TO: Charlie Dutra

TGG: ~~JCL~~: ~~FGJ~~: ~~AC~~: ~~AJO~~: RF

XF: none

FROM: T. G. Grumbles
DATE: August 26, 1991

Interoffice Communication

SUBJ: RECORD OF TRAINING

VISTA

Attached are the training records and overheads used for the Product Liability Awareness and New Product Development Process training.

T. G. Grumbles

dlj

Attachment

cc: P. D. Carrico-LCVCM, J. Ware-LCLAB

SYNOPSIS OF PRODUCT LIABILITY/NEW PRODUCT
DEVELOPMENT PROCESS TRAINING

NEW PRODUCT DEVELOPMENT TRAINING

An overview of the process and the specific items most applicable to the plants was presented. Manuals were distributed to appropriate supervisory personnel.

PRODUCT LIABILITY AWARENESS TRAINING

The intent of the training was to raise awareness on the issues of regulatory and product liability. The film "When Products Harm" was shown and discussed. The differences in regulatory and product liability were reviewed. Product defects and how we manage them were discussed. The differences in regulatory and product liability were reviewed. Product defects and how we manage them were discussed.

8:15-9:45 - Both
10:00-11:30 - Both
1:30-2:30 - New Product Development Only

Instructor: Tom Grumbles

LCCP/LCLAB/LCUCM Training
8/22/91
10:00 - 11:30

BONTON, ANDRE'	LCCP
VICKI HIGGINS	LCCP
Richard Boenig	LCCP
DENNY LEE	LCCP
DAVID ROSE	LCCP
HAROLD CORLEY	LCCP
W. D. Dulle	LCCP
J. L. Bizzat	LCCP
Don Barnow	LCCP
GRAHAM BACON	VCM
DAVID MOORE	VCM
MICHAEL WALLEY	VCM
Lance Dixon	VCM
DONALD MOSELEY	LCCP
Marjorie Melton	LCCP
[illegible]	LCCP.

LCCP/LCLAB/LCVCM Training
9/22/91 8:15-9:45

KEN ABRAHAMS	LCCP
NATALIE MILLIGAN	LCCP
Toni Latimer	LCVCM
Julie Wineman	LCCP
Diane Johnson	LCLAB
Tamra Radosevic	LCCP
Jan Dunk	LCVCM
Frank R. Adam	LCLAB
Todd Root	LCLAB
Rendell Newton	LCCP
Michael Milanowski	LCVCM
Tom Rutz	LCCP
Bill Orlosk	LCCP

LCCP/LCLAB/LCVCM
8/22/91
1:30 - 2:30

Steve Smith
Sue Rey
Mark Witten
Chris Turner
Randy Gantz
CHARLES R. DUTRA
KEITH L. FOGG
Mike Porter
Scott Holub
Michael Hayes
Steve Allen
Jim Shamburger
DAVE MULLENIX

LIABILITY

REGULATORY

- CIVIL/CRIMINAL/ADMINISTRATIVE
- MINIMUM STANDARDS

PRODUCT

- DESIGN
- MANUFACTURE
- INHERENT
- WARNINGS

PRODUCT LIABILITY

DESIGN - IS IT DESIGNED OR MEANT TO BE MANUFACTURED AS SAFE AS FEASIBLE (POSSIBLE)?

MANUFACTURE - WAS IT MADE ACCORDING TO DESIGN OR MANUFACTURING SPECIFICATIONS?

- IS QC IN-PLACE TO ASSURE THIS?

INHERENT - BASED ON PROPERTIES OF THE CHEMICAL OR PRODUCT.

WARNINGS - LABELS AND MSDS'S

PRODUCT LIABILITY WARNINGS

LABELS ARE JUDGED ON THE FOLLOWING:

1. VISIBLE AND READABLE

2. STATEMENT OF HAZARD

3. CONVEYING LEVEL OF HAZARD

4. DESCRIPTION OF CONSEQUENCES OF HAZARD

5. INSTRUCTIONS ON HOW TO AVOID HAZARD

6. INSTRUCTIONS ON WHAT TO DO IF HAZARD OCCURS

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PRODUCT LIABILITY

IS IT UNFAIR? YES

IS IT EXCESSIVE? OFTEN

IS IT AVOIDABLE? NO

IS IT MANAGEABLE? YES

PREVENTION COSTS LESS THAN DEFENSE

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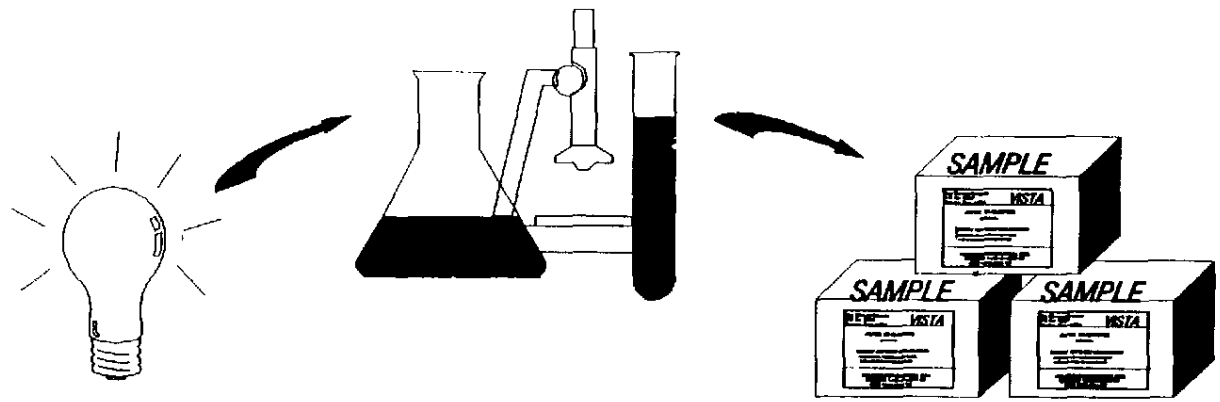
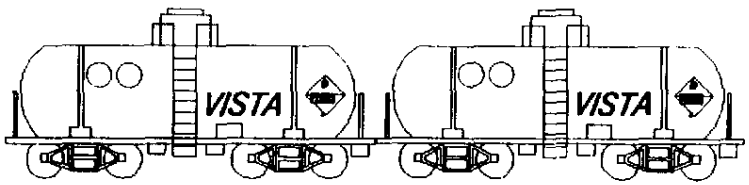
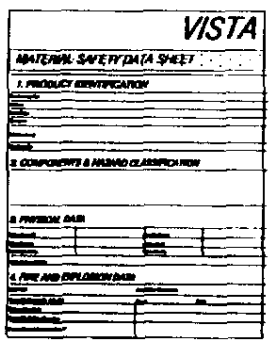
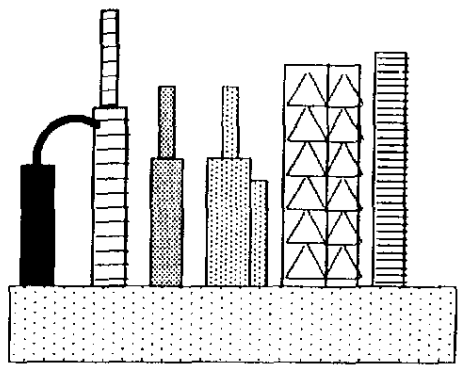


VISTA NEW PRODUCT DEVELOPMENT PROCESS







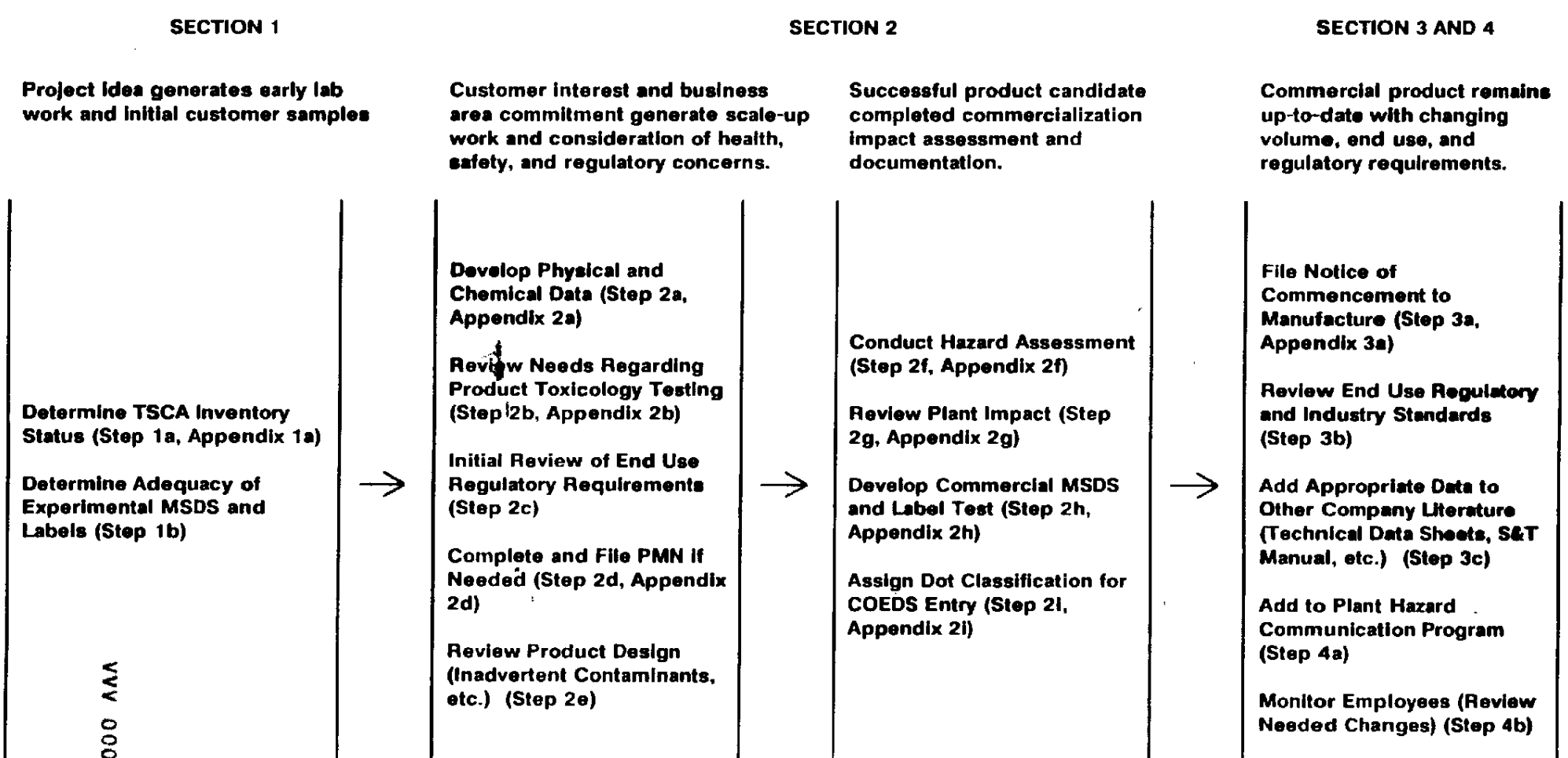
THE WHOLE PROCESS IS TO ASSURE:

A. TIMELY DEVELOPMENT OF DATA REQUIRED FOR HAZARD ASSESSMENTS AND REGULATORY CLASSIFICATIONS.

B. TIME TO ASSIMILATE DATA INTO QUALITY AND COMPLIANT WARNING MATERIALS.

C. IDENTIFICATION OF POTENTIAL BARRIERS TO PRODUCT DEVELOPMENT SUCH AS A LENGTHY PMN PROCESS, EXPENSE OF REQUIRED TOXICITY TESTING, REGULATORY ISSUES IN PLANT PRODUCTION, AND POSSIBLE UNACCEPTABLE PRODUCT LIABILITY RISKS.

SIMPLIFIED NEW PRODUCT DEVELOPMENT PROCESS FLOW



ACTIONS, RESPONSIBILITY AND DOCUMENTATION FOR NEW PRODUCT DEVELOPMENT

	ACTION	RESPONSIBILITY	DOCUMENTATION
1(a)	Determination of TSCA Inventory Status	Individual Researcher	Inventory Status Letter to new product file. Timing of transmittal is at discretion of the Product Manager or Supervisor
1(b)	Adequacy of Exp. MSDS and labels	Researcher w/safety & health professional or R&D Toxicologist	Documentation of review- revised MSDS's & labels to new product file. Timing of transmittal is at discretion of the Product Manager or Supervisor.

NOTE: Sample size may dictate that Step 2(i), DOT classification occur prior to sample shipment. Review sequence step 2(i) prior to sample shipment.

SAMPLE SENT - BUSINESS AREA COMMITMENT

2(a)	Development of physical & chemical data	Researcher	Laboratory reports to new product file
2(b)	Review of product toxicology testing needs	Product Manager or Supervisor & VPSAG	Request letter from Product Manager or Supervisor and response letter from VPSAG
2(c)	Initial end use regulatory review	Individual Researcher, Biomedical and Env. Affairs, and Marketing	Memo to new product file detailing review
2(d)	Complete and file PMN if needed	Individual Researcher Biomedical & Env. Affairs, and R&D Biological Technology Section	File copies of PMN at location and in Biomedical and Env. Affairs
2(e)	Product design review (inadvertent contaminants, etc.)	Manufacturing; R & D	Memo's to new product file on steps, results.
2(f)	Hazard assessment	VPSAG, Biomedical & Env. Affairs	Memo to new product file to include all regulatory classifications determined
2(g)	Review of Plant Impact (If process changes/modifications required)	Plant Engineering, Environmental Coord., Safety Director	Completed review checklist to new product file.
2(h)	Development of commercial MSDS and label text	Biomedical & Env. Affairs	Product Manager or Supervior written request, file documents & copy of MSDS and label text to new product file
2(i)	DOT classification for COEDS entry	Biomedical & Env. Affairs	COEDS entry form or request letter for non-COEDS entnes

COMMERCIAL PRODUCT SHIPPED

Additional items needed for good business practice/liability control.

3(a)	File commencement to manufacture notice	Manufacturing location (Env. Coord.)	Copy to new product file
3(b)	End use Regulatory/ Industry Standards Review	R & D; Biomedical & Env. Affairs; Mkt. Dept.	Memo of results to new product file
3(c)	Addition of appropriate data to other company literature (Tech Data Sheets, ST&S manual, etc.)	Product Manager	Letter of transmittal to system managers

IF NEW PRODUCT INVOLVES PLANT/PROCESS MODIFICATIONS THEN THE FOLLOWING MUST BE DONE

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4(a)	Addition to plant hazard communication program	Plant Safety Director	Specific to each plant location
4(b)	Employee monitoring	Plant Safety Director	Comply with OSHA regulatory requirements

THE PRODUCT MANAGER OR PRODUCT SUPERVISOR FOR THE PRODUCT AREA IN WHICH THE NEW PRODUCT OR PRODUCT USE IS BEING DEVELOPED IS RESPONSIBLE FOR THE MANAGEMENT AND ADMINISTRATION OF THE NEW PRODUCT DEVELOPMENT PROCESS.

MULTIPLE EMPLOYEES OR DEPARTMENTS ARE RESPONSIBLE FOR GENERATING INFORMATION AND DOCUMENTATION FOR THIS PROCESS.

AUTHORITY TO PROCEED WITH MANY OF THE STEPS ARE THE RESPONSIBILITY OF THE PRODUCT MANAGER OR SUPERVISOR.

NEW PRODUCT

NEW MOLECULE: ANY PRODUCT FOR WHICH A PREMANUFACTURE NOTIFICATION (PMN) WILL BE REQUIRED.

NEW COMMERCIAL PRODUCT: ANY PRODUCT WHICH HAS NEVER BEEN "SOLD" BY VISTA EVEN IF A PMN IS NOT REQUIRED BECAUSE IT'S ALREADY ON THE INVENTORY.

MODIFIED COMMERCIAL PRODUCTS: "RELATIVELY MINOR" MODIFICATIONS IN PRODUCT DESIGN, SPECIFICATION OR EVEN COMMERCIAL NAME MAY NECESSITATE A REVISED HAZARD ASSESSMENT, CHANGE IN REGULATORY CLASSIFICATION OR ALLOWABLE USES.

ANY COEDS CHANGE: THE COEDS ENTRY FORM IS THE FINAL CONTROL POINT BEFORE COMMERCIALIZATION.

NEW USE: IF AN EXISTING PRODUCT IS BEING PUT INTO A NEW MARKET, OR END USE, THERE MAY BE REGULATORY CONSTRAINTS REGARDING PRODUCT QUALITY, MANUFACTURE, OR AN INCREASED LIABILITY RISK THAT WOULD REQUIRE ELEMENTS OF THE PROCESS TO BE APPLIED.

RESEARCHER: IS DEFINED AS THE INITIATOR OF THE DEVELOPMENT WORK, OR THE PERSON THAT IS CLOSEST TO THE PRODUCTION OF THE INITIAL SAMPLES OR TEST RUN.

WHEN TO INITIATE THE PROCESS

THE DECISION TO BEGIN A NEW PRODUCT FILE AND COMMIT RESOURCES TO THE STEPS NECESSARY MUST BE GUIDED BY JUDGEMENT ON THE POTENTIAL FOR THE PRODUCT TO BE PUT IN COMMERCE.