APPLIED ORGANOMETALLIC CHEMISTRY
Appl. Organometal. Chem. 2005; **19**: 458–464
Published online in Wiley InterScience (www.interscience.wiley.com). DOI:10.1002/aoc.774

The organotin industry rises to the HPV challenge†

John M. Batt*

Organotin Environmental Programme (ORTEP) Association, USA

Received 26 June 2004; Revised 26 July 2004; Accepted 27 July 2004

In 1998, the US Environmental Protection Agency launched the High Production Volume (HPV) Challenge Program, which called for chemical manufacturers to voluntarily commit to fill gaps in basic screening-level hazard data for high volume chemicals they manufacture and to make the data available to the regulatory community as well as the public. Companies could sponsor chemicals individually or, if there were multiple manufacturers, companies could join together to form consortia to jointly sponsor work. The organotin industry, through the Stabilizer Task Force of ORTEPA, volunteered 27 organotin and related inorganic compounds for this program. This paper addresses setting up the industry effort, securing committed funding, sharing of existing data, establishing the test plans, contracting for the testing and administering the testing. It also provides an update as to where industry is in meeting its obligations. Copyright © 2005 John Wiley & Sons, Ltd.

KEYWORDS: Organotin; alkyltin; ORTEP; HPV

INTRODUCTION

In 1998, the US Environmental Protection Agency (EPA) challenged US manufacturers and importers to voluntarily provide a full set of toxicity screening data on nearly 2800 'high volume' chemicals. At the same time in Europe, the International Council of Chemical Associations (ICCA) initiated a High Production Volume (HPV) Initiative similar in nature to the US EPA HPV Challenge Program. The multi-point screening information data set (SIDS) to be provided is the same as that agreed to among member nations of the Organization for Economic Cooperation and Development (OECD) in the 1980s, and is intended to represent the minimum data needed to perform a basic toxicity risk screening.[1] The data set includes both human health and environmental toxicity endpoints (Table 1) and will become available to the regulatory community and the public. The HPV program allows for public tracking of progress and results via the Internet.

The USA and Europe define HPV chemicals somewhat differently. In the USA, HPV chemicals are those produced or imported in quantities greater than 1 000 000 pounds per year. In Europe, HPV means quantities greater than 1000 metric tonnes (2 204 600 pounds).[2]

*Correspondence to: John M. Batt, ATOFINA Chemicals Inc., 2000 Market Street, Philadelphia, PA 19103, USA.
E-mail: john.batt@atofina.com
†Dedicated to the memory of Professor Colin Eaborn who made numerous important contributions to the main group chemistry.

The US EPA HPV Challenge Program attracted hundreds of companies, representing over 2100 chemicals, to voluntarily provide the full screening-level base sets of hazard data. This is more than any regulatory requirement has ever accomplished anywhere in the world.[2] Chemicals not sponsored will be included in a Toxic Substance Control Act (TSCA) Test Rule that will require the same testing, but with less technical flexibility and, most likely, greater expense.[1]

HPV PROGRAM SCHEDULE

The target for the original HPV programs called for submittal of test plans by the end of 2003 and making the screening level health and environmental hazard data available by 2005. At the end of 2003, the US EPA HPV Challenge Program reached a major milestone. Information on almost 1200 of the chemical compounds tested had been voluntarily made available to the public. This is more than any government-sponsored program has achieved before. The American Chemistry Council (ACC) estimates that, by participating through consortia, companies reduced their total testing costs by at least $200 million[3] through the sharing of data and developing justification for the use of categories.

European, American and Asian companies are participating in both the ICCA and EPA programs, which are now being actively coordinated through the OECD. The participating companies or consortia, therefore, had to choose the

Table 1. Basic SIDS endpoints

Physical/chemical properties
Melting point
Boiling point
Density (inorganic chemicals only)
Vapor pressure
Partition coefficients
Water solubility
Environmental fate and pathways
Photodegradation
Stability in water (hydrolysis)
Transport between environmental compartments (fugacity)
Biodegradation
Ecotoxicity
Acute toxicity to fish
Acute toxicity to Daphnia
Toxicity to algae
Chronic Daphnia (conditional SIDS endpoint)
Health effects
Acute toxicity
Repeated dose toxicity
Genetic toxicity (two endpoints, *in vitro* and *in vivo*):
• gene mutations (*in vitro*)
• chromosomal aberrations (*in vivo*)
or
• mammalian erythrocyte micronucleus (*in vivo*)
Reproduction toxicity (including fertility and developmental toxicity

program under which they would volunteer their chemicals, and, if they participated through ICCA, then choose a rapporteur country to represent them.

ORTEPA AND THE STF

The Organotin Environmental Programme (ORTEP) Association was founded in 1978 in order to promote and foster the dissemination of scientific and technical information on the environmental effects of organotin compounds and to provide greater appreciation of the available scientific and technical information on environmental aspects of organotin compounds. The Stabilizer Task Force (STF) is a working group within ORTEP. In late 1998, the STF began discussions regarding participation in the HPV Program and agreed in 1999 to volunteer 27 organotin and related inorganic compounds for this program (Table 2), not all of which were produced by all STF companies. These 27 compounds were tin stabilizers, tin catalysts or related raw materials or intermediates used in their manufacture.

Tin stabilizers are used for processing polyvinyl chloride (PVC). The primary purpose of these tin stabilizers is to reduce the polymer backbone degradation of the PVC. They do this by scavenging the HCl lost during processing at high temperatures and stabilizing the unstable chloride sites in the PVC molecule. Tin catalysts are commonly used in chemical synthesis and the curing of coatings. In chemical synthesis, the organotins are commonly used for the esterification and transesterification of mono- and polyesters. As curing catalysts, one of the largest uses of organotins is in electrocoat (E-coat) coatings.

The ORTEP Association, being an international consortium with members in Europe, Asia and North America, elected to fulfill their HPV commitment through participation in the ICCA HPV Initiative. The ORTEP Association's participation in the ICCA and the OECD SIDS program also fulfilled the data requirements under the US EPA's HPV Challenge Program. The ICCA program has some advantages even though it involves more work. The main difference between the two programs is that the EPA's HPV program does not require an initial environmental exposure assessment, where the ICCA program does. This assessment includes both a source assessment as well as a fate and pathway assessment, conducted on a high level, global basis only. Also, the ICCA program involves international scrutiny and approval of test plans as well as preparation of a SIDS Initial Assessment Report with a presentation and defense of the data at an international meeting. The USA was chosen to serve as the rapporteur country for ORTEP, with data being submitted to the US EPA.

THE HPV PROCESS

The process to fulfill our HPV obligations was clear. Firstly, we needed to identify, retrieve, review and rate open literature and individual member company studies, then enter data into IUCLID (International Uniform ChemicaL Information Database) dossiers. Next, data gaps would be identified and test plans developed to address those gaps. After testing was arranged, conducted, and results obtained, SIDS initial assessment reports (SIARs) and SIDS initial assessment profiles (SIAPs) would need to be developed. These would then be submitted to a SIDS initial assessment meeting (SIAM) for review.

ORTEPA was faced with many decisions and considerations. There would be the direct costs of the testing program; the treatment of the costs of existing company-owned studies contributed to the Program; the less tangible costs such as 'sweat equity' (laboratory, analytical chemists, consortia involvement of multiple people for periods of 5 or more years); how to implement program cost effectively; what mix of internal/external skills/resources/time would be needed?

Beginning in 1999 the group put together a budget estimate for the proposed testing program of $6M. It then took over a year to develop, and come to agreement over, an acceptable cost sharing agreement. Originally, 12 companies set out, but in the end only 11 signed on. Subsequently, one signatory company went out of business and never contributed, and one new one volunteered to sign on.

Table 2. Chemicals sponsored by the ORTEP Association Stabilizer Task Force

Chemical name	CAS Number	Family
Methyltins		
Methyltin trichloride[a]	993-16-8	Monomethyltin
Dimethyltin dichloride[a]	753-73-1	Dimethyltin
Methyltin Tris(2-ethylhexylmercaptoacetate)	57583-34-3	Monomethyltin
Methyltin Tris(iso-octylmercaptoacetate)	54849-38-6	Monomethyltin
Dimethyltin bis(2-ethylhexylmercaptoacetate)	57583-35-4	Dimethyltin
Dimethyltin bis(iso-octylmercaptoacetate)	26636-01-1	Dimethyltin
Methyltin, 2-mercaptoethyl tallate ester reaction product	201687-57-2	Dimethyltin
Butyltins		
Mono-*n*-butyltin trichloride[a]	993-16-8	Monobutyltin
Di-*n*-butyltin dichloride[a]	753-73-1	Dibutyltin
Tri-*n*-butyltin chloride	1461-22-9	Not included in the butyltin family
Tetra-*n*-butyltin	1461-25-2	Not included in the butyltin family
Mono-*n*-butyltin Tris(2-ethylhexylmercaptoacetate)	57583-34-3	Monobutyltin
Mono-*n*-butyltin Tris(iso-octylmercaptoacetate)	54849-38-6	Monobutyltin
Di-*n*-butyltin bis(2-ethylhexylmercaptoacetate)	57583-35-4	Dibutyltin
Di-*n*-butyltin bis(iso-octylmercaptoacetate)	26636-01-1	Dibutyltin
Di-*n*-butyltin dilaurate	77-58-7	Dibutyltin
Di-*n*-butyltin maleate	78-04-6	Dibutyltin
Di-*n*-butyltin oxide	818-08-6	Dibutyltin
Octyltins		
Mono-*n*-octyltin trichloride[a]	3091-25-6	Mono-octyltin
Di-*n*-octyltin dichloride[a]	3542-36-7	Dioctyltin
Tri-*n*-octyltin chloride	2587-76-0	Not included in the octyltin family
Tetra-*n*-octyltin	3590-84-9	Not included in the octyltin family
n-Octyltin Tris(2-ethylhexylmercaptoacetate)	27107-89-7	Mono-octyltin
Di-*n*-octyltin bis(2-ethylhexylmercaptoacetate)	15571-58-1	Dioctyltin
Di-*n*-octyltin oxide	870-08-6	Dioctyltin
Other tin compounds		
Tin tetrachloride	7646-78-8	Not included in a family
Tin(II) 2-ethylhexanoate[b]	301-10-0	

[a] Anchor compound for organotin family.
[b] This material is being sponsored through the Metal Carboxylates Coalition.

Through the original cost sharing agreement, slightly over $5.1M was committed; this was not enough to cover the original estimate of the program but we were cautiously confident we could develop a strategy to accomplish our goals within the committed funding. Our goal remained to submit by the end of 2005: (1) completed data packages to the OECD member countries for review, including, IUCLID dossiers, (2) SIARs and (3) SIAPs.

ADMINISTRATION OF THE HPV PROGRAM

Because ORTEPA did not have the extensive, concentrated resources necessary to administer such a multifaceted program as the HPV Program, an independent third party program administrator needed to be selected. Paramterix Inc., an environmental services consultant, was chosen to support ORTEPA. Services provided by Parametrix included management and technical oversight of the laboratory studies (these activities included developing requests for proposals, tracking payments and costs, reviewing protocols, report reviews and submittals), review and assessment of existing data, preparation and submittal of the IUCLID dossiers, meetings with regulators, and maintenance of the HPV/SIDS database. Subcommittees within ORTEPA needed to be established to deal with the various administrative and technical aspects of the Program:

- administrative subgroup, to administer the Program on behalf all the participating companies;
- toxicology subgroup, to address toxicology and ecotoxicology questions, issues and strategy;

- analytical subgroup, to address the complicated analytical issues surrounding organotins;
- exposure subgroup, to address the needs for basic exposure data for the IUCLID dossiers in accordance with ICCA requirements.

These subcommittees enlisted diverse resources and expertise from various areas within the participating ORTEPA member companies. Periodic face-to-face meetings as well as teleconference calls were necessary to resolve issues, keep all parties in touch, and the program moving along on schedule. Program updates were given at all ORTEPA/STF meetings, which were held about every 4 months. These updates included not only a review of the testing progress, but also the financial situation covering cash flows, expected best-case and worst-case costs, as well as projected timing of invoicing participating companies for their committed share of the costs.

DATA GATHERING

Our first obligation was to review, validate and summarize any existing data, comparing them against the SIDS endpoints to determine whether any data gaps existed. Some of the data were found in the literature, some were contained in industry-sponsored reports, and some in individual company-owned reports, which were privately funded by member companies and considered confidential. In all, this totaled more than 1000 reports. Some of the testing requirements could be fulfilled using published or unpublished tests of a structurally similar compound that can be related to an HPV compound using Structure–activity relationship (SAR) techniques. Testing needs were further reduced by providing data for appropriate analogs and by testing anchor compounds for organotin families. Only where these attempts failed was actual testing deemed necessary to fill the data gaps.

EXISTING STUDIES

For each of the 27 compounds, data on physical property, environmental fate, ecotoxicity, and mammalian and genetic toxicity were collected from reports submitted by STF member companies, published literature and various standard compilations of physical property data. The collected data were reviewed for acceptability and entered into an IUCLID dossier for each of the compounds.

Ecotoxicity, mammalian toxicity and genetic toxicity data for each of the compounds were scored using the Klimisch *et al*. scoring system to assess data reliability. Data with scores of 1 or 2 (but not 3 or 4) were considered reliable. Robust summaries were prepared for reliable studies and entered into the corresponding IUCLID dossier.

Concern over confidentiality of data contained in company-sponsored studies was an overriding factor early in the process. Individual companies all agreed to submit their own studies to our administrator in total confidence and a robust summary of the results was then written to be included in the IUCLID dossier. The individual company submitting a confidential study reviewed the robust summary and provided authorization for its release.

DEVELOPMENT OF TEST PLANS AND THE FAMILY APPROACH

Test plans needed to be developed in order to fill the identified data gaps. The STF developed a category, or family, approach to the human health testing for most of our HPV compounds, which fit into six families based on methyl, butyl, and octyltins, with mono- or di-alkyl substituents (see Table 2). In fact, the use of the family approach was deemed the only way to minimize animal testing and still accomplish the goals of the HPV program while staying within the budget of committed funding we had secured. For the mono- and di-alkyltin compound families, the respective chloride was used as the 'anchor' compound to the extent possible for the repeated dose, reproductive and developmental effect endpoints. However, the alkyltin chlorides are generally more water-soluble than the other family members. The variation in water solubility impacts the bioavailability and distribution in the environment. Therefore, acute mammalian toxicology studies, environmental fate and effects studies, physical property testing and *in vitro* genetic toxicology studies were to be performed for the individual compounds in the families.[4]

The testing plans were also designed to address the fact that the HPV program is focused around named substances, even though many of the commercial tin stabilizer products are produced as mixtures.[5] The test plan approval process involved iterative discussions with our rapporteur, the EPA. After these initial discussions, the documents were formally submitted to EPA and posted on the Internet on OECD's electronic discussion group (EDG) site for review and comment before any needed testing commenced. Ultimately, six test plans were developed and submitted for mono/dimethyltin compounds, mono/dibutyltin compounds, mono/dioctyltin compounds, dialkyltin compounds, tri/tetraalkyltin compounds and tin tetrachloride.

THE TESTS

All testing was required to be carried out in compliance with good laboratory practice (GLP), either those of the USA or OECD, using established standard testing guidelines, again of either the US EPA or OECD. Our program specifically used OECD guidelines. Bids from competing testing laboratories were solicited and a final contract structured with the chosen testing laboratory in The Netherlands. In addition to the tests themselves that needed to be conducted, range-finding

tests had to be initially performed to determine the proper dose ranges to ultimately test. A total of 97 tests had to be contracted and scheduled for individual compounds or groups of compounds. Each test, or set of tests, required a separate Amendment to the original contract. In all, over 50 amendments were ultimately necessary to cover all the studies.

Prior to commencement of any testing, which began in December 2001, product samples had to be obtained from STF companies, but which companies should supply which samples? While a laboratory-prepared sample of high purity (>95% purity) product was required for physical/chemical testing, commercial-grade product was necessary for human health and environmental testing. Whereas soliciting companies to volunteer for laboratory preparation of certain high purity samples was fairly straightforward, although time-consuming, obtaining the commercial samples was somewhat more complex. With producing companies each having different overall purities and with differing levels of impurities in their commercial product, our administrator had to gather confidential analytical information from each company and determine the most appropriate sample to use. Decisions then needed to be made on proper storage conditions, and stability testing of the samples at the testing laboratory. This task fell to the analytical subgroup.

THE CHEMICAL CHALLENGES OF ORGANOTINS[6]

Organotin substances are generally represented by the formula:

$$R_xSn(L)_{(4-X)}$$

For these chemicals, R is a typical organic group such as methyl, butyl, octyl, etc., and it is connected to the tin atom by a carbon to tin bond. For the organotin stabilizers and catalysts, X is either 1 or 2, and the R group is a methyl, butyl or octyl group. For organotin biocides and pesticides (not part of our HPV program), X equals 3 and the R group is usually a butyl, cyclohexyl or phenyl group. In each individual compound the R groups are always the same; there is not a mix of R groups. Once these compounds are made and isolated, the R groups maintain their connection to tin; they do not transfer from one tin to another under normal conditions of use.

The ligands on tin, designated L, may be chloride or other sulfur- and oxygen-based organic ligands, such as –SR′, –OR′, –OC(O)R′, –S–, –O–, etc. The alkyltin chlorides are the main industrial precursors for all of the commercial organotin products. Conversion of a chloride to these other products is achieved through simple reaction of the chloride with the appropriate L group—a carboxylic acid or mercaptoester, for example. In this regard, these ligands L undergo displacement reactions while the alkyl R groups remain fixed to the tin atom. The ligands also can be displaced by water in hydrolysis reactions.

The organotin biocides and pesticides (R = 3) are produced as fairly pure materials. Most of the catalysts ($X = 1$ or 2, L═OCOR′, O) also are produced as pure materials, with controlled low levels of tri species. However, in the case of the organotin stabilizers ($X = 1$ or 2), most of these materials are produced as mixtures of mono- and dialkyltin compounds, in compositions ranging from 10 to 80% monoalkyl. This is due to both the chemistry of alkyltin compounds and the performance requirements for stabilizers, with both the mono- and di-components providing critical, but different, performance attributes. In addition, this allows the amount of trialkyl species present to be controlled to very low levels in these materials. Once a product is manufactured, the amounts of mono-, di- and trialkytin compounds present remain constant during use.

Solubility and stability in water (hydrolysis)

Most organotin compounds of industrial importance are sparingly soluble in water due to their strong hydrophobic character. However, as mentioned above, they do contain one to three reactive ligands (L). These ligands can be readily hydrolyzed in water to provide more soluble tin compounds:

$$R_xSnL_y + H_2O \longrightarrow R_xSnO_{y/2} \text{ or } R_xSnOH_y \text{ or } R_xSnL_yOH_y$$

Therefore, the inherent chemistry of these alkyltin compounds in water casts doubt on previously measured solubility values reported in scientific literature where this hydrolysis is not taken into account.

The recommended guideline for testing water solubility (OECD 105) 'addresses the determination of the solubility in water of essentially pure substances which are stable in water and not volatile. Before determining the water solubility, it is useful to have some preliminary information on the substance, like structural formula, vapor pressure, dissociation constant and hydrolysis as a function of pH.' It is clear that, for the materials that the STF is testing, it cannot be assured that they are *stable in water*, nor can it be assured that they are *not changed during the procedure*. Furthermore, preliminary tests show that the solubilities are much less than 0.02 g/l. Also, it is unlikely that the components of the organotin compounds dissolve in the same ratio that they exist in the original mixture.

The low solubility and hydrolysis chemistry present significant challenges to measuring the organotins in aqueous solution. For all of the work previously done in this area, no analytical technique currently exists that is capable of quantifying the entire organotin compound with its associated ligand(s) (i.e. the mercaptide, carboxylate, oxide or chloride portion of the molecule), in dilute aqueous solution. The quantitative analytical methods used to date focus on measuring the concentration of the stable alkyltin portion, through derivatization, and so they do not measure the reactive ligand portion of the molecules. This has led to a

misunderstanding in some reports regarding what is actually present in the aqueous solution, a misunderstanding that can further lead to a misjudgment regarding the environmental effects of these materials. Most importantly, organotin impurities, which include compounds of different alkylation levels, reaction products within the aqueous solution (e.g. hydroxides or oxides) and residual impurities from synthesis, will be present along with the parent organotin compound. At least some of these impurities are often more soluble in water than the named substance. Therefore, when reported solubility values (typically reported as tin) of commercial stabilizers are small, the relative quantities of these impurities present in the water are high compared with the named substance, and it is probable that the reported solubility value is not due entirely to the named substance. This illustrates that careful consideration must be given to conclusions based on solubility determined with methods unable to completely characterize the soluble organotin species present.

The limitations of the analytical methods also make it difficult to understand the hydrolysis chemistry of these organotins. Under a strict reading of the USEPA hydrolysis protocol (OPPTS 835.2110) the loss of any one of the reactive ligands (L), such as:

$$H_2O + R_xSn(L)_y \longrightarrow R_xSn(L)_{(y-1)}(OH) + LH$$

or the hydrolysis of a portion of the reactive ligand L to L′:

$$H_2O + R_xSn(L)_y \longrightarrow R_xSn(L)_{(y-1)}L' + HOR'$$

[where L′ is a hydrolysis product of one of the ligands, e.g. $L = -SCH_2C(O)_2R'$ and $L' = -SCH_2C(O)_2H$)] could constitute hydrolysis. However, the most sensitive quantitative analyses used to date utilize derivatization methods that displace all of the reactive ligands L on the tin. This is accomplished either through alkylation to a mixed tetraalkylated tin species (such as monomethyl triethyltin), or by reaction with HCl to form the alkyltin chlorides. Thus, none of these methods are acceptable for quantifying the resulting products of hydrolysis, because the parent compound, soluble impurities and hydrolysis products will be derivatized to the same final tetraalkyltin or alkyltin hydride compound. There is no differentiation between starting material and hydrolysis products.

A proposed method to determine solubility and rate of hydrolysis

Owing to these problems with conducting standard OECD tests of solubility and hydrolysis, the STF proposed using an alternative method, developed from discussions with the EPA, for assessing the solubility and rate of hydrolysis of these alkyltin compounds. The alternative method uses quantitative analysis to determine tin levels in solution, while a separate qualitative analysis is performed to identify the chemical species present in solution. The concentrations of the test substance or the combined hydrolysis products are plotted vs time, allowing for the estimation of the half-life of the test substance. Once the material has completely solubilized, the rate of hydrolysis will become constant (as will the half-life). Therefore, a plot of the half-life vs the concentration can be used to determine the approximate solubility of the test substance, as the slope of the line will 'break' as the test substance is completely solubilized.

An initial test of the method was conducted by STF using a dibutyltin stabilizer [dibutyltin bis(2-ethylhexylmercaptoacetate)]. The results were encouraging. The test substance was determined to be insoluble (solubility was estimated to be <320 ng/ml) and had a half-life of approximately 10–12 h. Qualitative analyses revealed that the primary hydrolysis products were dibutyltin thioglycolate and dibutyltin oxide. However, pilot studies at the testing laboratory on other organotin compounds were problematic. The method did not work uniformly for all the organotin compounds. This would require development of multiple methods to include all the organotin HPV compounds, with no guarantee it would be possible to do so.

Since the current OECD test methods are not appropriate for use with these compounds due to the inherent organotin chemistry in water, and with the failure of the proposed alternative method, STF came to the difficult decision that it would not be able to proceed with the planned solubility and rate of hydrolysis studies. A derogation for not conducting these studies is currently being drafted by the analytical and toxicology subgroups to be submitted to our rapporteur, the EPA.

ADDITIONAL FUNDING NECESSARY

Although it was hoped, as our testing program progressed, that we could accomplish our goals with the funding the 11 participating companies originally committed, it became painfully obvious in April 2003 that our HPV program, still projected at slightly under $6M, would need additional funding to be completed as planned. The analytical portion of the studies proved to be more difficult than originally estimated, adding significantly to our estimates. Currency exchange rate fluctuations also became a factor as the testing (in excess of $4.5M) was contracted in Euros while participating STF company shares were collected in US Dollars. An amendment to the original cost sharing agreement was necessary for the 11 participating companies to voluntarily commit the needed additional funding. All 11 participating companies signed this amendment in February 2004 after only 10 months of effort in drafting the amendment and determining the additional funding necessary.

STATUS EARLY 2004

As stated previously, ORTEPA's goal was to submit by the end of 2005: (1) completed data packages to the OECD

Member countries for review, including, IUCLID dossiers; (2) SIARs; and (3) SIAPs. We are on track.

In early 2004, most testing has been completed (90 of the 97 tests) and at least draft reports have been issued. The ecotoxicity testing for the trialkytins and tetraalkytins is underway and will be completed by the end of the third quarter of this year. We have compiled basic exposure, and source of exposure, information for the IUCLID dossiers as required under the ICCA Initiative for an initial risk assessment. We are also waiting for another consortium, the Thioesters Panel, to complete their work, as we need their data to complete some of our assessments. Draft SIARs and SIAPs are now under development. When completed they will be submitted to the US EPA for review and comment. We will then need to resolve any comments with the EPA prior to submitting the SIARs and SIAPs to OECD member countries for their comments. Any comments from them will then have to be resolved prior to a SIAM. At the SIAM, the EPA will serve as our rapporteur, although ORTEPA technical representatives are allowed to be in attendance to provide support if necessary. What currently remains unclear is whether our compounds will go through a SIAM in 2005, which is beyond our immediate control. Agendas for SIAMs are scheduled well in advance, and there is currently a backlog of compounds to be reviewed.

ORTEPA has made enormous progress over the course of the past 5 years. This has been due to the extraordinary efforts and devotion of resources of the eleven companies involved in accomplishing a common goal on a global basis.

REFERENCES

1. Outen RB, Stephens SH. EPA's HPV Chemical Challenge: a strategic perspective. *JSC J. Newsl. Environ. Sci. Advoc. Mngmt* 1999; Spring: 1, 5.
2. Cooper J. *Comparative Analysis of the European Union's proposed REACH System and the U.S. Toxic Substances Control Act*. Synthetic Organic Chemical Manufacturers Association (SOCMA): 2003; 10.
3. Lebedev G. A focus on results, *Chem. Bus. J. Am. Chem. Council* 2004; February: 5–12.
4. ORTEPA (Organotin Environmental Programme Association) Stabilizer Task Force. Test plan for the mono- and di-octyltin compounds. Prepared by Parametrix, Kirkland, WA, Revised 16 August 2002.
5. ORTEPA (Organotin Environmental Programme Association) Stabilizer Task Force. Test plan for the mono- and di-methyltin compounds. Prepared by Parametrix, Kirkland, WA, Revised 20 August 2002.
6. ORTEPA (Organotin Environmental Programme Association) Stabilizer Task Force. Test plan for the mono- and di-butyltin compounds. Prepared by Parametrix, Kirkland, WA, Revised 15 August 2002.