NTP
National Toxicology Program

NTP Scientific Publications: Fit for Purpose

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National Institute of Environmental Health Sciences

NTP Board of Scientific Counselors Meeting
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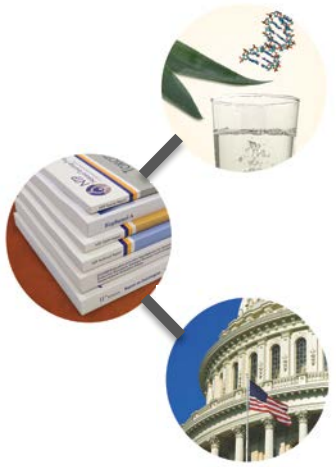
NTP Scientific Publications

Goal is to disseminate the outcomes of NTP's work in order to *strengthen the science base in toxicology* and provide *information useful for decision-making* by health research and regulatory agencies, medical and scientific communities, and/or public

Outline

- Traditional NTP scientific publications: what they are
- New NTP scientific publications: what they are and why they're needed
- New approaches for disseminating NTP scientific publications: what they are and why they're needed

Traditional NTP Scientific Publications



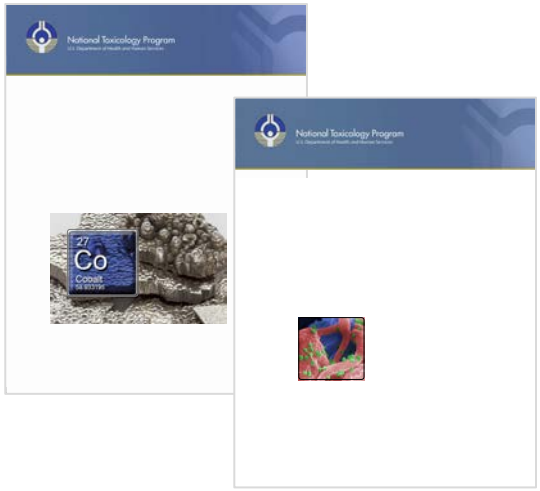
Traditional NTP Scientific Publications

- Types: report series, monograph series, journal publications
- Procedural standards for NTP reports and monographs
  - They are comprehensive with extensive detail on studies or literature analyses and appendices with supplemental information
  - Drafts undergo external peer review (individually via letter or by panel review)
  - Peer-review experts are screened for conflict of interest
  - Finals are publicly accessible:
    - Reports and data are available for *free* download from the NTP website: http://ntp.niehs.nih.gov
    - No copyright issues with use
    - *Many* are indexed in PubMed; working to have others included

Traditional NTP Scientific Publications, cont'd

- Some reports and monographs have NTP policy decisions about hazard
  - Developed using a structured process
  - Results are evaluated against established criteria
  - Opportunity for public comment on draft documents
- They are a trusted source for information
  - Widely used by federal and state agencies, non-governmental groups, international health research agencies, academia, industry, and public, and cited in proposed legislation, congressional testimony, and lawsuits
  - Not regulatory, although recognized as authoritative for identification of hazards by some groups (e.g., OSHA Hazard Communication Standard, California EPA Proposition 65)

Literature Analysis Publications



Report on Carcinogens (RoC) Monographs

- Monographs published on substances under review for *RoC* (previously developed as *background documents)*
- Have information on human exposure and an in-depth scientific assessment of published literature for evaluating a substance's potential carcinogenicity
- Contain NTP's policy recommendation to list a substance in the *RoC* as a *known* or *reasonably anticipated human carcinogen,* or *not to list*

Report on Carcinogens

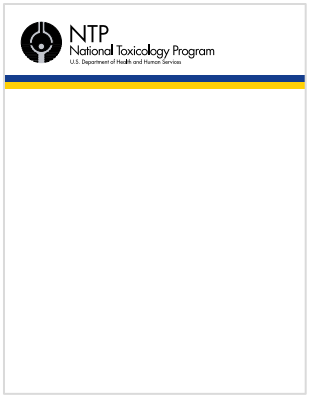
- NTP's assessment and policy recommendations reported in monographs inform *Report on Carcinogens* listings
- HHS Secretary has final approval

Literature Analysis Publications

NTP Monographs

- Previously developed as *CERHR Monographs* to identify risks to human reproduction and development and provide opinion on *level of concern* (1998-2010)
- Expanded scope of assessments in 2011 and series renamed
- Have information on human exposure and an in-depth scientific assessment of published literature for evaluating a substance's health outcomes other than cancer
  - Communicate state of science
  - May provide NTP's policy decision to identify a substance as a *known*, *presumed*, or *suspected* health hazard for humans or as *not classifiable*
- Research study underway to update *level of concern* categories

Testing Program Publications

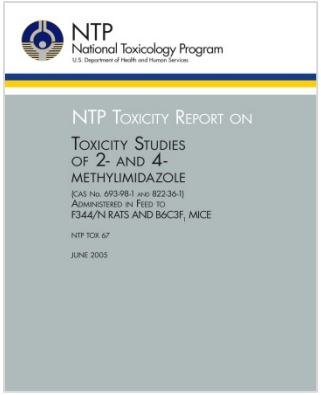


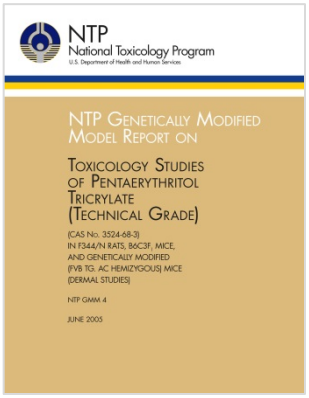
Technical Reports

- Reports published on 2-year NTP toxicology and carcinogenesis studies
- Provide NTP's policy decision on *level of evidence for carcinogenic activity* under the study conditions

Toxicity Reports

- Reports on short-term studies and AIDS therapeutics toxicity reports
- Evaluate and characterize the toxicologic potential of a substance under the study conditions

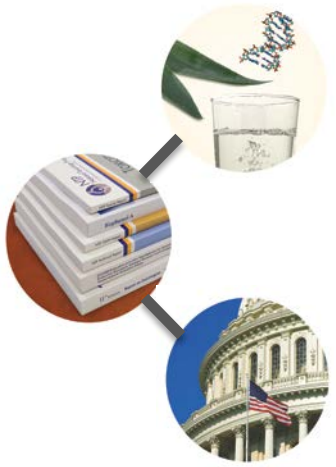




Genetically Modified Model Reports

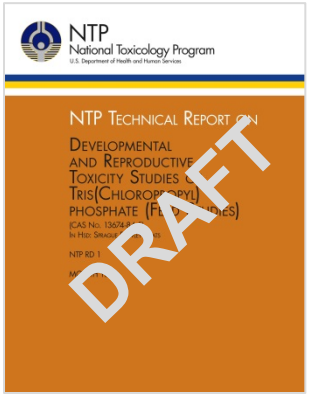
- Reports published on NTP studies conducted in transgenic mice
- Provide NTP's policy decision on *level of evidence for carcinogenic activity* under the study conditions for some models (e.g., p53 and p16/p19)

New NTP Scientific Publications



Upcoming NTP Scientific Publications

- Based upon its carcinogenicity classification system, NTP has developed 3 sets of *level of evidence* criteria for interpretation of toxicologic outcomes from its studies on reproduction, development, and immune system
- Need: NTP scientific publications to disseminate the information about these potential hazards to humans to strengthen the science base and for use in public health decision-making
- Solution: Create new report series

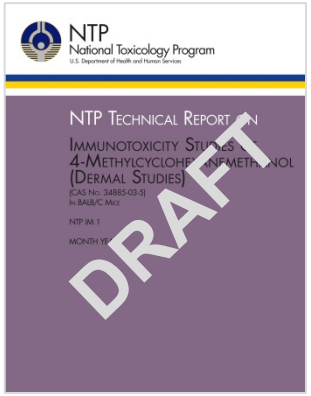


Technical Reports on Developmental and Reproductive Toxicity Studies

- Communicate findings and NTP policy decision on *level of evidence* for developmental toxicity and/or reproductive toxicity under the study conditions

Technical Reports on Immune System Toxicity

- Communicate findings and NTP policy decision on *level of evidence* for toxicity to the immune system under the study conditions



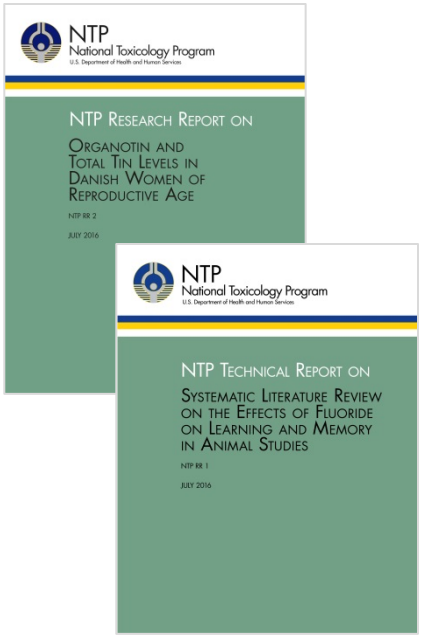
An NTP Scientific Publication Need

- NTP generates information that does not fit readily into existing report or monograph series
  - Pilot studies
  - Negative studies
  - Literature surveys/scoping to help inform problem formulation or research needs, or is companion to other testing/research efforts
  - Tox21 data analysis and pathway identification
  - Optimization studies for assay standardization
  - Assay development and assessment of utility (5-day *in vivo* genomic studies, 5-day *in vitro* transcriptomic studies)
  - Handbooks on systematic review and NTP study specifications

An NTP Scientific Publication Need, cont'd

- NTP generates information from its testing, research, and analysis activities beyond what's included in existing reports and monographs
  - Chemical characterization studies: evaluations of multiple lots of a commercial product to identify the "representative" test article to study (e.g., botanicals)
  - Class studies: preliminary studies on representative chemicals to determine whether to study further and what to study (e.g., C9 compounds, phenolic benzotriazoles)
- Need: A scientific publication to assimilate the information into a citable report and fill gaps in dissemination of NTP's work
- Solution: Establish a new NTP report series

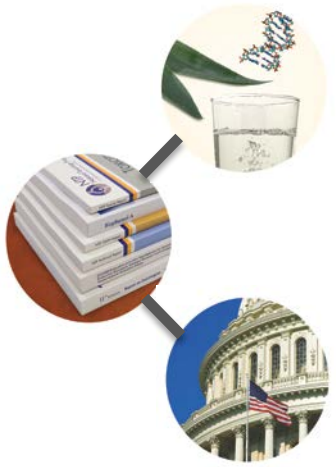
New “Multipurpose” NTP Scientific Publication



Research Reports

- Disseminate results from NTP testing, research, and analysis activities not covered in existing series
- Creation of this report series promotes:
  - Transparency and reproducibility by reporting the full range of NTP’s work on a substance or issue and providing free access
  - Cohesion and connectivity by reporting NTP studies “companion” to work in other NTP scientific publications and linking to data and the related work
  - NTP’s goals of strengthening the science base and providing information useful for public-health decision-making
  - Good stewardship of public funds by placing additional NTP work into the public domain, thereby preventing duplicative research by others

New NTP Scientific Publications and Dissemination Approaches



NTP Scientific Publication and Dissemination Needs

- In July 2014, NTP received a nomination from CDC/ATSDR to study the toxicity of chemicals spilled into the West Virginia Elk River
- NTP's WV Chemical Spill Research Program was set at ~one-year long
- Need: Periodic releases, as available, to communicate the findings of NTP's studies of the spilled chemicals to other federal agencies and public
  - Traditional route via journal publication was not quick enough and not most appropriate route for dissemination to persons affected by the spill
- Solutions:
  - NTP launched a website as the forum for disseminating it research plan and findings
  - NTP developed the new NTP scientific publication: *NTP Updates*

New Web-based Dissemination Approach

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Home » Study Results & Research Projects » Areas of Research » West Virginia Chemical Spill

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West Virginia Chemical Spill

http://ntp.niehs.nih.gov/go/wvspill

In January 2014, approximately 10,000 gallons of chemicals used to process coal spilled from a storage tank into the Elk River in West Virginia. The Elk River is a municipal water source that serves about 300,000 people in the Charleston area.

2014, NTP received a nomination from the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry to conduct toxicity studies on the predominant chemicals known to be involved in the West Virginia chemical spill. The primary spilled agent was 4-methylcyclohexanemethanol (MCHM). Other chemicals were also present in lower amounts in the tank. Limited data are available to address concerns for potential human health effects for the compounds in the crude liquid so NTP will study a number of chemicals (see the Table of Chemicals Under NTP Studies).

See the NTP research plan and studies and results for more information on NTP studies being conducted to provide information relevant to the potential exposures of the Charleston residents.

Photo by Raymond Thompson – West Virginia University researchers collect water samples at the confluence of the Elk and Kanawha Rivers.

Work at Other Federal and State Agencies

- U.S. Department of Health and Human Services
- Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry
- National Library of Medicine
- West Virginia Department of Health and Human Resources

NTP Quick Links:

- Calendar & Events
- Databases, Searches & Other Resources
- Evaluation of Alternative Toxicology Methods
- Federal Register Notices
- Health Assessment and Translation
- Nominate & Provide Input to NTP
- Pathology Tables for Peer Review
- Reports & Publications
- Report on Carcinogens
- Search Substances Studied by NTP
- Tox 21

- Website with research project plan, *NTP Updates*, and data
- Provided information on the progress of NTP's studies
- Email notification of new updates via NTP listserv

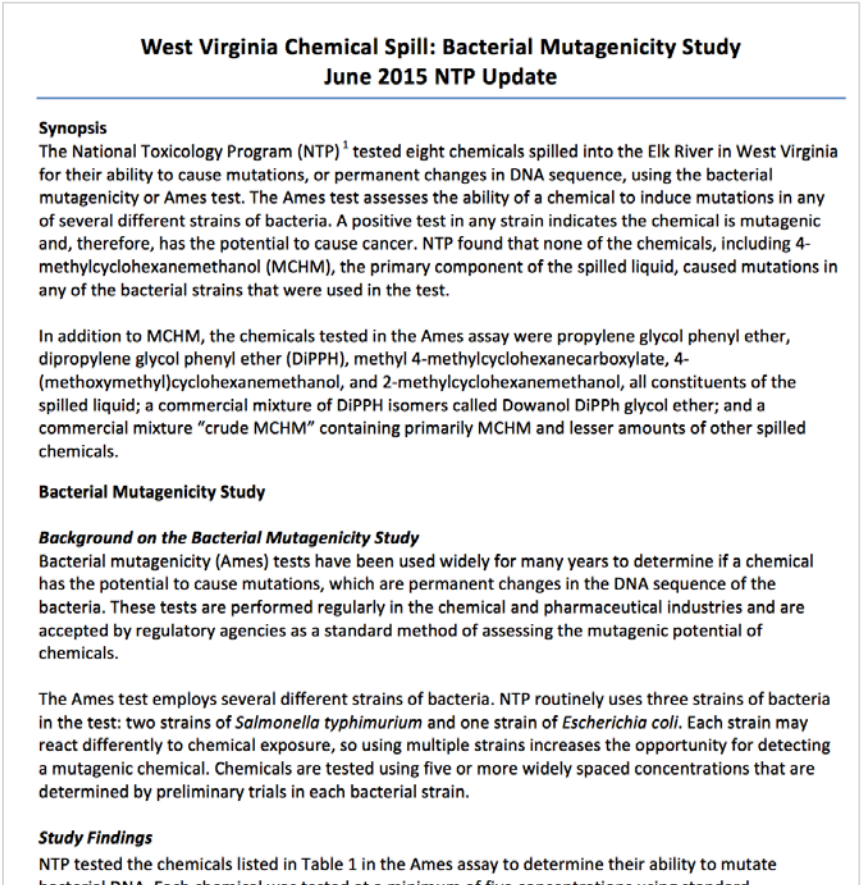
Table of Studies and Results

Studies	Description	Updates and Data*
High throughput screening assays	Assays to derive information about cellular and molecular targets and use for predicting potential biological effects	Dec 2014 Update
Structure-activity relationship analysis	A computational assessment that uses chemical structure to predict toxicological and biological properties	Dec 2014 Update
Bacterial mutagenicity	Short-term tests to evaluate DNA damage in the bacteria *S. typhimurium* and *E. coli* caused by exposure to a chemical	Jun 2015 Update Jul 2015 Update Data (posted Nov 19, 2015)
Zebrafish developmental toxicity and photomotor response	Short-term study to evaluate developmental effects in a vertebrate model system	Jun 2015 Update Jul 2015 Update Aug 2015 Update
Nematode (*Caenorhabditis elegans*) toxicity	Short-term study to evaluate chemical effects over the life span of the organisms	Mar 2015 Update
5-Day rat toxicogenomic	Short-term toxicity studies that identify subtle effects of a chemical on molecular processes in the liver and kidney and examine toxic effects in blood and damage to DNA (genetic toxicity)	Feb 2015 Update Jun 2015 Update Data (posted Feb 9, 2016) NEW
Mouse dermal irritation and hypersensitivity	Assays to evaluate the ability of chemicals to cause skin inflammation by directly damaging cells (irritation) or by inducing an immune response known as allergic hypersensitivitiy or contact allergy	Jun 2015 Update
Prenatal developmental toxicity	A study where rats are exposed to a chemical throughout pregnancy to determine if it produces adverse effects on the developing fetus	Dec 2014 Update Jun 2015 Update Data (posted Oct 2, 2015; format updated Dec 9, 2015)

New NTP Scientific Publication

NTP Updates

- Short write-up on the study, including the method, chemicals studied, findings, and next steps, if any
- Final *NTP Update* presents the NTP's collected findings and conclusions of the WV Chemical Spill Research Program



West Virginia Chemical Spill: Bacterial Mutagenicity Study
June 2015 NTP Update

Synopsis
The National Toxicology Program (NTP)[1] tested eight chemicals spilled into the Elk River in West Virginia for their ability to cause mutations, or permanent changes in DNA sequence, using the bacterial mutagenicity or Ames test. The Ames test assesses the ability of a chemical to induce mutations in any of several different strains of bacteria. A positive test in any strain indicates the chemical is mutagenic and, therefore, has the potential to cause cancer. NTP found that none of the chemicals, including 4-methylcyclohexanemethanol (MCHM), the primary component of the spilled liquid, caused mutations in any of the bacterial strains that were used in the test.

In addition to MCHM, the chemicals tested in the Ames assay were propylene glycol phenyl ether, dipropylene glycol phenyl ether (DiPPH), methyl 4-methylcyclohexanecarboxylate, 4-(methoxymethyl)cyclohexanemethanol, and 2-methylcyclohexanemethanol, all constituents of the spilled liquid; a commercial mixture of DiPPH isomers called Dowanol DiPPh glycol ether; and a commercial mixture "crude MCHM" containing primarily MCHM and lesser amounts of other spilled chemicals.

Bacterial Mutagenicity Study

Background on the Bacterial Mutagenicity Study
Bacterial mutagenicity (Ames) tests have been used widely for many years to determine if a chemical has the potential to cause mutations, which are permanent changes in the DNA sequence of the bacteria. These tests are performed regularly in the chemical and pharmaceutical industries and are accepted by regulatory agencies as a standard method of assessing the mutagenic potential of chemicals.

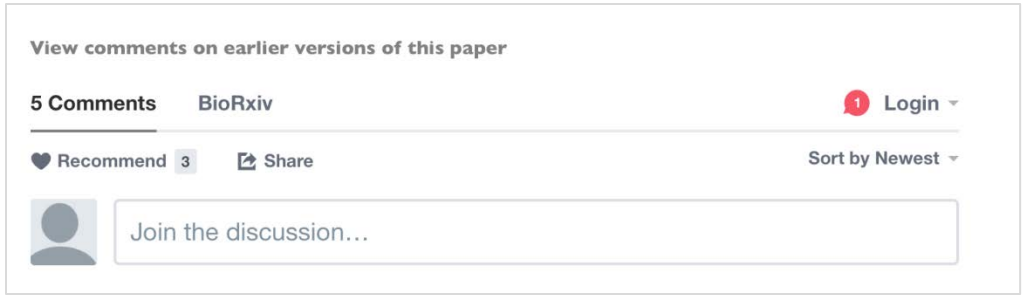
The Ames test employs several different strains of bacteria. NTP routinely uses three strains of bacteria in the test: two strains of *Salmonella typhimurium* and one strain of *Escherichia coli*. Each strain may react differently to chemical exposure, so using multiple strains increases the opportunity for detecting a mutagenic chemical. Chemicals are tested using five or more widely spaced concentrations that are determined by preliminary trials in each bacterial strain.

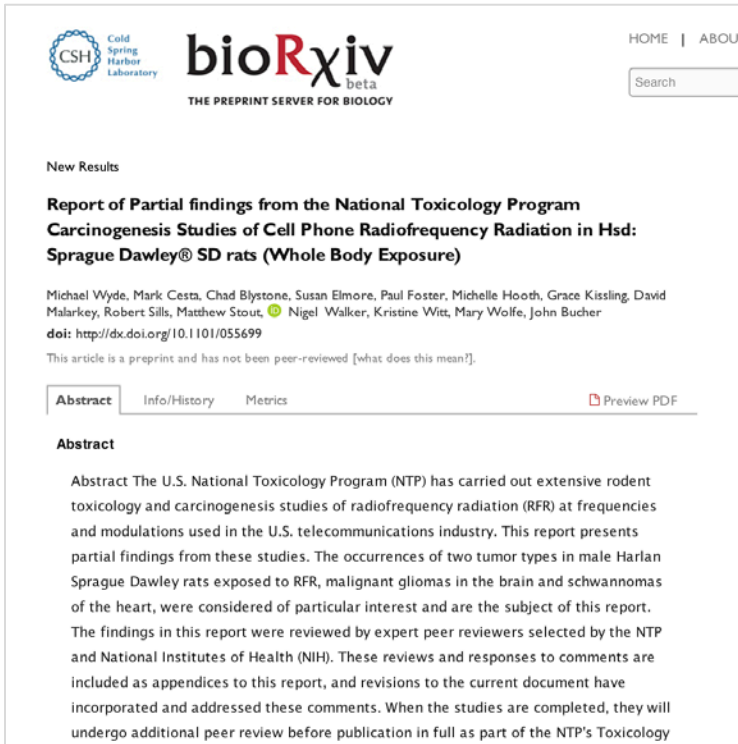
Study Findings
NTP tested the chemicals listed in Table 1 in the Ames assay to determine their ability to mutate

New Web-based Dissemination Approach

NTP Report on Partial Findings from Cell Phone Radiofrequency Studies

- Posted to pre-print server: free, on-line, archive, and distribution service for unpublished preprints
- Peer review not required for articles; NTP's report underwent peer review prior to publishing
- NTP report was posted on May 26, 2106, and revised article on June 23, 2016
- Readers could post public comments on report





New Web-based Dissemination Approach

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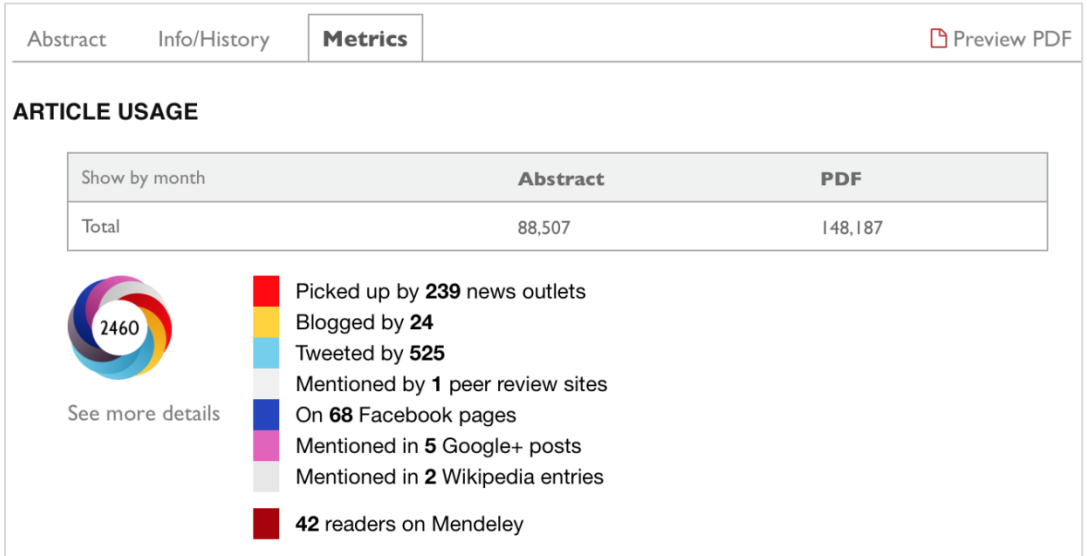
- Readers could post public comments on report
- bioRxiv provides metrics about article usage



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NTP Research Report. 2016 Jul;(2):1-33.

NTP Research Report on Organotin and Total Tin Levels in Danish Women on Reproductive Age

Authors: Kristina Thayer[1], Veronica G Robinson[1], Suramya Waidyanatha[1], Keith E Levine[2], Kyla Taylor[1], Daniel J Young[2], James M Harrington[2], Amal S Essader[2], Ellen M Mikkelsen[3], Catherine Wildenschild[3], Lauren A Wise[4], Elizabeth E Hatch[4]

Author Information

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Abstract

Background

Organotin compounds (OTCs) are organic derivatives of tin (Sn) used in the plastics and communication industries, and as antifouling agents in agriculture. Some OTCs have been shown to produce endocrine disrupting effects in aquatic species and rodent models, raising concern for effects on human reproduction and development. Little is known about exposure levels in women of reproductive age.

Objective

To collect pilot data on levels of OTCs and total Sn among Danish women of reproductive age.

Methods

Serum, whole blood, and urine samples were collected pre-pregnancy and during pregnancy from 55 women participating in the Snart-Forældre/Milieu (Soon-Parents/Environment) Study between November 2011 and May 2012. Six OTC species were measured in 47 serum samples using mass spectrometry (monobutyltin (MBT), dibutyltin (DBT), tributyltin (TBT), monophenyltin (MPT), diphenyltin (DPT), and triphenyltin (TPT)). In addition, the concentration of total Sn was determined in serum (n = 47), whole blood (n = 10), and urine (n = 29) study samples by mass spectrometry.

Results

The frequency of detection above the experimental level of quantitation (ELOQ) was 0% for MPT, TPT, DPT, and TBT, 2.1% for DBT, and 10.6% for MBT. Total Sn levels were above the limit of detection (LOD) in 100% of serum (median 1.51 ng/mL, average 1.86 ng/mL; n = 47) and whole blood (median 1.70 ng/mL, average 1.79 ng/mL; n = 10) samples. Total Sn concentrations were lower in urine samples compared with the blood-based measures.

Conclusions

OTCs were not readily detected in serum collected from Danish women of reproductive age. Total Sn concentrations, which include organic and inorganic

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Figures | Tables

Figure 1. Structures of orga

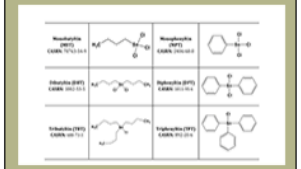

Figure 1. Structures of organotin compounds analyzed in the current study.

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Sample

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Introduction

Background

Navigate This Section

Organotin compounds (OTCs) are organic derivatives of tin (Sn) widely used in the plastics and communication industries, and in several agricultural applications. Tri-substituted OTCs such as triphenyltin (TPT) and tributyltin (TBT) previously were used primarily as antifouling agents in ship hull paints until concerns for marine organism toxicity led to prohibitions on the application (ATSDR 2005; Risk & Policy Analysts Limited (RPA) 2005; European Union 2006; WHO 2006). Most consumer exposure is assumed to occur through dietary sources (RPA 2005), especially fish, mussels, and other marine animals obtained from contaminated areas such as the vicinity of harbors and heavily used shipping routes. Tri-substituted OTCs might still be in use as active ingredients in biocides and pesticides for certain consumer products such as nonallergenic pillows, shoe insoles, cycling short padding, and athlete's foot spray (ATSDR 2005; RPA 2005).

Mono- and di-substituted OTCs, including monobutyltin (MBT), dibutyltin (DBT), and dioctyltin (DOT), are used in a range of applications that could result in exposure from household and consumer products. These compounds often are used together as stabilizers in polyvinyl chloride (PVC) plastics, which can be found in drinking water pipes, flooring and wall coverings, shower curtains, prints on t-shirts and other clothing, gloves, sandals, food packaging, toys, and other household items (RPA 2005; Antizar-Ladislao 2008). Overall, use of OTCs as PVC stabilizers dominates, accounting for an estimated 66–80% of [illegible] consumption based on information from the lat[illegible]990s and early 2000s (Fent 1996; ATSDR 2005; RPA 2005); more recent information does not [illegible] readily accessible. Beyond PVC stabilizers, mon[illegible]ted in Canadian drinking water distributed thr[illegible]VC pipes (Sadiki and Williams 1999). Di-substituted OTCs [illegible] of polyurethane foams and mattress fill[illegible] seats, diapers, female hygiene products, paints, adhesives, and [illegible] among other items (RPA 2005). [illegible]tin compounds might be present in medical devices due to their use as PV[illegible]oduction (European Union [illegible]ibutyltin chloride is listed by the US FDA as an indirect food additive for use in[illegible]tributyltin)oxide is lis[illegible]an indirect food additive for use as a preservative (ATSDR 2005). A study of household[illegible]f OTCs rangin[illegible]590 to 28,000 ng/g (Kannan et al. 2010), and similar levels have been described in house dust in Germany (Fromme et al. 2005).

Antizar-Ladislao B. 2008. Environmental levels, toxicity and human exposure to tributyltin (TBT)-contaminated marine environment. a review. Environ Int. Feb;34(2):292–308.

A 2005 analysis performed for the European Commission identified several scenarios in [illegible]stimated human intakes could approach 20% or more of the tolerable daily intake (TDI), assuming worst-case exposure conditions. Scenarios i[illegible]exposure to tri-substituted tins (mostly TBT) from consumption of fish and fish products, exposure to di-substituted tins (DBT, DOT) from indo[illegible]ust in children, di-substituted tins used in flexible PVC products (t-shirts, PVC gloves, PVC sandals), di-substituted tins used in rigid PVC prod[illegible]VC food packaging), and di-substituted tins used in catalysts (diapers, feminine hygiene products, dental moldings) (RPA 2005). The ban on TB[illegible]se as a biocide in consumer products and baking paper eliminated concern for certain exposure scenarios (e.g., food spray, insoles, cookies). M[illegible]arlo simulations of estimated adult and child exposures indicated that children were at a greater risk of exposure to OTCs; however, little da[illegible]available to confirm the modelled exposure predictions, and most human biomonitoring data are based on samples collected prior to 2005 (Table 1, Table S2).

Hide

Figures | Tables

Table 1. Serum concentratic

Table 1. Serum concentrations of organotins measured in samples collected from Danish women of reproductive age (ng Sn/mL).

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Appendix

▾ **Table S1**

Individual subjects

Table S1 is available at https://ntp.niehs.nih.gov/ntp/ohat/pubs/ntp_rr/02organotin_supp.xlsx

▸ **Table S2**

Summary of levels of organotins (OTCs) reported in humans

▸ **Table S3**

Human biomonitoring

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[a] LOD(Limit Of Detection) for speciation calculated as 3x the standard deviation of repeated analysis of low level matrix calibration standard.
[b] ELOQ (Estimated Limit Of Quantitation) of the speciation method calculated as the lowest acceptable matrix calibration standard.
[c] Calculated as (ICP-MS Measured Sn) x 5 mL/0.5 mL
[d] Represents the range of LODs from to analysis of samples in two batches, calculated as the lowest acceptable calibration standard in each analytical batch.
[e] Calculated by multiplying determined [Sn] by the dilution factor. Example calculation for sample A001: 0.139 ppb Sn x 5.0 mL final volume/0.50 mL of serum digested = 1.39 ppb Sn
[f] Sample to be reported required a repeat test and there was not enough sample to prepare for the additional test, therefor no results were released

CDC Comment Code (urine Sn)

0: OK (required for all valid results)
<LOD: less than limit of detection
21: Quantity no sufficient for testing (QNS)
22: QNS for repeat testing[f]
26: invalid sample
33: result repeated and confirmed

Sample Sequence (All)	Time Point	Date of Collection	[serum MBT][a]	[serum MPT][a]	[serum DBT][a]	[serum DPT][a]	[serum TBT]	[serum TPT]	[total serum Sn] (dilution corrected)[c]	[total whole blood Sn] (dilution corrected)[e]	Total Sn
			(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	(ng Sn/mL)	
			0.50	0.35	0.25	0.25	0.25	0.30	0.200 - 0.400[d]	0.600	
			1.71	1.60	1.59	1.40	1.48	1.25			
3	2nd trimester	24-May-12	1.63	<LOD	0.64	<LOD	<LOD	0.33	0.73		
2	1st trimester	15-Aug-12	2.90	<LOD	0.84	<LOD	0.41	<LOD	1.39		
3	2nd trimester	28-Sep-12	<LOD	<LOD	0.39	0.31	0.44	<LOD	1.46		
1	pre-pregnancy	15-Jun-12	<LOD	<LOD	0.37	0.34	0.41	0.40	1.57		
1	pre-pregnancy	15-Jun-12	<LOD	<LOD	0.30	0.30	0.40	<LOD	1.65		
1	pre-pregnancy	24-Jul-12	<LOD	<LOD	0.38	0.34	0.41	<LOD	0.78		
2	1st trimester	6-Nov-12	0.53	<LOD	<LOD	0.32	0.42	0.56	1.57		
3	2nd trimester	3-Jan-13	<LOD	<LOD	0.39	0.30	0.42	<LOD	1.29		
1	pre-pregnancy	27-Jul-12	1.63	<LOD	0.46	<LOD	0.41	<LOD	1.36		
2	1st trimester	31-Oct-12	<LOD	<LOD	<LOD	0.32	0.42	<LOD	1.76		
3	2nd trimester	3-Jan-13	0.65	<LOD	0.38	<LOD	0.40	0.30	2.65		

Appendix

Table S1

Individual subjects

Table S1 is available at https://ntp.niehs.nih.gov/ntp/ohat/pubs/ntp_rr/02organotin_supp.xlsx

Table S2

Summary of levels of organotins (OTCs) reported in humans

Table S3

Human biomonitoring

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  - Brogan and Partners Convergence Marketing

Summary

- NTP has a number of scientific publications to disseminate its work, each with a specific purpose
- NTP has addressed needs to increase access to its work, including data, through additional report series and the use of web-based approaches

Questions