



INTERNAL CORRESPONDENCE

VC FDA

RECEIVED

JUN 04 1975

R. N. WHEELER, JR.

CHEMICALS AND PLASTICS

RIVER ROAD, BOUND BROOK, NEW JERSEY 08805

To (Name) Mr. R. W. Lasher
 Division UCC Chemicals & Plastics
 Location 270 Park Avenue
 New York, New York

Date May 29, 1975
 Originating Dept. Research & Development

Answering letter date

Copy to Mr. R. W. Annonio - NY-32
 Mr. G. P. Bigelow - NY-33
 Dr. T. L. Dawson - SC
 Dr. W. F. Gorham - BB
 Mr. J. E. Griffin - SC
 Mr. D. E. Hardman - NY-33
 Mr. J. G. Kucsma - NY-31
 Dr. C. N. Merriam - BB
 Mr. N. H. Reinking - BB
 Dr. T. T. Szabo - NY-32
 Mr. R. N. Wheeler - SC-189-301-514
 Dr. J. J. Brezinski-SC

Subject ANALYSIS OF FDA
 REGULATIONS
 REGARDING
 VINYL CHLORIDE

Your letter to me dated May 19, 1975 requested a summary of the current status of the QEX-2033 terpolymer latex under the FDA food additive regulations and projections of FDA's future course of action in terms of most probable timing and most pessimistic timing.

Table I, attached, summarizes the chronology of the QEX-2033 program from its planning in September 1973 to this date and is given for background purposes.

Table II is a projected time table of future rulings and reports. Those dates that are underlined are fairly firm and provide a basis for the projection. Please note that by September 30, 1975 we will be in a good position to update this forecast.

Please understand this represents my best assessment of the technological and political factors which will influence FDA regulation of vinyl chloride polymers.

Very truly yours,

W B Ackart

W. B. Ackart

WBA:deb
 att.

UCC
 029388

TABLE I

CHRONOLOGY OF PROGRAM FOR FDA CLEARANCE OF QEX-2033

- | | | |
|-----|------------------|---|
| 1. | September 1973 | Program organized to obtain data for FDA petition. |
| 2. | March 15, 1974 | Preliminary extractions completed and interim report issued. |
| 3. | April 10, 1974 | Data discussed with FDA officials. No moratorium on vinyl chloride polymers. |
| 4. | June 1974 | Seven-day rat feeding study completed. |
| 5. | August 1974 | Additional extraction studies completed. |
| 6. | October 15, 1974 | Petition submitted to FDA. |
| 7. | December 6, 1974 | Petition judged incomplete by FDA and additional data requested. |
| 8. | January 20, 1975 | Additional data submitted. |
| 9. | January 27, 1975 | Receipt acknowledged. |
| 10. | March 31, 1975 | Petition accepted and filed for scientific review and evaluation. |
| 11. | April 1, 1975 | Preliminary report of Maltoni feeding study issued. After 52 weeks of feeding, one positive at each of two highest levels (67 and 68 animals surviving), no positives at lowest level and control rats (66 and 75 survivors). |
| 12. | May 9, 1975 | Canadian Health Protection Branch of Department of Nat. Health and Welfare issued proposed regulation to prohibit PVC food packaging materials which yield any amount of vinyl chloride to contents. Comments requested and final regulation expected late in 1975. |

TABLE II - EXPECTED FUTURE RULINGS

1. June 30, 1975 First evaluation period for QEX-2033 will lapse. FDA will extend evaluation period another 90-days (95% probability).
 2. August 1975 Dow feeding study on vinylidene chloride monomer will reach one-year period. Interim report will issue. Positive carcinogenicity would be fatal for QEX-2033 in foreseeable future, negative results would be big boost.
- (UCC is not part of this industry funded study. For about \$12,000 as a minor user we could buy in and gain a few months lead time. The data must be reported to FDA and will be made public by them if not by Dow.)
3. September 1975 The industry funded feeding study on vinyl chloride monomer, to be administered by SPI had not yet started as of May 28 and has yet to be reviewed by FDA before it begins. The intent will be to show the safety of low levels of Vcl monomer (under 50 ppb). Earliest possible starting date now seems to be September 1975.
 4. September 30, 1975 Second evaluation period for QEX-2033 will lapse. First critical check point. If Dow study positive (25% probability) FDA will request more data to justify another six month delay or will reject outright. If so QEX-2033 is effectively dead. If Dow study negative (75% probability) FDA will put QEX-2033 in limbo (administratively rejected as with VERR) pending interim regulation for prior sanctioned vinyl resins.
 5. November 1975 Final Regulation by Canadian Health Protection Branch expected. Canadians have reputation for prompt and fair regulatory practices. Will permit use of vinyl resins provided there is no detectable migration to food.
 6. December 1975 Interim regulation by FDA to permit continued use of prior sanctioned vinyl chloride resins provided there is no detectable migration to foods. This is a best guess based on probability the Canadian action will push FDA. Could come early as September 1975 or not at all.
 7. January 1976 Interim regulation will be followed immediately by amendment to Regulation 121.2514 for coating resins which adds VERR and QEX-2033 to list of acceptable resins. (The latter only if supported by the Dow data).

TABLE II - Expected Future Rulings (continued)

8. March 1976
- Maltoni final report due after two-years of feeding. Probably will show increased carcinogenic activity over one-year data (probability 80%). The Dulaney clause which prohibits carcinogens in foods will force FDA into one of the two following actions:
1. Permit continued use of vinyl chloride resins with no resultant migration to foods, but the 50 ppb limit will drop to a few ppb's. Calculations to reach this level may suffice.
 2. Prohibit vinyl chloride resins from food contact applications.
- Case one is the most logical but would require much political courage which FDA may not have.
9. August 1976
- Dow feeding study on vinylidene chloride monomer will be completed after two years. Favorable results could influence FDA toward Case One above.
10. September 1976
- SPI sponsored feeding study on vinyl chloride at low levels will reach one-year mark. Favorable results could influence FDA toward the "no-migration to food concept".