10 — THE OTHER TRACK: how "de minimis" became *law*

*The dossier traces de minimis as a chain of toxicologists citing each other (Frawley 1967 → NAS 1969 → Rulis 1987 → 21 CFR 170.39 (1995) → TTC). That is the **science/citation** lineage. It ran alongside a second, **judicial** lineage — the federal-courts doctrine that actually carries the name "de minimis" and that supplied the **legal authority** the 1995 rule needed. The two tracks converge in the 1995 Threshold of Regulation rule. This file reconstructs the legal track and ties it back to Frawley.*

Grading as elsewhere: [CONFIRMED-primary] (primary read) · **[P-cite]** (locator confirmed, opinion body not yet read directly this session) · **[secondary]** · **[absence-of-evidence]**. *No invented locators.* **Update (2026-06-10):** *Monsanto*'s de minimis passage has now been pulled **verbatim** from the opinion (CourtListener opinion **7840898**, 613 F.2d at 956; reproduced in §2), independently corroborated by FDA's rendering in the 1995 Federal Register and by vLex (which also confirms the caption and disposition). **All four case holdings are now [CONFIRMED-primary].** The full opinions for all three cases are **archived locally in `sources/`** (`Monsanto-v-Kennedy_613F2d947…txt`, `PublicCitizen-v-Young_831F2d1108…html`, `Les-v-Reilly_968F2d985…txt`; indexed in `sources/_SOURCES_INDEX.md`) — no longer dependent on a live fetch.

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0. Headline

- **The science chain doesn't explain how the idea became enforceable law. The court chain does.** When Frawley proposed his exemption (1966–68) and FDA's Ramsey tried to operationalize it (1969–71), FDA **abandoned it as legally unworkable** (3 Jun 1971) — i.e., the agency believed it **lacked statutory authority** to wave trivial migrants past the "food additive" definition. **[secondary]** (Heckman; register D4).
- **A court then granted that authority.** *Monsanto Co. v. Kennedy*, **613 F.2d 947 (D.C. Cir. 1979)** (Leventhal, J.) held the FDA Commissioner *may* decline to treat a substance as a "food additive," despite the literal statutory definition, where migration is **"so negligible as to present no public health or safety concerns"** — a **de minimis** judgment. **[CONFIRMED-primary]** (opinion verbatim, 613 F.2d at 956; corroborated by FDA, 60 FR at 36584).
- **A direct institutional through-line to Frawley:** the **co-petitioner** beside Monsanto was **the Society of the Plastics Industry** — *the same trade group that ran Frawley's 1967–68 de minimis campaign* (chaired by Hercules's Robert M. Miller; see `08_VINYL_CHLORIDE_CAMPAIGN.md`). SPI lost the administrative fight for Frawley's number in 1968 and won the **legal principle** in 1979. **[CONFIRMED-primary]** (caption) + **[CONFIRMED-primary]** (the SPI/Frawley campaign, `07` / `08`).

- **The courts also fixed de minimis's ceiling — exactly where Frawley had drawn his own carve-out.** *Public Citizen v. Young*, **831 F.2d 1108 (D.C. Cir. 1987)** (Williams, J.), and *Les v. Reilly*, **968 F.2d 985 (9th Cir. 1992)** (Schroeder, J.), held the **Delaney anti-cancer clauses admit no de minimis exception** — no trivial-risk escape for a carcinogen. **[CONFIRMED-primary]** (verbatim below).
- **The 1995 rule is the convergence. 21 CFR 170.39** (60 FR 36582, 17 Jul 1995) grounds itself **expressly in *Monsanto*'s de minimis authority**, names the doctrine in Latin (**"de minimis non curat lex — the law does not concern itself with trifles,"** the very maxim Frawley quoted in 1967–68), and **conditions the exemption on the substance "not having been shown to be" a carcinogen** — citing *Public Citizen v. Young*. The law thereby adopted **Frawley's own structure**: a presumptive safe-because-trivial level for "all other" chemicals, with carcinogens (and pesticides/heavy metals) carved out. **[CONFIRMED-primary]** (local FR text).

> **Why this was missed:** the existing investigation read the 1995 FR for its *number* (0.5 ppb) and its *citation silence* on Frawley (correct — the rule cites Rulis, not Frawley). It did **not** mine the same document's **legal reasoning**, which names *Monsanto* and *Public Citizen v. Young* and rests the entire rule on the judicial de minimis doctrine. The primary was already in `sources/`; only the doctrine was unread.

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1. Pre-history — FDA thought it *lacked* the power (1969–71)

Frawley's proposal needed someone with authority to declare a class of migrants exempt. Inside FDA, **Lessel L. Ramsey** (Bureau of Science — and the FDA officer SPI had been working since Dec 1966; `08`) drafted the **"Ramsey Proposal"**: exempt indirect additives migrating at **≤50 ppb**. At a **3 June 1971** meeting FDA concluded it could **not proceed** — the concept was judged **"scientifically sound" but legally unworkable**. **[secondary]** (Heckman / PackagingLaw; register **D4**; master dossier §2.2).

This is the linchpin the legal track resolves. "Legally unworkable" means FDA in 1971 did not believe the Food Additives Amendment let it exempt a substance that literally met the "food additive" definition. That belief is exactly what the D.C. Circuit overturned eight years later.

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2. *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979) — the doctrine is born

Field	Value
Caption	**Monsanto Company, and The Society of the Plastics Industry, Inc., Petitioners v. Donald Kennedy, Commissioner of Food and Drugs**

Field	Value
Court / panel	D.C. Circuit; **Bazelon** (Sr.), **Leventhal** (author), **Robinson**
Argued / decided	argued **15 Mar 1979**; decided **6 Nov 1979**
Locator	613 F.2d 947, 198 U.S.App.D.C. 214

Facts. Monsanto's **acrylonitrile copolymer** beverage bottles (the "Cycle-Safe" container) shed trace **acrylonitrile monomer** into the beverage. The Commissioner ruled the copolymer a "food additive" whose safety was not demonstrated, and barred it. **[CONFIRMED-primary]** (FDA's recitation, 60 FR at 36584; secondary case summaries). *Note the chemistry: this is precisely Frawley's domain — monomer migration from a food-contact plastic, the "indirect additive" problem.*

Holding — the de minimis authority. The court held the Commissioner **need not** treat every literal migrant as a regulated food additive. As FDA itself renders the holding, pin-cited to **613 F.2d at 956**:

> "…the Commissioner of Food and Drugs … may determine that the level of migration into food of a particular substance is so negligible as to present no public health or safety concerns and, in such cases, may decline to define the substance as a food additive even though it comes within the strictly literal terms of the statutory definition of a food additive." **[CONFIRMED-primary]** (60 FR at 36584, quoting/rendering 613 F.2d at 956)

The opinion's **own words** (Leventhal, J., **613 F.2d at 956**; pulled from CourtListener opinion 7840898, cross-confirmed by the 1995 FR rendering and vLex) — **[CONFIRMED-primary]**:

> "There is latitude inherent in the statutory scheme to avoid literal application of the statutory definition of 'food additive' in those *de minimis* situations that, in the informed judgment of the Commissioner, clearly present no public health or safety concerns."
>
> "Thus, the Commissioner may determine based on the evidence before him that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety."
>
> "However, if the Commissioner declines to define a substance as a 'food additive,' though it comes within the strictly literal terms of the statutory definition, he must state the reasons for exercising this limited exemption authority."

The Commissioner therefore also retains discretion **not** to exercise the exemption; FDA's paraphrase in the 1995 rule tracks the opinion exactly (60 FR at 36584).

Disposition (verbatim). *"The decision of the Commissioner is affirmed in part, and in part is remanded to provide the opportunity for reconsideration"* — i.e. remanded to let the Commissioner exercise (and explain) the de minimis judgment on the acrylonitrile record. **[CONFIRMED-primary]** (opinion; vLex).

Doctrinal root (optional, for completeness). *Monsanto* is the FDA-specific application of the general administrative **de minimis doctrine** the D.C. Circuit articulated the same era in **Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979)**. **[P-cite]** (not pulled; flagged in `05` for a clean read).

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3. The ceiling — de minimis stops at the carcinogen line (1987, 1992)

The doctrine has a hard limit: it cannot be used to read a trivial-risk exception **into the Delaney anti-cancer clauses**. Two opinions fix that limit — *at exactly the boundary Frawley himself drew* (he excluded carcinogens, pesticides, and heavy metals from his 0.1 ppm).

3.1 *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987)

- **Author / date: Stephen F. Williams, J.**; decided **23 Oct 1987**. *(Correction to a common misattribution to Bork, who sat on the court then but did not write it.)* **[CONFIRMED-primary]**.
- **Facts:** FDA listed cosmetic color additives **Orange No. 17** and **Red No. 19** despite animal carcinogenicity, on quantitative-risk grounds — lifetime cancer risk **"one in 19 billion at worst"** (Orange No. 17) and **"one in nine million at worst"** (Red No. 19). **[CONFIRMED-primary]**.
- **Holding — no de minimis under the color-additive Delaney Clause:**

  > "The natural — almost inescapable — reading of this language is that if the Secretary finds the additive to 'induce' cancer in animals, he must deny listing." "The language itself is rigid; the context — an alternative design admitting administrative discretion for all risks other than carcinogens — tends to confirm that rigidity." "We conclude, with some reluctance, that the Clause lacks such an exception." **[CONFIRMED-primary]** (law.resource.org reporter text).

- **Disposition:** the Orange No. 17 / Red No. 19 listings **vacated**.
- **Relevance:** the dyes here are the same *class* as Frawley's tabulated colorants (Citrus Red No. 2 and the azo dyes; `09`). Where his number met an explicit anti-cancer statute, the courts said the trivial-risk logic does not reach.

3.2 *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992)

- **Author / panel / date: Schroeder, J.** (with **Chambers**, **Beezer**); decided **8 Jul 1992**. **[CONFIRMED-primary]**.
- **Facts:** EPA let four carcinogenic pesticides — **benomyl, mancozeb, phosmet, trifluralin** — remain as food additives (residues concentrating in processed food) on a **de minimis / negligible-risk** theory, leaning on the NAS report ***Regulating Pesticides in Food: The Delaney Paradox* (1987)**. **[CONFIRMED-primary]**.
- **Holding:** the FFDCA §409 Delaney Clause is **"clear and mandatory"** and admits **no de minimis exception**; EPA lacked authority to create one. **[CONFIRMED-primary]** (CourtListener text; the longer holding sentences read as lightly paraphrased in fetch — treat the short phrase as verbatim, the rest as faithful sense).
- **Disposition:** EPA order **set aside**.
- **Relevance:** the pesticide branch — Frawley's other explicit carve-out — reaches the same wall. (*The political sequel, the **Food Quality Protection Act of 1996**, repealed Delaney for pesticides and substituted a risk-based "reasonable certainty of no harm" — i.e. it legislated the de minimis the court forbade. Reserved as context; see `05`.)*

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4. The convergence — 21 CFR 170.39 (1995), grounded in the doctrine

The Threshold of Regulation rule (**60 FR 36582**, 17 Jul 1995; local `sources/FDA_Threshold-of-Regulation_60FR36582_1995.txt`) is the codification of *Monsanto*'s de minimis authority for food-contact substances. From the preamble (**[CONFIRMED-primary]**, local text):

- **It rests the rule on *Monsanto*.** "A Federal court has addressed the issue… In *Monsanto v. Kennedy*, 613 F.2d 947… the court stated that the Commissioner… may decline to define the substance as a food additive even though it comes within the strictly literal terms of the statutory definition" (60 FR at 36584).
- **It names the doctrine — Frawley's own maxim.** Footnote 4: *"This doctrine is expressed in Latin as **de minimis non curat lex** (the law does not concern itself with trifles)."* (60 FR at 36585). Frawley used the identical maxim to the FDA's face in 1967–68 (`sections.md` §3; `_sourcepack`).
- **It adopts Frawley's carcinogen carve-out, via *Public Citizen*.** Rejecting comments that *Monsanto* would let trivial carcinogen migrants escape Delaney: "a carcinogenic additive is deemed to be unsafe, no matter how low the exposure… or how low the risk (see *Public Citizen v. Young*, 831 F.2d 1108, 1122…)"; therefore the exemption is "conditioned on such substances **not having been shown to be carcinogens**" (60 FR at 36586). **[CONFIRMED-primary]**.
- **The number.** Exempts food-contact substances at a dietary concentration **≤0.5 ppb** (≈1.5 µg/person/day). Cites **Rulis**, not Frawley. **[CONFIRMED-primary]** (already in `01` / `03`).

- **Only FDA may invoke it** — "only the Commissioner has the statutory authority to exempt a substance" (60 FR at 36586) — the discretionary half of *Monsanto*.

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5. The through-line to Frawley (what the legal track adds to the story)

1. **Same trade group, two fights.** SPI championed Frawley's **administrative** de minimis number (1967–68, chaired by his employer's Robert M. Miller) and **lost** at FDA; SPI then co-litigated the **judicial** de minimis principle in *Monsanto* (1979) and **won**. The 1995 rule that embodies Frawley's *kind* of number was built on the authority SPI helped win. **[CONFIRMED-primary]** on both ends.
2. **"Legally unworkable" → legally authorized.** FDA abandoned the idea in 1971 for want of authority; the court supplied the authority in 1979; FDA codified it in 1995. The lag the essay tracks for the *science* (the number outliving its evidence) has a clean **legal** counterpart (the authority arriving after the agency had given up).
3. **The law ratified Frawley's exclusions.** His instinct — trivial level ⇒ presumed safe **except** for carcinogens/pesticides/heavy metals — is now the literal architecture of 21 CFR 170.39 (de minimis exemption, carcinogen-conditioned per *Public Citizen v. Young*).
4. **The maxim came full circle.** Frawley invoked *de minimis non curat lex* as rhetoric in 1967; the courts turned the maxim into doctrine; the 1995 rule recites the maxim in a footnote. The essay quotes Frawley using the tag (§3) — it can now show the tag becoming enforceable law (§11).

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6. Open / next (for `05_OPEN_QUESTIONS`)

- **Pull *Monsanto* 613 F.2d at 956 verbatim** from the bound reporter / Westlaw / Google Scholar to upgrade the de minimis sentence from **[P-cite]** to **[CONFIRMED-primary]** in its own words (FDA's rendering is already primary; this is for the essay's verbatim quote). Free hosts (Justia, OpenJurist, casetext, ELR) were CAPTCHA/410-blocked this session.
- **Read *Alabama Power Co. v. Costle*, 636 F.2d 323 (D.C. Cir. 1979)** for the general administrative de minimis doctrine *Monsanto* applies (one paragraph of context). **[P-cite]**.
- **Verbatim *Les v. Reilly* holding sentences** (CourtListener fetch lightly paraphrased) — confirm against 968 F.2d at 988–990.
- **Reserved for later essays (per operator):** the **TTC / Cramer-class** machinery and the **genotoxic-TTC 0.15 µg/day** endpoint, and the **FQPA 1996** pesticide sequel — gestured as "not the end of the story," not developed here.

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7. Locators

Item	Cite	Locator / source	Grade
Monsanto Co. v. Kennedy	613 F.2d 947 (D.C. Cir. 1979), Leventhal, J.	613 F.2d 947, **at 956**; 198 U.S.App.D.C. 214; CourtListener opinion **7840898** (`/opinion/7893633/`); corroborated at **60 FR 36584** (local)	**[CONFIRMED-primary]** (opinion verbatim + FR)
SPI as co-petitioner	caption	reporter caption; OpenJurist title; vLex 886782951	**[CONFIRMED-primary]**
Public Citizen v. Young	831 F.2d 1108 (D.C. Cir. 1987), Williams, J.	law.resource.org `F2/831/831.F2d.1108.86-5150.86-1548.html` ; CourtListener `/opinion/496579/` ; cert. denied 485 U.S. 1006 (1988)	**[CONFIRMED-primary]**
Les v. Reilly	968 F.2d 985 (9th Cir. 1992), Schroeder, J.	CourtListener `/opinion/586411/` ; Justia `…/F2/968/985/98282/`	**[CONFIRMED-primary]** (core)
NAS, *Regulating Pesticides in Food: The Delaney Paradox*	NRC 1987	cited in *Les*; NAP catalog	**[P-cite]**
Threshold of Regulation rule	21 CFR 170.39; 60 FR 36582 (17 Jul 1995)	local `sources/FDA_Threshold-of-Regulation_60FR36582_1995.txt` ; FR Doc 95-17435	**[CONFIRMED-primary]**
Ramsey Proposal "legally unworkable," 3 Jun 1971	—	Heckman / PackagingLaw; register **D4**	**[secondary]**
SPI/Frawley campaign (Miller chair; Keller & Heckman; Ramsey)	—	`07_TOXICDOCS_FINDINGS.md` , `08_VINYL_CHLORIDE_CAMPAIGN.md`	**[CONFIRMED-primary]**

Companion: `08_VINYL_CHLORIDE_CAMPAIGN.md` (the SPI campaign behind Frawley's number) · `01_MASTER_DOSSIER.md` §2.3 (propagation lineage) · `03_DOCUMENT_REGISTER.md` §D (de minimis record) · `04_TIMELINE.md`.