

# 08\_VINYL\_CHLORIDE\_CAMPAIGN

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## THE "FRAWLEY PROPOSAL" CAMPAIGN, 1966–1972 — a fully-cited reconstruction

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Built from a deep read of 67 ToxicDocs files held locally in `./toxicdocs/` (records in `_campaign_records.json`). These are internal files of the plastics/chemical industry — chiefly **Allied Chemical** (tagged "Allied Signal"), the **Society of the Plastics Industry (SPI)**, and the **Manufacturing Chemists' Association (MCA)** — produced in vinyl-chloride/PVC litigation. **48 of the 67 are "core."** Each claim below cites a local file (by its `__hash tail`) + the document's own date; many carry Allied's Bates stamps (`ASI-PR ...`). Verbatim quotes are kept under 25 words.

**The headline this episode adds to the dossier:** Frawley's de minimis idea was not a lone proposal the FDA happened to weigh — it was the banner of a **coordinated, multi-association, lawyer-run industry campaign (1966–72)** to write a self-exempting threshold into FDA food-packaging law. And the campaign's own committee was **chaired by a Hercules man (Robert M. Miller)** — Frawley's employer.

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### 1. The machinery and the cast

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- **Vehicle:** the **SPI Food, Drug and Cosmetic Packaging Materials Committee** (founded 1936), and in parallel the **MCA Food, Drug and Cosmetic Chemicals Committee**.
- **Chairman:** **Robert M. Miller, Hercules, Inc.** (Delaware Trust Bldg., Wilmington — Frawley's own building) [`...qL0ea`, 1968-11-07; `...2NB`]. Vice-chair **Taylor W. Hanavan, DuPont**; committee founder/ ex-chair **George W. Ingle, Monsanto**.
- **Counsel & quarterback:** **Keller and Heckman** — **Jerome H. Heckman** (with Joseph E. Keller, Thomas J. Hughes) — SPI counsel, who drafted the filings and choreographed the FDA approach.
- **The scientist:** **Dr. John P. ("Jack") Frawley, Chief Toxicologist, Hercules**.
- **Industry toxicology hands:** **W. A. Knapp** (Allied Chemical), **Kenneth Morgareidge** (Food & Drug Research Labs), **Carrol S. Weil** (Mellon Institute).
- **FDA actors:** **Dr. W. H. Summerson** (Director, Bureau of Science), **Lesel L. Ramsey** (Deputy/ Assistant Director, Bureau of Science — later author of the

FDA "Ramsey Proposal"), Associate Commissioner **J. Kenneth Kirk**, **Fred J. Delmore** (Bureau of Voluntary Compliance), Commissioners **James Goddard** then **Herbert Ley**, Hearing Clerk **Beryl McCullar**.

- **Trade press:** *Food Chemical News* (eds. Louis Rothschild Jr., Raymond [Newton]) — the campaign's scoreboard, repeatedly reprinted to the committees by Keller & Heckman.

## 2. Phase 1 — Launch (Sept 1966 → Jan 1967)

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- **14 Sep 1966 — the debut.** Frawley reads "**Toxicological Evaluation of Migratory Food Additives**" at the ACS Symposium on Safety Evaluation of Coatings and Plastics for Food Packaging, New York; 143 chronic studies; the conclusion that any component "**present in the article or its coating at a level not exceeding 0.2% by weight is generally recognized as safe**" (...0orpG2Q7 , ASI-PR; his "denying the existence of zero" line appears here).
- **13–14 Dec 1966 — first FDA contact.** SPI convened a **Special Meeting with FDA** (Ramsey, McLoughlin) at the Shoreham Hotel, supplying **16 prepared questions in advance**; Question 3 teed up the Frawley thesis (...3eM2j552). Allied's **W. A. Knapp** reported candidly afterward: "*the writer gained the impression that FDA wanted migration data whether or not the migrant constituted any risk to public health*" (...zdMLyLZa , 1966-12-20, ASI-PR).
- **25–26 Jan 1967 — BIBRA.** Frawley delivers the mature version in London (published *Fd Cosmet Toxicol* 5:293–308), telling the audience FDA "**authorized me to tell you that they are giving it serious consideration**" (...Ne9DgGn7 , ...qdozKJ6e).

## 3. Phase 2 — Industry mobilization (1967)

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- **25 Jan 1967 — early FDA warmth.** MCA minutes record Associate Commissioner **J. Kenneth Kirk** said the proposal "**has much merit**" and "**referred Frawley's conclusion to the FDA Bureau of Science**" (...DXaG0). The MCA resolved to solicit member-company data to validate the 0.2% concept.
- **Feb–Jun 1967 — building the dossier.** Both committees gather supporting data. Frawley's **17 Mar 1967** letter asks members for unpublished 2-year chronic studies and migration data (...qkgD0); he notes "*the concept might be adopted in the European countries before anything is done in the U.S.*" Allied's Knapp supplies chronic-feeding data (...3NeeR4XZ , 1967-06-13).
- **20 Sep 1967 — the legal machine forms.** SPI creates a **Procedural Regulations Subcommittee** (Heckman coordinator; Knapp/Allied, Miller/Hercules, Hanavan/DuPont) and plans to remind **Commissioner Goddard** of the Kirk discussions (...x5DwB).
- **Oct 1967 — the formal filing.** On **23 Oct 1967** Frawley files comments with the **HEW Hearing Clerk** proposing to amend **Section 121.2500** to exempt packaging substances used at **≤0.2% by weight (except heavy metals and pesticides)** (...evvR1 , ...B6m47). Eastman calls the 1966 ACS paper "**the brilliant Frawley paper**" (...3eXr4j4v , 1967-10-06). **Both associations then formally endorse it to FDA:** MCA on **3 Nov 1967** (Decker; "185

companies... >90% of U.S. basic chemical capacity," ...pZpLVm8N ) and **SPI on 6 Nov 1967** (Heckman: "*the Society of the Plastics Industry hereby endorses the recommendation that Section 121.2500... be amended,*" ...wgmex ).

#### 4. Phase 3 — The FDA National Conference & the showdown (Feb 1968) ★ (your document)

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FDA's response to the mounting pressure was to convene the **National Conference on Indirect Food Additives, 13–14 Feb 1968**, opened by Commissioner **Goddard**, with **Frawley slotted to present "Toxicology of Indirect Food Additives"** (...wjga43zZ , agenda). Keller & Heckman told the SPI committee the conference's purpose bluntly: **"to get a public airing of the complaints before there is a Congressional hearing"** (...nka82JKV , 1968-01-08).

##### ★ "Frawley Proposal Praised for 'Soundness,' Hit as 'Sheer Nonsense'"

That is the verbatim *Food Chemical News* headline (issue of **19 Feb 1968**, pp. 5–6), reprinted to the SPI committee by Keller & Heckman — your document, local file `1yes_1968_AlliedSignal_PolyvinylC_Kza60dbJNXoEMZbe1v7QM7VxK` (Bates **ASI-PR 0000576–0000577**). It reports the head-to-head between Frawley and **Dr. W. H. Summerson, Director of FDA's Bureau of Science**, whose paper **"dealt almost solely with the Frawley proposal."** The drama is that Summerson did *both* things at once:

- **The praise:** under questioning Summerson conceded **"soundness of certain portions of Dr. Frawley's thesis,"** allowed there is some **"unjustifiable expense"** in testing, promised FDA would provide a **"documented commentary,"** and forecast: **"Somewhere in between will be a position that both Dr. Frawley and FDA can live with."** He even granted the 0.2% → <0.1 ppm generalization (minus pesticides/ heavy metals/carcinogens) **"has considerable appeal and some reliability on the basis of 'published' toxicity data."**
- **The "sheer nonsense":** *"much of what Frawley proposed for a 'single cut-off place' is 'sheer nonsense.'"* Summerson's scientific objection was **cancer latency:** because the *"'incubation' period... until... cancer occurs is often 10 years or more,"* retrospective detection is *"well nigh impossible,"* so *"we must require premarket testing."* He pointedly rebuked the industry posture — **"the proponent feels no food additive clearance is necessary because he has no knowledge of any bad effects from his product"** — and **denied that the past 10 years of testing had been "a waste of time and money,"** a direct rebuttal of Frawley's "negligible return on investment" thesis.
- **The split-the-difference dance:** Frawley argued it was **"just a matter of degree"** (FDA already accepted 0.01 ppm without tox work; he proposed 0.1 ppm) and urged a **"middle ground"; Delmore** (FDA) said the two sides were **"not too far apart"; Heckman** (SPI) called a "middle ground" *"a good place to start."*

So the document is the single best primary snapshot of what FDA's "serious consideration" actually was: a public, contested negotiation in which the agency's chief scientist simultaneously legitimized the proposal's premise and savaged its central device (the "single cut-off"), while signaling compromise.

### ★ NEW — the *Frawley side* of the same showdown, now in primary text

We now hold **Frawley's actual conference address**, printed as "**A Reasoned Approach to Regulation Based on Toxicologic Considerations**," *Food Drug Cosm. Law J.* 23(5):260–270 (May 1968) (local PDF [papers/food\\_drug\\_1968\\_v23\\_n5.pdf](#); excerpt in [sources/Frawley\\_Reasoned-Approach\\_NationalConf\\_Feb1968\\_...md](#)). So **both sides of 13 Feb 1968 are now documented from primary text** — Summerson's "sheer nonsense" paper (above, via *Food Chem. News*) and the speech he was rebutting. Three things the Frawley text adds:

- **It corroborates the campaign from the podium.** Frawley publicly claimed "**twenty-four other toxicologists... supported this proposal in writing to the FDA**" and that this support, per his lawyers, itself made the uses "gras." That "24 letters to FDA" is the public face of the SPI/Allied Signal coordination traced in §§2–3 — the organized effort presented to FDA as spontaneous scientific consensus.
- **The financial driver, first-person:** "**I personally had spent over a million dollars of my Corporation's money** investigating the safety of food packaging materials... it was all wasted."
- **Title drift:** the SPI agenda (...wjga43zZ) billed his talk as "**Toxicology of Indirect Food Additives**"; FDCLJ printed it under the "Reasoned Approach" title — same paper, and confirms he is the scheduled "Frawley" of the agenda. His data base is now **245** chronic studies; the rule is pinned to **Reg. 121.2500(d)**.

## 5. Phase 4 — The FDA counter-proposal and the long negotiation (1968–69)

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- **The FDA in-house counter.** Through 1968 FDA staff drifted toward its **own** threshold — exempt substances contributing **≤0.05 ppm (50 ppb)** — but, unlike Frawley, **conditioned on extraction studies**. SPI minutes call this "a *direct result of the much discussed 'Frawley concept'*" (...JN2yv, 1968-04-17); the "**key difference**" counsel repeatedly flagged was that "**the Frawley recommendations would exempt substances... without the need for extraction studies**" (...oea1Zq1, 1969-05-13). This is the primary-document birth of the "**Ramsey Proposal**" (the 50-ppb FDA version later abandoned 3 Jun 1971).
- **The NAS lever.** Heckman reported to Miller that the **NAS/NRC Food Protection Committee** had approved "**Quantitative Guidelines for Toxicologically Insignificant Levels of Chemical Additives in Food**" — on which "**Frawley participated**" — endorsing <0.1 ppm as toxicologically insignificant, and that "*there is good reason to believe that the Food and Drug*

*Administration will accept this basic principle"* (...1gK5pMrr , 1969-01-24; ...mbq0EvX , 1969-02-06).

- **Inter-industry coordination.** When FDA issued a "**discussion draft notice of proposed rule making**" (May 1969), Miller and Heckman organized a cross-industry response: a **3 Jun 1969** Washington meeting convened with **Einar Wulfsberg (American Paper Institute)**, forming an **Inter-Industry Committee on Indirect Additives** that filed with FDA (Aug 1969) and wrote directly to **L. L. Ramsey** (...oea1Zq1 ; 6/3, 8/27, 8/29 records). Monsanto's internal "FDA call report" (1969-11-25) and Knapp's memos-to-file (1970-02-03; 1970) track the back-channel.

## 6. Phase 5 — Stalemate, doctrine, and the long tail (1970–1972 →)

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FDA never adopted either threshold; the campaign nonetheless ran on — DuPont's Hanavan circulating draft regulations to Frawley (1970-02-09; 1970-08-11), Frawley corresponding with **Carrol Weil** of Mellon on the short-vs-long-study methodology (1970-03-04), and the SPI/MCA committees still pressing in **1971–72** (...QJ6Ez 1971; ...Va6X0 & ...DGyy 1972; MCA → Miller 1972-08-17). By the mid-1970s the idea had hardened into accepted doctrine abroad — a 1975 Japanese review cites the "**Frawley limiting value**" (0.1 mg/day) by name (...99R8Eq). FDA finally abandoned the Ramsey 50-ppb version on **3 Jun 1971** as legally unworkable; the concept was resurrected by **Rulis (1987)** and codified in the **1995 Threshold of Regulation rule** (see Strands I & 07\_TOXICDOCS\_FINDINGS).

## 7. What this adds to the dossier

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1. **Strand I upgraded from inference to documentation.** The "serious consideration" Frawley cited in 1967 is now a fully-dated, named negotiation — Kirk's "much merit," Summerson's "sheer nonsense," the FDA 0.05-ppm counter, the NAS lever, the inter-industry committee, Ramsey by name.
2. **The conflict of interest is structural, not incidental.** The proposal's author (Frawley) and the sponsoring industry committee's chairman (Miller) were **both Hercules men, in the same building** — and the whole apparatus (SPI, MCA, Keller & Heckman, *Food Chemical News*) existed to convert one employee's "common-sense" thesis into a self-exempting federal rule.
3. **It explains the GLP bitterness.** The 1981 manifesto's fury at regulators (06\_ANALYTIC\_MEMO §2.3) reads differently once you see that Frawley spent 1966–72 being told by FDA's own Bureau of Science chief that his central device was "sheer nonsense."

*Local source list: toxicdocs/\_campaign\_records.json (per-document date, author, quotes, Bates). The four richest files are the SPI committee minutes (...2NB 1966, ...wgmex 1967, ...qL0ea 1969, ...85ZZ 1972) and your "Soundness/Sheer Nonsense" clipping (...Kza60dbJ , ASI-PR 0000576–77).*