

CWA—Clean Water Act
 DMT—dry metric tons
 EFH—Exposure Factors Handbook
 EMS—Environmental Management System
 EPA—U.S. Environmental Protection Agency
 HQ—hazard quotient
 HEI—highly exposed individual
 LADD—lifetime average daily dose
 MGD—million gallons per day
 NBP—National Biosolids Partnership
 ng TEQ/kg—nanograms toxic equivalence per kilogram body weight
 NODA—Notice of Data Availability
 NSSS—National Sewage Sludge Survey
 PCBs—polychlorinated biphenyls
 PCDDs—polychlorinated dibenzo-p-dioxins
 PCDFs—polychlorinated dibenzofurans
 pg TEQ/day—picograms toxic equivalence per day
 pg TEQ/kg-d—picograms toxic equivalence per kilogram body weight per day
 POTWs—Publicly Owned Treatment Works
 ppt—parts per trillion
 Q1*—cancer slope factor
 RfD—reference dose
 SAB—Science Advisory Board
 SERA—screening ecological risk analysis
 TBD—Technical Background Document
 TCDD—2,3,7,8-tetrachlorodibenzo-p-dioxin
 TEF—toxicity equivalency factor
 TEQ—toxic equivalence
 WHO—World Health Organization

II. What Is the Legal History of the Standards for the Use or Disposal of Sewage Sludge?

EPA promulgated Standards for the Use or Disposal of Sewage Sludge (40 CFR part 503) under section 405(d) and (e) of the Clean Water Act (CWA), 33 U.S.C. 1345(d), (e), as amended by the Water Quality Act of 1987. In these amendments to section 405 of the CWA, Congress, for the first time, set forth a comprehensive program for reducing the potential environmental risks and maximizing the beneficial use of sewage sludge. As amended, section 405(d) of the CWA requires EPA to establish numerical limitations and management practices, when appropriate, that protect public health and the environment from the reasonably anticipated adverse effects of toxic pollutants in sewage sludge. Section 405(e) prohibits any person from disposing of sewage sludge from a publicly owned treatment works (POTWs) or other treatment works treating domestic sewage for any use except in compliance with regulations promulgated under section 405.

Section 405(d) calls for two rounds of sewage sludge regulations and sets

deadlines for promulgation. In the first round, EPA was to establish numerical limits and management practices for those toxic pollutants which, based on “available information on their toxicity, persistence, concentration, mobility, or potential for exposure, may be present in sewage sludge in concentrations which may adversely affect public health or the environment.” CWA section 405(d)(2)(A). The second round is to address toxic pollutants not regulated in the first round “which may adversely affect public health or the environment.” CWA section 405(d)(2)(B).

EPA did not meet the timetable in section 405(d) for promulgating the first round of regulations, and a citizen’s suit was filed to require EPA to fulfill this mandate, (*Gearhart v. Reilly*, Civ. No. 89–6266–HO (D. Ore.)). A consent decree was entered by the court in that case, establishing schedules for both rounds of sewage sludge rules. EPA promulgated the first rule, codified at 40 CFR part 503, in 1993 at 58 FR 9248 (February 19, 1993) (“Round One”). For the second round (“Round Two”), EPA identified 31 pollutants and pollutant categories not regulated in Round One that EPA was considering for regulation. In November 1995, EPA narrowed the original list of 31 pollutants to polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin-like coplanar polychlorinated biphenyls (PCBs) for the second round of rulemaking (USEPA, 1996). The consent decree required the Administrator to sign a notice for publication proposing Round Two regulations no later than December 15, 1999, and to sign a notice taking final action on the proposal no later than December 15, 2001.

On December 15, 1999, the Administrator signed a proposal to establish numerical limits for dioxins, dibenzofurans, and co-planar PCBs (“dioxins”) in sewage sludge that is applied to the land and proposed not to regulate dioxins in sewage sludge that is disposed of in a surface disposal unit or fired in a sewage sludge incinerator (December 23, 1999, 64 FR 72045). On December 15, 2001, the Administrator signed a final notice of EPA’s determination that numerical limitations or management practices are not warranted for dioxins in sewage sludge that are disposed of in a surface disposal unit or incinerated in a sewage sludge incinerator (66 FR 66228). In that notice, EPA also announced that a final action on the Round Two proposal to amend the Standards for the Use or Disposal of Sewage Sludge for sewage sludge that is applied to the land would

be published at a later date. The consent decree in *Gearhart* was amended to extend the deadline for final action on the land application Round Two rulemaking from the original date of December 15, 2001, to a new date of October 17, 2003.

On June 12, 2002, EPA published a Notice of Data Availability (NODA) containing new information relating to dioxins in land-applied sewage sludge and requested public comments (67 FR 40554). The NODA provided a revised cancer risk assessment for dioxins in land-applied sewage sludge, newly collected data regarding concentration of dioxins in sewage sludge, and a new ecological screening risk analysis and solicited public comments.

III. What Did EPA Propose for Dioxins in Land-Applied Sewage Sludge?

A. Proposed Rule

EPA proposed a numeric limitation of 300 part per trillion (ppt) for “dioxins” measured as toxic equivalence (TEQ) in land-applied sewage sludge, and related monitoring, record-keeping and reporting requirements. EPA proposed a definition of “dioxins” to mean 29 specific congeners of PCDDs, PCDFs, and coplanar PCBs that have been found in sewage sludge. The proposed definition of “dioxins” specified seven 2,3,7,8-substituted congeners of PCDDs, ten 2,3,7,8-substituted congeners of PCDFs, and twelve coplanar PCB congeners.

The December 1999 proposal included a monitoring schedule for dioxins in land-applied sewage sludge that would have required wastewater treatment plants to monitor for dioxins in their sewage sludge for two consecutive years. EPA also proposed a modified frequency of monitoring based on analytical results from the first two years of monitoring.

EPA also proposed to exclude from the proposed numeric limit and monitoring requirements those treatment works having a flow rate equal to or less than one million gallons per day (MGD) and certain sewage sludge-only entities that receive sewage sludge for further processing prior to land application. This proposed exclusion was based on the relatively small amount of sewage sludge that is prepared by these facilities and entities and, therefore, the low probability that land application of these materials could significantly increase risk from dioxins to human health or the environment.

EPA’s proposal was based on a deterministic risk assessment and data regarding dioxins in sewage sludge