for PEC_{sludge}.

Applying the 2st refinement of the PEC_{sludge} to the outcome of Tier 2 led to the identification of 17 drug substances from different therapeutic groups with $PEC_{sludge(Tier3)}$ exceeding Cut-Off_{sludge} = 587 µg/kg.

Additionally, for hormones, anti-cancer drugs and antibacterial drugs, the dedicated Cut-Off_{sludge} = 59 µg/kg (calculated by Eq. 7B, s. 6.1.6) was applied for the evaluation of the $PEC_{sludge(Tier3)}$. Only 5 of antibacterial drugs remained (Table 63).

The number of drug substances was reduced by Tier 3 to = 22

Table 63. Drug substances with $PEC_{sludge(Tier3)}$ exceeding Cut-Offsludge = 587 µg/kg (Cut-Offsludge = 59 µg/kg for hormones, anti-cancer drugs and antibacterial drugs). Information on the substances' biodegradation in sludge has been included.

Therapeutical Group	Drug Substance	$PEC_{sludge(Tier3)}$ [µg/kg]	Biodegradation in sludge or soil (% degraded or half-life in days)
Alimentary tract and metabolism			
Drug used in diabetes	Metformin	40202	No information available[a]
Drug for peptic ulcer	Ranitidin	1760	No information available[a]
Intestinal anti-inflammatory agent	Mesalazin[1]	39268	No information available[a] (V_D not applicable)
Blood and blood forming organs			
Anti-thrombotic agent	Dipyridamole	1008	Not readily biodegradable in OECD 301assay[a]
Cardiovascular system			
Beta-blockers	Sotalol	866	Only 2% degradable over 28 days period in OECD 301b assay[a]
	Metoprolol	753	No information available[a]
Diureticum	*Hydrochlorotiazide*	767	26% degraded over 28 days in OECD 301E assay[b]
Angiotensin II antagonists	Losartan[2]	1352	Photodegradable[c]
	Irbesartan	2920	26% degraded over 28 days in FDA 3.11 assay[a]
Lipid-lowering agents	Atorvastatin	2014	Less than 10 % aerobically biodegraded within 28 days[a]
Antimicrobial agents			
Tetracyclines	Tetracycline[3]	885	Less 1 % degraded after 28 days in OECD 301F assay[a]
Penicillin with extended spectrum	*Mecillinam*[4]	693	Rapidly biodegraded in activated sludge; T½ 0,5-0,7 days[d]
Beta-lactamase sensitive penicillin	*Phenoxymethyl -penicillin*	1647	Probably rapidly biodegraded as mecillinam
Beta-lactamase resistant penicillin	*Dicloxacillin*	872	Probably rapidly biodegraded as mecillinam
Fluoroquinolone	Ciprofloxacin	1704	Persistent in sludge
Musculo-skeletal system			
Anti-inflammatory agent	*Ibuprofen*	2036	More than 90% were found to be degraded in STPs already after six hours (Buser *et al*., 1999).
Muscle relaxant	Carisoprodol	3983	No information available[a]
Nervous system			
Analgeticum	*Paracetamol*	5134	99% biodegradable in 5 days OECD 302A assay[e]
Anti-epileptics	Gabapentin	2302	No information available[a]
	Levetiracetam	722	No information available[a]
Anti-psychoticum	Chlorprothixene	963	Not readily degradable in all Estimation Programs Interface (EPI) Suite models[a] developed by US-EPA (www.epa.gov)
Respiratory organs			
Anti-histamine	Fexofenadine	989	Persistent as no mineralisation in 28 days FDA 3.11 assay[a]

1. Includes also: Balsalazide, a pro-drug metabolised in the gut to mezalazine; 100% metabolism to mezalasin was assumed; and sulfalazine, a pro-drug metabolised in the gut to sulfapyridin and mesalazine; 100% metabolism to melzalazin was assumed.
2. Pro-drug to EXP3174.
3. Includes lymecycline, a pro-drug to tetracycline
4. Includes pivmecillinam, a prodrug to mecillinam

a. www.fass.se
b. Novartis (1999). Safety data sheet for Hydrochlorothiazide 13.07.1999
c. Toxikon Environmetal services 1993 "Losartan (MK -0954): Determination of aqueous photolysis, july 2 1993.
d. Halling-Sørensen B et al. (2000), J. Antimicr. Chemother. 46: 53-58
e. Joss A et al. 2006, Water Research 40:1686-96

Drug substances in Italics are extensively biodegraded in sludge and soil.

Tier 4: Exclusion of drug substances considering biodegradation in the STPs. Substances that degrade rapidly in sewage sludge was considered to be of low environmental concern. From the 22 drug substances identified by Tier 3, 7 could be excluded because of their instability in sludge:
Ibuprofen and its metabolites are extensively biodegradable; more than 90% were found to be degraded in STPs already after six hours (Buser *et al.,* 1999). The antibacterial drugs *mecillinam*, *phenoxymethylpenicilin* and *dicloxacillin* are rapidly degraded because the betalactamase ring in the molecule is subjected to hydrolysis. *Paracetamol* degraded rapidly in biodegradation simulation assay; approximately 99% disappeared over 5 days (Joss *et al.,* 2006). *Hydrochlorohtiazide* and *irbesartan* were shown to biodegrade with more than 25% in degradation experiments simulating soil environments (Novartis, 1999).

Exclusion of drug substances considering experimental data on STP removal efficiencies. The 15 drug substances that were identified by the tiered approach to be potentially hazardous to the environment via the dispersal of sewage sludge belong to different therapeutical groups and have different molecular properties. This reflects the various substances' individual affinities to sludge and varying removal efficiencies from the wastewater in a STP. A review on SPT influent and effluent concentration data compiled from 115 studies (Miege *et al.*, 2007) illustrate this diversity (Figure 13):

Drug substances like iopromide, tamoxifen, carbamacepin, erythromycin, dextropropoxyphene and *metformin* apparently neither do bind to sludge nor biodegrade because their STP influent and effluent concentrations are practically identical. However, the $PEC_{sluge(Tier3)}$ predicted for metformin in the present assessment (Table 63) was rather high and requires validation by measured real-life results. VKM Panel 5 has therefore chosen to exclude metformin for further evaluation.

A considerable number of drug substances have removal efficiencies in the range from 20% to 70% from the wastewater in a SPT (Figure 13). This group includes beta-blockers like atenolol, propanolol and *metoprolol*, antibacterial drugs like trimetroprim, sulfamethazine, sulfamethoxazole and *ciprofloxacin* as well as lipid-lowering agents like clofibric acid.

Several drug substances generally are removed from the wastewater in a STP to more than 80%. Among these are *paracetamol*, *ibuprofen*, naproxene and estrogens like estrone, 17-β-estradiol, 17-α-estradiol. In the present assessment, however, paracetamol and ibuprofen have been excluded because of their potential for extensive biodegradation in sludge.

Mesalazin is an intestinal anti-inflammatory agent that acts locally in the gastro-intestinal tract. Thus, the V_D cannot be determined as it is not appropriate. Consequently, K_{oc} could not be derived (Eq. 4B, s. 6.1.5) and the refinement of $PEC_{sludge(max)}$ by using K_d (Tier 2) was not possible. Therefore, the PEC_{sludge} finally estimated for mesalazin (Table 63) appears to be rather high, but in reality the consideration of the substance's lipophilicity and binding characteristics is lacking.

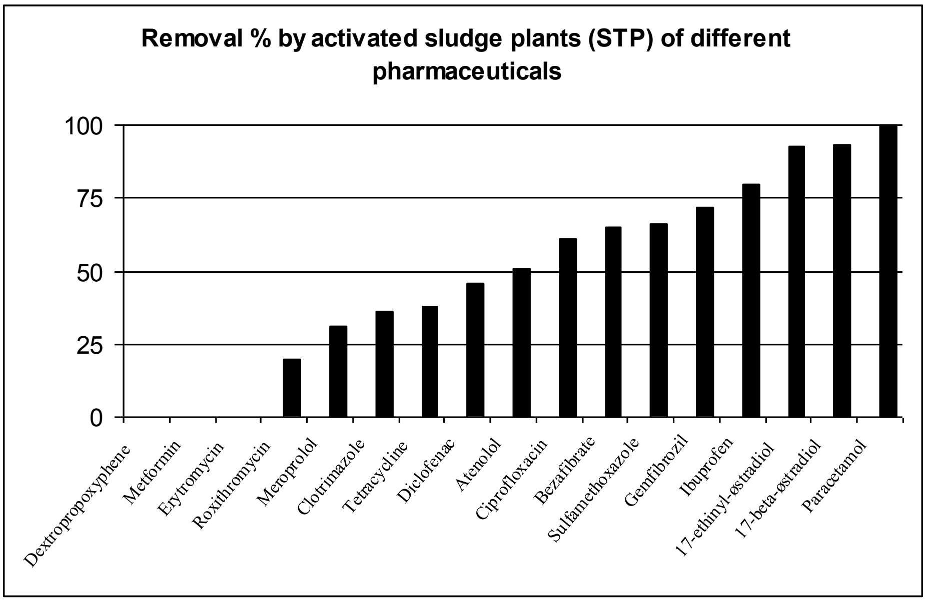


Figure 13. Removal efficiencies [%] of high volume pharmaceuticals in STPs calculated by comparing the mean influent and effluent concentrations (Miege *et al.,* 2007; Halling-Sørensen: unpublished data from different STPs in Copenhagen).

Applying biodegradation and removal efficiencies data to the outcome of Tier 3 led to the identification of 14 drug substances for which an environmental risk assessment had to be performed.

The number of drug substances was reduced by Tier 4 to = 14

6.1.8. Summary of the tiered approach

The tiered approach on the 1414 drug substances on the Norwegian market led to the identification of 14 specific drug substances for which an environmental risk assessment had to be performed (Table 64).

For a final evaluation, the PEC_{sluge} were recalculated (Eq. 3B and Eq. 5B, s. 6.1.5) by varying the fraction of organic carbon in sludge [(f_{oc}), Eq. 2B, s. 6.1.5]. As described before (s. 6.1.5), the upper range of organic carbon that can be expected in Norwegian sewage sludges, f_{oc}=0.35, was used for the determination of PEC_{sludge} in Tier 2. If the lower range, f_{oc} = 0.13, is used in the same equations, the PEC_{sludge} are considerably lower (Table 64).

The tiered approach was conducted by application of worst-case values/scenarios for the different parameters that were applied in the four steps of the exclusion process. Parameters given in ranges, those with the maximum impact were applied in the calculations of the PEC_{sludge}. Therefore, the resulting PEC_{sludge} as well as the number of drug substances identified are likely to be overestimated. However, tetracycline and ciprofloxacin may be exceptions because of their high affinity to zwitterions (Halling-Sorensen *et al.,* 2003).

Table 64. Drug substances included in the environmental risk assessment as identified by the tiered approach. PEC_{sludge} are calculated using the lower and upper range for f_{oc} (0.13 and 0.35, respectively) in Norwegian sludge.

Drug groups	Drug substance	PEC_{sludge} (f_{oc} =0.35) [µg/kg]	PEC_{sludge} (f_{oc} =0.13) [µg/kg]
Alimentary tract and metabolism			
Intenstinal anti-inflammatory agent	Mesalazin	39268	Unaffected*
Drug for peptic ulcer	Ranitidin	1760	719
Blood and blood forming organs			
Anti-thrombic agent	Dipyridamole	1008	420
Cardiovascular system			
Beta-blockers	Sotalol	866	367
	Metoprolol	753	352
Angiotensin II antagonists	Losartan[1]	1352	517
Lipid-lowering agents	Atorvastatin	2014	957
Antimicrobial agents			
Tetracyclines	Tetracycline[2]	885	358
Fluoroquinolone	Ciprofloxacin	1704	742
Musculo-skeletal system			
Muscle relaxant	Carisoprodol	3983	1526
Nervous system			
Anti-epileptics	Gabapentin	2302	894
	Levetiracetam	722	276
Anti-psychoticum	Chlorprothixene	963	559
Respiratory organs			
Anti-histamine	Fexofenadine	989	476

[1] Prodrug to EXP3174

[2] Includes lymecycline, a pro-drug to tetracycline

*As V_d is not set for mezalasin PECsludge is based on worst case (i.e. f_{oc} has not been used to calculate PEC_{sludge})

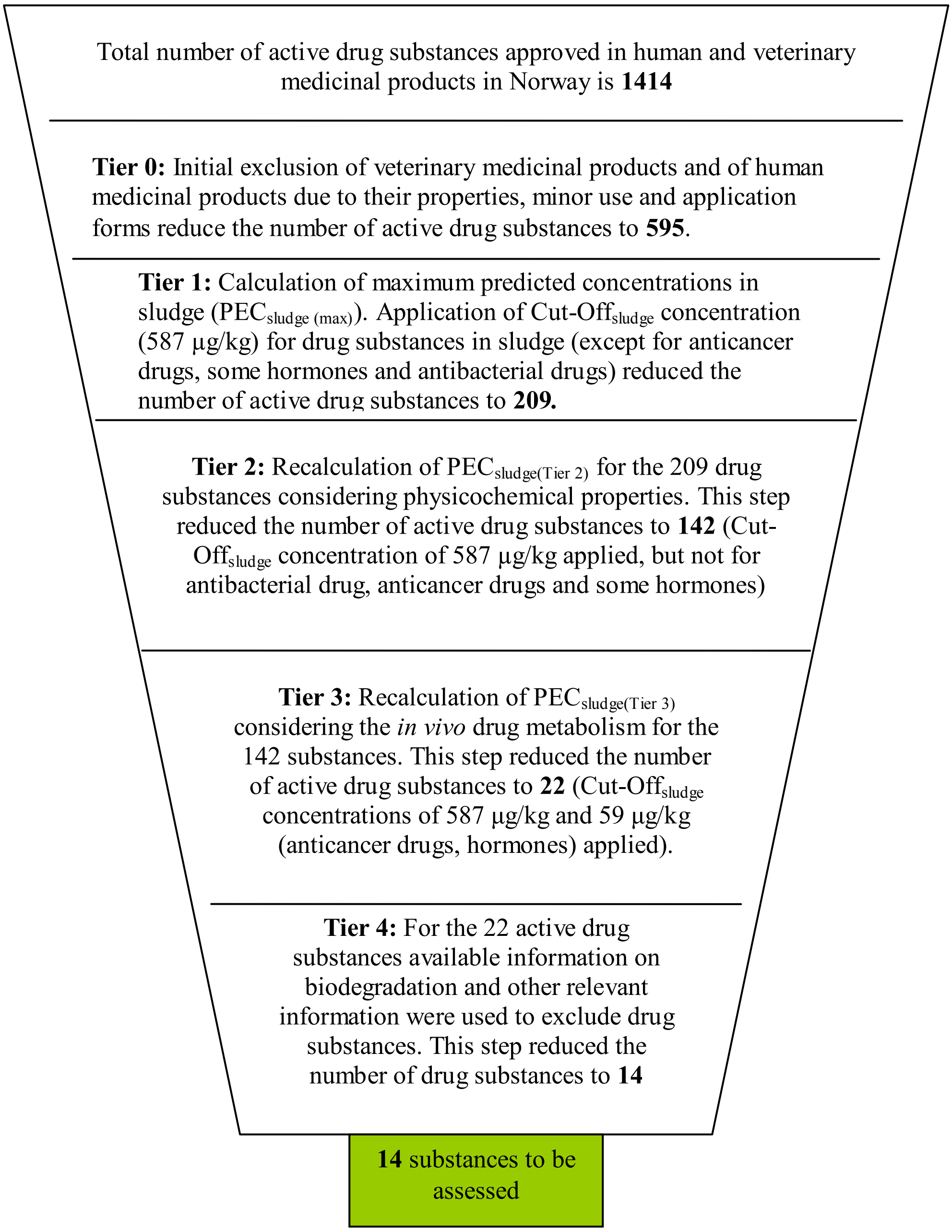
Summarizing the tiered approach used for the identification of drug substances for which an environmental risk assessment, concerning the use of sewage sludges as soil conditioner, had to be performed it can be observed that the different refinement steps for PEC_{sludge} had different impact on the reduction of substance numbers (Figure 14).

Most importantly, the refinement of the PEC_{sludge} in Tier 2 taking into account the physiochemical properties of the drug substances (Eq. 3B, s.6.1.5) considerably reduced the total number of substances that had PEC_{sludge} exceeding the $Cut\text{-}Off_{sludge}$ concentrations (Eq. 7B, s. 6.1.6) estimated for soils containing sewage sludges from Norwegian STPs.

Comparing the PEC_{sludge} of three drug substances with different physiochemical properties at the different steps in the tiered exclusion process (Table 65) demonstrates the impact of the 1st (Tier 2) and 2nd (Tier 3) refinements of the $PEC_{sludge(max)}$ that were calculated in Tier 1. The PEC_{sludge} of the hormone tibolone, the substance with the highest *in vivo* volume of distribution [(V_D), Eq. 3B and 4B, s. 6.1.5] and the largest fraction excreted unchanged [(fe), Eq. 5B, s. 6.1.5], was the least affected by the refinements.

Table 65. Reduction of predicted sludge concentrations (PEC_{sludge}) for three drug substances by the tiered approach.

Drug substances	$PEC_{sludge(Tier 1)}$ [µg/kg]	$PEC_{sludge(Tier 2)}$ [µg/kg]	$PEC_{sludge(Tier 3)}$ [µg/kg]	% reduction ($PEC_{sludge(Tier 3)}$/ $PEC_{sludge(Tier 1)}$
Anticancer drug Mycophenolic acid	7221	2382	24	0.03
Antibacterial drug Spiramycin	589	266	266	42.5
Hormone drugs Tibolone	61	61	61	100



Total number of active drug substances approved in human and veterinary medicinal products in Norway is **1414**

Tier 0: Initial exclusion of veterinary medicinal products and of human medicinal products due to their properties, minor use and application forms reduce the number of active drug substances to **595**.

Tier 1: Calculation of maximum predicted concentrations in sludge ($PEC_{sludge\ (max)}$). Application of $Cut\text{-}Off_{sludge}$ concentration (587 µg/kg) for drug substances in sludge (except for anticancer drugs, some hormones and antibacterial drugs) reduced the number of active drug substances to **209.**

Tier 2: Recalculation of $PEC_{sludge(Tier\ 2)}$ for the 209 drug substances considering physicochemical properties. This step reduced the number of active drug substances to **142** ($Cut\text{-}Off_{sludge}$ concentration of 587 µg/kg applied, but not for antibacterial drug, anticancer drugs and some hormones)

Tier 3: Recalculation of $PEC_{sludge(Tier\ 3)}$ considering the *in vivo* drug metabolism for the 142 substances. This step reduced the number of active drug substances to **22** ($Cut\text{-}Off_{sludge}$ concentrations of 587 µg/kg and 59 µg/kg (anticancer drugs, hormones) applied).

Tier 4: For the 22 active drug substances available information on biodegradation and other relevant information were used to exclude drug substances. This step reduced the number of drug substances to **14**

14 substances to be assessed

Figure 14. Summary of the tiered approach used to select drug substances for which an environmental risk assessment, concerning the use of sewage sludge as soil conditioner, had to be performed.

6.1.8.1. Validation of the PEC_{sludge} values

The occurrence of drug substances in e.g. sludge depend on the prescribing patterns that may vary considerably between countries and the amount of sludge produced in STPs. Unless the prescribing patterns are similar, data on the occurrence of drug substances in sludge from one country cannot be used to validate data from another country.

As there are few available occurrence data for drug substances in sludge from Norwegian STPs (SFT, 2006; Thomas, 2007), the possibilities to validate the estimated PEC_{sludge} values are limited. In the study by Thomas (2007) the concentrations of drug substances in sludge were measured in wet weight and the results could not be compared with the estimate PEC_{sludge} values on dry weight without further calculations. For the substances investigated by SFT (2006) their measured concentrations were found substantially higher for zopiklone and linezolid, within the same order for ciprofloxacin and ethinylestradiol while for the other substances the measured values were substantially lower compared to the estimated PEC_{sludge} values (Table 66).

Table 66. Concentrations of human drug substances (µg/kg DW) found in sewage sludge from 6 different STPs in Norway (SFT, 2006) and PEC_{sludge} (µg/kg DW) estimated in the present assessment.

Drug substance	**BE** µg/kg DW	**BE** µg/kg DW	**VEAS** µg/kg DW	**VEAS** µg/kg DW	**TAU** µg/kg DW	**TAU** µg/kg DW	**REM** µg/kg DW	**SOL** µg/kg DW	**RA-2** µg/kg DW	**PEC_{sludge}** (tier 3) µg/kg DW
Zoplikon	<400	<400	<400	<400	1000	500	630	<400	830	112
Trimethoprim	<5	<5	<5	<5	63	23	70	<5	12	516
Sulfamethoxazole	<5	<5	<5	<5	5.0	<5	20	<5	<5	64
Ciprofloxacin	3300	3500	2300	2100	2700	1700	1100	100	3800	1704
Furosemid	35	40	<30	<30	79	75	<30	<30	50	513
Fluoxetine	41	31	32	<30	<30	<30	<30	<30	<30	465
Felodipine	25	<20	23	39	<20	<30*	62	<20	<30*	312
Estrone(1,2	40	31	12	9.0	17	21	8.4	<2*	9.4	Not relevant(2
Beta-estradiol(1,3	6.1	<3*	1.2	3.3	5.9	1.2	0.84	<2*	3.5	28
Ethinylestradiol	<5*	<3*	<0.5	<2*	<3*	<2*	0.64	<2*	<2*	6
Ibuprofen	<50	<50	<50	<50	<50	<50	<50	<50	<50	2036(4
Linezolid	<20	<20	<20	<20	<20	<20	720	<20	<20	5

BE: Bækkelaget STP, VEAS: VEAS STP, TAU: Tønsbergfjorden avløpsutvalg STP, REM: Remmendalen STP, SOL: Solumstrand STP, RA-2: Sentralrenseanlegget STP

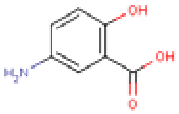
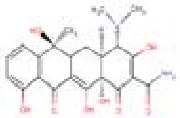
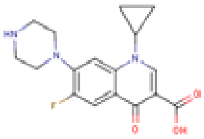
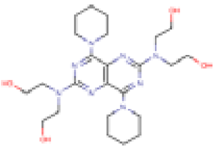
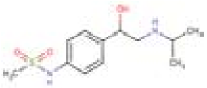
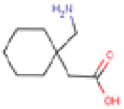
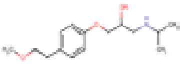
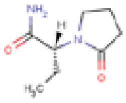
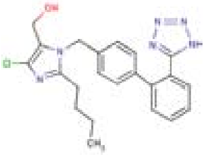
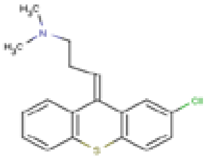
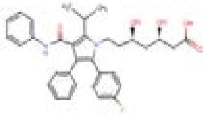
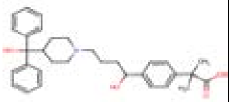
1) Also produced in the human body
2) Not approved in any human medicines in Norway
3) Beta-estradiol – synonyms are estradiol and 17β-estradiol
4) Degrade rapidly in STPs
*Higher detection limit due to interference

6.2. Hazard characterisation of medicinal products

The 14 identified drug substances (Table 64) belong to several classes of medicinal products, including compounds for the alimentary tract and metabolism treatment (ranitidin, mesalazin), the cardiovascular system (metoprolol, losartan, atorvastatin), antimicrobial agents (tetracycline, ciprofloxacin), muscular-skeletal system (carisoprodol), nervous system (gabapentin, levetiracetam, chlorprothixene), and respiratory organs (fexofenadine).

No hormone drugs were identified, and only two antibacterial drugs were among the identified drug substances.

Table 67. Structure of the selected drug substances.

Drug substance	CAS no	Molecular structure	Drug substance	CAS no	Molecular structure
Mesalazin	89-57-6		Tetracycline	60-54-8	
Ranitidine	66357-59-3		Ciprofloxacin	85721-33-1	
Dipyridamole	58-32-2		Carisoprodol	78-44-4	
Sotalol	3930-20-9		Gabapentin	60142-96-3	
Metoprolol	37350-58-6		Levetiracetam	102767-28-2	
Losartan	114798-26-4		Chlorprothixene	113-59-7	
Atorvastatin	134523-00-5		Fexofenadine	83799-24-0	

6.2.1. Aquatic environment

A search on ecotoxicology data reveals that data are only available for ten out of the 14 identified drug substances and only for aquatic species (Table 68). No data for terrestrial species is presently available even that the Knappe project EU database was available. PNEC values are generally in levels between 100 and 6000 µg/L for most of the drug substances. These values are probably far higher than any measured concentration level due to leaching of these compounds from biosolids.

For the drug substances metoprolol, atorvastatin and the antibacterial drugs tetracycline and ciprofloxacin PNEC values for the aquatic environment are less than 1 µg/L. Therefore, these compounds could probably pose an effect in the aquatic environment.

Table 68. PNEC values for aquatic organisms for the 14 selected drug substances.

Drug groups	Drug substance	PNEC$_{water}$ µg/L	Source
Alimentary tract and metabolism	Mesalazin	6078	Jones et al. 2002 Water research
	Ranitidin	167	SLM
Blood and blood forming organs	Dipyridamole	-	
Cardiovascular system	Sotalol	97.7	fass.se
	Metoprolol	58.3	fass.se
	Losartan	143	fass.se
	Atorvastatin	0.13	Brain 2004
Antibacterial drugs	Tetracycline[2]	0.31	fass.se
	Ciprofloxacin	0.52	Robinson et al., 2005
Musculo-skeletal system	Carisoprodol	1592	Ecosar
Nervous system	Gabapentin	1100	UK env agency
	Levetiracetam	-	
	Chlorprothixene	-	
Respiratory organs	Fexofenadine	-	

- No PNEC available

6.2.2. Soil environment

Since PNEC data for the terrestrial environment were not available, it is not possible to perform an initial hazard characterisation for the drug substances for this environment. Transformation of aquatic effect data to terrestrial effect data using the conversion: $\underline{PNEC_{terrestrial} = kd\ (DW\ soil) * PNEC_{aquatic}}$ may identify a level of effects in the terrestrial environment (Table 69). However, such data should be used carefully as specific mechanisms for soil organisms are not taken into account using the proposed equation.

Table 69. PNEC for soil and plants ($PNEC_{soil/plant}$) for the 14 selected drug substances.

Drug groups	**Drug substance**	**$^*PNEC_{soil/plant}$ µg/L**
Alimentary tract and metabolism	**Mesalazin**	12.2
	Ranitidin	5277
Blood and blood forming organs	**Dipyridamole**	-
Cardiovascular system	**Sotalol**	4095
	Metoprolol	589
	Losartan	-
	Atorvastatin	11
Antibacterial drugs	**Tetracycline**	8.8
	Ciprofloxacin	26
Musculo-skeletal system	**Carisoprodol**	24368
Nervous system	**Gabapentin**	20460
	Levetiracetam	-
	Chlorprothixene	-
Respiratory organs	**Fexofenadine**	-

$^*PNEC_{soil/plant}$ is calculated form $PNEC_{water}$ using the equation:
$PNEC_{terrestrisk}$=Kd* $PNEC_{aquatic}$. Kd is given in Table 71.

6.2.3. Humans

6.2.3.1. Acceptable Daily Intake (ADI)

For VMP the approach used by the Committee of Veterinary Medicinal Products (CVMP) for the evaluation of the safety of residues in food for human consumption is based on the determination of Acceptable Daily Intake (ADI) for the drug substance. However, as only a limited number of drug substances are used both in food producing animals and in humans, ADI are established for a few of the HMPs.

The ADI values identified for HMPs are applied in the present risk assessment to evaluate residues of HMPs in soil mixtures (intake by children) and food following uptake in plants.

6.2.3.1. Threshold of Toxicological Concern (TTC)

The threshold of toxicological concern (TTC) is a pragmatic risk assessment tool that is based on the principle of establishing a human exposure threshold value for chemicals, below which there is a very low probability of an appreciable risk to human health. It proposes that, in the absence of a full toxicity database, a minimum value of exposure can be identified for many chemicals based on their chemical structure and the known toxicity of chemicals with similar structural characteristics.

The application of the TTC principle in safety evaluations of chemical contaminants in food has recently been reviewed and evaluated by the VKM (VKM, 2006). The concept of generic thresholds by analysing toxic effects of chemicals, according to their chemical structure was developed by Munro et al. in 1996, however, genotoxic and non-genotoxic carcinogenic substances were not included in this analysis. Based on a “decision tree” approach developed by Cramer *et al.* in 1978, a total of 613 chemicals were classified into one of three structural classes, I, II and III, reflecting a presumed low, moderate and serious toxicity (Box 1). The toxicological reference database used for the classification contained 137, 28 and 448 chemicals in class I, II and III, respectively.

Box 1. Cramer's structural classes (Cramer et al, 1978)

- Class I: substances with simple chemical structures, for which efficient modes of metabolism exist or other data suggests a low degree of oral toxicity, i.e. substances normally present in the body.
- Class II: intermediate substances; they have structures that are less clearly innocuous compared with substances in class I, but do not have structures indicative of toxicity, or of a clear lack of knowledge of their characteristics, as substances in class III. Most of these substances have functional groups that are similar to, but somewhat more reactive than functional groups in class I, or they have more complex structures than substances in Class I, but they are common components of food.
- Class III: substances with structures that do not indicate strongly that they are innocuous, or that have indications of significant toxicity, or have reactive functional groups.

The TTC values established for the various group of substances as summarized by Barlow (2005) and VKM (VKM, 2006) are shown in Table 70.

Table 70. Human exposure threshold of toxicological concern (TTC) values currently used or suggested to be used for chemicals (Barlow, 2005; VKM, 2006).

Type of chemical	µg/60 kg person/day	µg/kg body weight/day
Genotoxic compounds	0.15[a]	0.0025
Non-genotoxic carcinogenic compounds	1.5[b]	0.025
Organophosphates	18[c]	0.3
Cramer class III	90[d]	1.5
Cramer class II	540[e]	9
Cramer class I	1800[f]	30

[a] TTC value not used at present, but suggested for genotoxic compounds by the ILSI Europe Expert Group.
[b] TTC value used in regulation of food contact materials in U.S.A. (ToR), and in risk assessment of flavouring substances by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
[c] TTC value not used at present, but suggested for organophosphates by the ILSI Europe Expert Group.
[d,e,f] TTC values used by the Scientific Committee on Food (SCF)/the European Food Safety Authority (EFSA)/the EU Flavour Information System (FLAVIS) Working Group, and JECFA, for risk assessment of chemically defined flavouring substances, and for natural flavour complexes (NFCs) by the Expert Panel of FEMA (the Flavor and Extract Manufacturers Association of the United States) in U.S.A.

In the present risk assessment, we selected the TTC value set for genotoxic compounds for all the anticancer drugs, as they may be potential genotoxic. For all the other HMPs for which no ADI are established and for which there are no indications of being genotoxic, the TTC value for Cramer III chemicals (1.5 µg/kg body weight/day), reflecting a presumed serious toxicity, was selected as reference limit to assess exposure in humans. This is a conservative approach that is assumed to give a high level of protection.

6.3. Predicted soil concentrations of medicines after sewage sludge applications

The methodologies used in the calculation of soil concentrations of drug substance are similar to the methodology used for heavy metals and organic contaminants described in chapter 5.2. The starting concentrations in sludge have not been analysed but have been estimated by modelling as described in 6.1. The common parameters used in the calculations are given in

Table 16, while specific chemical and physical data for the various drug substances are given in Table 71.

Table 71. Predicted concentration of drug substance in sewage sludge (PEC$_{sludge}$), and chemical and physical constants used in the model calculations of soil and plant concentrations.

Drug groups	Drug substance	PEC$_{sludge}$	Vd	Koc soil	Kd soil	logKoc	DT$_{50}$ soil	LogK$_{ow}$*
		mg/kg	l/kg	l/kg	l/kg		Days	
Alimentary tract and metabolism	Mesalazin	39.3	-	1	0.02	1	360	0.98[1]
	Ranitidin	1.76	1.7	1582	31.6	4.44	360	0.27[2]
Blood and blood forming organs	Dipyridamole	1.01	1.4	1349	27.0	4.07	360	2.74[1]
Cardiovascular system	Sotalol	0.87	2.4	2100	42.0	1.58	180	0.24[2]
	Metoprolol	0.75	4.9	3773	75.5	1.79	20	1.88[2]
	Losartan	1.35	0.69	755	15.1	5.96	90	4.0[1]
	Atorvastatin	2.01	5.4	4086	81.7	4.31	180	6.36[1]
Antibacterial drugs	Tetracycline	0.46	1.5	1427	28.5	1.76	180	-1.3[2]
	Ciprofloxacin	1.70	3	2522	50.4	1.55	360	0.28[2]
Musculo-skeletal system	Carisoprodol	3.98	0.7	764	15.3	2.86	360	2.36[1]
Nervous system	Gabapentin	2.30	0.89	930	18.6	1.77	360	-1.1[2]
	Levetiracetam	0.72	0.7	764	15.3	-	360	-0.49[1]
	Chlorprothixene	0.96	15.5	9711	194.2	5.65	360	5.18[2]
Respiratory organs	Fexofenadine	0.99	5.8	4333	86.7	4.89	360	2.81[1]

* Data from ChemIdPlus (http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp); [1]Calculated using the programme Kowwin 1.67 (EpiSuite); [2]experimental data.

The volume of distribution (V$_D$) for the different drug substances were used to calculate Koc (using equation 4) and to calculate K$_d$ values using the general relationship Kd= f$_{oc}$ * Koc (with soil f$_{oc}$=0.02).

The soils half-lives (DT$_{50}$ soil) were estimated using information from Table 63 and from (Daughton & Ternes, 1999). For drug substances that have been shown to be persistent in sewage sludge (ciprofloxacin, chlorprothixiene, fexofenadine), a DT$_{50}$ soil of 360 days were used. If degradations had been tested according to the OECD 301 test (or similar test) a DT$_{50}$ soil of 180 days were used. Because losartan is shown to be photosensitive (Table 63) a DT$_{50}$ soil of 90 days was used. According to Daughton & Ternes (1999) a removal efficiency of 83% has been measured for metoprolol and a DT$_{50}$ soil of 20 days was used in the calculations. For the other drug substances no information about stability and degradation exists and since it cannot be excluded that they are persistent, a DT$_{50}$ soil of 360 days were used in the calculations (conservative estimate).

The Kow-values used in the calculations of BCFs for plant uptake are predicted using the program Kowwin 1.67 (EpiSuite) or experimental values found in the database ChemidPlus (Table 71).

6.3.1.1. Input of drug substances to soils

The concentrations of drug substances in sewage sludge used in the model were calculated using the tiered approach described in Chapter 6.1. It lack of data on background concentrations of drug substances in the soil, the background concentrations were set equal to zero (as for the organic contaminants).

6.3.1.2. Removal of drug substances from soil

Leaching, biodegradation and plant uptake are assumed to be the most important processes in the removal of drug substances from the soils.

Leaching (k_{Leach}) is calculated according to equation 7A (part A), biodegradation is calculated using equation 10A (part A), while the removal rate of drug substances through plant uptake is calculated according to equation 9A (part A).

The mean concentration of drug substances in soils over a certain time period after the first application of sewage sludge was calculated using equation 13A (e.g. the average soil concentration in the 90 day period after sludge application). To calculate the initial soil concentration after a certain number of sewage sludge applications (e.g after 10 or 100 years), equation 14A (part A) was used.

6.3.1.3. Soil concentrations of drug substances

The calculated soil concentrations of drug substances are shown in Table 72. The mean soil concentrations of most drug substances are in the range 5-50 µg/kg DW in the 90 day period after sludge application, with the exception of metformin which has a calculated mean soil concentration of nearly 600 µg/kg and carisoprodol which has a concentration of 77 µg/kg. For ranitidin, ciprofloxacin, carisoprodol, gabapentin, levetiracetam, chlorprothixene and fexofenadine, which half-lives (DT_{50} soil) are set to 360 days, the soil concentrations after 100 years are slightly higher because of accumulation in the soil.

Table 72. Predicted soil concentrations (mg/kg DW) of 14 drug substances in agricultural soils, park areas and soil mixtures. Mean soil values in the period of 0, 90 days and 100 years are shown for agricultural soils, while the period is 0 and 90 days for park areas and soil mixture.

Drug substance	Time after application	Sewage sludge	Agricultural soil		Park areas	Soil mixture
		Predicted value	40 tons	60 tons	5 cm sewage sludge, 10cm soil	30% sewage sludge (w/w)
Mesalazin	0 day	39.3	0.654	0.9817	6.69	5.95
	90 days		0.354	0.5315	3.26	2.90
	100 years		0.654	0.9817	-	-
Ranitidine	0 day	1.76	0.029	0.0440	0.30	0.27
	90 days		0.023	0.0341	0.02	0.02
	100 years		0.030	0.0449	-	-
Dipyridamole	0 day	1.01	0.017	0.0252	0.17	0.15
	90 days		0.013	0.0195	0.13	0.12
	100 years		0.017	0.0258	-	-
Sotalol	0 day	0.87	0.014	0.0216	0.15	0.13
	90 days		0.010	0.0156	0.04	0.09
	100 years		0.014	0.0216	-	-
Metoprolol	0 day	0.75	0.013	0.0188	0.13	0.11
	90 days		0.004	0.0056	0.04	0.03
	100 years		0.013	0.0188	-	-
Losartan	0 day	1.35	0.023	0.0338	0.23	0.20
	90 days		0.014	0.0213	0.15	0.13
	100 years		0.023	0.0338	-	-
Atorvastatin	0 day	2.01	0.034	0.0503	0.34	0.31
	90 days		0.024	0.0359	0.25	0.22
			0.034	0.0503	-	-
Tetracycline	0 day	0.89	0.008	0.0114	0.08	0.07
	90 days		0.005	0.0079	0.05	0.05
	100 years		0.008	0.0114	-	-
Ciprofloxacin	0 day	1.70	0.028	0.0426	0.29	0.26
	90 days		0.022	0.0329	0.22	0.20
	100 years		0.029	0.0434	-	-
Carisoprodol	0 day	3.98	0.066	0.0996	0.68	0.60
	90 days		0.051	0.0770	0.52	0.47
	100 years		0.068	0.1016	-	-
Gabapentin	0 day	2.30	0.038	0.0576	0.39	0.35
	90 days		0.029	0.0433	0.29	0.26
	100 years		0.038	0.0577	-	-
Levetiracetam	0 day	0.72	0.012	0.0180	0.12	0.11
	90 days		0.009	0.0139	0.09	0.08
	100 years		0.012	0.0184	-	-
Chlorprothixene	0 day	0.96	0.016	0.0241	0.16	0.15
	90 days		0.012	0.0187	0.13	0.11
	100 years		0.016	0.0247	-	-
Fexofenadine	0 day	0.99	0.016	0.0247	0.17	0.15
	90 days		0.013	0.0192	0.13	0.12
	100 years		0.017	0.0254	-	-

6.4. Predicted concentrations of drug substances in plants after sewage sludge application

The models for uptake of contaminants in plants are not developed for polar or ionisable compounds. Most drug substances have functional groups and are ionised at a certain pH. An improved model for plant uptake has been published, but VKM has not access to the needed input parameters or the expertise to be able to take these models in use. Uptake of drug substances into plants was therefore not estimated in this risk assessment.

6.5. Predicted concentrations of drug substances in surface- and groundwater after sewage sludge application

The calculation of the concentrations of the drug substances in groundwater and surface water was performed using the same models as used for heavy metals and organic contaminants (described in Chapter 5.4).

For all the included drug substances except from levetiracetam, the surface runoff is more important for transport of the drug substances to water recipients than drainage through soil (Table 73). PEC surface water is calculated assuming that the drainage water and surface runoff are diluted by a factor of 10.

Table 73. Calculated concentrations of drug substances in drainage water (groundwater), runoff, and PEC surface water (assuming that the drainage water and surface runoff are diluted by a factor of 10).

Drug substance	Drainage	Run-off	Sum	PEC surface water
	µg/L	µg/L	µg/L	µg/L
Mesalazin	39	$2x10^{-09}$	39	3.9
Ranitidin	0.11	0.49	0.60	0.06
Dipyridamole	0.12	17	17	1.7
Sotalol	0.0041	3.4	3.4	0.34
Metoprolol	$1x10^{-12}$	0.0005	0.0005	0.00005
Losartan	0.03	0.16	0.20	0.02
Atorvastatin	0.0001	0.21	0.21	0.021
Tetracycline	0.02	0.18	0.20	0.02
Ciprofloxacin	0.02	0.36	0.37	0.04
Carisoprodol	1.1	1.3	2.5	0.24
Gabapentin	0.53	0.75	1.3	0.13
Levetiracetam	0.35	0.23	0.59	0.06
Chlorprothixene	$3.8x10^{-08}$	4.5	4.5	0.45
Fexofenadine	0.0003	6.3	6.3	0.63

6.6. Exposure assessment – production animals

The exposure of food production animals to drug substances following the use of sewage sludge as soil conditioner could not be estimated due to the lack of information on concentrations in plants.

6.7. Exposure assessment - humans

6.7.1.1. Children eating soil added sewage sludge

For the 14 identified drug substances through the tired approach, environmental cut-off concentrations have been used (tiered approach), based on the assumption that levels of drug substances below 100 µg DW/soil would not be of ecotoxicological concern. This cut-off concentration is, however, not appropriate to evaluate risk for humans.

Soil mixture is added 30% w/w sewage sludge. Children eating such soil mixture could be exposed to drug substances present in the sludge, and a daily consumption of 0.2 g soil has been used in the calculations (see Chapter 4.3.1.).

To identify drug substances of possible concerns for children eating soil ADI or TTC values where used as cut-off concentrations instead of the environmental cut-off concentrations used in the tiered approach described in Chapter 6.1.6. For most drug substances, the TTC value for Cramer III chemicals where used (1.5 µg/b.w./day), while the TTC value set for genotoxic compounds (1.5 µg/b.w./day) where used for all the anticancer drugs (see Chapter 6.2.3.).

The intake of a drug substance of children should therefore not exceed 15 µg/day (most drug substances) or 0.025 µg/day (anticancer drug), assuming a body weight of 10 kg for children eating soil.

To calculate estimated PEC in soil mixture, the tiered approach described in Chapter 6.1. was used. The refined PEC in Tier 3 (PEC$_{\text{soil (Tier 3)}}$) was regarded as the likely concentration of a given drug substance in soil mixture after use of sewage sludge. To facilitate the comparisons with cut-off concentrations for human exposure, the concentrations of each drug substance was estimated in 0.2 g soil.

Table 74. Estimated PEC in Tier 1, 2 and 3 of drug substances in 0.2 g soil mixture following application of 30 % w/w sewage sludge in soil mixtures. Concentrations are given in µg in 0.2 g soil**.**

Drug groups	**Drug substance**	**Tier 1 PEC$_{\text{soil (max)}}$ µg in 0.2 g soil**	**Tier 2 PEC$_{\text{soil (Tier 2)}}$ µg in 0.2 g soil**	**Tier 3 PEC$_{\text{soil (Tier 3)}}$ µg in 0.2 g soil**
Antineoplastic agents	Capecitabine	**0.03**	0.001	0.0001
	Hydroxycarbamide	**0.04**	0.003	0.001
Anti-androgens	Bicalutamide	**0.03**	**0.03**	0.0006
Immunosupressive agents	Ciclosporin	**0.05**	0.01	0
	Azathioprine	**0.03**	0.006	0.006
	Mycophenolic acid	**0.22**	**0.07**	0.0007

When calculating maximum concentration in 0.2 g soil mixture (PEC$_{soil\ (max)}$) for all drug substance (n=595) identified in Tier 0, six substances, all anticancer drugs, obtained an estimated maximum concentration in 0.2 g soil mixture above 0.025 µg in Tier 1 (Table 74). Following the 1st refinement of PEC$_{soil\ (Tier\ 2)}$ in Tier 2, two of these substances would obtain an estimated concentration in 0.2 g soil above 0.025 µg. Following the 2nd refinement of PEC$_{soil\ (Tier\ 3)}$ in Tier 3, none of the drug substances would exceed the cut-off concentration of 0.025 µg/0.2 g soil mixture.

6.7.1.2. Humans eating food produced on sludge amended soil

The exposure of humans to drug substances in food following the use of sewage sludge as soil conditioner could not be estimated due to the lack of information on concentrations in plants and in food producing animals (see Chapter 6.4.).

6.8. Risk characterisation

6.8.1. Risk characterization for soil organisms and plants

In Table 75 PECs, PNECs and RQs for drug substances in soil are shown. All RQs are well below 1.

Table 75. PEC, PNEC and risk quotients (RQ =PEC/PNEC) for drug substances in soil.

Drug substance	**PEC Agricultural Soil (60 ton)**	**PEC Park areas**	**PEC Soil mixture**	**PNEC**	**RQ Agricultural soil (60 ton)**	**RQ Park areas**	**RQ Soil mixture**
	Mg/kg DW	**mg/kg DW**	**mg/kg DW**	**mg/kg DW**			
Mesalazin	0.98	6.7	6.0	12	0.08	0.56	0.5
Ranitidin	0.04	0.30	0.27	5277	$0.5 x 10^{-5}$	$3.6 \text{ x} 10^{-5}$	$3.2 \text{ x} 10^{-5}$
Dipyridamole	0.03	0.17	0.15	-	-	-	-
Sotalol	0.02	0.15	0.13	4095	$0.5 x 10^{-5}$	$3.6 \text{ x} 10^{-5}$	$3.2 \text{ x} 10^{-5}$
Metoprolol	0.02	0.13	0.11	589	$0.3 x 10^{-4}$	$2.2 x 10^{-4}$	$1.9 x 10^{-4}$
Losartan	0.03	0.23	0.2	-	-	-	-
Atorvastatin	0.05	0.34	0.31	11	0.005	0.03	0.02
Tetracycline	0.01	0.08	0.07	8.8	0.001	0.009	0.008
Ciprofloxacin	0.04	0.29	0.26	26	0.02	0.01	0.01
Carisoprodol	0.10	0.68	0.6	24368	$0.4 x 10^{-5}$	$2.7 x 10^{-5}$	$2.5 x 10^{-5}$
Gabapentin	0.06	0.39	0.35	20460	$0.3 x 10^{-5}$	$1.9 x 10^{-5}$	$1.8 x 10^{-5}$
Levetiracetam	0.02	0.12	0.11	-	-	-	-
Chlorprothixene	0.02	0.16	0.15	-	-	-	-
Fexofenadine	0.03	0.17	0.15	-	-	-	-

6.8.2. Risk characterization for aquatic organisms

In Table 76 PECs, PNECs and RQs for drug substances in surface water are shown. All RQs are well belove 1.

Table 76. PEC, PNEC and RQ for the various drug substances for aquatic organisms in surface water as a result of application of sewage sludge in soil.

Drug groups	**Drug substance**	**PEC**	**PNEC**	**RQ**
Alimentary tract and metabolism	Mesalazin	3.9	6078	0.0006
	Ranitidin	0.06	167	0.0004
Blood and blood forming organs	Dipyridamole	1.7	-	-
Cardiovascular system	Sotalol	0.34	97.7	0.0003
	Metoprolol	0.00005	58.3	$8.6 \text{ x} 10^{-6}$
	Losartan	0.02	143	0.0001
	Atorvastatin	0.021	0.13	0.16
Antibacterial drugs	Tetracycline	0.02	0.31	0.06
	Ciprofloxacin	0.04	0.52	0.08
Musculo-skeletal system	Carisoprodol	0.24	-	-
Nervous system	Gabapentin	0.13	1100	0.0001
	Levetiracetam	0.06	-	-
	Chlorprothixene	0.45	-	-
Respiratory organs	Fexofenadine	0.63	-	-

6.8.3. Risk characterization humans

The estimated concentrations for all drug substances in soil mixture after use of sewage sludge as soil conditioner is lower than the food safety reference values (TTC, ADI). VKM Panel 5 considers it unlikely that consumption of soil mixture added sewage sludge will pose any risk to the children’s health.

6.9. Antibacterial drug residues in sewage treatment plant water, sludge and soil: Development of antibacterial resistance

6.9.1. Introduction

The most important location for the development antibacterial resistance is probably in the gut of humans or animals receiving antibacterial drug therapy. Resistant bacteria and resistance genes that have developed due to presence of antibacterial drugs in the gut will be excreted together with the faeces. When that faeces becomes part the waste water sludge, resistant bacteria and resistance genes may reach arable land if the sludge is used as soil conditioner. Such resistance may be further spread, either vertically or by horizontal spread of genetic elements to other bacteria (see bacteria (I) in Figure 15).

A second way, but probably less important as described above, is the resistant development due to a selection pressure of dissolved antibacterial drug residues in sewage water, typically in the µg/l concentration level (see bacteria (II) in Figure 15). Those residues may exert a selection pressure to bacteria that favours resistance development in the sewage treatment plant (STP) (resistant bacteria III and IV in Figure 15). Again the sludge may, as above, contain genetic elements that can at a later stage be transferred to other bacteria (resistant bacteria V and VI in Figure 15).

Finally, a third way that may impose a selection pressure can happen in the soil compartment itself due to antibacterial drug residue molecules (typically in the low µg/kg soil DW). They are transported with sludge to the topsoil and desorbs from the waste to the soil compartment. Theoretically, they can exert a selection pressure to existing soil bacteria which may develop resistance (resistant bacteria V and VI in Figure 15). These genetic elements may again be transferred to other soil bacteria. Probably this is the less important way of inducing resistant elements into the soil compartment.

In the present risk assessment, we have assessed the risk of increase of the occurrence of antibacterial-resistant bacteria and resistance genes in soil following application of sludge as fertilizer by evaluating the likeliness of development of resistance by the antibacterial drug residues contained in the STP water, in the dry sludge and in soil.

Various sludge treatment methods that are applied prior to the use of sludge in agriculture are intended to remove pathogenic microorganisms and may also reduce the presence of pharmacologically active substances. Although treatment of sludge may decrease, but not eliminate, the problem, inadequate sludge treatment cannot be excluded as a contributor to the spread of resistant bacteria to the environment. It should be noted that naturally occurring antibacterial drugs (antibiotics) often degrade more readily in the environment than synthetic antibacterial drugs (Jorgensen & Halling-Sorensen 2000).

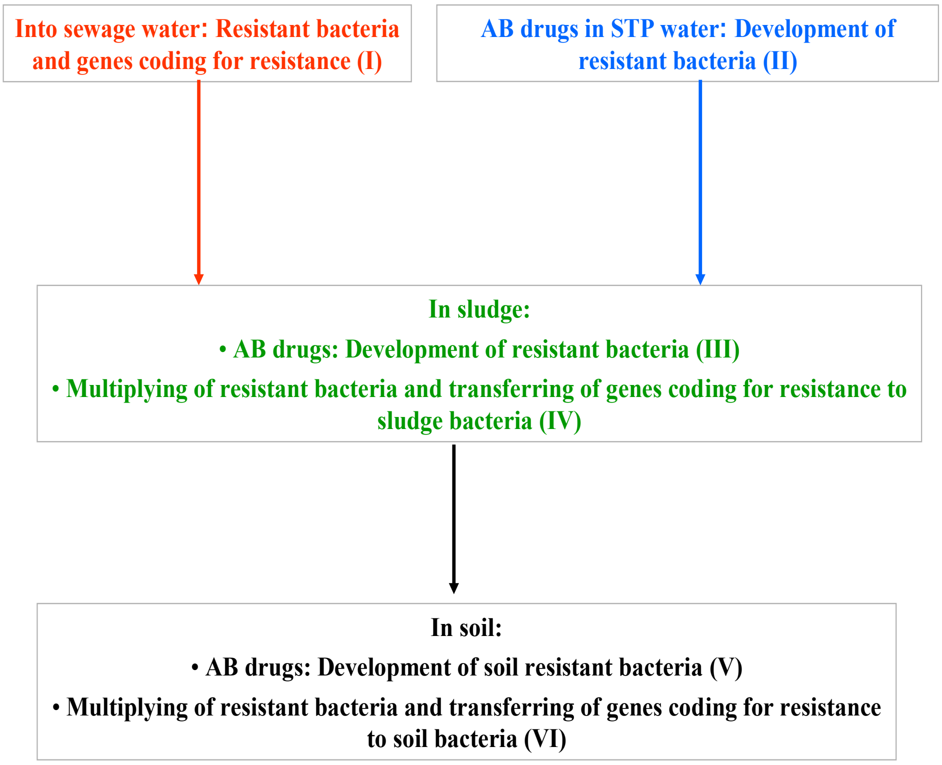


Figure 15. Schematic description of the various pathways for development and spread of antibacterial (AB) drug resistance in sewage treatment plant (STP) water, sludge and in soil bacteria following application of sludge as soil conditioner.

As above introduced, the presence of antibacterial drug residues in the STP-water and in sludge may exert selection pressures in these segments and thus contributes to the development and dissemination of antibacterial resistance. These resistant bacteria and resistance genes may be transferred to soil following application of sludge as fertilizer and transferable resistance genes are likely be transferred to soil bacteria as the resistance genes frequently neither respect phylogenetic nor ecological borders. Soil bacteria can then act as a reservoir of resistance genes from which the genes can be further disseminated and ultimately end up in human pathogens (Figure 15). Application of sewage sludge containing antibacterial drug residues may also contribute to a reservoir of resistant bacteria in soil. Many bacteria that have their ecological niches in soil and water are from nature themselves well equipped with resistance mechanisms.

Data on the occurrence of antibacterial resistance in sewage sludge from Norwegian sewage treatment plants or in soil following use of sewage sludge as fertilizer are not available. But even if such data were available, the assessment of the impact to human health from occurrence data, e.g. in soil, is not possible as models to perform such an assessment are actually non-existing.

6.9.2. Hazard identification and characterisation

It is generally acknowledged that antibacterial resistance is an emerging human health problem as this inevitably will lead to increased number of suboptimal treatments and treatment failures of bacterial diseases. The emergence and spread of antibacterial resistance are complex possesses. They are driven by numerous interconnected factors and selective pressure from exposure to antibacterial drugs resulting in emergence of resistant bacteria that subsequently will be predominating within the population is considered the most important factor.

Several different mechanisms are involved in the development of resistance to antibacterial drugs. Exposure to antibacterial drugs may cause intrinsic processes or mutations in bacterial DNA (e.g. chromosome, plasmid) resulting in reduced susceptibility or resistance to one or more antibacterial drugs (Lipsitch & Samore 2002). Furthermore, acquisition of resistance by bacteria through uptake of new genetic elements through horizontal gene transfer coding for resistance is another mechanism (Lipsitch & Samore 2002; Yazdankhah *et al.,* 2006). Resistance genes may be acquired by uptake of pieces of DNA originating from the chromosome of other bacteria or by acquiring mobile genetic elements such as plasmids or transposons (Davies 1994). This increases the occurrence of resistance genes associated with transferable genetic elements, and may entail further dissemination of resistance genes to other bacterial species (Lipsitch & Samore 2002).

Various studies have reported the presence of multiresistant bacteria both in untreated and treated sludge (Boczek *et al.,* 2007; Ferreira *et al.,* 2006; Ferreira *et al.,* 2007; Prado *et al.,* 2008; Schluter *et al.,* 2007). Although treatment of sludge reduces the number of bacteria, including the resistant ones, it will not entirely eliminate all such bacteria. If inadequately treated sludge is used as fertilizer, agricultural products used as food or animal feed may be contaminated (Ensink *et al.,* 2007; Heaton & Jones 2008; Keraita *et al.,* 2008), and such phenomena have been the sources of several outbreaks of enteropathogenic infections (Heaton & Jones 2008). Proved spread of enteropathogenic pathogens may be regarded as indications on spread of other enterobacteria (Høiby *et al.*, 1995) and these may carry resistance genes.

Bacterial DNA that contain resistance genes can be released to soil from microorganisms after treatment of sludge. Bacterial DNA may persist in soils for weeks and months (Picard *et al.,* 1992; Recorbet *et al.,* 1993; Romanowski *et al.,* 1991) but the biological activity of DNA released into natural soils has been demonstrated for bacterial DNA for limited periods of time (Nielsen *et al.,* 1997b). The stability of DNA in soils is dependent upon several factors like soil type, its composition and pore sizes, temperature, soil moisture, aeration, concentration of in/organic nutrients and salts, pH, bacterial activity and density, extracellular enzymatic activity, and soil interaction with meso-macrofauna and flora (Nilsen, 1997c). Mostly in laboratory models the transformation of bacterial DNA to environmental bacteria have been demonstrated in several studies and often due to an induction of antibacterial drugs in concentration at much higher level (mg/kg DW soil) than found in natural soil environment (Nielsen *et al.,* 1997a; Nielsen *et al.,* 2000; Nielsen *et al.,* 1997b; Smalla *et al.,* 2000). Transformation to soil bacteria of antibacterial resistance genes from manure used as fertilization has also been confirmed (Binh *et al.,* 2008; Heuer & Smalla 2007), and again this has been demonstrated only at the mg/kg DW manure of an antibacterial drug. The frequency of such transformation is depending on several factors like the number of bacterial species capable of transferring genes, factors that regulate their host range, the nature and availability of transferred DNA, the transfer efficiencies, and the selective pressure acting on the bacterial transformation (Nilsen, 1997c).

6.9.2.1. Field conditions

Sengeløv *et al.* (2003) reported that resistance to tetracycline, macrolides and streptomycin was measured for a period of 8 months in soil bacteria obtained from farmland treated with pig manure slurry. The control soil was not amended with animal manure. The occurrence of tetracycline-resistant bacteria was elevated after spread of pig manure slurry but declined throughout the sampling period to a level corresponding to the control soil. Higher load of pig manure slurry yielded higher occurrence of tetracycline resistance after spreading; however, the tetracycline resistance declined to normal occurrence defined by the tetracycline resistance occurrence in the control soil. Results obtained indicate that tetracycline resistance levels in soil are temporarily influenced by the addition of pig manure slurry and that increased amount may result in increased levels of resistance for a shorter time.

In a second field study in southern consistently reported that the level of aerobic antibiotic-resistant bacteria in the soil over time and soil fauna community was assessed in relation to application of manure containing antibacterial drugs to the agricultural fields (Halling-Sørensen *et al.*, 2005. The level of both CTC- and TYL-resistant bacteria was affected in the soil by amendment of manure, but declined during the study to the same level as observed at the beginning.

The informations of spreading of genetic material from biosolids to soil under field conditions are still very limited. Demoling & Baath (2008) reported that no long-term persistence of bacterial pollution-induced community tolerance was observed in tylosin-polluted soil.

6.9.2.2. Use of minimum inhibitory concentration (MIC)

The susceptibility of a bacterial strain to an antibacterial drug is expressed as its minimum inhibitory concentration (MIC) towards that drug. MIC is defining the lowest concentration of a given antibacterial drugs that inhibits growth of a bacterium under standard laboratory conditions. For clinically-resistant bacterial strains (Smaill, 2000) the MIC values are usually between 0.25–16 µg/ml (mg/L). In susceptible bacteria, the MIC values usually range between 1 ng/ml (µg/L) and the breakpoint (Andrews, 2001). A similar range of susceptibility has been suggested for non-pathogenic bacteria (Halling-Sorensen, 2000; Lutzhoft *et al.,* 1999). Bacteriological breakpoints provide information regarding the *in vitro* susceptibility of bacteria to antibacterial drugs.

Kümmerer and Henninger (2003) suggest that concentrations of antibacterial drugs in sewage water with 10% effects (MIC_{10}) on bacteria could be used as PNEC with respect to promotion of resistance. Since there are no published data on 10% effect concentration for bacteria (e.g. MIC_{10}), Kümmerer and Henninger suggest using MIC_{50} and dividing this value with 10. To describe the risk of promotion of resistance the PEC of the various antibacterial drugs in sewage water, the authors compared this value with the corresponding PNEC value and the authors applied PEC/PNEC- values of >1 and > 10 as risk levels, 10 being the highest level. But in contrast to toxicological effects, antibacterial resistance may be favoured by sub-inhibitory concentrations of antibacterial drugs, i.e. by concentrations lower than the MIC value for the species in question. Whilst very low concentrations of antibacterial drugs may induce already existing resistance mechanisms in bacteria, higher concentrations are needed to exert a selection pressure that gives the antibacterial-resistant strains a selective advantage (Courvalin, 2008). Furthermore it is not likely that resistance is promoted at concentrations of antibacterial drugs substantially lower than the MIC value. Consequently, the method used by Kümmerer and Henninger (2003) to characterize the risk of promotion of resistance is not applicable, i.e. PEC/PNEC >10 is not likely to exert any selection pressure.

In the present risk assessment VKM Panel 5 has chosen to use the wild type MIC value for each antibacterial drug for two common enterobacteria (see Table 77) as reference values for resistance development. The wild type MIC values are taken form the European Committee of Antimicrobial Susceptibility Testing (EUCAST). The wild type MIC values were chosen because these are considerably lower than the clinical breakpoint MIC values and are therefore more conservative.

Little information is available regarding synergic interactions between antibacterial drugs present in sludge. Such possible synergic effects may theoretically promote mutation in bacteria and thus act as selection pressures.

Table 77. Wild type MIC values (range, **µg/L**) for the antibacterial drugs for two common enterobacteria, *E.coli* and *E.facium*.

Group of substances	**Drug substance**	**MIC values µg/L *E. coli***	**MIC values µg/L *E. facium***
Tetracyclines	Tetracycline[1]	1000-8000	250-2000
	Doxycycline	250-4000	125–500
	Oxytetracycline	-	-
Amphenicols	Chloramphenicol	2000-16000	2000-32000
Penicillins with extended spectrum	Amoxicillin	1000-8000	125-8000
	Ampicillin[2]	1000-8000	250-4000
	Mecillinam[3]	64-1000	-
	Piperacillin	500-8000	1000-16000
Beta-lactamase sensitive penicillins	Phenoxymethylpenicillin	-	-
	Benzylpenicillin	-	125-16000
Beta-lactamase resistant penicillins	Dicloxacillin	-	-
	Cloxacillin	-	-
Cephalosporins (1st generation)	Cefalexin	-	-
	Cefalotin	-	-
(2nd generation)	Cefuroxime	500-8000	-
(3rd generation)	Cefotaxime	16-250	-
	Ceftazidime	32-500	-
	Ceftriaxone	8-125	-
Monobactams	Aztreonam	32-125	-
Carbapenems	Meropenem	8-125	64-8000
Sulfonamides	Sulfamethoxazole	8-125	64-8000
Trimethoprimes and derivatives	Trimethoprim	125-2000	-
Macrolides	Erythromycin	-	125-4000
	Clarithromycin	-	64-4000
	Azithromycin	-	-
	Spiramycin	-	-
Lincosamides	Clindamycin	-	-
Aminoglycosides	Tobramycin	250-2000	2000-32000
	Gentamicin	125-2000	2000-32000
Fluoroquinolones	Ciprofloxacin	4-32	250-4000
	Ofloxacin	32-250	500-64,000
Glycopeptide antibacterials	Vancomycin	-	250-4000
Nitrofuran derivatives	Nitrofurantoin	4000-64000	16000-256000
Steroidantibacterials	Fusidic acid	-	-
Other antibacterials	Linezolid	-	500-4000
Antimycotic antibacterials	Amphotericin B	-	-
Antituberculostatic antibacterials	Rifampicin	-	-

[1] Includes lymecycline, a prodrug to tetracycline; [2] Includes pivampicllin, a prodrug to ampicilllin; [3] Includes pivmecillinam, a prodrug to mecillinam

- ; This species is a poor target for therapy with that antibacterial drug (and thus resistance is unlikely to develop) or data not public available

6.9.3. Exposure assessment of antibacterial drugs to bacteria in STP-water, sludge and soil

The exposure of bacteria in the STP water ($PEC_{STP\text{-}water}$), in the dry sludge (PEC_{sludge}) and in the soil (PEC_{soil}) to the various antibacterial drugs was calculated as follows:

$$PEC_{STP\text{-}water}\ (\mu g/l) = M_{act} - M_{metab} / (V_W) \qquad \textbf{Eq. 9B}$$

Where:
M_{act} = the annual usage, in weight of active substance, of the antibacterial drugs in question in the included geographical area
V_w = the total annual wastewater volume that enters the STPs in the included geographical area (see chapter 6.1.3.3)
M_{metab} = the amount of the antibacterial drugs in question metabolised in the human body

In the calculation of $PEC_{STP\text{-}water}$ sorption of the antibacterial drugs to sludge was not taken into consideration as it was assumed that this occurred gradually in the treatment phase in the STPs; the $PEC_{STP\text{-}water}$ values calculated are thus considered to be conservative.

PEC_{sludge} (µg/kg) for the various antibacterial drugs was calculated by use of the tiered approach described in 6.1.3 and PEC_{soil} (µg/kg) for the various antibacterial drugs were calculated for the various application scenarios on the basis of the estimated PEC_{sludge} values for the different antibacterial drugs.

The estimated $PEC_{STP\text{-}water}$ values (Table 78) were approximately in the same size as those estimated by Kümmerer and Henninger (2003) in German STP influent water; the differences seen may be explained by differences in prescribing patterns of antibacterial drugs.

It should be noted that for the PEC values given in Table 78, biodegradation of the antibacterial drugs in the STP water, sludge or soil has not been taken into consideration. Thus the PEC values for antibacterial drugs for STP water, sludge and soil for this part of the risk assessment may be regarded as conservative.

Table 78. PEC for antibacterial drugs in STP water (amount metabolised in human body excluded) and in sewage sludge, in soil and in park areas.

Drug substance	PEC STP water µg/L	PEC Sewage sludge µg/kg	PEC Agriculture (40 tons/ha) µg/kg soil	PEC Agriculture (60 tons/ha) µg/kg soil	PEC Park areas (30% w/w) µg/kg soil
Tetracycline[1]	2	885	15	22	134
Doxycycline	1	155	3	4	23
Oxytetracycline	0.4	116	2	3	18
Chloramphenicol	0.003	1	0.02	0.03	0.2
Amoxicillin	4	544	9	14	82
Ampicillin[2]	1	285	5	7	43
Mecillinam[3]	3	693	11	17	105
Piperacillin	1	46	1	1	7
Phenoxymethylpenicillin	13	1647	27	41	250
Benzylpenicillin	3	480	8	12	73
Dicloxacillin	6	872	15	22	132
Cloxacillin	0.1	9	0.1	0.2	1
Cefalexin	2	306	5	8	46
Cefalotin	2	123	2	3	19
Cefuroxime	2	144	2	4	22
Cefotaxime	1	141	2	4	21
Ceftazidime	0.2	21	0.3	1	3
Ceftriaxone	0.1	9	0.2	0.2	1
Aztreonam	0.01	1	0.02	0.04	0.2
Meropenem	0.3	29	0.5	1	4
Sulfamethoxazole	1	64	1	2	10
Trimethoprim	1	516	9	13	78
Erythromycin	1	416	7	10	63
Clarithromycin	0.3	261	4	7	40
Azithromycin	0.1	112	2	3	17
Spiramycin	0.3	266	4	7	40
Clindamycin	0.2	26	0.4	1	4
Tobramycin	0.05	6	0.1	0.1	1
Gentamicin	0.04	7	0.1	0.2	1
Ciprofloxacin	2	1380	23	35	209
Ofloxacin	0.1	39	1	1	6
Vancomycin	0.1	21	0.4	1	3
Nitrofurantoin	0.2	42	1	1	6
Fusidic acid	0.001	0.1	0.002	0.003	0.02
Linezolid	0.02	5	0.1	0.1	1
Amphotericin B	0.02	8	0.1	0.2	1
Rifampicin	0.2	86	1	2	13

[1]Includes lymecycline, a prodrug to tetracycline; [2]Includes pivampicllin, a prodrug to ampicilllin; [3]Includes pivmecillinam, a prodrug to mecillinam

6.9.4. Risk characterisation

The risk of increasing the occurrence of antibacterial resistant bacteria and resistance genes in soil following application of sewage sludge as soil conditioner has been assessed by evaluating the likeliness of development of resistance by the antibacterial drug residues contained in the STP water, in the dry sludge and in soil.

Table 79. Comparison of PEC for antibacterial drugs in STP water (amount metabolised in human body excluded), in sewage sludge, in soil and in park areas with wild type MIC values (range, **µg/L**) for the antibacterial drugs for *E.coli* and *E.facium*.

Drug substance	**PEC STP water µg/L**	**PEC Sewage sludge µg/kg**	**PEC Agriculture (60 tons/ha) µg/kg soil**	**PEC Park areas (30% w/w) µg/kg soil**	**MIC values µg/L *E. coli***	**MIC values µg/L *E. facium***
Tetracycline[1]	2	885	22	134	1000-8000	250-2000
Doxycycline	1	155	4	23	250-4000	125–500
Oxytetracycline	0.4	116	3	18	-	-
Chloramphenicol	0.003	1	0.03	0.2	2000-16000	2000-32000
Amoxicillin	4	544	14	82	1000-8000	125-8000
Ampicillin[2]	1	285	7	43	1000-8000	250-4000
Mecillinam[3]	3	693	17	105	64-1000	-
Piperacillin	1	46	1	7	500-8000	1000-16000
Phenoxymethylpenicillin	13	1647	41	250	-	-
Benzylpenicillin	3	480	12	73	-	125-16000
Dicloxacillin	6	872	22	132	-	-
Cloxacillin	0.1	9	0.2	1	-	-
Cefalexin	2	306	8	46	-	-
Cefalotin	2	123	3	19	-	-
Cefuroxime	2	144	4	22	500-8000	-
Cefotaxime	1	141	4	21	16-250	
Ceftazidime	0.2	21	1	3	32-500	-
Ceftriaxone	0.1	9	0.2	1	8-125	-
Aztreonam	0.01	1	0.04	0.2	32-125	-
Meropenem	0.3	29	1	4	8-125	64-8000
Sulfamethoxazole	1	64	2	10	8-125	64-8000
Trimethoprim	1	516	13	78	125-2000	-
Erythromycin	1	416	10	63	-	125-4000
Clarithromycin	0.3	261	7	40	-	64-4000
Azithromycin	0.1	112	3	17	-	-
Spiramycin	0.3	266	7	40	-	-
Clindamycin	0.2	26	1	4	-	-
Tobramycin	0.05	6	0.1	1	250-2000	2000-32000
Gentamicin	0.04	7	0.2	1	125-2000	2000-32000
Ciprofloxacin	2	**1380**	**35**	**209**	**4-32**	250-4000
Ofloxacin	0.1	39	1	6	32-250	500-64,000
Vancomycin	0.1	21	1	3	-	250-4000
Nitrofurantoin	0.2	42	1	6	4000-64000	16000-256000
Fusidic acid	0.001	0.1	0.003	0.02	-	-
Linezolid	0.02	5	0.1	1	-	500-4000
Amphotericin B	0.02	8	0.2	1	-	-
Rifampicin	0.2	86	2	13	-	-

Table 79 shows that the $PEC_{STP\text{-}water}$ values for the various antibacterial drugs are several orders of magnitude lower than the corresponding lowest MIC values for *E. coli* and *E. facium.* It is therefore unlikely that antibacterial drug resistance will be promoted in the STP water.

The PEC_{sludge} values for the various antibacterial drugs are considerably lower than the corresponding highest MIC values for *E.coli* and *E. facium* (Table 79), and in many of the cases the PEC_{sludge} values were also lower than the lowest MIC values. An exception is ciprofloxacin for which the PEC_{sludge} value was found to be several order higher than the highest MIC values for *E.coli* (i.e. MIC for strains with low sensitivity). As ciprofloxacin is a persistent substance (Sukul & Spiteller, 2007) it is unlikely that it will be degraded in the sludge.

The PEC_{soil} values for the various antibacterial drugs following application of sewage sludge on agricultural land (Table 79) are substantially lower than the MIC values for *E. coli* and *E. facium.* An exception is ciprofloxacin for which the PEC_{soil} values are close to the MIC values for the bacterial strains with lowest susceptibility.

VKM Panel 5 concludes that 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 for ciprofloxacin due to the long-term persistence of such substances in soils because of its covalent binding to i.e. Ca, Mg, Al and Fe and indication of a limited mobility of fluoroquinolones into the subsoil (Golet *et al.,* 2003).

6.9.5. Comparison of usage of antibacterial drugs in human and veterinary medicine

According to the terms of reference the contribution of certain pharmaceuticals (antibacterial drugs) from the agriculture sector should be compared with the contribution from sewage sludge. In Norway, antibacterial drugs are not applied for plant protection thus the only contribution from the agriculture sector is treatment of food producing animals. Due to time constraint it was not possible to calculate PEC_{manure} and consequently PEC_{soil}, by application of a tiered approach taking into concideration metabolism of the antibacterial drug in the animal body, potential biogdradation in manure and soil etc. Therefore, we present the "gross" contribution from use in animals and humans, i.e. overall national sales of veterinary and human antibacterial drugs in Norway in 2006 (Table 80).

Table 80. Sales, in kg active substance, of veterinary and human antibacterial drugs in Norway in 2006. Sales data were obtained from the Norwegian Institute of Public Health and represent wholesalers level. Antibacterial drugs for farmed fish are not included.

Veterinary antibacterial drugs	Kg	Human antibacterial drugs	Kg
Group of substances		**Group of substances**	
Aminoglycosides	157		
Tetracyclines	278	Tetracyclines	2169
Sulfonamides, combinations[1]	197		
		Amphenicols	7
Penicillins with extended spectrum	303	Penicillins with extended spectrum	3826
Beta-lactamase sensitive penicillins	2070	Beta-lactamase sensitive penicillins	16 392
		Beta-lactamase resistant penicillins	2187
Comb. of penicillins and beta-lactamase inhibitors	290	Comb. of penicillins and beta-lactamase inhibitors	325
		Cephalosporins, 1st generation	1311
		Cephalosporins, 2nd generation	633
		Cephalosporins, 3rd generation	721
		Monobactams	5
		Carbapenems	133
		Trimethoprim and derivatives	477
Comb. of sulfonamides and trimethoprim, incl. deriv.	1652	Comb. of sulfonamides and trimethoprim, incl. deriv.	1076
Sulfonamides	20		
		Macrolides	2991
Lincosamides	19	Lincosamider	528
		Other aminoglycosides	30
Fluoroquinolones	29	Fluoroquinolones	974
Comb. of penicillins and aminoglycoside antibacterials	529		
		Glycopeptide antibacterials	27
		Polymyxins	11
		Steroid antibacterials	14
		Nitrofuran derivatives	124
Other antibacterials[2]	154	Other antibacterials[3]	13
		Antimycotic antibacterials	0,2
		Antibacterials for tuberculosis	32
Beta-lactamase antibacterials, comb with other antibacterials	749		
Total	**6449**	**Total**	**34 005**

[1] Includes aminoglycosides and beta-lactamase sensitive penicillins; [2] Includes only pleuromutilins; [3] Includes only linezolid

7. CONCLUSION

The application of sewage sludge as soil condtioner implies a potential dispersal of a wide range of contaminants in 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 into plants used for food or feed production or grazing purposes and result in animal and human exposure to the contaminants through feed or food. The Norwegian Scientific Committee for Food (VKM) was asked to assess the risk a list of contaminants or group of contaminants in sewage sludge. This list of contaminants (Table 2) was prepared after a pilot project where available information on occurrence in Norwegian sludge and available toxicological information had been collected. The predicted environmental concentrations (PECs) in soil and water, as well as human and animal exposure to the contaminants following the use of sewage sludge on Norwegian soils have been estimated by use of validated mathematical model equations recommended in the European Union's (EU) Technical Guidance Document for Risk Assessment of Chemicals (TGD). The guidelines were not always completely followed in the work, but to some extent adapted to Norwegian conditions when relevant. In case of adaptation to Norwegian conditions it is clearly discussed in the report. The exposure of the aquatic environment has been estimated by use of models developed, validated and used for pesticides.

The risks associated with the estimated levels of exposure were then assessed by comparing the estimated exposure levels to available estimated safe levels of exposure, such as predicted no effect concentrations (PNECs), or tolerable dayily intake (TDI).

There is very limited information on the occurrence of pharmaceuticals in Norwegian sewage sludge. The selection of pharmaceuticals included in the few studies available appears not to be based on risk of effect or probability of occurrence. Therefore, a tiered approach to estimate the concentrations of pharmaceuticals in sewage sludge was developed. The potential concentrations in sewage sludge were estimated based on statistical information on sold amounts of pharmaceuticals 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 pharmaceuticals with potential occurrence in soil after sewage sludge application exceeding the EMEA cut off value of 100 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.

VKM was asked to assess the current use of sewage sludge in Norway and a potential increase of 50% of the present maximum use of sludge. The assessment takes into account dispersal of sewage sludge on all food crop producing soil as well as soil for feed production.

Only risks associated with chemical contaminants and medicines in sludge have been assessed. Other relevant aspects such as pathogens and the potential risk of eutrophication of the aquatic environment following sewage sludge application were outside the scope of this assessment. Furthermore, the risk of application of sewage sludge on areas with grazing animals without ploughing within 18 hours has not been evaluated. Metabolites of the assessed substances formed either in humans (drug substances) or in the environment are not evaluated. Furthermore, the establishment of new tolerable weekly intake (TWI) or Predicted No Effect Concentration (PNEC) values has not been within the scope of this assessment and the lack of such values has been pointed out as data gap for some substances. In addition, the mathematical models applied for uptake in plants have not been validated for ionisable and polar compounds. Drug substances often fall into these categories and uptake in plants are therefore not estimated for these substances and consequently human and animal exposure to drug substances through plant consumption could not be estimated. 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 (VKM, 2008c).

Effects on soil environment (plants and other soil organisms)

Metals

- The estimated soil concentrations of metals following repeated application of sewage sludge are all below the relevant soil PNEC values. Metals in sewage sludge applied according to the assessed scenarios are consequently assumed to constitute a low risk to the soil environment.
- Calculations show that soils amended with the maximum amount of sewage sludge (40 tons per hectare every 10th year) increase their total concentrations of cadmium (Cd), mercury (Hg), zinc (Zn) and copper (Cu) 2-4 times during 100 years. The soil concentrations are not estimated to exceed the PNEC values for the terrestrial environment during a time period of 100 years. Only minor changes occur for the other metals. Cadmium and Hg are of particular concern due to their inherent toxic properties in both animals and humans. A certain increment of lead (Pb) may also be of toxicological concern. Only minor changes were found to occur for the other metals.

Organic contaminants

- The concentration of linear alkylbenzenesulphonate (LAS) in park areas and soil mixtures far exceeds the PNEC value for soil living organisms and plants.
- Octylphenol is the only assessed organic contaminant that is estimated to reach soil concentrations exceeding the PNEC in agricultural soils. This contaminant is, however, degradable in soil and the highest soil concentrations are reached immediately after each sewage sludge application. There is also limited information available on the effects of this compound in soil, and the used PNEC value is therefore estimated from an available aquatic PNEC and a large safety factor has been used in the assessment (Table 10). The available occurrence data for octylphenol in Norwegian sludge are limited and levels are uncertain. Thus, VKM Panel 5 considers octylphenol to constitute a relatively low risk to the soil compartment.
- Some polycyclic aromatic hydrocarbons (PAHs) and some polychlorinated biphenyls (PCBs) are expected to accumulate with repeated use of sewage sludge in a 100 years period. Calculations indicate that the concentrations of these compounds are well below the PNEC value at the end of the 100-year period.
- No PNEC value for the environment has been available for octylphenol ethoxylates, nonylphenol ethoxylates and PCBs.

Medicines

- No PNEC values for drug substances in soil have been available in this work. Soil PNEC values have been estimated from the aquatic environment where PNEC values for a range of drug substances have been set. This estimation is based on the partitioning coefficients (K_d values). The estimated PNEC values should be used with special care for drug substances due to their chemical properties, making calculations based on the K_d value particularly uncertain.
- The estimated soil concentrations of drug substances are low (concentration range 0.01 – 2 mg/kg DW) and well below the estimated PNEC values. VKM still consider the drug substances in sewage sludge to constitute a low risk to the soil compartment.

Aquatic environment

- Neither **metals** and **organic contaminants** nor **drug substances** have been estimated to reach the environmental PNEC values on short or long term. The use of sewage sludge therefore seems to constitute a negligible risk to the aquatic environment. A risk assessment of PCB in the aquatic environment could not be performed due to lack of PNEC values.

Food production animals

- Generally, meat-producing animals have a short life span and are consequently not expected to be a subject to long-term effects of substances with potential for accumulation. Milk-producing and breeder animals have a longer life span but the expsoure to contaminants through application of sewage sludge may anyway be regarded as low. The results of this known-compound-approached risk assessment indicate a negligible risk concerning animal health for a range of compounds. 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 limitations of relevant toxicological data for several of the compounds. Furthermore, there is not possible to assess the combined effects of the coctail of known and unknown chemicals in sewage sludge. However, perturbated development is revealed in young ruminants pre- and postnatally exposed to contaminants via fields treated with sewage sludge three weeks before grazing.

Human exposure

- Humans are potentially exposed to contaminants from dispersal of sewage sludge through consumption of crop plants grown on sludge-treated soil, consumption of meat from food-producing animals grazing on or given feed based on crops produced on this soil or through consumption of drinking water.

Metals

- Intake of metals from consumption of food from sewage sludge treated soil is assumed to constitute a low risk to the general population.
- It is highly unlikely that a major fraction of the vegetables consumed by the general population will be grown on soil treated with the maximum amount of sewage sludge due to the limited availability of sewage sludge. Locally, vegetable farmers who cover their daily consumption of vegetables grown on soils that has received the maximum

amount of sewage sludge during 100 years will exceed the PTWI for Cu and Cd. The probability of this scenario has not been looked at.

- There is no model available from the TGD to assess the transfer of metals from feed to animal-derived food products. A relationship between animal intake of Cd, Pb and Hg and concentrations in muscle and liver has been estimated based on available values in the literature. 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 little concern.
- There are uncertainties relating to the potential presence of methylated Hg in sewage sludge. Methyl-Hg have a higher absorption and accumulation in muscle tissue compared to Hg. The few available studies indicate that 4% of the Hg in sewage sludge is methylated. Given that this is a representative value, sewage sludge will only represent a minor source of dietary Hg and Methyl-Hg.
- The human intake of the other metals are estimated to be low and of little concern. A verification of the assumption that chromium is mainly present as Cr III and not the more toxic Cr VI may be desirable.

Organic contaminants

- Sewage sludge application on agricultural soil is estimated to have a low contribution to human intake of these contaminants from food for the general population.
- The estimations indicate a higher contribution to food intake for individuals only consuming vegetables grown on sludge-amended soil. These estimations are probably overestimations since the calculated values are unrealistic high in root vegetables compared to experimental data from relevant field studies. VKM has not evaluated the probability of a scenario of a farmer consuming only vegetables from his own fields with maximum allowed amounts of sewage sludge.
- The carry-over from feed to animal-derived human food has been estimated according to the TGD and considered to have little impact on the estimated total dietary intake.

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 for the fluoroquinolone ciprofloxacin in soil due to persistence and limited mobility of fluoroquinolones into the subsoil.

Knowledge Gaps

In order to perform risk assessment for environmental contaminants in sludge, as well as in other media, knowledge about their chemical properties, sources, persistence, environmental distribution, toxicity and health effects are needed. For relative new potential environmental pollutants there are still gaps of knowledge and for the emerging compounds (e.g. selected drugs) the need for knowledge is rather broad.

PNEC-values for soil environments are lacking for several substances and the knowledge about environmental effects and occurrence for drug substances is generally scarce.

VKM has identified some specific knowledge gaps in the risk assessment of sewage sludge applied on soil:

Sludge
- Occurrence data for certain contaminants are scarce, particularly for drug substances.
- Speciation of certain metals in sewage sludge and soil, and particularly the occurrence of methylated Hg.

Soil
- Accumulation of drug substances in soil and the influence of soil type, pH, redox conditions, organic matter content etc.
- Lack of knowledge for behaviour in soil such as e.g. biodegradation, distribution coefficients (K_d, K_{oc}), plant uptake) for several compounds under Nordic soil conditions and climate.
- Effects of organic matter on stability/mobility of trace metals in soil.
- PNEC-values for several contaminants in soil.
- Effect on soil dwelling organisms on most important drugs in Norwegian list.
- Influence of environmental factors on absorption of trace metals and organic contaminants (speciation, soil parameters, plant types, etc).
- Several factors related to plant uptake:
    - Uptake of surface active organic compounds, e.g. perfluorinated compounds into plants. Probably experimental data is needed since log K_{ow} is not suitable for predicting their environmental fate.
    - More experimental data and evaluation of existing models is needed.
    - Information about absorption and translocation of trace metals in plants.
    - Absorption and translocation of polar and ionisable organic contaminants in plants. Improved models are available, but the input information needed is not easily available.

Aquatic environment
- The main data gaps identified are lack of PNEC values for certain compounds.

Food production animals
- There is little information about the effects of contaminants on food production animals. More information about the potential exposure through plant consumption may however limit the number of contaminants for which more toxicological information is needed.
- Effects of mixed chemical exposure via sludge on grazing animals after ploughing the sludge.

Humans
- TDIs or similar safety factor for human risk assessment for certain organic contaminants.
- Improved exposure estimates are needed. These would largely depend on improved models or experimental data for plant concentrations in edible parts.

Recommendations

- Continuous efforts to reduce the levels of toxic heavy metals such as Cd, Hg, Cu and Zn in Norwegian sewage sludge are recommended.

- Measure concentration of the 14 drug substances in sewage sludge that have been identified in this risk assessment (Table 64) to validate the predicted environmental concentration of these drug substances in sewage sludge.
- It is important to monitor the pattern of use of chemicals in the society and follow the potential occurrence of new chemicals into the sewage and fate of these in the sewage treatment plants.
- An evaluation of compounds with less data available (Table 4). VKM Panel 5 is of the opinoun that there is a need to evaluate which compound that should included in a risk assemment of these compounds.
- It should be considered to establish/initiate test fields for agricultural soils receiving different kind of organic wastes including sewage sludge, manure and composts. The test sites should focus on achieving information on soil accumulation, leaching, biodegradation, and plant uptake of inorganic and organic contaminants. Data on soil and plant concentrations of contaminants will give valuable information for animal and human risk characterisation following sewage sludge application to Norwegian soils. Measures to prevent accumulation of undesired contaminants in soil could also be addressed at these sites.
- Evaluation and validation of models used in risk assessments, e.g. plant uptake. Different plant specific models exist but they should be validated.

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APPENDICES – PART A

Appendix A1

Background concentrations inorganic contaminants

Cadmium

Content in Norwegian sewage sludge and soil

The content of cadmium in sewage sludge has decreased during the last decade (Table A1). Today the mean concentration in sewage sludge is only 20% of the concentration in 1980.

The maximum permissible concentration of cadmium in class I sludge (allowing 4 tons per daa) is 0.8 mg kg^{-1}, the same as the mean concentration in 2005 (Table A1). Applying 4 and 6 tons sewage sludge per daa every ten years results in an annual application of 320 and 480 mg/daa.

Table A1. Mean concentration of cadmium (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	**1991**	**1995**	**1996**	**1997**	**1998**	**1999**	**2000**	**2001**	**2003**	**2005**	**% reduction (1980-2005)**
Cd	4	1.7	1.1	1.0	0.86	0.97	0.96	1.0	0.98	0.9	0.8	80

There has been no national survey of heavy metals in Norwegian agricultural soils. The existing data for Cd in soils therefore consist of scattered investigations first of all from southeastern Norway. The data presented here are the best available information from the different regions (Table 4).

The concentration of Cd in Norwegian agricultural soils is generally quite low with a median value of 0.24 mg Cd/kg (Table 4). The mean and median values in region 5 (north-eastern part of Norway) is influenced by industrial activity in north-western Russia (Almås *et. al*1995). The level of Cd found in region 4 (Nord-Trøndelag) is probably representative for the level of Cd in region 5.

The alum shale areas have a mean content of Cd in the soil, which is 6-7 times higher than the rest of the country (Table A2).

Table A2. Mean, median, minimum and maximum concentrations of HNO_3- extractable Cd (mg/kg DM) in agricultural soils in different regions and in the whole country (Amundsen *et al.* 2000).

Region[1]	**No of samples**	**Mean**	**Median**	**Minimum**	**Maximum**
Østfold, Akershus+Oslo,Vestfold	47	0.18	0.17	0.09	0.33
Vest-Agder and Rogaland	31	0.21	0.19	0.03	0.4
Sør-Trøndelag	51	0.11	0.11	0.02	0.26
Eastern Finmark	48	0.75	0.72	0.32	1.75
Alun shale areas in Hedmark	64	1.39	1.13	0.04	4.3
Whole country	241	0.6	**0.24**	0.02	4.3

The concentration of Cd in Norwegian agricultural soils varies from 0.05 to more than 4 mg kg-1 (Table A2), while the median concentration is 0.24 mg kg-1 dm (used in the risk assessment), which amounts to 72 000 mg Cd daa-1. The annual amount applied by 4 and 6 tons of sewage sludge is equal to 4.4 and 6.6% of the amount in soil on a 10 year basis.

Removal processes from soils

The crop production per unit area and the concentration of contaminant in the crop are the basis for all calculations of crop removal. Crop production in 2005 (Table A3) is numbers given by SSB (2006) and the concentrations in the crops is either measured or it is calculated using BCFs or algorithms describing the concentration dependence between crop content and soil parameters.

Table A3. Crop production (SSB 2007), water content of crops and concentrations of Cd in various crops (Amundsen et al. (2000)).

Crop	Crop production Kg daa-1 year-1 (ww)	Water content (%)	Kg m-2 (dm)	Measured concentration in plant Cd (µg kg-1 dm)
Wheat	469	15	0.39865	60
Barley	369	15	0.31365	17
Oat	355	15	0.30175	24
Potato	2600	70	0.78	54
Carrot	3500	70	1.05	270
Salad	1900	70	0.57	2000
Grass	1057	30	0.7399	50
Oil seeds	214	30	0.1498	82

One way to estimate the crop concentrations of contaminants is to use BCFs (Table A4).

Table A4. BCF for Cd in stem and root and calculated crop concentrations of cadmium using these BCFs.

Crop	BCF	Crop Conc. (µg/kg)
BCF stem	0.15	
BCF root	0.7	
Leafy vegetables		154
Other vegetables (carrot)		154
Potatoes		154
Cereals (wheat, oat, barley)		33

The second way of calculating the crop concentration is to use algorithms describing the relationship between plant content and various soil parameters including the total concentration in the soil (Table A5).

Table A5. Calculations of crop concentrations using algorithms from Eriksson (1996).

Crop	Algoritm	Time (year)		+/- (%)
		0	100	
Leafy vegetables	$\log Cdp=7.86-0.72pH+\log Cds$	2656	4869	83
Carrot (root)	$Cdp=1516-165pH-7.6(\%OM)$	597	571	-4
Potato (tuber)	$Cdp=193-24.1pH-0.94(\%OM)+39Cds$	69	74	7
Oat (grain)	$Cdp=139-18pH-1.79(\%OM)-0.28(\%Clay)+52Cds+0.13Zns$	52	56	8
Wheat (grain)	$Cdp=78.8-7.26pH-1.58(\%OM)+0.8(\%Clay)+184.8Cds-0.73Zns$	36	81	122

Cd_p=Cd concentration in plant (µg kg^{-1} DM); Cd_s=Cd concentration in soil (mg kg^{-1} DM); Zn_s=Zn concentration in soil (mg kg^{-1} DM) (competing ion); %OM=Percentage organic matter in soil (adsorb Cd); %Clay=Percentage clay in soil (adsorb Cd); pH=soil pH

In the calculations 10% clay content is used, soil pH ($CaCl_2$) is 5.3, and organic matter is 5.8%.

Comparison of the calculated removal rates (Table A6) for five crop rotations shows that the largest differences between the methods are for rotations involving potatoes and carrots.

Table A6. Comparison of calculated crop removal rates for Cd.

	Crop rotations	Measured crop content	BCF	Eriksson 1996
			µg m-2 year-1	
1	Autumn wheat	23.9	13.2	14.5
2	Autumn wheat-autumn wheat-oat-barley-oil seed	14.5	13.2	13.7
3	Potato-autumn wheat-oat	24.4	48.8	28.0
4	Carrot-potato-wheat	117	98	232
5	Grass-grass-wheat	32.6	29.0	22.8
	Mean removal	42.4	40.5	62.2

The mean removal rate (considering all crop rotations) using the measured concentrations in crops and BCFs are almost equal (Table A6), while using the crop concentrations calculated from the plant-soil algorithms (Eriksson 1996), the removal rate is 50% higher.

Soil concentrations used in the calculation of plant removal

When calculating the amount of contaminant that is removed by plant uptake different approaches are possible. The soil concentration is the basis for the plant removal. In this assessment different approaches will be used for heavy metals and organic contaminants.

1. Plant uptake of heavy metals during a 100 year period

When calculating the annual removal rate for heavy metals during a 100 year period the calculated soil concentration due to sludge application in 50 years is used plus the background concentration.

Most organic contaminants have a half-life in soils much shorter than one year. This means that after the first growing season the organic contaminant is degraded and the uptake thereafter is only dependent on the background concentration. During the 100 year period the soil concentration of most organic contaminants will be influenced by sludge application only in 10 out of 100 years. In this risk assessment the plant removal rate will be calculated using the mean soil concentration in the 90 days period after sludge application. The background concentration is not included in the calculations for organic contaminants.

2. Plant uptake after 100 years of sludge application

When calculating the maximum exposure concentration of heavy metals for humans and animals the calculated soil concentration after 100 years of sludge application is used. For organic contaminants the calculated mean soil concentration in the 90 day period after sludge application will be used to calculate maximum exposure concentration.

The background concentration is not included in the calculations for organic contaminants.

The reason for omitting the background concentration in the calculations for organic contaminants is that the background level for most substances is generally unknown. When calculating the plant removal rate in agricultural soils concentrations (receiving sludge once every 10th year), the level of background concentration is more important than in calculations regarding park areas and soil mixtures. Due to lower application rates for agricultural soils the background concentration will be higher than the sludge applied concentrations most of the time for many substances.

Lead

Content of lead in Norwegian sewage sludge and soil

Concentrations of lead in Norwegian sewage sludge has decreased by about 80 percent in the period 1980-2005, but the concentrations of lead the last 10 years have been relatively constant (Table A7).

Table A7. Mean concentration of lead (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Pb	118	36	24	25	22	22	24	21	16	22	21,7	82

The concentration of Pb in Norwegian agricultural soils varies from a few mg kg-1 to about 80 mg kg-1 (Table A8). Mean and median concentrations of Pb in soils are equal to (or somewhat higher than) the mean concentration in sewage sludge reported in 2005 (SSB 2007) indicating that the accumulation potential for Pb in agricultural soils when applying sewage sludge is small.

Table A8. Soil concentrations of lead in Norwegian agricultural soils (data from Esser 1996).

	Mean	Median	Min - Max
Pb	23.9	21.4	3.5 - 77.7

Mercury

Concentrations of mercury in soil and sewage sludge

The concentration of mercury in sewage sludge is reduced by 94 percent in the period 1980-2005. There has also been a marked decrease during the last ten years (Table A9).

Table A9. Mean concentration of mercury (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Hg	12	2.1	1.4	1.2	1.3	1.3	0.95	0.90	0.83	0.,90	0.7	94

The mean mercury concentration in sewage sludge is about 15 times higher than the mean concentrations for agricultural soils (Table A10). The potential for soil accumulation is therefore quite high for mercury.

Table A10. Concentration of mercury (mg/kg) in agricultural soils (data from Esser 1996).

	Mean	Median	Min - Max
Hg	0.047	0.045	0.005 - 0.12

Nickel

Nickel in sewage sludge and soil

The concentration of nickel in sewage sludge has been constant during the last 10 years, but the mean concentration in the sludge has decreased by 58% since 1980. The level of nickel in sewage sludge is lower than the mean concentration in Norwegian agricultural soils (Table A11).

Table A11. Mean concentration of nickel (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al. 2001*; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Ni	42	12	13	13	12	15	14	15	13	14	17,5	58

Table A12. Concentrations of nickel in soils in Norway (data from Esser 1996).

	Mean	Median	Min - Max
Ni	21,1	15,6	0,7 - 85,6

Zinc

Concentration in soil and sewage sludge

Table A13. Mean concentration of zinc (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Zn	687	376	373	376	360	340	361	317	303	326	331	52

The mean concentration of Zn in sewage sludge is about 5 times higher than mean soil concentrations (Table A13 and Table A14).

Table A14. Concentrations of zinc in soils from different regions in Norway (data from Amundsen *et al.* 2000).

Region	No of samples	Mean	Minimum	Median	Maximum
1	118	78	17,4	74,5	199
2+3	31	25,9	7,3	25,9	157
4	51	65,2	27	64	108
5	48	36	8,75	28,8	145
6	53	112	25	108	282
Whole country	301	71,3	7,3	66,7	282

Copper

Concentrations in sewage sludge and soil

The concentration of Cu in sewage sludge has been constant during the last 10 years (Table A15). The mean concentration in sewage sludge is 14 times higher than the mean concentration in agricultural soils.

Table A15. Mean concentration of copper (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Cu	474	399	300	271	299	287	248	244	227	268	269	43

Copper soil concentrations vary considerably and in many areas the concentrations are too low to maintain plant nutrition.

Table A16. Concentrations of copper in soils in Norway (data from Esser 1996).

	Mean	Median	Min - Max
Cu	19,2	15,6	1,7 - 87,1

Chromium

Concentrations of chromium in sewage sludge and soil

The concentration of Cr in sewage sludge has been relatively constant during the last 10 years, but there has been a significant reduction (89 %) since 1980 (Table A17).

Table A17. Mean concentration of chromium (mg kg-1 dm) in Norwegian sewage sludge in the period 1980-2005 (Amundsen *et al.* 2001; SSB 2007).

	1980	1991	1995	1996	1997	1998	1999	2000	2001	2003	2005	% reduction (1980-2005)
Cr	233	30	26	30	41	29	30	25	25	23	25.4	89

The mean concentration level of Cr in sewage sludge is about the same as the mean concentrations in Norwegian agricultural soils (Table A17) and the accumulation potential for chromium in most soils due to sludge application therefore is small.

Soil concentrations of chromium vary considerably in Norwegian soils (Table A18). Application of sewage sludge with a content equal to or lower than the soil concentration will not lead to elevated soil concentrations with time

Table A18. Concentrations of chromium in Norwegian agricultural soil (0-5cm) (data from Esser 1996).

	Mean	Median	Min - Max
Cr	27.1	20.6	1.4 - 92.2

Concentrations of organic contaminants in sewage sludge

DEHP, DPB, octylphenole, octylphenolethoxilates, nonylphenole, nonylphenolethoxilates and LAS

For the contaminants DEHP, DPB, octylphenol, octylphenolethoxilates, nonylphenol, nonylphenolethoxilates and LAS mean values from investigations of Norwegian sewage sludge performed in 2001/2002 (Nedland 2002) and 2006/2007 (Blytt 2007), as well as results from the screening investigation performed in 2006 (Nedland and Paulrud 2006). Only values above detection limit are used in the calculations.

In the risk assessment the mean concentration for these contaminants in Norwegian sewage sludge is used.

Table A19. Concentrations of DEHP, DPB, octylphenol, octylphenolethoxilates, nonylphenol, nonylphenolethoxilates and LAS in sewage sludge (mg/kg DM).

	DEHP	**DBP**	**Oktylfenol**	**Oktylfenol-etoksilat**	**Nonylfenol**	**Nonylephenol-ethoksilate**	**LAS**
Minimum	13	0.12	0.26	0.16	12.3	5.7	570
Maximum	178	2.8	32.5	0.93	44	39	3200
Mean	49	0.34	0.47	0.57	32	28	1400
Median	53	0.64	5.9	0.53	30	24	1441
N	52	41	52	12	52	51	40

PAH

For PAHs the mean values from investigations of Norwegian sewage sludge performed in 2001/2002 (Nedland 2002) and 2006/2007 (Blytt 2007) are used. Only values above detection limit are used in the calculations.

In the risk assessment the mean concentration for the different PAHs in Norwegian sewage sludge is used.

Table A20. Concentrations of PAHs in sewage sludge (mg/kg DM).

	Naphtalene	**Acenaphtalen**	**Acenaphten**	**Fenantren**	**Antracen**	**Fluoren**
Minimum	0.053	0.01	0.015	0.18	0.014	0.062
Maximum	1.4	0.041	0.26	1.1	0.13	0.71
Mean	**0.26**	**0.02**	**0.08**	**0.42**	**0.04**	**0.18**
Median	0.33	0.02	0.10	0.48	0.05	0.21
N	40	10	30	40	33	33

	Fluoranthene	**Pyrene**	**Benzo(a)antracen**	**Crysene**	**Benzo(b.j.k) fluoranten**	**Indeno (1.2.3-cd) pyren**
Minimum	0.076	0.086	0.029	0.04	0.021	0.017
Maximum	0.6	0.69	0.24	0.32	0.36	0.16
Mean	**0.21**	**0.25**	**0.05**	**0.10**	**0.09**	**0.05**
Median	0.23	0.27	0.07	0.12	0.12	0.06
N	40	40	40	40	40	34

	Dibenzo(a.h)antracene	Benzo(g.h.i)perylene	Benzo(a)pyrene	Sum PAH 16
Minimum	0.014	0.022	0.012	0.62
Maximum	0.029	0.19	0.14	4.3
Mean	**0.02**	**0.07**	**0.05**	**1.80**
Median	0.02	0.09	0.06	2.1
N	6	33	28	52

PCB

For PCBs the levels in sewage sludge in 2001/2002 (Nedland 2002) in most samples were below the limit of detection. Data from the investigation performed in 1996 therefore were used as basis for input values for the different PCB congeners. In the table below the concentrations of PCB congeners from the 1996-investigation are shown. As input data in this risk assessment 25% of these values is used which results in 0.012 mg sum PCB/kg sludge, which is at the same level as the mean value found in the 2001/2002-investigation (0.014 mg/kg dm; Nedland 2002). Since the level of PCBs is not measured in Norwegian sewage sludge since the 2001/2002-investigation, and the level of PCBs in sewage sludge is assumed to have decreased since 2001, we assume that the input values given in the table below are in the upper range of present sewage sludge concentrations.

Table A21. **Concentrations of PAHs in sewage sludge (mg/kg DM).**

	PCB-28	PCB-52	PCB-101	PCB-118	PCB-138	PCB-153	PCB-180	PCB: 1996/97
Mean	0.0067	0.0041	0.008	0.006	0.0127	0.006	0.0038	0.0473
Risk assessment	**0.0017**	**0.0010**	**0.0020**	**0.0015**	**0.0032**	**0.0015**	**0.0010**	**0.0118**

Appendix A2

Table A22. Chemical parameters for organic contaminants used in the risk assessment of sewage sludge.

Compound	CAS # [1]	MW	log K_{ow}	Kd[2] [Lkg^{-1}]	$T_{1/2}$ [day^{-1}]	K_H [$Pa\ m^3\ mol^{-1}$]	Ref
DEHP	117-81-7	390.6	7.5	1E+05	300	4,46E-02	EU (2008)
DBP	84-74-2	278.34	4.57	63	20	1,32E-01	EU (2003)
4-Octylphenol	27193-28-8, 140-66-9	206.32	4.12	25	10	4,90E-01	Mackay et al. 2006
Octylphenolethoxilate	9002-93-1	250.32	4	21	5	4,90E-01	
4-Nonylphenol	25154-52-3, 104-40-5	220.35	4.48	66	10	1,57E+00	Mackay et al. 2006
Nonylphenolethoxilate	9016-45-9	264.35	4	21	5	1,57E+00	
LAS	68411-30-3	418	3.7	20	8	4,90E-01	Jensen 1999
Naphftalene	91-20-3	128.17	3.3	10	30	4,89E+01	Mackay et al. 2006
Acenaphtylene	83-32-9	152.19	3.9	30	50	1,16E+01	Mackay et al. 2006
Acenaphtene	83-29-9	154.21	3.9	34	50	1,48E+01	Mackay et al. 2006
Phenanthrene	85-01-8	178.23	4.47	170	50	5,50E+00	Mackay et al. 2006
Anthracene	120-12-7	178.23	4.45	200	50	6,60E+00	Mackay et al. 2006
Fluorene	86-73-7	166.22	4.2	59	50	7,80E+00	Mackay et al. 2006
Fluoranthene	206-44-0	202.25	5.1	1514	150	1,10E+00	Mackay et al. 2006
Pyrene	129-00-0	202.25	5.1	676	200	1,10E+00	Mackay et al. 2006
Benz(a)anthracene	56-55-3	228.29	5.54	6172	150	8,00E-01	Mackay et al. 2006
Chrysene	218-01-9	228.29	5.81	5253	300	5,00E-01	Mackay et al. 2006
Benzo(a)pyrene	50-32-8	252.31	6.1	9160	365	7,90E-03	Mackay et al. 2006
Benzo(b)fluoranthene	205-99-2	252.31	5.78	2188	450	5,10E-02	Mackay et al. 2006
Indeno(123cd)pyrene	193-39-5	276.33	6.87	10482	600	2,90E-02	Mackay et al. 2006
Dibenz(ah)anthracene	53-70-3	278.35	6.6	18804	600	7,40E-03	Mackay et al. 2006
Benzo(ghi)perylene	191-24-2	276.33	6.22	26942	600	2,70E-02	Mackay et al. 2006
PCB-28	7012-37-5	257.54	5.6	632	1000	3,0E+01	Mackay et al. 2006
PCB-52	35693-99-3	291.99	5.8	1590	3600	1,7E+01	Mackay et al. 2006
PCB-101	37680-72-3	326.43	6.2	7960	3600	1,7E+01	Mackay et al. 2006
PCB-118	31508-00-6	326.43	6.5	12620	3600	1,2E+01	Mackay et al. 2006
PCB-138	35065-28-2	360.88	7.0	15900	6900	1,1E+01	Mackay et al. 2006
PCB-153	35065-27-1	360.88	7.0	20000	6900	1,0E+01	Mackay et al. 2006
PCB-180	35065-29-3	395.32	7.2	79600	13000	3,2E+00	Mackay et al. 2006

Appendix A3

Table A23. Summary of calculated removal constants (Eq.6) for heavy metals

Removal process	Eq 6	Eq no	Cd	Pb	Cu	Cr	Hg	Ni	Zn
Leaching	kleaching	7	3.20E-06	1.60E-06	1.60E-06	7.99E-07	1.60E-06	1.60E-06	1.60E-06
Plant uptake	kplant	9.17	1.96E-06	1.79E-08	4.45E-06	1.47E-07	2.74E-07	5.64E-07	2.82E-06
Volatilisation	kvolat	11.12							
Biological deg	kbiosoil	10							
Sum			5.15E-06	1.62E-06	6.04E-06	9.46E-07	1.87E-06	2.16E-06	4.42E-06

Table A24. Summary of calculated removal constants (Eq 6) for organic contaminants

Removal process	Eq 6	Eq no	DEHP	DBP	Octyl-fenol	Octylfenol-ethoxilat	Nonyl-phenol	Nonylphenol-ethoxilate	LAS
Leaching	kleaching	7	1.3E-08	2.5E-05	6.4E-05	7.6E-05	2.4E-05	7.6E-05	7.9E-05
Plant uptake	kplant	9.17	1.1E-06	9.5E-06	1.1E-05	1.1E-05	7.8E-06	1.1E-05	6.7E-07
Volatilisation	kvolat	11.12	1.5E-09	3.9E-06	1.9E-05	2.3E-05	1.8E-05	5.7E-05	2.4E-05
Biological deg	kbiosoil	10	2.3E-03	3.5E-02	6.9E-02	1.4E-01	6.9E-02	1.4E-01	8.7E-02
Sum			2.3E-03	3.5E-02	6.9E-02	1.4E-01	6.9E-02	1.4E-01	8.7E-02

Removal process	Eq 6	Eq no	Naftalen	Acenaftylen	Acenaften	Fenantren	Antracen	Fluoren
Leaching	kleaching	7	1.58E-04	5.30E-05	4.68E-05	9.39E-06	7.99E-06	2.70E-05
Plant uptake	kplant	9.17	5.73E-06	6.71E-06	5.93E-06	2.97E-06	2.45E-06	5.50E-06
Volatilisation	kvolat	11.12	3.26E-03	2.64E-04	2.96E-04	2.27E-05	2.30E-05	9.14E-05
Biological deg	kbiosoil	10	2.31E-02	1.39E-02	1.39E-02	1.39E-02	1.39E-02	1.39E-02
Sum			2.65E-02	1.42E-02	1.42E-02	1.39E-02	1.39E-02	1.40E-02
			Fluoranten	**Pyren**	**Benzo(a) antracen**	**Krysen**	**Benzo(b) fluoranten**	**Ind(1.2.3-cd) pyren**
Leaching	kleaching	7	1.06E-06	2.36E-06	2.59E-07	3.04E-07	7.30E-07	1.52E-07
Plant uptake	kplant	9.17	9.75E-07	2.18E-06	5.15E-07	9.74E-07	3.07E-06	5.16E-06
Volatilisation	kvolat	11.12	5.93E-07	1.33E-06	1.13E-07	9.42E-08	8.69E-08	1.65E-08
Biological deg	kbiosoil	10	4.62E-03	3.47E-03	4.62E-03	2.31E-03	1.54E-03	1.16E-03
Sum			4.62E-03	3.47E-03	4.62E-03	2.31E-03	1.54E-03	1.16E-03
			Dibenzo(a.h) antracen	**Benzo(g.h.i) perylen**	**Benzo(a)pyren**			
Leaching	kleaching	7	8.50E-08	5.93E-08	1.74E-07			
Plant uptake	kplant	9.17	4.41E-06	6.36E-07	9.56E-05			
Volatilisation	kvolat	11.12	7.75E-09	6.37E-09	1.61E-08			
Biological deg	kbiosoil	10	1.16E-03	1.16E-03	1.90E-03			
Sum			1.16E-03	1.16E-03	1.99E-03			

Removal process	Eq 6	Eq no	PCB28	PCB52	PCB101	PCB118	PCB138	PCB153	PCB180
Leaching	kleaching	7	2.53E-06	1.01E-06	2.01E-07	1.27E-07	1.01E-07	7.99E-08	2.01E-08
Plant uptake	kplant	9.17	1.43E-05	2.44E-05	1.01E-05	1.08E-05	2.64E-05	2.10E-05	8.58E-06
Volatilisation	kvolat	11.12	3.22E-05	7.29E-06	1.46E-06	6.52E-07	4.75E-07	3.44E-07	2.90E-08
Biological deg	kbiosoil	10	6.93E-04	1.93E-04	1.93E-04	1.93E-04	1.00E-04	1.00E-04	5.33E-05
Sum			7.42E-04	2.25E-04	2.04E-04	2.04E-04	1.27E-04	1.22E-04	6.20E-05

Appendix A4

In a outdoor meso-scale experiment performed in the period 1996-2001, different amounts of sewage sludge were added to various soils contained in 0,2 m^2 plastic cases (30 kg of soil). The main objective of these experiments was to improve the knowledge on how soil and sludge properties influence microbial activity in soil. Organic contaminants were determined in both reference and sludge amended soils (Amundsen *et al*., 1997a).

In another investigation performed in 1992-93 (Amundsen *et al*., 1997b) some of the organic contaminants from Table 2 were determined in surface soils from five farms in Ås municipality.

The concentration levels for park areas (Table A25) are mean values of 17 soil samples from two park areas in the Oslo-region were sewage sludge was used as part of a top layer som years before soil sampling and analysis (Amundsen *et al*. 1997b). These values can therefore not be considered background, but for e.g. PCB the levels represent soil concentrations that may be typical for park areas which received sewage sludge in the 1980ies.

Concentrations of PAHs and PCBs in the top layer of forest soils are from Lead *et al*. (1997) and Aamodt *et al*. (1996).

Table A25. Background concentrations for organic contaminants in Norwegian soils. Unit: mg/kg dw

	DEHP	**DBP**	**Nonylphenol**	**NFEO1**	**LAS**	**Sum PCB**	**Sum PAH**
Agr soil*	<1	<1	<1	<1	0.7	<0.003	<0.3
Agr soil**	0.07	0.47	<0.03	<0.03	0.003		
Park areas**	0.03	1.2	<0.03	<0.03	0.074		
Forest soil (podzol)#					0.014		
Birkenes¤							0.502
Lyngdal¤							0.556
Hølonda/Klæbu¤							0.054

* Amundsen *et al.* (1997a); **Amundsen *et al.* (1997b); #Lead *et al.* (1997); ¤Aamodt *et al.* 1996.

Amundsen, C. E., Hartnik, T., og Linjordet, R., 1997a. Forekomst og stabilitet av organiske miljøgifter i jord tilført avløpsslam. Kjemiske og mikrobiologiske endringer etter slamtilførsel. Jordforsk-rapport nr. 139/97. Jordforsk, Fredrik A Dahlvei 20, N-1432 Ås.

Amundsen, C. E., Andersen, S., Vethe, Ø., og Esser, K. 1997b. Organic contaminants in some Norwegian sludge amended soils. Konferanse: "Management and fate of toxic organics in sludge applied to land", København, april-mai 1997.

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Appendix A5

Plants – inorganic contaminants

Plant available Cd in soil

Naturally the total content of Cd in soils varies between 0.01 to 0.2 mg kg^{-1} soil DM, while polluted soil may contain up to 160 mg Cd Kg^{-1} DM. There is correlation between the total content of Cd in soil and plant Cd concentrations, but dependent of several soil factors, only a minor fraction of the soil total Cd content is usually plant available. Soil pH is the factor found to be most important for the concentration of Cd in soil solution, and hence the plant availability. Additionally soil organic matter content, clay content and concentration of competing ions as eg. Zn^{2+} has been found to influence the plant Cd concentration. Based on studies of plant Cd uptake from soil at varying soil properties ERM (2000) recommended to use some algorithms in order to predict future plant Cd concentrations (Cd_p). These algorithms are simply based on multiple regression equations where those soil factors which have been found to influence the plant Cd concentrations are included (Eriksson *et al.* 1996) (Table A26). By use of the suggested algorithms, or somewhat simplified equations, transfer factors from soil to plant is calculated (Table A27).

Table A26. Algorithms (multiple regression equations) expressing the plant Cd concentration (Cd_p) as a function of soil properties (from ERM (2000)).

Crop	Algorithm	Reference
Potato (tuber)	Cd_p=193-24.1pH–0.94(%OM)+39Cd_s	Eriksson *et al* (1996)
Carrot (root)	Cd_p=1516-165pH–7.6(%OM)	Eriksson *et al* (1996)
Leafy vegetables	logCd_p=7.86-0.72pH+logCd_s	Environmental Agency (2000)Eriksson et al (1996)
Oat (grain)	Cd_p=139-18pH–1.79 (%OM)–0.28(%Clay)+52Cd_s+0.13Zn_s	Eriksson *et al* (1996)
Wheat (grain)	Cd_p=78.8-7.26pH–1.58(%OM) +0.8(%Clay)+184.8Cd_s-0.73Zn_s	Eriksson *et al* (1996)

Cd_p=Cd concentration in plant (µg kg^{-1} DM).

Cd_s=Cd concentration in soil (mg kg^{-1} DM).

Zn_s=Zn concentration in soil (mg kg^{-1} DM) (competing ion).

%OM=Percentage organic matter in soil (adsorb Cd)

%Clay=Percentage clay in soil (adsorb Cd)

pH=soil Ph

Table A27. Transfer factors (TF) for Cd from soil to plant. Cd_p = TF*Cd_s where Cd_s has the unit of mg kg^{-1} (soil DM), and Cd_p mg kg^{-1} (plant fresh weight).

Plant	TF
Lettuce	0.1
Potato	0.2
Carrot	0.1

Cd in plants

Cd is not an essential plant nutrient. Critical concentrations of Cd in plants are in the range 5 to 10 mg kg^{-1} DM (Sauerbeck 1982). Concentrations above this level are harmful. When high availability of Cd in soil (soil solution concentration) the plant can take up relatively high amounts of Cd. High concentrations of Cd in plants disturb the enzyme activity, and disturb the Fe metabolism and cause chlorosis, necrosis and growth inhibition.

Translocation within the plant

The uptake of Cd from soil varies considerably dependent on plant species. In some species such as lettuce and celery the uptake rate of Cd is very high. Strong growth inhibition has e.g. been found in lettuce, beet and beans. High concentrations of Cd have also been found in potato and carrots. Cd usually is readily transported from the plant root to the top. However, translocation from the leaves into seeds is usually low, presumably because Cd is as Ca not phloem mobile. In grain plants the translocation of Cd from leaves to grain has been found to be very slow, thus most of the Cd taken up is left in the straw. In Norwegian grain production usually 75% of the wheat straw is returned to land. This means that there is a high risk for unwanted transfer of Cd from Cd contaminated soil to animals and human beings trough those plants which leaves are consumed. While the risk for unwanted transfer of Cd to animals and human beings through grains is low. However, it must be of concern that the critical concentrations in the diet of animals is significantly lower that those critical for plant health (i.e. 0.5-1mg kg^{-1} DM in animal diet vs. 5-10 mg kg^{-1} DM in plant (Sauerbeck 1982). Plants do no necessarily act as an indicator of Cd levels toxic to humans and animals since plants tolerate higher levels of Cd than do animals.

Appendix A6

The simulation of the runoff to water is based on real data from a field trial at a farm (Foss gård, Lier) in the period from 1998 to 2001. The physical and chemical properties of the soil are described below in Norwegian.

Profilbeskrivelser fra NORPRE's automatiske værstasjoner

Stasjon nr. : 19 LIER **Beskrevet:** 25. juni 1997

Beliggenhet : Profilet ligger i øvre delen av en ravine, i en rett, svakt hellende (6%), vestvent skråning.

Lokalisering : Profilet er beskrevet 5,5 m og 260 nygrader fra værstasjonen.

Opphavsmateriale	: havavsetning	**Vekst**	: havre
Dreneringsgrad	: dårlig	**Profildybde**	: 96 cm
Stein og blokk	: ingen	**Fjellblotninger**	: ingen
Grunnvannsnivå	: ikke observert		

Klassifikasjon

FAO$_{90}$	: Eutric Cambisol
WRB$_{98}$	: Hypereutric Gleysol
Soil Taxonomy$_{98}$	: Typic Epiaquept
NIJOS jordtype	: He6

Merknad:

Profilbeskrivelse (alle farger er beskrevet i fuktig jord, sjiktdybder i cm)

Ap1 (0 - 15) Mørk gråbrun (2.5Y 4/2) siltig lettleire; moderat utviklet, fin, avrundet blokkstruktur, og moderat utviklet, fin, grynstruktur; smuldrende i fuktig tilstand, klebrig og plastisk i våt tilstand; skarp og svakt bølgende sjiktgrense.

Ap2 (15 - 36) Gråbrun (2.5Y 5/2) siltig lettleire; sterkt utviklet, tykk platestruktur (plogsåle) som brytes opp i moderat utviklet, middels, skarpkanta blokkstruktur; smuldrende i fuktig tilstand, klebrig og plastisk i våt tilstand; noen middels porer; få svært fine røtter fordelt i sprekker; skarp og svakt bølgende sjiktgrense.

Btg (36 - 55) Grå (2.5Y 5/1) siltig mellomleire; mange (20-50%), gulbrune (10YR 5/4), fine og middels, avrundete redox-ansamlinger i aggregater og på aggregatoverflater; sterkt utviklet, tykk platestruktur som brytes opp i moderat utviklet, middels, skarpkanta blokkstruktur; smuldrende i fuktig tilstand, klebrig og plastisk i våt tilstand; tynne, sammenhengende belegg av leirmineraler i markganger; noen middels og få grove porer; svært få svært fine røtter fordelt i sprekker; tydelig og plan sjiktgrense. Sjiktet inneholder også et 0,3 til 1 cm tykt, horisontalt orientert, lys brungrått (2.5Y 6/2) siltlag.

BCg (55 - 71) Olivengrå (5Y 5/2) siltig mellomleire; mange (20-50%), sterk brune (7.5YR 5/6), fine og middels, avrundete redox-ansamlinger i aggregater og på aggregatoverflater; svakt utviklet, svært tykk platestruktur; fast i fuktig tilstand, klebrig og plastisk i våt tilstand; noen middels og få grove porer;

ingen røtter; tydelig og sterkt bølgende sjiktgrense.

C (71 -) Olivengrå (5Y 5/2) siltig lettleire med mørk grå (5Y 4/1) større felt som dekker 20-50 % av sjiktet; noen (10-20%), gulbrune (10YR 5/4), fine og middels, avrundete redox-ansamlinger; massiv med sedimentær lagstruktur; mange middels og få svært grove porer

Fysiske og kjemiske data for stasjon 19, LIER

Sjikt	Tykkelse	Frasikt	Kornstørrelsesfordeling (%)								%		
	cm	%	2-0,6 mm	0,6-0,2 mm	0,2-0,1 mm	0,1-0,06 mm	0,06-0,02 mm	0,02-0,006 mm	0,006-0,002 mm	<0,002 mm	Sand	Silt	Leir
Ap1	0 - 15	0	0,4	2,2	1,7	1,0	25,7	32,6	11,5	24,9	5,3	69,8	24,9
Ap2	15 - 36	0	0,5	2,3	1,3	0,9	23,6	34,0	13,0	24,4	5,0	70,6	24,4
Btg	36 - 55	0	0,2	0,6	0,6	0,6	20,7	35,3	15,2	26,9	2,0	71,2	26,9
BCg	55 - 71	0	0,1	0,4	0,4	0,3	27,2	32,9	11,4	27,3	1,2	71,5	27,3
C	71 +	0	0,0	0,4	0,2	0,6	28,6	33,1	13,2	23,9	1,2	74,9	23,9

Sjikt	Tykkelse	pH		Tot C	Tot N	Ombyttb. Kationer (meq/100g)					B.met.	Tørrst.
	cm	H_2O	$CaCl_2$	%	%	H	K	Na	Mg	Ca	%	%
Ap1	0 - 15	6,5	6,0	1,3	0,13	2,90	0,35	0,05	0,83	7,38	75	99,1
Ap2	15 - 36	6,7	6,2	1,1	0,11	1,80	0,42	0,05	0,76	7,78	83	99,2
Btg	36 - 55	7,1	6,5	0,1	0,05	1,40	0,27	0,05	1,13	6,25	85	99,3
BCg	55 - 71	6,9	6,3	0,2	0,05	1,30	0,30	0,04	1,29	5,81	85	99,3
C	71 +	6,9	6,3	0,1	0,05	1,30	0,22	0,07	1,32	4,88	83	99,4

Sjikt	Tykkelse	Prøve-dyp	Penetr.*	Luft	Porer	Mat. tetthet	Jord-tetthet	Vann led
	cm	cm	kN/cm^2	vol %		g/cm^3		cm/h
Ap1	0 - 15	5-9	Ikke målt	7,7	45,0	2,69	1,47	0,92
Ap2	15 - 36	20-24	Ikke målt	4,8	42,5	2,75	1,58	2,74
Btg	36 - 55	41-45	Ikke målt	5,7	40,4	2,77	1,65	0,46
BCg	55 - 71	Ikke prøvetatt	Ikke målt	-	-	-	-	-
C	71 +	71-75	Ikke målt	4,0	39,5	2,77	1,67	0,07

* Gjennomsnitt av 5 målinger med penetrometer

Sjikt	Tykkelse	Prøve - dyp	Volumprosent vann ved					Nytt.b. vann
	cm		Metn	pF 1,2	pF 2	pF 3	pF 4,2	Vol %
Ap1	0 - 15	5-9	45,0	41,3	37,8	33,3	11,2	26,6
Ap2	15 - 36	20-24	45,1	41,4	38,0	33,3	11,9	26,1
Btg	36 - 55	41-45	44,8	39,9	34,7	29,7	14,7	20,0
BCg	55 - 71	Ikke prøvetatt	-	-	-	-	-	-
C	71 +	71-75	43,5	39,3	35,5	31,4	14,2	21,3

Stasjon nr.	: 15 HOKKSUND	**Beskrevet:**	26. juni 1997
Beliggenhet	: Flatt område (< 2% helling) på elveslette.		
Lokalisering	: Profilet er beskrevet 9 m og 200 nygrader fra værstasjonen.		

Opphavsmateriale	: elveavsetning	**Vekst**	: kortklipt plen
Dreneringsgrad	: dårlig	**Profildybde**	: 103 cm
Stein og blokk	: ingen	**Fjellblotninger**	: ingen
Grunnvannsnivå	: 100 cm		

Klassifikasjon
FAO$_{90}$: Gleyic Phaeozem
WRB$_{98}$: Orthieutri-Mollic Gleysol
Soil Taxonomy$_{98}$: Oxyaquic Hapludoll
NIJOS jordtype : Om7

Merknad:

Profilbeskrivelse (alle farger er beskrevet i fuktig jord, sjiktdybder i cm)

Ap (0 - 33)	Svært mørk grå (2.5Y 3/1) siltig lettleire; svakt utviklet tykk platestruktur; lett smuldrende i fuktig tilstand, svakt klebrig og svakt plastisk i våt tilstand; noen middels porer; svært mange svært fine og svært få svært grove tilfeldig fordelte røtter; skarp og svakt bølgende sjiktgrense. Nedre del av sjiktet er preget av bioturbasjon.
Bw (33 - 41)	Olivengrå (5Y 5/2) og sterk brun (7.5YR 5/6) sjattert siltig lettleire; svakt utviklet tykk platestruktur; lett smuldrende i fuktig tilstand, svakt klebrig og svakt plastisk i våt tilstand; noen middels porer; svært få grove røtter lokalisert i markganger; tydelig stratifisering i opphavsmaterialet; skarp og plan sjiktgrense.
Cg1 (41 - 56)	Grå (5Y 5/1) og brun (10YR 5/3) sjattert siltig finsand; få (2-10%), brune (7.5YR 4/4), middels, avrundete redox-ansamlinger; massiv med sedimentær lagstruktur; få middels porer; ingen røtter; tydelig og plan sjiktgrense.
Cg2 (56 - 72)	Mørk grå (5Y 4/1) siltig finsand; mange (20-50%), gulrøde (5YR 4/6), middels og grove, avrundete redox-ansamlinger; svært få (<2%), svært mørk grålig røde (10R 2.5/2), middels, avrundete konkresjoner; massiv; noen middels porer; skarp og plan sjiktgrense. Synlig redusert matriks.
Cg3 (72 - 88)	Grønnlig grå (5GY 5/1) siltig lettleire; massiv; synlig redusert matriks. Sjiktet lå delvis under vann ved beskrivelsen.
Cg4 (88 -	Sandig silt eller siltig finsand. Ikke prøvetatt.

Fysiske og kjemiske data for stasjon 15, HOKKSUND

Sjikt	Tykkelse	Frasikt	Kornstørrelsesfordeling (%)								%		
	cm	%	2-0,6 mm	0,6-0,2 mm	0,2-0,1 mm	0,1-0,06 mm	0,06-0,02 mm	0,02-0,006 mm	0,006-0,002 mm	<0,002 mm	Sand	Silt	Leir
Ap	0 - 33	3	4,1	6,9	6,4	13,0	32,3	14,2	8,0	15,1	30,4	54,5	15,1
Bw	33 - 41	0	0,0	0,2	4,3	18,0	42,5	14,0	7,0	14,0	22,5	63,5	14,0
Cg1	41 - 56	0	0,1	2,1	25,9	26,6	28,3	5,6	2,9	8,5	54,7	36,8	8,5
Cg2	56 - 72	0	0,0	1,3	33,5	30,3	23,5	3,5	1,8	6,1	65,1	28,8	6,1
Cg3	72 - 88	0	0,2	0,7	1,2	4,1	28,7	27,2	15,3	22,6	6,2	71,2	22,6

Sjikt	Tykkelse	pH		Tot C	Tot N	Ombyttb. Kationer (meq/100g)					B.met.	Tørrst.
	cm	H_2O	$CaCl_2$	%	%	H	K	Na	Mg	Ca	%	%
Ap	0 - 33	5,9	5,4	2,4	0,17	4,90	0,30	0,14	0,95	5,91	60	98,9
Bw	33 - 41	6,7	5,9	0,2	0,05	1,40	0,06	0,06	1,12	3,07	76	99,5
Cg1	41 - 56	6,7	6,0	0,1	0,05	0,80	0,06	0,07	0,69	2,01	78	99,7
Cg2	56 - 72	6,9	6,2	0,1	0,05	1,50	0,06	0,09	0,49	1,74	61	99,7
Cg3	72 - 88	7,1	6,3	0,1	0,05	2,00	0,28	0,30	3,60	2,91	78	99,3

Sjikt	Tykkelse	Prøve-dyp	Penetr.*	Luft	Porer	Mat. tetthet	Jord-tetthet	Vann led
	cm	cm	kN/cm²	vol %		g/cm³		cm/h
Ap	0 - 33	5-9	Ikke målt	6,6	44,7	2,66	1,47	0,82
Bw	33 - 41	35-39	Ikke målt	1,8	34,7	2,81	1,84	0,04
Cg1	41 - 56	44-48	Ikke målt	3,7	37,4	2,77	1,73	0,06
Cg2	56 - 72	60-65	Ikke målt	3,8	47,1	2,77	1,45	1,36
Cg3	72 - 88	Ikke prøvetatt	Ikke målt	-	-	-	-	-

* Gjennomsnitt av 5 målinger med penetrometer

Sjikt	Tykkelse	Prøve-dyp	Volumprosent vann ved					Nytt.b. vann
	cm		Metn	pF 1,2	pF 2	pF 3	pF 4,2	Vol %
Ap	0 - 33	5-9	43,9	41,5	39,0	34,8	9,6	29,4
Bw	33 - 41	35-39	39,5	36,4	32,9	23,0	7,2	25,6
Cg1	41 - 56	44-48	41,4	37,9	33,7	18,0	6,2	27,6
Cg2	56 - 72	60-65	53,3	48,1	43,7	36,9	11,0	32,7
Cg3	72 - 88	Ikke prøvetatt	-	-	-	-	-	-

Stasjon nr.	**:** 36 FÅVANG	**Beskrevet:**	7. juli 1997
Beliggenhet	**:** Profilet ligger i et lite søkk, helling 2% mot NV, på elvesletta mellom Gudbrandsdalslågen og Tromsa.		
Lokalisering	**:** Profilet er beskrevet 7,3 m og 140 nygader fra værstasjonen.		
Opphavsmateriale	**:** elveavsetning	**Vekst**	**:** bygg
Dreneringsgrad	**:** godt	**Profildybde**	**:** 120 cm
Stein og blokk	**:** < 0,1 %	**Fjellblotninger**	**:** ingen
Grunnvannsnivå	**:** > 120 cm		
Klassifikasjon			
FAO$_{90}$	**:** Dystric Regosol		
WRB$_{98}$	**:** Dystric Cambisol		
Soil Taxonomy$_{98}$	**:** Typic Dystrocryept		
NIJOS jordtype	**:** Ls5		
Merknad:			

Profilbeskrivelse (alle farger er beskrevet i fuktig jord, sjiktdybder i cm)

Ap1 (0 - 26)	Mørk grå (10YR 4/1) sandig silt; 2-5% små, uregelmessig formet stein av krystallinsk opprinnelse; moderat utviklet grov skarpkanta blokkstruktur og moderat utviklet grov kornstruktur; ikke klebrig og ikke plastisk i våt tilstand; mange middels porer; noen tilfeldig fordelte svært fine røtter; tydelig og svakt bølgende sjiktgrense.
Ap2 (26 - 45)	Mørk gråbrun (10YR 4/2) sandig silt; svakt utviklet grov avrundet blokkstruktur som brytes opp i svakt utviklet fin grynstruktur; ikke klebrig og ikke plastisk i våt tilstand; noen fine og mange middels porer; få svært fine røtter fordelt i markganger; skarp og svakt bølgende sjiktgrense.
Bw1 (45 - 50)	Lys oliven brun (2.5Y 5/3) sandig silt; svakt utviklet middels avrunda blokkstruktur; ikke klebrig og ikke plastisk i våt tilstand; mange middels og mange grove porer; få svært fine røtter fordelt i markganger; tydelig og svakt bølgende sjiktgrense.
Bw2 (50 - 80)	Mørk gulbrun (10YR 4/4) siltig mellomsand; enkeltkorn; mange middels og mange grove porer; få svært fine røtter fordelt i markganger; skarp og brutt sjiktgrense.
C (80 -)	Mineralfarget grovsand; enkeltkorn; opptrer som lommer i Bw2.

Fysiske og kjemiske data for stasjon 36, FÅVANG

Sjikt	Tykkelse	Frasikt	Kornstørrelsesfordeling (%)								%		
	cm	%	2-0,6 mm	0,6-0,2 mm	0,2-0,1 mm	0,1-0,06 mm	0,06-0,02 mm	0,02-0,006 mm	0,006-0,002 mm	<0,002 mm	Sand	Silt	Leir
Ap1	0 - 26	5	4,7	7,7	7,3	5,6	34,8	22,5	8,1	9,2	25,3	65,4	9,2
Ap2	26 - 45	2	3,3	12,9	10,4	7,8	24,5	23,5	9,4	8,3	34,4	57,4	8,3
Bw1	45 - 50	2	1,2	20,0	10,8	6,3	21,5	25,1	8,3	6,9	38,3	54,9	6,9
Bw2	50 - 80	0	4,8	37,1	20,6	8,0	14,3	7,3	4,5	3,5	70,5	26,1	3,5
C	80 +	6	39,6	41,3	6,9	2,5	4,2	2,2	0,4	2,8	90,3	6,8	2,8

Sjikt	Tykkelse	pH		Tot C	Tot N	Ombyttb. Kationer (meq/100g)					B.met.	Tørrst.
	cm	H_2O	$CaCl_2$	%	%	H	K	Na	Mg	Ca	%	%
Ap1	0 - 26	6,3	5,7	2,1	0,21	3,90	0,06	0,33	1,43	8,99	73	98,8
Ap2	26 - 45	6,2	5,4	1,3	0,11	5,10	0,06	0,08	1,11	5,39	57	98,8
Bw1	45 - 50	6,0	5,4	0,6	0,06	4,20	0,06	0,08	0,59	2,52	44	99,2
Bw2	50 - 80	6,1	5,4	0,2	0,05	2,40	0,06	0,02	0,32	1,25	41	99,6
C	80 +	6,1	5,3	0,1	0,05	1,60	0,06	0,02	0,16	0,61	35	99,8

Sjikt	Tykkelse	Prøve-dyp	Penetr.*	Luft	Porer	Mat. tetthet	Jord-tetthet	Vann led
	cm	cm	kN/cm^2	vol %		g/cm^3		cm/h
Ap1	0 - 26	1-5	4.45	8,3	49,6	2,75	1,39	9,46
Ap2	26 - 45	32-36	3,15	17,3	54,2	2,80	1,27	4,33
Bw1	45 - 50	Ikke prøvetatt	2,60	-	-	-	-	-
Bw2	50 - 80	69-73	0,70	30,3	51,1	2,78	1,32	14,34
C	80 +	Ikke prøvetatt	0,18	-	-	-	-	-

* Gjennomsnitt av 5 målinger med penetrometer

Sjikt	Tykkelse	Prøve-dyp	Volumprosent vann ved					Nytt.b. vann
	cm		Metn	pF 1,2	pF 2	pF 3	pF 4,2	Vol %
Ap1	0 - 26	1-5	52,1	46,6	41,3	35,0	9,2	32,1
Ap2	26 - 45	32-36	51,1	46,1	37,5	27,2	6,0	31,4
Bw1	45 - 50	Ikke prøvetatt	-	-	-	-	-	-
Bw2	50 - 80	69-73	43,2	38,7	22,3	12,0	3,0	19,4
C	80 +	Ikke prøvetatt	-	-	-	-	-	-

Stasjon nr. : 6 SKOGMO **Beskrevet:** 9. oktober 1997

Beliggenhet : Profilet ligger i midtre del av en rett moderat hellende (10%) nordøstvent skråning, på en elveterasse.

Lokalisering : Profilet er beskrevet 8 m nord for værstasjonen.

Opphavsmateriale	: elveavsetning	**Vekst**	: korn
Dreneringsgrad	: dårlig	**Profildybde**	: 110 cm
Stein og blokk	: < 0,1 %	**Fjellblotninger**	: ingen
Grunnvannsnivå	: 100 cm		

Klassifikasjon
FAO$_{90}$: Anthrosol
WRB$_{98}$: Orthidystric Gleysol
Soil Taxonomy$_{98}$: Typic Cryaquent
NIJOS jordtype : Po3

Merknad: Lokaliteten ble planert på 70-tallet.

Profilbeskrivelse (alle farger er beskrevet i fuktig jord, sjiktdybder i cm)

Ap (0 - 25) Mørk gråbrun (2.5Y 4/2) siltig mellomsand; svakt utviklet, grov, avrundet blokkstruktur og svakt utviklet, middels, grynstruktur; ikke klebrig og ikke plastisk i våt tilstand; få svært fine og få fine porer; noen svært fine tilfeldig fordelte røtter; tydelig og svakt bølgende sjiktgrense.

Apd (25 - 35) Olivenbrun (2.5Y 4/3) siltig mellomsand; svakt utviklet, svært tykk platestruktur; sammenhengende plogsåle; ikke klebrig og ikke plastisk i våt tilstand; få svært fine porer; få svært fine tilfeldig fordelte røtter; tydelig og svakt bølgende sjiktgrense.

Cg (35 -) Mørk grønngrå (5GY 4/1) siltig finsand med olivengrå (5Y 4/2) større felt som dekker 20-50% av sjiktet; få svært fine porer; sjiktet bærer preg av planeringen med en blanding av opprinnelig C-sjikt materiale, A-sjikt materiale og begravde røtter.

Fysiske og kjemiske data for stasjon 6, SKOGMO

Sjikt	Tykkelse	Frasikt	Kornstørrelsesfordeling (%)								%		
	cm	%	2-0,6 mm	0,6-0,2 mm	0,2-0,1 mm	0,1-0,06 mm	0,06-0,02 mm	0,02-0,006 mm	0,006-0,002 mm	<0,002 mm	Sand	Silt	Leir
Ap	0 - 25	0	0,2	19,4	22,1	14,2	32,6	7,2	1,6	2,7	55,9	41,4	2,7
Apd	25 - 35	0	0,0	17,6	19,6	13,4	38,9	6,9	1,2	2,4	50,6	47,0	2,4
Cg	35 +	1	0,5	14,5	28,9	17,5	30,1	5,3	1,2	2,0	61,4	36,6	2,0

Sjikt	Tykkelse	pH		Tot C	Tot N	Ombyttb. Kationer (meq/100g)					B.met.	Tørrst.
	cm	H_2O	$CaCl_2$	%	%	H	K	Na	Mg	Ca	%	%
Ap	0 - 25	5,4	4,5	0,7	0,05	3,90	0,06	0,02	0,07	0,38	12	99,5
Apd	25 - 35	5,8	5,0	0,2	0,05	2,80	0,15	0,04	0,03	0,28	15	99,7
Cg	35 +	6,1	5,4	0,1	0,05	1,60	0,13	0,07	0,04	0,58	34	99,8

Sjikt	Tykkelse	Prøve-dyp	Penetr.*	Luft	Porer	Mat. tetthet	Jord-tetthet	Vann led
	cm	cm	kN/cm^2	vol %		g/cm^3		cm/h
Ap	0 - 25	11-15	2,00	10,1	46,5	2,84	1,52	0,90
Apd	25 - 35	27-31	4,15	2,3	40,1	2,74	1,64	0,78
Cg	35 +	60-64	0,81	19,5	47,2	2,72	1,43	4,96

* Gjennomsnitt av 5 målinger med penetrometer

Sjikt	Tykkelse	Prøve - dyp	Volumprosent vann ved					Nytt.b. vann
	cm		Metn	pF 1,2	pF 2	pF 3	pF 4,2	Vol %
Ap	0 - 25	11-15	43,9	42,9	36,3	20,8	3,3	33,1
Apd	25 - 35	27-31	42,7	40,7	38,3	18,9	2,9	35,4
Cg	35 +	60-64	41,2	39,9	28,8	8,6	1,6	27,2

Appendix A7

Table A28. Input data used for the calculation of exposure concentrations for phatlaic esters, octyl- and nonylephenol and octyl- and nonylephenolmonoethoxilates, as well as LAS.

	DEHP	DBP	Octyl-Phenol	Octylphenol-etoksilat	Nonyl-phenol	Nonylphenol ethoxilate	LAS
Fordelingskoeffisient jord/vann (Kd) (m3 m-3)	90000	45	18	15	47	15	71
Fordelingskoeffisient jord/vann (Kd) (l/kg)	126000	63	25	21	66	21	100
Halveringstid i jord (dager)	300	20	10	5	10	5	8
Foc	0.02	0.02	0.02	0.02	0.02	0.02	0.02
log Kow	7.5	4.57	4.12	4.00	4.48	4.00	3.70
Koc (Kd/foc)	6300000	3150	1250	1050	3300	1050	5000
Henry (Pa m3 mol-1)	0.0446	0.132	0.49	0.49	1.57	1.57	0.49
Kair-water	1.882E-05	5.571E-05	2.07E-04	2.07E-04	6.63E-04	6.63E-04	2.07E-04

Table A29. Input data used for the calculation of exposure concentrations for PAHs

	Naftalen	Ace-naftylen	Acenaften	Fenantren	Antracen	Fluoren	Fluoranten	Pyren	Benzo(a) antracen	Krysen	Benzo(b) fluoranten	Indeno (1.2.3-cd)pyren	Dibenzo (a.h)antracen	(g.h.i
(Kd) (m3 m-3)	7	21	24	121	143	42	1081	483	4409	3752	1563	7487	13431	
(Kd) (l/kg)	10	30	34	170	200	59	1514	676	6172	5253	2188	10482	18804	
Halflife (days)	30	50	50	50	50	50	150	200	150	300	450	600	600	
Foc	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	
Log Kow	3.30	3.90	3.90	4.47	4.45	4.20	5.10	5.10	5.54	5.81	5.78	6.87	7.11	
Koc (Kd/foc)	500	1500	1700	8500	10000	2950	75700	33800	308600	262650	109400	524100	940200	
Henry (Pa m3 mol-1)	48.900	11.600	14.800	5.500	6.600	7.800	1.100	1.100	0.800	0.500	0.051	0.029	0.007	
Kair-water	2.06E-02	4.90E-03	6.25E-03	2.32E-03	2.79E-03	3.29E-03	4.64E-04	4.64E-04	3.38E-04	2.11E-04	2.15E-05	1.22E-05	3.12E-06	

Table A30. Input data used for the calculation of exposure concentrations for PCBs.

	PCB-28	PCB-52	PCB-101	PCB-118	PCB-138	PCB-153	PCB-180
Fordelingskoeffisient jord/vann (Kd) (m3 m-3)	451	1136	5686	9014	11357	14286	56857
Fordelingskoeffisient jord/vann (Kd) (l/kg)	632	1590	7960	12620	15900	20000	79600
Halveringstid i jord (dager)	1000	3600	3600	3600	6900	6900	13000
Foc	0.02	0.02	0.02	0.02	0.02	0.02	0.02
log Kow	5.60	5.80	6.20	6.50	7.00	7.00	7.20
Koc (Kd/foc)	31600	79500	398000	631000	795000	1000000	3980000
Henry (Pa m3 mol-1)	30	17	17	12	11	10	3
Kair-water	1.27E-02	7.17E-03	7.17E-03	5.06E-03	4.64E-03	4.22E-03	1.35E-03

Appendix A8

Table A31. Intake of cadmium from food.

Cadmium						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present** **µg/dag**	**After 100 years** **µg/dag**	**40 tons/year** **µg/dag**	**60 tons/year** **µg/dag**	**40 tons/year** **µg/dag**	**60 tons/year** **µg/dag**
Cereals	5.67	0.52	3.42	5.13	9.6	11
Potato	2.43	0.22	0.66	2.20	3.3	4.85
Carrot	0.63	0.06	0.38	0.57	1.1	1.25
Swede	0.20	0.02	0.12	0.18	0.35	0.41
Cabbage	0.17	0.02	0.10	0.15	0.28	0.33
Cauliflower	0.02	0.00	0.01	0.02	0.04	0.05
Chinese cabbage	0.18	0.02	0.11	0.16	0.31	0.36
Cucumber	0.27	0.02	0.16	0.24	0.45	0.54
Tomato	0.27	0.02	0.16	0.24	0.45	0.54
Peppers	0.18	0.02	0.11	0.16	0.31	0.36
Mixtures	0.42	0.04	0.25	0.38	0.71	0.84
Unspecified vegetables	0.75	0.07	0.45	0.68	1.3	1.49
Meat	0.013	0.001	0.01	0.01	0.02	0.03
Liver	0.031	0.003	0.02	0.03	0.05	0.06
Fish	3.55				3.6	3.6
Total daily intake (mean)	**15**	**1.0**	**6.0**	**10**	**22**	**26**
High intake of main source	**21**	**1.6**	**9.5**	**15**	**32**	**38**

Table A32. Intake of lead from food.

Lead						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present µg/dag**	**After 100 years µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**
Cereals	4.1	0.06	0.62	0.93	4.79	5.1
Potato	0.88	0.01	0.13	0.20	1.03	1.1
Carrot	0.23	0.004	0.03	0.05	0.26	0.28
Swede	0.07	0.001	0.01	0.02	0.09	0.09
Cabbage	0.13	0.002	0.02	0.03	0.15	0.16
Cauliflower	0.02	0.0003	0.00	0.004	0.02	0.02
Chinese cabbage	0.14	0.002	0.02	0.03	0.16	0.17
Cucumber	0.21	0.003	0.03	0.05	0.24	0.26
Tomato	0.21	0.003	0.03	0.05	0.24	0.26
Peppers	0.14	0.002	0.02	0.03	0.16	0.17
Mixtures	0.15	0.002	0.02	0.03	0.18	0.19
Unspecified vegetables	0.27	0.0043	0.04	0.06	0.32	0.34
Meat	0.01	0.0002	0.00186	0.003	0.01	0.02
Liver	0.03	0.0005	0.00440	0.007	0.03	0.04
Fish	2.2				2.2	2.2
Total daily intake (mean)	**8.8**	**0.1**	**1.0**	**1.5**	**9.9**	**10**
High intake of main source	**13**	**0.2**	**1.6**	**2.5**	**15**	**16**

Table A33. Intake of mercury from food.

Mercury						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present µg/dag**	**After 100 years µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**
Cereals	0.12	0.01	0.39	0.58	0.52	0.71
Potato	0.03	0.003	0.08	0.12	0.11	0.15
Carrot	0.01	0.0007	0.02	0.03	0.03	0.04
Swede	0.002	0.0002	0.01	0.01	0.009	0.01
Cabbage	0.001	0.0001	0.002	0.004	0.003	0.004
Cauliflower	0.0001	0.00001	0.00034	0.001	0.0005	0.0006
Chinese cabbage	0.001	0.00009	0.003	0.004	0.004	0.005
Cucumber	0.001	0.0001	0.004	0.006	0.005	0.007
Tomato	0.001	0.0001	0.004	0.006	0.005	0.007
Peppers	0.001	0.00009	0.003	0.004	0.004	0.005
Mixtures	0.00	0.0005	0.01	0.02	0.02	0.03
Unspecified vegetables	0.01	0.0009	0.03	0.04	0.03	0.05
Meat	0.00003	0.000003	0.0001	0.0001	0.0001	0.0002
Liver	0.00007	0.000008	0.0002	0.0003	0.0003	0.0004
Fish	4.1				4.1	4.1
Total daily intake (mean)	**4.2**	**0.02**	**0.6**	**0.8**	**4.8**	**5.1**
High intake of main source	**4.1**	**0.03**	**1.0**	**1.4**	**5.3**	**5.8**

Table A34. Intake of nickel from food.

Nickel						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present µg/dag**	**After 100 years µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**
Cereals	254	4.9	28	42	286	300
Potato	78	1.5	8.5	13	88	92
Carrot	20	0.38	2.2	3.3	22.6	24
Swede	6.5	0.13	0.71	1.1	7.4	7.7
Cabbage	1.6	0.03	0.17	0.26	1.8	1.9
Cauliflower	0.22	0.004	0.02	0.04	0.25	0.26
Chinese cabbage	1.7	0.03	0.19	0.00	1.95	1.8
Cucumber	2.6	0.05	0.28	0.42	2.90	3.0
Tomato	2.6	0.05	0.28	0.42	2.90	3.0
Peppers	1.7	0.03	0.19	0.28	1.95	2.0
Mixtures	13	0.26	1.5	2.2	15	16
Unspecified vegetables	24	0.46	2.6	3.9	27	28
Meat	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Liver	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Fish	n.a.	n.a.			n.a.	n.a.
Total daily intake (mean)	**406**	**7.8**	**44**	**66**	**458**	**480**
High intake of main source	**669**	**13**	**73**	**110**	**755**	**792**

n.c: not calculated
n.a. no data available

Table A35. Intake of zinc from food.

Zinc						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
	Present	**After 100 years**	**40 tons/year**	**60 tons/year**	**40 tons/year**	**60 tons/year**
Food item	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**	**µg/dag**
Cereals	2194	67	1856	2784	4117	5045
Potato	940	29	795	1193	1764	2162
Carrot	242	7.4	205	307	455	557
Swede	79	2.4	67	100	148	182
Cabbage	69	2.1	58	88	129	159
Cauliflower	9.6	0.3	8.1	12	18	22
Chinese cabbage	75	2.3	63	95	140	172
Cucumber	111	3.4	94	141	209	256
Tomato	111	3.4	94	141	209	256
Peppers	75	2.3	63	95	140	172
Mixtures	163	5.0	138	207	306	376
Unspecified vegetables	290	8.9	245	368	544	666
Meat	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Liver	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Fish	n.a.	n.a.			n.a.	n.a.
Total daily intake (mean)	4359	133	3687	5531	8180	10024
High intake of main source	6641	203	5617	8425	12460	15269

n.c: not calculated
n.a. no data available

Table A36. Intake of copper from food.

Copper						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present µg/dag**	**After 100 years µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**
Cereals	989	40	2278	3417	3307	4446
Potato	212	8.6	488	732	708	952
Carrot	55	2.2	126	189	183	245
Swede	18	0.7	41	61	60	80
Cabbage	6.2	0.3	14	21	21	28
Cauliflower	0.9	0.0	2.0	3.0	2.9	3.9
Chinese cabbage	6.7	0.3	16	23	23	30
Cucumber	10	0.4	23	35	34	45
Tomato	10	0.4	23	35	34	45
Peppers	6.7	0.3	16	23	23	30
Mixtures	37	1.5	85	127	123	165
Unspecified vegetables	65	2.6	150	226	218	294
Meat	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Liver	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Fish	n.a.	n.a.			n.a.	n.a.
Total daily intake (mean)	**1416**	**57**	**3261**	**4892**	**4734**	**6365**
High intake of main source	**2444**	**99**	**5629**	**8444**	**8172**	**10986**

n.c: not calculated
n.a. no data available

Table A37. Intake of chromium from food.

Chromium						
	Background	**Other sources**	**Sewage sludge 100 years**		**Total**	
Food item	**Present µg/dag**	**After 100 years µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**	**40 tons/year µg/dag**	**60 tons/year µg/dag**
Cereals	93	1.5	13	20	108	115
Potato	20	0.31	2.9	4.3	23	25
Carrot	5.1	0.08	0.74	1.11	6.0	6.3
Swede	1.7	0.03	0.24	0.36	1.9	2.1
Cabbage	0.29	0.00	0.04	0.06	0.34	0.36
Cauliflower	0.04	0.00	0.01	0.01	0.05	0.05
Chinese cabbage	0.32	0.00	0.05	0.07	0.37	0.39
Cucumber	0.47	0.01	0.07	0.10	0.55	0.58
Tomato	0.47	0.01	0.07	0.10	0.55	0.58
Peppers	0.32	0.00	0.05	0.07	0.37	0.39
Mixtures	3.46	0.05	0.50	0.75	4.0	4.3
Unspecified vegetables	6.1	0.10	0.88	1.3	7.1	7.6
Meat	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Liver	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Fish	n.a.	n.a.			n.a.	n.a.
Total daily intake (mean)	**131**	**2.1**	**19**	**28**	**152**	**162**
High intake of main source	**228**	**3.6**	**33**	**49**	**264**	**281**

n.c: not calculated
n.a. no data available

APPENDICES – PART B

Appendix B1: The Anatomical Therapeutic Chemical (ATC) classification system

In Norway, as well as in many other countries worldwide, the Anatomical Therapeutic Chemical (ATC) classification system is used (http://www.whocc.no/atcddd). This classification system divide the drugs into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. The various drugs are classified into groups at five different levels of which the 1st level consist of the following main groups:

A	Alimentary tract and metabolism
B	Blood and blood forming organs
C	Cardiovascular system
D	Dermatologicals
G	Genito-urinary system and sex hormones
H	Systemic hormonal preparations, excl. se hormones and insulins
I	Immunologicals
J	Antiinfectives for systemic use
L	Antineoplastic and immunomodulating agents
M	Musculo-skeletal system
N	Nervous system
P	Antiparasitic products, insecticides and repellents
R	Respiratory organs
S	Sensory organs
V	Various

Each main group (1st level) is split into therapeutic subgroups (2nd level) that are further split into pharmacological subgroups (3rd level) and chemical subgroups (4th level). The 5th level represents the chemical substance. The complete classification of norethisterone illustrates the system:

G	Genito-urinary system and sex hormones (1st level, anatomical main group)
G03	Sex hormones and modulators of the genital system (2nd level, therapeutic subgroup)
G03A	Hormonal contraceptives for systemic use (3rd level, pharmacological subgroup)
G03AC	Progestogens (4th level, chemical subgroup)
G03AC01	Norethisterone (5th level, chemical substance)

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Postboks 4404 Nydalen
0403 Oslo
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