MONITORING FOR TOXICOLOGICAL SAFETY

AN=339

Nina I. McClelland
President and
Chief Executive Officer
National Sanitation Foundation

Presented at the
International Conference
on Underground Plastic Pipe,
sponsored by the Pipeline
Division of the American
Society of Civil Engineers
New Orleans, Louisiana, 1981

National Sanitation Foundation
3475 Plymouth Road
P.O. Box 1468
Ann Arbor, Michigan 48106 U.S.A.

MONITORING FOR TOXICOLOGICAL SAFETY[1]

Nina I. McClelland, PhD[2]

ABSTRACT

In the U.S., monitoring for toxicological safety of plastic piping system components is accomplished by the National Sanitation Foundation (NSF) through a voluntary program of testing and listing under NSF Standard 14. Samples collected during unannounced visits to production facilities are tested for extraction of potentially toxic chemical substances, in accordance with requirements in the Standard. In addition, RVCM is measured in the wall of PVC and CPVC pipe and fittings. Test protocols, ingredient review procedures, and recent results are presented. The logo NSF-pw on a product - pipe or fitting - is assurance that the product has been tested and found to conform with all Standard 14 requirements for potable water applications.

INTRODUCTION

In October 1965, the Board of Trustees of the National Sanitation Foundation (NSF) adopted NSF Standard No. 14, "Plastic Piping System Components and Related Materials"(1). The Standard, revised in February 1977, November 1978, and December 1980, forms the basis for toxicological monitoring of plastic pipe, fittings, and related products used in the U.S. for potable water applications. Products tested by NSF and shown to conform with Standard 14 are included in a product listing published annually by NSF (2), and authorized to bear the appropriate NSF logo; i.e., NSF-pw .[2]

This program, although entirely voluntary, is widely used by official regulatory agencies in all 50 states, and by plastics manufacturers who contract directly with NSF for testing/listing services. From 1956 to 1965, evaluation and listing was conducted under contract with each participating manufacturer. The contracts provided for testing and regulation of all parameters originally adopted in Standard 14.

In the listing published in January 1980, the section relating to potable water includes materials, designated by end use (as pipe, fittings, pipe and fittings, appurtenances and coatings other than pipe or fittings, special pipe application - i.e., nonpressure or tubing - and well casing pipe/couplings); special compounders of materials and coatings; pipe and fittings; and appurtenances, special engineered products, and coated products. Two hundred sixteen (216) companies and 1,368 products are included in the 1980 listing.

In a use survey(3), conducted in 1980 by the NSF public relations consultant, 957 questionnaires were returned by agencies at the state level[3]; 33 (54.1 percent) indicated that evidence of compliance with Standard 14 was required by law, regulation, or agency policy.

NSF

The National Sanitation Foundation was chartered in 1944 under the laws of Michigan to engage in service, education, and research in areas relating to health and environment. It is a not-for-profit, private company recognized internationally for its role as an objective third party certifier of products covered by its 42 standards and criteria. In 1971, a suit was brought in federal court by Eliason Corporation (a Kalamazoo, Michigan manufacturer of walk-in refrigerators and freezers for food stores), charging NSF with violation of the Sherman Anti-Trust Act. The lower court ruled in favor of NSF; the U.S Courts of Appeals supported the ruling; and in October 1980, the U.S. Supreme Court closed the case with the words "Petition of certiorari denied." This decision specifically approved voluntary standards as instruments of governmental regulation in protection of public health; affirmed their legality in the interest of free and fair competition; and embedded in American law the ruling on NSF standards and certification programs.

By policy, the NSF standards development process requires consensus of the concerned groups: regulatory, industry and user, working as a "joint committee." Acceptance by the NSF Council of Public Health Consultants is required before a Standard is referred to the Board of Trustees for adoption. Assurance of health and environmental integrity of an NSF standard is clear from the expertise at all levels of development, review, and acceptance.

When a product is listed for conformance with any NSF standard, continued compliance is determined by annual unannounced inspection of the production facility. Quality control practices are reviewed and products sampled for additional testing by qualified field personnel from NSF's regional offices located in Lodi, California; Ann Arbor, Michigan; Chalfont, Pennsylvania; and Atlanta, Georgia. Established enforcement procedures provide for dealing with products not in compliance, and range from removing the NSF logo to delisting the product(4).

---

[1]Presented at the International Conference on Underground Plastic Pipe, sponsored by the Pipeline Division of the American Society of Civil Engineers, New Orleans, Louisiana, 1981.

[2]President and Chief Executive Officer, National Sanitation Foundation.

[3]In addition to potable water, the listing includes plastic products for drain, waste, and vent; continuous waste systems; corrosive waste system; and sewer mains. In this paper, further reference to the listing relates only to potable water applications.

[4]Generally responsible for minimum requirements for acceptance of plastics piping system components for potable water applications.

ORIGIN OF STANDARD 14

"A Study of Plastic Pipe for Potable Water Suppliers" was published by NSF in 1955(5). This report describes a three-year study of 22 samples of plastic pipe "to determine their suitability for underground use in conducting cold potable water," by demonstrating "whether any substances that might be deleterious to health would be extracted from the plastic by an aggressive potable water, and whether the passage through plastic pipe might affect the appearance, odor, or taste of the water"(5). As a final test of potential health effects, for a period of 18 months, colonies of Wistar strain white rats drank water exposed to the plastics. No significant differences were observed between test and control populating.

"In these days of rapid development of untried new materials health officials naturally are concerned about the possible effects of adding such materials to our environment. This is especially true when these substances are in intimate contact with public water or food supplies.

This impartial study of plastic pipe from a public health point of view is an attempt to secure, for health officials much needed basic information. It should simplify the problem of offering the greatest protection to the health of the community without standing in the way of progress."

These words which are the "Preface" to the 1955 report, are as appropriate in 1980 as they were in 1955. With technology and resource availability rapidly changing, attention must be focused on health and environmental effects of new and old products available in the marketplace. Further, the control targets are continually shifting, reflecting new information. Cost benefit, health risk, and environmental impact are critical concerns. It is prudent, therefore, to monitor for toxicological safety virtually all products which contribute to our dietary intake or environmental exposure.

PURPOSE

The purpose of this paper is to describe the NSF program for monitoring plastic piping system components for potable water applications. Toxicological safety of these products is a significant part of the NSF monitoring program.

PROCEDURE

A ***new ingredient*** is defined as, "any chemical or substance not previously accepted for use in products intended for application in potable water systems." new and ***generically similar***[1] ingredients must be accepted by NSF prior to their use in products listed for conformance with Standard 14. To be accepted, complete chemical information must be provided, and the ingredient submitted, in both pipe and compound, formulated to contain two times the recommended maximum use level. These samples are exposed to water using conventional extraction procedures(1), and the extractant water tested for constituents of interest, listed in Table I. To be accepted, no maximum contaminant level (MCL) in Table I can be exceeded. Further, if the ingredient is not included in the Food and Drug Administration's (FDA) "list of sanctioned materials," 90-day feeding studies at established levels of effect, no effect, and an intermediate level, and Ames tests must be undertaken by the manufacturer at a laboratory acceptable to NSF, and the data provided for review by one or more of NSF's consultant toxicologists.

Following the acceptance of a new ingredient, and to change the formulation of a listed product, the product and compound containing the new ingredient or modified formulation must undergo qualification testing. Pipe and compound containing the ingredient at the proposed recommended maximum use level are submitted for extraction testing. Again, the MCL's specified in Standard 14 may not be exceeded. Qualification testing provides for evaluation of an ingredient in any product in which it will be used. Production variations (e.g., type of extruder, temperature profiles, etc.) make this an important requirement before new ingredients or formulation changes appear in the marketplace. Procedures for acceptance, qualification, and monitoring under NSF Standard 14 are summarized in Table II.

Routine product monitoring refers to testing of products sampled by regional personnel during the annual unannounced visits to production facilities. The number of plant inspections and number of samples tested varies by type of listed product. By policy, three annual visits are required for pipe and fittings producers. Currently, one annual sample of pipe and fittings is subjected to complete chemical extraction and taste and odor testing; one annual sample of materials and two annual samples of in-plant compounds are tested similarily.

[1]Generically similar to accepted ingredients but vary in composition as a result of manufacturing process, source of materials, or not [illegible] trace contaminants.

TABLE I. CHEMICAL CONSTITUENTS REFERENCED IN NSF STANDARD 14

Parameter (as total)	Maximum Contaminent Level (MCL) mg/l[1]
Antimony (Sb)	0.05
Arsenic (As)	0.05[2]
Barium (Ba)	1.0[2]
Cadmium (Cd)	0.010[2]
Chromium (Cr)	0.05[2]
Lead (Pb)	0.05[2]
Mercury (Hg)	0.002[2]
Selenium (Se)	0.01[2]
Tin (Sn)	0.05

[1] milligrams per liter≈ parts per million (ppm)
[2] Reference: U.S. Environmental Protection Agency (EPA), National Interim Primary Drinking Water Regulations(6).

TABLE II. SUMMARY OF PROCEDURES FOR ACCEPTANCE, QUALIFICATION, AND MONITORING PLASTIC PIPING SYSTEM COMPONENTS

	Acceptance	Qualification	Monitoring
Ingredient Level	2x Recommended Maximum Use	Recommended Maximum Use	Actual Use
Sample	Pipe and Compound	Product and/ or Compound	Product and/or Compound
Exposure (@pH 5.0)	Multiple	Multiple	Multiple
Criteria, All Parameters in Standard 14	1st extraction ≤10x MCL and 3rd extraction ≤MCL	1st extraction ≤10x MCL and 3rd extraction ≤MCL	3rd extraction ≤MCL

In November 1980, the Industry Advisory Committee for Thermoplastics recommended that finished products (e.g., pi[illegible] and fittings) made from in-plant compounds, be sampled and tested three times annually, and routine testing of in-pla[illegible] compounds be discontinued. If a failure occurs, it is recommended that product and the compound from which it is made be sampled for retest. The product would be tested first; the compound, tested only if the second product sample fails. Although pass/fail status would be determined by results for product testing only, results from testing the compound would assist in identifying the source of the problem (i.e., processing or compounding). This change must be approved by the Joint Committee before it is implemented. The purpose of the recommended change is to provide more quality assurance of products which reach the marketplace, versus materials used in their production.

In 1977, a maximum permissible level for residual vinyl chloride monomer (RVCM) was added to Standard 14. Through extraction testing and mathematical modelling, it was shown that no detectable monomer (where detection limit is 2 parts per billion (ppb)) would leach to water exposed to pipe and fittings when RVCM in the product wall is equal to or less than (≤) 10 parts per million (ppm). This level was adopted for Standard 14. The Standard requires that three samples of each listed polyvinyl chloride (PVC) and chlorinated polyvinyl chloride (CPVC) pipe and fittings be tested annually.

TEST PROTOCOL

Routine quality assurance practices are followed with all laboratory procedures (8).

EXPOSURE

Exposures are made at a ratio of 240 square inches (in^2)[1] to 1.0 liter (ℓ) of formulated extracted water. Samples are cut as required to fit into exposure vessels (e.g., pipes are cut into 5 $inch^2$ sections); compounds are compression or injection molded into plaques and cut to an appropriate size for exposure. (Refer to Standard 14(1) for special procedures for solvent cements, appurtenances, and related items.) Samples are washed with detergent and rinsed with distilled water to remove surface grime, then dried prior to exposure.

A chemically defined aggressive extractant water is prepared to contain 100 mg/l hardness (as $CaCO_3$) and 0.5 mg/l total residual chlorine, and adjusted to pH 5.0±0.2 with carbon dioxide (CO_2). The specific formulation is shown in Table III. pH 5.0, selected for plastics exposure during the early special study(5), was reported by Durfer and Becker as the lowest in the range (5.0-10.5) for treated water in the 100 largest U.S. cities(7).

TABLE III. FORMULATED EXTRACTANT WATER

	Stock Solutions, ml			
Distilled Water,	Buffer[1]	Hardness[2]	Chlorine[3]	Co_2
to 1.0	25	25	0.5	bubbled to pH 5.0 ± 0.2

[1] 3.36g $NaHCO_3$ dissolved in distilled water and made to 1ℓ ; prepared fresh daily.
[2] 4.44 g $CaCl_2$ dissolved in distilled water and made to 1ℓ ; prepared fresh daily.
[3] 7.3ml NaOCl (5.5 percent) added to 200ml distilled water; prepared fresh weekly.

A "standard" multiple exposure technique has been adopted for both cold and hot application plastics. For products listed for cold water application, exposure conditions are shown in Table IV. For hot water applications, exposure conditions are shown in Table V. Controls; i.e., an equivalent volume of water without sample under similar conditions of exposure, are included with every set of samples tested.

TABLE IV. EXPOSURE CONDITIONS FOR PLASTICS LISTED FOR COLD WATER APPLICATIONS

Extraction	Time, hrs.	Temperature, C
First	24 ± 1	37 ± 0.5
Second[1]	24 ± 1	37 ± 0.5
Third[1]	72 ± 4	37 ± 0.5

[1]Fresh formulated extractant water.

[1]1,612.5 square centimeters (cm^2)
[2]127 millimeters (mm)

METALS

Following exposure, the water is filtered through paper and prepared for chemical or taste and odor testing. All of the metals except mercury are analyzed by flameless atomic absorption spectophotometry (AAS), using a Perkin Elmer (PE) Model 560 atomic absorption spectrophotometer with a PE heated graphite atomizer (HGA), Model 2200.

Mercury is measured by cold vapor analysis, using a PE Mercury Analysis System (Model 303-0830). Current detection limits and reproducibilities are shown in Table VI.

TABLE V. EXPOSURE CONDITIONS FOR PLASTICS LISTED FOR HOT WATER APPLICATIONS

Extraction	Time, hrs.	Temperature, °C
First	1	82 ± 0.5
Second[1]	1	82 ± 0.5
Third[1]	0.5 plus 72 ± 4	± 0.5 37 ± 0.5
[1] Fresh formulated extractant water.		

TABLE VI. DETECTION LIMITS AND REPRODUCTIBILITIES FOR METALS

Metal	MCL mg/l	Reproducibility[1] at MCL, mg/l	DL[2] mg/l	Reproducibilty at Lowest Standard[3], mg/l
Antimony	0.05	±0.0007	0.007	±0.0005
Arsenic	0.05	±0.0007	0.004	±0.0008
Barium	1.0	±0.05	0.008	±0.004
Cadmium	0.01	±0.0002	0.0005	±0.0001
Chromium	0.05	±0.002	0.005	±0.002
Lead	0.05	±0.0009	0.002	±0.0007
Mercury	0.002	±0.0004	0.0003	±0.0004
Selenium	0.01	±0.001	0.003	±0.0005
Tin	0.05	±0.002	0.005	±0.0009

[1]Reproducibility = standard deviation of absorbance values obtained for standard prepared to contain a specified level of the metal of interest (e.g., MCL).
[2]Detection limit = 2 x noise level of recorder output.
[3]Three standards prepared for calibration; levels are selected to represent the range of levels expected in samples to be analyzed.

RVCM

The test procedure for RVCM includes a Perkin Elmer Head Space Analyzer (gas chromotograph), Model F-42 with a flame ionization detector and two Carbowax 1500 columns. A small (0.5±0.1 gram) sample - pipe or fitting - is dissolved in dimethyl acetamide (DMAC) in a sealed tube, and heated. The monomer volatilizes to the head space in the tube. An aliquot from the vapor phase is analyzed for VCM. Reproducibility at 10 ppm is ± 25 percent.

TASTE AND ODOR

A qualified panel of ten or more persons determines taste and odor in water exposed to plastics. Panelists taste the undiluted sample and judge it "satisfactory," "unsatisfactory," or "questionable." A sample fails when it is rated unsatisfactory. A questionable sample fails the taste test if it does not pass the odor requirements.

Odor is tested using a modification of a paired dilution techniques, described by ASTM(9). In this procedure, the sample is diluted to the level established in Standard 14 as pass/fail (i.e., "40" for cold applications, and "60" for hot applications). Two randomly placed sample-control pairs are presented for each sample tested; panelists identify the member of each sample pair in which the strongest odor is detected. A sample fails when, with 99 percent confidence, a sufficient number of panelists identify it as the strongest in the pair.

RESULTS

Failure experience for chemical, taste, and odor (CTO) testing in 1980 is summarized in Table VII[1]. Twenty-eight samples of pipe and six fittings did not meet the CTO requirements of Standard 14. Four hundred ninety-one (491) samples were tested, for an overall failure experience of 6.9 percent. Of the 34 failed samples, 25 (73.5 percent) were taste and odor related: nine extracted tin greater than the established MCL (i.e., 0.05 ppm).

TABLE VII. SUMMARY OF CTO FAILURE EXPERIENCE IN 1980

Number of Samples		
Total Tested	Sn > 0.05 ppm	Taste, Odor, or Taste and Odor Permissable Threshold
491	9	25

In the U.S., tin has long been used successfully as a heat stabilizer in PVC and CPVC potable water piping system components; calcium-zinc, zinc, antimony, and antimony-tin have recently been accepted as alternative stabilizers. The greates volume is tin, where the metal is an organo-complex of the methyl, butyl, or methyl-butyl form.

Tin is not regulated in U.S. water supplies; thus, an MCL was established by NSF. Consultant toxicologist indicated that tin was no more toxic than lead, which is known to be cumulative in the body.The MCL for lead established in the National Interim Primary Drinking Water Regulations(6) and previously in the U.S. Public Health Service Drinking Water Standards(10) is 0.005 ppm. An equivalent level was adopted for tin.

Similarly, antimony is not included in the U.S. regulations. Based on an evaluation of comparative known toxicities of lead, tin, and antimony, an MCL of 0.05 ppm was adopted for antimony. This level is equivalent to the MCL established by USSR in 1972. Table VIII compares current MCL-s establsihed by national and international regulatory agencies for inorganic substances in drinking water.

DISCUSSION

The use of plastic pipe in construction continues to grow. Seven years ago, it was forecast at 450,000 tons in 1980. Actual current useage is greater than 700,000 tons and an eight-million-ton year is projected for 1985(11).

Two major challenges to plastics have occurred in the recent past: RVCM was added to the list of known carcinoge[illegible] in 1976, and joining cements were suspected of contributing high levels of organic solvents in 1980; however, ***no [illegible] of plumbing system components alternative to plastics are tested by an objective third party certifier, and no standards similar to NSF Standard 14 are known to exist for the commonly used metal plumbing systems (copper and galvanized steel).***

[1]Does not include RVCM, reported in Table IX.

TABLE VIII. MAXIMUM LIMIT VALUES FOR HEALTH RELATED INORGANIC SUBSTANCES[1] INCLUDED IN STANDARD 14

	PARAMETER							
	Sb	As	Ba	Cd	Cr	Pb	Hg	Se
WHO (European) 1970 Upper Limit Concentration	-	0.05	-	0.01	0.05	0.1	-	0.01
WHO (Intern'l) 1970 Upper Limit Concentration	-	0.05	-	0.01	-	0.1	0.001	0.01
EEC 1980 Maximum Admissible Concentration	0.01	0.05	-	0.005	0.05	0.05/0.1	0.001	0.01
USSR 1972 Maximum Permissible Concentration	0.05	0.05	4.0[2]	0.01	0.1/0.5[2]	0.1	0.005[2]	0.001
USA 1976 Maximum Contaminant Concentration	-	0.05	1.0	0.01	0.05	0.05	0.002	0.01
CANADA 1978 Maximum Acceptable Concentration	-	0.05	1.0	0.005	0.05	0.05	0.001	0.01
INDIA 1976 Cause for Rejection	-	0.05	-	0.01	0.05	0.1	0.001	0.01
EGYPT 1980 Maximum Permissible Limit	-	0.05	-	0.01	-	0.01	0.001	0.01
JAPAN 1978 Maximum	-	0.05	-	0.01	0.05	0.1	0.005	0.01
AUSTRALIA 1980 Health Investigation Levels	-	0.05	1.0	0.01	0.05	0.05	0.001	0.0[illegible]

[1] All values are mg/l

[2] Value footnoted, but footnote not identified in available reference.

RVCM

Prior to adopting an RVCM-MCL in Standard 14, a comprehensive survey was undertaken to determine the current (1976) level of monomer in PVC and CPVC pipe and fittings. All listed customers were asked to submit to NSF samples of current production one day each week for a period of five weeks. Participation was entirely voluntary, and samples were coded by NSF to preserve anonymity.

Seven manufacturers with analytical capability for detecting and measuring vinyl chloride monomer participated in the project. Each sample was sent by NSF to two or more of the participating laboratories. All data were reported to - and analyzed by - NSF. Levels of RVCM in pipe were generally found to be less than 10 ppm; but, more than 50 ppm was common in fittings. In addition to the current survey, diffusivity calculations were used to show that no detectable monomer ("detection" defined as 2 ppb) is expected to leach to water exposed to pipe containing 10 ppm or less RVCM. This, then, was the level adopted as minimum permissible in Standard 14.

Also in 1976, the U.S. Environmental Protection Agency completed a pilot study with test loops constructed from two different samples of CPVC purchased randomly in the marketplace. In addition, five PVC field installations were sampled to demonstrate whether or not RVCM in pipe "can migrate into the water flowing through it"(12). The abstract reads, "Drinking water that passes through pipes made of polyvinyl chloride (PVC) does pick up unpolymerized residuals of that material - but in concentrations far below the level that has adverse effects on experimental animals."

One of the pipe samples used by EPA in the pilot test was not listed by NSF for conformance with Standard 14; the second sample was an NSF listed product. Although no reference to RVCM was made in the Standard at that time, the nonlisted product contained a higher level of monomer; i.e., 16 mg/kg,[1] and EPA concluded that it did "not present an accurate picture" of the quality of PVC pipe which was available at that time from major manufacturers. By contrast, the listed product contained a "very low level" of residual monomer; i.e., 3 mg/kg[2] "and is typical of both PVC and CPVC pipe currently being produced by major manufacturers." Test results from the listed pipe "show that the concentration of vinyl chloride did not increase with time of standing, and in fact actually dropped to a relatively low 2.9 μg/l[3] level at the end of seven days test at no flow." The combination of purge traps, innovative columns, and a microcoulometric titration system permitted EPA to detect and accurately measure VCM at parts per trillion (ppt) levels.

In the Federal Register for November 28, 1980(13), EPA announced the availability of water quality criteria for 64 toxic pollutants, including vinyl chloride. Data from the 1976 EPA field studies are referenced for vinyl chloride. "Sites chosen were representative of extremes in climatic conditions and of variable age, length, and size of pipe. Low concentrations of vinyl chloride were detected in three of the five water supply systems. Water from the most recently installed and the longest pipe system had the highest vinyl chloride concentration (1.4 μg/l). Traces of vinyl chloride (0.03 and 0.06 μg/l) were still present in the other two systems (which were the oldest) about nine years after installation." A multi-stage model was used to provide a linear, non-threshold, dose-response relationship to estimate levels which "may result in incremental increase of cancer risk over the human lifetime." For levels of risk equivalent to 10^{-5}, 10^{-6}, and 10^{-7} (i.e., one in 100,000, one in 1 million; and one in 10 million), the corresponding water quality criteria for vinyl chloride are 20 μg/l (ppb), 2 μg/l, and 0.2 μg/l, respectively, assuming the daily diet of a 70-kilogram male person would include two liters of drinking water and 6.5 grams of freshwater and estuarine fish and shellfish products. (Criteria based on these assumptions are estimated to be protective of an adult male who experiences average exposure conditions.)

Applying the risk estimates to data from the EPA field study suggests that the level of VCM in the highest sample tested was "acceptable;" i.e., less than 2 ppb. It was estimated that the pipe in that study was manufactured from 1964 to 1975. It is clear from the NSF monitoring program (refer to "Results" presented earlier in this paper), that RVCM levels in pipe and fittings produced in 1980 are significantly less than levels in products produced before this parameter was routinely monitored, and that fewer extreme levels of RVCM are reaching the marketplace.

Of the first 200 samples tested in 1977 (period through 9-23), 18 (9 percent) contain more than 10 ppm RVCM. Two of the 18 contained greater than 10 but equal to or less than 20 ppm (>10≤20); five contained >20≤50 ppm; six were >50≤100; and five were >100. In 1979, 21 of 650 samples tested (3.2 percent) contained more than 10 ppm RVCM; 11 of these were >10≤20 ppm; seven were >20≤50, one was >50≤100, and two were greater than 100 ppm. In 1980 to date 457 samples have been tested; two samples (0.4 percent) exceeded the 10 ppm limit established in Standard 14. One contained >10≤20; and one, >20 ppm. Further, "resamples" of each of the "failed" products contained >10 ppm RVCM. These data are summarized in Table IX.

TABLE IX. SUMMARY OF RVCM FAILURE EXPERIENCE

	Number of Samples					
Year	Total,n	≤10 ppm	>10≤20	>20≤50	>50≤100	≤100
1977	200	182	2	5	6	5
1979	650	629	11	7	1	2
1980	457[1]	455	1[2]	1[3]	0	0

[1] n for 1980 is expected to reach 585; 117 listed samples have not been available to date, principally because of reduced production schedules.
[2] 14.1 ppm; retest sample <10 ppm.
[3] 21.7 ppm; retest sample <10 ppm.

CEMENTS

On January 15, 1980, Assembly Concurrent Resolution (ACR) No. 98 was introduced into the California Legislature to "request the Commission of Housing and Community Development Code to allow the extensive use of plastic pipe in construction until it has received a documented, written report from the Toxic Substances Hazard Alert System of the State Department of Health Services on the safety of such use, including , but not limited to, a consideration of the safety of acrylonitrile, methyl-ethyl-ketone (MEK), methyl-butyl-ketone (MBK), dimethyl formamide (DMF), cyclohexanone, tetrahydrofuran (THF), polyvinylchloride (PVC) as well as any other chemicals found in the cements and primers used for the installation of plastic pipe."(14).

In response to ACR No. 98, a comprehensive testing program was undertaken by James. M. Montgomery, Consulting Engineers, Inc. at its laboratory in Pasadena, California. The contractor was selected by the staff of the State Toxic Substances Hazard Alert System (HALTS), and accepted by the manufactuers who funded the more than $80 thousand study. The test protocol, developed by HALTS staff, representatives of James Montgomery, and representatives of the sponsoring manufacturers, was designed to demonstrate whether or not significant levels of organic solvents, trihalomethanes[1], heavy metals, and RVCM would leach from PVC and CPVC piping systems under simulated end use. Two typical conditions were included in the study: static exposure, to demonstrate leaching characteristics in new constructions where water may remain stagnant in a system prior to occupancy and use of the system; and dynamic exposure, to demonstrate leaching during typical patterns of daily use. A further study related to the kinetics of leaching from joints under static exposure conditions.

The final report was published in October 1980 and provided the basis for an "Executive Summary" and recommendation prepared by HALTS staff. The Summary addresses both worker and consumer health and finds that adverse worker health effects from the principal solvents in cements and primers are "unlikely," based on their relatively low toxicities and field measurements of exposures made under a range of working conditions. With respect to worker health, five findings are presented:

- Under controlled conditions, water held in new installations may exceed calculated "safe" levels of organic solvents leached from cemented joints.
- Excessive levels of two volatile organic compounds, including carbon tetrachloride, can accumulate in chlorinated water held two weeks in CPVC.
- Two phthalates were found sporadically at low levels in water exposed to the plastics tested.
- A "substantive potential health risk" is associated with water carried in newly installed PVC and CPVC systems. "The risk is small" but requires safeguards.
- Flushing reduces contaminants to low levels. Flushing during construction is not sufficient safeguard to assume acceptable contaminants levels prior to occupancy. Labelling as "non potable" and a specific flushing protocol for contractors was recommended. It was further noted that it would be beneficial to extend the flushing requirements to all piping systems.

[1] A family of organic compounds included in the EPA National Interim Primary Drinking Water Regulations(16).

It is important to emphasize that, in the static tests, all four solvents tested (DMF, MEK, THF, and cyclohexanone) dropped to acceptable[1] levels in all samples taken after the initial two-week dwell time. Routine plumbing inspection practices require filling and draining of fixtures prior to occupancy of new construction[2], a procedure which should be expected to flush from the system stagnant water with high levels of leached contaminants.

In the dynamic tests simulating actual use conditions, solvents were extracted only at very low levels in samples representing typical flow through—and dwell in—household plumbing systems. These data indicate that the consumer should not expect to ingest unacceptable levels of organics leached from solvents under conditions of normal end use.

The phthalates (dibutyl- and BIS(2-ethylhexyl-)) reportedly found in some of the samples are likely attributable to plasticized laboratory flexible tubing attached to the water supply used in filling the test loops. Phthalates are commonly used as plasticizers in the tubing. By definition, plasticizers are chemically and thermally stable materials used to impart flexibility, resilience, and softness to plastics. They are not used in rigid pipe and fittings; and, a review of confidential formulations maintained by NSF confirms that they were not used in the samples of PVC or CPVC pipe and fittings included in the Montgomery study.

Further, it is noted that RVCM was not detected in water exposed to any of the samples tested.

METAL PIPING SYSTEMS COMPONENTS

The previously referenced "Executive Summary" pepared by HALTS referred to "a previous study of the health risks posed by metal pipes to consumers," completed by the California Department of Health Services, from which it was concluded that, "a health hazard does not exist under normal usage conditions." A copy of the report of that study was appended to the "Final Report on Potential Health Hazards Associated with the Use of Plastic Pipe in Potable Water Systems," prepared by HALTS and the California Department of Industrial Relations(15) to comply with the directive of ACR 98.

Both galvanized steel and copper plumbing systems were considered in the California study. Test parameters included cadmium (Cd), lead (Pb), iron (Fe), copper (Cu), and zinc (Zn). Maximum contaminants levels for cadmium and lead are established at 0.01 and 0.05 mg/l, respectively, in the U.S. (6). The Water Quality Criteria Documents (12) recommend maximum levels in water for copper and zinc of 1 and 5 mg/l, respectively, based on organoleptic (taste and odor) considerations only.

During the first ten days of use, Pb extracted at 0.43 mg/l from one of the copper systems tested. Thirty-five results were reported over a period of 350 days of use and sampling. Only eight of the 35 results were less than the established MCL for Pb (0.05 mg/l). The report indicated that principal variables associated with extraction of the metals are water quality, plumbing materials, age of the system, and residence time in the system (i.e., length of time water is left standing in the pipe).

The film (principally calcium carbonate) deposited by some waters places a protective layer on the inner surface of metal pipes, creating a barrier to long term extraction of metals to those waters. However, with corrosive waters in copper piping, the report states, "it appears that the concentration of lead picked up from the solder in the joints[1] decreases with age of the system, but probably continues indefinitely." And, "it is expected that the lead concentration in copper water tubes will increase nearly linearly with time because it is known that the corrosion of solder is the result of galvanic action and tests have shown the galvanic current to be relatively constant." If a potential health effect exists when established MCL's are exceeded, the reported California study results are not consistent with the previously quoted HALTS conclusion (i.e., that a health hazard does not exist from "normal" use of metal pipes).

In addition to exposure to high levels of lead, there is evidence of concern about high levels of copper leached from copper plumbing systems. Nicholas, in a paper presented recently during the annual meeting of the Australian Corrosion Association, reported sickness apparently associated with high levels of copper in water exposed to "recently installed copper water services—usually in the order of 3-18 months old"(17).

[1] "Acceptable" refers to criteria established by HALTS for calculating exposure risk to the four principal solvents tested.
[2] Uniform Plumbing Code (UPC), Section 318-26.

[1] The report suggests that the solder was an alloy of 50 percent tin and 50 percent lead and calculates an exposure of 2.2 square millimeters (mm^2) of solder per joint for nominal ½ inch pipe.

The American Medical Association (AMA), in response to a report from Oregon that persons who complain about disagreeable tastes and odors in drinking water and have suffered apparently related mild diarrheal symptoms may have been affected by contamination from galvanized systems(18).

SUMMARY

It is clear that excessive levels of regulated substances may extract from any newly installed household plumbing system, but should not be expected to persist from plastics listed for conformance with NSF Standard 14.

An effective, ongoing program for assuring quality consistent with a national standard for plastic piping system components has been available at NSF on a voluntary basis for more than 20 years. Incidence of chemical failures in more than 450 products tested in 1980 was less than seven percent. Products tested are selected randomly during NSF staff visits to production facilities. Established enforcement procedures requrire retest of failed samples and results in delisting a product when repeated failure occurs.

New ingredients are evaluated prior to their acceptance in products listed under NSF Standard 14. In 1980, eight new stabilizers - tin, zinc, and calcium-zinc compounds - were accepted, and previously accepted antimony stabilizers were qualified in 12 materials and compounds. Also in 1980, three new pigments, five lubricants, and six fillers were accepted, and approximately 150 new or alternate ingredients (other than the antimony stabilizers) were qualified in individual materials and compounds. ***No potable water plumbing system components alternative to plastics have been so thoroughly tested.***

The product logo NSF-pw , and publication in the annual listing of plastic piping system components and related materials for potable water applications are asurance that an item is monitored for toxicological safety in accordance with all current requirements of NSF Standard 14.

REFERENCES

1. Standard No. 14, "Plastic Piping System Components and Related Materials," National Sanitation Foundation, Ann Arbor, MI, 1980.
2. "Listing of Plastic Piping System Components and Related Materials," National Sanitation Foundation, Ann Arbor, MI, 1980.
3. "Results of the NSF 1980 Standards Use Survey," National Sanitation Foundation, Ann Arbor, MI, 1980.
4. "Plastics Program Administrative Policies," National Sanitation Foundation, Ann Arbor, MI, 1979.
5. Tiedeman, Walter D., and Milone, Nicholas A., "A Study of Plastic Pipe for Potable Water Suppliers," National Sanitation Foundation, Ann Arbor, MI, 1955.
6. U.S. Environmental Protection Agency, "National Interim Primary Drinking Water Regulations," Federal Register, Vol. 40, No. 248, December 24, 1975.
7. Durfor, C.N., and Becker, E., "Public Water Supplies of the 100 Largest Cities in the United States, 1962," U.S. Geological Survey, Washington, D.C., 1964.
8. U.S. Environmental Protection Agency, "Handbook for Analytical Quality Control in Water and Wastewater Laboratories, USEPA Monitoring and Support Laboratory, Cincinnati, OH, 1979.
9. American Society for Testing and Materials, "manuals on Sensory Testing Methods," ASTM Special Technical Publication 434, ASTM, Philadelphia, PA, 1968.
10. U.S. Department of Health, Education, and Welfare, "Public Health Service Drinking Water Standards." USHEW, Washington, D.C., 1962.
11. "1975-2000: Plastics the Next 25 Years," Modern Plastics, New York, NY, 1975.
12. Dressman, Ronald C., and McFarren, Earl, "Determination of Vinyl Chloride Migration from Polyvinyl Chloride Pipe Into Water Using Improved Gas Chromatography Methodology," J. American Water Works Association, Cincinnati, OH, 1978.
13. U.S. Environmental Protection Agency, "Water Quality Criteria Documents; Availability," Federal Register, Vol. 45, November 28, 1980.
14. Popan, Assembly Concurrent Resolution No. 98, California Legislature, February 5, 1980.
15. "Final Report in Potential Health Hazards Associated With The Use of Plastic Pipe In Potable Water Systems." Hazard Evaluation System and Informatin Services, Department of Health Services, and Department of Industrial Relations, Berkeley, CA, 1980.
16. U.S. Environmental Protection Agency, "National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water; Final Rule," Federal Register, Vol. 44, November 29, 1979.
17. Nicholas, David, "Corrosion of Copper Water Tubes in the Hunter Region of NSW," presented at the annual meeting of the Australian Corrosion Association, November 1980.
18. Sammons, J.H., American Medical Association, personal communication, May 29, 1980.