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U.S. Consumer Product Safety Commission
LOG OF MEETING

DEPARTMENT OF THE SECRETARY
FREEDOM OF INFORMATION
2000 NOV 17 A 9

SUBJECT: Phthalate Meeting in Ipsra, Italy

DATE OF MEETING: 10/30/00

LOG ENTRY SOURCE: Warren K. Porter, Jr.

DATE OF LOG ENTRY: 11/1/00

LOCATION: Joint Research Council, Ipsra, Italy

CPSC ATTENDEE(S): Warren K. Porter, Jr.

NON-CPSC ATTENDEES: See attachment

SUMMARY OF MEETING: The meeting purpose of the meeting was to discuss the upcoming interlaboratory test of two methods for determining the migration of phthalates from PVC articles.

Standard Operating Procedures (SOP) Status

A number of changes to the draft protocol and clarifications within the protocol were discussed. Specific clarification for the operation of the shaker bath was discussed and will be clarified in the SOP.

Currently butylbenzyl phthalate is being used as the internal standard. It was noted that this plasticizer is one that will be on the controlled list in the EU standard. Thus it is problematical that it can remain as an internal standard. Several other phthalates were proposed but some had problems of volatility. No decision was reached but two options were presented:

- First, for the interlab study retain butylbenzyl phthalate as the internal standard.
- Second, use duterated phthalates. These can be synthesized for the specific alcohol involved in the analysis, have the advantage that they will have no greater volatility than the phthalate of interest, and they would not have absorption/adsorption properties different from the phthalate of interest. They are easily synthesized for the specific phthalate of interest.

The point at which the internal standard should be added was discussed. It was agreed that it should be added at some point after the shaking or HOH treatment, probably at the point of combining the saliva simulants and before the cyclohexane extraction.

The saliva extraction will most likely be modified to perform 2 extractions with 20 ml of cyclohexane, diluting the combined extracts to 50 ml (volumetrically), and adding anhydrous Na₂SO₄ as a drying agent. This will allow direct analysis, concentration if required to achieve adequate sensitivity, or other handling to be performed on small portions while retaining the bulk of the extract in its original state.

The solvent evaporation was addressed. Rotary evaporation is currently in the protocol but volatility was raised as a potential source of loss. Kuderna-Danish concentrators were suggested and may be more desirable, less costly than the rotovaps and require less handling/transfer of the concentrated materials.

Integration of the peaks was discussed but no conclusion was reached on the procedure. Currently the calibration curves from 0 to 30 ppm show quadratic behavior rather than a linear line. This may be due to detector response or to rejecting areas at low concentrations. The group will use, at this time, peak height for HPLC and peak area for GC/MS.

Generally it appears that GC/MS will need to be performed to positively identify the phthalates of interest. It is not clear how, for mixed phthalates, the distribution of individual phthalates will be accomplished with HPLC. Generally although HPLC is more rapid, provides greater sensitivity, and is consistent in response, it does not have the specificity that appears to be necessary. The lack of specificity is due to the fact that the restrictions on

phthalates used will be for specific phthalates and not for phthalates generically.

The above issue was raised since one phthalate contains a mixture of DINP and DIDP. The latter is not on the proscribed list.

Stringent Method:

Several labs have experienced precipitate formation during the migration phase.

One lab reports migration was not as high as expected.

The order of dissolving the salts is important, this is incorporated in the SOP.

The Laboratory of the Government Chemist (United Kingdom) will look into this.

Samples and Schedule

Additional standard disk material is being prepared and characterized for homogeneity. It is hoped that the study will incorporate more than on standard disk. Toys will continue to be present in the test even though it is recognized that they will not appreciably add to the statistical description of the study. They are known to have greater variation than the standard disks.

It has been proposed that the standard disks will be analyzed first and completed before Christmas. The toys will be analyzed next and hopefully completed by February, 2001.

State	Organisation	Name of the expert
B	Scientific Inst. of Public Health, B-1050 Brussels	Mr. L. Goeyens
B	Research Institute for Chromatography, B-8500 Kortrijk	Mr. F. David
B	Euroftal NV, B-8400 Oostende	Mr. F. Van Wallegghem
DK	Nationall Environment Research Institute, DK-4000 Roskilde	Mr. T. Kroongaard
D	Bg VV, D-14195 Berlin	Mrs. K. Pfaff
D	Chem. Landes- & Staatl. Vet.unters.-Anst, D-48007 Münster	Mrs. B. Brauer
D	Oxeno, Marl D-45764	Mr. N. Scholz
E	Instituto Nacional del Consumo, E-20842 Madrid	Mr. C. Arnaiz
E	Toys Research Institute (AIJU), E-03440 IBI Alicante	Mrs. M.L. Marin
F	DGCCRF- LIR 13, F-13388 Marseille Cedex 13	Mr. F. Saltron
FIN	Finnish Customs Laboratory, FIN-02150 Espoo	Mrs A. Meriläinen
I	Istituto Superiore di Sanita, I-00161 Roma	Mrs. M.R. Milana
NL	Inspectorate for Health Protection, NL-9700 AL Groningen	Mrs. K. Bouma, Mr. D. Schakel
P	INETI / LAQAS- Inst. Consumidor, PO-1699 Lisboa Codex	Mr. A. Teixeira
UK	LGC- Lab.Gov.Chem., UK-TW11OLY, Teddington	Mr. J. Braybrook, I. Axford
USA	Consumer Pdct & Safety Comm., Washington, DC 20207	W. Porter
USA	Hasbro Inc., Pawtucket, RI 02861	Mr. L. Doane

INDUSTRY PLATFORM

State	Organisation	Name of the expert
B	Toy Industries of Europe, B-1040 Brussels	Mr. M. Twist, Mrs. C. Morris

CO-ORDINATOR

State	Organisation	Name of the expert
EU	EC, DG-JRC, IHCP-FP&CG, I-21020 Ispra	Mrs. C. Simoneau

CPSC PUBLICATION, AUDIO-VISUAL, FILM, SPEECH AND REPORT CLEARANCE

1. PROJECT TITLE EU Phthalate Migration Study	2. DUE DATE 11/14/00
3. PROJECT MANAGER (Name, room number, telephone) Warren Porter, 301-413-0040	
4. THE INTENDED AUDIENCE/PURPOSE IS: Meeting log from 10/30/00 EU meeting on the round robin _____	
<input type="checkbox"/> yes <input type="checkbox"/> no (initials of project manager) _____	

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1. PROJECT TITLE: Phthalate Migration, EU Round Robin Testing		2. DUE DATE: 11/15/00			
3. PROJECT DIRECTOR (Name, room number, telephone): Warren Porter, LSC 301-413-0040					
4. THE INTENDED AUDIENCE/PURPOSE IS: FOI Meeting Log of 10/30/00 EU Meeting on Round Robin Test					
<p>IMPORTANT</p> <p>The attached project material is not to be distributed to any person or Organization outside the EXHR until the following offices have authorized clearance</p>					
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Associate Executive Director for Economic Analysis					
Associate Executive Director for Engineering Sciences					
Associate Executive Director for Health Sciences					
Associate Executive Director for Epidemiology					
Associate Executive Director or Laboratory Sciences	<i>Andrew Haduik, P.E.</i>	X		11-9-00	OK
Division of Human Factors					

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