EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Preliminary report on the environmental risks and indirect health effects of mercury in dental amalgam

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

The SCHER approved this preliminary report for the public consultation at the 20th plenary on 29 November 2007

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER
Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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http://ec.europa.eu/health/ph_risk/risk_en.htm

3.1.2 Screening risk assessment

3.1.2.1 Direct risk for aquatic organisms: inorganic mercury

Information on emissions of mercury from dental practices can be assessed in a preliminary manner on the basis of Hg concentrations measured in dental clinic wastewaters. Two studies, covering current practice in Sweden and USA are available. The Swedish study (Hylander et al., 2006) presents measurements for several locations ranging from 0.77 to 74.1 mg Hg/l. It must be underlined that, due to legal requirements, Swedish clinics use amalgam separators prior to wastewater discharge. The efficiency of these systems was observed to be highly variable. Indeed, the wastewater concentrations measured after inspection and revision of these systems were about one order of magnitude lower, i.e. ranging from 0.23 to 6.6 mg Hg/l.

The concentrations measured in the USA (Stone et al., 2003) are similar to those reported for Sweden, ranging between 1.8 and 173 mg Hg/l for individual measurements. Site averages (5.4, 13.4 and 45.1 mg/l) were within the range observed for the Swedish locations. The presence of amalgam separators is not mentioned in the USA study, but the samples were collected from the liquid portion of the wastewater (avoiding settled material).

SCHER used the above information to estimate the releases of mercury to the wastewater system.

The Swedish study also reports annual release estimations, ranging from 0.32 to 83.8 g Hg per dental chair and per year, with a mean value of 14.5 g. Considering an average EU value of 80 dentists per 100,000 inhabitants (Eurostat web page, 2007), and the default values for a wastewater treatment plant (WWTP) described in the TGD (2003), the concentration of Hg in the WWTP inflow due to dental practice are estimated to be in the range of 3.5 to 918 µg Hg/l with and average value of 159 µg Hg/l. Assuming a retention at the WWTP of 96% due to sludge adsorption and a default dilution factor of 10, the expected Hg contribution from dental clinics in river waters receiving municipal effluents is calculated to range between 0.000014 and 0.0037 µg Hg/l, with an average value of 0.00064 µg/l or 0.64 ng/l.

It is clear that this contribution of Hg originating from dental amalgam use should be added to the natural and historical background concentrations as well as to the contribution from other Hg sources to fully assess the risks of Hg to the environment.

The comparison of these exposure estimations with the EC proposal for an Ecological Quality Standard (EQS) for direct effects of mercury on aquatic organisms (0.05 µg Hg/l as annual average and 0.07 µg Hg/l as maximum permissible concentration) indicates that the added risk to aquatic organisms from the contributions from dental clinics to the total mercury should be considered low.

3.1.2.2 Direct risk for soil organisms: inorganic mercury

A similar approach, using the generic TGD scenarios and default values, can be used for the preliminary assessment of the potential risk for soil dwelling organisms of mercury released from dental practice. Based on a default average production of 0.071 kg of sludge per person per day at the WWTP, the concentration of mercury in sludge as a consequence of releases from dental clinics is calculated to range between 0.001 and 2.4 mg Hg/kg dw with and average value of 0.42 mg/kg dw.

Considering that the reported EU average Hg concentration in sludge is 1.5 mg Hg/kg (http://ec.europa.eu/environment/chemicals/mercury), it is suggested – based on this information – that the contribution of dental clinics represents about one third of the Hg total releases to the terrestrial compartment.

From a risk assessment perspective these values are well below the current EU legal limits established under Directive 86/218/EEC. However, it should be mentioned that these limits have not been updated based on current knowledge. The added predicted

environmental concentrations (PEC) soil resulting from the contribution of dental clinic emissions - following the TGD default values - range from 0.016 to 4.1 µg Hg/kg i.e. concentrations well below the reported NOECs for soil dwelling organisms (e.g. Verbruggen et al., 2001; de Vries et al., 2007). Thus, based on this screening risk assessment, a low direct risk to the soil compartment of dental Hg is expected.

The atmospheric emissions and further deposition of mercury from crematoria should be considered as an additional contribution of mercury from dental amalgams. The few measurements which are available indicate a large variability. The contribution from this source may be significant in some local scenarios, while the environmental relevance cannot be assessed without an in-depth analysis of the soil fate and ecotoxicology of mercury in soils based on recent developments concerning the environmental risk assessment of metals (e.g. SCHER opinions on the RAR for several metals).

3.1.2.3 Risks associated to the direct emissions of methylmercury from dental practice.

The concerns related to mercury in dental amalgams have been enhanced by the identification of methylmercury in wastewater from dental units in the USA. The measured concentrations where particularly high in tanks from large clinics (up to 0.2% of the total mercury) suggesting methylation within the tank. This maybe the result of the activity of sulphate reducing bacteria, which are present in the oral cavity of humans, and can therefore be released during the dental intervention. Methylation may also occur in the oral cavity but the methylmercury levels measured in the chair side wastewater where at least one order of magnitude lower that those measured in the tanks (Stone et al., 2003).

It should be noted that although the study was conducted in the USA, the levels of total mercury measured in the wastewater were similar to those reported for the EU.

Assuming 0.2% of the total mercury is released as methylmercury (Stone et al., 2003), and using similar exposure estimations as those conducted for inorganic mercury, the concentration of methylmercury in the WWTP inflow due to dental practice is estimated to be in the range of 0.000007-0.0018 MeHg µg/l with an average value of 0.0003 µg/l. Assuming a retention at the WWTP of 96% due to sludge adsorption and a default dilution factor of 10, the expected contribution from dental clinics in river waters receiving municipal effluents is estimated to range between 7×10^{-9} to 1.8×10^{-6} µg/l, with an average value of 3.2×10^{-7} µg/l. Also here, this value need to be added to the natural and historical background concentrations as well as to the contribution from any additional sources of methylmercury - including the methylation in the environment of the inorganic mercury released by the dental clinics – to assess the overall risk of methylmercury.

The main environmental concern for methylmercury is its potential for bioaccumulation and food web biomagnification resulting in a risk for secondary poisoning in ictivorous vertebrates. Thus, this screening risk assessment focused on secondary poisoning. It should be noted that the reported bioaccumulation factors (BAF) measured in the field for fish species collected at different locations range from about 20,000 to over 20,000,000. Using the larger values in this range, the releases of methylmercury (originating from dental amalgam) would exceed the EC proposal (within the Water Framework Directive (WFD)) of 20 µg methylmercury/kg in the prey of birds and mammals (EC, 2006a).

A preliminary risk estimation can be done by combining the TGD defaults with the individual values for each Swedish location and the field BAF (geometric means) reported in the WFD-EC document (EC, 2005). The Swedish values were considered as estimations of the expected releases to the WWTP. The default generic values of the TGD were used for estimating the PEC in water from these releases. The PECs were the multiplied by the BAF to estimate the expected concentration of mercury resulting from releases due to amalgam uses. Individual releases and BAF values were randomly combined using Monte Carlo analysis. The results are presented in Figure 1 and show that the risk of exceeding

the EC proposal considering exclusively the direct emissions of methylmercury from dental facilities is of about 6%. If this contribution is assumed to represent about 10% of total anthropogenic contribution for methylmercury, the exceedance risk would rise to about 18%.

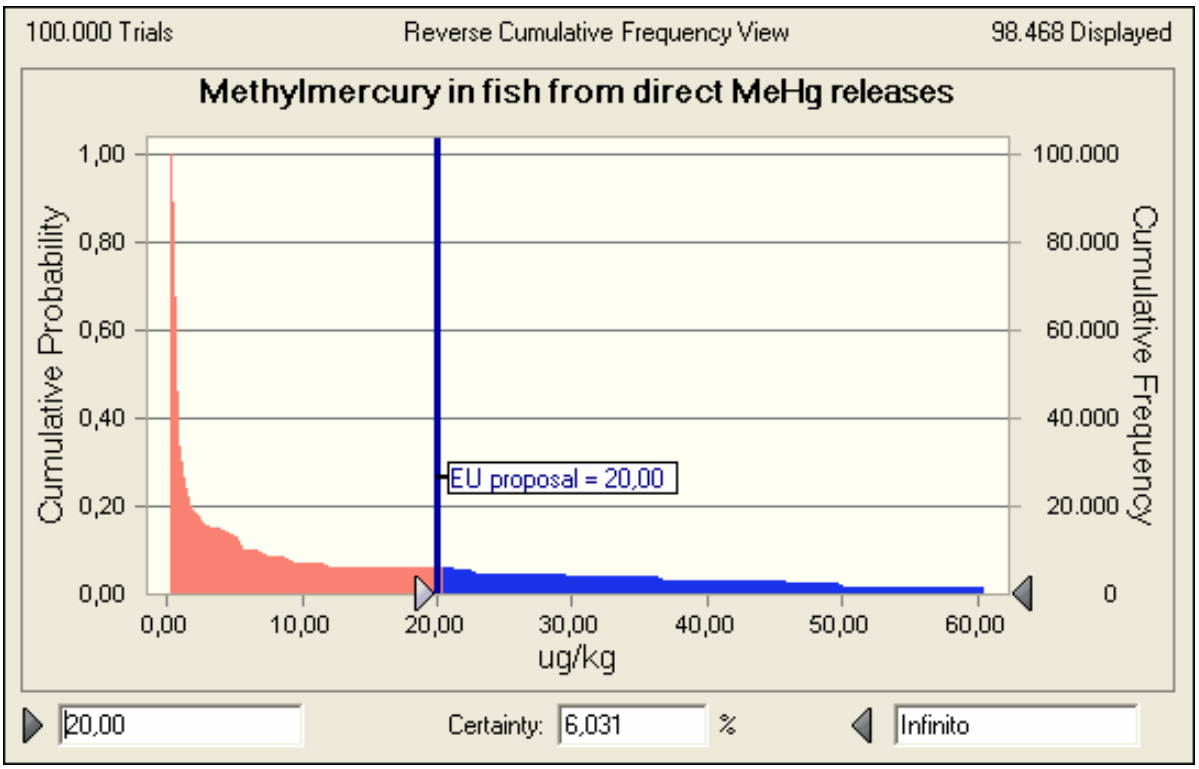

Figure 1- Preliminary estimation of the risk for exceeding the EC proposal for the concentration of methylmercury in aquatic organisms as the result of the direct emissions of methylmercury from the dental use.

3.1.2.4 Risk associated to the environmental methylation of inorganic mercury: secondary poisoning, bioaccumulation and biomagnification potential for inorganic mercury releases.

The main concern related to the anthropogenic emissions of mercury into the environment is related to the well-known potential of this metal to bioaccumulate and biomagnify through the food chain resulting in high levels of exposure for top predators, including humans.

The bioaccumulation of inorganic mercury in biota - although significant and described even for the mercury present in dental amalgams (Kennedy, 2003) - is generally regarded to be of low relevance compared to that of organic forms of mercury and particularly methylmercury.

The potential for biomagnification is, therefore, related to the methylation of inorganic mercury which may result from both abiotic and biotic processes. The later seems to be the most relevant under environmental conditions.

The potential for bioconcentration of methylmercury in aquatic organisms is orders of magnitude higher than for inorganic mercury.

When the food-web bioaccumulation is considered, the overall bioaccumulation factor (ratio between the concentration in the organisms and the concentration in water) may be well above one million (cf. above).

Although there are several models describing the bioaccumulation and biomagnification potential of mercury in different ecosystems, the variability - in terms of both the

methylation potential and the overall biomagnification - is so high that no sound generic estimations can be done with the current level of knowledge.

In fact, the conclusion presented by the European Commission within the process of setting EQSs for mercury under the FWD was that "*Due to the different site specific factors driving bioaccumulation of mercury in aquatic food webs, it seems on the basis of the current knowledge not appropriate to derive a general* $QS_{secpois}$*, water. An in depth assessment of the uncertainties associated with the bioaccumulation potential of (inorganic and organic) mercury and its toxicity to predators is required in order to derive reliable quality standards depending on site specific factors. Thus, it is suggested to set the QS for methylmercury for the time being for the concentration in biota only*".

SCHER supports this conclusion for both the aquatic and soil compartments and hence considers that it is not possible to conduct a quantitative assessment of the risk of inorganic mercury releases from dental amalgams for top predators. Nevertheless, the development of probabilistic risk estimations offers alternatives, and the possibility for conducting sensitivity analysis should be investigated (see question 4).

A preliminary assessment covering apparent methylation rates (overall result of the processes covering methylation, demethylation and transport from water column to sediment and vice versa) ranging from 0.0001 to 1% is presented in Figure 2. These results clearly show that assessing the methylation rate is a key element for a correct evaluation.

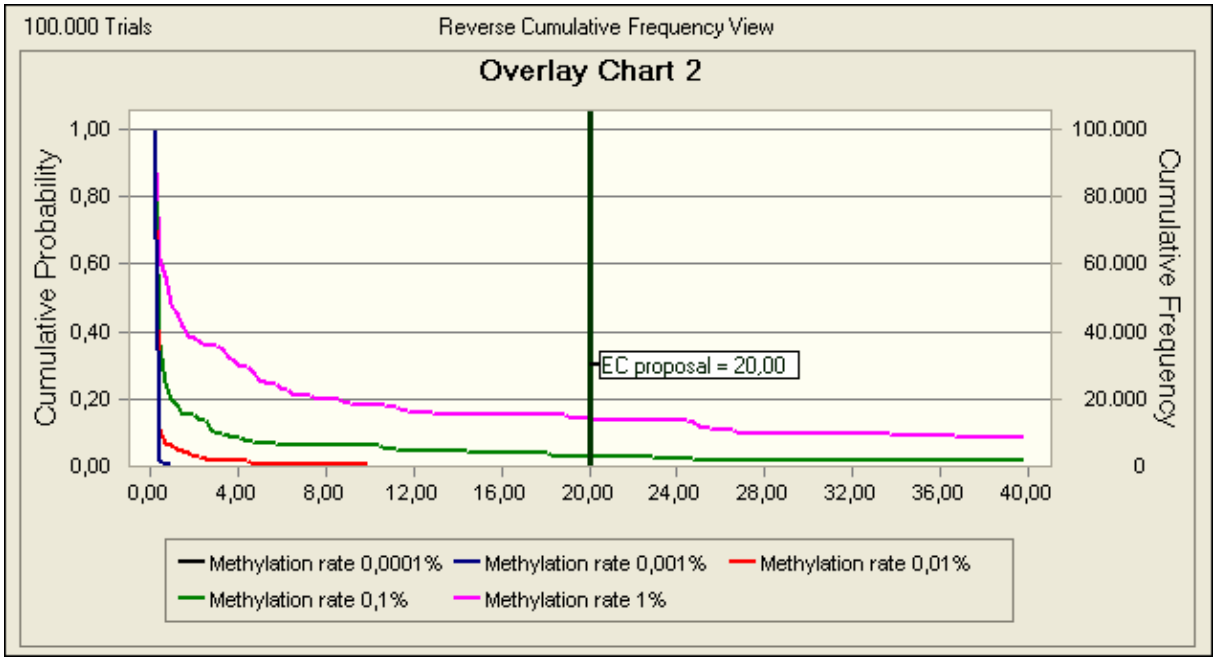

Figure 2 - Preliminary assessment of the role of environmental methylation when assessing the risk of inorganic mercury emissions from dental amalgams.

3.2 Question 2

Is it scientifically justified to conclude that mercury in dental amalgam could cause serious effects on human health due to mercury releases into the environment?

Mercury is distributed ubiquitously in the environment from many sources and can therefore be taken up by the general population via food, water and air.

Potential sources of exposure to mercury include inhalation of mercury vapours in ambient air, ingestion of drinking water and food contaminated with mercury, and exposure to mercury through dental treatments.

Dietary intake is the most important source of non-occupational exposure to mercury, with fish and other seafood products being the dominant source of mercury in the diet. Most of the mercury consumed in fish or other seafood is methylmercury (WHO 1990, 1991) (Table 1).

Sources of exposure	Elemental mercury vapour	Inorganic mercury compounds	Methylmercury
Air	0.030 (0.024)	0.002 (0.001)	0.008 (0.0064)
Food			
Fish	0	0.600 (0.042)	2.4 (2.3)
Non-fish	0	3.6 (0.25)	0
Drinking water	0	0.050 (0.0035)	0
Dental amalgams	3.8 – 21 (3 – 17)	0	0
Total	3.9 – 21 (3 – 17)	4.3 (0.3)	2.41 (2.31)

Table 1: Estimated average daily intake and retention of total mercury and mercury compounds in the general population. Values given are the estimated average daily intake (µg/day) for adults. The figures in parentheses represent the estimated amount retained in the body of an adult.

Taking these considerations on exposure into account, for indirect intake of mercury from the environment due to the uses of dental amalgams, the toxicology of inorganic mercury and methylmercury are relevant for risk assessment.

In general, the toxicology of mercury is highly depending on the route of administration and speciation of mercury (elemental mercury; inorganic salts of mercury; or methylmercury).

Oral ingestion of elemental mercury results only in a very limited absorption (< 0.01 % of dose). Dermal absorption of liquid elemental mercury is also very limited. In contrast, approximately 80 % of the inhaled elemental mercury is absorbed in the lungs. Due to the high lipid solubility, elemental mercury rapidly penetrates alveolar membranes and is then distributed to all tissues of the body. Elemental mercury is slowly oxidized in the blood.

After consumption of inorganic mercury (Hg^{2+}), only a small part of the dose ingested is absorbed from the gastrointestinal tract. Hg^{2+} absorbed or formed by oxidation of elemental Hg may be eliminated by excretion with urine and/or faeces. The elimination of elemental mercury or Hg^{2+} follows complex kinetics with half-lives in the range of 20 to 90 days.

In contrast to inorganic mercury, most of an oral dose of methylmercury is absorbed from the gastrointestinal tract. Absorbed methylmercury is rapidly and evenly distributed in the organism. The biological half-life of methylmercury blood is around 70 days. The faeces are the most important route of excretion for mercury after short-term or long-term absorption of methylmercury (approximately. 90 % of a single oral dose).

The major target organ for the toxicity of inorganic mercury is the kidney. Ingestion of high doses of Hg^{2+} results in kidney damage characterized by proximal tubular injury. In contrast, long term oral administration of Hg^{2+} to rodents causes glomerulonephritis as the most sensitive endpoint. Higher doses of inorganic mercury also cause neurotoxicity.

Methylmercury is highly toxic. Human exposures following high dose poisonings resulted in effects that included mental retardation, and sensory and motor impairment. Long term, low dose prenatal exposures to methylmercury due to maternal fish consumption has been associated with more subtle endpoints of neurotoxicity. Results from animal studies also show effects on cognitive, motor and sensory functions indicative of neurotoxicity.

Legal limits for human exposures to both Hg^{2+} and methylmercury have been established by several organisations (Table 2).

Limit value	Refers to	Organisation
0.1 μg/kg/day (methyl-mercury)	„reference dose“	US EPA, 2001
0.3 μg/kg/day (Hg^{2+})	„reference dose“	US EPA, 1987
5 μg/kg/day total mercury, maximum of 1.6 μg/kg/day as methylmercury	Provisional weekly intake	JECFA, 2003

Table 2: Limits for the intake of $Hg2^{+}$ and methylmercury.

Tolerable limits for methylmercury content of fish have also been set by different organisations. The US EPA, in a detailed analysis of studies on effects of methylmercury in humans and average fish consumption in the US, has developed a fish tissue residue criterion (concentration in fish that should not be exceeded) of 0.3 mg methylmercury/kg fish (regarding human consumption) which is similar to a maximum tolerable content of 0.5 mg methylmercury for many fish species set by EU. For a group of fish including tuna, sword fish, and halibut a limit value of 1 mg/kg is established (EC, 2006b). Therefore, the predicted indirect exposures of humans to methylmercury resulting from emissions due to dental amalgams are much lower than these tolerable limits indicating a low risk for serious health effects.

3.3 Question 3

Comparison of environmental risks from use of mercury in dental amalgam and use of alternatives without mercury

Alternatives without amalgams for dental restoration often are resins generated by polymerisation processes. Data on toxic effects of resin monomers in animals and ecotoxicological data are not available from publicly accessible sources. However, since the materials used as a basis for resin generation are derivatives of methacrylic acids and glycidyl ethers, the well studied toxicology of methacrylate and its esters may be used as a basis for structure activity relationships to predict major toxicities.

Methylmethacrylate is rapidly absorbed after oral administration in experimental animals and is rapidly catabolized by physiological pathways to carbon dioxide. The major toxic effects of methylmethacrylate in animals are skin irritation and dermal sensitization. In repeated dose-inhalation studies, local effects on respiratory tissue were noted after methylmethacrylate inhalation. Neurotoxicity and liver toxicity were observed as systemic effects after inhalation of methylmethacrylate in rats and in mice to concentrations above 3000 ppm for 14 weeks. No developmental toxicity after methylmethacrylate with a NOAEC > 2000 ppm was observed. Methylmethacrylate is also clastogenic at toxic concentrations (EU-RAR 2002).

Regarding glycidyl ethers a detailed overview of the toxicity of these compounds based mainly on unpublished study reports is available (Gardiner et al. 1992). Based on this report, skin irritation and skin sensitization are the major toxicities observed. In addition, positive effects in genetic toxicity testing were seen with many glycidyl ethers at comparatively high concentrations.

Regarding the environmental risk, the available information is too limited for conducting a proper comparative assessment of amalgams and their alternatives. It should be noted that the assessment of environmental impacts of the substitute would require two complementary studies: a comparative risk assessment for the relevant environmental compartments, and a life-cycle assessment covering non ecotoxicological impacts such those related to energy and natural resources consumption, atmospheric emissions including greenhouse gases, waste production, etc.

3.4 Question 4

If the Committee under its work finds out that more information is needed, for one or more questions, the Committee is asked to provide a detailed list on what this kind of information is needed to carry out the tasks.

From the responses given in the previous sections, it is clear that the information presently available does not allow to comprehensively assessing the environmental risks and indirect health effects from the use of dental amalgam in the Member States of the EU 27.

To allow this type of assessment, the following information is required:

- More specific information on possible regional-specific differences in the use, release and fate of Hg originating from dental amalgam. This includes detailed quantitative information on the use and release pattern in all EU 27 countries, possible country-specific abatement measures, and differences in the fate of mercury due to regional-specific municipal wastewater treatment and sludge application practices.
- A comprehensive and updated data compilation on the effects to humans and (various) environmental species of Hg and methylmercury.
- A more comprehensive evaluation of atmospheric emissions and further deposition of mercury from crematoria, taking into account EU-wide practices and possible region-specific local scenarios.
- A comprehensive literature review of the bioaccumulation and biomagnification of methylmercury under different EU conditions.
- A detailed comparison of the relative contribution of dental Hg to the overall mercury pool - originating from intended and non-intended Hg - in the environment.

4. LIST OF ABBREVIATIONS

BAF	Bio-Accumulation Factor
CSTEE	Scientific Committee on toxicity Ecotoxicity and the Environment
EEB	European Environmental Bureau
EPA	Environmental protection Agency
EQS	Ecological Quality Standard
EUSES	European Union System for the Evaluation of Substances
NO(A)EC	No Observed (Adverse) Effect Concentration
PEC	Predicted Environmental Concentration
RAR	Risk Assessment Report
RPA	Risk & Policy Analyst Ltd.
TGD	Technical Guidance Document
WFD	Water Framework Directive
WWTP	Waste Water Treatment Plant