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From: W. A. Dickenson

Date: January 25, 1990

Subject: **Revised R&D TSCA Compliance Policy**

Please review and comment on this proposed revised R&D TSCA Compliance Policy that is attached. Send comments to me in Austin, or call me at extension 2369. We are planning to conduct TSCA ~~Training for New~~ Employees in mid-February and hope to issue the revised policy in time to use it for the training session, so please review the policy and make comments by Friday, February 9.

As those of you who are familiar with the original R&D TSCA compliance policy will be aware, the new policy expands considerably on it. There are several reasons for this, the most obvious being that we have considerably more experience with TSCA now than we did two and one-half years ago when the first policy issued, so we have a better idea what questions will arise and what the answers are to those questions.

Two changes with regard to the R&D TSCA Compliance Policy's relationship to other Vista policies and training have also had and impact. One is the New Product Development Management System Manual which was issued last year. I have tried to make the new R&D TSCA policy consistent with that Management System. The introduction of a more formal process for product development (an activity that obviously accounts for a large share of our time in R&D and of our interaction with TSCA) has necessitated some additional provisions in the R&D TSCA policy. In addition, when the original policy was issued, it had been only a year since a general TSCA training session had been presented to all of R&D. This allowed the earlier R&D policy to focus on TSCA Research and Development Exemption issues. With that training now more than three years in the past, it seemed appropriate to add short sections to the R&D policy to discuss some of the other provisions of TSCA which could have an impact on R&D.

A final, and quite important, influence on this expansion of the R&D TSCA Policy is my experience in attending a two-day TSCA workshop conducted by the Chemical Manufacturers Association and the Synthetic Organic Chemical Manufacturers Association last April. The discussion on the first day of this workshop, for which only industry representatives were present, made it clear that virtually all of the companies represented (at least among the speakers and questioners) have formal processes for product development and regulatory compliance in place. Most or all place a great deal of emphasis on TSCA policy and TSCA training in R&D (and also in manufacturing). Seeing how extensive these programs appeared to be suggested that our R&D program could and perhaps should be more detailed.

There were a variety of approaches to training among companies represented at the workshop. Some, like Vista, only attempted to teach R&D personnel how to answer very simple TSCA questions for themselves. Their emphasis was to teach when (and who) to ask more difficult questions. At least some took a different approach, issuing all R&D employees large book-like manuals covering all aspects of TSCA and providing broad-scope training.

Many, if not most, of these companies appeared to have employees in operating departments who devoted their time exclusively to regulatory compliance issues. This is unlike the approach we have taken in R&D but may well be worthy of consideration in the future. I would be very interested in discussing these and other observations from the workshop with any of you who are interested.

Feel free to make any and all suggestions about how this policy can be changed and improved whether in overall scope or in its specific recommendations. We all want to make it both correct from legal and policy standpoints and useful on a practical basis. Thank you for your help.

Wayne Dickenson

Wayne Dickenson

Distribution: RBM DAP JEY WRC (Austin)
TGG WLMc DLC MJH (Houston)

A

VISTA RESEARCH AND DEVELOPMENT
TSCA COMPLIANCE POLICY

INTRODUCTION

In 1976 Congress passed the Toxic Substance Control Act (TSCA), an extensive law regulating the manufacture and importation of new and existing chemicals. While there are a number of sections of the act that apply primarily to commercial manufacturing of chemicals or to regulation of a specific list of chemicals, there are several sections which are general enough in scope to affect our activities in Research and Development. In particular, Section 5, which regulates (among other things) development of new chemicals, has special relevance for our activities in R&D.

SECTION 5: NEW CHEMICALS

Premanufacturing Notice (PMN)

A Premanufacturing Notice (PMN) must be submitted to the EPA and reviewed before manufacture or importation of a new chemical substance can begin. The EPA reviews these notices over a 90-day period. From the standpoint of TSCA, any chemical is considered new unless it is already listed on the Chemical Substance Inventory (see Section 8(b) below).

There are certain commercial uses of chemicals which are not subject to TSCA requirements. By and large these are areas which were already heavily regulated under other federal statutes before the Toxic Substance Control Act became law. Included among these are chemicals to be used only for foods, drugs, cosmetics, tobacco, firearms, nuclear applications, and pesticides. If use of a new or existing Vista product for any of these applications is contemplated, contact Tom Grumbles (Vista Environmental) or Robert Martin.

In order to make or import any individual sample of any chemical compound (or complex product mixture from a chemical process) that is not already on the TSCA Chemical Substance Inventory (see below), either a PMN must be filed and reviewed by the EPA or the sample must qualify for exemption from the PMN process. Most of our work with experimental materials in Vista R&D can be covered by the R&D Exemption.

The R&D Exemption

Manufacture of materials for research and development purposes is covered by the Research and Development Exemption to the PMN process. There are risk notification and record keeping requirements for each sample that must be met to maintain the new substance's TSCA R&D Exemption. This section of the compliance policy describes the procedures that must be followed to

insure these requirements are met.

What Is Considered Research and Development?

There are no set weight or volume limitations on R&D samples that may be covered by the Research and Development Exemption. The critical issue is whether the samples are made for legitimate R&D purposes. A legitimate R&D purpose can include anything from preparation of a ten-gram laboratory sample to test a synthetic reaction to manufacture of tons of material if that is required to accurately test suitability of the material in the application for which it is intended or the ability of the material to be processed in manufacturing equipment.

Test marketing and distribution in commerce (and manufacturing for them) are not R&D activities, but the ultimate test of whether an activity is legitimately R&D is not whether the material is sold. A manufacturer of a new chemical might well charge another company for the time, equipment, and raw material costs involved in making the chemical without exceeding the limits of the Research and Development Exemption provided that its customer planned to use the material for research purposes only (and, in fact, chemical supply houses make a living by doing just this with chemicals that are not, in many cases, on the TSCA Chemical Substance Inventory). On the other hand, a manufacturer who gives out free samples of his product to consumers for the sole purpose of promoting future sales is clearly engaged in a commercial activity not in research and development.

What Requirements Must Be Met?

Basically, there are four types of requirements which must be met, depending on the circumstances, to maintain the TSCA R&D Exemption for a chemical that is not listed on the Chemical Substance Inventory. First, anyone who will handle a sample or be exposed to it must be notified that the material may not be on the TSCA inventory and that the risks associated with the material may not be well defined. Second, the health and environmental risks of the sample must be evaluated and notification of the risks given to those working with the material unless prudent laboratory practices will be used at all times in that work. Third, written notification of the status of the sample and restrictions on its use must be given, and records of the notification and of some additional information about the sample must be kept if samples are transferred outside of the company. Finally, records of the disposition of all new chemical samples made for R&D must be maintained.

Procedures to maintain the R&D exemption for various types of samples are outlined below. Figure 1 is a flow chart of the R&D TSCA procedures for new product development.

Vista Analytical Samples

A new Analytical Tag form will soon be available. It will ask the sample

submitter to state whether the sample is of a material on the TSCA Chemical Substance Inventory or not. Check the appropriate box. Until the new Analytical tags are available, write "On TSCA Inventory" or "Not on TSCA Inventory" on every analytical tag as shown in Figure 2.

Submission of samples to Vista Analytical frequently occurs at a very early stage in the project. The TSCA status and, before analysis, the composition of the sample may well be unknown. If the TSCA status of the material is in doubt, mark the box stating that the sample is not on the TSCA inventory to assure that the sample is treated in a manner consistent with the unknown risks that may accompany a new chemical product.

Within Vista Analytical, where prudent laboratory practices will be used, any form of notification will satisfy the TSCA requirements, and no risk evaluation is required. Naturally, when you know of likely hazards of volatility, toxicity, irritation, etc., you must inform Vista Analytical just as you would those who handle the materials in your own laboratory.

Samples Within Vista (Excluding Analytical Samples)

This category includes a variety of situations: samples sent to a Vista plant location, samples sent from one Vista R&D Group to another for testing, individual or boxed samples destined for long-term storage, etc. Once the samples leave the lab and group in which they were made, the potential of risks associated with a particular new chemical may not be communicated verbally as a matter of routine. This requires some other form of notification for samples not on the TSCA Chemical Substance Inventory. Such samples should be given a "Not on the TSCA Inventory" label (see Figure 3). The labels state that the material is not on the TSCA inventory and note some of the requirements regarding use of the sample. The labels are available from Robert Martin. For samples sent from one group to another, a letter of transmittal must be written and must include the warning that the material is not on the TSCA Chemical Substance Inventory and, as such, may have unknown and unexpected risks associated with it. Any known risks of materials similar to the new chemical should also be discussed.

Samples Sent To Customers and Outside Analytical Labs

This category includes any sample sent outside of Vista whether to a customer or to a contract analytical laboratory. (The only exceptions are samples sent to Conoco Analytical or NMR samples sent to the University of Texas. See the appendix for an explanation of how these samples will be treated.) For these samples we are required to keep written record of the notice given. In addition we have no information concerning the laboratory practices of these outside labs, so a health and environmental risk evaluation is required.

When a sample is sent outside of the company it is ordinarily accompanied by a letter of transmittal. For those samples of materials not on the TSCA

Chemical Substance Inventory a second letter should be attached giving the TSCA notification and stipulations for use. Two copies of each letter must be prepared. One copy should be included with the shipped sample as notification to the customer or outside analytical lab. The other copy should be attached to the sample request. It will be removed by Tom Jackson (Shipping and Receiving) and forwarded to a central file in the R&D Library.

A sample of a letter for Notification to Customer (or Outside Analytical Lab) of Sample TSCA Status is shown in Figure 4. As much as possible the letters will follow a standard format. Portions of the letter which will change for the individual sample are underlined in the example. Essential features of the notification which must be individualized for the particular sample (keyed to the numbered sections of the example) are as follows:

1. The letter must be addressed to the recipient of the sample as given on the Sample Request form.

2. The chemical identity of the material must be stated either in this letter or in the typical letter of transmittal which this letter accompanies. In the example shown it was given in the letter of transmittal. If the identity is not known, the starting materials and process by which the sample was made must be given along with what information is available about the product identity. (Such information would normally be in the letter of transmittal for any sample.)

   If the identity or process is confidential and cannot be given to the customer or analytical lab, a handwritten note detailing the chemical identity or process must be attached to the copy of the letter which in turn is attached to the sample request. It, too, will be kept on file in the R&D Library.

3. The letter must contain a health and environmental risk evaluation. This does not mean that extensive testing must be performed on any material not on the TSCA Chemical Substance Inventory before it is sent to a customer. However, any specific data which is known regarding the material must be revealed. Also, if there is information that is known or that could reasonably be expected to be known about the likely hazards associated with the sample based on the type or chemical class of the sample, this must be given as part of the notification.

   For all customer samples an Experimental MSDS (see below) will be included with the sample. It must be referenced in this

section of the TSCA letter. To the degree that it is practical to do so, risk information should be communicated in the Experimental MSDS. Any additional risk information must be noted in the letter. In all cases it should be explicitly stated that there may be additional, unknown health or environmental risks since the material is new and has not been exhaustively tested.

For samples of materials not on the TSCA Chemical Substance Inventory sent to outside analytical labs an Experimental MSDS may also be prepared. In some cases, however, it may be difficult to prepare an Experimental MSDS for a new material since the composition and/or properties of the sample are still under investigation. A risk evaluation for such a sample is still required. If an Experimental MSDS is not prepared, notification of any risks must be included in this paragraph of the TSCA Notification Letter.

Other warnings which are required will remain the same in each letter: the sample is for R&D use only; no commercial use is permitted; the quantity is consistent with what is needed for R&D purposes; there will be supervision by qualified personnel. Vista must also keep a record of the amount of material sent. Be accurate when reporting this on the Sample Request form.

Experimental MSDS's

All samples of chemicals not on the TSCA Chemical Substance Inventory sent to customers must be sent with an Experimental MSDS. Experimental MSDS's must also accompany samples sent to internal Vista customers when the samples will be used outside of laboratories (for instance in a pilot plant or plant test run). Preparation of Experimental MSDS's is optional for samples sent from one group to another or to outside analytical labs but should be provided if they are available. (Note that health and environmental risks must be evaluated in some way for samples sent to outside analytical labs. While this requirement may be addressed in the TSCA Notification letter, as shown in Figure 4, in many cases preparation of an Experimental MSDS will be the easiest way to satisfy this need.)

In some cases an MSDS for an existing Vista product will provide useful safety information for a related experimental material either as written or with modifications. Several "generic MSDS's" are available for materials that are modified versions of existing Vista products (different ethoxylate alcohol homolog or percent ethylene oxide, different alkylate homolog, etc.) In these cases an Experimental MSDS can be prepared relatively easily. The experimental product name should be added to the MSDS (after blanking out the Vista commercial product name in the case where an existing product MSDS is used), and it should be explicitly stated that the product is

experimental. Any physical data including flash point that is incorrect for the new chemical must also be blanked out (and replaced with data measured for the new chemical if available). The toxicity data (if included in the original MSDS) may need to be generalized to indicate that it is test data for a related compound. When modification of an existing MSDS is appropriate, most of the other information on the MSDS should apply, as well, for the experimental chemical.

In some cases an Experimental MSDS will be required for a new chemical for which no existing MSDS will be a useful guide. Such an MSDS must be prepared by the researcher in cooperation with Dave Penney (Biological Technology). Consult him, also, if you have questions regarding modification of an existing Vista MSDS to be used with an experimental chemical. Houston Environmental will participate, as well, in preparation of a commercial product MSDS for a new material that is approaching commercialization.

Pilot Plant Operations

Pilot plant operations involving chemicals not on the Chemical Substance Inventory must be proceeded by a review of the potential risks to health and the environment. Such a review will be much like the review required before samples of new chemicals can be sent to customers. An Experimental MSDS must be generated by this review. In addition, a risk notification letter must be prepared. The notification letter will state explicitly that there may be additional, unknown health or environmental risks since the material is new and has not been exhaustively tested. It must also describe any other potential risks revealed by the review which are not easily included within the MSDS format. The risk notification letter and Experimental MSDS must be distributed to all personnel who will be involved in operation of the pilot plant.

Pilot plants are specifically stated by the TSCA regulations not to be included within the definition of a laboratory. As such they are ineligible for the exemption, available to laboratories using prudent laboratory practices, to the risk evaluation and notification.

For the purposes of TSCA, the EPA defines a laboratory as "a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual". Though it may casually be referred to as a "pilot plant", a small R&D unit which is designed so that it can be operated routinely by a single person can be considered to fall within the scope of the EPA's definition of a laboratory.

Disposition and Waste Disposal Records for R&D Materials

Records of disposition (including disposal) are required for Research and Development chemicals that will either be manufactured at more than 100 kg/year or that will be distributed to customers. Since our intention, in general, is for new chemical development to proceed successfully and, ultimately, for samples to be provided to customers for testing, this means such records must be kept for all new chemicals. This requirement applies unless a chemical is known to be listed on the TSCA Chemical Substance Inventory.

Records must be kept in the research notebook of to whom new chemicals are distributed and of the quantities involved. This applies for chemicals distributed to other researchers in R&D (including analytical samples to Vista Analytical) or to employees at other Vista locations. Quantities of new chemicals sent to external customers are recorded as described in the procedures for samples sent to customers or outside analytical labs.

Excess R&D materials may be sent for disposal by incineration by placing them in the lab carboys. No special sample by sample notification to the operator of the incinerator is required. Again, however, the quantity of material and means of disposition must be recorded in the research notebook (for example, "the remaining 123g of this product was dissolved in hexane and disposed of in the organic waste carboy".)

Excess R&D quantities of a chemical for which a PMN has been submitted and reviewed by the EPA may be distributed in commerce. Such distribution does not require a Notice of Commencement (NOC) of manufacturing to the EPA and, as such, does not result in the in the listing of the new chemical on the Chemical Substance Inventory.

Other Exemptions

There are several other exemptions to the full PMN process in addition to the Research and Development Exemption. These include the Polymer Exemption, the Test Marketing Exemption, and the Low Volume Exemption. Unlike the R&D Exemption, specific applications must be made and reviewed by the EPA to receive any of these three exemptions.

Polymer Exemption

New chemicals that are polymers are subject to an abbreviated 21-day Polymer Exemption review by the EPA. Under TSCA a polymer is defined as a substance with four or more subunits at least two of them internal, a distribution of subunits such that no one specific product comprises half or more of the weight of product, and a molecular weight of over 1000 g/mole (except for certain polyester polymers which qualify regardless of molecular weight). In addition, certain kinds of polymers are excluded from eligibility for the polymer exemption if the polymers or monomers contain specific

functional groups.

All R&D procedures for polymers will be the same as procedures for any other new chemicals. The Chemical Substance Inventory should be searched and a TSCA Inventory Status Form filled out early in the course of any work leading toward manufacture of a potentially new polymer (and in any case before samples are transmitted outside of the lab and group in which they are made except for submission to Vista Analytical). Polymers not found on the TSCA Chemical Substance Inventory must be accompanied by all of the same risk notifications and records as other new chemicals when they are distributed to internal or external customers.

In general, new polymers are considered to be on the TSCA Chemical Substance Inventory if they contain the same covalently bound monomers as previously-listed polymers regardless of the proportions of those monomers. Monomers that comprise less than two percent of the polymerized product are excluded from consideration. (This "two-percent rule" will not necessarily apply if the monomers introduce excluded functional groups to the polymer.) Processing aids and true polymerization catalysts (that are not incorporated covalently into the final product) are not considered monomers. Polymerization initiators and crosslinking agents which are incorporated covalently into the final polymer product are considered monomers if they are present at a concentration of two percent or greater.

Test Marketing Exemption

A Test Marketing Exemption must be filed with the EPA by Vista (or by our customer if the customer will conduct the test marketing) before any activity associated with test marketing begins. Manufacturing or importation of material to be used for a test market is a test marketing activity. It cannot begin before the Test Marketing Exemption review period has concluded. The Test Marketing Exemption review period is 45 days. Robert Martin will aid in coordinating with Vista Environmental in Houston and with the customer.

Low Volume Exemption

A Low Volume Exemption is available for new chemicals for which total manufacturing will be less than 1000 kg/year. As for the Polymer Exemption, an expedited 21-day review period is available for Low Volume Exemptions. All R&D procedures for a chemical of this type will be the same as for those expected to require the full PMN review process.

SECTION 8(b): THE CHEMICAL SUBSTANCE INVENTORY

The TSCA Chemical Substance Inventory is an inventory of all chemical products distributed in commerce at any time since the initiation of TSCA in the 1970's. New chemical products gain listing on the inventory by submission to the EPA of premanufacturing notices (PMN's) before

manufacture or importation and notices of commencement (NOC's) when manufacture or importation begins. The NOC must be received by the EPA before actual listing of a new product on the inventory occurs. No new chemical product may be manufactured or imported unless the PMN for the product has been submitted and reviewed or unless the product qualifies for one of the various exemptions such as the Research and Development Exemption or the Test Marketing Exemption.

When to Search the Inventory

The TSCA status (presence or absence of the product on the Chemical Substance Inventory) must be determined for every new or contemplated product early in the development process. It is appropriate to determine the TSCA status of a new product before laboratory work begins. The TSCA status of a new chemical product must be determined before the chemical is distributed outside the lab in which it is produced unless that distribution is within the immediate group in which the chemical is produced or to Vista Analytical. This will assure that the required risk notifications are made and records are kept of the disposition of a new chemical sample whether it is to internal or external customers or to chemical disposal.

The TSCA status of imported chemical samples must also be determined. Since Vista is considered under TSCA to have introduced these materials to the U.S. just as if we had manufactured them ourselves, records of the use and disposition of these materials are also essential for us to maintain TSCA compliance under the R&D Exemption.

All commercial Vista products are listed on the TSCA Chemical Substance Inventory. Note, however, that seemingly minor changes in the exact chemical composition or in the properties of a product may be sufficient to make the product a new product from the standpoint of TSCA.

Chemical samples obtained from domestic suppliers should already be on the TSCA Chemical Substance Inventory if they are distributed commercially. However, Vista also has a responsibility to assure that raw materials to be used in manufacturing a new commercial product are on the TSCA inventory in addition to the responsibility of the supplier. Since preparation and EPA review of a PMN requires approximately four months (minimum), verification of the TSCA listing of a raw material must be obtained from the supplier well in advance of anticipated commercialization. Be aware that reagents obtained from chemical supply houses are frequently sold for "laboratory [or research] purposes only" and, as such, may not be on the TSCA Chemical Substance Inventory.

How to Search the Inventory

The 1985 update of the Chemical Substance Inventory consists of five volumes and is located in the R&D Library, room 2109. Substances on the

inventory are indexed by Chemical Abstracts Service (CAS) registry number (Volume 1), substance name (Volumes 2 and 3), and molecular formula (Volume 4). Volume 5 is an index of unknown and variable composition listings in the inventory.

Access to an on-line computer database of the TSCA Chemical Substance Inventory is also available through Jane McDowell, R&D Librarian. The on-line database can be useful in locating a new chemical added to the Chemical Substance Inventory since publication of the most recent printed update in 1985.

Chemical names used in the inventory generally follow the naming system of the Chemical Abstracts Service with a few notable exceptions:

- Some common names are used (ethylene, not ethene);
- Some chemical products (particularly when there is no one defined structure for the substance) are named using the process by which they are manufactured (alkylation stripper bottoms; alcohols, C_{12-14}, ethoxylated);
- Iso as a prefix generally indicates a random distribution of monomethyl branches as from an oxo process;
- Polymers are usually named by their monomers without regard to the relative quantities of each monomer (vinyl chloride-vinylidene chloride polymer);

In general, it is worthwhile to look for a substance listing in the inventory under a few alternative chemical names if you are unable to locate the substance using the name with which you expect it to be listed.

If the CAS registry number of the chemical is available, the CAS registry number index can often be the easiest index to use to locate a particular chemical substance. Even this technique is not foolproof since what is considered to be a single chemical substance by the inventory may be considered to be several different chemicals, each with its own registry number, by the CAS.

All searches of the Chemical Substance Inventory must be documented. A TSCA Inventory Status Form (Figure 5) should be filled out in duplicate. This documentation is required regardless of whether the chemical in question is located in the Chemical Substance Inventory or not. The forms are available in the R&D Library. One copy of the form should be sent to the Product Manager of the business area involved in development of the new product of interest. The other should be placed in the tray provided in the Library for inclusion in the R&D file of TSCA Inventory Status Forms.

Technically, there are several types of materials that are not considered new chemical products under TSCA. These include mixtures of existing chemical products. If you think a new Vista commercial product will be exempt from

the PMN requirement because it is a mixture of substances already on the inventory, record that belief and the Chemical Substance Inventory listings of the components of the proposed mixture on your TSCA Inventory Status Form. Sending the copy of this form to the business area Product Manager will initiate further examination of this question.

Product impurities, byproducts with no commercial application, and process intermediates which are not isolated also need not listed on the TSCA Chemical Substance Inventory. It is frequently not obvious what will or will not be considered a new product on the basis of these unregulated areas. In the case of a new product, establish the status of intermediates and byproducts with a TSCA Status Form just as you do it for the final, primary product. In some cases even a change in an existing plant process can make the product of the process a new product for the purposes of TSCA. If you are aware, based on chemical composition or property analysis, of any change in an existing Vista product which will result from a proposed plant process change, bring that information to the attention of Robert Martin or Tom Grumbles (Vista Environmental) for further review of possible TSCA implications.

In practice, it is not always easy to locate a chemical's listing even when it is on the inventory. We urge you to familiarize yourself with the TSCA Chemical Substance Inventory. If needed, Robert Martin, Wayne Dickenson, or Bill Carradine (R&D TSCA Committee members) can assist in searching the inventory if there is reason to believe a chemical should be listed but an initial search does not locate it.

SECTION 8(c): ALLEGATIONS OF ADVERSE HEALTH OR ENVIRONMENTAL REACTIONS

Manufacturers, processors, and distributors of chemical substances are required to keep "records of significant adverse reactions to health or the environment" under Section 8(c) of TSCA. A statement does not need to be accompanied by formal proof or supporting evidence to be an allegation. Records of allegations of significant adverse reaction must be kept for 30 years from the time of the allegation.

There is no Research and Development exemption from the Section 8(c) requirement. It is Vista policy that any significant adverse reaction to health or to the environment be reported if it occurs at our facility regardless of whether we manufactured the chemical in question or whether it was supplied to us from an outside source. In addition, any such allegations received by any Vista employee about a Vista product (commercial or research and development) from a person outside the company (from a customer or from the community) must by law be recorded.

Allegations of significant risk should be reported to your supervisor or to Robert Martin. All such allegations will be considered. Those that are judged significant will be recorded and maintained on a standard Vista form which you will be asked to complete.

A significant adverse reaction as defined for Section 8(c) is one "that may indicate a substantial impairment of normal activities, or long-lasting or irreversible damage to health or the environment".

SECTION 8(e): REASONABLY SUPPORTED CONCLUSIONS OF SUBSTANTIAL RISK

All reasonably supported conclusions that a chemical substance presents a substantial risk of injury to health or the environment must be reported to the EPA under Section 8(e) of TSCA. While there is at least one exception (for risks of a particular chemical substance that are well-known), this requirement has generally been interpreted broadly by the EPA in terms of what constitutes a new or previously unknown risk.

Primarily, this provision refers to studies specifically initiated to study health or environmental effects of chemical substances. Any such studies of new or existing chemical substances must be conducted under the direction of the Vista Toxicology Assessment Committee (VTAC) and the Biomedical and Environmental Affairs Department to assure that such studies are monitored carefully and that regulatory requirements with regard to such studies are met, including notification to the EPA under Section 8(e) of TSCA if appropriate.

SECTION 13: IMPORTS

Under TSCA, importation of chemicals is considered much the same as manufacture of chemicals. Ordinarily, the U.S. company which is the recipient of the imported chemical is considered the importer of the chemical. This means that Vista is subject to all the same regulations (and potentially, if those regulations are not followed, penalties) for chemicals we import as for chemicals we manufacture.

TSCA Inventory Status for Imported Raw Materials

Determine whether a potential imported raw material for a Vista product is on the TSCA Chemical Substance Inventory as soon as you receive it. Send one copy of the TSCA Inventory Status Form to the Product Manager in the appropriate business area, and place one copy in the tray provided adjacent to the TSCA Chemical Substance Inventory Index volumes in the R&D Library. A PMN must be filed for a new chemical which is not on the TSCA inventory list, and the EPA must complete its 90-day review before the new chemical can be imported for distribution in commerce (either as is or after

subsequent manufacturing into a final product). It is vital to know the TSCA status for an imported raw material to avoid delays as the product approaches commercial distribution. This is particularly so since it can be difficult to obtain the chemical data from a foreign supplier necessary to be able to file a PMN.

Sample Shipments for Import

Every sample shipped to us from outside of the U. S. must be imported in compliance with TSCA. The shipping papers of each shipment from a foreign source must contain (verbatim) this statement certifying compliance: "I certify that all chemical substances in this shipment comply with all applicable rules under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA." Otherwise, the sample will be held in customs until the TSCA status can be ascertained. A frequent foreign supplier who is familiar with this import requirement may well be willing to include this statement with the bill of lading on request, but, if you have doubts, the most effective way of assuring that a shipment will not be delayed is to fax the certification to the foreign supplier with instructions for its inclusion.

Samples imported into the U. S. for research purposes will be in compliance with TSCA regardless of whether the chemicals are on the TSCA Chemical Substance Inventory list or not. If the chemical is on the inventory list, no PMN is required before importation. If the chemical is not on the TSCA Inventory List, it is still exempt from the PMN requirement as long as it is to be used for research and development purposes only.

Mailed Imported Chemicals

If a sample from a foreign supplier is sent by ordinary mail, it will not pass through an official customs entry. Nevertheless, certification to the EPA that its entry into the U. S. is in compliance with TSCA is still required. The EPA has recently established an interim procedure to cover such cases. A copy of the certification (as quoted above) must be sent on receipt of the imported chemical (presumably along with a brief description of the shipment) to:

Ms. Barbara Ostrow (TS-778)
Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

APPENDIX: CONOCO AND UT NMR ANALYTICAL SAMPLES

We know a great deal about the laboratory practices of certain outside analytical laboratory vendors: Conoco Analytical, the Conoco Refinery Lab, and the University of Texas NMR Lab. This gives us a degree of confidence that these labs will use prudent laboratory practices in handling our

experimental samples which we do not have when we send samples to customers or to other outside analytical labs. This exempts us from the TSCA risk evaluation requirement. However, since these labs are not within Vista, certain written notification and record keeping requirements are required under TSCA for samples of materials not on the Chemical Substance Inventory.

To satisfy this requirement special forms, Notification of TSCA Status to Conoco Analyst or Notification of TSCA Status to University of Texas NMR Spectroscopist, are required (see Figures 6 and 7). A standard form for the Notification of TSCA Status to Conoco Analyst is available from Vista Analytical (Craig Mercy). Both copies of the form must accompany the sample when it is delivered to Shipping and Receiving (Tom Jackson) for shipment to Conoco. One will be retained by Vista for our records while the other will be shipped with the sample. Charles Hammond (Vista Analytical) will complete and duplicate all Notification of TSCA Status to University of Texas NMR Spectroscopist forms. Let him know when an NMR sample to be sent to UT is of a material that may not be on the TSCA Chemical Substance Inventory.

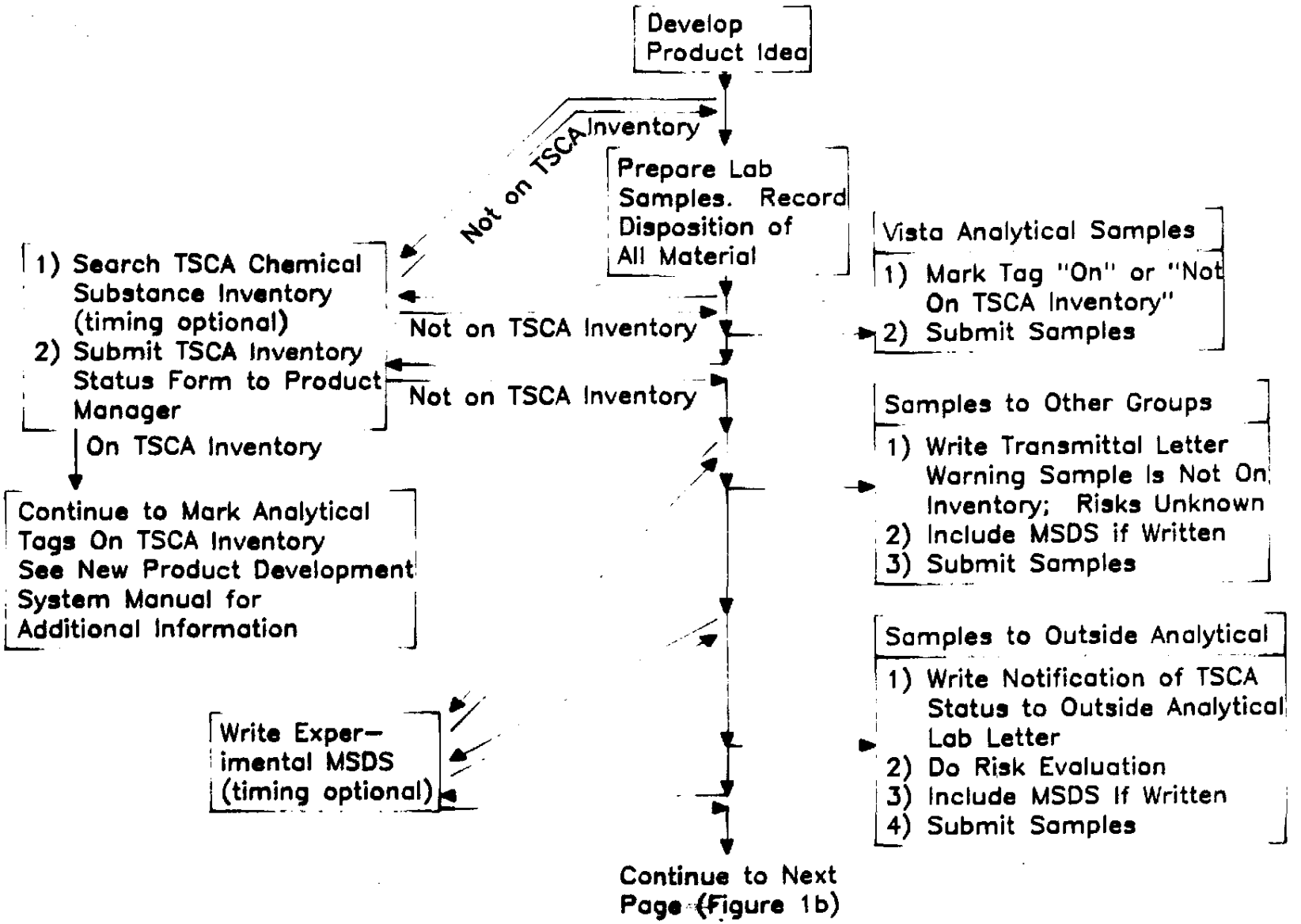


FIGURE 1a: TSCA PROCEDURES FLOW CHART FOR NEW PRODUCT DEVELOPMENT

VEV-182495

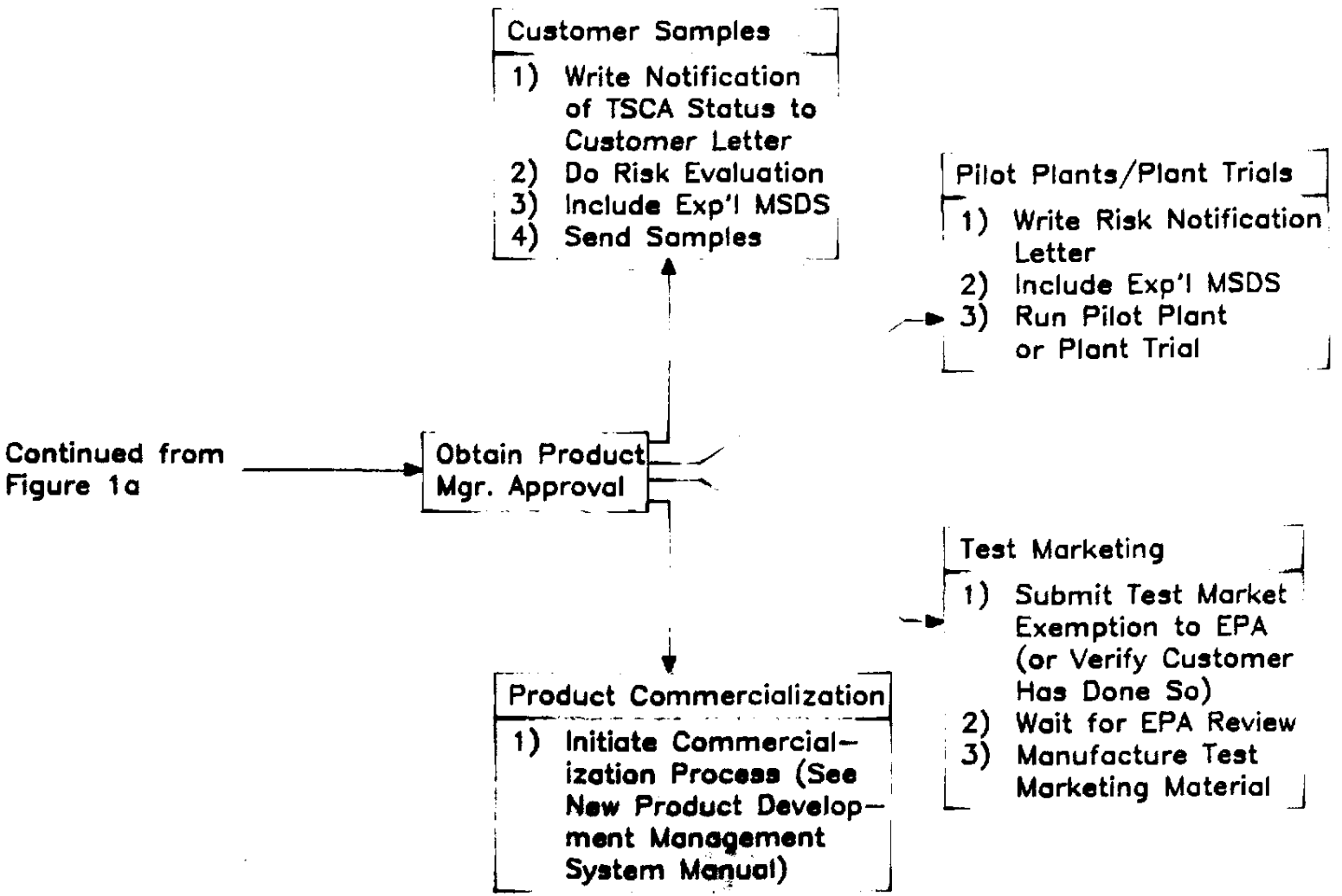
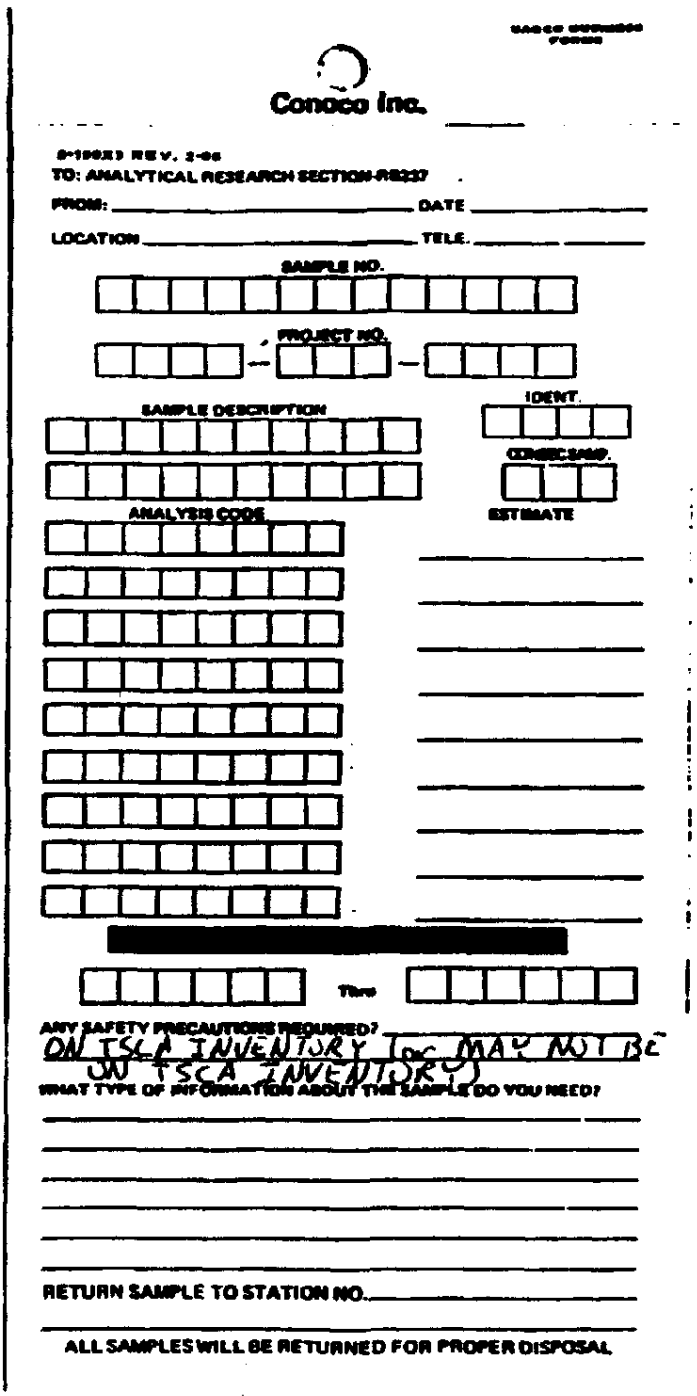


FIGURE 1b: R&D TSCA PROCEDURES FOR NEW PRODUCT DEVELOPMENT



Conoco Inc.

TO: ANALYTICAL RESEARCH SECTION-RB237

FROM: _____ DATE _____

LOCATION _____ TELE. _____

SAMPLE NO.

PROJECT NO.

SAMPLE DESCRIPTION

IDENT.

ANALYSIS CODE

ESTIMATE

ANY SAFETY PRECAUTIONS REQUIRED?

ON TSCA INVENTORY (OR MAY NOT BE ON TSCA INVENTORY)

WHAT TYPE OF INFORMATION ABOUT THE SAMPLE DO YOU NEED?

RETURN SAMPLE TO STATION NO. _____

ALL SAMPLES WILL BE RETURNED FOR PROPER DISPOSAL

FIGURE 2: TSCA STATUS MARKED ON ANALYTICAL TAG

This substance is not on the TSCA inventory. It is to be used solely for research & development purposes & only by technically qualified personnel. Do not handle this material until you have received handling instructions & proper health/safety data.

FIGURE 3: NOT ON TSCA INVENTORY SAMPLE LABEL

VEV-182498

Vista Chemical Company

12025 Vista Parke Drive
Austin, Texas 78726
(512) 331-2500

P.O. Box 200135
Austin, Texas 78720-0135

January 18, 1990

VISTA

E. W. Saybolt
Attn.: Cindy King
1404 S. Houston/Pasadena Rd.
Pasadena, TX 77502

1

Dear Ms. King:

This letter constitutes notification of E. W. Saybolt by Vista Chemical Company that the oil-soluble sulfonate sodium salts in pale oil (V3233C, V3234C, and V3235C) that we are submitting to you for viscosity analysis contain compounds that may not be included on the TSCA (Toxic Substance Control Act) Chemical Substance Inventory. Vista Chemical will maintain records of this notification for a period of five years.

2

The quantity of the three oil-soluble sulfonate sodium salts in pale oil being supplied is based on your estimate of the amount of material required for analysis for R&D purposes. Only R&D use of the samples is permitted, and the samples may not be used for any commercial purpose. This material is to be used only under the direct supervision of a technically qualified person.

Vista Chemical Company does not possess specific information regarding the effects of this chemical on health or the environment. We believe, based on our experience with alkylbenzenesulfonic acid products, that the materials will likely cause irritation if skin or eyes are directly exposed. The aromatic material included in the approximately 40% oil base of each sample may include highly condensed aromatic compounds. Some such compounds have been implicated as potentially mutagenic or carcinogenic with prolonged exposure. Since the products contain new chemicals, they may well pose additional health or environmental risks of which we are unaware, and they should be handled accordingly. In the event that further, specific information becomes known to Vista Chemical Company, we will provide your company with that information.

3

Sincerely,

Wayne Dickenson

FIGURE 4: NOTIFICATION TO CUSTOMER/OUTSIDE ANALYTICAL LAB OF SAMPLE TSCA STATUS

A

To: New/Experimental Product File

From:

Interoffice Communication

Date:

VISTA

Subject: **TSCA Inventory Status of** _____

On _____, I reviewed the TSCA Inventory to determine whether
(date)

_____ was or was not listed.
(compound name)

☐ I found that _____ **was on the TSCA**
(compound name)
Inventory and has the CAS-Registry Number _____.

☐ I did **not** find _____ **on the TSCA Inventory.**

Signed,

_____
(Researcher Name)

FIGURE 5: TSCA INVENTORY STATUS FORM

VISTA

NOTIFICATION OF TSCA STATUS TO CONOCO ANALYST

To: _____ **(Conoco Analyst)**

From: _____ **(Vista Experimenter)**

Date: _____

Sample(s): _____ **(Notebook Reference)**

This sample is of an experimental material that may not be on the TSCA inventory list.

We are sending a _____ **sample for analysis:**
(quantity)

Sample description and chemical structure (if known):

_____

_____

This sample must be used for research purposes only and may not be used commercially. It must be used only under supervision of a technically qualified person and must be handled using prudent laboratory practices.

_____
(Signature)

Complete and submit both copies with sample to Vista Analytical.

FIGURE 6:
NOTIFICATION OF TSCA STATUS TO CONOCO ANALYST

A

VISTA

Notification of TSCA Status To

University of Texas NMR Sprectroscopist

To: _____ **(U.T. NMR Analyst)**

From: Charles Hammond **(Vista Representative)**

Date: _____

Sample(s): _____ **(Notebook Reference)**

This sample is of an experimental material that may not be on the TSCA inventory list.

We are sending a NMR tube(s) containing less than 200 mg of sample for analysis in an appropriate solvent(s).

Sample description and chemical structure (if known):

_____

_____

This sample must be used for NMR analysis purposes only. It must be used only under supervision of a technically qualified person and must be handled using prudent laboratory practices.

_____
(Signature)

FIGURE 7:
NOTIFICATION OF TSCA STATUS TO UNIVERSITY OF TEXAS NMR SPECTROSCOPIST

VEV-182502