

NLWJC - Kagan

DPC - Box 008 - Folder 010

Consumer Protection - Vinyl Toys

01/11/99 17:05

Cms pro - vinyl toys

U.S. HOUSE OF REPRESENTATIVES

NEWS RELEASE

FOR IMMEDIATE RELEASE
Friday, January 8, 1999

CONTACT: Danny Weiss 202/225-2095
Phil Schiliro 202/225-3976

Administration Takes Encouraging Steps on Toxic Toys

Joint Statement by
U.S. Representatives George Miller and Henry Waxman

WASHINGTON, DC — U.S. Representatives George Miller and Henry Waxman expressed their approval today of the Clinton Administration's response to concerns they raised in a November 18, 1998 letter signed by 26 other Members of Congress about protecting children from toys containing phthalates, a toxic component of some plastics. The response from Vice President Gore (attached), is a promising demonstration of the Administration's willingness to take necessary steps to ensure children's safety and also indicates a reversal of its policy of trying to dissuade other nations from taking precautionary steps against the risk of phthalates.

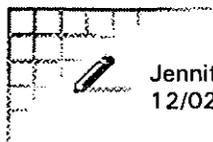
Miller and Waxman, both Democrats of California and leaders of Congressional efforts to protect children from environmental health risks, released the following statement:

"We are encouraged by Vice President Gore's detailed response to the concern about the safety of children's toys. The actions announced by the Administration will help identify and address environmental health risks to children possibly posed by toys containing phthalates.

"Statements released by the Consumer Product Safety Commission have left parents uncertain if phthalates in toys pose a hazard to their children. We hope the extensive studies the Administration has called for will remove the ambiguities and ensure greater safety for children.

"We are also pleased that the Vice President made clear that the United States will not pressure other nation's against taking steps they believe will protect children from toxic exposure."

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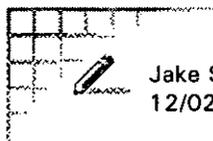


Jennifer M. Palmieri
12/02/98 12:34:54 PM

Record Type: Record

To: Jake Siewert/OPD/EOP
cc: Elena Kagan/OPD/EOP
bcc:
Subject: Re: Was This our News? -- What's Left? 

No -- as I understand it we will announce additional actions (studies, funding) in response to this action by CPSC. Right, Elena?
Jake Siewert



Jake Siewert
12/02/98 09:01:15 AM

Record Type: Record

To: Jennifer M. Palmieri/WHO/EOP, Elena Kagan/OPD/EOP
cc:
Subject: Was This our News? -- What's Left?

Commission Won't Seek Toxic Toy Ban

WASHINGTON (AP) -- Government safety regulators are asking toymakers to quit using a suspected carcinogen as a plastic-softening compound in baby rattlers and teething toys, but have decided against trying to ban all toys made with the substance.

The Washington Post quoted Consumer Product Safety Commission officials in today's editions as saying studies show that the amount of the chemical -- diisononyl phthalate -- ingested by small children ``does not even come close to a harmful level.''

The agency was scheduled to announce its actions today, along with advice to parents to discard soft vinyl toys that their children chew or hold in their mouths for long periods of times.

``Few children, if any, are at risk,''' Ronald Medford, the commission's assistant executive director for hazard identification and reduction, told the Post. ``But given the number of uncertainties, we are -- as a precaution -- asking the toy industry to take certain steps to reformulate their products intended to go

into children's mouths."

The newspaper said phthalates have been linked in laboratory studies to cancer in mice and rats. They also are a suspected source of liver and kidney damage in laboratory animals.

The commission identified only one line of pacifiers and nipples -- Clear and Soft made by Gerber Products Co. -- that parents should immediately discard, the Post said.

Some major retailers, including Kmart and Toys R Us, have already begun pulling plastic teething toys made with phthalate from their shelves.

"We've just been looking at the research and reading up on it," Kmart spokeswoman Michele Jasukaitis said in an interview with The Associated Press. "We are going forward in the interest of our customer safety."

Jasukaitis said Kmart would continue to monitor other products containing phthalate, including those that might not be explicitly for teething but could end up in the mouths of young children anyway.

Toys R Us, the world's largest retailer of children's products, promised last month to have the teething toys off its shelf by Nov. 18.

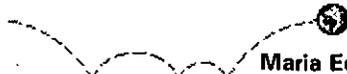
The commission said Sears, Roebuck and Co., Wal-Mart Stores and Target Stores also have announced plans to remove phthalate teething toys and rattlers from their shelves.

Several toy manufacturers, including Mattel Inc., Walt Disney Co. and Little Tikes Co., have said they plan to phase out use of the additive.

Environmental groups had asked the commission to ban the chemical ingredient and issue an advisory to parents on its dangers.

At least seven European governments have banned the use of phthalates in certain toys that commonly are put in children's mouths.

Cons pro-vinyl toys

 **Maria Echaveste**

11/30/98 04:46:41 PM

Record Type: Record

To: Elena Kagan/OPD/EOP
cc: Marjorie Tarmey/WHO/EOP, Leslie Bernstein/WHO/EOP
Subject: Phthalates

fyi--how does this play into our own CPS--let me know when your meeting is tomorrow but what I'd really like is a readout on it

----- Forwarded by Maria Echaveste/WHO/EOP on 11/30/98 04:44 PM -----

**LESLIE
BERNSTEIN**
11/30/98 03:16:24 PM



Record Type: Record

To: Maria Echaveste/WHO/EOP
cc:
Subject: Phthalates

I don't know if I told you, but I've been receiving updates from ENDS (a European environmental policy journal) on the EU's actions on this issue. It's probably easiest if I just email this to you. If your interest (or that of Europe's...) has waned, let me know and I'll cease and desist.

Here's today's update:

EU phthalates ban back on the agenda
ENDS Daily - 30/11/98

The potential for children to be harmed by phthalate softeners used in PVC toys remains a cause for concern, an EU scientific committee said on Friday. The opinion is expected to lead to renewed pressure on the European Commission to propose an emergency ban on the use of two phthalates in PVC toys.

The EU committee on toxicity, ecotoxicity and the environment gave its first opinion on phthalate migration from toys to children's saliva in April (ENDS Daily 29 April). EU consumer protection commissioner Emma Bonino then pushed unsuccessfully for the EU to institute an emergency

ban on phthalates (ENDS Daily 12 June). She failed to achieve the backing of other commissioners by just one vote, Commission sources now say.

The committee's revised opinion will strengthen Ms Bonino's hand if she proposes emergency action once more, according to sources. "The review is definitely showing that this stuff is not safe," one told ENDS Daily.

Requested as an update on new evidence, the committee's opinion is not radically different from its earlier one. However, it continues to suggest that children could ingest quantities of two phthalates above the main safety threshold of one-hundredth of the "no observed adverse effects level" or NOAEL.

For DINP - the main phthalate used in PVC toys - the committee has revised its assessment to give a greater margin of safety - 75 compared with just 8.8 in its April opinion. The finding "still raises some concern" since it remains below the threshold of 100, the committee stresses.

The committee has revised its opinion the other way for another phthalate, DEHP. Following publication of a study suggesting that the substance can cause testicular cancer in mice and rats, the committee assesses the margin of safety for DEHP at 19, compared with 67 in April. Margins of safety for another four phthalates - BBP, DNOP, DIDP and DBP, were between 380 and 26,000, and therefore not a cause for concern, the committee added.

Reacting to the committee's opinion today, Greenpeace called on Emma Bonino to "urgently propose an EU-wide emergency ban on soft PVC toys for children under three". An increasing number of national governments were taking action, Greenpeace said, as well as toy manufacturers and retailers. Ms Bonino would show that she was "politically ruined" if she did not take action now.

Toy industries of Europe, however, suggested that the committee's opinion revealed "nothing new," and that there was therefore no more evidence for banning phthalates now than there had been in the spring. The association also stressed that DEHP was almost never used to soften PVC toys.

Contacts: European Commission (<http://europa.eu.int/comm>), tel: +32 2 295 1111; Greenpeace (<http://www.greenpeace.org>), tel: +31 20 523 6222; Toy Industries of Europe, tel: +32 2 732 7040. References: The committee's opinion is to be posted on the web site of the Commission's consumer protection directorate, DGXXIV (<http://europa.eu.int/comm/dg24/index.html>).

AGENDA FOR MEETING ON TOYS
November 30, 1998

I. Background

There have been recent allegations by environmental and health groups (led by Greenpeace and the National Environmental Trust) that the Department of Commerce has lobbied the European Union to prevent it from banning the sale of toys containing chemicals called phthalate that are harmful to children. Phthalates are used in toys, teething rings, and pacifiers to soften plastic. The allegations have provoked intense media interest and significant public concern, and have raised two issues: (1) how to respond to claims that the Department of Commerce -- responding to requests by US toy manufacturers -- improperly influenced the European Union's recent decision not to ban the chemicals in Europe; and (2) what action to take given widespread concern about the danger to children from phthalates.

Scientific Evidence. According to the Consumer Product Safety Commission (CPSC), there is no definitive scientific evidence of danger to children who put products containing phthalates in their mouths. (The phthalate most widely used today is DINP. Another phthalate, DEHP, was voluntarily removed from these products in 1986 when research showed a danger to children, and DINP has been used since then in its place.)

There are two types of studies that have been done on phthalates: (1) studies to determine whether the chemicals actually leach or migrate to the bloodstream when a child sucks or chews on a product containing it; and (2) studies of the health effects of these chemicals once they have entered the bloodstream. According to the CPSC, studies on health effects have linked phthalates to liver and kidney damage and to certain types of cancer. At least one study looking at the risk of ingesting the chemical (a 1998 Dutch study) indicated that these chemicals can leach in unacceptable amounts, but other studies have shown no danger to children who mouth, suck, chew or bite products containing phthalates. *So if they did leach...?*

The CPSC has conducted ongoing research on this and is scheduled to release a new, comprehensive study (we believe on December 2). The study evaluates existing research on both migration and health effects and includes the results of new CPSC conducted research. We believe that the report will indicate that there is no compelling evidence of danger, but will recommend further research.

Action in Europe and Canada. After review of the existing science, the European Union determined that there was not sufficient evidence to impose a ban on phthalates in teething rings, pacifiers and toys. Several member countries have acted, including Denmark, Norway, Sweden, and Austria, which have imposed bans, and the Netherlands which has urged voluntary action.

Action in US. In response to extensive media attention (print and television) and public concern, Toys R' Us has removed all products containing DINP from their shelves. Lego and Nike have also pledged to remove phthalates from their products. An industry group, the American Council on Science and Health, has announced the formation of a blue ribbon ||

committee of independent scientists and physicians, chaired C. Everett Koop, to review all available scientific research on the safety of phthalate.

II. Issues Needing Immediate Attention

- A. Response to Release of CPSC Study
- B. Response to Congressional Letter to the President (attached)

III. Longer Term Issues

- A. Additional Scientific Studies
- B. US Coordination/Interaction with European Union

Congress of the United States
Washington, DC 20515

November 18, 1998

Hon. William Jefferson Clinton
President of the United States
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Mr. President:

Recently there have been allegations that the Administration may be attempting to block efforts by the European Union to protect children from a plastic additive used in toys and other products. We are writing to inquire whether these allegations are true.

According to news reports and numerous environmental and health organizations, the Department of Commerce is lobbying to prevent the European Union from banning the sale of toys made with phthalates, a chemical additive used as a softener in plastics. Some studies have indicated that phthalates used in soft polyvinyl chloride (PVC) baby toys leach out when children suck on them. Other studies suggest that in sufficient quantity, phthalate exposure is identified as causing hormonal disturbance, liver and kidney damage, and cancer.

The EU is considering the ban to reduce health risks to children based on studies undertaken by Dutch Ministry of Health, Welfare and Sport, the Netherlands' Health Protection Inspectorate, Greenpeace, and others. In 1998, a risk analysis of phthalates by the Dutch National Institute of Public Health and Environment found that "the resulting uptake by young children was estimated to approximate or exceed the tolerable daily intake," and the Chief Inspector for Health Protection recommended that retailers voluntarily withdraw soft baby toys from the market. A study by Brunel University in the United Kingdom identified other sources of phthalate exposure in food samples, river water, and printing inks and adhesives used in food packaging.

Several individual countries and companies are also acting to minimize risks of PVCs and its chemical additives. Austria, Sweden, Denmark, and Norway have initiated bans on toys containing phthalates. Lego and Nike have pledged a comprehensive phase-out of vinyl in all of their products.

We recognize that the science on phthalates is evolving and there is scientific uncertainty about the risks these compounds pose. Nevertheless, if the reports about the Department of Commerce's actions are accurate, we are very concerned that they represent an unwarranted intrusion into the ability of other countries to make their own decisions about public health risks.

Hon. William Jefferson Clinton
November 18, 1998
Page 2

During the 1993 NAFTA debates, U.S. Trade Representative Kantor wrote members of Congress that "each government may establish those levels of protection for human, animal or plant life or health that the government considers to be appropriate." In the context of the General Agreement on Tariffs and Trade negotiations, the Sanitary and Phytosanitary Standards (SPS) Agreement specifically recognizes that "the basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate," so long as protections are not used to create an unfair trade barrier. Application of these principles to phthalates would seem to require that the United States respect the EU's right to determine for itself an appropriate level of risk.

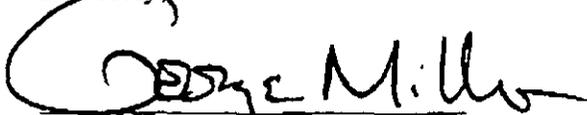
To help us better understand these issues, we ask you to provide the Administration's views on whether toys and other products made with phthalates are potentially hazardous to children's health and whether safe alternatives are available as a replacement. The Consumer Product Safety Commission is undertaking a study of phthalate exposure that will be released shortly. Will the Administration and relevant agencies consider aggregate exposure of phthalates to children in determining appropriate levels of risk and product safety? In addition, we request a detailed account of Administration actions with regard to the EU's proposed ban on toys made with phthalates. Did the Departments of Commerce or State lobby against the proposed ban?

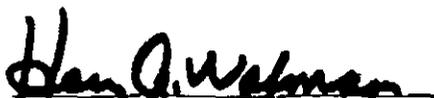
The Administration has taken the lead on protecting children. Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," which we strongly support, directs each federal agency to "ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks." Consistent with this objective, we urge you to take all necessary steps to ensure that children's toys and other products are safe for children.

It is our understanding that the EU and individual countries are considering this ban in order to protect children's health. It would be unfortunate if the United States found itself undermining these efforts for the benefit of toy company profits.

In advance, we appreciate your timely attention to these allegations and the serious nature of this issue.

Sincerely,


GEORGE MILLER, M.C.


HENRY A. WAXMAN, M.C.

Hon. William Jefferson Clinton
November 18, 1998
Page 3

Connie Morella
CONNIE MORELLA, M.C.

Wayne T. Gilcrest
WAYNE T. GILCREST, M.C.

George E. Brown Jr.
GEORGE E. BROWN, JR., M.C.

Maurice D. Hinchey
MAURICE D. HINCHEY, M.C.

Pete Stark
PETE STARK, M.C.

Dale E. Kildee
DALE E. KILDEE, M.C.

Max Sandlin
MAX SANDLIN, M.C.

Dennis J. Kucinich
DENNIS J. KUCINICH, M.C.

Sam Farr
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Frank Pallone Jr.
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Carolyn B. Maloney
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Thomas H. Allen
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Bernard Sanders
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Nita M. Lowey
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John W. Olver
JOHN W. OLVER, M.C.

Elizabeth Furse
ELIZABETH FURSE, M.C.

Jose E. Serrano
JOSE E. SERRANO, M.C.

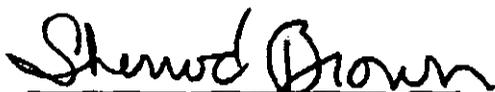
Lucille Roybal-Allard
LUCILLE ROYBAL-ALLARD, M.C.

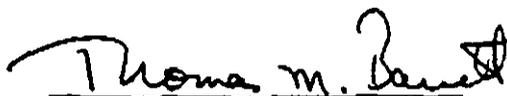
Barbara Lee
BARBARA LEE, M.C.

Hon. William Jefferson Clinton

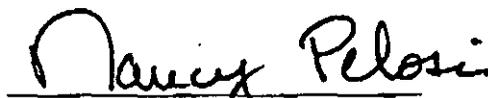
November 18, 1998

Page 4


SHERROD BROWN, M.C.


THOMAS M. BARRETT, M.C.


LLOYD DOGGETT, M.C.


NANCY PELOSI, M.C.

cc: Hon. William Daley, Secretary of Commerce
Hon. Ann Brown, Chairman, Consumer Product Safety Commission
Hon. Carol Browner, Administrator, Environmental Protection Agency

GEORGE MILLER
7TH DISTRICT, CALIFORNIA
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WASHINGTON, DC 20515-0507
(202) 225-2095
DANIEL WEISS
ADMINISTRATIVE ASSISTANT
COMMITTEE ON RESOURCES
COMMITTEE ON EDUCATION
AND THE WORKFORCE
VICE CHAIR
DEMOCRATIC POLICY COMMITTEE

Congress of the United States
House of Representatives
Washington, DC 20515-0507

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November 18, 1998

Hon. William Jefferson Clinton
President of the United States
The White House
1600 Pennsylvania Ave.
Washington, DC 20500

Dear Mr. President:

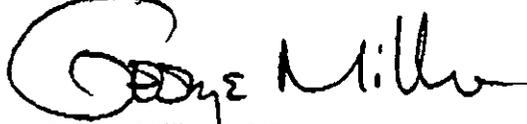
I inadvertently left out two names of Members of Congress who joined me today in writing to you concerning recent allegations that your Administration may be attempting to block efforts by the European Union to protect children from a plastic additive used in toys and other products.

Reps. Thomas Manton and Donna Christian-Green also agreed to sign the letter.

I regret this oversight and I would appreciate your adding their names to the list of those who signed the letter.

Thank you very much.

Sincerely



George Miller, M.C.

Cc: Hon. William Daley, Secretary of Commerce
Hon. Ann Brown, Chairman, Consumer Product Safety Commission
Hon. Carol Browner, Administrator, Environmental Protection Agency

Letter to Clinton on Toxic Toys 11/18/98

George Miller
Henry Waxman
Connie Morella
Wayne Gilchrest
George Brown Jr.
Maurice Hinchey
Pete Stark
Dale Kildee
Max Sandlin
Dennis Kucinich
Sam Farr
Frank Pallone
Martin Meehan
Carolyn Maloney
Lucille Roybal-Allard
Thomas Allen
Bernard Sanders
Nita Lowey
John Oliver
Elizabeth Furse
Jose Serrano
Barbara Lee
Sherrod Brown
Lloyd Doggett
Thomas Barrètt
Nancy Pelosi
Thomas Manton
Donna Christian-Green

Office of Congressman George Miller

July 1, 1998

The Vice President
The White House
Washington, DC 20501

Dear Mr. Vice President:

We are deeply concerned by recent reports that the Commerce Department, at the behest of U.S. toy manufacturers, has instructed U.S. diplomats to block efforts in Europe to control the use of a class of chemicals called "phthalates" in children's toys, chemicals that have been linked to a range of potentially serious health effects. These actions run contrary to Administration policy to "ensure that policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks" (Executive Order, April 21, 1997).

Commerce officials have explained their actions by pointing to the absence of a scientific consensus on the health risks associated with phthalates. Even as the Consumer Product Safety Commission has identified carcinogenic, developmental, and other physiological effects such as liver and kidney damage associated with various phthalates, no one disputes the need for more scientific information on this and a range of other toxic-related health issues. But as scientists and physicians we know all too well how science is manipulated by lobbyists and policymakers to delay action. We do not believe that precautionary protections for children should wait years until science renders a final judgment, especially where potential effects are serious and irreversible.

Recognizing that protecting children from certain risks should not wait for scientific certainty, your Administration signed the Food Quality Protection Act (FQPA) mandating specific protection factors for children when full health information about a chemical is lacking. And your Administration issued an executive order designed to protect children from health risks not just clear and present dangers.

Several European countries, after considering conclusive studies of health effects of phthalates in animals and proof of leaching from various products, have mandated controls of phthalates in children's products. These nations are merely recognizing the principle already embodied in the FQPA and your Administration's executive order that children deserve greater protection because their developing systems are more vulnerable to environmental insults and because any developmental impacts they might experience are irreversible. We hope the U.S. Government will respect the decisions of its trading partners when it comes to precautionary measures concerning matters of public safety, especially child safety.

Page Two

Here in the U.S., polls suggest that vast majorities of the American people believe that products and technologies should be proven safe before being placed in commerce. As you know, many of our regulations controlling toxic harms reverse this burden, requiring the public to prove that a product is harmful. With the FQPA and the children's health executive order, your Administration has taken the very first steps toward bringing our regulatory system more in line with the public's expectations. We hope your Administration will more vigorously implement the FQPA and the children's health executive order and take steps to ensure that all agencies follow the spirit and letter of these critically important policies. A good place to start would be to direct the Department of Commerce to end its campaign to protect U.S. toy companies at the expense of increasing a health risk to children.

Nicholas Ashford, Ph.D.
Professor of Technology and Policy
Massachusetts Institute of Technology

Devra Lee Davis, Ph.D.
Strang Cancer Prevention Center
Cornell Medical School

Peter deFur, Ph.D.
Virginia Commonwealth University

Cathey Falvo, MD, MPH
New York Medical Center

Erica Frank, MD
Emory University School of Medicine

Howard Frumkin, MD, DrPH
Rollins School of Public Health

Kenneth Geiser, Ph.D.
Director, Toxics Use Reduction Institute
University of Massachusetts, Lowell

Molly Tan Hayden, MD
Retired Pathologist

Guy Lanza, Ph.D.
Professor and Director, Environmental
Sciences Program
University of Massachusetts, Amherst

Michael McCally, MD, Ph.D.
Mt. Sinai School of Medicine

Peter Montague, Ph.D.
Executive Director
Environmental Research Foundation

Robert K. Musil, Ph.D.
Physicians for Social Responsibility

John Peterson Myers, Ph.D.
W. Alton Jones Foundation

Peter Orris, MD, MPH
Cook County Hospital

David Ozonoff, Ph.D.
Professor and Chair, Dept. of Environmental
Health
Boston University School of Public Health

Ted Schettler, MD, MPH
Boston Physicians for Social Responsibility

Ellen Silbergeld, Ph.D.
Director, Program in Human Health and the
Environment
University of Maryland
MacArthur Fellow

Allen Silverstone, Ph.D.
State University of NY Health Science Center
at Syracuse

Gina M. Solomon, MD, MPH
Natural Resources Defense Council

Abbey Strauss, MD
Private Practice

Tim K. Takaro, MD, MPH
University of Washington, School of
Medicine

David B. Wallinga, MD
Natural Resources Defense Council



Mattel, Inc.

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March 9, 1988

The Honorable William M. Daley
 Secretary of Commerce
 14th St. & Constitution Ave., NW
 Washington, DC 20230

Dear Secretary Daley:

I am writing to express Mattel's appreciation for the invaluable work being done by the European country desk of Commerce's Market Access and Compliance (MAC) office. Under the direction of Acting Deputy Assistant Secretary of Commerce for Europe Charles Ludolph, this office has been critical in helping the U.S. toy industry defend against recent EU initiatives to ban the use of polyvinyl chloride (PVC) in toys.

Reacting to Greenpeace allegations that lack scientific justification, several EU member states recently implemented unilateral restrictions on the sale of PVC toys and the European Commission is currently considering the possibility of an EU-wide ban. These actions threaten a European market that is of major importance to Mattel and other U.S. toy companies, who are the most competitive in the world. In 1987, toy sales by Mattel alone in Europe exceeded \$1 billion.

Over the past several months, Charles Ludolph and other MAC staff have responded to our requests for support and have taken the lead within the Administration in aggressively fighting these restrictive European actions. These Commerce efforts played a major role in a decision last week by the Emergency Committee of DG-XXIV to postpone a vote on imposing a ban on PVC toys. Had Ludolph and his staff not been there to take charge of this matter in the last few months, the U.S. toy industry interests would have been seriously jeopardized.

While the battle on this issue is far from over, I wanted to take this opportunity to thank you for the excellent service that your staff has provided U.S. industry to date on this important matter.

Sincerely,

Fermin Cuza
 Fermin Cuza
 sp830801

UNITED STATES REPRESENTATIVE
TO THE
EUROPEAN UNION

27 February, 1998

Dear Mr. Bessler:

I am writing to you today to alert you to the concerns my Government has about the upcoming Product Safety Emergency Committee meeting on March 3, 1998, and any action it might take to ban products containing phthalates. I understand that the Committee will review the work of the Scientific Committee on Toxicity, Ecotoxicity, and the Environment with a view toward making a determination of the risks involved in exposure to phthalates, the substance used to soften vinyl, as found in toys, blood bags, IV medical systems and numerous other products.

We are very much concerned about all health issues, and would not want to suggest that the EU or its Member States should not take very precaution to protect the safety and well being of its citizens. However, a substantial body of research leaves few, if any unanswered questions about risk from phthalates. It is a product that has been used widely and safely over a long period in a number of products. I understand that scientific studies are underway in Europe, but are not yet concluded, and that work also continues on an internationally accepted standardized test for phthalate toxicity.

The United States is prepared to have both its industry and its governmental experts cooperate fully with their EU counterparts in analyzing any risks involved with phthalates, and, in fact, at least one video conference between EU product safety officials and those of my government has already taken place.

However, I would like to advise you of my concern that the Product Safety Emergency Committee, using authority under Directive 92/59, might invoke an interim 90 day ban on phthalates, based on conflicting scientific evidence. This is particularly troublesome as extensive testing in the United States has not revealed a health risk from phthalates. The sudden ban on products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the United States and the European Union. It could also weaken consumer support for product safety processes on both sides of the Atlantic.

I therefore, I respectfully request that all haste be taken to undertake a thorough investigation of the issue, and that United States officials and industry be given the opportunity to present scientific evidence we have compiled. Further I ask that any decision, even an interim one, to ban products containing phthalates only be taken after the thorough objective, scientific review of all the evidence.

I appreciate you taking this matter under consideration and I look forward to having my staff work with the Commission on investigating this matter.

Sincerely yours,



A. Vernon Weaver
Ambassador

Mr. Hans Besler
Directorate-General
Commission of the
European Communities,
Brussels

cc: Mr. Stefano Micossi
Mr. James Carris
Mr. Horst Reichenbach

Jan -

How are we doing
on this? There's an
article in Friday's
Times too. RESIDENT HAS SEEN
11-16-98

Eleve

cmu pro-vinyl toys

THE NEW YORK TIMES, SUNDAY, NOVEMBER 15, 1998

Podesta/Mau
What's this about?
Pls check out advice

Is This a Test Group for Chemical Experiments?



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The Clinton-Gore Administration Seems to Think So.

Babies put toys in their mouths, then chew and suck on them.

So why is a class of dangerous chemicals still permitted in teething rings, rattles and other infant toys? Chemicals that can leach into the mouths of children.

And why has the Clinton-Gore Administration not only done nothing to protect American children from this group of chemicals, but also tried to prevent action by health officials across Europe?

The story begins with a plastic called PVC. Some companies use it to make soft plastic toys. Though safer, alternative materials are available—including other plastics—PVC is cheap.

Unfortunately, recent laboratory tests confirm that PVC teething rings and toys, when exposed to saliva, can leach up to seven times acceptable levels of toxic compounds called phthalates (*thAL-ates*).

The phthalates most commonly used in toys have been consistently linked to organ damage and possibly cancer. Measured by weight, these toxic compounds can account for as much as 40 percent of some PVC toys.

The presence of phthalate softeners is just one of the problems with PVC. The Attorneys General of eleven states are cooperating in a joint investigation of lead and cadmium levels in PVC toys. These toxic metals can also migrate into children's mouths.

Based on the latest research (part of a growing body of worldwide data on the danger of phthalates), a ban on these additives in PVC baby toys was recently announced in Austria, Denmark and Sweden. Voluntary withdrawals from store shelves have been requested by government health officials in Germany, Holland and Belgium. And the Spanish government has requested consideration of Europe-wide restrictions.

So why has the Clinton-Gore Administration tried to scuttle these important consumer health actions?

By their own admission, the U.S. Commerce and State Departments have aggressively lobbied to prevent passage of any health restrictions on PVC toys in Europe. According to their own memoranda, Commerce and State Department officials embarked on a crusade to protect the continued sale of these products in at least 18 foreign nations.

They've admitted they acted at the request of "major U.S. toy manufacturers" including Mattel, as well as the trade association that represents the U.S. toy industry.

Why? As Mattel stated in a memo to Commerce Secretary William Daley:

"These actions [health restrictions] threaten a European market that is of major importance to Mattel and other U.S. toy companies."

What must worry lobbyists for toy manufacturers is that if Europe bans these chemicals, the American public will demand the same safety standards.

We suggest the Secretary of Commerce read the Executive Order on children's health issued by President Clinton on April 21, 1997. It states:

"Each Federal agency shall ensure that its policies, programs, activities and standards address disproportionate risks to children that result from environmental health risks or safety risks."

President Clinton and Vice President Gore, why is your Administration protecting toy companies rather than the children who play with their products?

Alliance to End Childhood Lead Poisoning • Center for International Environmental Law
Children's Health Environmental Coalition • Consumer Federation of America • Environmental Working Group
Greenpeace USA • Learning Disabilities Association • National Consumers League
National Council of the Churches of Christ USA • National Environmental Trust
Physicians for Social Responsibility • United Methodist Church (General Board of Church and Society)
U.S. Public Interest Research Group • Canadian Institute of Child Health

Friday 30 October 1998

New phthalate migration tests launched

Next article**Previous article**

Two new test methods for predicting how fast phthalate softeners are likely to leach from PVC toys to young children's saliva provide an "important advance" in assessing the risks of phthalates in toys, according to the independent UK laboratory that has developed them.

The Laboratory of the Government Chemist (LGC) says the two tests "represent a solid basis for reaching a common European approach" for testing phthalate migration. Furthermore, the same tests could also be used to measure migration of any other organic chemical. The tests are a "significant step forward" according to Julian Braybrook of the laboratory, because they are backed by a detailed scientific protocol that can be followed by other laboratories. Details of the methods have been sent to official laboratories around the EU, he told ENDS Daily.

Publication of the UK test methods follows completion of a Dutch method in September ([ENDS Daily 22 September](#)). This filled key gaps in knowledge about phthalate migration; specifically how long children actually suck or chew on articles such as teething rings that can contain phthalates, and how fast phthalates leach from items to actual people rather than in laboratory tests.

The LGC claims that its methods are an advance on the Dutch one, partly because they can be copied, but also because migration tests it has performed using the methods have been more comprehensive. Whereas only one phthalate-softened PVC product and one phthalate compound were tested in the earlier study, the LGC has tested two phthalates and five products, according to Dr Braybrook. The laboratory now plans to test a further 12 products.

The broader range of tests performed also advances understanding of the actual likely risks of phthalate migration, according to the LGC. The laboratory says that the tests it has carried out suggest similar phthalate migration levels to those found in the Dutch study, but more firmly.

If further tests confirm the picture then the test could have significant policy implications. The European Commission is drafting a directive on phthalate migration risks that would ban articles with migration levels above limits suggested by an EU scientific committee this spring.

Based on tests carried out so far, Dr Braybrook said, "we are not seeing products that fail the limits set by the Commission". If further research gives similar results, and if the Commission's guidelines for safe migration levels remain unchanged, then a future EU directive on phthalate migration would have little or no effect on the market. Furthermore, EU member states planning unilateral action against PVC baby toys would likely face EU pressure to rescind the measures.

Contacts: Laboratory of the Government Chemist, tel: +44 181 943 7000.

Thursday 6 August 1998

Denmark bans phthalates in children's toys

Next article

Previous article

Denmark has become the second EU country in as many months to decide to ban the use of phthalate plasticisers in toys and child-care articles for children under three years. The ban, due to take effect from November, will effectively rule out the use of soft PVC in such items, prompting complaints from Denmark's PVC industry that it is based on "emotion and politics" rather than science.

The Danish government's decision was notified to the EU on Tuesday. It follows a recommendation from the European Commission last month that member states should decide for themselves whether regulatory measures against phthalates are necessary after assessing their health risks ([ENDS Daily 1 July](#)). The recommendation was issued after Commissioners decided there was insufficient scientific justification for an EU-wide ban.

But Denmark's ban goes further than the Commission's recommendation in two ways. It applies to all toys and child-care articles for children - whether or not they are intended to be placed in the mouth. The Commission envisaged possible action only against toys intended to be sucked, such as teething rings.

It also bans the use of all phthalates, not just the two widely used chemicals - DEHP and DINP - that the Commission highlighted as giving cause for concern because of their relatively high rates of migration from toys when sucked. Lisbet Seedorff, head of the Danish Environmental Protection Agency's chemicals division, told ENDS Daily: "We are covering all phthalates because maybe tomorrow a new one will be used and we will have to start [this process] all over again."

In addition, the EPA says it is "still sensitive to the risks associated with toys for children over the age of three". It will continue to investigate whether there is a need for additional action.

The Danish toy industry says it has already voluntarily replaced most soft PVC toys for children under three in expectation of the EPA's decision. The PVC Information Council - the industry's trade association in Denmark - also says the decision "comes as no surprise".

The council's General Manager, Ole Grøndahl Hansen, said the EPA had essentially rejected the argument that restrictions on phthalates should be based on an assessment of their migration rate from toys when sucked. He also questioned whether there had been an adequate risk assessment of the materials likely to replace soft PVC.

He told ENDS Daily: "If you can use the precautionary principle with such thin arguments as you have in this case, then it can be very serious for society in the future - if we can ban everything, every chemical with such thin arguments."

Contacts: Danish EPA, tel: +45 32 66 01 00.

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Los Angeles Times

AT

Thursday
May 28
1998

U.S. Urges European Union to Avert Toy Restrictions

■ **Trade:** Firms protest efforts to ban some chemicals. Studies suggest they may cause medical problems.

By JAMES GERSTENZANG
TIMES STAFF WRITER

WASHINGTON—The Clinton administration, acting at the behest of Mattel Inc. and other toy companies, is lobbying against European efforts to ban controversial chemical compounds from teething rings and other toys for young children.

With the European Union nearing a decision on whether to prohibit the sale of toys made with polyvinyl chloride, or PVC, the Commerce Department has instructed U.S. diplomats to try to turn around several such bans already in effect.

The toy companies are concerned about the potential ban because of the eventual negative impact it

could have on their sales in the United States—as well as the immediate impact it could have on their sales in Europe.

At issue are compounds known as phthalates (pronounced thalates). They are softening components that provide a spongy, chewy feel when added to plastics. They also help plastics absorb the reds and yellows and other bright colors that children find appealing.

Among the compounds that would be banned is one that has been voluntarily left out of U.S. products for 13 years. But other compounds targeted by the European Union are key components of toys and other plastic products made and sold in this country.

Please see TOYS, A9

[\[Next Page\]](#) [Return To The PVC Page\]](#)

**CPSC Staff Activities to Assess the
Risk of Chronic Toxicity Associated with
Exposure to Diisononyl Phthalate (DINP) in
Children's Polyvinyl Chloride (PVC) Products**

I. Background

o The U.S. Consumer Product Safety Commission is investigating the potential exposure and health risks to children under three years of age from teething rings, pacifiers, rattles, and toys that are made from polyvinyl chloride (PVC) containing various dialkyl phthalate (DAP) plasticizers. Plasticizers are used by manufacturers to soften the PVC.

o In 1983, the Commission investigated the use of di(2-ethylhexyl) phthalate (DEHP), that was used as a plasticizer in children's products. At that time, the Commission staff concluded that DEHP should be considered a probable human carcinogen based on the findings that it caused cancer in animals. This conclusion was supported by a Chronic Hazard Advisory Panel of non-CPSC scientists. At that time, manufacturers voluntarily removed DEHP from pacifiers, teething rings, and rattles.

o Manufacturers replaced DEHP with another phthalate known as diisononyl phthalate (DINP). Over the past year, the Commission along with several European countries, the European Union, and Canada have been assessing the potential health risks to children resulting from the use of DINP.

II. Current Activities

o The CPSC staff is evaluating various children's products and the available scientific literature. Staff is:

- measuring the release (migration rate) of DINP through laboratory tests intended to simulate mouthing behaviors of young children and by using human subjects,

- evaluating the observational behavior study conducted by the Dutch Consensus Group to estimate the amount of time each day that a child would mouth the products under question, and

- evaluating all existing noncancer and cancer health effects data.

✓ | o The CPSC staff's evaluation will be completed within the next two weeks. At that time, the Commission will issue its report and announce its conclusions.

o The report will also provide information to consumers about the safety of the product and will describe future plans by CPSC to study this issue further.

Los Angeles Times

A1

Thursday

May 28

1998

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Among the compounds that would be banned is one that has been voluntarily left out of U.S. products for 13 years. But, other compounds targeted by the European Union are key components of toys and other plastic products made and sold in this country.

Please see TOYS, A9

Continued from A1

At least one Danish study has suggested that some phthalates, which are used not only in toys but in the strong plastic bags that contain intravenously-delivered medications and blood, may cause cancer, disrupt endocrine function or weaken immune systems. Other studies have raised similar concerns and suggested they may also cause liver and kidney damage and disruptions in reproduction, including lowered sperm counts.

But the studies were conducted only on animals, and it is unclear what impact, if any, the chemicals have on people.

No study has replicated the initial Danish study, said David Miller, president of the Toy Manufacturers of America. "The science is not in that direction," he said in an interview. "The science is on our side."

Miller's group represents the makers and importers of 85% of the toys sold in the United States, 20% of which are made of vinyl.

Enough questions have been raised about one chemical,

that the EU countries' actions are having a negative effect on the marketing of these products absent of any scientific-based information. The U.S. has found no apparent health hazard related to plasticizers used in toys, and, in fact, information received from other countries completely contradicts the need for these actions," the department said in the cable.

Sean Fitzgerald, Mattel's vice-president for corporate communications, said Wednesday the El Segundo-based company had contacted the Commerce Department, along with representatives of the chemical and plastics industries and the toy manufacturers' association, seeking support in their opposition to a European ban.

Officials in the European Union administrative bureaucracy "are approaching this issue without solid information and they're approaching it from a reactionary basis," he said. "There has never been a formalized test that accurately duplicates the chewing process or sucking process of little kids on toys."

diethylhexylphthalate, or DEHP, that manufacturers voluntarily took it out of the formula for the plastics used in children's toys in 1985, substituting another phthalate.

"There's not the definitive study that says we've got to stop manufacturing these things, but there's growing evidence and growing concern that we're doing a global experiment on children by dramatically altering the chemical environment," said Michael McCally, a public health physician and a professor in the department of public health and preventive medicine at the Mt. Sinai Medical School in New York.

U.S. Wants 'Objective Scientific Evidence'

Charles Ludolph, a deputy assistant secretary of Commerce responsible for European affairs, said the U.S. position is that "decisions on a threat to health

should be based on objective scientific evidence." He said the administration wants the Europeans to delay any decision until they can study a report that the U.S. Consumer Product Safety Commission is expected to complete next month on phthalates.

But Jeff Wise, policy director of the National Environmental Trust, which describes itself as a national public education group focusing on environmental issues, said: "There's always more science you can do. There's enough science to indicate there is concern."

A decision by the 15-nation European Union could come as early as next week.

In December, the Commerce Department sent a cable to embassies throughout western Europe, saying it had been contacted by "representatives of one of the leading U.S. toy manufacturers ... in an effort to rectify a problem regarding the marketing of certain PVC toys placed on the market in the EU."

"The U.S. remains concerned

In March, Mattel hired a leading Washington lobbying firm to fight legislation that would require disclosure of chemicals used in children's products, according to a newsletter on lobbying. Federal election reports show that Mattel contributed \$85,000 to various Democratic Party committees in 1997 and \$25,000 to Republican Party committees.

European Efforts Gather Steam

In addition to the proposed restrictions throughout the European Union, Austria, Belgium, the Netherlands and Denmark have taken steps to remove these products from the marketplace, and others might follow, said the Commerce Department cable.

A. Vernon Weaver, the U.S. ambassador to the European Union, recently wrote to Hans Beseler, the senior EU administrative officer, warning that "the sudden ban on

products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the United States and the European Union."

"The U.S. government is expending a fairly large amount of energy and time on behalf of the toy industry," said Rick Hind, legislative director of the toxics campaign run by the environmental group Greenpeace. He said other softening agents can be substituted safely for the phthalates.

Hind complained in a letter to Commerce Secretary Bill Daley that the department's position is "inconsistent with U.S. regulations" and with a presidential executive order instructing government agencies to make sure their "policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."

Researcher Tricia Ford contributed to this story.

The Washington Post

FRIDAY, MAY 29, 1998 F3

U.S. Toymakers Battle EU Over Plastic Playthings

By BETH BRASELLI
Washington Post Staff Writer.

The European Union next week may impose a temporary ban on children's toys containing a controversial chemical compound, prompting a fierce counter-offensive by U.S. toy manufacturers who fear any European action will damage sales in the United States and overseas.

Toymakers have enlisted the Clinton administration to join their campaign to help block the EU action. The Commerce Department has coaxed U.S. diplomats to lobby against the proposal.

As early as next Wednesday, the 12-nation EU will vote to prohibit the sale of certain children's toys made from a plastic called polyvinyl chloride, or PVC. But the toymakers contend that the EU is acting on uncertain scientific evidence.

At issue is a group of chemicals known as phthalates. These compounds are added to plastic toys such as teething rings and pacifiers to

make them soft and spongy and give them a chewy feel.

Studies involving laboratory animals have linked phthalates to liver and kidney disorders, damage to the reproductive tract and increased incidence of certain kinds of cancer. These findings have prompted some European countries, including Austria, the Netherlands and Belgium to take steps to remove these soft plastic toys from store shelves. In the mid-1980s, U.S. toy manufacturers voluntarily agreed to remove one kind of phthalate—diethylhexyl-phthalate, or DEHP—from the formula for plastics used in children's toys.

The EU, however, is considering a 90-day ban on selling plastic toys that contain two kinds of phthalates—DEHP and dibutyltinyl phthalate, or DINP. Toy manufacturers, along with representatives of the chemical and plastics industries, are vigorously fighting the measure.

"Our concern as a company is that the actions of a handful of individuals

within the European Union are based on questionable scientific evidence," said Sean Fitzgerald, vice president of corporate communications at Mattel Inc.

"This could have a huge effect on our business," Fitzgerald said, pointing out that Europe is Mattel's largest market outside North America. "But the processes [in the tests] that have been used are in question. There has been no formalized testing procedure that replicates the actual chewing process."

The U.S. Consumer Product Safety Commission is conducting its own tests to assess what, if any, risk the phthalates pose. Toymakers and Commerce Department officials are urging the EU to wait for those results before making any decision. The CPSC said the study should be completed in the next several weeks.

"The U.S. remains concerned that the EU countries' actions are having a negative effect on the marketing of these products absent of any scientific-based information," the Commerce

Department wrote in December in a cable sent to embassies throughout western Europe. "The U.S. has found no apparent health hazard related to plasticizers used in toys."

But critics of soft plastic toys say there is plenty of scientific data showing these are potentially dangerous products. "There is enough science to say it's questionable, so let's not put it in our children's mouth," said Rick Hind, legislative director of the toxics campaign run by the environment group Greenpeace. "We shouldn't have our infants turned into guinea pigs."

In the past year, Greenpeace has lobbied hard against soft plastic toys, conducting several studies to show the risk posed by these products.

Fitzgerald and other toy industry officials blasted Greenpeace for unnecessarily alarming consumers, saying it is just interested in gaining publicity.

Staff writer Carolina Mayer contributed to this report.

July 1, 1998

The Vice President
The White House
Washington, DC 20501

Dear Mr. Vice President:

We are deeply concerned by recent reports that the Commerce Department, at the behest of U.S. toy manufacturers, has instructed U.S. diplomats to block efforts in Europe to control the use of a class of chemicals called "phthalates" in children's toys, chemicals that have been linked to a range of potentially serious health effects. These actions run contrary to Administration policy to "ensure that policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks" (Executive Order, April 21, 1997).

Commerce officials have explained their actions by pointing to the absence of a scientific consensus on the health risks associated with phthalates. Even as the Consumer Product Safety Commission has identified carcinogenic, developmental, and other physiological effects such as liver and kidney damage associated with various phthalates, no one disputes the need for more scientific information on this and a range of other toxic-related health issues. But as scientists and physicians we know all too well how science is manipulated by lobbyists and policymakers to delay action. We do not believe that precautionary protections for children should wait years until science renders a final judgment, especially where potential effects are serious and irreversible.

Recognizing that protecting children from certain risks should not wait for scientific certainty, your Administration signed the Food Quality Protection Act (FQPA) mandating specific protection factors for children when full health information about a chemical is lacking. And your Administration issued an executive order designed to protect children from health risks not just clear and present dangers.

Several European countries, after considering conclusive studies of health effects of phthalates in animals and proof of leaching from various products, have mandated controls of phthalates in children's products. These nations are merely recognizing the principle already embodied in the FQPA and your Administration's executive order that children deserve greater protection because their developing systems are more vulnerable to environmental insults and because any developmental impacts they might experience are irreversible. We hope the U.S. Government will respect the decisions of its trading partners when it comes to precautionary measures concerning matters of public safety, especially child safety.

Page Two

Here in the U.S., polls suggest that vast majorities of the American people believe that products and technologies should be proven safe before being placed in commerce. As you know, many of our regulations controlling toxic harms reverse this burden, requiring the public to prove that a product is harmful. With the FQPA and the children's health executive order, your Administration has taken the very first steps toward bringing our regulatory system more in line with the public's expectations. We hope your Administration will more vigorously implement the FQPA and the children's health executive order and take steps to ensure that all agencies follow the spirit and letter of these critically important policies. A good place to start would be to direct the Department of Commerce to end its campaign to protect U.S. toy companies at the expense of increasing a health risk to children.

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March 9, 1998

The Honorable William M. Daley
 Secretary of Commerce
 14th St. & Constitution Ave., NW
 Washington, DC 20230

Dear Secretary Daley:

I am writing to express Mattel's appreciation for the invaluable work being done by the European country desk of Commerce's Market Access and Compliance (MAC) office. Under the direction of Acting Deputy Assistant Secretary of Commerce for Europe Charles Ludolph, this office has been critical in helping the U.S. toy industry defend against recent EU initiatives to ban the use of polyvinyl chloride (PVC) in toys.

Reacting to Greenpeace allegations that lack scientific justification, several EU member states recently implemented unilateral restrictions on the sale of PVC toys and the European Commission is currently considering the possibility of an EU-wide ban. These actions threaten a European market that is of major importance to Mattel and other U.S. toy companies, who are the most competitive in the world. In 1997, toy sales by Mattel alone in Europe exceeded \$1 billion.

Over the past several months, Charles Ludolph and other MAC staff have responded to our requests for support and have taken the lead within the Administration in aggressively fighting these restrictive European actions. These Commerce efforts played a major role in a decision last week by the Emergency Committee of DG-XXIV to postpone a vote on imposing a ban on PVC toys. Had Ludolph and his staff not been there to take charge of this matter in the last few months, the U.S. toy industry interests would have been seriously jeopardized.

While the battle on this issue is far from over, I wanted to take this opportunity to thank you for the excellent service that your staff has provided U.S. Industry to date on this important matter.

Sincerely,

Ferrin Cruz
 Ferrin Cruz
 sp830801

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DUBLIN, LUXEMBOURG, LISBON, MADRID, STOCKHOLM

USEC FOR SCO MU

N/A

BEXP, BE, EEC

USG CONCERNS OVER REGULATION OF TOYS MADE
OF POLYVINYL CHLORIDE (PVC).

1. THIS IS AN ACTION CABLE. PLEASE SEE PARA. 6.
2. REPRESENTATIVES OF ONE OF THE LEADING U.S. TOY MANUFACTURERS HAVE CONTACTED THE COMMERCE DEPARTMENT IN AN EFFORT TO RECTIFY A PROBLEM REGARDING THE MARKETING OF CERTAIN PVC TOYS PLACED ON THE MARKET IN THE EU.
3. IN APRIL 1997, DENMARK'S ENVIRONMENTAL PROTECTION AGENCY RECOMMENDED THAT CERTAIN FLEXIBLE PVC TEETHING RINGS BE WITHDRAWN FOR THE DANISH MARKETPLACE. ALTHOUGH THERE HAS BEEN NO SCIENTIFIC EVIDENCE TO PROVE ANY DANGER FOR THE HEALTH AND SAFETY OF THE CHILD, THE DANISH MAINTAIN THAT THERE IS A POSSIBILITY OF NEGATIVE TOXIC EFFECTS TO BABIES STEMMING FROM THE PHTHALATES FOUND IN

PVC. IN ADDITION, IT IS REPORTED THAT THE DANISH AUTHORITIES ARE CURRENTLY PREPARING LEGISLATION BANNING THE USE OF PHTHALATES IN CERTAIN TYPES OF TOYS AND CHILD RELATED PRODUCTS FOR CHILDREN UNDER 36 MONTHS OF AGE.

4. IN JULY, THE NETHERLANDS MINISTRY OF HEALTH HAS ALSO URGED TOY IMPORTERS AND DISTRIBUTORS NOT TO MARKET SOFT PVC TOYS FOR BABIES.

5. IN AUGUST, THE BELGIAN MINISTRY OF HEALTH SENT A NOTICE TO RETAILERS ASKING THAT THEY VOLUNTARILY DISCONTINUE MARKETING PVC TOYS FOR CHILDREN UNDER THREE YEARS OF AGE. IN OCTOBER, THE HEALTH FEDERAL MINISTER CONFIRMED THIS ACTION AND RECOMMENDED THAT RETAILERS TAKE ACTION IMMEDIATELY.

6. IN DECEMBER, THE AUSTRIAN GOVERNMENT IS EXPECTING TO RELEASE A DRAFT REGULATION REGARDING THE USE OF PVC IN TOYS FOR CHILDREN UNDER 36 MONTHS.

7. THE U.S. BELIEVES THAT THE MARKET RESTRICTIONS PLACE ON THESE PRODUCTS GO BEYOND THE SCOPE OF EXISTING TOY SAFETY STANDARDS. THE U.S. AND EU APPLY IDENTICAL SAFETY STANDARDS OF SOLUBLE LEAD AND SOLUBLE CADMIUM IN TOYS. IN THE CASE OF THE U.S. PHTHALATES ARE LIMITED TO UNDER 3 PERCENT IN PACIFIERS AND TEETHERS UNDER A VOLUNTARY STANDARD ESTABLISHED BY THE TOY MANUFACTURERS OF AMERICA (TMA).

8. IN THE U.S. THE CONSUMER PRODUCT SAFETY COMMISSION HAS PLAYED A PROMINENT ROLE IN PROTECTING THE PUBLIC, ESPECIALLY CHILDREN FROM THE HAZARDS OF EXPOSURE TO LEAD AND OTHER TOXIC CHEMICALS. IN 1996, CPSC CONDUCTED SEVERAL TESTS ON LEAD AND CADMIUM AND PLASTICISERS TO ENSURE THE SAFETY OF PVC IN TOYS AND OTHER HOUSEHOLD ITEMS. IN OCTOBER, 1997, THE CPSC REPORTED THAT THE OUTCOME OF THESE TESTS AND EVALUATIONS INDICATED THAT THESE PRODUCTS WERE NOT FOUND TO BE HAZARDOUS. HEALTH CANADA CONDUCTED THE SIMILAR TESTS AND REACHED THE SAME CONCLUSIONS

9. THE U.S. REMAINS CONCERNED THAT THE EU COUNTRIES ACTIONS ARE HAVING A NEGATIVE EFFECT ON THE MARKETING OF THESE PRODUCTS ABSENT OF ANY SCIENTIFIC BASED INFORMATION. THE U.S. HAS FOUND NO APPARENT HEALTH HAZARD RELATED TO PLASTICISERS USED IN TOYS, AND, IN FACT, INFORMATION RECEIVED FROM OTHER COUNTRIES COMPLETELY CONTRADICTS THE NEED FOR THESE ACTIONS.

10. WHILE THE U.S. GOVERNMENT IS TREMENDOUSLY CONCERNED ABOUT ISSUES INVOLVING HEALTH AND SAFETY, U.S.-EU TRADE HAS AND WILL CONTINUE TO BE ADVERSELY AFFECTED DUE TO THIS BAN. AUSTRIA, BELGIUM, THE NETHERLANDS, AND DENMARK HAVE ALREADY TAKEN STEPS TO REMOVING THESE PRODUCTS FROM THEIR SHELVES, AND IT IS IMPORTANT TO NOTE THAT OTHER EU COUNTRIES MIGHT ALSO TAKE SIMILAR STEPS RESULTING IN A ENORMOUS LOSS OF TRADE IN THESE AND SIMILAR PRODUCTS.

11. THROUGH THE EFFORTS OF THE TRANSATLANTIC BUSINESS DIALOGUE (TABD), THE UNITED STATES AND EUROPE ARE ATTEMPTING TO COMMERCIALY COOPERATE AND HARMONIZE STANDARDS RELATED TO THESE AND OTHER PRODUCT CATEGORIES. THEREFORE, THE ESTABLISHMENT OF A BAN IN EUROPE ON PRODUCTS THAT ARE IMPORTANT EXPORTS ONLY OBSTRUCTS THE PROGRESS OF THE TABD INITIATIVE AND UNDERMINES THE GOALS OF FREE TRADE. ALTHOUGH THE U.S. SUPPORTS EFFECTIVE MEASURE TO CONTROL AND/OR REDUCE EMISSIONS OF PRODUCTS IN ORDER TO PROTECT HUMAN HEALTH AND THE ENVIRONMENT, WE HAVE NEVER SUPPORTED AN OUTRIGHT BAN ON THESE PRODUCTS.

12. UNDER THE NEW TRANSATLANTIC INITIATIVE, THE US. AND EU HAVE COMMITTED OURSELVES TO STRENGTHENING REGULATORY COOPERATION BY ESTABLISHING AN ACTIVE AND ONGOING TECHNICAL DIALOGUE WITH REGULATORY AUTHORITIES. UNDER THE NTA, THE U.S. AND EU AGREED THAT THERE WOULD BE CONSULTATION IN THE EARLY STAGES OF DRAFTING REGULATIONS THEREBY ALLOWING EACH TO BETTER RELY ON THE OTHER'S TECHNICAL RESOURCES AND EXPERTISE. FINALLY, THIS WOULD EVENTUALLY MOVE TOWARDS THE HARMONIZATION OF REGULATORY REQUIREMENTS OR THE ESTABLISHMENT OF A MUTUAL RECOGNITION AGREEMENT FOR THAT PRODUCT.

13. ACTION REQUIRED. USEU - PLEASE PRESENT CONCERNS AND COLLECT INFORMATION FROM THE COMMISSION AND OTHER NECESSARY RESOURCES ON THIS MATTER. PLEASE EMPHASIZE THE NEED FOR UTILIZING THE FACETS OF THE REGULATORY COOPERATION AGREEMENT BETWEEN THE U.S. AND EU. IN ADDITION, USEU IS REQUESTED TO FIND OUT AND REPORT WHETHER THE EU OR SEPARATE MEMBER STATES ARE CONSIDERING SIMILAR ACTIONS.

14. ACTION REQUESTED. MEMBER STATES ARE ASKED TO ALSO REPORT FINDINGS RELATED TO THIS MATTER.

15. THE U.S. PROPOSES THAT AN IMMEDIATE MEETING BE HELD TO ESTABLISH A MECHANISM TO BEGIN WITHDRAWING EU BANS AND WARNINGS ON THESE AND OTHER SOFT PVC PRODUCTS IN TIME FOR

THE CHRISTMAS PURCHASING SEASON.

16. PLEASE SLUG RESPONSES TO DON WRIGHT, CHARLES LUDOLPH
AND KIM COPPERTHITE AT CABLE CODE 4211, 4210 AND 6332
RESPECTIVELY. THANK YOU IN ADVANCE.

UNCLASSIFIED

attention.

Helen - FYI

It's gone!

Di

UNCLASSIFIED
 COML 08/18/97
 EPCS:SBALLARD, ECOM:MGALLAGHER
 EPCS:OHLQVERSSON
 EPCS:HDELANEY
 COML

USEU BRUSSELS
 USDOC WASHDC, IMMEDIATE
 SECSTATE WASHDC, IMMEDIATE
 ALL EUROPEAN UNION POST COLLECTIVE, PRIORITY

USDOC FOR 3133/USFCS/OIO/JWILSON
 USDOC FOR 6320/TD/TAI
 USDOC FOR 4211/MAC/EUR/OEURA/LCOOPER
 USDOC PLS PASS/NIST/BCOLLINGS/RRENSBERGER/MGAUNDERS
 STATE FOR EB/CIP AND EUR/ERA
 STATE PLEASE PASS TO USTR/STROJE

E.O. 12958: N/A
 TAGS:ECPS, EUN, ETRD, KTRB

SUBJECT: REVP: EU PRODUCT SAFETY EMERGENCIES COMMITTEE MEETS
 ON MARCH 3 TO DISCUSS BAN ON TOYS CONTAINING PVC.

1. THIS IS AN ACTION REQUEST (SEE PARAGRAPH 3) WITH STRINGENT
 TIME LIMITS. POSTS ARE REQUESTED TO TAKE ACTION BEFORE CLOSE
 OF BUSINESS IN BRUSSELS ON MONDAY MARCH 2, I.E. 1100 HOURS
 EST.

2. MISSION HAS LEARNED THAT EUROPEAN COMMISSION DG-XXIV
 RESPONSIBLE FOR CONSUMER POLICY IS WORKING ON A PROPOSAL TO
 RESTRICT THE USE OF PVC IN CHILDREN'S TOYS OR EVEN BAN IT
 ALTOGETHER. RESPONDING TO CONCERNS RAISED BY EUROPEAN CONSUMER
 AND ENVIRONMENTAL INTEREST GROUPS THE ISSUE IS BEING DISCUSSED
 IN THE CONTEXT OF THE EUROPEAN UNION'S GENERAL PRODUCT SAFETY
 DIRECTIVE. TO DISCUSS THIS, THE COMMISSION HAS CALLED A
 MEETING ON MARCH 3 IN A SPECIAL EMERGENCY COMMITTEE WHICH
 CONSISTS OF PRODUCT SAFETY EXPERTS FROM ALL EU MEMBER STATES.
 WE UNDERSTAND NO VOTE WILL BE CARRIED OUT ON MARCH 3 TO ISSUE
 A BAN, BUT OPINIONS RAISED WILL INFLUENCE FUTURE DECISION ON
 THE MATTER, WHICH COULD BE TAKEN AS SOON AS LATE MARCH. USEU
 AMBASSADOR HAS WRITTEN A LETTER TO THE DIRECTOR GENERAL OF THE
 EU'S DIRECTORATE GENERAL I (EXTERNAL RELATIONS), WITH COPIES
 TO DIRECTOR GENERALS OF DG-III (INDUSTRY), DG-XXI (CUSTOMS) AND
 DG-XXIV (CONSUMER POLICY). IN THAT LETTER THE AMBASSADOR
 POINTS OUT PROBLEMS OF INVOKING AN INTERIM BAN BEFORE A
 CONCLUSIVE INVESTIGATION HAS BEEN COMPLETED. COPY OF THE

AMBASSADOR'S LETTER WILL BE SENT OUT TO ALL ADDRESSEES.

3. ACTION REQUEST: IF WASHINGTON APPROVES, WE SUGGEST EUROPEAN UNION POSTS CONTACT NATIONAL AGENCIES AND OFFICIALS RESPONSIBLE FOR CONSUMER SAFETY TO EXPRESS CONCERN OVER THIS ISSUE ON BEHALF OF U.S. INDUSTRY. OF IMMEDIATE CONCERN ARE THE NATIONAL MEMBERS OF THE EU EMERGENCY COMMITTEE WHICH WILL MEET IN BRUSSELS ON MARCH 3. DUE TO TIME RESTRAINTS, POST WAS ONLY ABLE TO PARTLY ACQUIRE THE NAMES OF NATIONAL MEMBERS OF THE EMERGENCY COMMITTEE WHICH ARE LISTED BELOW. RELEVANT POSTS ARE ASKED TO CONTACT THESE INDIVIDUALS DIRECTLY BEFORE THE MARCH 3 MEETING.

4. POINTS TO KEEP IN MIND WHEN CALLS ARE BEING MADE: WE HAVE BEEN WORKING WITH TOY MANUFACTURERS ASSOCIATIONS ON BOTH SIDES OF THE ATLANTIC ON THIS ISSUE AND EXPRESSED CONCERN TO THE EUROPEAN COMMISSION ON BEHALF OF U.S. INDUSTRY. BOTH AMERICAN AND EUROPEAN INDUSTRIES CLAIM THAT THE DISCUSSION OF A BAN IS BASED ON HYPE RATHER THAN SCIENTIFIC EVIDENCE. VERY LITTLE SCIENTIFIC DATA SUPPORTS THE CLAIM FOR A BAN AND NO STANDARD TEST METHOD HAS BEEN ESTABLISHED TO MEASURE THE POTENTIAL HARM OF PVC IN TOYS. INDUSTRY THEREFORE SUGGESTS THAT NO DECISION SHOULD BE TAKEN ON PVC RESTRICTIONS IN TOYS UNTIL FURTHER SCIENTIFIC DATA IS AVAILABLE, WHICH WILL NOT BE BEFORE MID-1998.

5. NAMES OF INDIVIDUALS IN THE EU PRODUCT SAFETY EMERGENCIES COMMITTEE RESPONSIBLE FOR THE EU GENERAL PRODUCT SAFETY DIRECTIVE:

A) UNITED KINGDOM: MR PETER MASON, MINISTRY OF TRADE AND INDUSTRY, TEL 44 471 215 0379.

B) ITALY: DR SAVERIO LEONE, MINISTRY OF INDUSTRY, TEL 39 6 59941.

C) FRANCE: MR EUGENE JULIAN, HEAD OF QUALITY AND SAFETY, DGCCRFPS (GOVERNMENT AGENCY RESPONSIBLE FOR CONSUMER SAFETY), MISSION UNABLE TO PROVIDE A PHONE NUMBER AT THIS STAGE.

G) GERMANY: MR WIST, GERMAN ECONOMIC MINISTRY, TEL 49 228 615 4552.

H) THE NETHERLANDS: MR JAN VUAN LEENT, MINISTRY OF HEALTH, UNIT RESPONSIBLE FOR INSPECTION HEALTH PROTECTION, TEL 31 70 34 06 989.

ALL COMMITTEE MEMBERS LISTED ABOVE ARE BELIEVED TO BE PROPONENTS OF POSTPONING A BAN UNTIL FURTHER RESEARCH DATA IS AVAILABLE.

(DRAFTED: CS/OHLQVERSSON)WEAVER#

UNITED STATES REPRESENTATIVE
TO THE
EUROPEAN UNION

27 February, 1998

Dear Mr. Baseler:

I am writing to you today to alert you to the concerns my Government has about the upcoming Product Safety Emergency Committee meeting on March 3, 1998, and any action it might take to ban products containing phthalates. I understand that the Committee will review the work of the Scientific Committee on Toxicity, Ecotoxicity, and the Environment with a view toward making a determination of the risks involved in exposure to phthalates, the substance used to soften vinyl, as found in toys, blood bags, IV medical systems and numerous other products.

We are very much concerned about all health issues, and would not want to suggest that the EU or its Member States should not take very precaution to protect the safety and well being of its citizens. However, a substantial body of research leaves few, if any unanswered questions about risk from phthalates. It is a product that has been used widely and safely over a long period in a number of products. I understand that scientific studies are underway in Europe, but are not yet concluded, and that work also continues on an internationally accepted standardized test for phthalate toxicity.

The United States is prepared to have both its industry and its governmental experts cooperate fully with their EU counterparts in analyzing any risks involved with phthalates, and, in fact, at least one video conference between EU product safety officials and those of my government has already taken place.

However, I would like to advise you of my concern that the Product Safety Emergency Committee, using authority under Directive 92/59, might invoke an interim 90 day ban on phthalates, based on conflicting scientific evidence. This is particularly troublesome as extensive testing in the United States has not revealed a health risk from phthalates. The sudden ban on products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the United States and the European Union. It could also weaken consumer support for product safety processes on both sides of the Atlantic.

Therefore, I respectfully request that all haste be taken to undertake a thorough investigation of the issue, and that United States officials and industry be given the opportunity to present scientific evidence we have compiled. Further I ask that any decision, even an interim one, to ban products containing phthalates only be taken after the thorough objective, scientific review of all the evidence.

I appreciate you taking this matter under consideration and I look forward to having my staff work with the Commission on investigating this matter.

Sincerely yours,



A. Vernon Weaver
Ambassador

Mr. Hans Beauler
Directorate-General
Commission of the
European Communities,
Brussels

cc: Mr. Stefano Micossi
Mr. James Currie
Mr. Horst Reichsbach



Questions & Answers

Enforcement Action Against Hasbro, Inc., for Public Health Claims on Antibacterial Toys

1. What action is EPA announcing?

The U.S. Environmental Protection Agency (EPA) has reached an enforcement agreement that prevents Hasbro, Inc. manufacturer of Playskool toys, from claiming that toys treated with the antibacterial pesticide, Microban, protect children from infectious diseases caused by bacteria.

2. What is the basis for EPA's actions?

Hasbro recently introduced a new line of toys that make public health claims to protect children from germs and disease-causing bacteria, such as E. coli and Salmonella. The plastic material used in these toys is treated with the antibacterial pesticide, Microban, which is registered by EPA to inhibit bacterial growth in plastic. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), public health claims of products treated with pesticides cannot be made for any products distributed or sold unless the products themselves have been approved and registered by EPA or have been granted an exemption from registration. While Microban is registered with EPA to inhibit the growth of bacteria in plastic, neither Microban nor any toy containing Microban have been registered for a public health use. Nevertheless, Hasbro's promotional materials suggest that the toys will actually prevent the spread of disease-causing bacteria among children.

Hasbro's promotional material for the antibacterial line of toys claim "After a day of sharing, sneezing, mouthing and all the other messy things children encounter during play and learn time, parents will appreciate Microban antibacterial protection. It inhibits the growth of a broad range of bacteria (e.g., E. coli, Salmonella, Staph and Strep) as well as mold, mildew and fungus. Playskool toys with Microban antibacterial protection help provide a better environment in which children play and learn." EPA considers these statements to be public health claims.

-2-

Microban is registered by EPA to inhibit bacterial growth in plastic. Under provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, public health claims of products containing pesticides cannot be made for any products distributed or sold unless the products have been approved and registered by EPA or have been granted an exemption from registration. The toys were not registered by EPA.

Under terms of the agreement, Hasbro will take an immediate series of steps to inform the public about the claim, to be concluded within 90 days, including relabeling or repackaging all affected toys, as well as publish large (specified size) advertisements in USA Today newspaper, Parents, American Baby, Child, and Parenting magazines with the message that Microban is used to protect the plastic toy and inhibits the growth of bacteria on the toy. In a supplemental environmental project under the agreement, Hasbro also will also publish two full page advertisements in Parenting, Baby Talk, Child, and American Baby about protecting children from health risks related to lead-based paint in the home.

The nine Playmate toys are: Stack N Scoop Whale, Hourglass, Roll N Rattle Ball, Busy Beads Pal, Pop N Spin, Laptop, Rockin Radio, Sound Around Driver, and Animal Sounds Phone.

E-59

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3. Are toys treated with Microban safe considering the behavior of infants and toddlers, who are likely to chew or suck on them?

Yes. Our safety assessments show no evidence that this chemical, when used in the plastic material to make toys, poses a health risk to children, EPA's Enforcement action is based on Hasbro's distribution of products which make unsubstantiated public health claims.

4. What are the terms of the agreement?

Hasbro has agreed to take immediate steps to revoke earlier claims and to correct the information through advertisements in various print media and appropriate store and toy placarding. Hasbro has agreed on the following actions:

- * relabel products already produced (within 90 days of the agreement)
- * repackage all affected toys (within 6 weeks of the agreement)
- * display correctional placards in retail stores
- * publish correctional advertisements in USA Today, Parents, American Baby, Child, and Parenting magazines
- * publish two full-page advertisements in Parenting, Baby Talk, Child and American Baby regarding the health-risk related to children and lead-based paint in the home prior to December 31, 1997
- * pay a penalty of \$120,000.
- * correct misleading statements on 1800-PLAYSKOOL immediately

5. Does EPA know whether Playskool toys or other consumer products containing Microban are effective against "germs" as claimed?

No. EPA does not have information that demonstrates Microban's effectiveness against "germs" Microban is registered for use to protect plastic and textiles from the growth of bacteria which cause odors or deterioration of the products. Microban cannot claim to protect public health.

Under FIFRA, anytime Microban is added to plastic, the plastic may only be advertised as treated with Microban for the sole purpose of protecting the plastic itself. As a general rule, if a statement suggests to the consumer that a treated object will have any pesticidal benefits other than the protection of the product itself, the treated object must demonstrate effectiveness for that claim and must be approved by the Federal government to make such claims.

6. What is Microban and how is it used?

EPA registered Microban as a non-public health antimicrobial pesticide in the late 1980s and has approved its use in a variety of plastic and textile products to protect the product. It is used as a bacteriostatic agent (which means it prevents the growth of bacteria) for the protection and preservation of plastic material and textiles from the growth of bacteria which cause odors or deterioration of the plastic. Triclosan, the active ingredient in Microban, is added to plastic material in a concentrated form. This concentrated form is then marketed to other companies that manufacture plastic products (e.g., cutting boards, garbage pails, plastic toys, conveyor belts).

7. What Playskool toys are affected by this action?

The following nine Playskool toys are affected by this action:

- * Stack 'n Scoop Whale
- * Hourglass
- * Roll 'n Rattle Ball
- * Busy Beads Pal
- * Pop 'n Spin Top
- * Lights 'n Surprise Laptop
- * Rockin' Radio
- * Sounds Around Driver
- * Animal Sounds Phone

8. Is EPA concerned that statements like "fights germs, antibacterial protection, controls fungus" mislead the public?

Yes. If the public believes that the product has a self-sanitizing quality, they may inadvertently not practice standard hygiene (i.e., cleaning with soap and water) to prevent transmission of harmful germs.

9. What has EPA done to address the growing trend of unregistered products that are marketed with public health pesticide claims?

Increasingly, complaints are being brought to EPA's attention regarding false or misleading public health benefit claims for products that contain pesticides. Some of these claims have been determined to be in violation of FIFRA, and the Agency is pursuing enforcement actions. If companies misrepresent the performance of products in a manner not authorized by law, we will investigate and take steps as appropriate to stop the unlawful activity.

In addition to this action with Hasbro, EPA has issued an order to stop the sale of 3M's O-Cel-O sponges that contain public health claim on the package because of Agency concern with their advertisements. Furthermore, EPA is developing a pesticide regulation notice to clarify to companies what claims are acceptable for pesticide-treated products so that they may be sold without registration under the "Treated Articles Exemption."

10. What should companies do if they are currently marketing an unregistered product?

EPA is becoming very concerned about the number of products that are being marketed with false or misleading claims with regard to public health protection from infectious bacteria and viruses. Some of these companies may not understand the EPA registration procedures. To the extent a company misunderstands the law, they should come to EPA for clarification of pesticide registration requirements. Any company that is marketing a product with claims of public health protection from infectious organisms, and the product is not specifically registered for that purpose, should immediately contact the EPA Office of Enforcement and Compliance Assurance at (202) 564-2325. Self disclosure of illegal activity and prompt correction of the violation could qualify a company for substantially reduced penalties, or under certain circumstances, no penalty.

11. Does EPA require the registration of all products that make pesticidal claims?

Under FIFRA all products that make pesticidal claims must be registered by EPA before they may be legally marketed in the United States, unless they are specifically exempt from registration. The "treated articles exemption" allows pesticide-treated products to be sold without registration, so long as any claims are limited to protection of the product itself. Products making claims that are not limited to protection of the product itself (e.g. public health claims such as "kills germs, stops E.coli . . .") need to be registered.

12. What can consumers do to make sure that their children's toys are safe and free of harmful germs?

Whether products treated ⁽¹⁷⁾ Microban have any special germ fighting qualities or not, parents should take common sense steps to reduce the spread of germs, such as washing children's hands and toys regularly.

United States
Environmental Protection
Agency

Communications, Education,
And Public Affairs
(1703)



Press Advisory

Friday, December 12, 1997

EPA ISSUES COMPLAINT FOR ILLEGAL CLAIMS THAT PESTICIDE PRODUCT PROTECTS CHILDREN FROM BACTERIAL INFECTIONS

Denise Kearns 202-260-4376

On Dec. 5, EPA issued a civil administrative complaint charging Microban Products Co., Huntersville, N.C., with making unsubstantiated public health claims for its pesticide, Microban Plastic Additive "B." The complaint charges Microban with making claims that certain consumer products treated with the pesticide protect children from infectious diseases caused by bacteria such as E. Coli, Staph, and Strep., when in fact the treatment was approved only to protect the plastic in the products from deterioration. The Agency is seeking \$160,500 in civil penalties. With today's action against Microban, EPA is assuring that registrants limit their claims to those permitted by the product's registration. The use of unapproved public health claims in conjunction with the sale of consumer goods such as sponges, toys and cutting boards may pose a risk to the public. In the case of toys, parents and child care providers could easily conclude from the claims authorized by Microban that the mere presence of Microban in toys provides protection from harmful germs and hence a public health benefit. If parents and child care providers believe that toys are sanitary or self-sanitizing, they may not practice standard hygiene to prevent transmission of harmful germs, or be as careful as they should be. The net result may be that children's health is less protected. Microban Plastic Additive "B" is registered by EPA to inhibit bacterial growth in plastic. No public health-related claims have ever been accepted for this pesticide. Under the Federal Insecticide, Fungicide, and Rodenticide Act, it is illegal to make claims for any pesticide which differ from those claims approved in connection with the pesticide's registration. EPA will contact companies which incorporate registered products to emphasize their obligation to comply with the law and to provide such companies with an opportunity to come into compliance.

R-172

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TALKING POINTS

- EPA is taking enforcement action against Microban Products Company for the sale or distribution of a registered pesticide with claims that substantially differ from those accepted in connection with its registration.
- The Agency is seeking \$160,500 in civil penalties.
- In connection with its sale of Microban Plastic Additive "B" to a major toy manufacturer, Microban claimed that its product virtually eliminates microorganisms infectious to man such as Salmonella and E. Coli.
- Microban's registration allows it to make claims that it inhibits bacterial growth in plastic.
- Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) it is illegal to make claims for any pesticide which differ from those claims accepted in connection with the pesticide's registration.
- Microban's claims must be limited to non-public health statements and must not imply that its use in any product can confer public health benefits such as protection of consumers from the transmission of disease causing bacteria.
- EPA is concerned about the proliferation of products being sold or distributed that make claims beyond the scope of their registration, particularly with regard to public health protection from infectious bacteria. The use of unapproved public health claims in conjunction with the sale of "consumer goods" such as sponges, toys, and cutting boards may pose a risk to the public.
- In the case of toys, if parents and child care providers believe that the toys are self-sanitizing they may not practice standard hygiene to prevent transmission of harmful germs, or be as careful as they should be.
- FIFRA requires all pesticide products to be registered prior to marketing. EPA's regulatory scheme requires all products that make public health claims to demonstrate effectiveness for those claims by submission of efficacy data.
- EPA evaluates the data and approves labeling language designed to convey an accurate assessment of a pesticide's effectiveness. When companies fail to submit the required data and fail to receive proper Agency approval for pesticidal claims, the regulatory system may be undermined and public health may be endangered.

National Journal's GreenWire

THE ENVIRONMENTAL NEWS DAILY

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LINKS ABOUT GREENWIRE CONTACT GREENWIRE

A National Journal Daily Briefing

Friday, November 20, 1998

► SPOTLIGHT

Groups Seek Ban On Toys Containing Phthalates

Twelve consumer, environmental and religious groups yesterday urged the Consumer Product Safety Commission to ban plastic toys that contain phthalates, a group of chemicals linked to health risks in laboratory animals.

The day before, 28 members of Congress led by Reps. **George Miller** (D-CA) and **Henry Waxman** (D-CA) urged the Clinton admin. not to intervene in European deliberations over whether to ban such toys.

Toy makers insist the products in question pose no risk. But National Environmental Trust Pres. **Philip Clapp** said that if the feds fail to act before Christmas, the NET will sue toy makers and retailers under CA's right-to-know law. (#1)

QUOTE OF THE DAY

"The key is not merely to balance the twin goals of economic growth and environmental protection, but to connect them."

-- VP Al Gore, on the development of cleaner, more fuel-efficient cars. (#14)

TOP NEWS

Plucked From The Patch

The House's new Republican leadership is dominated by members from the "Oil Patch." (#2)

A Sensitive Move

MT resource officials will begin taking bids for oil and gas leases on 5,000 acres of sensitive lands along the Rocky Mountain Front. (#7)

Burden On The People

Taxpayers pay a large chunk of environmental cleanup costs through "corporate welfare," *TIME* magazine reports. (#11)

Newsweek Tackles Cars

Auto manufacturers worldwide are moving toward developing cleaner, more fuel-efficient vehicles; more. (#14)

Depechez Vous!

France is making slow progress in addressing enviro issues, a gov't agency reports. (#19)

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**National
Journal**

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The Kicker

UPDATE your Rolodex! Are you still sending news tips to our old email address? Please send all email communication to Greenwire@njdc.com.

FACT OF THE DAY

Approximately 170 million board feet of timber in several national forests are still required to be sold under the infamous "salvage-logging" rider, which was in effect from 7/95 to 12/31/96. (#6)

▶ SPOTLIGHT STORY

1 PHTHALATES: Critics Raise Pressure On US, Toymakers

Twelve consumer, environmental and religious groups yesterday urged the Consumer Product Safety Commission to ban plastic toys that contain certain chemicals linked to health risks in laboratory animals.

The day before, 28 members of Congress asked Pres. Clinton about reports that the Commerce Dept. was lobbying to keep European markets open to such toys, and they urged a stop to any such lobbying.

At issue are toys made from polyvinyl chloride (PVC) mixed with plasticizers, called phthalates, to make them soft. Chemical manufacturers acknowledge that a commonly used phthalate called DINP causes health damage in laboratory rodents at high doses, but the damage occurs via a physiological mechanism "that is not relevant to humans" (*Greenwire*, 11/16).

The actions by the groups and members of Congress come just days after Canadian officials advised parents to throw away vinyl teething rings and rattles because of possible organ damage. And it follows the announcement that the Toys "R" Us chain has voluntarily withdrawn "direct-to-mouth" infant toys containing DINP (*Greenwire*, 11/18).

National Environmental Trust Pres. Philip Clapp "said it was unacceptable that American parents would have to go to a Canadian Web site to get authoritative government advice on the issue."

The product safety commission said yesterday that it is researching how much of the plasticizer a child can safely ingest, and it is reviewing studies on animals. The commission hopes to make some kind of announcement soon.

Do Pacifiers Cause Health Damage?

David Miller of the Toy Manufacturers of America "said the plasticizers had been thoroughly studied, used for years and represented no risk." He said Canadian officials had "grossly" overestimated the amount of phthalates that could be ingested by a child chewing on a toy. According to Miller, the toys should not be banned until proven unsafe, because "on that logic, you can rule out half the products sold in the US today" (Matthew Wald, *New York Times*).

But Clapp said if the safety commission fails to respond to the coalition's formal request before the Christmas toy-buying season, the NET will sue major manufacturers and retailers under California's toxics right-to-know law. Such a move would have a national impact, Clapp said, because all US toymakers sell products in California (Caroline Mayer, *Washington Post*).

Lawmakers: Don't Push These Toys On European Kids

Meanwhile, a bipartisan coalition of lawmakers urged the Clinton administration not to intervene in European deliberations over whether to ban toys containing phthalates (*Greenwire*, 5/29). In an 11/18 letter, the lawmakers -- led by Reps. George Miller (D-CA) and Henry Waxman (D-CA) -- said "it would be unfortunate if the US found itself undermining these efforts for the benefit of toy company profits." The group said any such lobbying by the Commerce Dept. amounts to an "unwarranted intrusion" into the public health affairs of other countries (*Greenwire sources*).

The lawmakers also asked Clinton to clarify the administration's stance on whether the toys pose a risk to children and whether safe alternatives exist (Miller release, 11/18). (All cites 11/20 unless noted.) ([Back to Contents](#))



EXECUTIVE OFFICE OF THE PRESIDENT
COUNCIL ON ENVIRONMENTAL QUALITY
WASHINGTON, D.C. 20503

November 23, 1998

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: GEORGE T. FRAMPTON *GTF*

CC: BRUCE REED
SALLY KATZEN

SUBJECT: "TOXIC TOYS" ISSUE

A recent full-page advertisement, which first ran in the *New York Times* on November 15, 1998 attacked the Clinton Administration for its opposition to efforts by the European Union (EU) to ban toys made of polyvinyl chloride (PVC) that may contain or release compounds known as phthalates. Phthalates are used in PVC toys to soften the plastic, and so are found in teething rings and pacifiers, among other articles. The advertisement followed a series of critical print news articles and television coverage that began in late May. A number of environmental and public health organizations, including the organizations that sponsored the advertisement, wrote to Vice President Gore in July asking him to take action. I have attached a sampling of the press accounts and a letter, which specifically assert that the Departments of Commerce and State have opposed the EU product bans at the behest of domestic toy manufacturers, notably Mattel, Inc.

In response to the public criticism, the retailer "Toys 'R' Us" has removed from its shelves all products containing diisonnyl phthalate (DINP) that are intended for "direct to mouth" use, primarily teething rings and pacifiers. Manufacturers Lego and Nike have pledged similar action.

These responses are taking place despite an apparent dearth of strong evidence about the health risks involved. The Consumer Product Safety Commission (CPSC), which has primary regulatory jurisdiction of the articles at issue, does not believe that there is an adequate scientific basis on which to ban or restrict use of these products. CPSC believes that there is no data to support the view that the phthalates in these products are actually released from the plastic or otherwise result in human exposure. Furthermore, CPSC is concerned that a precipitous move to ban these products will result in substitution of potentially more hazardous plastics. CPSC plans to release a research report on health risks of phthalates in toys later this month. We expect the report to conclude that the current claims of risk are unfounded.

We are working with DPC and NEC to ensure that we have a coherent strategy to address this issue before the report is released. Clearly, we must take care not to contribute to a public health scare that

may be unjustified and may result in product substitutions that present increased risk to children. We need to look closely at the science that CPSC relies on for its conclusions, and we must also consider how to respond to the criticisms of State and Commerce.

In the interim, in response to inquiries, we should emphasize that while we do not believe there is any basis to assume that these products are a risk to children, the White House and CPSC are looking very seriously at the claims that have been presented to see if further action is warranted.

Attachment

The Washington Post

Friday, May 29, 1998 \$3

U.S. Toymakers Battle EU Over Plastic Playthings

By Sara Bassett
Washington Post Staff Writer

The European Union last week may impose a temporary ban on children's toys containing a controversial chemical compound, prompting a fierce counter-offensive by U.S. toy manufacturers who fear any European action will damage sales in the United States and overseas.

Toymakers have enlisted the Clinton administration to join their campaign to help block the EU action. The Commerce Department has coaxed U.S. diplomats to lobby against the proposal.

As early as next Wednesday, the 12-nation EU will vote to prohibit the use of certain children's toys made from a plastic called polyvinyl chloride, or PVC. But the toymakers insist that the EU is acting on scant scientific evidence.

An issue is a group of chemicals known as phthalates. These compounds are added to plastic toys such as teething rings and pacifiers to

make them soft and spongy and give them a chewy feel.

Studies involving laboratory animals have linked phthalates to liver and kidney disorders, damage to the reproductive tract and increased incidence of certain kinds of cancer. These findings have prompted some European countries, including Austria, the Netherlands and Belgium to take steps to remove these soft plastic toys from store shelves. In the mid-1980s, U.S. toy manufacturers voluntarily agreed to remove one kind of phthalate—diethylhexyl-phthalate, or DEHP—from the formula for plastics used in children's toys.

The EU, however, is considering a 90-day ban on selling plastic toys that contain two kinds of phthalates—DEHP and dibenzyol phthalate, or DINP. Toy manufacturers, along with representatives of the chemical and plastics industries, are vigorously fighting the measure.

"Our concern as a company is that the actions of a handful of individuals

within the European Union are based on questionable scientific evidence," said Sean Fitzgerald, vice president of corporate communications at Mattel Inc.

"This could have a huge effect on our business," Fitzgerald said, pointing out that Europe is Mattel's largest market outside North America. "But the processes [in the tests] that have been used are in question. There has been no formalized testing procedure that replicates the actual chewing process."

The U.S. Consumer Product Safety Commission is conducting its own tests to assess what, if any, risk the phthalates pose. Toymakers and Commerce Department officials are urging the EU to wait for those results before making any decision. The CPSC said the study should be completed in the next several weeks.

"The U.S. remains concerned that the EU countries' actions are having a negative effect on the marketing of these products absent of any scientific-based information," the Commerce

Department wrote in December in a cable sent to embassies throughout western Europe. "The U.S. has found no apparent health hazard related to phthalates used in toys."

But critics of soft plastic toys say there is plenty of scientific data showing these are potentially dangerous products. "There is enough science to say it's questionable, so let's not put it in our children's mouth," said Rick Hind, legislative director of the union campaign run by the environment group Greenpeace. "We shouldn't have our infants turned into guinea pigs."

In the past year, Greenpeace has lobbied hard against soft plastic toys, conducting several studies to show the risk posed by these products.

Fitzgerald and other toy industry officials blamed Greenpeace for unnecessarily alarming consumers, saying it is just interested in gaining publicity.

Staff writer Caroline Meyer contributed to this report.

Los Angeles Times

A1

Thursday

May 28

1998

U.S. Urges European Union to Avert Toy Restrictions

■ **Trade:** Firms protest efforts to ban some chemicals. Studies suggest they may cause medical problems.

By JAMES GERSTENZANG
TIMES STAFF WRITER

WASHINGTON—The Clinton administration, acting at the behest of Mattel Inc. and other toy companies, is lobbying against European efforts to ban controversial chemical compounds from teething rings and other toys for young children.

With the European Union nearing a decision on whether to prohibit the sale of toys made with polyvinyl chloride, or PVC, the Commerce Department has instructed U.S. diplomats to try to turn around several such bans already in effect.

The toy companies are concerned about the potential ban because of the eventual negative impact it

could have on their sales in the United States—as well as the immediate impact it could have on their sales in Europe.

At issue are compounds known as phthalates (pronounced thal'lates). They are softening components that provide a spongy, chewy feel when added to plastics. They also help plastics absorb the reds and yellows and other bright colors that children find appealing.

Among the compounds that would be banned is one that has been voluntarily left out of U.S. products for 13 years. But, other compounds targeted by the European Union are key components of toys and other plastic products made and sold in this country.

Please see **TOYS, A9**

Continued from A1

At least one Danish study has suggested that some phthalates, which are used not only in toys but in the strong plastic bags that contain intravenously-delivered medications and blood, may cause cancer, disrupt endocrine function or weaken immune systems. Other studies have raised similar concerns and suggested they may also cause liver and kidney damage and disruptions in reproduction, including lowered sperm counts.

But the studies were conducted only on animals, and it is unclear what impact, if any, the chemicals have on people.

No study has replicated the initial Danish study, said David Miller, president of the Toy Manufacturers of America. "The science is not in that direction," he said in an interview. "The science is on our side."

Miller's group represents the makers and importers of 85% of the toys sold in the United States, 20% of which are made of vinyl.

Enough questions have been raised about one chemical,

diethylhexylphthalate, or DEHP, that manufacturers voluntarily took it out of the formula for the plastics used in children's toys in 1985, substituting another phthalate.

"There's not the definitive study that says we've got to stop manufacturing these things, but there's growing evidence and growing concern that we're doing a global experiment on children by dramatically altering the chemical environment," said Michael McCally, a public health physician and a professor in the department of public health and preventive medicine at the Mt. Sinai Medical School in New York.

U.S. Wants 'Objective Scientific Evidence'

Charles Ludolph, a deputy assistant secretary of Commerce responsible for European affairs, said the U.S. position is that "decisions on a threat to health

should be based on objective scientific evidence." He said the administration wants the Europeans to delay any decision until they can study a report that the U.S. Consumer Product Safety Commission is expected to complete next month on phthalates.

But Jeff Wise, policy director of the National Environmental Trust, which describes itself as a national public education group focusing on environmental issues, said: "There's always more science you can do. There's enough science to indicate there is concern."

A decision by the 15-nation European Union could come as early as next week.

In December, the Commerce Department sent a cable to embassies throughout western Europe, saying it had been contacted by "representatives of one of the leading U.S. toy manufacturers ... in an effort to rectify a problem regarding the marketing of certain PVC toys placed on the market in the EU."

"The U.S. remains concerned

that the EU countries' actions are having a negative effect on the marketing of these products absent of any scientific-based information. The U.S. has found no apparent health hazard related to plasticizers used in toys, and, in fact, information received from other countries completely contradicts the need for these actions," the department said in the cable.

Sean Fitzgerald, Mattel's vice president for corporate communications, said Wednesday the El Segundo-based company had contacted the Commerce Department, along with representatives of the chemical and plastics industries and the toy manufacturers' association, seeking support in their opposition to a European ban.

Officials in the European Union administrative bureaucracy "are approaching this issue without solid information and they're approaching it from a reactionary basis," he said. "There has never been a formalized test that accurately duplicates the chewing process or sucking process of little kids on toys."

In March, Mattel hired a leading Washington lobbying firm to fight legislation that would require disclosure of chemicals used in children's products, according to a newsletter on lobbying. Federal election reports show that Mattel contributed \$85,000 to various Democratic Party committees in 1987 and \$25,000 to Republican Party committees.

European Efforts Gather Steam

In addition to the proposed restrictions throughout the European Union, Austria, Belgium, the Netherlands and Denmark have taken steps to remove these products from the marketplace, and others might follow, said the Commerce Department cable.

A. Vernon Weaver, the U.S. ambassador to the European Union, recently wrote to Hans Beseler, the senior EU administrative officer, warning that "the sudden ban on

products which have been sold for years and which is based on incomplete and perhaps erroneous information could cause trade misunderstandings between the United States and the European Union."

"The U.S. government is expending a fairly large amount of energy and time on behalf of the toy industry," said Rick Hind, legislative director of the toxics campaign run by the environmental group Greenpeace. He said other softening agents can be substituted safely for the phthalates.

Hind complained in a letter to Commerce Secretary Bill Daley that the department's position is "inconsistent with U.S. regulations" and with a presidential executive order instructing government agencies to make sure their "policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."

Researcher Ticia Ford contributed to this story.



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March 9, 1998

The Honorable William M. Daley
 Secretary of Commerce
 14th St & Constitution Ave., NW
 Washington, DC 20230

Dear Secretary Daley:

I am writing to express Mattel's appreciation for the invaluable work being done by the European country desk of Commerce's Market Access and Compliance (MAC) office. Under the direction of Acting Deputy Assistant Secretary of Commerce for Europe Charles Ludolph, this office has been critical in helping the U.S. toy industry defend against recent EU initiatives to ban the use of polyvinyl chloride (PVC) in toys.

Reacting to Greenpeace allegations that lack scientific justification, several EU member states recently implemented unilateral restrictions on the sale of PVC toys and the European Commission is currently considering the possibility of an EU-wide ban. These actions threaten a European market that is of major importance to Mattel and other U.S. toy companies, who are the most competitive in the world. In 1997, toy sales by Mattel alone in Europe exceeded \$1 billion.

Over the past several months, Charles Ludolph and other MAC staff have responded to our requests for support and have taken the lead within the Administration in aggressively fighting these restrictive European actions. These Commerce efforts played a major role in a decision last week by the Emergency Committee of DG-XXIV to postpone a vote on imposing a ban on PVC toys. Had Ludolph and his staff not been there to take charge of this matter in the last few months, the U.S. toy industry interests would have been seriously jeopardized.

While the battle on this issue is far from over, I wanted to take this opportunity to thank you for the excellent service that your staff has provided U.S. industry to date on this important matter.

Sincerely,

Fermin Cuza
 Fermin Cuza
 ap830901

Cus pro - vinyl toys

Bradley M. Campbell 12/04/98 09:42:41 AM

Record Type: Record

To: Laura Emmett/WHO/EOP
cc: Jennifer L. Klein/OPD/EOP
Subject: Toxic Toys Letter

This is just FYI for Elena, since Jen and I still need to confer.

----- Forwarded by Bradley M. Campbell/CEQ/EOP on 12/04/98 09:39 AM -----

Bradley M. Campbell 12/04/98 09:18:56 AM

Record Type: Record

To: Jennifer L. Klein/OPD/EOP, Bruce McNamer/OPD/EOP
cc: Janet Murguia/WHO/EOP, Lisa M. Kountoupes/WHO/EOP, Roger S. Ballentine/WHO/EOP
Subject: Toxic Toys Letter



TOYS_LTR.BC Herewith a letter, revised to reflect events of the week and Commerce/USTR concerns raised to Bruce (State called me to clear on the previous draft, and they should be even happier with this one). Let's try to conference as soon as you have had a chance to review. (Bruce: I never received options from you but I think the changes here meet the concerns you raised).

D R A F T -- Not Administration Policy

Dear Congressman Miller:

Thank you for your letter about potential health risks to children from phthalates in toys. I am very concerned about this issue.

As you know, the Administration has made a high priority of identifying and addressing these types of environmental health risks to children. More than a year ago, I signed Executive Order 13045 (April 2, 1997), directing all Executive Branch agencies to ensure that their standards and safeguards recognize the special risks to children in the environment, because children often are more vulnerable than adults to the substances and products found where they live and play.

The Consumer Product Safety Commission (CPSC), the independent regulatory agency that has primary jurisdiction over the asserted risks from phthalates in toys, has been investigating this issue according to the standards I articulated in that Executive Order. In a survey of the available research and data released on Wednesday, December 2, the CPSC reports that it has not yet found a scientific basis to believe that children are exposed to phthalates in toys at a level that would present possible risks. Under these circumstances, CPSC does not yet support a restriction or ban on the use of products containing phthalates under U.S. law. The CPSC has worked with interested retailers and manufacturers, however, on precautionary steps that will restrict the future use of phthalates in toys and the marketing of articles containing phthalates. I commend CPSC Commissioner Ann Brown, as well as the many companies that worked in partnership with the CPSC, on the added measure of caution reflected in this response.

The initial CPSC report makes clear that further work to address this issue is needed. I will make sure that our agencies give full attention to, and appropriate respect to the views of other nations on, this very serious issue. Accordingly, the Administration is taking several further steps to respond to the concerns raised in your letter.

Most importantly, we will continue our work to uncover and to inform parents of any possible risk to their children. I have asked CPSC Commissioner Ann Brown to continue and expedite the Commission's diligent investigation of this issue, and to consider the issue you raise concerning aggregate risk. I also have asked OMB to ensure that my budget provides CPSC with the funding needed to fully address these types of possible hazards. In addition, the Administration also has offered to support CPSC with any resources or technical assistance available from the Department of Health and Human Services or the Environmental Protection Agency that might help expedite the Commission's work in risk assessment and toxicology.

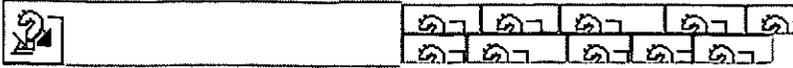
While the CPSC and other agencies proceed with this work, we will be supportive of the precautionary steps that are being considered here and abroad. We recognize and respect each nation's right to set legitimate public health and environmental standards, and to take

precautionary measures, provided those measures are not a mere pretext for restricting trade. I would like to make clear that the Departments of Commerce and State will refrain from any actions to discourage individual countries, whether in the European Union or elsewhere, from implementing precautionary measures they deem appropriate to restrict marketing or use of these products. In addition, the Commerce Department will provide appropriate support to those manufacturers and retailers of these products who wish to restrict sales of particular products in response to parents' concerns.

I appreciate your concern about this issue, and the Administration will keep you apprised of our progress. I look forward to our continued work together to maintain the highest standards of protection for our children.

Sincerely

Clear pro-vinyl toys



DECEMBER 02, 04:47 EST

Commission Won't Seek Toxic Toy Ban

WASHINGTON (AP) — Government safety regulators are asking toymakers to quit using a suspected carcinogen as a plastic-softening compound in baby rattlers and teething toys, but have decided against trying to ban all toys made with the substance.

The Washington Post quoted Consumer Product Safety Commission officials in today's editions as saying studies show that the amount of the chemical — diisononyl phthalate — ingested by small children "does not even come close to a harmful level."

The agency was scheduled to announce its actions today, along with advice to parents to discard soft vinyl toys that their children chew or hold in their mouths for long periods of times.

"Few children, if any, are at risk," Ronald Medford, the commission's assistant executive director for hazard identification and reduction, told the Post. "But given the number of uncertainties, we are — as a precaution — asking the toy industry to take certain steps to reformulate their products intended to go into children's mouths."

The newspaper said phthalates have been linked in laboratory studies to cancer in mice and rats. They also are a suspected source of liver and kidney damage in laboratory animals.

The commission identified only one line of pacifiers and nipples — Clear and Soft made by Gerber Products Co. — that parents should immediately discard, the Post said.

Some major retailers, including Kmart and Toys R Us, have already begun pulling plastic teething toys made with phthalate from their shelves.

"We've just been looking at the research and reading up on it," Kmart spokeswoman Michele Jasukaitis said in an interview with The Associated Press. "We are going forward in the interest of our customer safety."

Jasukaitis said Kmart would continue to monitor other products containing phthalate, including those that might not be explicitly for teething but could end up in the mouths of young children anyway.

Toys R Us, the world's largest retailer of children's products, promised last month to have the teething toys off its shelf by Nov. 18.

The commission said Sears, Roebuck and Co., Wal-Mart Stores and Target Stores also have announced plans to remove phthalate teething toys and rattlers from their shelves.

Several toy manufacturers, including Mattel Inc., Walt Disney Co. and Little Tikes Co., have said they plan to phase out use of the additive.

Environmental groups had asked the commission to ban the chemical ingredient and issue an advisory to parents on its dangers.

At least seven European governments have banned the use of phthalates in certain toys that commonly are put in children's mouths.

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Conspira-vinyl toys



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CPSC Won't Seek Phthalate Ban

Agency Asks That the Chemicals Not Be Used in Some Toys

By Caroline E. Mayer
 Washington Post Staff Writer
 Wednesday, December 2, 1998; Page C16

The Consumer Product Safety Commission staff has decided against recommending a ban on soft plastic toys made with phthalates, a controversial group of chemical additives that have been linked to cancer and kidney and liver damage in animals.

In an announcement scheduled for release today, the agency will say its studies show that the amount of phthalates ingested by small children "does not even come close to a harmful level."

Even so, the agency has asked the nation's toymakers to remove phthalates from soft plastic baby rattles and teething toys because significant uncertainties remain about the chemical used to make vinyl toys flexible and pliable.

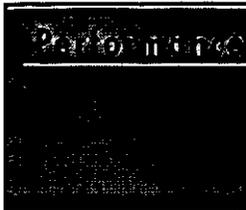
For products already in the home, the CPSC is advising concerned parents to discard any soft plastic teethers, rattles or toys that their children may chew or hold in their mouths for long periods of time.

"Few children, if any, are at risk," said Ronald L. Medford, the CPSC's assistant executive director for hazard identification and reduction. "But given the number of uncertainties, we are -- as a precaution -- asking the toy industry to take certain steps to reformulate their products intended to go into children's mouths," such as teethers and rattles.

The agency says about 90 percent of the nation's toymakers have indicated that they will stop making phthalate teethers and rattles by early next year.

Many of these companies, including Mattel Inc., Walt Disney Co. and Little Tikes Co., have already announced plans to discontinue using phthalates in some toys, including rattles and teethers, after an aggressive publicity campaign by the international environmental group Greenpeace questioned the safety of children's toys made with phthalates.

In early November, Toys R Us Inc., the nation's largest toy retailer, also announced it would pull all phthalate teethers and rattles from its shelves -- a move that was more critical to toy manufacturers' decisions to reformulate their products than the CPSC request, according to an industry official who declined to be named.



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The CPSC also is asking toymakers to reconfigure other soft vinyl toys containing phthalates -- such as bath toys and squeeze toys -- intended for children under age 3 that could end up in a child's mouth.

But the Toy Manufacturers Association indicated yesterday it is doubtful that many companies will comply with that request.

"We believe vinyl toys are safe for children of all ages," said association President David Miller. Individual companies have agreed to reformulate their teething rings and rattles "not because they're being precautionary but because Greenpeace has managed to frighten parents. We as an industry are proud to make safe products and this [soft vinyl toys] is a safe product. We will not sit idly by and let them do us in over a safe product."

In addition to Toys R Us and Kmart Corp., CPSC said Sears, Roebuck and Co., Wal-Mart Stores Inc. and Target Stores Inc. also have announced plans to remove phthalate teething rings and rattles from their shelves.

The CPSC found that almost all baby-bottle nipples and pacifiers are made with latex or silicone and therefore do not pose health concerns. There was, however, one exception: the Clear and Soft line of pacifiers and nipples, made by Gerber Products Co., which contain phthalates. The CPSC said parents should immediately discard these products, which Gerber has stopped making and had retailers pull from their shelves.

Gerber also has decided to eliminate any phthalate products designed for children's mouths -- less than 10 percent of its entire line -- "not because they are harmful but because there are some doubts and we build our business on trust and we're doing what's right for babies," said Alfred A. Piergallini, Gerber's CEO.

In recent weeks, the CPSC has come under mounting criticism from environmental and consumer groups for failing to take action on toys made with polyvinyl chloride (PVC). Two weeks ago, Canada issued a health advisory, urging parents to dispose of PVC toys and rattles. Meanwhile, several European countries have announced plans to ban PVC toys.

PVC toys often contain high levels of phthalates to make them soft and pliable. But laboratory studies have shown that phthalates may damage the liver, kidneys and other organs and cause cancer in mice and rats.

Rick Hind, legislative director for Greenpeace's toxics campaign, called CPSC's action "only a baby step because the agency fails to definitively require any action by toymakers." He said "we'll have to pursue litigation for any companies that are not responding," under California's Proposition 65 product-labeling law. That law requires health warnings on all products sold in California containing ingredients that can cause cancer or birth defects.

Twelve years ago, the toy industry decided to limit the use of one particular phthalate, diethylhexyl-phthalate (DEHP), in vinyl toys because it was found to be carcinogenic.

The industry replaced DEHP with diisononyl phthalate (DINP) and other phthalates, which more recent studies have linked to cancer and other health concerns.

Laboratory animal studies show phthalates to be "clearly toxic," Medford said. But even so, he said, that finding, doesn't permit the CPSC, under its legal authority, to ban the product.

"The agency also needs to prove that there is significant exposure to the chemical to ban the product," he said. "And so far, our data shows that exposure is not at a significant health risk to justify a mandatory ban."

CPSC said it relied on its own tests and two Dutch studies to come to its conclusions.

In one CPSC laboratory test, 35 PVC toys were placed in stainless-steel beakers with artificial saliva and then pounded by a piston for six hours. Only a moderate amount of phthalates were released.

But another study, in which 10 human volunteers chewed a PVC toy and then spit out the accumulated saliva, showed that the amount of phthalates released was nearly 40 times higher than the beaker test. Even then, the commission found that the level released was far less than what it considered the acceptable daily intake. Even so, the commission's scientists were concerned because they found that the amount of DINP released from a product varied widely -- and could not be predicted with any consistency.

"We had expected we would be able to predict how much DINP would come out, based on how much DINP was in a product or how a product was made but there was absolutely no correlation," Medford said.

Meanwhile, a Dutch study that closely observed 42 children showed that babies, 3 to 12 months old, mouthed toys (excluding pacifiers) an average of 12 minutes a day. Children 13 to 26 months old chewed toys (excluding pacifiers) an average of 2.1 minutes a day.

Based on that study, the CPSC calculated that daily exposure to phthalates was far less than it had expected -- and consequently few if any children were at risk from DINP.

Because the study was so small, however, the commission wants to run a larger human observation test, using about 200 children.

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