

US EPA ARCHIVE DOCUMENT

# Regulatory and Voluntary Actions on Select Substances



**Presentation to Great Lakes Stakeholder  
Community  
June 9<sup>th</sup>, 2010**

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# Overview

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- Review of relevant regulatory and voluntary activities for US Action Plan substances:
  - Phthalates
  - Polybrominated diphenyl ethers (PBDEs)
  - Chlorinated Paraffins
  - Perfluorinated compounds (PFCs)
  - Bisphenol A (BPA)
  
- Future US action plans (under development):
  - Benzidine dyes and pigments
  - Nonylphenols/Nonylphenol ethoxylates
  - Siloxanes
  - HBCD
  - Isocyanates/Diisocyanates



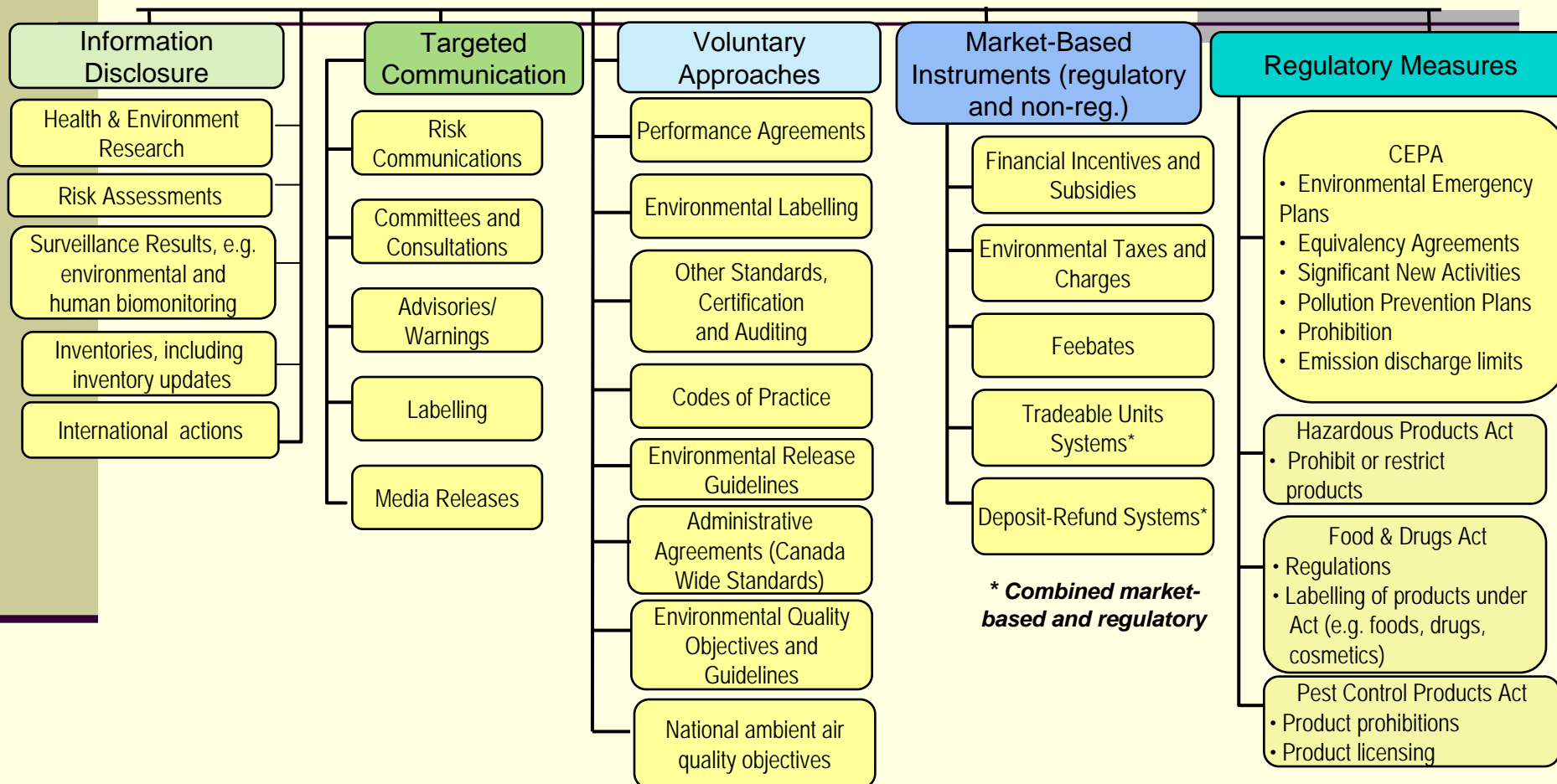
# CMP Challenge : Milestones

Milestones	Batch Number (number of substances in parenthesis)											
	1 (15)	2 (17)	3 (19)	4 (18)	5 (19)	6 (18)	7 (14)	8 (14)	9 (17)	10 (12)	11 (16)	12
Launch of batch: Substance profile of technical data; 4-6 month call for information (s.71 Survey Notice, voluntary questionnaires)	Feb 3 2007	May 12 2007	Aug 18 2007	Nov 17 2007	Feb 16 2008	May 31 2008	Aug 30 2008	Jan 31 2009	Mar 14 2009	Jun 20 2009	Sep 26 2009	Dec 26 2009
Publication of Draft Screening Assessment Reports (SAR) and risk management scopes for a 60-day public comment period	Jan 19 2008	May 17 2008	Aug 23 2008	Jan 24 2009	Feb 21 2009	May 30 2009	3 toxic* Sept 5 2009	Jan 30, 2010	Mar 20 2010	June 26 2010	Oct 2 2010	Jan 8 2011
Publication of Final SAR and proposed risk management approach (60-day public comment period for risk management approach)	9 toxic* July 5 2008	9 toxic* Jan 31 2009	4 toxic* Mar 7 2009	3 toxic* Aug 1 2009	2 toxic* Aug 22 2009	1 toxic* Nov 20 2009	3 toxic* Mar 6 2010	July 31, 2010	Sept 18 2010	Dec 25 2010	Apr 2 2011	July 16 2011
Proposed Risk Management Instrument Published	July 2010	Jan 2011	Mar 2011	Aug 2011	Aug 2011	Nov 2011	Mar 2012	July 2012	Sept 2012	Dec 2012	Apr 2013	July 2013
Final Risk Management Instrument Published	Jan 2012	July 2012	Sept 2012	Feb 2013	Feb 2013	May 2013	Sept 2013	Jan 2014	Mar 2014	June 2014	Oct 2014	Jan 2015

\* as defined in s.64 of CEPA 1999



# A suite of tools can support Risk Management Activities...



\* The Canadian Environment Protection Act (1999) registry outlines current and proposed Canadian risk management strategies: <http://www.ec.gc.ca/CEPARRegistry/regulations/>



# Phthalates – US Action Plan

- Initiate TSCA §5(b)(4) Concern List rulemaking on the eight phthalates. Proposed rule in fall 2010.
- Initiate TRI rulemaking to add six phthalates not already covered in fall 2010.
- Consider initiating TSCA §6(a) rulemaking in 2012, to limit or ban phthalates, utilizing CPSC and EPA IRIS assessments currently under development and working with FDA on future work.
- For DnPP, propose a TSCA §5 Significant New Use Rule (SNUR) to require submission of new chemical notices (or confirm production status)
- Develop a DfE/Green Chemistry program for alternatives assessment.



# Phthalates – Canadian Actions

## Existing Activities:

- DEHP releases are reported by industry under the National Pollutant Release Inventory (NPRI)
- DEHP is subject to the general food packaging safety requirements under the *Food and Drugs Act*
- DEHP is listed on the Cosmetic Hotlist of the *Foods and Drugs Act*
- New [phthalates regulations](#) were posted in Canada Gazette June 20, 2009 for 75 day public comment

## RM Measures under development:

- Proposed ban on the use of DEHP, DBP, and BBP in children's products intended to be mouthed.
- Proposed that the concentrations of DEHP, DBP and BBP be restricted to no more than 1 000 mg/kg in soft vinyl of all children's toys and child care articles, and the concentration of each of DINP, DIDP and DNOP be restricted to no more than 1 000 mg/kg in soft vinyl of children's toys and child care articles where the soft vinyl can be placed in the mouth of a child under four years of age
- Obligations for reporting and development of reduction plans under Ontario's Toxics Reduction Act (Phase II) anticipated for 2012 (DEHP, DBP, BBP, DNOP)

## Voluntary Activities:

- In 1998, industry was asked to voluntarily stop using DINP in products intended for infants one year of age and under
- Public pressure and voluntary action from the industry has resulted in some DEHP reductions in several products
- Health Canada's Medical Devices Bureau is working on finalizing some clinical practice guidelines regarding the use of DEHP plasticized medical devices to be used by Canadian health care institutions



# PBDEs – US Action Plan

## Regulatory:

- Support phase-out of DecaBDE following commitments from the principal manufacturers and importers to phase-out use by December 31, 2013.
- Initiate TSCA §5(b)(4) Concern List rulemaking on PBDEs. Proposed rule in late 2010.
- Initiate action to include articles in current penta/octaBDE SNUR. Proposed rule in late 2010.
- Initiate rulemaking to simultaneously propose a SNUR and a TSCA §4 test rule for DecaBDE. Proposed rules in late 2010.

## Voluntary:

- DfE - Furniture Flame Retardancy Partnership
- DfE - Flame Retardants in Printed Circuit Boards
- Dec. 2009 Industry agreement to voluntarily phase out decaBDE





# PBDEs – Canadian Actions

- As there is no manufacture of PBDEs in Canada and the commercial use of tetra-penta-, hexa-, henta-, and octa-BDE congeners have been phased out in Canada and internationally, the PBDE Regulations constitute a preventative approach to ensure that these activities are not introduced in Canada

## **Existing Activities:**

- DecaBDE release trends monitored through the National Pollutants Release Inventory
- *Polybrominated Diphenyl Ether Regulations* in force June 19, 2008, effectively ban the manufacture and use of the PentaBDE and OctaBDE commercial mixtures in Canada
- Ongoing collaboration in international and multi-lateral foray to manage risks associated with PBDEs

## **RM Measures under development:**

- Regulatory controls under CEPA 1999 to restrict PBDEs (tetra, penta, hexa, hepta, octa, nonaBDE and decaBDE) in domestic and imported manufactured products
- Management strategy for PBDE-containing products at end-of-life
- Obligations for reporting and development of reduction plans under Ontario's Toxics Reduction Act (Phase II) anticipated for 2012



# PBDEs – Monitoring

- Comprehensive environmental and bio-monitoring program was initiated in 2008 under the Chemicals Management Plan (CMP) to supplement historical data for aquatic biota, sediment, air, wildlife
- Monitoring of wastewater treatment plant influents, effluents, bio-solids and landfill leachate started in 2009
- PBDE alternatives are also being monitored as the market transitions to new products
- Monitoring study on levels in baby food entitled Dietary exposure of young children to emerging persistent organic pollutants and plasticizers (2011)
- [Canadian Health Measures Survey](#)
- [Maternal-Infant Research on Environmental Chemicals \(MIREC\)](#)
- Monitoring of food via [Total Diet Study](#)
- [Commission for Environmental Cooperation](#) Tri-national Report on Maternal Blood Monitoring (publication TBD)
- [Northern Contaminants Program](#) and the [Arctic Monitoring and Assessment Program](#)



# Short-Chain Chlorinated Paraffins – US Action Plan

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- Consider initiating TSCA §6(a) rulemaking to limit or ban SCCPs.
- Address SCCP reporting issue on TSCA inventory and take follow-up action, as appropriate.
- Address reporting issues on TSCA inventory for medium-and long-chain chlorinated paraffins, taking follow-up action, as appropriate.
- Evaluate potential risks from medium-and long-chain chlorinated paraffins.



# Chlorinated Paraffins – Canadian Actions

## Existing Activities:

- CPs are reported by industry to the National Pollutant Release Inventory
- The assessment report published in 2008 concluded that CPs containing up to 20 carbon atoms have or may have an immediate or long-term harmful effect on the environment or its biological diversity and that all CPs constitute or may constitute a danger in Canada to human life or health

## RM Measures under development:

- Proposed regulation to prohibit the manufacture, use, import, sale and offer for sale of CPs up to 20 carbon atoms:
  - Specific use exemptions for some CP uses may be allowed where it can be demonstrated that alternatives are not technically or economically feasible.
- RM objective is to reduce releases of CPs to the lowest level possible, from all sources and prevent the re-introduction of their manufacture in Canada
- It is anticipated that the final RM Instrument will be published in 2012

## Monitoring Activities:

- Under the CMP Monitoring and Surveillance Program, samples in fish and sediment from different Canadian locations, including the Great Lakes, have been collected and stored
- Analysis of both stored and recent samples is planned, and datasets should be available in the medium-term future



# Long-Chain Perfluorinated Chemicals (LCPFCs) – US Action Plan

- Intend to propose actions in 2012 under TSCA section 6 to address the potential risks from LCPFCs.
  - TSCA section 6 provides authority for EPA to ban or restrict the manufacture, processing, and use of these chemicals.
- Continue with the 2010/15 PFOA Stewardship Program to work toward the elimination of PFOA, PFOA precursors, and higher homologues from emissions and products.
- Continue to evaluate alternatives under EPA's New Chemicals Program.
- Continue with international collaboration on PFCs.



# Perfluorinated compounds – Canadian Actions

## Existing Activities:

- *Perfluorooctane Sulfonate and its Salts and Certain Other Compounds Regulations (2008)* prohibit the manufacture, use, sale, offer for sale and import of PFOS, its salts and its precursors
  - Some exemptions related to photography, metal plating, aviation hydraulic fluid; products that were manufactured or imported before the Regulations came into force
- Four new fluorotelomer-based substances (precursors to PFCAs) prohibited from import and manufacture in Canada

## Voluntary Actions:

- Signed on March 30, 2010, an Environmental Performance Agreement respecting PFCAs commits participating companies to voluntarily work towards the elimination of residual PFCAs in products sold in Canada

## Monitoring Activities:

- PFOS, PFHxS and PFOA are among the substances being analysed as part of the Canadian Health Measures Survey
- Various perfluorinated compounds have been monitored in water, sediment, air, aquatic biota and wildlife as well as at wastewater treatment facilities and landfills under the CMP Monitoring and Surveillance Program
- The CMP Monitoring and Surveillance Fund is contributing to a two year study initiated in 2009 in Ontario examining the consumption of fish caught near possible major industrial sources and exposure to perfluorinated compounds



# Bisphenol A (BPA)

## – US Action Plan

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- Consider initiating TSCA §5(b)(4) Concern List rulemaking on BPA. Proposed rule in fall 2010.
- Consider initiating TSCA §4 rulemaking to develop data on environmental effects. Anticipated notice of proposed rulemaking in late 2010.
- Initiate collaborative DfE alternatives assessment activities in April 2010.
- Continue to consult and coordinate closely with FDA, CDC, and the National Institute of Environmental Health Sciences (NIEHS) to better determine and evaluate the potential health consequences of BPA.



# BPA – Canadian Actions

## **Existing Activities:**

- Releases of Bisphenol A reported under the National Pollutant Release Inventory
- Ban on BPA in polycarbonate baby bottles (June 2009)

## **RM Measures under development:**

- Proposed Industrial Effluent Release Limit - planned instrument to establish maximum BPA concentrations in effluent and require the implementation of a substance management plan which includes monitoring and record keeping.
- Migration targets for BPA in infant formula cans will be developed.
- Engage industry in the development and implementation of codes of practices for existing food packaging
- Obligations for reporting and development of reduction plans under Ontario's Toxics Reduction Act (Phase II) anticipated for 2012

## **Monitoring Activities:**

- BPA is monitored in water and aquatic biota and at wastewater treatment facilities and landfills under the CMP Monitoring and Surveillance Program
- [Maternal-Infant Research on Environmental Chemicals study](#)
- [Canadian Health Measures Survey](#)
- Plastics and Personal-care Product use in Pregnancy
- Continue to scrutinize pre-market submissions for infant formula
- Targeted survey of BPA in packaged drink products
- Targeted surveys of BPA in infant formula and food products
- Dietary exposure of young children to plasticizers and emerging POPs (including BPA & Phthalates, PFCs, and BFRs)
- [Canadian House Dust Study](#)





# Proposed Future US Action Plans

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- Future Sets of US action plans (Under Development):
  - Benzidine dyes and pigments
  - Nonylphenols/Nonylphenol ethoxylates
  - Siloxanes
  - HBCD
  - Isocyanates/Diisocyanates



# Benzidine Dyes and Pigments

- Currently, Canada is addressing numerous azo- and benzidine-based chemicals largely used as colourants, through the CMP
- A group approach is being proposed for approximately 350 aromatic azo- or benzidine-based substances on the Domestic Substances List (DSL) that have been prioritized for further work under the CMP.
  
- 3,3'-Dichlorobenzidine
  - On CEPA Schedule 1 (Toxic Substances List)
  - “Tier II” substance, targeted for reduction under the Canada-Ontario Agreement respecting the Great Lakes Basin Ecosystem
  
- Benzidine and Benzidine Dihydrochloride
  - On CEPA Schedule 1 (Toxic substances list)
  - Restricted use to specialty laboratory applications, and for research and development purposes



# Siloxanes

## **RM Measures Under Development (D4 & D5):**

- Proposed Regulations to limit the quantity or concentration of these substances in certain personal care products and, where appropriate, in consumer products that are manufactured in and imported into Canada
- Regulations to prevent or minimize releases to the aquatic environment
- Final RM Instrument scheduled to be published in 2011

## **Monitoring Activities:**

- Monitoring in air and landfill gas started in 2008 under the CMP Monitoring and Surveillance Program
- Method development work is ongoing to facilitate future monitoring of siloxanes in wastewater, landfill leachate and aquatic biota



# HBCD

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## RM Measures:

- A risk assessment is under development

## Monitoring Activities:

- HBCD is monitored in sediment, aquatic biota, air, wildlife and wastewater treatment facility effluent under the CMP Monitoring and Surveillance Program



# Nonylphenols/Nonylphenol ethoxylates

## RM Measures

- 2001 - Added to CEPA Schedule 1 (Toxic Substances List)
- 2003 – Publication of RM Strategy targeting five priority sectors
- 2004 – Two pollution prevention (P2) Notices published with requirements for facilities that manufacture or import soap and cleaning products, or processing aids used in the wet textile industry or pulp and paper processing aids

## Results (as at March 31, 2010)

### **Nonylphenol and its Ethoxylates Contained in Products**

- 75 facilities had prepared / were implementing P2 plans; reports received to date indicate annual use reductions of 90% and imports were reduced by 83% (1998 base year)

### **Textile Mills that Use Wet Processing**

- 44 facilities had prepared/were implementing P2 plans; reports indicate 100% reduction, surpassing the objectives established in the P2 planning Notice
- Further analysis is required to evaluate progress towards reduction targets for toxicity of effluent to a maximum acute toxicity of 13% IC50 (50% inhibiting concentration)

### Monitoring Activities:

- Planned monitoring of effluent from wastewater treatment facilities in 2010 under CMP Monitoring and Surveillance Program



# Isocyanates/Diisocyanates

## Existing Activities:

- TDI (toluene diisocyanates) releases reported under the National Pollutant Release Inventory
- Mandated Material Safety Data Sheet for TDI with concentration of 0.1% w/w for occupational settings (does not include consumer products for the general public).
- Specific residues from TDI production covered by the *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999.
- Ingredient Disclosure mandated for certain concentrations under the *Controlled Products Regulations* under the *Hazardous Products Act*
- The Pest Management Regulatory Agency (PMRA) lists 2,6-TDI and 2,4-TDI as List 2 formulators
  
- Ontario has established air quality criteria for TDI
  - 24-hour ambient air quality criterion is 0.2µg/m<sup>3</sup>.
  - Half-hour point of impingement guideline is 0.6 µg/m<sup>3</sup>
- TDI designated under the Ontario *Occupational Health and Safety Act* Regulation 842



# Isocyanates/Diisocyanates

## RM Measures under development:

- Proposed regulations to prescribe maximum TDI concentrations at air stack exhaust to control and reduce TDI releases to the environment from the foam industry.
- Proposed pollution prevention planning notice for the Urethane and other Foam Sector (excluding polystyrene) under CEPA, 1999 requiring the preparation and implementation of pollution prevention plans for TDIs (expected July 2010)
- Proposed addition of TDIs to the Cosmetics Ingredient Hotlist
- Additional actions being considered are the investigation of the management of non-foam consumer products
  
- Releases of TDI from industrial sites may be decreased by the use of abatement technology. Neutral and alkali aqueous scrubbing and carbon adsorption methods have proved to be both practically and economically viable (Alliance for the Polyurethanes Industry 2005).
  
- Benzene, 2,4-diisocyanato-1-methyl
- Benzene, 1,3-diisocyanatomethyl-



# Isocyanates/Diisocyanates

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## Industry/American Chemistry Council SPF product stewardship program

- Assure all spray applicators have access to health and safety training through a proposed on-line certification/testing course.
- Commitment to exposure research, including support for the DAN method to measure total isocyanate(s).





# Contacts & Resources

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  - Region 5 & Its States: Bradley Grams,  
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- Essential TSCA Reform Principles  
<http://www.epa.gov/oppt/existingchemicals/pubs/principles.html>
  
- Enhanced Chemical Management Program:  
<http://www.epa.gov/oppt/existingchemicals/pubs/enhanchems.html>



# Contacts & Resources

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- Julie Schroeder, Ontario Ministry of the Environment  
[Julie.Schroeder@ontario.ca](mailto:Julie.Schroeder@ontario.ca) (416) 325-3475
  
- Chemicals Management Plan  
<http://www.chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>
- National Pollutant Release Inventory
- [www.ec.gc.ca/npri](http://www.ec.gc.ca/npri)
- Canadian Pollution Prevention Information Clearinghouse (CPPIC)  
<http://www.ec.gc.ca/cppic/En/index.cfm>
- GreenCentre Canada  
<http://www.greencentrecanada.com/>
- Ontario Toxics Reduction Strategy  
<http://www.ene.gov.on.ca/en/toxics/index.php>