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(Draft #2 --SPI-PAC-PVC)

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(This Draft #2 will consist of pages 1-8)

SPI- 12290

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In February, 1979 Ethyl Corporation submitted data to support a no migration status at a 2 PPB VCM level - FDA scientists concur with the finding of a nonlinear response - cautioned FDA Administration that the search for "ZERO" was a scientific impossibility and that regulations should be based on evaluations of risk. (Complete details of this recommendation have not been made public).

5. Toxicological Data -Feb. 9, 1974 - B.F. Goodrich reported to the Center For Disease Control that four (4) polymerization workers in a PVC Plant at Louisville, Kentucky had died from Angio Sarcoma. A world wide investigation revealed some 35 cases identified prior to 1974. This discovery led a nationally recognized toxicological authority to predict "thousands" of deaths based on the long history of exposure. The press labeled VCM as the KILLER CHEMICAL.

- New cases reported world wide.

		Cumulative
1974	7	42
1975	10	52
1976	7	65
1977	6	71
1979	1	72
Anticipated, Fall of 1980		85

Dr. John Stafford (ICI) points out that the cases reported since 1974 essentially involve the same locations as those prior to 1974.

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- In 1975 Dr. Caesar Maltoni provided an interim report of a VCM Oil Gavage Study at three levels which did not identify a no effect level. A final report on this and an additional study which did identify a no effect level was published in 1979.

Study BT 11	Feeding Levels
	50.0 mg/kg
	16.6 mg/kg
	3.3 mg/kg

Study BT 27	Feeding Levels
	1.0 mg/kg
	.3 mg/kg
	.03 mg/kg (No effect level)

The no effect level is equivalent to 0.6 PPM in the diet assuming that a 0.3 kg rat was administered 9 ug vc per 159 of feed without loss prior to ingestion (100% availability), and equivalent bioavailability between oil gavage and feed mix.

- British Industrial Biological Research Association (BIBRA) has also conducted a feeding study - final report was due April 1979 but has not been released. The draft is under review by the British Government. Rats were fed VCM in water, and water intake and administration control were maintained within a known shelf life period of VCM in water. The lowest feeding level of 250 PPM is equivalent to a 2 mg/kg dose. It is believed that a no effect level was not established.

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- The Dutch "Central Institute for Nutrition and Food Research" (CIVO) aslo conducted a lifetime feeding study. The lowest dose level was 1.7 mg/kg. No Angio Sarcoma was observed at this level but hepatocellular carcinomas were observed. Since a different rat strains were used the data is not directly comparable to that of Maltoni.

6. Legal Aspects

The Food Additive Amendment in 1958 included a clause regulating the use of carcinogen. This amendment, known as the Delaney Amendment, has been popularly described as prohibiting the addition to food of any amount of a human or animal carcinogen. The legislative history of the amendment does not support this narrow interpretation since it describes a finite "ZERO" tolerance which is incompatible with todays ever improving analytical technology. (In 1958 we could not measure less than one part per 10,000 of VCM in PVC. Today we can measure one part per billion thanks to a procedure developed by FDA scientists).

- In 1979 the U. S. Court of Appeals in Washington D. C. rendered a landmark decision which will provide guidance to FDA. The court said:
  (1) FDA may not conclude that a substance is present in food (and therefore regulate it as a food additive) simply because it comes in contact with food, the substance must be shown to be present on the basis of scientifically reliable evidence in order for it to be regulated.

  (2) Even if present, a substance is not a food additive if the amount does not present a risk to public health.

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Since the 20 plus years of human experience is available and the incidence is limited it probably will be proven that VCM is a pre or pro carcinogen that must be metabolized to the ultimate carcinogen and that the body defense mechanisms must be overwhelmed to trigger the response. The animal feeding data can be used to complete an acceptable risk level.

Using the 1975 Maltoni interim report the FDA published an acceptable VCM risk example in the S.O.M. proposal. The level identified was 6.7 PPB VCM in the diet to assure a risk level no greater than one in a million for a life time. Whether this number will be changed by the availability of later data is unknown.

7. The FDA plans to issue a constituent policy (target date now over due). The FDA has discretion to apply the De Minimus principle in these situations.

8. FDA has identified to individuals and leaked to the press that:

   (a.) The 1975 proposed PVC regulation is no longer applicable because the hazard has been eliminated.

   (b.) A new regulation will be forth coming (first set for Mid "79", then end of "79", then April of "80", and now Spring of "81").

9. Food packagers are confused and bewildered by the delay. (Desirous of using PVC to reduce cost and energy consumption).

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10. BATF has asked FDA to provide guidance for a regulation for PVC use in packaging alcoholic beverages. To date FDA has not responded.

11. At Risk

1. Food Packaging applications involving semi-rigid food packaging in U.S. (bottles and thermoformed packages).

2. Potential carry over (consumer product manufacturers reaction) to cosmetic, toiletry and household chemical packaging.

3. Precedent for other countries (most do not have FDA type operation - rely on FDA activity).

4. Influence on other governmental agencies - EPA - OSHA.

12. What If

(1) FDA finalized 1975 proposal.

- Impact - Very High
- Influence - Very High

(2) FDA proposed to limit VCM extractable to non-detectable, sensitive to 10 PPB.

- Impact - None
- Influence - Positive/High

(3) FDA proposes to regulate migratable VCM in food products to non-detectable by analytical method having sensitivity derived from dietary exposure calculations.

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- Impact - None
- Influence - Very High/Positive

13. Tracking

Information sources:

- Contact with FDA officials
- Federal Register
- Food Chemical News
- Keller & Heckman
- Trade & Associated Press

14. Triggers

1. FDA issues "Constituent Policy"
2. FDA finalizes 1975 proposal
3. FDA proposes new regulations (3a & 3b)

15. Contingency Plans

Trigger 1 - FDA issues "Constituent Policy"

- SPI Group meets with Keller & Heckman to evaluate - Keller & Heckman issues advisory report.

- SPI Group prepares comments to FDA if appropriate.

- SIP Group to establish sub committee to prepare industry's case assuming "most likely" regulatory proposal.

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Trigger 2 - FDA finalizes 1975 proposal.

- SPI Group meet with Keller & Heckman to assess legal options available. Stay, hearing, suit, etc.

Trigger 3a - FDA proposed regulation 10 PPB

- Individual companies assess.
- SPI Groups meet with Keller & Heckman to prepare comments indicating proposed action.

Trigger 3b - FDA proposed regulation based on risk assessment and dietary exposure concept.

- Individual companies assess.
- SPI Group meets with Keller & Heckman to prepare comments indicating proposed compliance schedule.

16. Action Underway

Follow up with FDA personnel.

SPI- 12297