Genealogy of the Species Sensitivity Distribution — who built it, and how it became law

Companion to `SSD_DE-MINIMIS_LINEAGE.md`. That file argues the SSD is the de minimis idea applied to ecosystems; this one traces where the SSD came from, who developed it, and the pathway by which it was written into regulation — and notes the one important way the story differs from Frawley's.

Grading. [2] established in the peer-reviewed / agency literature (cited) · **[synthesis]** our reading · **[open]** to verify. No invented locators. Local primary snapshots are in `sources/`.

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0. The shape of it

The SSD has **two roots and one graft.** A **United States, regulatory-engineering root** grew out of fish toxicology at an EPA laboratory in the 1960s. A **Dutch, academic-and-policy root** grew out of theoretical biology and soil-protection law in the 1980s. They converged in the 1990s through a scientific society (SETAC) and a textbook, were codified across EU and U.S. chemical and water law, and were then tuned — toward leniency — with the chemical industry's research arm (ECETOC) at the table.

The crucial contrast with the de minimis story: **Frawley's threshold was pushed onto a reluctant FDA by an industry campaign.** The SSD was, in the main, **built by government scientists and academics and pulled into law by regulators themselves.** Industry shaped the dials afterward. Same destination — a number below which harm is declared acceptable — reached from the opposite direction. **[synthesis]**

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1. The precursor: the "application factor" (US fisheries toxicology, 1940s–1970s)

Before any distribution, there was a ratio. Aquatic toxicologists needed a way to get from what they could measure — the concentration that kills half a batch of fish in a few days (the acute LC50) — to a concentration safe for a population over a lifetime. The device was the **application factor**: divide the acute number by some figure to cover everything you did not test. **[2]**

It was given its regulatory form by two scientists at the EPA's National Water Quality Laboratory in **Duluth, Minnesota**: **Donald I. Mount and Charles E. Stephan (1967)**, *"A method for establishing acceptable toxicant limits for fish."* They ran full life-cycle tests on fathead minnows and defined the **Maximum**

Acceptable Toxicant Concentration (MATC) and the application factor that bridged acute to chronic. **[2]** This is the direct ancestor of the modern PNEC, and the names matter: **Stephan** carries straight through to the 1985 guidelines that put the 5th percentile into U.S. law.

The application factor is, structurally, the same object as the human **safety factor of 100** our first essay traced — a divisor standing in for ignorance. The SSD was sold, on both continents, as the rigorous replacement for it. **[synthesis]**

2. Root A — the EPA line: from the application factor to the 5th percentile (US, 1978–1985)

By the late 1970s the EPA wanted a less arbitrary method than a single divisor. It began assembling toxicity values from many species and reading a low percentile off the spread. The agency **first used SSDs of acute values in 1978**, and formalized the method in **1985**: *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses*, by **C. E. Stephan, D. I. Mount, D. J. Hansen, J. H. Gentile, G. A. Chapman and W. A. Brungs** — the work of EPA's environmental research laboratories at **Duluth, Narragansett (RI), and Corvallis (OR)**. **[2]** (Local snapshot: `sources/EPA_1985_Guidelines_...pdf`.)

The 1985 method takes the **Genus Mean Acute Values** for at least eight families, ranks them, and computes the **Final Acute Value as the 5th percentile** of that distribution — the concentration that protects all but the most sensitive 5%. That number, still in force, underlies U.S. **National Ambient Water Quality Criteria** for aquatic life. The 5th percentile entered U.S. environmental law here, as an engineering choice by federal lab scientists. **[2]**

3. Root B — the Dutch line: from theoretical biology to national policy (Netherlands, 1987–1989)

In parallel and apparently independently, the statistical SSD was given its modern form in the Netherlands.

- **S. A. L. M. Kooijman (1987)**, theoretical biologist at the **Vrije Universiteit Amsterdam**, published *"A safety factor for LC50 values allowing for differences in sensitivity among species"* in *Water Research*. He modeled species sensitivity as a probability distribution and asked how far into the lower tail one must go to protect a community. The method is born, again, as a *better safety factor.* **[2]**
- **Nico M. van Straalen and C. A. J. Denneman (1989)**, *"Ecotoxicological evaluation of soil quality criteria"* (*Ecotoxicology and Environmental Safety*), turned the statistic into policy. The Dutch **Soil Protection Act of 1986** had created reference values the authors judged "insufficiently based on ecotoxicological evidence"; they proposed instead a concentration that **protects 95% of soil species** — the HC5. (Worked for cadmium, they put it at 0.16 µg/g in a standard soil.) **[2]** Note the order: the *policy demand came*

first (the Soil Protection Act needed numbers), and the method was built to fill it.

Then the Netherlands did what no one else had done — it made the 5% cut-off **national standard-setting policy**. The 1988–1989 government document **"Premises for Risk Management" (*Omgaan met risico's*)**, an annex to the **National Environmental Policy Plan** laid before the Lower House, adopted Van Straalen and Denneman's **5% cut-off** as the basis for environmental standards. **[2]** Out of it came the Dutch ladder of **environmental risk limits** — the **Negligible Concentration (NC)**, the **Maximum Permissible Concentration (MPC = the HC5)**, the **Serious Risk Concentration (SRC)**, and the **Maximum Acceptable Concentration for ecosystems** — operationalized by the national institute **RIVM**, with **Theo Aldenberg and Wim Slob (1993)** adding confidence limits to the HC5 to make it look like a measurement. **[2]** (For non-threshold substances — genotoxic carcinogens — the Dutch MPC was instead pinned to a 10^{-6} individual risk, the same one-in-a-million line the human de minimis world uses; the threshold method was reserved for the substances assumed to *have* a threshold. The carve-out is the SSD's version of de minimis's Delaney exclusion. **[synthesis]**)

So the Dutch root runs: theoretical biology (Kooijman) → a statute needing numbers (Soil Protection Act) → a method to supply them (Van Straalen & Denneman) → a cabinet policy adopting the 5% (Premises for Risk Management) → an institute operationalizing it (RIVM). Regulator-pulled at every step.

4. Convergence and institutionalization (SETAC and ECETOC, 1990s–2000s)

The two roots were braided together by a professional society and a textbook, and then refined by industry.

- **SETAC** (the Society of Environmental Toxicology and Chemistry) — the venue where academic, government, and industry ecotoxicologists meet — consolidated SSD as standard practice. The canonical reference, ***Species Sensitivity Distributions in Ecotoxicology*** (2002), edited by **Leo Posthuma (RIVM), Glenn W. Suter II (US EPA/ecological risk assessment), and Theo P. Traas (RIVM)** and published by SETAC Press, fused the U.S. and Dutch traditions into one method. **[2]** The roster is itself the genealogy: an EPA risk assessor and two RIVM scientists, the two roots in three names.
- **ECETOC** — the **European Centre for Ecotoxicology and Toxicology of Chemicals**, the chemical industry's research and advocacy body — entered to tune the parameters. Its **Workshop Report No. 28** (*Estimating toxicity thresholds for aquatic ecological communities*; local snapshot: `sources/ECETOC_WR28_...pdf`) and its **hSSD tool** argue for a **default assessment factor of 2** on the HC5. **[2]** A smaller factor means a higher "safe" concentration and a less stringent limit, so this is where the industry interest enters — not in inventing the method but in setting how conservative

it is. It is the same lever Frawley reached for when he argued the safety factor of 100 was "overly conservative," one institution removed. **[synthesis]**

5. Into the law (EU, US, and beyond)

The method then propagated through codified guidance, the way the human threshold propagated through *Monsanto* and the Code of Federal Regulations. **[2]**

- **EU Technical Guidance Document (TGD)** on risk assessment for new and existing substances (1996, revised 2003): the **PNEC** may be derived either by an assessment factor on the lowest NOEC **or by the lower 5th percentile of an SSD** (requiring data for at least 8 taxonomic groups / 10 species), divided by an assessment factor (1–5).
- **REACH** (Regulation 1907/2006): the PNEC is central to every chemical safety assessment; ECHA Guidance R.10 carries the SSD method forward.
- **Water Framework Directive** (2000/60/EC) and the **EQS Directive** (2008/105/EC): Environmental Quality Standards are derived under **Technical Guidance Document No. 27 (2011, rev. 2018)** of the Common Implementation Strategy — same SSD/5th-percentile machinery.
- **United States**: the 1985 EPA guidelines still govern aquatic-life criteria; SSDs also now frame endangered-species and site-specific assessments.
- **Elsewhere**: Australia/New Zealand water-quality guidelines (the *BurrliOZ* software), Canada, and China have all adopted SSD/HC5 standard-setting.

A statistic devised to protect 95% of fathead minnows and soil mites now sets legal limits for thousands of chemicals across the chemical and water law of much of the world.

6. Who built it — the roster

Person / body	Role	Affiliation
Donald I. Mount, Charles E. Stephan	application factor / MATC (1967); the precursor	US EPA, Duluth
Stephan, Mount, Hansen, Gentile, Chapman, Brungs	1985 EPA Guidelines — the 5th-percentile FAV in US law	US EPA (Duluth, Narragansett, Corvallis)
S. A. L. M. Kooijman	statistical SSD (1987)	Vrije Universiteit Amsterdam
Nico M. van Straalen, C. A. J. Denneman	SSD as policy / 95% protection (1989)	VU Amsterdam; Dutch govt
"Premises for Risk Management" (1988–89)	adopted the 5% cut-off as national policy	Dutch cabinet / Min. of Environment (VROM)
Theo Aldenberg, Wim Slob	HC5 confidence limits (1993); operationalization	RIVM (Netherlands)
Leo Posthuma, Glenn W. Suter II, Theo Traas	the consolidating textbook (2002)	RIVM; US EPA; RIVM — via SETAC
ECETOC	tuned the assessment factor toward leniency (AF=2)	chemical-industry research body
EU TGD / ECHA / WFD CIS; US EPA OW	wrote it into REACH, the WFD EQS, and US AWQC	regulators

7. How it differs from de minimis — and why that matters

The de minimis essay is, at bottom, a capture story: a corporate toxicologist, an industry trade campaign, a reluctant agency overridden. The SSD genealogy is not that, and we should say so plainly. Its authors were government and university scientists; the demand came from environmental statutes (the Dutch Soil Protection Act, the EU substances regulations, the WFD); the regulators pulled it in to make their own standards look less arbitrary than a divisor pulled from the air. **[synthesis]**

But the convergence is the point of putting the two stories side by side. Whether an industry pushes a threshold onto regulators (Frawley) or regulators reach for one themselves (RIVM, EPA), the result is the same object: a database, a chosen low percentile, a factor, and a line below which harm is administratively "insignificant" or "acceptable." The de minimis logic is attractive enough that it does not need a lobby — a bureaucracy facing an impossible question (how much of everything is safe for everyone, or everything?) will build it on its own. And once built, industry's role is the familiar one: not to invent the threshold but to argue, as Frawley did of the factor of 100, that it is set too conservatively. The assessment factor of 2 is the "overly conservative" complaint, made quietly, in a workshop report. **[synthesis]**

Sources

Peer-reviewed / agency literature; two local primary snapshots in `sources/` *(EPA 1985; ECETOC WR28). Full abstract capture is a follow-up.*

- **Mount, D.I. & Stephan, C.E. (1967).** "A method for establishing acceptable toxicant limits for fish — Malathion and the butoxyethanol ester of 2,4-D." *Trans. Am. Fish. Soc.* — MATC / application factor. **[2]**
- **US EPA — Stephan, Mount, Hansen, Gentile, Chapman & Brungs (1985).** *Guidelines for Deriving Numerical National Water Quality Criteria…* — 5th-percentile FAV. **Local:** `sources/EPA_1985_Guidelines_...pdf`. **[2]**
- **Kooijman, S.A.L.M. (1987).** *Water Research* 21(3):269–276 — statistical SSD origin. **[2]**
- **Van Straalen, N.M. & Denneman, C.A.J. (1989).** *Ecotoxicol. Environ. Saf.* 18(3):241–251 — 95% protection; Dutch Soil Protection Act. PMID 2693071. **[2]**
- **"Premises for Risk Management" / *Omgaan met risico's* (Netherlands, 1988–89)** — annex to the National Environmental Policy Plan; adopted the 5% cut-off (NC / MPC / SRC / MACeco). **[2]**
- **Aldenberg, T. & Slob, W. (1993).** *Ecotoxicol. Environ. Saf.* 25(1):48–63 — HC5 confidence limits (RIVM). **[2]**
- **Posthuma, L., Suter, G.W. II & Traas, T.P. (eds.) (2002).** *Species Sensitivity Distributions in Ecotoxicology.* SETAC/Lewis — the consolidating reference. **[2]**
- **ECETOC, Workshop Report No. 28**, *Estimating toxicity thresholds for aquatic ecological communities* (default AF of 2 on the HC5). **Local:**

`sources/ECETOC_WR28_...pdf`. **[2]**

- **EU TGD (1996/2003); ECHA Guidance R.10 (REACH); WFD TGD No. 27 (2011/2018, EQS).** Regulatory codification. **[2]**

Open / next

> - **[open]** Snapshot the primary abstracts (Kooijman 1987; Van Straalen & Denneman 1989; Posthuma et al. 2002) and the **EU TGD No. 27** PDF; capture verbatim the "lower 5th percentile of an SSD + assessment factor" wording into `sources/`.
> - **[open]** Find the original **"Premises for Risk Management" (1989)** document (RIVM/Dutch govt archive) to quote the policy adoption of the 5% directly — the closest analogue to our 1995 ToR-rule primary.
> - **[open]** Read the **ECETOC WR28** (local) for the verbatim argument for AF=2, the industry "overly conservative" move — a direct rhyme with Frawley's complaint, worth quoting.
> - **[synthesis → develop]** The roster shows RIVM at the center of *both* the SSD and parts of the human-tox threshold world (Posthuma, Traas). Worth checking whether the same Dutch risk-assessment school built the human and ecological thresholds in tandem — a documented single source for both branches would be a strong find.