sources__Frawley_Reasoned-Approach_NationalConf_Feb1968_FDCLJ23-260_excerpt

John P. Frawley — "A Reasoned Approach to Regulation Based on Toxicologic Considerations"

The *Frawley side* of the 13 Feb 1968 showdown. This is the published text of the speech Frawley delivered at FDA's **National Conference on Indirect Food Additives, Washington D.C., Tuesday, 13 Feb 1968** — the very paper that **Dr. W. H. Summerson** (FDA Bureau of Science) was rebutting when he called its central device "sheer nonsense" (see the companion file `Summerson_FDA-BureauOfScience_paper_NationalConf_Feb1968_excerpt.md` and `08_VINYL_CHLORIDE_CAMPAIGN.md` §4). Together the two excerpts give **both sides** of that exchange from primary text.

Citation. John P. Frawley, "A Reasoned Approach to Regulation Based on Toxicologic Considerations," *Food Drug Cosmetic Law Journal* **23(5):260–270** (May 1968), Commerce Clearing House / Food and Drug Law Institute. **Local primary:** `papers/food_drug_1968_v23_n5.pdf` (pp. 260–270); OCR in `papers/fdclj_1968.txt`. Byline: **"Dr. Frawley Is Chief Toxicologist for Hercules, Incorporated, Wilmington, Delaware."** All quotes verbatim, kept short; page pinpoints noted.

> **Naming note.** The SPI conference *agenda* (a ToxicDocs doc) listed Frawley's talk as **"Toxicology of Indirect Food Additives"**; the published title above is what FDCLJ printed. Same paper, two titles.

The financial driver / conflict of interest, in his own words (p. 261)

> "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."

He frames the whole problem as wasted effort: essentially all pre-1958-Amendment packaging practices "had been confirmed as safe and inscribed into a set of regulations too complex for anyone to understand."

The "de minimis" trichotomy and his three escape routes (pp. 262)

The "ever famous trichotomy": a chemist finds **10 ppb** migrating; the **lawyer** says it is therefore a food additive needing clearance; the **toxicologist** won't call it safe without studies. Three ways to "break this vicious circle": (1) the chemist uses a less sensitive method and reports "not there"; (2) the lawyer invokes **"de minimis non curat lex"**; (3) the toxicologist declares it safe **on the basis of insignificance.** Frawley puts the duty on toxicologists first, lawyers second — *not* chemists.

The experience-based derivation of the threshold (pp. 263–265)

Self-questioning ladder: one molecule is accepted as safe (else no new chemical could ever be made); **1 ppb** in diet is accepted daily (chemists are exposed above it); **1 ppm** he answers "emphatically no" (a few compounds + chemical-warfare agents are toxic there). Then the literature review:

> "I have been able to locate two-year chronic toxicity studies on **245 different substances**… it represents between **15 and 20 million dollars** in toxicological research… I now have collected over **90%** of all such studies."

Result: for the **"all other"** class (excluding **pesticides and heavy metals**), *every* compound was without toxic effect at **40 ppm** lifetime feeding; most safe above 100 ppm. Applying the **100-fold FDA margin of safety** → safe at **1 ppm**; then a further **10×** cushion (his tabulation only "90% complete") → **0.1 ppm as the level of toxicological insignificance.**

The container-level rule and the rosin-size experiment (pp. 266–268)

Using **radioactive rosin size in paper** (the most permeable substrate / most-extracted additive — an "experimental market basket survey," 24 foods) he finds **1.0% use → 0.5 ppm** diet, **0.2% use → ≤0.1 ppm**. Hence the operative rule, formally submitted to FDA:

> "I submitted a formal proposal to the FDA to incorporate this concept in **Regulation 121.2500**, which would exempt… '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.'"

He notes a PVC datum (a "radioactive plasticizer used at **28%** in a polyvinyl chloride film," footnote 4) suggesting ~0.6% in plastics → ≤0.1 ppm, but says the plastics data are "insufficient" to propose a dividing line yet — confirming paper/rosin as the deliberate worst case. The Delaney Clause is acknowledged as still applicable.

The claim of professional / industry consensus (pp. 265, 268) — corroborates the organized campaign

> "**Twenty-four other toxicologists** from universities and industries have supported this proposal in writing to the FDA. Almost as many others have privately supported it."

> "two dozen experts have advised the FDA of their endorsement… Several lawyers have advised me that this support from the scientific community… confirms that these uses are generally recognized as safe or 'gras' and that no action on the part of the FDA is necessary."

(This public "24 toxicologists wrote to FDA" line is the visible tip of the coordinated SPI / Allied Signal indirect-additives campaign documented in `08_VINYL_CHLORIDE_CAMPAIGN.md`.)

The three proposed categories (Conclusion, pp. 269–270)

1. components used **≤0.2%** → cannot "reasonably be expected" to become food components → **exempt**;
2. components used **>0.2%** but shown by migration studies to contribute **≤0.1 ppm** → **nonmigratory**;
3. components used **>0.2%** that *do* migrate significantly → genuine food additives → tested & regulated.

> "Only by accepting some level of insignificance and recognizing the relative risk to public health from different uses can we avoid wasting our resources on predictably unprofitable research."

Data-base progression across his three airings (analytic note)

Same thesis, growing N of chronic studies: **143** (ACS, 14 Sept 1966) → **220** (BIBRA London / FCT, 25 Jan 1967) → **245** ("$15–20M"; this Feb 1968 conference). The "~18 months ago" backref on p. 265 dates the original 0.1-ppm proposal to the **Sept 1966 ACS** symposium.