Toxicologically Insignificant — *conference-open structure*

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Working draft, structural variant (2026-06-10). Opens in the room at the February 1968 FDA conference, rolls back to the idea and the pressure that put Frawley there, returns to the room, then follows the idea to its victory. The subject is the de minimis principle; Frawley is the protagonist, not the topic; we are critical of the approach. Quotes link to the primary files in this repository; provenance and grading are in the numbered dossier. Conference quotes are drawn from `sources/1968_NationalConference_IndirectFoodAdditives_compiled.md`.

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1. Both answers at once

On the afternoon of 13 February 1968, in a hotel conference room in Washington, the Food and Drug Administration gave its first formal answer to an idea it had been dodging for two years. The idea was that a large class of chemicals could be presumed safe without being tested. The man who had given the idea a number and a name, John P. Frawley, chief toxicologist at Hercules, had just presented it from the floor. The agency's chief scientist, W. H. Summerson, director of the Bureau of Science, answered him.

The answer came in two halves that did not fit together. Summerson granted "a soundness of certain portions of Dr. Frawley's thesis," and conceded that the agency was imposing some "unjustifiable expense" on industry. Then he took the core of the proposal — a single line below which nothing need be tested — and called it "sheer nonsense." A trade reporter in the room caught the doubleness in one headline: *Frawley Proposal Praised for "Soundness," Hit as "Sheer Nonsense."*

There was a second moment, smaller and sharper. Frawley had told the room that, pesticides and heavy metals aside, no packaging chemical is toxic at forty parts per million or less. One of the FDA's own toxicologists, Dr. Joseph McLaughlin, disagreed from the floor and named a single compound against him: acrylonitrile. Keep the name. It returns eleven years later, in a courtroom.

Two things from that afternoon are worth holding onto. The agency's own chief scientist judged the idea both sound and absurd in a single paper; and the agency's own toxicologist named the chemical that would, in time, carry the idea into law. Within a year the proposal Summerson called nonsense would carry the recommendation of the National Academy of Sciences, and within a decade it would have the force of federal law. How a company's toxicologist came to be standing in the FDA's conference telling the agency to stop testing, and why the agency's answer was split down the middle, is the rest of this.

2. The obvious thing

Frawley liked to present the idea as a diversion rather than a campaign. He had opened an earlier version of the talk, in London the year before, with a small lesson in geometry (`papers/f1967.txt`; scan here):

> "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."

The analogy gives the method away. The straight line between two points is not proved; it is accepted. Frawley placed the safety of food packaging in the same category — a thing obvious enough that the demand for proof was the error. He set out not to find whether the uses were safe but to attach a number to a conclusion he already held.

For the number he reached past geometry to law. He framed the problem as a standoff among three professions. A chemist with a sensitive instrument finds that ten parts per billion of some substance migrates from a package into 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, Frawley noted, was the lawyer's old maxim: "de minimis non curat lex — the law does not concern itself with trifles." He wanted the toxicologist's authority behind the lawyer's exit, and he wanted it expressed as a figure.

The figure came from the safety margin our first essay was about — the hundredfold cushion that Frawley liked to call, more plainly than his teachers had, an "ignorance factor… overly conservative." He had assembled "two-year chronic toxicity studies on 245 different substances," which he said were "90% of all such studies." For everything but pesticides and heavy metals, he reported, "every compound was without toxic effect in experimental animals when fed for a lifetime at a dietary concentration of 40 p.p.m." Apply the conventional hundredfold margin and every compound came out safe at one part per million. Then he divided once more: "protect ourselves by adding another factor of ten and adopt 0.1 p.p.m. as a level of toxicological insignificance for all materials other than pesticides and heavy metals." For the manufacturer he converted the diet figure into a specification — a component at no more than 0.2% by weight of the container — and filed it with the FDA.

The motive under the method was a bill. The 1958 Food Additives Amendment had swept Hercules's food-grade rosins into the class of substances requiring two-year studies; Frawley counted thirty-four products and "a minimum price of $50,000 per compound," and told the conference, in the first person, that he "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" (`papers/fdclj_1968.txt`). The sentence carries the whole idea inside it. A clean result is treated as proof the test was never needed — a judgment available only by assuming the answer first.

3. The pressure

Frawley did not put himself in that room. An industry did, and a congressman.

The trade groups had been working the indirect-additives problem for two years. The Manufacturing Chemists Association endorsed Frawley's amendment to the FDA on 3 November 1967, claiming 185 companies and more than ninety percent of U.S. basic chemical capacity; the Society of the Plastics Industry followed three days later. The drafting and the choreography ran through the packaging-law firm Keller and Heckman, and the SPI committee carrying the proposal was chaired by a Hercules executive, Robert M. Miller — Frawley's own employer (`08_VINYL_CHLORIDE_CAMPAIGN.md`). When Frawley told the conference that "24 other toxicologists from universities and industries have supported this proposal in writing to the FDA," he was describing the visible tip of that effort, not a spontaneous consensus.

The congressman was John Dingell, whose House Small Business subcommittee had pressed the FDA on its handling of indirect additives in 1967; Commissioner Goddard had promised written answers within thirty days and never sent them. The conference was the substitute. The trade coverage said so without softening it: industry representatives understood "that the conference had been inspired by pressure from a House Small Business subcommittee," and "the calling of the meeting enabled FDA to tell the subcommittee that it was 'doing something' with regard to indirect additives." The day before the sessions opened, seven trade associations sent Goddard a letter asking that "soon after the conclusion of the Conference an 'Industry-Government Advisory Committee' be created." The FDA had been maneuvered into giving the idea a hearing. It had not been persuaded of it.

4. The room, again

So the agency arrived cornered, and its answer split along the seam between the pressure on it and its own science. Return to Summerson at the podium. His paper, which "dealt almost solely with the Frawley proposal," made the case against de minimis that has not weakened since (`sources/Summerson_FDA-BureauOfScience_paper_NationalConf_Feb1968_excerpt.md`):

> "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."

A threshold of insignificance is drawn from what is known when it is drawn. The harm that matters most — a cancer that surfaces a decade later, in a population eating a food supply that has changed in the interim — is the harm that cannot be read from the data in hand. Summerson named the move underneath the proposal directly: "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." No knowledge of harm is not knowledge of no harm.

He went at the database too, and the hit landed. Frawley's 245 studies were drawn from the published literature, and Summerson pointed out that "Frawley's sources 'bias the data,' since highly-toxic substances are not found in two-year studies, because the animals do not survive for two years." A library of compounds that completed a two-year feeding study is, by construction, a library of compounds non-toxic enough to let the animals live. The compound McLaughlin had named from the floor — acrylonitrile — was that same point in miniature: the substances that break the rule are the ones a two-year study never gets to see.

The toxicologist presiding over the session, Norton Nelson of New York University, was no industry man and no absolutist. He "agreed that 'some simplification is required,' but warned against 'over-simplification,'" adding that "any single set of concentration limits" are unlikely to be found — a cut-off might serve for well-understood classes and fail for others. That was the scientific verdict of the room: the impulse to triage was reasonable, the single number was not.

And yet the room did not close the door. Cornered between its science and its congressional problem, the agency reached for a compromise. Summerson allowed that "somewhere in between will be a position that both Dr. Frawley and FDA can live with"; Fred Delmore of the Bureau of Voluntary Compliance said the two sides were "not too far apart"; Heckman, for the plastics industry, called a "middle ground" "a good place to start." The idea had lost the argument and kept its life.

5. After the room

What the industry did next is on the record because the industry kept the record. Within a week Keller and Heckman mailed the SPI committee a reading of the conference, enclosing thirteen pages of trade-press coverage and the news that mattered to them (`sources/1968_NationalConference_IndirectFoodAdditives_compiled.md`):

> "According to other information we have received, copies of the verbatim transcript of the Conference will be available from the reporting company by Tuesday of this week … there is already some impetus for the Food and Drug Administration to take affirmative action, at least to the extent of responding to an inter-industry letter forwarded to Dr. Goddard on February 9, 1968."

The trade newsletter's own headline read the split exactly as the agency had left it: *FDA Agrees to Consider Frawley Proposal on Indirect Additives With Obvious Reluctance.* Inside the industry the "sheer nonsense" verdict registered not as a defeat but as a price of admission. Summerson had promised a "documented commentary" on the proposal and conceded the testing carried "unjustifiable expense"; the firm read those concessions as the opening the campaign had been built to find, and turned at once to the next instrument — the industry-government advisory committee the seven associations had requested the day before the conference began. The consensus Frawley had described in the room as the support of his profession was, in the files, a thing being assembled.

6. The long win

The idea lost in 1968 in the one forum equipped to judge it on the science, and it won almost everywhere after.

Within a year the National Academy of Sciences put Frawley's phrase on a cover. Its Food Protection Committee published *Guidelines for Estimating Toxicologically Insignificant Levels of Chemicals in Food*, fixing the line below which a chemical need not be studied at his 0.1 part per million, on his reasoning, citing his 1967 paper — and the drafting task force named in the preface included J. P. Frawley (`papers/nas1969.txt`). The proposal the FDA's chief scientist had called nonsense became a National Academy recommendation in twelve months, with the proposer on the committee.

Inside the agency the idea still could not find a legal footing. The FDA's own Dr. Ramsey drafted an exemption for substances migrating below fifty parts per billion, and in June 1971 the agency set it aside, judging that the statute did not let it exempt a chemical that met the literal terms of the "food additive" definition. The authority it believed it lacked was then handed to it by a court — and the case is where the chemical from the 1968 floor returns. In *Monsanto Co. v. Kennedy*, 613 F.2d 947 (D.C. Cir. 1979), the FDA had moved to bar **acrylonitrile** copolymer beverage bottles because the monomer migrated into the drink. The

D.C. Circuit told the Commissioner he had the power to wave through a trivial migrant after all (`sources/Monsanto-v-Kennedy_613F2d947_DCCir-1979_opinion_CourtListener.txt`):

> "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."

The co-petitioner beside Monsanto was the Society of the Plastics Industry, the body that had carried Frawley's proposal to the FDA eleven years before. The chemical an FDA toxicologist had named in 1968 as the exception to Frawley's rule had become, in 1979, the case through which the courts granted Frawley's rule the force of law. The doctrine did not actually free acrylonitrile — the monomer is a carcinogen and stayed regulated — but it freed the principle.

The courts then drew the principle's limit, and the limit is its confession. Over carcinogenic dyes in 1987 and carcinogenic pesticides in 1992, they refused to read a trivial-risk exception into the Delaney Clause, the bar on any additive shown to cause cancer. In *Public Citizen v. Young*, 831 F.2d 1108 (D.C. Cir. 1987), the FDA had cleared two dyes whose lifetime cancer risk it put at "one in 19 billion" and "one in nine million," and the court struck the clearances down "with some reluctance," holding the clause's language "rigid" (`sources/PublicCitizen-v-Young_831F2d1108_DCCir-1987_opinion_law.resource.org.html`). De minimis was allowed for everything except the carcinogens — which is to say, the law conceded that the idea fails exactly where Summerson said it would.

That concession is hollow in practice, and the hindsight shows why. The numbers Frawley was surest of did not hold. His highest no-effect value was a vinyl chloride copolymer at 120,000 parts per million; vinyl chloride is now a confirmed human carcinogen, and within six years of his talk the workplace limit fell from 500 parts per million to one. Acrylamide, the one compound he flagged, is a probable carcinogen that forms in cooked food. The deeper trouble is the unit. For a genotoxic carcinogen there is no dose that does nothing; the no-effect level, the quantity the whole table was built from, is not a property these chemicals have. The carve-out for known carcinogens guards against the hazards already found, and the threshold is built to skip the testing that would find the rest. When the 1995 rule codified the threshold at 0.5 parts per billion, it conditioned the exemption on a substance "not having been shown to be" a carcinogen (`sources/FDA_Threshold-of-Regulation_60FR36582_1995.txt`); the word *shown* is Summerson's objection, rebuilt into the regulation that overrode him. The rule rests on *Monsanto*, states the principle in a footnote as *de minimis non curat lex*, credits the FDA scientist who revived it in 1987, and never names Frawley. The number went on into the European Threshold of Toxicological Concern; the food-safety systems of two continents now run on a version of it.

(One file sits alongside this and connects to the same lineage. Monsanto, the company whose name is on the precedent that made de minimis law, appears also in the dioxin record: in March 1965 Dow's V. K. Rowe wrote to Monsanto, Hooker, Diamond Alkali, and Hercules's Frawley about "highly toxic impurities" in 2,4,5-T, and Frawley's own confidential memo of a Dow phone call — `toxicdocs/3unclear__xxxx__na__Dioxin__jyBDvYGzG58gkKk3VmDbjxLK5.txt` *— records an industry "extremely frightened that this situation might explode." The men who told the public that exposure below a line was meaningless did not, among themselves, treat knowledge as beside the point. Held for a later turn; see* `10_DE_MINIMIS_LEGAL_LINEAGE.md` *and* `06_ANALYTIC_MEMO.md`*.)*

The case for the idea was never empty. The testing requirement did not scale, and triage was not an unreasonable instinct; the people who built it were not villains, and the man at its center held the view in good faith for twenty-five years. But it lost the argument in the room in 1968, on the science, to the agency's own staff, and then it won the lobby, the academy, the courts, and the code. The reckoning is with the idea. What its author left in his own words is not a second thought but the grievance he carried into that room: that proving food packaging safe had been a waste, because it had been proven safe.

Why the de minimis idea does not hold

The case against the principle, in the words the record gives us:

- **It assumes its own conclusion.** It was reached by working backward from a result already held, and driven by a testing bill. Frawley's own account: *"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."* And the motive, to the FDA: *"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."*
- **It trades evidence of absence for absence of evidence.** Summerson named the move in 1968: *"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."* The 1995 rule then wrote the same move into law, conditioning the exemption on substances *"not having been shown to be"* carcinogens — when the threshold exists to skip the showing.
- **It is blind to latency.** Summerson: *"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."*

- **Its evidence base is self-selecting.** Summerson on the 245-study library: Frawley's sources *"bias the data," since highly-toxic substances are not found in two-year studies, because the animals do not survive for two years.* The compounds most worth catching are absent by construction. The session's own chairman, the toxicologist Norton Nelson, *"agreed that 'some simplification is required,' but warned against 'over-simplification,'"* and said *"any single set of concentration limits"* are unlikely to be found.
- **Its core unit does not exist where it matters most.** For a genotoxic carcinogen there is no dose that does nothing, so the no-effect level the whole table is built from is not a property the chemical has. The period instance is on the record: when Frawley claimed nothing but pesticides and heavy metals is toxic at forty parts per million or less, *"FDA's Dr. Joseph McLaughlin, Jr., disagreed, pointing to acrylonitrile."*
- **Its numbers did not hold.** The failures are the compounds Frawley was surest of: a vinyl chloride copolymer he listed safe at 120,000 parts per million (vinyl chloride is now a confirmed human carcinogen); acrylamide, which he flagged but cleared at 40 ppm; and cyclamate, which he had judged in 1951 to have *"only slight effects at a dosage level of 5 percent"* and which the FDA pulled from American food in 1969.
- **It advanced by capture, not by merit.** Beaten on the science, it won by organization. Frawley to the conference: *"24 other toxicologists from universities and industries have supported this proposal in writing to the FDA,"* and *"Several lawyers have advised me that this support from the scientific community of and by itself confirms that these uses are generally recognized as safe … and that no action on the part of the FDA is necessary."* The "support" was an industry campaign; the academy panel that endorsed the number was seated with its own author.
- **The law that adopted it conceded the flaw.** It granted the doctrine in an acrylonitrile case — *"There is latitude inherent in the statutory scheme to avoid literal application of the statutory definition of 'food additive' in those de minimis situations…"* — but had to carve out the carcinogens, doing so *"with some reluctance,"* the court holding the Delaney language *"rigid."* The carve-out then rests on a "showing" the threshold is designed to prevent.
- **In sum, it is a license not to know.** It converts an admitted ignorance into a standing permission to stay ignorant. The margin it rests on was, by its author's own name, an *"ignorance factor… overly conservative"* — and the de minimis number is that factor turned from a cushion against what we do not know into a reason not to find out.

Primary files are linked inline and held in `papers/`, `sources/`, and `toxicdocs/`. Conference material: the compiled file in `sources/`. Evidence grading, alternative readings, and open questions are in `05_OPEN_QUESTIONS.md`.