



03-TS
Agenda item 10

Chemical Safety for Sustainable Development

IFCS/FORUM-V/03-TS
Original: English
11 July 2006

FORUM V
Fifth Session
of the
Intergovernmental Forum on Chemical Safety

Budapest, Hungary
25 - 29 September 2006

TOYS AND CHEMICAL SAFETY
A THOUGHT STARTER

Prepared by: Forum Standing Committee Working Group

THOUGHT STARTER

Toys and Chemical Safety

A Thought Starter

The information presented in this paper comes primarily from references and reports published in the industrialized world. Very little information is available from other countries. The situation in industrialized countries may or may not represent the situation in developing countries. The information from the industrialized world can provide valuable lessons learnt for everyone.

Introduction

All children play. It is an important part of growing up. Through play children have fun, exercise and discharge energy, explore the physical world, and develop knowledge and skills in the social world. Toys are an integral part of play at all ages and can add to intellectual growth, stimulate creativity, and enhance social interaction and learning. Experience with toys begins soon after birth and continues throughout childhood, but the way a child uses a toy will vary with age, developmental stage, intellect, and physical ability. What constitutes a toy at one age, may be uninteresting or dangerous at another age. To be a positive factor in a child's life, toys must be safe both for their intended uses, and for reasonably anticipated misuse by children. Safe toys must be well designed and age appropriate, durable, and non-toxic. Some toys are inherently hazardous and appropriate only for use by older children and under adult supervision.

Playing with toys should be fun and worry-free, but sometimes toys inflict harm.¹ The majority of reported harms from toys have been accidents, that is lacerations produced by sharp edges or points, choking events due to swallowing or aspiration of small parts, or other mechanical injuries such as electrical injury, hearing loss from excessive noise, penetrating wounds from projectiles, strangulation, or burns from flammable materials. A recent US hazard analysis conducted by the Consumer Product Safety Commission (CPSC) found that of 144,240 hospital emergency room treated toy-related injuries in 2002, 92.5% were mechanical, 1% were chemical, less than 1% were electrical or fire related and 6.4% were unspecified. Forty-six percent of visits were children under 5 years, 22% were children 5-9 years, 8% were children 10-14, and 24% were 15 years and older.² This analysis considered only toys and excluded nursery products, children's clothing, furniture, and personal care products. Most toy-related injuries are minor and do not require hospitalization. Death linked to toy use is rare and most often caused by choking or aspiration; death from acute poisoning is reported, but it is also rare.^{3,4}

For the purposes of this Thought Starter a **toy** is defined as *any product or material designed or clearly intended for use in play by children (0-9 years of age) or adolescents (10-18 years of age)*. Especially with very young children or children with developmental disabilities, the line between toys and children's product can become blurred. In this paper we include consideration of traditional toys as well as teething rings, pacifiers and chew toys for infants and toddlers, but not children's clothing, furniture, and personal care products marketed directly for use by children.

Estimates are that the international toy market in 2003 (traditional toys excluding video games) was \$59.4 billion US dollars: 41%-United States, 30%-Europe, 29%-Asia/Oceania and 1%-

Africa.⁵ This represents billions of toys produced and sold annually. The small number of annual emergency room visits for toy-related chemical injury in the US cited above suggests that there are effective mechanisms in place to protect children from most acute chemical harms. Uncertainty and data gaps remain, however, about possible non-acute health harms to children from chemicals used in toys. This Thought Starter will explore the context of potential chemical risks from toys *linked* to chemical exposures, the question of prevalence of chemical related harms, the current approaches taken to assess potential chemical risk, and actions already taken in the industrialized world to protect children from chemical harms from toys. A series of case studies is used to illustrate lessons learnt, successes, and controversies related to chemicals in toys. The paper concludes with a series of questions to stimulate thinking and discussion.

Potential Risks from Toys Linked to Chemical Exposures

For there to be health harm from a chemical three elements are required: 1) a chemical must have toxic effects; 2) an individual must be vulnerable to the toxic effects; and 3) sufficient exposure must occur. Children and toys represent a special case of this triad, termed the "risk triangle," because children may have increased vulnerability to chemical harms, and children have potential exposure to chemicals through play with toys. Figure 1 depicts the relationship between these three elements and children. If chemicals used in toys are potentially toxic and capable of migrating out of the toy into the child during normal play or foreseeable misuse, then adverse health effects are possible.

IFCS Forum IV adopted a decision on Children and Chemical Safety that explicitly acknowledges that special consideration needs to be given to children because of their "potential enhanced exposures and/or vulnerabilities."⁶ This applies to chemical exposure through toys in a number of ways. Children are *physically and physiologically immature*.⁷ Throughout childhood they grow and change in terms of their physical size and proportions, and their vital organs and organ system functions. Chemical exposures during certain critical periods of development can result in damage, at times permanent, to critical structures and functions such as the brain and nervous system, the endocrine and reproductive systems, and others. Depending on the state of development and a variety of other factors, a child's ability to successfully metabolize and excrete chemicals differs from that of an adult, sometimes offering them greater protection and sometimes increasing their vulnerability. Children's *behaviors* put them in intimate contact with toys and potentially the chemicals in toys through normal and intended play, as well as through excessive mouthing, sniffing, cuddling, rough-housing, breaking, swallowing, or inserting into nose, ears or other orifices. Finally, the *cognitive development* of a child may be inadequate for him/her to appreciate warnings or dangers associated with a given toy. For all of these reasons, chemicals used in toys have the potential to end up inside a child's body, either at a dose that is sufficient to cause harm, or at a time when even small doses can be harmful.

Reported and potential adverse health effects associated with chemicals in toys can be categorized as acute poisonings, chemical burns, allergic sensitization, or more subtle, sub clinical damage from low-dose exposure, damage from short or long-term exposures to chemicals that lack acute toxicity, or early life exposures contributing to delayed illness expressed in adult life. (See Table 1) Acute poisonings are most commonly a result of ingestion of a toy, toy part or toy fragment, but may also occur with inhalation of volatile materials, or absorption from excess dermal contact. Burns from caustic chemicals can affect the skin, mucus membranes including eyes, or the lining of the gut or lungs. Both acute poisonings and burn events are readily identifiable, and are frequently associated with visits to medical professionals. Thus, systems could be developed to track acute toy-related chemical events through poison control centers, or hospital and emergency room admissions. In contrast, current surveillance mechanisms do not allow for definition, identification, tracking, or control of risks and harms associated with early life chemical exposures linked to sub clinical illness or allergies during childhood, or delayed illness in adulthood.⁸

Prevalence of chemical related toy injury – How much do we know?

Information on disease, injury or death from chemicals in toys is not systematically collected. Individual case reports of acute poisonings appear in the medical literature. Most commonly these are related to heavy metal poisoning, such as lead, or mercury, following the inappropriate ingestion of a small toy, toy part, or toy fragment, by a young child.⁹ Acute poisonings are also reported in older school aged children and adolescents who "sniff" or "snuff" volatile compounds such as glues, solvents, or fuels that are used in craft kits and art and craft supplies.^{10,11} Burns or perforations of the gut have been reported from ingestion of small button batteries, again usually by younger children.¹² A few reviews of toy-related hospital emergency room visits are available.^{13,14} A minority of these emergency events are chemical related. Most poison control centers do not separate out toy-related calls or emergency events as part of their standard reporting. The most recent report from US poison control centers does indicate that 13% of poisoning inquiries for children under 6 years of age were related to cosmetics and personal care products, and 2.4% were related to arts and crafts materials.¹⁵

One source of data that illustrates to some extent the potential exposures of children to health hazards from toys is the record of toys recalled as unsafe by national consumer product safety agencies in a number of countries. While the majority of these recalls are due to potential mechanical risks, such as small parts violations,¹⁶ some are for chemical related risks.¹⁷ Table 2 lists examples of recent US Consumer Product Safety Commission recalls related specifically to chemicals in toys and children's jewelry.

Anecdotal evidence on risks posed by toys is available from media reports, studies by non-profit organization, and experts in child health and safety from developing countries and countries with economies in transition (CEIT). For example, two poison centers in Argentina (Children's Hospital Ricardo Gutierrez in Buenos Aires^{18,19} and Serotox in Rosario²⁰) report cases of lead poisoning in children from ingestions of lead containing modeling plastic (plastilina), watercolors, crayons, pencils, jewelry, small toy parts, and metallic paper packaging materials for toys. The centers also treated a child with gastroenteritis from consuming "bola de moco" (plastic substance that looks like mucus), children with toluene poisoning from ingestion of the liquid in a toy known as "yo-yo loco", and dermal reactions from exposure to brilliant powder used by girls on the skin (cosmetics).

These sources may capture only the most obvious and acute cases of toy-related chemical health effects, and may not present a full picture of the scope of the problem. It may be that this represents only a small portion of the problem, or it may be that in the end there is relatively little risk of harm from toy-related chemical exposures. At this time, there is not sufficient data to know if or how many children suffer acute, sub clinical, chronic, or delayed adverse health effects as a result of chemical exposures from toys.

Approaches to Assessing Risks from Chemicals Used in Toys

In the absence of population based measures of risks associated with chemical exposures from toys, alternative approaches to assessing or predicting risks are needed, particularly in the area of non-acute health risks. Ideally, we would know the precise chemical content of toys, the full spectrum of toxicities associated with all chemicals used in toys, the bioavailability of potentially hazardous chemicals within toys, the level of exposure from intended play and reasonably anticipated abuse, and the number of children with unsafe exposures would all be objectively measurable. There are many barriers to gathering such complete information, yet all of these categories of information are relevant and necessary if risk is to be quantitatively defined.

Most often the chemical content of toys is not readily available. Commercial toy manufacturers are likely to know relevant information on chemical hazards from safety data sheets transmitted from suppliers. It cannot be assumed, however, that toy manufacturers know the exact chemical content of all of the components of their products. Toys may be made from a number of

pre-manufactured parts, such as fabric, metal pieces (springs, rods), electronic motors, beads, stuffing, etc. for which the precise chemical content may not be readily available, and chemical manufacturers often supply chemicals as a mixture that meets certain performance specifications. Absent strict specifications about chemical content, there also may be batch to batch variation in chemical mixtures used for toys. Additionally, the chemicals used in toys may change rapidly in response to market forces, or may be protected as proprietary information. The chemicals used in toys made by smaller manufacturers, at home, or in cottage industries may be less well controlled and/or undocumented.

Even if chemical content is consistent and recorded, *toxicological information* about chemicals used in toys may not be complete. The Forum IV information paper noted that complete basic Screening Information Data Sets (SIDS) were not available for over 80% of the 5000 high production volume (HPV) chemicals in current use.²¹ Since that time, more data are becoming available on HPV chemicals. (see SIDEBAR) SIDS data, however, are for screening purposes only, and not intended to directly explore risks to children from early life-stage exposures. For non-HPV chemicals fewer toxicity data are available. Thus, there remain few data directly related to understanding the potential for early life toxicity. The SIDEBAR describes some efforts to address this knowledge gap. A wide range of potential chemical harms pertain to early life exposures, and protocols to test for some hazards are still underdevelopment. Both the dose and the timing of exposures are important in evaluating children's chemical risk. New work evaluating low-dose effects of chemical exposures on cell-to-cell signaling, endocrine sensitive pathways, and functional developmental differentiation have added to concerns about how to evaluate chemical toxicities in infants, children and adolescents. Thus, even if all chemical content were known and fully disclosed, without complete, life-stage specific, toxicological data it may be difficult to ensure chemical safety.

The *bioavailability* of a chemical in the context of toy safety refers to the ability of the chemical to be released from a product or toy and absorbed into a child's body via the gastrointestinal tract, the lungs, or the skin and mucus membranes. If a chemical is not bioavailable, even if it has some toxicity in pure form, it may not represent a health hazard. Both the physical design of a toy and the chemical composition can affect the bioavailability of a specific chemical. For example, a toy that contains a liquid can be problematic if the structure is not engineered to ensure that the liquid remains locked in place. A plastic toy may contain plasticizers, softeners or stabilizers to reduce fragility and breakage, but these modifying chemicals may be capable of leaching from the structural material, making them bioavailable to a child rubbing or mouthing the object.

It is well established that bioavailability does not correlate simply with chemical content; i.e. the mere presence of a chemical in a toy does not translate into *exposure*.²² Methods for estimating a child's level of exposure to chemicals from playing with toys are under active development.²³ A variety of approaches are being explored, but none has emerged as the "gold standard." Because children interact with toys differently at different ages and developmental stages, exposure models must consider a range of behaviors including both intended use and reasonably anticipated misuse of the toy. Children interact and experiment with objects in their environment and will mouth, throw, hit, scrape, scuff, bend and break toys just to learn what will happen. They may attempt to eat small toys or toy fragments or insert such small pieces into nose, ears or other body orifices. They will cuddle, rub, or sniff surfaces of toys. Different children have different sensory preferences, and the behavior of a given child will change from day to day. Finally, while certain behaviors tend to cluster at certain chronological ages, (e.g. mouthing behaviors peak between 6 and 36 months), there is a considerable range of normal behaviors which extend well beyond the "average" or "median" age. This range is further enlarged when considering children with developmental delay or disability, mental retardation, emotional or behavior problems, or other mental health conditions.

SIDEBAR:

Some Current Initiatives to Increased Relevant Toxicological Information

OECD member countries and their chemical industries are working together to investigate all chemicals produced or imported into their countries in quantities greater than 1000 tonnes per year. There are over 5000 HPV chemicals that fall into this category. The outcome of the screening includes a public chemical hazard assessment document. The U.S. High Production Volume Information System (HPVIS)²⁴ developed by EPA contributes to the OECD programme and will provide access to basic health and environmental effects on 1400 HPV chemicals sponsored under the HPV Challenge Program.²⁵ Within the European Union, a new proposal for the Registration, Evaluation and Authorization of Chemicals (REACH) was initiated in October 2003, with a view to address improved human health and environmental protection from chemicals.²⁶ Under this program, chemicals sold and used in Europe in quantities greater than one tonne per manufacturer per year are to be registered on a central database. Information required for registration increases with tonnage, including the compilation of life stage-specific toxicological data for HPV chemicals. Use of chemicals identified on the basis of their hazardous properties as being of 'very high concern' will require specific authorization. To facilitate access to these and other sources of information, an OECD Global HPV Chemicals Portal is being developed to allow web based simultaneous search and query of multiple sources of information on health and environmental effects data free of charge.

A second U.S. HPV program, EPA's Voluntary Children's Chemical Evaluation Program (VCCEP), was developed to obtain toxicity, exposure, and risk information to understand the effects on children from chemicals to which they were likely to be exposed. In addition to collecting SIDS screening level data, EPA identified two tiers of advanced toxicity tests and exposure information which it considered necessary to more fully understand and characterize the risk of childhood exposure to certain chemicals. Chemicals which had been found in human tissues and the environment were selected for a pilot of VCCEP. EPA had decided at the initiation of VCCEP to run a pilot of the program to determine what efficiencies could be identified which could benefit the implementation of a larger program. In December 2000, EPA requested chemical manufacturers to sponsor the chemicals selected for the VCCEP pilot. Chemical manufacturers responded by volunteering to sponsor the development and collection of information on 20 pilot VCCEP chemicals. To date information has been submitted and reviewed on 12 of the 20 pilot chemicals. The information collected by the chemical sponsors has been made available to the public on the VCCEP website.²⁷ The pilot program is currently under evaluation.

In the United States, EPA is sponsoring a study with the National Academy of Sciences²⁸ (BEST-U-03-08-A) to assess and advance current approaches to toxicity testing and assessment to meet regulatory data needs. The NAS has been tasked with developing a long-range vision and strategic plan for advancing the practices of toxicity testing and human health assessment for environmental contaminants. In developing the vision and strategic plan, the committee is considering evolving regulatory data needs; current toxicity testing guidelines and standards used by EPA and other federal agencies; the use of emerging science and tools (e.g., genomics, proteomics, transgenics, bioinformatics, computational toxicology, in vitro testing, and other alternatives to animal testing); and the challenges of incorporating more complex understanding of toxicity (e.g., toxicokinetics, mechanisms of action, systems biology) into human health risk assessment. The NAS has been asked to consider how any new system might lead to the collection of new data relevant to better assessing children's risks.

Some of the approaches used to estimate children's exposures have involved short-term direct observation of children at play to assess behaviors such as mouthing of objects and hands, analysis of video recordings of children at play, and parental logs of specified behaviors over several days.^{29,30,31} In some cases, adults have been used to simulate play in a variety of settings. *In vitro*, and mechanical approaches have been used to simulate chewing of toys and measure chemical leaching rates.³² All of this work has been done in industrialized, western countries, raising questions of cultural bias in the data collected, and its relevance to the rest of the world. On the other hand, these approaches can be enhanced and adjusted statistically to aid in accounting for various sources and levels of uncertainty.

For any model to be useful, it must be validated, a process which involves testing predictions for accuracy and reproducibility against empiric data from groups of representative individuals. None of the available exposure models for assessing likely or predicted exposures from toys has been validated on large numbers of children, across cultures and regions, or with matched biomonitoring and toy chemical content sampling. All of these models are based on small sample sizes and short duration of observations. For ethical reasons, it will never be possible to validate the accuracy of exposure model predictions using direct biomonitoring of children exposed to toys of known chemical content. Validated *in vitro* studies, and validated and controlled studies of adults will always need to be extrapolated to the special case of children and some uncertainty is unavoidable. *In vitro* leaching methods were developed in Europe in the late 1990s as a proposed basis for a regulatory approach to limit the risks from exposure to phthalates in teething toys, although the conclusion that these methods had been validated for this purpose received some criticism.^{33,34}

Assessing chemical risks to children from exposure to toys requires considering information on the nature of the chemical itself, the actual use of the product and the characteristics of the population or populations of concern in order to establish an expected range of effects. (Figure 1) By convention, ***chemical risk assessment*** is a four part process involving 1) identifying a specific chemical hazard, 2) determining the amount or dose that causes damage, 3) estimating levels of exposure in the population at risk, and 4) generating a risk estimate usually expressed as the probability of adverse health effects from a range of specific exposures to the populations of concern. For non-cancer causing chemicals, it is generally assumed that there is a threshold effect, i.e. a level of exposure below which no harm occurs. There is no threshold assumed for carcinogens. In general, the likelihood of cancer occurring is considered proportional to the dose, and exposures are usually averaged over a 70 year lifetime regardless of when exposures occur. Regulations are then set in the case of carcinogens to prevent excess cancers above a level set by authorities, and in the case of non-carcinogens to hold exposures below the theoretical threshold level causing disease. When assessing chemical risks for children, however, additional issues must be considered.³⁵ The traditional emphasis on dose may be inadequate without also considering the timing of the exposure with respect to critical windows of development. For example, recent data suggest that the relative importance of early life-stage exposures to later disease, both cancer and non-cancer, may be disproportionately large for some chemicals.³⁶ This may require additional "weighting" of chemical exposures during childhood, rather than a simple averaging. In some cases there is an additional uncertainty factor added for children. The assumption that non-cancer adverse health outcomes exhibit threshold behavior is called into question when toxicities associated with early life-stage exposures are considered. An example of this is the failure to demonstrate a true threshold to the developmental neurotoxicity of lead poisoning in children.³⁷ These examples illustrate the complexities involved in attempting to assess and mitigate risks, particularly non-acute risks, to children from chemicals in toys. When considering the toxic potential of a chemical used in a toy, it should be within the context of the benefits of using that same chemical, as well as the suite of alternatives to that use, i.e., changes in toy design and the use of alternatives.

Which Chemicals? Which Toys?

It is useful to identify categories of chemicals used in toys which may be dangerous, as well as toys which may contain harmful chemicals. Many hazardous chemicals have been eliminated or severely restricted from use in toys produced in or for industrialized countries. Others have been restricted for use in toys intended only for older children and/or used under direct adult supervision. As global trade and manufacturing continues to expand rapidly, previously identified and restricted chemicals can erroneously be reintroduced into toy manufacturing. Examples of these identified and potential hazard categories are listed in Table 3. Several reports over the past few years provide snapshots of the presence of some of these chemicals in selected toys. Some of these reports are tabulated briefly in Appendix I.

Alternatively, some toy categories may be intended for particularly vulnerable children, such as the very young, and thus require especially careful scrutiny for chemical safety. Other toy categories may have significant or highly bioavailable chemical content and also require careful attention to chemical safety. Examples of these are listed in Table 4.

A number of case studies are offered below to illustrate various aspects of chemical safety and toys. These are used, not to support any particular point of view, but to illustrate the complexity of determining, maintaining, ensuring and enforcing chemical safety of toys.

WHEN CHILDREN HAVE NO TOYS

Impoverished children need to play, too. Often experts in scavenging, poor children will find enticing objects to use as toys in dumps, in the garbage, and on the streets. These discarded objects can be anything from a used bottle of pills, to contaminated rags, to an old pesticide drum, and very dangerous.

CASE STUDIES

Lead in Children's Jewelry:

Lead is a potent neurotoxicant, particularly for children. The adverse health effects of lead range from subtle deficits such as learning and behavioral problems to frank mental retardation and, in rare cases, death. Many children are exposed to lead through normal hand to mouth activity such as chewing or mouthing nonfood items.

The experience of a little boy in state of Oregon, USA led to a national recall of 1.4 million potentially toxic toys by the United States Consumer Product Safety Commission (Table 2).^a The child swallowed a small medallion necklace purchased from a toy vending machine with a lead content of 39%. His blood lead level was 123 µg/dL at the time he was diagnosed. Health department workers found similar medallions for sale with high concentrations of lead ranging from 37-44%.³⁸

In the 3 years following this recall the CPSC issued an additional 12 voluntary recalls of children's jewelry that contained lead. The 12th recall was issued following the death of a 4 year old boy from acute lead poisoning caused by lead encephalopathy after the ingestion of a heart-shaped metallic charm whose inner core was >99% lead. The child's blood lead level was 180 µg/dL at the time he was diagnosed. Several similar charms purchased across the country and on the internet had lead contents that varied from 67% lead by weight to 0.004% lead by weight.³⁹ The variation in lead content in these samples is consistent with previous test results for small, inexpensive metallic jewelry.⁴⁰

^a CPSC authorities to address lead: Under the FHSA, 15 U.S.C 1261 (f) (1) which is administered and enforced by the CPSC, household products that expose children to hazardous quantities of lead (or any other toxicant) under reasonably foreseeable conditions of handling or use are "hazardous substances." A toy or other article intended for use by children which contains a hazardous substance that is accessible for children is automatically banned. 15 U.S. C. 1261 (q). By regulation, the Commission has banned toys and other articles intended for use by children that uses paint with a lead content in excess of 600 parts per million because of the risk of lead poisoning (16 CFR Part 1303).

The US CPSC issued an enforcement policy in 2005 that specifically addressed the lead hazard in children's metal jewelry. The policy gave manufacturers and importers an incentive (avoidance of CPSC enforcement actions) to reduce the total lead content of every component below 600 parts per million.

This case illustrates the difficulty in identifying hazardous products once they are brought to market. The fact that some charms tested had minimal lead content demonstrates the availability of reasonable alternatives to lead. Recalls can effectively remove specific products from retailers and consumers and increase public awareness, but to protect children from potentially hazardous exposures to lead, manufacturers and importers should eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation.

Elemental Mercury

Elemental mercury, also known as quicksilver, is used in thermometers, switches, thermostats and lights. It is available in ethnic and specialty shops for use in spiritual, religious, and healing rituals. Quicksilver is a liquid at room temperature. When ingested, it is not absorbed and represents negligible health risk.⁴¹ When it is agitated, however, it readily volatilizes and can be breathed into the lungs where it is 75-85% absorbed and goes directly into the blood stream. Mercury is a potent poison, particularly harmful to the central nervous system, kidneys and immune system. Acutely, it can damage the lung lining, eyes, gums, and skin. Children playing with quicksilver can become acutely ill, or suffer chronic exposure and central nervous system damage.

While not a toy per se, elemental mercury illustrates the reality that children use many items found in their environments as toys.

Di-isononyl phthalate (DINP)

Di-isononyl phthalate (DINP), a variable mixture of 30 or more phthalate esters, is currently the most common plasticizer used in polyvinyl chloride (PVC) toys.⁴² Historically, a different phthalate, di-ethylhexyl phthalate (DEHP), was used more extensively in toys, but in the 1980s it was found to be an animal carcinogen. Some manufacturers began to use DINP as a substitute, though long-term toxicity studies, developmental and reproductive studies were not available until the late 1990s.

DINP is added to PVC toys to confer flexibility and softness, and is present often in high concentrations of 20-40% by weight or more.⁴³ As with all of the phthalates, DINP is not covalently bound in the chemical matrix of the PVC, so it can and does leach out under normal circumstances of use. Leaching is increased by heat, agitation, friction and impaction, all conditions that could possibly be reproduced when a child plays with or chews on a toy. Leaching may also increase with age and conditions of storage of the toy. Exposure to leached DINP is primarily oral. DINP is not acutely toxic to humans or animals. Oral exposure to DINP has been associated with liver and kidney damage including cancers in adult rodents, and skeletal and genito-urinary tract damage in rodent pups exposed *in utero*.^{44,45,46} There is wide-spread disagreement about the risk to children who play with toys containing DINP. Biomonitoring studies show that children 6-19 years old have metabolites of DINP in their urine, but studies of the younger children have not been done.⁴⁷ Surveys of toy content show that DINP has become the preferred phthalate used in PVC toys in recent years.^{48,49,50,51,52,53} Advocates for the use of DINP point out: that it improves toy safety by reducing the chance of breakage and injuries from sharp edges; that it is not acutely toxic to humans; that it is toxic in animal experiments at doses that are several orders of magnitude above estimated and documented exposures in children; that it is less toxic than other well studied phthalates such as DEHP (the plasticizer used in medical devices); that the mechanism of carcinogenesis in rodents is likely not relevant in humans; and that it has been used for decades without evidence of harm to children.⁵⁴ Detractors of its use argue: that some exposure estimates predict oral exposures in children above levels approved by some governments; that data from biomonitoring of young children are scant; that precise knowledge of the toxicokinetics of DINP in children is unknown; that there is uncertainty about the effects of exposure to immature humans (in contrast to rodents); that they believe there are safer and equally well tested alternatives to PVC which would obviate the need to use any phthalates;

and that as a precaution it should not be used in children's toys.⁵⁵ In some countries, government agencies have responded to this controversy differently. The EU instituted a temporary ban on the use of DINP and five other phthalates in toys in 1999, and made it permanent in 2005.⁵⁶ The US CPSC has denied petitions which would include a ban on DINP use in toys, and agency scientists recently published a risk assessment concluding that DINP used in toys does not represent a health hazard to children.⁵⁷ In some countries, industry has voluntarily agreed to stop using phthalates in teething rings, pacifiers and toys intended for children under age 3.⁵⁸ An unregulated "phthalate-free" label has appeared on toys in the marketplace, but a study by USPIRG, a watchdog organization in the US, found that 6 of 8 toys tested contained measurable phthalates despite being labeled as phthalate-free, albeit some only in very low amounts.⁵⁹

The case of DINP use in toys illustrates the dynamic and complex issues that are considered by consumers, governments and manufacturers with regard to chemical toy safety. These include 1) industry's move to improve safety by making chemical substitutions, 2) persistent uncertainties about toxicity despite rich toxicity database, 3) scientific and regulatory disagreements about exposure estimates based on toy chemical content, leaching studies and assumptions in exposure models, 4) the power of consumer pressure for precautionary action, and 5) difficulties with unregulated labeling.

Wooden Play Structures:

Children enjoy climbing and playing on jungle gyms, swing sets and other climbing structures. Play structures are common features in public parks, school yards and home play areas. Often, they are built of wood and the treatments on that wood can represent chemical hazards. Children using play structures have frequent and intense dermal contact, especially with their hands. Because of the tendency of children to have high rates of hand mouth and object mouth activity, and occasionally actually chew on these structures, any surface treatments which are bioavailable are of potential concern.

For example, peeling brightly colored lead paint on play structures in a public park was found to be a source of lead poisoning of child in India with a blood lead level of 72.7 µg/dL.⁶⁰ When made aware of the problem, the municipality removed the leaded paint from these playground structures and repainted them with lead free products. Three weeks later, the child's lead level, though still elevated, had fallen to 49.5 µg/dL, and the improvement was attributed to the environmental intervention. Lead paint has also been found on play structures in the USA.⁶¹

A second example of concern is chromated copper arsenate (CCA), a preservative used to increase the lifetime of wood used outside. Arsenic, a human carcinogen, leaches out of CCA-treated wood and appears on the surface as well as weathering into soil beneath the structures. Higher arsenic has been demonstrated on the hands of children playing on CCA-treated wood play structures compared to children not playing on CCA-treated wood play structures.⁶² This adds to cumulative exposure and raises concerns about incremental increased risk of cancer later in life. In addition, preliminary studies have shown that regular application of penetrating sealants every 1-2 years can reduce arsenic leaching by up to 90% from those structures made from CCA-treated prior to market removal.^{63,64} In the USA, the wood industry removed CCA-treated wood from the market for residential uses in 2003 by voluntary agreement.⁶⁵ The Agency has worked with pesticide manufacturers to voluntarily phase out CCA use for wood products around the home and in children's play areas. Effective December 31, 2003, no wood treater or manufacturer may treat wood with CCA for residential uses, with certain exceptions. In Europe, this was achieved through regulation. Directive 2003/2/EC⁶⁶ prohibited the use of CCA treated wood in applications likely to result in repeated skin contact (including play equipment) from 30th June 2004. However, this restriction does not apply to existing structures, such that a large number of items of play equipment constructed using CCA-treated wood remain in use in many parts of Europe. Penetrating sealants are available, but are by no means universally applied.

These two examples demonstrate acute and chronic risks from play structure surface treatments as well as several effective mechanisms to control or eliminate those risks.

Arts and Crafts Materials:

Children begin to use arts and crafts materials at early ages in their homes, schools, child care facilities, churches, and other community gathering places. Arts and crafts materials include such things as crayons, chalks, pencils, pens, inks, paints, glazes, glues, modeling materials, adhesives, and solvents. Potentially dangerous chemicals found in these materials can be divided into metals, solvents, dusts and fibers.⁶⁷ Exposure can occur from ordinary use via inhalation or dermal contact, as well as misuse such as ingestion, or abuse such as intentional sniffing. Both acute and chronic exposures are of potential concern.

In 2000, long-term health concerns were raised when a US newspaper reported that some brands of children's crayons contained asbestos fibers, a known human carcinogen.⁶⁸ CPSC investigated and concluded that asbestos contamination of talc, used in crayons as a binding agent, was very low, that transitional fibers, not asbestos per se, was a larger component of the talc, and that risk of exposure of children to asbestos and transitional fibers was extremely low.⁶⁹ Nonetheless, as a precaution, CPSC asked the industry to reformulate crayons to eliminate these fibers. Independent analysis raised some health concerns,⁷⁰ but others criticized the methods of this independent analysis.⁷¹ In response to CPSC request and public concerns, companies changed formulae and eliminated talc, the source of the questionable fibers, from crayons.⁷²

This example illustrates several important issues including 1) the effectiveness of public disclosure of potential risk to stimulate regulatory investigation and action, 2) the technical difficulties inherent in testing toys for chemical content and extrapolating that to risk, and 3) the willingness of industry to cooperate with regulatory requests and consumer concerns to alter chemical formulations of toys.

Chemistry Sets:

Toy chemistry sets are a popular way to encourage older children to explore science via hands-on experiments. By nature, these toys carry some hazard and must be utilized under adult supervision by children of appropriate age. A poisoning incident in 1988 prompted investigators to analyze chemical content of toy chemistry sets for the presence of toxic chemicals present in sufficient quantity to be lethal to a 2 year old child weighing 12 kg.⁷³ They found that 58% of chemicals included were potentially toxic, 13% were present in potentially lethal quantities, 16% could not be evaluated due to lack of toxicological data, and 18% were non-toxic. In 1991, the British Paediatric Surveillance Unit undertook a prospective postal survey of chemistry set poisonings which they supplemented with a retrospective study from poison control centers.⁷⁴ They found an incidence rate of 0.3 cases of chemistry set poisonings per 100,000 children. Most poisonings were accidental and associated with lack of adult supervision, but toy design was implicated as well. Several recommendations were made to reduce risks including child-resistant containers, toxic hazard warnings, parental education programmes, and legal restrictions on which chemicals that can be included in these sets, excluding the most toxic. Statutes were developed in the EU governing chemistry sets in 1993 (EN71- 5: 1993, BS 5665-5:1993).⁷⁵

This case study demonstrates the importance of toy design, manufacturer's chemical choices, parental education, and prevention of misuse by age inappropriate children.

Actions for Toy Safety

There are a number of approaches used primarily in industrialized countries to provide protections to children from harmful toy-related chemical exposures. Measures to achieve chemical safety in toys can be mandated by law, produced using voluntary industry standards, forced by consumer demand, or stimulated by watchdog consumer or environmental health groups. Some approaches are primarily proactive and precautionary; others are reactive and aimed at mitigation of identified risks.

Many countries have general laws which define the limits of use of toxic chemicals in consumer products. For example, in the United States, the Toxic Substances Control Act of 1976

provides authority to the US Environmental Protection Agency (EPA) to prohibit the manufacture, processing or distribution in commerce of a substance for a particular use or a particular use above a certain concentration if the Administrator of EPA finds that there is a reasonable basis to conclude that such use results in an unreasonable risk to people. Australia requires the setting of mandatory safety and information standards under the Trade Practices Safety Act of 1974. Canada provides protection through the Hazardous Products Act enacted in 1969.⁷⁶

Recognizing that children are a special population at increased risk, a number of countries have promulgated additional toy-specific safety amendments, laws and regulations. These include in the US, Child Protection Act 1966, later changed to Federal Hazardous Substances Act (FHSA), which bans the use of hazardous substances in toys,⁷⁷ and the Labeling of Hazardous Art Materials Act (LHAMA) 1990 which requires that all arts and crafts materials be evaluated by a toxicologist for acute and chronic health hazards and appropriately labeled.⁷⁸ Since 1970, Canada has had the Hazardous Products (Toys) Regulations in place to address chemical, mechanical, electrical and flammable hazards which may be found in toys.⁷⁹ Australia has mandatory information and safety standards applying to some toys, usually for mechanical hazards.⁸⁰ The European Union (EU) enacted the Safety of Toys Directive (Directive 88/378/EEC) in 1988 which sets fundamental health and safety requirements for playthings, including explicit discussion of chemicals used in the manufacture or function of toys.⁸¹

In a number of countries, specialized agencies have been created or empowered at the national level to regulate and enforce consumer protection laws. These functions vary by country and legal system but may include the development of specific product standards, rules, labeling requirements, testing protocols, surveillance programs, and fines and penalty schedules for compliance failure. In the US, the Consumer Product Safety Commission administers the FHSA and LHAMA. Health Canada administers and enforces the Hazardous Products Act and the Hazardous Products (Toys) Regulations, and takes action when products do not meet the requirements of the legislation.⁸² Health Canada also identifies potentially hazardous toys through monitoring and testing, as well as receiving consumer or trade complaints. Similarly, Australian toy standards are enforced by Australian Competition and Consumer Commission (ACCC).⁸³

In addition to general and specific laws, some countries also have a backdrop of common law torts and product liability that complements these legislative, regulatory and administrative codes as a further deterrent and preventive measure to placing defective products on the market.⁸⁴ Such regimes in some countries provide a very meaningful incentive to design and manufacture safe toys, including consideration of chemical risks. Particularly with products like toys, an award of substantial compensatory and punitive damages to an injured party for the negligent manufacture or design of a toy is possible.

Voluntary industry standards and programs are also used. At times industry has taken the lead in setting standards that then become statutory, at other times they have been developed at the direction of regulatory bodies. Standards may also provide guidance to suppliers, drive purchasing specifications, product inputs and become enforceable through private contracting. These voluntary standards reflect the long standing emphasis on safety maintained by toy manufacturers associations. For example, in the United States an initial voluntary standards effort was sponsored by the Toy Manufacturers of America (now Toy Industry Association-TIA⁸⁵) with the National Bureau of Standards (PS 72-76), which was taken over in 1980 by the American Society of Testing and Materials (ASTM) and resulted in the promulgation of ASTM F963.⁸⁶ This first voluntary safety standard provided a basis for toy regulation in the United States and elsewhere in the world. Its provisions have been incorporated in statutes and voluntary standards of several dozen countries around the world. The Australian Toy Standard (AS/NZ 8124) was established by the federal government commission on standards and requires all participants in the toy industry to adhere to what are largely voluntary standards.⁸⁷ In Japan, by voluntary agreement with industry, toys have been free of lead paint since 1960.⁸⁸

Whereas mandatory and voluntary standards by defining limits of materials and designs to be used in toys are proactive and preventive in nature, recalls are primarily reactive and imperfect. Recalls are triggered by the identification of a toy produced in violation of mandatory safety standards, or when a toy is identified as hazardous by virtue of some aspect of construction or function that is not covered by mandatory standards. Sometimes a recall is initiated because a child has already been harmed; more often it occurs because a testing or screening system identifies a problem, or a consumer makes a complaint to the appropriate regulatory agency or body. Recalled products are readily retrieved if they have not left distribution or retail outlets, but are more difficult to collect from consumers. Despite multimedia public notification and warnings, some recalled toys may remain in circulation causing ongoing hazard.

Finally, labeling standards and enforcement are a major approach to toy safety. Regulators and child specialists in many countries have developed age related guidelines to toy safety which address the issues of safety related to children's developmental stage and toy design and function.⁸⁹ Linked to age standards, are issues related to chemical content of toys, likely exposures based upon behavior and misuse, body size, and cognitive development.

Recent increases in international and internet commerce have created new challenges and stimulated activity on harmonization of toy safety standards. For example, approximately 70% of the toys sold in the United States and a large portion of those sold in the EU and elsewhere come from China.⁹⁰ These toys are largely produced under the comprehensive requirements of the U.S. Consumer Product Safety Commission and ASTM F963, and the European Union as set forth in EN71. These requirements include a general prohibition precluding the manufacture and sale of any toy which presents a risk of illness or injury and are further defined in subsections which set forth specific requirements for manufacturing safe toys. The standards of both the U.S. and the EU address mechanical and physical properties; requirements for testing foreseeable use and abuse; flammability; migration of harmful substances including heavy metals; experimental sets for chemistry; age warning labeling and appropriate age recommendations for certain toys.

The development of mandatory regulation and voluntary standards in the United States and European Union has led to the development of ISO Standard 8124, a harmonized voluntary standard for use internationally. ISO 8124 and a code of practice for its enforcement have been made available for developing countries by the International Council of Toy Industries (ICTI), a not-for-profit trade association representing toy trade associations from 20 countries.^{b,91} ISO 8124 is available for use by any country in the world that desires to immediately adopt voluntary standards for the safety of toys it may manufacture.⁹² Most recently a number of countries including China and Korea have adopted those standards for their national standard.⁹³

In the United States, compliance with toy standards is supported by manufacturers sending toys to outside independent laboratories to confirm compliance before they are launched in commerce and by retailers who confirm compliance with outside independent laboratories before receiving shipments of toys. In the European Union, manufacturers are required to maintain a technical

ICTI was formed in 1975 to respond to rapidly developing European and American toy safety standards in an increasingly global market. In 1997 it was awarded United Nations NGO status. Currently, there are toy association members from 20 nations around the world. The Code of Conduct states the associations strong commitment to the promotion of safe play environments for children, safe toys and compliance with national and international toy safety standards.

^b ICTI member Toy Manufacturer Associations include the following countries: Australia, Austria, Brazil, Canada, China, Chinese Taipei, Denmark, France, Germany, Hong Kong, Hungary, Italy, Japan, Mexico, Netherlands, Russia, Spain, Sweden, United Kingdom, United States.

file showing compliance with EN71 before they distribute their toys in commerce.⁹⁴

In this global context, with the large volume of toys produced by large and small manufacturers, who may or may not be members of ICTI or other relevant associations, it remains a challenge to ensure universal compliance with international, regional and country specific standards. For example, in the mid-1990s crayons imported into the US labeled as "non-toxic" appeared on the market, were discovered to contain high levels of lead, and were recalled.⁹⁵ In addition, many of the current labeling rules and standards may predate the internet and may not be universally applied by internet based merchants.⁹⁶ The World Health Organization European region has recommended that governments "enact/enforce legislation to protect children from exposure to hazardous chemicals in toys and other products used by them."⁹⁷ At the Fourth Ministerial Conference on Environment and Health, held in Budapest, Hungary, 23-25 June 2004 [European health] ministers declared that "more attention needs to be focused on the chemical composition of children's products and toy," and called on "manufacturers to stop placing on the market products containing substances that have, or may have, adverse effects on children's health".

Summary and Departure Points for Discussion

Toys are intended specifically for use by children. Children's use of toys is part of normal and necessary play. In this Thought Starter, we define toys as products or materials designed and intended for use in play by children or adolescents, including chew toys and teething rings. Forum IV recognized the important and unique aspects of chemical safety for children. Information on effective safeguards already in place and other actions should be widely disseminated and opportunities pursued to develop improved approaches to protecting children from chemical risks and harms. Several points from this Thought Starter should be highlighted.

1. Data on toy-related chemical harms to children are not systematically collected. We do not have sufficient information on the extent of the problem of either acute or other chemical related health effects. The most substantial data gaps are in developing and CEIT countries. In terms of acute toy-related injury in the US chemical harms from toys represent only a small portion of documented cases.
2. Non-acute, sub clinical, chronic or delayed health effects from chemicals used in toys are inevitably more difficult to identify than acute poisonings. As with all chemical hazards, children's unique vulnerabilities related to physiology and exposure may not be well captured by current approaches to chemical risk analysis and formal risk assessment.
3. Chemical content of toys is often unknown, and varies with market forces, including economics, laws and regulations, and consumer concerns.
4. Toxicological information about the chemicals used in toys is often incomplete; particularly related to non-acute risks from exposures at various life-stages.
5. Chemical safety of toys has long been a concern of the toy manufacturers associations. Numerous approaches exist and are applied within specific countries as well as at the international level to ensure that toys are safe and non-toxic. Chemical toy safety approaches, where established, vary, but tend to be most well developed in highly industrialized countries.
6. Ensuring compliance with safety standards is increasingly challenging as toy manufacturing and commerce expand internationally in conventional markets and on the internet. This also limits the ability of consumers and parents to be confident about the chemical safety of toys their children use.
7. Children in poverty are at substantially increased risk because they do not have access to high quality toys. They may also receive donated, second-hand toys that do not meet the highest safety

standards. While outside of the scope of this Thought Starter, it is important to remember that poor children play with what they can find, often things that are contaminated, dangerous and breakable.

With these points in mind, a series of questions and sub-questions is offered below to stimulate thinking and begin discussion. The WG recognizes that this extensive list of issues will require further prioritization for use during the discussion during the plenary session at Forum V.

DESIGN AND MANUFACTURE

What is or can be done at the design stage to prevent chemical risk from toys?

1. How can designers be educated about chemical risks and children's health?
2. What incentives can be used to encourage "safe" or "green" chemicals to be identified, used or given preference by designers, manufacturers and institutional purchasers such as retailers or individual consumers?
 - a. Is it possible to identify a universal list of "safe" materials for toy manufacturers?

When chemical toxicity and potency are well defined, what are the best ways to prevent use of hazardous materials in toys and/or prevent children's exposures?

1. Heavy metals such as lead are well known to be toxic yet continue to be found in paints and inexpensive children's jewelry
 - a. What sorts of controls or enforcement strategies at the national level would be most effective?
 - b. Are voluntary standards preferable and/or sufficient?
 - c. Should there be global registry or adverse event reporting?
 - d. Could there be universal bans on some chemicals?
2. Solvents used in model sets known to be intoxicants
 - a. What is the balance between protecting against abuse, versus foreseeable misuse?
 - b. What is the balance between product performance and product safety?

When potential for toxic exposure has been identified and substitutes or design options are available, what are the important considerations?

1. Are substitute chemicals equally or more thoroughly studied?
2. Is the risk considered within the context of the benefits of use?
 - a. Is bioavailability considered?
3. Is it appropriate to consider age and developmental stage of intended toy use in balancing risks?
4. Are public pressure, market forces and concerns about potential liability sufficient to encourage substitution with safer alternatives (chemicals, materials, designs, etc.), or should substitution with safer alternatives be mandatory?

What are generic uncertainties and data gaps about chemicals in toys?

1. Lack of knowledge about chemical composition of toys
 - a. Which chemicals are used?
 - b. How much of each chemical?
 - c. Does the chemical composition change over time, between batches of toys of the same design, and from the same manufacturer/facility?
 - d. Does the chemical composition vary with country of manufacture?
 - e. How do commerce patterns affect chemical composition of toys regionally, geographically?
2. Lack of knowledge about bioavailability of chemicals in toys
 - a. How is bioavailability modified by chemical composition, design, use/misuse, age, exposure of toy?
 - b. How does this affect exposure and risks to children?

- c. Will it ever be possible to develop accurate predictions of children's exposures based on leaching studies?
 - i. The ethical issues associated with research on children preclude performing validation studies in children of models developed on adults or in laboratory simulations.
 - ii. The potential variability in chemical content of toys among batches, manufacturers and geographic regions complicate predictability.
 - iii. How can research testing methods be standardized sufficiently to achieve comparable measures of leaching rate under idealized conditions?
 - iv. How can idealized leaching rates be extrapolated to encompass all potential use and exposure scenarios, including unintended uses?
3. Lack of toxicity data relevant to early life-stage exposures about chemicals used in toys
 - a. Complete SIDS?
 - b. Research on immature animals at various lifestages consistent with human exposure scenarios?
 - c. Relevance to human endpoints – issues of extrapolation from experimental animal data?
4. Uncertainties about exposures from toys
 - a. How much is "average"?
 - b. What are the upper limits of exposure?
 - c. Which route of exposures are important?
 - d. How do other sources of chemical exposure interact with exposure from toys?
 - e. What assumptions are made in exposure estimates?
 - f. Can exposure simulations (practical and/or modeled) provide sufficient certainty to be used as a regulatory basis?
 - g. How should the precautionary approach be practiced in this regard?

What are the critical research needs?

1. Surveillance of toy content
 - a. Who should be responsible; industry, governments, independent agencies?
2. Toxicology
 - a. Lifestage exposures
 - i. Both high and low dose
 - ii. Short duration but during critical windows
 - iii. Subtle functional endpoints
 - iv. Endocrine disruption, signal disruption
 - b. Adult diseases related to early exposures
3. Exposure
 - a. How to model lifestage exposures?
 - b. How to validate the models?
 - c. International and cross cultural validation?
4. Biomonitoring, environmental public health tracking?

STANDARDS AND CONTROLS

What are the strengths and shortcomings in current approaches?

1. Voluntary Standards
 - a. What protections does consumer have if market or materials change?
 - i. How are they monitored?
 - ii. Can they be enforced?
 - b. When effective, risk is eliminated only as long as companies comply
 - i. Industry self regulation?
 - ii. Watchdog organizations?
2. Legal Standards
 - a. What toxic endpoints are chosen?
 - b. Who has burden of proof of safety?
 - c. Prevention or limitation of exposure to risk?

3. Recalls
 - a. Reactive, harms may have already occurred
 - i. How well do they work?
 - ii. How dependent on infrastructure such as access to media, transportation, literacy?
 - b. Effectiveness limited once toys out of distribution centers (wholesale or retail)

How well are current standards monitored and enforced?

1. By governments
2. By industry
 - a. Large multinational corporations
 - b. Small manufacturing entities
 - c. Cottage industry

How can enforcement of existing standards be improved?

1. Can surveillance and screening programs be augmented?
2. Role of consumers, NGOs?

INTERNATIONAL AND GENERAL CONSIDERATIONS

How can information be made more accessible?

1. Database for surveillance, recalls, adverse events and increased access
2. Harmonization of information on databases
3. Multi-stakeholder mechanisms for sharing concerns, adverse events, research data

What are the compliance and enforcement challenges with regional, international and electronic commerce?

1. Regulations for exports/imports
 - a. Is it desirable to harmonize?
 - b. How can they be harmonized?
 - c. What costs would be associated with international controls?
 - i. Who would pay?
2. Internet commerce
 - a. How extensive is it?
 - b. What controls exist if any?
3. Should there be a mechanism for qualification or entry into international toy trade?
 - a. Are there parallels in other areas, for example food trade, which would apply to toys and chemical safety?

Who should be involved in chemical safety of toys?

1. Toy Manufacturers
2. Governments
3. Consumers (especially parents and children)
4. NGOs
5. IGOs
6. Health Agencies
7. Teachers and Child Care Providers
8. Customs Officials

**Figure 1: The Risk Triangle
The Special Case of Children and Toys**

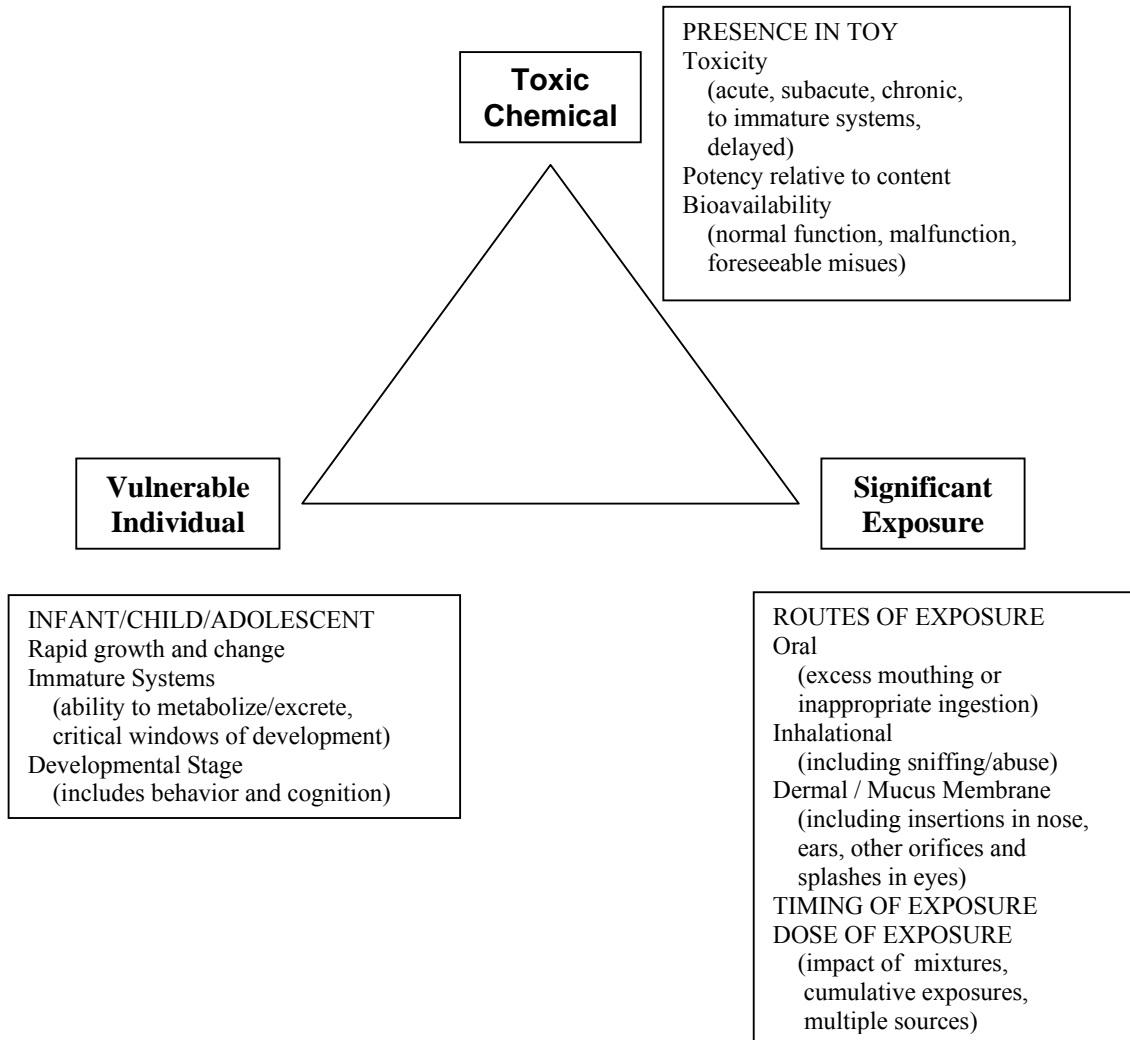


Table 1 – Examples of Chemical Harms associated with Toys

Chemical Related Syndrome	Route of Exposure	Chemical, category, or source	Toy Category	Representative Reference(s) (not exhaustive)
Causality Proven				
Fatal, Acute Poisoning	ingestion	lead	jewelry charm	MMWR, 2006 ⁹⁸
Non-fatal, Acute Poisoning	ingestion	lead	jewelry charm	Pediatrics, 2004 ⁹⁹
Chemical burn -internal	ingestion	button battery	battery operated toys	Indian J Pediatr 2005 ¹⁰⁰ Pediatr Surg Int, 2004 ¹⁰¹
Acute Poisoning	inhalation	solvents	model kit, arts and crafts material	Am Fam Physician, 2003 ¹⁰² Malays J Pathol, 2001 ¹⁰³
Causality Feasible, Postulated				
Allergic Sensitization	dermal	fragrances	toy cosmetics	Contact Dermatitis, 1999 ¹⁰⁴
Developmental or Chronic Toxicity	oral or dermal	phthalates	PVC toys	CPSC, 2001 ¹⁰⁵

Table 2:
Examples of US CPSC active recalls related to toys and chemical safety¹⁰⁶
<http://www.cpsc.gov/cpsc/pub/prerel/prerel.html>

Date Issued	Toy Item	Reason for Recall	Units Recalled
10 May 2006	jewelry	lead	2,800
5 May 2006	jewelry	lead	730,000
27 April 2006	jewelry	lead	55,000
30 March 2006	jewelry	lead	180,000
26 March 2006	jewelry	lead	300,000
1 March 2006	flashlight	lead	20,800
11 Jan 2005	jewelry	lead	7,100
8 July 2004	jewelry	lead	150,000,000
7 July 2004	flashlight	battery leakage	24,000
2 Mar 2004	jewelry	lead	1,000,000
10 Sept 2003	jewelry	lead	1,400,000
15 Nov 2002	flashlight	battery leakage	9,500
17 Sept 2002	doll	lead	100,000
21 Feb 2001	doll sunglasses	petroleum distillate	70,000
1 June 2000	picnic set	lead	1,200

Table 3: Chemical Categories of Potential Concern for Toys

- Metals (eg lead, mercury, cadmium)
- Plasticisers/softeners (eg phthalates)
- Musks, fragrances, and allergens
- Glues, solvents, fuels
- Lacquers, paints, varnishes, colourants
- Antioxidants, antimicrobials, pesticides, flame retardants, stabilisers
- Other chemical additives and/or contaminants

Table 4: Toy Categories to Consider for Potential Chemical Hazards (Examples)

- Chew Toys (including pacifiers, teethingers)
- Toy Cosmetics and Jewelry
- Arts and crafts and learning materials
 - Crayons, pencils, pens, markers, paints, glazes
 - Clays and molding materials, playdough, plaster of Paris
 - Model sets (cars, airplanes, boats, figurines)
- Chemistry sets
- Cap tapes for gun toys
- Toys powered by batteries
- Toys containing liquids
- Toys with plastic sections of components
- Toys made of textiles, stuffed toys
- Playground equipment
 - surface materials (rubber, sand, wood chips)
 - wood and surface treatments and paints (CCA-treatment, lead paint)
 - lead used to line playing fields
- Second-hand toys, Hand-me-down old, unlabeled, unsafe toys

APPENDIX I

Readers are cautioned to remember that these are merely "snap shots" of a small number of globally available toys, not systematic studies. This table is offered for illustration only. The chemicals reported are not the only chemicals present in the toys tested; they are merely the chemicals the study authors chose to identify. Finally, the presence of a chemical in a toy does not translate in a simple way to either exposure or risk.

TOYS TESTED FOR SOME MANMADE CHEMICALS – EXAMPLES OF STUDIES

TOY	Number Tested	CHEMICALS FOUND	Comments	Reference
toys	27	DINP 12.9% -39.3%		Babich, 2004
teether	2	DEHP 0.2%-0.26% DINP 28.7%-20.8%		Harmon, 2001
rubber duck	?	DINP 227000ppm BBP 448 ppm	Thailand	Stringer, 2001
squeeze toy	?	DINP 197000ppm	Thailand	Stringer, 2001
pencil case	?	DEHP 204000 ppm DINP 1550 ppm	Denmark	Stringer, 2001
Swim Ring	?	DEHP 1310 ppm BBP 220 ppm DINP 249000ppm	Australia	Stringer, 2001
squeeze ball	?	DINP 114 ppm	Japan	Stringer, 2001
pencil case	?	Pb 197 ppm Cd 25.6 ppm		DiGangi, 1997
toy hackey sack	?	Pb1610 ppm		DiGangi, 1997
toy	?	Pb 207 ppm Cd344 ppm		DiGangi, 1997
toy cosmetics pouch	?	Pb 392 ppm Cd 152 ppm		DiGangi, 1997
doll stroller	?	Pb 7115 ppm Cd 22.6 ppm		DiGangi, 1997
tweety toy	8	Pb 1774 ppm (190-7490)		DiGangi, 1997
various toys	68	DINP 308000ppm (15000-580000ppm)	48/ of 68 highest content in pacifier	Sugita, 2001
dolls, doll parts	17	DEHP 3-44% DINP 29-44% %	4 of 17 positive 13 or 17 positive	Bouma, 2002
Animal Figures	5	DINP 16-34%	4 of 5 positive	Bouma, 2002
bath toys	6	DINP 33-42	4 of 6 positive	Bouma, 2002
teethers	1	DINP 45%		Bouma, 2002
inflatable ball	1	DINP 30%		Bouma, 2002
swimming tool	5	DEHP33-37% DINP 31%	4 of 5 1 of 5	Bouma, 2002
key rings figures	4	DINP 36-45%	4 of 4	Bouma, 2002
ball	2	DEHP 34% DINP 35%	1 of 2 1 of 2	Bouma, 2002
Jewelry – adult and children's	285	lead mean 30%, range <3 to 100%	45.6% <3%, 39.4% >50%	Maas, 2005

toys or toy parts	46	DINP 0.4-51% DEHP 0.004-16% Total Phthalates 19-51% nonyl phenol 0.021-0.36%	36 of 46 China 18 of 36 China 39 of 46 China 11 of 46 China	Stringer, 2000
toy or toy parts	9	DINP 31.7% DEHP 0.005-11.4% Total Phthalates present - 37.7% nonyl phenol none detected	1 of 9 unknown 6 of 9 unknown 7 of 9 unknown 9 of 9 unknown	Stringer, 2000
teether/pacifier	4	DINP 43.8% DEHP 0.005-0.34% Total Phthalates present-43.8% nonyl phenol 0.02-0.36%	1 of 4 USA 2 of 4 USA 4 of 4 USA 2 of 4 USA	Stringer, 2000
toys or toys parts	19	DINP 30.6-37.9% DEHP 0.008-35.5% Total Phthalates 0.01-38% nonyl phenol 0.009-0.17%	7 of 19 other 8 of 19 14 of 19 other 2 of 19 other	Stringer, 2000
all toys sampled	72	"other chemicals" identified by not quantified included pesticides, antioxidants, paraffins, alkyl benzenes, various esters and acids.	78%	Stringer, 2000
action figure	1	phthalates DIBP 1.6 ppm DINP 85828 ppm organotins MBT 3.6 ppm DBT 28 ppm TBT 0.08 ppm TeBT 0.02 ppm MOT 34 ppm DOT 42 ppm	other non-toy consumer products were also studied	Peters 2005
doll	1	phthalates DCHP 3.4 ppm DEHP 24 ppm DINP 151916 ppm DIDP 11455 ppm organotins DBT 0.12 ppm MOT 0.02 ppm DOT 0.03 ppm	other non-toy consumer products were also studied	Peters 2005
rubber duck	1	DBP 49 ppm	labeled phthalate free	Cassidy, 2005
water teether	1	no phthalates	labeled phthalate free	Cassidy, 2005
cool animal teether	1	DEHP 100 ppm, DBP 380 ppm, DNOP 54000 ppm	labeled phthalate free	Cassidy, 2005
baby books	1	DEHP 280 ppm DINP 2200 ppm DBP 68 ppm, DNOP8000 ppm	labeled phthalate free	Cassidy, 2005
soft freezer teether	1	none	labeled phthalate free	Cassidy, 2005
ice teether	1	DEP 53 ppm	labeled phthalate	Cassidy, 2005

			free	
pink pig	1	DINP 110 ppm	labeled phthalate free	Cassidy, 2005
snail	1	DEHP 57 ppm	labeled phthalate free	Cassidy, 2005
worm	n/a	DEHP, DBP, DNOP		Cassidy, 2005
playmat	n/a	DEHP, DEP		Cassidy, 2005
Nail Polish	n/a	DBP, xylene	product labels	Cassidy, 2005
makeup 5 piece nail polish set	n/a	zylene	product labels	Cassidy, 2005
Manicure set	n/a	DBP	product labels	Cassidy, 2005
child make-up	n/a	toluene	product labels	Cassidy, 2005
lip and nail cosmetic	n/a	xylene	product labels	Cassidy, 2005
cosmetic	n/a	xylene	product labels	Cassidy, 2005
play putty	?	DMP 1.6 ppm DEP 1.6 ppm DIBP 16 ppm DBP 16 ppm BBP 3.6 ppm	other non-toy consumer products were also studied	Peters 2003
modeling material	?	DIBP 196 ppm DBP 162 ppm BBP 32349 ppm DCHP 388 ppm DEHP 364 ppm DOP 3988 ppm DINP 18493 ppm	other non-toy consumer products were also studied	Peters 2003
bath toy	?	NP 2306 ppm (not a phthalate) DEP 1.6 ppm DIBP 37 ppm DBP 36 ppm DINP 7297 ppm DIDP 6247 ppm	other non-toy consumer products were also studied	Peters 2003

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