Frawley — story sections (a kit, to be sequenced)

Movable blocks. ***This is the quote-rich working version*** *— quotes are deliberately over-long; we trim them at assembly. Each fact and quote still lives in exactly one block, so nothing repeats. Tagged with rough dates; listed chronologically by default. Suggested dramatic order at the bottom. This is the sequel to the "factor of 100" essay; the through-line is the numerology of toxicology — round numbers standing in for knowledge we don't have. Each block opens with a bulleted* ***Highlights*** *digest — a working navigation aid, to be stripped at assembly (so it does not count against the one-fact-per-block rule).*

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1 · The ignorance factor · [1950s–1965]

- FDA-trained under Arnold Lehman (Division of Pharmacology, with Fitzhugh & Nelson), then defected to **chief toxicologist at Hercules**.
- Named the 100-fold safety factor an **"ignorance factor"** — and called it "overly conservative," i.e. too big.

John Frawley learned the trade at the FDA. Through the 1950s he worked in the Division of Pharmacology under Arnold Lehman — the lab that built the two-year feeding study and the 100-fold safety factor, the subject of our first essay. He published with O. Garth Fitzhugh and Arthur Nelson, Lehman's own men. Then he switched sides. By the mid-1960s he was Chief Toxicologist at Hercules, the Wilmington chemical company. Nothing in the work changed except who paid for it.

He also said, more plainly than his teachers ever had, what the factor of 100 really was:

> "The original basis for this conservativeness is cited as a device to compensate for our lack of precise means of predicting the effect of a compound on the most sensitive human. I like to call it an 'ignorance factor,' but more traditionally it is called a 'margin of safety.' The figure is based on the assumption that man is 10 times as sensitive as the experimental animals and the most sensitive human is 10 times as sensitive as the average. Experience has taught us that this factor is overly conservative."

A confession of ignorance — and a complaint that the confession was too large.

(Frawley, Investigations Establishing the Safety of Rosin Products, Naval Stores Work Conference, 1965.)

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2 · Northbrook · [1963–1973]

- The 1958 Food Additives Amendment forced **34 two-year rosin studies (~$50k each ≈ $1.75M)** on Hercules — the commercial driver of the whole de minimis idea.
- He farmed the work to **Industrial Bio-Test (IBT)**; its president, Joseph Calandra, was his repeat co-author (1963 / 1965 / 1973).
- IBT became the largest safety-data fraud — EPA voided **594 of 801 studies (74%)**; one invalid Hercules toxaphene study was never replaced.

The 1958 Food Additives Amendment caught Hercules with a bill. The company sold dozens of food-grade rosins — the resins that size paper and seal packaging — and each now needed a two-year animal study to stay on the market. Frawley counted thirty-four. As he put it: "Simple arithmetic of a minimum price of $50,000 per compound times 34 told us we faced an expenditure of 1-3/4 million dollars just for animal studies."

He sent the work to Industrial Bio-Test Laboratories, a contract house in Northbrook, Illinois — 5,000 rats and 138 dogs, he reported, all "conducted under contract by the Industrial Bio-Test Laboratories, of Northbrook, Ill." IBT was not a vendor he used once. Its president, Joseph Calandra, was his co-author. They published together across a decade. The first paper, in 1963, was on the organophosphate Delnav. A 1965 study followed, on the preservative BHT; a 1973 one on a pesticide. Both of the latter were multigeneration reproduction studies — dosing animals and watching their pups — which was IBT's specialty.

It was also its undoing. When the EPA finished auditing IBT's pesticide files in 1983, it found 594 of 801 studies invalid — 74 percent: animals recorded as examined after they had died, results massaged or invented. The fraud ended in criminal convictions and erased a generation of safety data. One Hercules study sat in the wreckage: a toxaphene reproduction study, stamped invalid, never replaced. Frawley had been about as close to the lab as a client and a co-author can be.

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3 · Proving the obvious · [1966–1968]

- Frawley set out to "prove the obvious" — **the number first, the justification second**.
- 100-fold margin over a **245-study** database → 1 ppm; "another factor of ten" → **0.1 ppm "toxicologically insignificant"** (pesticides/heavy metals carved out), filed as a ≤0.2%-of-container rule.
- Stated motive: **$1M of Hercules money "wasted"** proving packaging safe.

Frawley presented the whole project as a lark. He opened a 1967 lecture in London like this:

> "When was the last time you sat down in the solitude of your study and attempted to write out a geometrical proof that the shortest distance between two points is a straight line? Most of us would have a difficult time doing it today because, as you recall, it is not susceptible to proof. It must be accepted. Indeed, some of the most difficult things in life to prove are the obvious ones. A number of months ago, I sat down to try to prove something which was obvious to me — that there are some uses of food-packaging materials which cannot involve any hazard to health of the consumer of food. I had no preconceived idea of the end point I would reach, but it seemed like it would be fun. Sometimes now I wish I had resisted the temptation and invested my time in some other form of recreation."

He was not testing whether those uses were safe. He had decided that already. The job was to fit a foregone conclusion with a number — get the figure first, justify it second.

He framed the deadlock as a "trichotomy." "His bright young chemist with a new and expensive analytical instrument discovers that 10 parts per billion of a chemical migrates from the container to food. The lawyer says that because it can migrate to food, it is a food additive and must be established as safe. The toxicologist says that he cannot conclude that it is safe until toxicologic studies are conducted." One way out, he noted, was the lawyer's: "de minimis non curat lex — the law does not concern itself with trifles." He wanted a number instead.

The number came out of the ignorance factor and a database he was proud of: "I have been able to locate two-year chronic toxicity studies on 245 different substances, and although this may seem like a modest number, it represents between 15 and 20 million dollars in toxicological research. I estimate that I now have collected over 90% of all such studies which have ever been conducted." Run the 100-fold margin across them, he argued, and every compound was safe at 1 part per million; then "protect ourselves by another factor of ten and adopt 0.1 parts per million as a level of toxicological insignificance for all materials other than pesticides and heavy metals." Below it, no test required. For industry he turned it into a spec-sheet rule and filed it with the FDA — an exemption for "substances used at a level of no more than 0.2% by weight of the container … provided these substances are not heavy metals … or pesticides."

Why bother? His own answer, to a 1968 conference:

> "I realized that I personally had spent over a million dollars of my Corporation's money investigating the safety of food packaging materials, and from society's point of view it was all wasted, because all were proven to be safe. The benefit to the consumer was zero. The loss to society was a million dollars."

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4 · "Sheer nonsense" · [February 1968]

- FDA's Feb 1968 conference — held partly to preempt a congressional hearing.
- Chief scientist **W. H. Summerson called the single-cutoff idea "sheer nonsense"**: cancer's 10+-year latency blinds a no-effect level, and no-known-harm isn't proof of safety.
- The "24 toxicologists" endorsing it were an **organized industry campaign** (MCA + plastics group, chaired by a Hercules executive).

The FDA gave Frawley a room. It convened a National Conference on Indirect Food Additives in February 1968 — partly, a trade paper noted, "to get a public airing of the complaints before there is a Congressional hearing." Its own chief scientist was waiting.

W. H. Summerson, head of the FDA's Bureau of Science, devoted his paper almost entirely to Frawley. He granted "a soundness of certain portions of Dr. Frawley's thesis," then took the central idea — a single number below which nothing gets tested — and called it "sheer nonsense." His reason has only sharpened since:

> "Unless premarketing clearance is practiced, the only method of detecting harmful effects is retrospective with respect to exposure to the suspected agent. The latent or 'incubation' period from the time a chemical agent is first applied to the human being until the time that cancer occurs is often 10 years or more … after the 10 year period, with changing food habits, additives and packaging, it is well nigh impossible to isolate an additive as the original causative agent of a cancer. Thus, if we are to give the consumer the protection he expects and demands, we must require premarket testing."

And he named the sleight of hand under the whole proposal: "even today we have offered to us a statement to the effect that the proponent feels no food additive clearance is necessary because he has no knowledge of any bad effects from his product."

Frawley had told the room his case was strong: "twenty-four other toxicologists from universities and industries have supported this proposal in writing to the FDA." It sounded spontaneous. It was organized. The Manufacturing Chemists Association had endorsed the amendment in November 1967, claiming 185 companies and more than ninety percent of U.S. basic chemical capacity; the plastics trade group followed days later. The campaign was run by a packaging law firm and chaired, on the plastics side, by a Hercules executive — Frawley's own employer.

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5 · The Academy blesses it · [1969]

- Within a year the **NAS Food Protection Committee** published *Guidelines… Toxicologically Insignificant Levels* — Frawley's phrase and his **0.1 ppm**.

- It cited his 1967 paper; its drafting task force **included Frawley himself**.
- "Sheer nonsense" at FDA (1968) → a **National Academy recommendation** (1969), co-written by its proponent.

Losing the FDA's room was not losing the argument. Within a year the National Academy of Sciences took the idea up and put Frawley's own phrase on the cover.

Its Food Protection Committee published Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Food. The report opened on the first essay's number — "the safe level is frequently expressed as 1/100 of the experimentally determined 'no-adverse-effect level'" — then went further and fixed the line below which a chemical need not be studied at all, at exactly Frawley's 0.1 part per million for an established commercial chemical. His was the reasoning, too:

> "The principle of toxicological insignificance is a valid concept for separating potential health hazards from predictably safe applications. Guidelines on toxicological insignificance are needed to eliminate wasteful diversion of scientific resources in university, industry, and government laboratories."

The report cited his 1967 paper. It was also, in part, his report: the seven-man drafting task force — Smyth, Coon, Hall, Oser, Schramm, Zapp — included J. P. Frawley. One year the FDA's chief scientist had called the idea sheer nonsense. The next, it was a National Academy recommendation, co-written by the man who proposed it.

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6 · Both sides of the table · [synthesis — placeable anywhere]

- The conflict, three times over: co-authored with his **contract lab's president**; his **employer chaired the lobby**; he **sat on the NAS panel** that blessed his proposal.
- Documented and more or less in the open — yet never disclosed beyond the Hercules byline.

By now the shape has repeated three times. Frawley co-authored studies with the president of the contract lab he hired. His employer chaired the industry committee that lobbied his proposal through. He sat on the National Academy panel that recommended it. Each fact is documented, and each was, at the time, more or less in the open. None was ever flagged as a conflict — except by the byline that named his employer, which was disclosure enough that no one had to call it anything else.

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7 · The other file · [1963–1965; 1983]

- Public register: chemicals beneath notice. Private register: a 1965 **Confidential memo** of a Dow call — industry "extremely frightened," "the whole industry will suffer," "fearful of a congressional investigation" over dioxin in 2,4,5-T.
- In his favor: Hercules's own product was at the clean end — and his sworn "clean" testimony **won Hercules 1983 Agent Orange summary judgment** (a ruling later withdrawn).

In public Frawley argued that chemicals were beneath notice. In private he kept a correspondence that read nothing like it.

In March 1965, V. K. Rowe of Dow Chemical wrote to a short list of manufacturers — Monsanto, Hooker, Diamond Alkali, and Hercules's Frawley — to convene a meeting about "highly toxic impurities" in the herbicide ingredient 2,4,5-trichlorophenol. The impurities were dioxins. (The line ran both ways; a litigation exhibit index lists a Frawley letter to Rowe from July 1963.) Four months later Frawley wrote up a phone call from Dow's Earl Farnham on a memo he marked Confidential. As a plaintiffs' brief later reproduced it:

> "Mr. Farnham was convinced that no one else in the industry had done anything to remove the contaminant from their 2,4,5-T. Mr. Farnham further stated that Dow was extremely frightened that this situation might explode. Mr. Frawley quotes Mr. Farnham as stating that Dow [was] 'aware that their competitors are marketing 2,4,5-T which contains alarming amounts of acnegen and that if the government learns of this the whole industry will suffer. They are particularly fearful of a congressional investigation and excessive restrictive legislation on the manufacture of pesticides which might result.'"

Set the two files beside each other. The public one is written in the language of trifles and insignificance. The private one is written in the language of a fire alarm.

Fairness demands the qualifier, and it is real: Hercules's own product was at the clean end — the court later found no measurable dioxin in it but for a single 1966 trace, and Frawley was recording the industry's fear, not his company's guilt. Which is what makes the memo such a clean specimen of the two registers a corporate toxicologist keeps. When the Agent Orange suits reached summary judgment in 1983, it was Frawley's sworn testimony that Hercules's product was clean which won the company its release — a ruling the chief judge later withdrew before it stood.

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8 · The loop · [1951 / 1967 / 1969]

- Cyclamate, full circle: Frawley judged it nearly harmless as an FDA man in **1951**, tabulated it safe in **1967** — and the FDA **banned it (bladder tumors in rats) in Oct 1969**.

Cyclamate makes a closed circle. As a young FDA man in 1951, Frawley co-authored the study of artificial sweeteners that concluded "saccharin and sodium cyclohexyl sulfamate had only slight effects at a dosage level of 5 percent." Sodium cyclohexyl sulfamate is cyclamate. He tabulated it as safe in his 1967 list. In October 1969 — twenty months after his conference talk — the FDA pulled it from American food over bladder tumors in rats. Measured, cleared, banned, by versions of the same man.

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9 · The numbers that didn't hold · [hindsight]

- His highest "safe" value — a **vinyl chloride copolymer at 120,000 ppm** — is now a confirmed human carcinogen (workplace limit later cut 500→1 ppm); acrylamide and Citrus Red No. 2 also failed.
- The deeper flaw: for **genotoxic carcinogens no dose does nothing** — the "no-effect level" his table is built on doesn't exist for them.

The chemicals Frawley cleared did not all keep their grades. His highest "safe" value for a substance now known to cause cancer was a vinyl chloride copolymer at 120,000 parts per million. Vinyl chloride is a confirmed human carcinogen, the cause of a rare liver cancer in the men who made it; within six years of his talk the workplace limit dropped from 500 parts per million to one. Acrylamide, the single compound he had flagged as troubling, is a probable carcinogen. Citrus Red No. 2, which he listed safe at 500 ppm, gives rats bladder tumors.

There is a harder point under the scorecard. For a genotoxic carcinogen — vinyl chloride, acrylamide — there is no dose that does nothing; the risk runs down to a single molecule. The no-effect level, the unit his whole table was built from, does not exist for these chemicals. The number wasn't merely too high. It names a quantity the chemical doesn't have.

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10 · Decade of change · [1981]

- IBT's fraud produced the FDA's **Good Laboratory Practice** rules; Frawley's **1981 manifesto attacked the reform** ("a reputation… worth nothing today"; "peer review… replaced by peer intimidation").
- The same essay attacked "zero risk" / the "Delaney philosophy" and argued for a calculable threshold — his packaging exemption, matured.

The fraud at IBT produced a reform: the FDA wrote the Good Laboratory Practice rules, the chain-of-custody and record-keeping standards meant to stop the next invented study. Frawley's answer, in a 1981 manifesto for the new journal Regulatory Toxicology and Pharmacology, was to attack the reform:

> "For the regulatory agency, GLPs merely refer to proof that there was no cheating in the experiment … Only a few years ago, we were willing to take this for granted. We had mutual trust in each other, scientist to scientist … It is a sad commentary that the signatures and reputations of all of us in this room

> are not sufficient in the judgment of the regulatory agencies to validate a study. A reputation, built on a career of integrity, is worth nothing today. Peer review has been replaced by peer intimidation."

The same essay argued against "zero risk" and what he called "the Delaney philosophy," and for a tolerable, calculable threshold of harm — the mature form of the idea he had floated as a packaging exemption fifteen years earlier. His answer to a data-fraud scandal was to object that the regulators no longer took a toxicologist's word.

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11 · It became law · [1971–1995]

- FDA dropped the idea in 1971 believing it **lacked the legal authority**; the D.C. Circuit granted it in ***Monsanto v. Kennedy* (1979)** — co-petitioner: the **Society of the Plastics Industry**, Frawley's campaign vehicle.
- Courts capped de minimis at the **Delaney carcinogen line** (*Public Citizen v. Young* 1987; *Les v. Reilly* 1992) — Frawley's own carve-out.
- The **1995 Threshold of Regulation rule (0.5 ppb)** codified it, resting on *Monsanto* and reciting *de minimis non curat lex*; it credits Rulis, never Frawley.

Frawley's 0.1 ppm never became an FDA rule. The agency tried and gave up. Its own Dr. Ramsey drafted a version, then dropped it in June 1971 — sound enough, his colleagues decided, but beyond their power to grant. To exempt a chemical that met the letter of the "food additive" definition was not, they concluded, the agency's call to make.

The courts made it for them. In 1979, in a fight over acrylonitrile leaching from a plastic soda bottle, the D.C. Circuit told the FDA Commissioner he had "latitude inherent in the statutory scheme" to decide that a chemical migrating in amounts "so negligible as to present no public health or safety concerns" need not be regulated as a food additive at all. The case was Monsanto v. Kennedy. Listed as co-petitioner beside Monsanto was the Society of the Plastics Industry — the trade group that had run Frawley's campaign eleven years before. What the industry could not get from the agency in 1968, it got from the bench in 1979.

The new authority had a limit, and it fell where Frawley had drawn his own. Twice — over carcinogenic dyes in 1987, over carcinogenic pesticides in 1992 — the courts refused to read a trivial-risk exception into the Delaney Clause, the 1958 bar on any additive shown to cause cancer. A color the court rated at a lifetime cancer risk of "one in 19 billion" still had to come off the market; the judges ordered it "with some reluctance." De minimis governed everything below the line. The carcinogens stayed above it — Frawley's own carve-out, now the law's.

The number resurfaced in 1987, when an FDA scientist named Alan Rulis renamed it "the threshold of regulation" and traced it home: "actually not new at all, having been observed and duly noted by Frawley in 1967." Eight years later the agency wrote it into the Code of Federal Regulations. The 1995 rule exempts a food-contact chemical from review when its use stays "at or below 0.5 parts per

billion" — two hundred times under Frawley's figure, carcinogens excepted, and resting, the preamble says, on the de minimis authority the court had granted in Monsanto. A footnote sets the principle out in Latin — de minimis non curat lex — the same tag Frawley had recited to the FDA in 1968. The rule credits Rulis, and never names him.

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12 · Not the end · [coda]

> - The number traveled on — into Europe's **Threshold of Toxicological Concern**, the food-safety math of two continents.
> - What was "sheer nonsense" in 1968 is now routine; how a no-effect level became a no-test threshold is **the next essay**.

It did not stop at the American code. The number kept moving — into a European database of hundreds of chemicals, into the Threshold of Toxicological Concern that the food-safety systems of two continents now run on. What the FDA's chief scientist called sheer nonsense in 1968 is now ordinary practice. How a no-effect level hardened into a no-test threshold for whole classes of chemistry — that is the next essay.

Sequencing notes

- **Default above is chronological.** A stronger *dramatic* order may be: **1 → 2 → 3 → 4 → 5 → 6 → 9 → 8 → 11 → 10 → 7 as the close.** Ending on §7 (the dioxin file) leaves the reader with the man's private knowledge; ending on §11/§12 leaves them with the idea's victory. Pick the note you want last.
- **§11 now carries the legal-doctrine spine** (Ramsey gives up 1971 → *Monsanto v. Kennedy* 1979, SPI a co-petitioner → Delaney ceiling 1987/1992 → 1995 codification); **§12 is the short forward-pointing coda** that hands the TTC off to a later essay (TTC/Cramer kept out of this one, per plan).
- **§6 and §8** are short connective beats; §6 (the conflict pattern) can also be dissolved into one-line plants inside §2/§4/§5.
- **Open questions:** is §10 (1981) a coda, or does it belong right after §2 (its IBT through-line)? Does §7 move early (it's contemporary with §2) or stay as the reveal?
- **Quotes are intentionally long here** — at assembly we cut each to its sharpest line or two.

Sources & references

One entry per source, grouped by the section that uses it. URLs are given where a stable public copy resolves; where a source exists only behind a paywall, on local disk, or as an archive item with no clean public URL, the archive + verified locator is named instead (per project rule: never invent a locator). Full provenance and evidence grading live in the numbered dossier (`02`, `03`).

§1 · The ignorance factor

- Frawley, *Investigations Establishing the Safety of Rosin Products for Food and Food-Packaging Applications*, Proc. Naval Stores Work Conference (1965), pp. 65–70 — the "ignorance factor… overly conservative" quote. Internet Archive scan: https://archive.org/details/proceedingsofnav7250nava · local `papers/Frawley - 1965 ...pdf` (OCR `papers/rosin_1965.txt`). **[P]**
- FDA Division of Pharmacology co-authorships with Fitzhugh & Nelson (the "learned the trade at the FDA" claim) — see `02_Frawley_bibliography.md` items 1–8 (PMIDs there).

§2 · Northbrook

- Frawley 1965 rosin paper — the IBT contract clause ("conducted under contract by the Industrial Bio-Test Laboratories, of Northbrook, Ill.") and "almost 5,000 rats and 138 [dogs]." Same source as §1.
- Frawley–Calandra (IBT) co-authorships: Delnav/dioxathion 1963 (*Toxicol. Appl. Pharmacol.* 5:605); BHT 1965 (*Food Cosmet. Toxicol.* 3(3):377); pesticide reproduction 1973 (*TAP* 25(4):589). Cites in `02_Frawley_bibliography.md` items 9, 12, 24.
- EPA Office of Pesticide Programs, *Summary of the IBT Review Program* (1983) — "801 studies on 140 pesticides… 594 (74%) … invalid"; the invalid Hercules toxaphene reproduction study (#2476). Local `papers/Summary of the IBT Review Program- Office of Pesticides Program 1983.PDF` (OCR `papers/ibt_review_1983_ocr.txt`); analysis in `09_IBT_FRAWLEY_OVERLAP.md`. **[P]**

§3 · Proving the obvious

- Frawley, "Scientific Evidence and Common Sense as a Basis for Food-Packaging Regulations," *Food Cosmet. Toxicol.* 5(3):293–308 (1967) — the geometric-proof opening, the "trichotomy," "245 different substances," the 100-fold→1 ppm→"another factor of ten"→0.1 ppm derivation, the 0.2%-of-container rule. PubMed: https://pubmed.ncbi.nlm.nih.gov/4861454/ · local `papers/Frawley - 1967 ...pdf` (OCR `papers/f1967.txt`). **[P]**
- Frawley, "A Reasoned Approach to Regulation Based on Toxicologic Considerations," *Food Drug Cosm. Law J.* 23(5):260–270 (May 1968) — the "million dollars … all wasted … benefit to the consumer was zero" passage; the 245-studies / 90% figures. HeinOnline `hein.journals/foodlj23`; local `papers/food_drug_1968_v23_n5.pdf` (OCR `papers/fdclj_1968.txt`). **[P]**

§4 · "Sheer nonsense"

- *Food Chemical News*, 8 Jan. 1968 — the conference convened to "get a public airing of the complaints before there is a Congressional hearing." Trade press, no public URL; excerpt in `sources/`.
- W. H. Summerson (FDA Bureau of Science), rebuttal paper reported in *Food Chemical News*, 19 Feb. 1968 ("Frawley Proposal Praised for 'Soundness,' Hit as 'Sheer Nonsense'") — the "sheer nonsense," cancer-latency, and "no knowledge of any bad effects" quotes. Local `sources/Summerson_FDA-BureauOfScience_paper_NationalConf_Feb1968_excerpt.md`. **[P]**

- Frawley 1968 *FDCLJ* (above) — the "twenty-four other toxicologists … in writing to the FDA" claim.
- MCA (3 Nov. 1967) and SPI (6 Nov. 1967) endorsements; Keller & Heckman-run campaign; Hercules-chaired SPI committee — chemical/plastics industry files in **ToxicDocs** (Allied Signal / SPI vinyl-chloride collection); see `08_VINYL_CHLORIDE_CAMPAIGN.md` and dossier `07`. Archive items by hash; local copies in `toxicdocs/`.

§5 · The Academy blesses it

- National Research Council, Food Protection Committee, *Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Food* (1969) — the 1/100 framing, the 0.1 ppm recommendation, the "wasteful diversion of scientific resources" rationale, the Smyth/Coon/Frawley/Hall/Oser/Schramm/Zapp task force, the citation to Frawley 1967. DOI 10.17226/20376: https://nap.nationalacademies.org/catalog/20376 · local `papers/1969 - Guidelines ...pdf` (OCR `papers/nas1969.txt`); excerpt in `sources/`. **[P]**

§6 · Both sides of the table — synthesis; sources are those of §2 (IBT co-authorship), §4 (Hercules-chaired lobby), and §5 (NAS task force).

§7 · The other file

- V. K. Rowe (Dow) → "Dr. John P. Frawley, Hercules Powder Company," 19 Mar. 1965, convening the dioxin-impurities meeting — The Poison Papers, Bates **B 1575**; DocumentCloud doc **3253794**: https://www.documentcloud.org/documents/3253794 · local `sources/PoisonPapers_B1575_Rowe-to-Frawley_1965-03-19.txt`. **[P]**
- Doc A — Frawley → Rowe, 3 Jul. 1963 (the July-1963 letter in the litigation exhibit index) — **ToxicDocs** exhibit **H281 14-1 5**, archive id `RBqNnvVrnkZ54xyyyqd9OyKV`; local `toxicdocs/3unclear__xxxx__na__Dioxin__RBqNnvVrnkZ54xyyyqd9OyKV.txt`. **[P-cite]** (index entry; page scan not yet pulled).
- Doc B — Frawley confidential Hercules memo, 12 Jul. 1965, of the 9 Jul. 1965 Farnham (Dow) phone call ("extremely frightened that this situation might explode," etc.) — verbatim text from an Agent Orange MDL plaintiffs' brief, **ToxicDocs** archive id `jyBDvYGzG58gkKk3VmDbjxLK5` (local `toxicdocs/3unclear__xxxx__na__Dioxin__jyBDvYGzG58gkKk3VmDbjxLK5.txt`); indexed Poison Papers DowDATA Bates **A303**. **[P-cite]** (Bates scan still to pull).
- *In re "Agent Orange" Prod. Liab. Litig.*, 565 F. Supp. 1263 (E.D.N.Y. 1983) — the summary-judgment win on Frawley's testimony; Hercules's "no measurable dioxin" but for a 1966 trace. CourtListener: https://www.courtlistener.com/opinion/2312256/ (Justia mirror: law.justia.com/cases/federal/district-courts/FSupp/565/1263/1458052/); local `sources/565_F.Supp.1263_AgentOrange_1983_opinion.txt`. **[P]**
- Weinstein's withdrawal of the Pratt opinion / 1984 settlement — recited in *Hercules, Inc. v. United States*, 516 U.S. 417 (1996), Cornell LII:

https://www.law.cornell.edu/supct/html/94-818.ZO.html · local `sources/516_US_417_Hercules-v-US_1996_CornellLII.html`. **[P]**

§8 · The loop

- Fitzhugh, Nelson & Frawley, "A Comparison of the Chronic Toxicities of Synthetic Sweetening Agents," *J. Am. Pharm. Assoc.* 40(11):583–586 (1951) — "saccharin and sodium cyclohexyl sulfamate had only slight effects … 5 percent." DOI 10.1002/jps.3030401117: https://onlinelibrary.wiley.com/doi/abs/10.1002/jps.3030401117 (PMID 14907466); local `papers/Fitzhugh et al. - 1951 ...pdf`. **[P]**
- Cyclamate in Frawley's 1967 list — Frawley 1967 *FCT* (above). FDA removal of cyclamate from GRAS, Oct. 1969 — secondary; no single public locator captured (FDA history). **[2]**

§9 · The numbers that didn't hold

- Vinyl chloride–vinyl acetate copolymer at 120,000 ppm; acrylamide "toxic below 100 ppm," listed at 40 ppm; Citrus Red No. 2 at 500 ppm — Frawley 1967 *FCT* appendix (above); table cross-check in `09_IBT_FRAWLEY_OVERLAP.md`.
- Vinyl chloride = IARC Group 1 (Monograph 100F): https://publications.iarc.who.int/123 . **[P]**
- Acrylamide = IARC Group 2A (Monograph vol. 60): https://www.inchem.org/documents/iarc/vol60/m60-11.html . **[P]**
- Citrus Red No. 2 = IARC Group 2B (Monograph vol. 8): https://www.inchem.org/documents/iarc/vol08/citrusredno2.html . **[P]**
- OSHA vinyl-chloride limit cut 500→1 ppm (1974) — OSHA Vinyl Chloride Standard, 29 CFR 1910.1017 (39 FR 35890, 1974). **[secondary]**

§10 · Decade of change

- Frawley, "The 1980s — A Decade of Change," *Regul. Toxicol. Pharmacol.* 1(1):3–7 (1981) — the GLP/"peer intimidation"/"reputation … worth nothing" passage and the anti-"zero risk"/Delaney argument. PubMed: https://pubmed.ncbi.nlm.nih.gov/7186152/ · local `papers/Frawley - 1981 ...pdf` (OCR `papers/f1981.txt`). **[P]**

§11 · It became law *(full reconstruction + grading: `10_DE_MINIMIS_LEGAL_LINEAGE.md`)*

- Ramsey Proposal abandoned 3 June 1971 as "scientifically sound" but legally unworkable — Keller & Heckman history; dossier `10` §1, register D4. **[secondary]**
- *Monsanto Co. v. Kennedy*, 613 F.2d 947, **at 956** (D.C. Cir. 1979) (Leventhal, J.) — FDA's de minimis authority ("latitude inherent in the statutory scheme… *de minimis* situations… no public health or safety concerns"); **the Society of the Plastics Industry was co-petitioner** (the trade group that ran Frawley's campaign). Acrylonitrile-bottle case. Opinion text: CourtListener opinion 7840898 (`/opinion/7893633/`); corroborated at 60 FR 36584 (local). **[CONFIRMED-primary]**.

- *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987) (Williams, J.) — no de minimis exception to the color-additive Delaney Clause; Orange No. 17 "one in 19 billion," ordered off "with some reluctance." law.resource.org `F2/831/831.F2d.1108.86-5150.86-1548.html`; CourtListener `/opinion/496579/`. **[P]**
- *Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992) (Schroeder, J.) — no de minimis under the §409 Delaney Clause for carcinogenic pesticide residues. CourtListener `/opinion/586411/`. **[P]**
- A. M. Rulis, "De Minimis and the Threshold of Regulation," in *Food Protection Technology* (C. W. Felix ed., 1987), pp. 29–37 — "duly noted by Frawley in 1967, using a different data base." Mirror: https://downloads.regulations.gov/EPA-HQ-OPP-2013-0821-0008/content.pdf . **[P]**
- FDA, Threshold of Regulation final rule, 21 CFR 170.39 — 60 FR 36582 (17 Jul. 1995); "at or below 0.5 parts per billion"; rests on *Monsanto*'s de minimis authority; footnote 4 recites *de minimis non curat lex*; conditions the exemption on non-carcinogenicity (citing *Public Citizen v. Young*); cites Rulis, not Frawley. GovInfo: https://www.govinfo.gov/content/pkg/FR-1995-07-17/pdf/95-17435.pdf · local `sources/FDA_Threshold-of-Regulation_60FR36582_1995.txt`. **[P]**

§12 · Not the end (coda) — *the TTC endpoint is reserved for a later essay; named here only as the forward gesture.*

- Threshold of Toxicological Concern adopted by EFSA (2019): https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2019.5708 ; Munro ~600-chemical database / Cramer decision tree — Food Packaging Forum TTC dossier (2024). **[secondary]**