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October 15, 2008

Phthalates: An Overview

By Michael Kamrin

In the years since the 1999 Koop report on DEHP and DINP -- and the NTP-CERHR evaluations of seven phthalate esters conducted from 1998-2000 -- there have been a large number of new studies on possible toxic effects of phthalates. Many of these have been incorporated into the deliberations of expert panels, including those representing a variety of European Commission scientific agencies. The latest of these, focused on DEHP, appeared in early 2008. Although there have been some minor changes and refinements in the evaluations over time, none of the additional research and deliberations have significantly altered the earlier assessments of lack of phthalate risks.

The summaries presented in the risk characterization section thus reflect the accumulated judgments of a large number of scientists who have studied the data carefully over more than a decade. As the citations show, while many of these judgments are based largely on research that was performed in the years previous to 2000, they also reflect additional studies that were conducted more recently in response to requests from expert panels for the scientific community to fill gaps in the data -- including epidemiological investigations.

Overall, although the laboratory data suggest that the phthalates vary in potency, the risk from even the most potent of them, individually or in combination, is quite small for all age ranges in the general population. Although exposure levels are much higher for the very small sub-population of individuals, both adults and neonates, undergoing certain medical procedures, there is little evidence of adverse effects in this population as well.

Despite these conclusions resulting from a large effort in the U.S. and Europe to investigate and evaluate possible adverse effects of phthalates, there have been increasing efforts to regulate these compounds. In the EU, this resulted in regulations essentially banning six phthalates in plastics to which infants and children may be exposed. These took full effect in 2005 and in the past few years a number of states in the U.S. have attempted, in some cases successfully, to emulate this regulation. It appears that this trend will continue although the scientific evidence very strongly suggests that such risk management efforts are unlikely to lead to any improvement in public health.

Some basic phthalate facts to keep in mind:

1. Phthalates are a group of related compounds that are very widely used as

plasticizers and solvents. They have been in use for about 75 years and can be found in a great variety of products including building materials, personal care products, toys and medical devices.

2. Originally, the two phthalates of most concern were DEHP in medical devices and DINP in toys. Expert panel reports that evaluated such exposures concluded that the risks were low although additional data would be useful in addressing remaining uncertainties. At about this time, the focus of concern shifted and broadened to possible adverse effects on the reproductive and developmental potential of infants and children exposed to a number of phthalates in plastics.

3. During the past decade governments and agencies in Europe and the U.S. have taken or proposed regulatory actions to limit exposures to phthalates in toys and other plastics to which infants and children may be exposed. The phthalates that have been the subjects of these actions are DnOP, DIDP, DINP, BBP, DBP, and DEHP.

4. While these actions were under consideration, a variety of expert panels met in Europe and the U.S. to carefully evaluate the exposures to and toxicities of the individual phthalates of most concern. These assessments have continued to the current date and have incorporated a large body of new research performed in the past decade.

5. As a result of new data, especially from biomonitoring studies, and expert re-evaluations, estimates of exposure of infants and children, especially from plastics, have decreased significantly.

6. While a variety of laboratory animal studies have been performed to fill data gaps, these new data have not resulted in significant changes in conclusions about the possible toxicity of phthalates.

7. Although there have been a number of epidemiological studies of possible adverse effects of phthalates, especially on male reproduction, the results have been inconclusive and/or contradictory.

8. Based on the most recent exposure and toxicity data, including epidemiological study results, it can be concluded that human exposures to the phthalates of most concern are generally thousands of times lower than the lowest adverse effect levels for these phthalates, even in the most sensitive animal species.

9. Thus, re-evaluating the risk from phthalates leads to the same conclusions that were drawn almost a decade ago: (1) as currently used, phthalates do not pose a significant risk to the general public, including infants and children; and (2) there is no evidence of adverse effects, even in adults and children heavily exposed to phthalates due to leaching from medical devices, such as tubing, used during intensive treatment procedures.

10. Since the evidence indicates that phthalates do not pose a significant risk to humans, current and proposed regulations to limit phthalate exposure are highly unlikely to be of any benefit to public health.

The lowest dose that causes effects in animals is in most cases thousands of times higher than the exposures that humans, including infants and children,

experience. For DEHP, this dose was about a thousand times higher than non-medical human exposure levels. In addition, there is no convincing evidence that links adverse effects in humans to phthalate exposures, even for those who were exposed to very high levels during medical procedures. In light of these conclusions, the current and proposed regulations effectively banning phthalates in toys and other plastic objects that infants and children may come into contact with are unlikely to provide any reduction in the risk, if any exists, from phthalate exposure. Thus, these regulations are not likely to provide any public health benefit. In addition, based on current data, any broader regulations aimed at other sources of phthalates are also unlikely to be of benefit to the health of the public.

In addition to the lack of public health benefit from the proposed and enacted regulations, there is the strong possibility that these regulations will result in negative impacts on public health. The replacement of phthalates with other compounds for which much less toxicity data is available and which have not been subject to the same degree of scrutiny as phthalates leaves open the possibility of yet unknown risks. Also, the combination of properties that make phthalates useful in commercial products; e.g., providing flexibility of plastics as well as transparency, are likely to be difficult to duplicate and thus substitute products may be inferior in quality. This is of particular concern with regard to medical devices and is reflected in the reluctance of medical professionals to use substitutes for phthalate plasticized materials in some applications.

In sum, the benefits of phthalates for public health and the lack of comprehensive toxicological information on substitute compounds leave open the possibility that replacement of phthalates may lead to a net reduction in the overall health of the public. The outcomes of the expert panel deliberations provide little, if any, scientific justification for the regulation of phthalates in toys and other plastic objects to which children may be exposed.

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