

# sources\_\_Summerson\_FDA- BureauOfScience\_paper\_NationalConf\_Fe b1968\_excerpt

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## Dr. W. H. Summerson (Director, FDA Bureau of Science) — his National Conference paper attacking the Frawley proposal

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**Provenance / caveat.** Summerson delivered this paper at FDA's **National Conference on Indirect Food Additives, 13–14 Feb 1968** (where his paper "dealt almost solely with the Frawley proposal"). **The full standalone paper is NOT among the 251 ToxicDocs "Frawley" documents** — those contain only the *Food Chemical News* report that quotes it "**in part.**" The fullest text available locally is reproduced below, verbatim from that report: *Food Chemical News*, **19 Feb 1968, pp. 5–7** (reprinted to the SPI committee by Keller & Heckman), local file `toxicdocs/1yes_1968_AlliedSignal_PolyvinylC_Kza60dbJ...`, Bates **ASI-PR 0000576–0000578**. (Light [sic] /OCR notes added; the full paper would be in the FDA conference proceedings — an unlocated, operator-retrieval item, see `05_OPEN_QUESTIONS`.)

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### Headline (verbatim): "*Frawley Proposal Praised for 'Soundness,' Hit as 'Sheer Nonsense'*"

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Despite Summerson's concession that there is "soundness" in part of Frawley's proposal, the FDA-er said much of what Frawley proposed for a "single cut-off place" is "sheer nonsense."

### Summerson's paper "said, in part" (verbatim excerpt)

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#### (1) The cancer-latency argument for premarket testing:

"Unless premarketing clearance is practiced, the only method of detecting harmful effects is retrospective... 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... it is well nigh impossible to isolate an additive as the original causative agent of a cancer. Thus... we must require premarket testing."

**(2) A direct rebuke of the industry's "no known harm" posture:**

"...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." "...unless a relatively acute poison is involved an effect is not likely to be routinely traced to a causative agent in food or packaging."

**(3) A partial concession — then the demolition of the "single cut-off":**

"Can we assume that any component of a food container that does not exceed a certain amount, say 0.2%, will always give an insignificant amount (less than 0.1 p.p.m.) in the total diet and therefore be safe? If we eliminate the pesticides, heavy metals, and carcinogens..., this generalization has considerable appeal and some reliability on the basis of 'published' toxicity data." "This generalization does not take into consideration whole meals in packaged materials, the use of an ingredient in [more] than one class of packaging material, and the additive effect of similar ingredients. Nor does it account for the food faddists... [or] that thick containers, such as plastic bottles, contribute far more to the food than plastic coating of a few mils thickness..."

**(4) The "published data are biased" methodological point + specific counter-examples:**

"Long-term feeding studies as reported in the literature may not be representative of the total scientific knowledge on all possible and useful food packaging chemicals." — Some plasticizers extract into fatty foods at **100 p.p.m. or more**; FDA has had requests for **triorthocresyl phosphate**; sensitizers like **toluene diisocyanate** and epoxy curing agents are objected to **"even at levels below 0.2%"**; monomers like **acrylamide** are tightly restricted.

**(5) Conclusion:**

"...more and more segments of our population are exposed to greater amounts of packaging chemicals. Some, including babies, may have their entire diet exposed... Therefore, I believe... that industry and FDA must know the relative safety of each migrant."

## The floor exchange that followed (verbatim report)

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- **On migration evidence:** asked if there's evidence of migration greater than Frawley presented, Summerson "does not know"; Frawley said there is, but most substances do not.
- **On contrary studies:** asked whether any two-year studies "did not gibe with Frawley's," Summerson said there are "**plenty**" — "but not necessarily on known packaging components."
- **The survivorship-bias charge:** *"Summerson said 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 sharp methodological hit: Frawley's 220-study database could only contain compounds non-toxic enough to *complete* a 2-year study.)
- **A prescient counter-example:** Frawley claimed nothing but pesticides/heavy metals is toxic at  $\leq 40$  ppm; **FDA's Dr. Joseph McLaughlin, Jr. disagreed, "pointing to acrylonitrile."** (Acrylonitrile — the monomer in SAN/ABS food-packaging plastics — was later classified a probable human carcinogen.)
- **The split-the-difference signals:** Summerson — *"Somewhere in between will be a position that both Dr. Frawley and FDA can live with"*; Delmore (FDA) — the two sides are "not too far apart"; Heckman (SPI) — a "middle ground" is "a good place to start." Frawley — it's "just a matter of degree."

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*To obtain Summerson's FULL paper: the proceedings/transcript of the FDA National Conference on Indirect Food Additives (Feb 13–14, 1968) — not located online; try the FDA History Office, Food Drug Cosmetic Law Journal 1968, or Food Chemical News' complete conference coverage (this clipping is pp. 5–7 only).*