

TO		FIELD POINT OR DEPT. & BLDG. NO.	DATE YOUR LETTER
CPSC Members Below			
FROM		FIELD POINT OR DEPT. & BLDG. NO.	DATE THIS LETTER
Marie Schmiederer		D/5428	2/21/77
SUBJECT			

Consumer Product Safety Committee
Monday, February 21, 1977
3:30 p.m. - 3A Conference Room

AGENDA

1. Toxicity:

a. Residual Acrylonitrile	B. M. G. Zwicker
b. Styrene/NIOSH	R. D. Savage
c. Maltoni Data Outlook	R. D. Savage
d. FDA/Bottles/Ethyl Corp.	J. F. Malone
e. New Jersey - MRC Conference	R. B. Downey
Hearings	M. Schmiederer

2. Combustibility:

SPI PVC Combustibility/Safety Group	D. Kent
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Distribution: R. B. Downey
J. R. Goots
D. L. Kent
F. E. Krause
J. F. Malone
J. P. Morrill
R. D. Savage
R. L. Steller

22547001

BFG21502

Trade - minutes
CPSC
Cambridge



CPSC

BMZ, AK, JM, LL, JM, TR, RBD, RDS, RS, MS

① Residual Acrylonitrile -

FDA did more in FR, Regs forthcoming in next couple weeks (this is one step beyond recommendations.)

Abson → margarine tubs

nitrile rubber - foot conveyor belt

latex - labels, men-women fabrics

Previously W. Bachtel said OK per GHS listing

Concern → 1 person in marketing dept to sitting criteria of DeCapite, Corder & Whitney what comes out for eval. of who takes priority in testing

② Still don't have a good analytical procedure. Work will for only

BMZ - take head space for rubbers Latimer Bickel

method + DeCapite's have Whitney develop process so that other facilities can use.

[use powdered PVC from fork head space sample]

Whitney starting with latexes

resid styrene, benzene, ENB → Co Orange

RS → FDA doesn't use head space

BZ → 10, 100, 1000 ppm D. where problems are, tell manuf. to solve their problems & strip ACN better.

Previously Goot was liaison

Probably rubber no latex

OSHA will ask how much resid. ACN coming off

Meantime - ACN: notices to plt mgs from J. Nelson + ACN that for employees

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(3) Styrene NIOSH - RDS → Dow @ Burgess has seen NIOSH comments, not consider sty. as carcinogen. 250ppm on 10 hr TWA. NIOSH checks NCI reports as data.

(4) Maltoni Data Outline → RDS → review going on - question - low level exposure of mammary tumors. Data will not be any more favorable than now. Sup. this SPI for public comment. Report visited Maltoni last wk. BMZ: 2 publications imminent to support mammary tumor label @ 50 ppm. DMCA industrial vertest on rats, mice, hamsters, not previously tested. Cited as interim @ VC hearing; mam tumors higher in older; results corresponded with Maltoni's 300 animals now → his incidence of mam. tumors. Control had spontaneous tumors. Reported @ end of March - @ 1 ppm. (2) EPA's Maltoni Research Inst @ 50 ppm: increased incidence of mammary tumors. → & OLC study incidence in firm employees in PVC processing industry. → re-examined before work history, (early April) Dow → reg felt > 20-50 ppm you overwhelmed the natural defense mechanism is evidence for threshold level. Dr. Gehring backed off → & no longer will to support a threshold limit for VC.

FROM THE DESK OF
DICK SAVAGE

MES

for 2/21 CPSC
agenda. (Melone)

Prescription.

PN
2/17

BFG21507

22547005 A

TO	FIELD POINT OR DEPT. & BLDG. NO.	DATE YOUR LETTER
R.W. Tannehill		
FROM	FIELD POINT OR DEPT. & BLDG. NO.	DATE THIS LETTER
N.D. Friedberg	(NDF-017-77)	2/11/77
SUBJECT		

Discussion with G. Hughmark and G.C. Gaeke of Ethyl Corporation at ALTC
on 1/26/77

BFGCC Personnel

E.G. DeCapita
L. Crider
J.R. Goots
A.P. Metzger
C. Daniels
N.D. Friedberg

Ethyl Corporation Personnel

G. Hughmark
G.C. Gaeke

Purpose

The purpose of this meeting was for us to have a chance to review, criticize, and strengthen in any way we can Ethyl's proposed experimental program to establish a VCM non-migration level for PVC bottles (see G. Hughmark's 1/17/77 revised draft). Ethyl is ready to blow the bottles for this program the first week in February 1977. They estimate the program will take 12 weeks to complete including the 2 month's of storage at 120°F. FDA has encouraged Ethyl to proceed.

Discussion

Ethyl says their head space GC method is sensitive to about 5-10 ppb for powder blend bottle compound; once they make pellets, their sensitivity drops off to about 30 ppb. Ethyl does not feel their mass spectroscopy capability is as good as ours and they want us to participate in their program to the extent we wish.

Hughmark reviewed his experimental approach which all of us had previously read over. No one from BFGCC had any serious disagreement with the approach. A key part of the experiment will be to obtain bottle compound with the desired levels of RVCM, with the same heat history, but without severe enough heat history to cause any heat degradation of the PVC. Ethyl feels this can be accomplished by driving off essentially all the VCM by blowing warm air through the PVC, then spiking the resin with VCM (allowing sufficient time to reach equilibrium) to hopefully obtain RVCM levels in the bottle walls of about 0.01, 0.01-0.02, 0.03-0.05, 0.1, 0.3, and 1 ppm. Actually Ethyl will make up two powder blends from the same compound additives other than the PVC resin. One powder blend will contain a high RVCM resin and the other will contain a very low RVCM resin. Portions of the two blends will be mixed to give bottles with the RVCM levels mentioned above. Ethyl has determined that the VCM loss from going from powder blend to pellet is about 10% and the VCM loss from pellet to bottle, another 10-15%. Ethyl will blow enough 16 oz. bottles (about 30g.) for 4 weeks and 2 months storage with aqueous 50% ethanol and with pure water.

Lin Crider briefly described our recent work with our GC-MS instruments to try to determine the level of detection of GC-MS in various solvents. We have found that MS can confirm VCM in water down to about 15 ppb and in 50% ethanol-water somewhere between 37-55 ppb. Based on the diffusion model, then, we would need bottles containing about 2-5 ppm RVCM in the bottle wall in order to extract sufficient RVCM into water or aqueous ethanol for MS to confirm the presence of RVCM in the extracts. Thus, even the highest level RVCM bottles that Ethyl plans to blow (1 ppm in bottle wall) are not expected to diffuse enough VCM into the media for MS to detect and confirm. Crider et al feel that BFGCC's GC-MS capabilities are about average in the industry although at least one published work (a group in Holland) claims to have MS techniques capable of detection as good as GC head space methods. There was some discussion on whether it would be useful to send some outside group such as a commercial testing laboratory or a university (e.g. S. Gilbert at Rutgers) to try to confirm RVCM by mass spec. at various levels but the general consensus was that there are so many pitfalls (even preparing standard solutions of known concentrations is very tricky) involved that funding such work would not likely produce results that we would have confidence in. DeCapita did describe some work he is doing with Hewlett-Packard to evaluate their GC-MS instrument but this study will not be a part of the Ethyl-BFGCC program.

Action Required

1. It was decided that Ethyl will send A.P. Metzger two sets of empty bottles, a set from near the low end of the RVCM in the bottle wall (2.5 ppm) and a set at the highest RVCM in the bottle wall (>1ppm). Al will fill one set (about 6 bottles) with aqueous ethanol and the other set with water. After 2 months of storage at 120°F, we will test the extract with head space GC and with MS. Ethyl will provide us with RVCM data on the resin, on the powder blend, and on the cubed compound. *For their conversation with Dr. Houghman, Ethyl will also send us a set of bottles with 2-3 ppm RVCM in the bottle wall.*
2. Lin Crider will write a report describing our work at determining the level of MS sensitivity for analyzing VCM in aqueous ethanol and in water. This report will be ready in about one week. It will contain raw data, MS spectra, the techniques used, and our conclusions that MS will not confirm the presence of RVCM in water below 20 ppb and in aqueous ethanol below somewhere between 37-55 ppb. This report will be sent to me and after review with Cleveland personnel (Malone, Tannehill, Zwicker, Savage) we will send the report to Dixler-Heckman. If Dixler-Heckman agree, we will submit this report to FDA and have someone such as Crider go along with Dixler-Heckman for presenting this work to FDA. It is ours and Ethyl's hope that this work will lead to FDA establishing a reasonable non-migration level of RVCM in the bottle wall, or in the resin, as opposed to the other alternative of FDA simply banning the use of PVC bottles as food packages.

N.D. Friedberg
N.D. Friedberg

22547007

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Distribution

E.G. DeCapita - ALTC
L. Crider - ALTC
J.R. Goots - ALTC
A.P. Metzger - ALTC
C. Daniels - ALTC

N.D. Friedberg - Cleveland
R.W. Tannehill - Cleveland
J.F. Malone - Cleveland
B.M.G. Zwicker - Cleveland
R. Savage - Cleveland

G.R. Talley/W.S. Litkowitz/T.A. Gibson/File

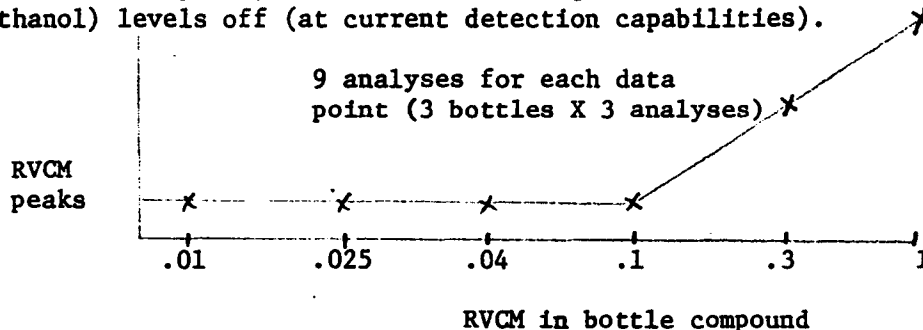
J.R. Lees - Ethyl Corporation, P.O. Box 341, Baton Rouge, LA.

G. Hughmack - Ethyl Corporation, P.O. Box 341, Baton Rouge, LA. 70821

G.C. Gaeke - Ethyl Corporation, P.O. Box 341, Baton Rouge, LA 70821

P.S. - (to BFGCC personnel only)

Subsequent to this meeting, we had some internal discussions about how FDA may react to the data already submitted to FDA by Ethyl. Ethyl's data (shown graphically below) essentially shows that below about 0.10 ppm in the bottle compound, the amount diffusing into the media (water or aqueous ethanol) levels off (at current detection capabilities).



Thus, the cut off point or maximum RVCN in the bottle wall that represents a no-migration level is somewhere between .030 and .100 ppm in the bottle wall. If FDA sets 0.030 ppm in the bottle wall as the cut off point, both us and Ethyl, and probably the rest of the PVC bottle compound industry will have a very tough time meeting this requirement (confirmed in a phone call from me to G.C. Gaeke on 1/27/77). For us, 0.030 ppm in the bottle wall would mean we would need to produce resin with an upper RVCN level of about .075 ppm because our experience generally with PVC bottle compounds shows the follow losses or reduction in RVCN due to processing:

Resin to pellet compound

with resin <1ppm, compound should be <.5 ppm (nominal 50% reduction)

Pellet compound to bottle

with compound <.5ppm, bottle wall should be <.4 ppm (nominal 20% reduction)

Thus, if we need to have no more than 0.030 ppm in the bottle wall, we would need to consistently produce resin with <0.075 ppm*. In Jean Malone's 1/23/76 letter to Jerry Heckman, we estimated an intensive, costly, one year or longer R & D program would be needed to even reach RVCN levels in the resin in the range of 0.1-0.2 ppm.

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A requirement to meet .030 ppm in the bottle wall would require a 10 fold improvement in our stripping/compounding technology, no mean feat. Our hope is that the FDA, when they learn that mass spec. cannot even confirm RVCM in extraction done from bottles made with resin at 1 ppm, will either set the bottle wall RVCM much higher than .030 ppm (we could live with .4 ppm in the bottle wall) or let PVC suppliers continue to make food grade bottle compound by certifying resin <1 ppm.

*Assume we need to be .030 ppm or less in bottle wall. Let X = resin RVCM. Then .5X equals pellet RVCM, and $(.5X)(.8) = \text{bottle wall RVCM}$. Therefore, $.030 = (.5X)(.8)$ and $X = \frac{.030}{.4} = .075 \text{ ppm}$.

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